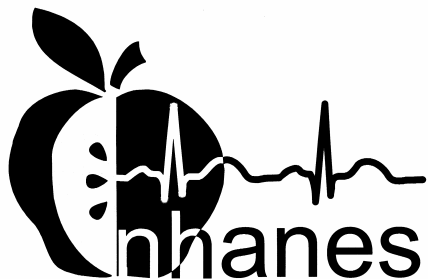

National Health and Nutrition
Examination Survey

LABORATORY
PROCEDURES
MANUAL



January 2005



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1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

This chapter provides a general history and description of the National Health and Nutrition Examination Survey (NHANES), and an overview of the tasks that staff perform during the survey.

1.1 History

The National Health Survey Act, passed in 1956, provided the legislation authorizing for a survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. NHANES was created to fulfill the purpose of this act. The NHANES 99 for 2004 was the eighth in a series of national examination studies conducted in the United States since 1960, but effective in 2005, NHANES will become a continuous field survey with year-round data collection.

To fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) direct interviews with Americans of all ages; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) facilities where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, the National Center for Health Statistics (NCHS), a branch of the U.S. Public Health Service in the U.S. Department of Health and Human Services, has conducted seven separate examination surveys to collect interview and physical examination data.

The first three of these national health examination surveys were conducted in the 1960s:

1. 1960-62—National Health Examination Survey I (NHES I);
2. 1963-65—National Health Examination Survey II (NHES II); and
3. 1966-70—National Health Examination Survey III (NHES III).

NHES I focused on selected chronic disease of adults aged 18-79. NHES II and NHES III focused on the growth and development of children. The NHES II sample included children aged 6-11,

while NHES III focused on youths aged 12-17. All three surveys had an approximate sample size of 7,500 individuals.

Beginning in 1970 a new emphasis was introduced. The study of nutrition and its relationship to health status gained importance as researchers began to discover links between dietary habits and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutrition Surveillance System was instituted by NCHS. The purpose of this system was to measure the nutritional status of the U.S. population and changes over time. A special task force recommended that a continuing surveillance system include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutrition Surveillance System was combined with the National Health Examination Survey to form the National Health and Nutrition Examination Survey (NHANES). Five surveys of this type have been conducted since 1970:

1. 1971-75—National Health and Nutrition Examination Survey I (NHANES I);
2. 1976-80—National Health and Nutrition Examination Survey II (NHANES II);
3. 1982-84—Hispanic Health and Nutrition Examination Survey (HHANES);
4. 1988-94—National Health and Nutrition Examination Survey (NHANES III); and
5. 1999-05—National Health and Nutrition Examination Survey (NHANES 99).

NHANES I, the first cycle of the NHANES studies, was conducted between 1971 and 1975. This survey was based on a national sample of about 28,000 persons between the ages of 1-74. Extensive data on health and nutrition were collected by interview, physical examination, and a battery of clinical measurements and tests from all members of the sample.

NHANES II began in 1976 with the goal of interviewing and examining 28,000 persons between the ages of 6 months and 74 years. This survey was completed in 1980. To establish a baseline for assessing changes over time, data collection for NHANES II was made comparable to NHANES I. This means that in both surveys many of the same measurements were taken in the same way, on the same age segment of the U.S. population.

While the NHANES I and NHANES II studies provided extensive information about the health and nutritional status of the general U.S. population, comparable data were not available for many

of the ethnic groups within the United States. HHANES, conducted from 1982 to 1984, aimed at producing estimates of health and nutritional status for the three largest Hispanic subgroups in the United States—Mexican Americans, Cuban Americans, and Puerto Ricans—that were comparable to the estimates available for the general population. HHANES was similar in design to the previous HANES studies, interviewing and examining about 16,000 people in various regions across the country with large Hispanic populations.

NHANES III, conducted between 1988 and 1994, included about 40,000 people selected from households in 81 counties across the United States. As previously mentioned, the health status and characteristics of minority groups can be very different from that of nonminority groups. Thus, black Americans and Mexican Americans were selected in large proportions in NHANES III. Each of these groups comprised separately 30 percent of the sample. It was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. For the first time a home examination was developed for those persons who were unable or unwilling to come into the examination center but would agree to an abbreviated examination in their homes. To obtain reliable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure the levels of pesticide exposure, the presence of certain trace elements in the blood, and the amounts of carbon monoxide present in the blood.

NHANES 99, conducted between 1999 and 2005, was the first of the series of surveys designed with the goal of becoming a continuous, annual survey. Each single year, and any combination of consecutive years of data collection, comprises a nationally representative sample of the U.S. population. This new design allows annual statistical estimates for broad groups and specific race-ethnicity groups as well as flexibility in the content of the questionnaires and exam components. New technologic innovations in computer-assisted interviewing and data processing result in rapid and accurate data collection, data processing, and publication of results.

The number of people examined in a 12-month period is about the same as in previous NHANES—about 5,000 a year from 15 different locations across the Nation. The data from the NHANES are used by government agencies, state and community organizations, private researchers, consumer groups, companies, and health care providers.

In addition to NHANES I, NHANES II, Hispanic HANES, and NHANES III, several other HANES projects have been underway since 1982. These projects have been a part of the HANES Epidemiological Follow-up Survey, a multiphase project that has been conducting follow-up interviews with the NHANES I survey population in order to provide a longitudinal picture of the health of the U.S. population.

1.2 Goals of the Survey

NHANES 2005, the current version of the survey, was designed to continue the collection of information about the health and diet of people in the United States. These data are used to fulfill specific goals. The overall goals of NHANES 2005 are to:

- Estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposures;
- Analyze risk factors for selected diseases;
- Study the relationship between diet, nutrition, and health;
- Explore emerging public health issues and new technologies; and
- Establish a national probability sample of genetic material for future genetic testing.

1.3 NHANES Data Accomplishments

NHANES data have been used to influence policy and improve the health of the U.S. population in many ways since the survey series was established. For the past 40 years, the U.S. Public Health Service has been interviewing and examining tens of thousands of Americans. Currently, teams of doctors, nutritionists, and health technologists are conducting the National Health and Nutrition Examination Survey (NHANES) in communities across the United States. Information from the survey will be updated annually.

Some of the contributions of the NHANES data include:

- **Pediatric growth charts.** Developed by the National Health and Nutrition Examination Survey, the NHANES growth charts are found on the walls of pediatricians' offices and clinics not only across the United States, but also around the world. With new information on younger babies, the current charts have been expanded and improved.
- **Vitamins and minerals.** The earlier NHANES showed that low iron levels were a serious problem for many people, including women of childbearing age, preschool children, and the elderly. As a result, the government decided to fortify grain and cereal with iron to correct this deficiency. The surveys also showed the need for folate to eliminate another deficiency and prevent birth defects. Today, we have a wealth of information at our fingertips and, indeed, on our food labels to help us make better choices about our diets. Much of that information comes directly from the National Health and Nutrition Examination Survey.
- **Cholesterol levels.** The first survey in the 1960s led public health officials to sound the alarm about the link between high cholesterol levels and the risk of heart disease. When NHANES started testing, one-third of adults had high cholesterol. Today fewer than 1 in 5 adults have high cholesterol. Changes in diet and lifestyle, all built on information from the national survey, have sharply reduced our risk of dying from a heart attack. These strategies have also helped doctors find ways to better treat heart attack patients and speed their recovery.
- **Lead-free gasoline.** It was NHANES that gave the first clear-cut evidence that Americans had too much lead in their blood. This led Congress, the Environmental Protection Agency, and others to phase out the use of lead as an additive in gasoline, and the results have been remarkable. By the 1990s, NHANES found that only 4 percent of Americans had elevated lead in their blood, but it remains a problem for certain groups, especially poor children living in old houses, in cities where lead paint was once common. The survey helps public health agencies pinpoint where lead still remains a problem.

As the NHANES survey continues to collect and update health information, there are other ways in which the information will be of use, including:

- **Osteoporosis.** This condition, in which bones get weaker as people grow old, is blamed for many of the fractures among the elderly. The National Health and Nutrition Examination Survey measures bone density of participants.
- **Environmental smoke.** Recent NHANES data found that nearly 9 out of 10 nonsmoking Americans were exposed to smoke either at home or on the job.
- **Obesity.** Despite the public health gains in recent years, more Americans are overweight than ever before. Today, more than half of the adults in the U.S. are overweight, and the number of overweight children and teens has doubled in the past

decade. This has led public health experts to look for ways to improve both diet and fitness.

- **Changes in Food/Diet.** Today consumers can find a wide range of low fat and light foods in their grocery stores, from dinner entrees to snacks. As the food we eat changes, NHANES helps monitor whether these new foods and dietary changes actually are in the best interest of our health.
- **Immunizations.** The National Health and Nutrition Examination Survey has turned up important information about the extent of hepatitis B infections, and led to the recommendation that all infants and children be vaccinated against it. Though babies and children are the primary targets for immunizations, the survey also has alerted doctors to the importance of tetanus shots for older people.

1.4 National Center for Health Statistics

The Division of Health and Nutrition Examination Surveys (DHANES) is one of the survey divisions at the CDC's National Center for Health Statistics (NCHS).

DHANES is responsible for planning, operations, informatics, analysis, and reporting activities related to the family of health and nutrition examination surveys. These surveys range from the capstone cross-sectional National Health and Nutrition Examination Survey, to longitudinal studies, and more recent efforts with community-based studies. DHANES is comprised of more than 60 Federal employees who have training and expertise in diverse areas including public health, informatics, survey methodology, and statistics. The Federal staff are augmented by contractor staff working on- and offsite.

The Division consists of four branches and the Office of the Division Director. The DHANES Office of the Director coordinates the major activities in the Division. Each of the four branches consists of a multidisciplinary team with specific duties and responsibilities.

1.5 Sample Selection

A sample is defined as a representative part of a larger group. Since it is impossible to interview and examine everyone in the United States for NHANES, a representative sample is taken of the U.S. population. By studying a representative sample of the population, it is assumed that the findings would not have been too different had every person in the U.S. been studied. Because generalizations

about the population will be made, it is extremely important that the sample be selected in a way that accurately represents the whole population. Statisticians calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population, such as age, gender, race, and income.

An introductory letter is sent to each household in the sample. A few weeks after the letter goes out, interviewers visit each listed household and use carefully designed screening procedures to determine whether any residents are eligible for the survey. If eligible residents are present, the interviewer then proceeds to introduce the study, presents the Sample Person (SP) with a survey brochure, and obtains a signed consent for the household interview. The brochure contains detailed information on the survey, the household interview, and the MEC examination.

A signed consent form must be obtained from each eligible individual before the household interview can be conducted. A refusal to sign the consent form is considered a refusal to participate in the survey. After the interview is completed, the interviewer then explains the MEC exam, obtains another signed consent form for the MEC exam, and contacts the field office to schedule a MEC appointment for the SP. All SPs aged 12 years and older must sign the Examination Consent forms to participate in the MEC examination. Parental consent is also required for SPs under 18 years of age. SPs aged 7-11 years old are asked to sign the Examination Assent form. An additional consent form is required for consent to future general research for both adults (ages 18+) and parents of children under 18 years. This consent form gives permission to store a small sample of blood and urine for future specimen testing. A refusal to sign the MEC consent or assent form is considered a refusal to participate in the examination phase of the survey. Examinations will not be performed on sample persons who do not sign a consent form.

1.6 Field Organization for NHANES

There are two levels of field organization for this study - the home office staff and the field staff.

- **Home Office Staff from Westat** – Project staff from Westat are responsible for overseeing the field teams and field work.

- **Field Office (FO) Staff** – For this survey, an office will be opened at every survey location (stand). Each field office will have a Study Manager (SM), Office Manager (OM), a Field Manager (FM), and one Assistant Office Manager (AOM).
 - The **Study Manager (SM)** is responsible for the overall management of operations at a stand.
 - The **Office Manager (OM)** is responsible for the stand office operations and is the main conduit for the flow of work and information between the MEC and the household interviewing staff. She or he will supervise one or more local office clerks hired to assist with office activities. The OM reports to the SM.
 - The **Field Manager (FM)** has primary responsibility for the supervision of the household interviewers. The FM also assists the SM and supervises the activities of the Assistant Office Managers. She or he will deal with administrative issues, ISIS problems, and preparations for the next stand.
 - The **Assistant Office Managers (AOMs)** are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. The AOMs report to the FM and also work closely with the OM.
- **Facilities Specialist** – One Facilities and Equipment Specialist will travel with each field office team and caravan to oversee the maintenance and operation of the trailers.
- **Household Interviewers** – These staff members are primarily responsible for identifying and enrolling the survey participants, conducting the household interviews, and appointing the study participants for the MEC exam. Specifically, household interviewers will locate occupied residential dwelling units, administer the Screener to select eligible sample persons, obtain signed consents to the household interview, conduct the interviews, set up examination appointments, obtain consents for the MEC exam, conduct field reminders for MEC appointments, and assist in rescheduling broken, cancelled, and no-show appointments.

Several times a week, household interviewers visit the field office and report to the field manager. During the course of the study, interviewers also interact on a daily basis with other field office staff and home office staff.

- **MEC Staff** – These health professionals conduct the health exams. The survey includes two exam teams. There are 16 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 3 medical technologists, 4 health technologists, 2 MEC interviewers, 2 dietary interviewers, and 1 phlebotomist. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff. A data manager also travels with each team.

The following section describes the steps that are always completed before the opening of a stand and provides an overview of the tasks that interviewers are expected to perform.

Steps completed prior to interviewing include:

1. Statisticians scientifically select certain segments in the sampling area. A segment is an area with definite boundaries, such as a city block or group of blocks containing a cluster of households.
2. Segments are listed by NHANES staff. Listing is the systematic recording on special forms of the address of every dwelling unit (DU) located within the segment. Commercial buildings and other structures not intended as living quarters are not listed.
3. A sample of dwelling units is selected from the listing forms. This sample is the group of addresses that interviewers visit in order to conduct interviews.
4. Immediately before data collection begins, an advance letter is sent to each dwelling unit with a mailing address. This letter briefly describes the study and informs the household that an interviewer will contact them in the near future.

Steps followed by the interviewers at a stand include:

1. Obtain assignment of sampled dwelling units to contact from the field manager.
2. Locate dwelling units using addresses on the Household Folders and listing/mapping materials in the Segment Folder.
3. Contact an adult who lives in the selected household (occupied residential dwelling unit) and administer the Screener using a laptop computer.
 - The Screener is an interview that lists all the individuals who live in the household, divides the household into families, and collects all the demographic characteristics necessary to immediately determine if there are persons in the household eligible for further interviewing.
 - All instructions necessary to determine eligibility and to select sample persons (SPs) are programmed in the CAPI Screener.
4. If all persons in a household are ineligible, no further work is done with the case. If eligible household members are identified, interviewers continue to conduct all the necessary tasks associated with the case.
5. In eligible households, obtain a signed interview consent form prior to completing the medical history and/or the family questionnaire.

6. Administer the appropriate medical history CAPI interview to eligible respondents. The questions asked depend on the age of the SP.
7. Administer Family questionnaire to one adult family member from each eligible family in the household.
8. Schedule a MEC appointment for each SP, coordinating the MEC schedule and the SP schedule.
9. Obtain signed consent form(s) for each SP for the examination, confirm the examination appointment(s) with the field office, and give each SP an appointment slip.
10. If there is more than one eligible family in a household, repeat this process with each additional family.
11. Record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.

Interviewers also support the survey by conducting field reminders prior to MEC appointments and reschedule broken, cancelled, or no-show MEC appointments. When an interview has been completed, interviewers edit their work, carefully reviewing all forms for completeness and legibility. Interviewers report in person to the field manager at the stand office for regularly scheduled conferences, usually every other day. During these conferences, interviewers discuss completed cases, discuss problems with incomplete cases, receive new case assignments, and report time, expenses, and production.

To ensure the accuracy and completeness of the survey, all interviewer work is edited by the field office staff, and then validated by recontacting respondents. After this review, supervisors provide interviewers with feedback concerning the quality of the work.

1.7 Exams and Interviews in the Mobile Examination Center (MEC)

Examinations and interviews are conducted in a mobile examination center (MEC), which is composed of four specially equipped trailers. Each trailer is approximately 48 feet long and 8 feet wide. The trailers are set up side-by-side and connected by enclosed passageways. During the main survey, detachable truck tractors drive the trailers from one geographic location to another.

Exhibit 1-1 shows a floor plan for the MEC. The interior of the MEC is designed specifically for this survey. For example, the trailers are divided into specialized rooms to assure the privacy of each study participant during exams and interviews. Many customized features have been incorporated including an audiometry room that uses a soundproof booth, a wheelchair lift, and a wheelchair-accessible bathroom available to assist participants with mobility problems. Exhibit 1-2 shows the locations of the various exams within the MEC.

1.7.1 Exam Sessions

The MEC operates 5 days a week and includes weekday, evening, and weekend sessions. Two 4-hour sessions are scheduled each day with approximately 10-12 SPs per session. During a stand, workweeks rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

Exhibit 1-1. Floor plan of the MEC

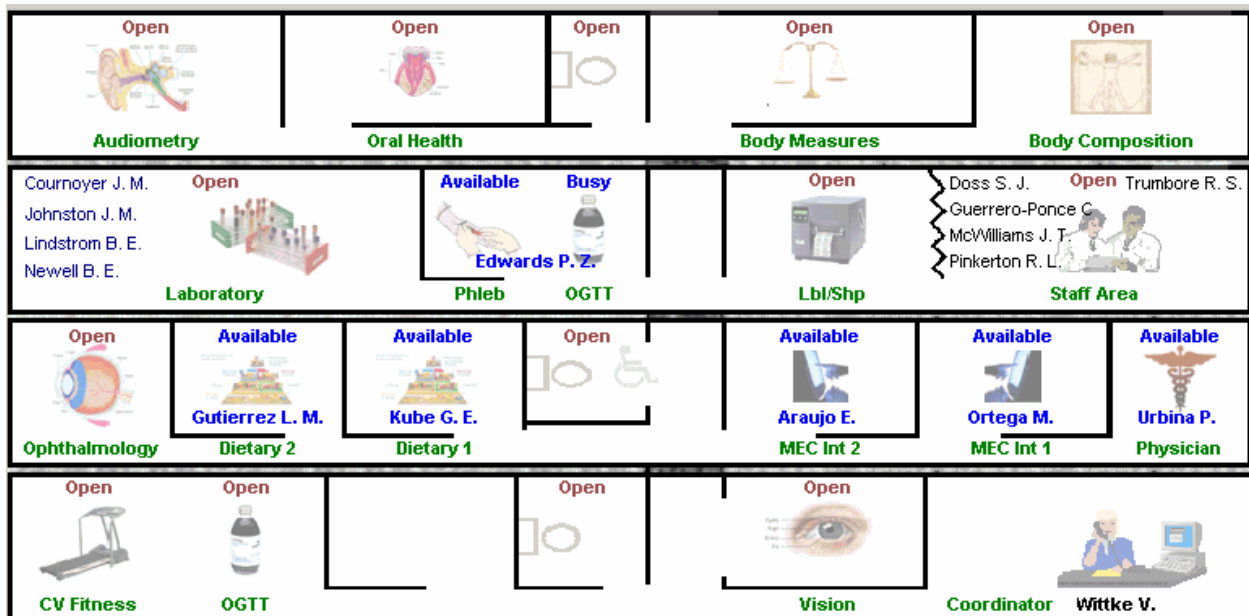


Exhibit 1-2. MEC exams and rooms

| Trailer | Room | Room Use |
|-----------|--|---|
| Trailer 1 | Coordinator Vision CV Fitness OGTT | Welcoming and waiting area for SPs Vision tests Cardiovascular fitness test Oral glucose tolerance Trutol administration |
| Trailer 2 | Physician MEC Interview 1 MEC Interview 2 Dietary Interview 1 Dietary Interview 2 Ophthalmology | Physical examination Health interview Health interview Dietary interview Dietary interview Vision tests |
| Trailer 3 | Phlebotomy/OGTT Laboratory Label/shipping area Staff area | Drawing of blood samples Oral glucose tolerance Trutol administration Processing of biological samples Lab area for labeling and shipping specimens Staff area that houses main computer system |
| Trailer 4 | Body Composition Body Measures/PAM Oral Health Audiometry | Total body composition scans Body measurements and physical activity monitor Dental examination Hearing tests |

1.7.2 Exam Team Responsibilities

There are 16 individuals on each exam team. In addition, a local assistant will be hired to assist the staff in managing examinee flow. The duties of the exam team members are summarized below:

- One MEC manager supervises the exam staff, manages the facility, and supports exam operations.
- One coordinator directs the flow of SPs through the MEC examination process. The coordinator manages all SP appointments, verifies that all components are completed for each SP, and exits SPs from the MEC.
- One physician conducts the medical examination and records results, reviews the results of the complete blood count and pregnancy test, and serves as the safety officer for the MEC.

- Two health (MEC) interviewers administer questionnaires for physical health information.
- Two dietary interviewers administer the dietary questionnaire. The interviewers record a 24-hour dietary recall of the types and amounts of foods consumed by the SP in the last 24 hours.
- Four health technologists (some with radiologic technology and/or other health training) take and record body measurements, recruit SPs to participate in the physical activity monitor component, perform vision tests, cardiovascular fitness tests, and total body composition (DXA) scans, administer hearing tests, and administer the Trutol solution for the glucose tolerance test.
- Three medical technologists conduct clinical laboratory tests on biological and environmental specimens, record the results of the tests, and prepare and ship specimens to various laboratories.
- One phlebotomist conducts the phlebotomy interview, administers the fasting questionnaire, and draws blood for laboratory tests and special studies like the volatile organic compound special study. The phlebotomist is also responsible for administering the Trutol and drawing a second blood sample for the GTT test. They are trained as a backup examiner for other MEC components like body measures and the physical activity monitor.

Each staff member is part of a team of professional persons with specific assignments that must be completed in order to accomplish the overall objective of the survey. Each individual must be aware of and respect the job demands placed upon other staff members, maintain an attitude of tolerance and consideration for fellow members of the team, and willingly perform extra tasks that may be assigned to support other staff members in the performance of their duties. MEC staff members may be requested to perform tasks not directly related to their specific professional skills in order to implement the overall data collection plan.

1.7.3 Examination Components

The full examination for an adult takes approximately 3½ hours, but the actual length depends on the SP's age. Some exams are done only on certain age groups so the exam profiles vary, even among adult SPs. The exam components are described briefly below and summarized in Exhibit 1-3.

Exhibit 1-3. Examination components

| Examination | Age group |
|-----------------------------|---------------|
| Audiometry | 12-19 and 70+ |
| Body Composition | 8 + |
| Body Measures | All ages |
| Cardiovascular (CV) Fitness | 12-49 |
| Dietary Interview | All ages |
| Glucose Tolerance | 12+ |
| Laboratory | 1+ |
| Urine Sample | 6+ |
| MEC (Health) Interview | 8 + |
| Ophthalmology | 40+ |
| Oral Health | 5+ |
| Phlebotomy | 1+ |
| Physical Activity Monitor | 6+ |
| Physician | All ages |
| Blood Pressure | 8+ |
| Vision | 12+ |
| Volatile Organic Compounds | 12+ |

- **Audiometry**

The goals of the hearing exam are to obtain normative data on the hearing status of the adult U.S. population, and to evaluate certain covariates that may be related to hearing loss, such as occupational exposure. The hearing component tests adults by performing pure tone audiometry and tympanometry. Because pure tone screening by itself may not be sensitive enough to detect middle ear disease, tympanometry is conducted to provide an estimate of tympanic membrane compliance.

- **Body Composition**

The body composition component will use dual energy x-ray absorptiometry (DXA) to evaluate both body composition and skeletal health on SPs aged 8 years and older. Three DXA scans will be used to (1) monitor secular trends in overweight prevalence; (2) describe the prevalence of obesity; and (3) examine the relationship between overweight and obesity and other examination measures, including blood pressure, glucose intolerance, and a battery of indicators for cardiovascular disease.

DXA will be used to assess overall skeletal changes that often occur with age by measuring bone mineral content (BMC) and bone mineral density (BMD); determine the prevalence of osteopenia and osteoporosis; and provide information on early gender and ethnic changes in the rate of bone accretion; and determine the age when skeletal accretion ceases and when peak bone mass occurs.

- **Body Measures or Anthropometry**

All SPs will have body measurements taken. The exam will include height, weight, and other body measurements such as skinfold and arm girth. These measurements will be used to assess growth, obesity, and body fat distribution, and will provide information that can be used as a reference for later studies. Measurements of height and weight will allow for a revision of the child growth charts now in widespread use. Measuring body fat is important because it is associated with hypertension, adult diabetes, cardiovascular disease, gallstones, arthritis, and some forms of cancer. Furthermore, obesity and overweight can have an affect on the mental, physical, and social well-being of individuals.

- **Cardiovascular (CV) Fitness**

One important part of overall physical fitness and functioning is cardiorespiratory fitness. To measure this, SPs aged 12 to 49 will be administered a submaximal treadmill test. During this test, SP blood pressure and heart rate will be monitored. This information will provide key data on many health factors including the association between physical fitness and cardiovascular disease and hypertension.

Cardiovascular disease is currently the leading cause of death in the United States for both men and women. A sedentary lifestyle (along with elevated blood cholesterol levels, hypertension, and smoking) is a major modifiable risk factor for cardiovascular disease. According to current data however, only about 24 percent of American adults currently meet the physical activity recommendations outlined in the 1996 Surgeon General's Report.

SPs are carefully screened prior to the treadmill test using questionnaires and measurements of resting heart rate and resting blood pressure. High risk (symptomatic, with disease, etc.) individuals will be excluded, so that only apparently healthy individuals will undergo treadmill testing. The combination of screening, monitoring, and the submaximal nature of the test will all contribute to the safety of this component.

- **Dietary Interview**

Dietary information has been collected in NHANES since the 1970s. Researchers and policymakers rely on NHANES data for detailed information about the foods and beverages that are consumed by the U.S. population. In addition to providing important national reference data on food and nutrient intakes that are obtained on all survey participants, the data help us to learn about food patterns of ethnic subgroups, the adequacy of diets consumed by young children and older persons, and the contribution of food to total nutrient intakes. Total nutrient intakes from food and

dietary supplements can be computed by combining NHANES Dietary Recall data with household interview dietary supplement information. Many Federal agencies use NHANES data to evaluate Federal regulations in the areas of food fortification and human risk assessment analyses that are used to measure human exposure to contaminants that are found in food.

Two dietary interviews will be administered to all SPs. The primary dietary interview is administered in person in the MEC (the MEC In-person interview). At the end of the MEC dietary interview, the interviewers will schedule the SPs for a Phone Follow-up (PFU) 3-10 days later. The PFU is a follow-up dietary interview conducted by telephone by dietary interviewers from the home office. In addition, a self-administered form, the Food Frequency Questionnaire, will be offered to SPs who complete the MEC dietary interview. It is mailed from and returned to the home office.

The goal of the dietary component is to estimate total intake of foods, food energy and nutrients, nonnutrient food components, and plain drinking water by the U.S. population; and assess dietary behaviors and the relationship of diet to health. Quantitative dietary intake data are obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system.

- **Oral Glucose Tolerance Test (OGTT or GTT)**

The purpose of this test is to reassess the prevalence of diabetes and impaired glucose tolerance (IGT) in the US population. Persons with impaired glucose tolerance (IGT) – 15.6 percent of the U.S. population – are at high risk for developing diabetes. Also, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined on the basis of an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hr value of 140-199 mg/dl are considered to have IGT. Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT.

The GTT will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts.

A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast. After the venipuncture, participants are asked to drink 75 milligrams of Trutol® and to have a second venipuncture 2 hours (plus or minus 15 minutes) after consuming the Trutol. The blood glucose level from the second venipuncture will be used to determine if an SP has IGT.

- **Laboratory**

The laboratory component includes the collection and processing of various biological and environmental specimens including blood for subjects 1 year and older, and urine for subjects 6 years and older. On-site pregnancy testing excludes pregnant women from other examination components such as DXA. Complete Blood Counts (CBCs) are also performed in the MEC laboratory. All other specimen testing is performed by Federal, private, and university-based laboratories under contract to NCHS.

Urine is collected from SPs age 6 and older to assess kidney function, measure levels of mercury, heavy metals, iodine and arsenic, and assess environmental exposures to pesticides such as organophosphates, phthalates, polycyclic aromatic hydrocarbons, phytoestrogens, and perchlorates.

- **MEC (Health) Interview**

SPs aged 8 and older will have a health interview in the MEC. Generally, the questions asked in the MEC are considered to be more sensitive than the questions asked in the household. The MEC "clinic" environment is believed to be a more appropriate setting for the administration of these questions. All SPs will be asked questions in a face-to-face interview. In addition, persons who are 12-59 years old will be asked a series of more personal questions in complete privacy. The SP will listen to questions through a set of earphones and will enter responses by touching a computer screen.

Depending upon the age of the SP, the interview may consist of questions about tobacco, drug, and alcohol use, reproductive health (birth control practices, pregnancy and reproductive history, sexual activity), health behaviors (physical activity, weight history), kidney conditions and bowel health, current health status and mental health, and exposure to certain chemicals. Children 8-11 years will only be asked questions about weight history.

- **Ophthalmology**

The ophthalmology component consists of two eye examinations completed on all SPs 40 years and above. SPs will be excluded if they have an eye infection, eye patches or blindness. The first exam is visual field testing using Frequency Doubling Technology (FDT) perimetry to test for visual field loss from glaucoma. The second exam is digital fundus photography using an ophthalmic digital imaging system to assess the presence of diabetic retinopathy, age-related macular degeneration, and other retinal diseases.

The leading causes of visual impairment in the United States are primarily age-related eye diseases including cataract, diabetic retinopathy, glaucoma, and age-related macular degeneration. More than 3.4 million Americans aged 40 years and older are either blind or are visually impaired. Glaucoma is the leading cause of irreversible blindness and a prevalent disease associated with aging. Although glaucoma can usually be controlled by early detection and treatment, half of people with glaucoma

are not diagnosed, and glaucoma is still the number one blinding disease among African Americans.

Diabetic retinopathy is the leading cause of new blindness among adults aged 20-74 years. It can affect almost anyone with diabetes, and contribute both to individual and societal burden. Age related macular degeneration (ARMD) is the leading cause of visual impairment and blindness in the United States among people 65 years and older. The frequency of ARMD is expected to increase as the population lives longer.

■ **Oral Health**

SPs aged 5 and older will receive a simplified oral health exam conducted by health technologists trained to administer the screening assessments. All examinees will be checked for tooth loss, cavities, restorations, and sealants. SPs 25 years and older will also be asked some questions about denture use and will be assessed for dental function.

Oral and dental diseases affect many in the United States. Dental caries and tooth loss remain significant problems affecting the Nation's oral health. Although average dental caries rates for school-aged children have declined, nearly a half of all children still have caries. Additionally, more than 90 percent of adults in the United States have experienced caries. Dental sealants, an effective caries prevention measure, have been underutilized in the United States, with less than one-quarter of children aged 5-17 having them.

Over the past four decades, oral and dental health characteristics collected in national surveys supported by the Federal Government have been critical for monitoring health status, risk factors for disease, and access to preventive and treatment services. The 2005-06 NHANES oral health component will meet a critical need to continue monitoring trends in dental caries and tooth retention. More specifically, this NHANES will produce oral health data to monitor five oral health objectives in the Healthy People 2010 health promotion: dental caries experience, untreated dental decay, no permanent tooth loss, complete tooth loss, and dental sealants.

■ **Phlebotomy**

SPs aged 1 and older will have blood drawn. The amount drawn will depend on the person's age. It is important to draw blood from study participants for a number of reasons:

- Knowledge can be gained about how healthy a person is by measuring for various substances in his or her blood.
- Blood tests can provide early warnings of potential health problems, perhaps before physical signs appear. For example, a blood test for lead might indicate exposure to unsafe lead levels before an individual shows any physical signs of lead poisoning. Also, diabetes mellitus will be assessed by measures of plasma glucose, insulin, and glycohemoglobin in examinees ages 12 years and older. Diabetes is a large, growing, and costly public health problem in the United

States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and more than 1 million new cases of diabetes are diagnosed each year. Alarming, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.

- Blood tests will also indicate the presence of STDs such as Chlamydia and gonorrhea, hepatitis, herpes, and HIV infection.
- Blood tests help in monitoring nutritional status, one of the key goals of NHANES. What researchers discover from this data can lead to health policy recommendations—the need for more vitamin fortification, for example.
- The blood testing also provides information about the levels of cholesterol and other blood lipids, another important study goal.

■ **Physical Activity Monitor**

The purpose of the Physical Activity Monitor component (PAMC) is to assess the physical activity levels of NHANES examinees 6+ years of age. Approximately 4,000 individuals are expected to participate in this component annually. NHANES examinees wear a physical activity monitor (PAM) to examine physical activity patterns over a 7-day monitoring period. The monitors detect locomotion-type activities such as walking or jogging. Physical activity data are linked to other household interview and health component data and are used to track changes that occur in body weight, functional status, bone status, and health status over time.

■ **Physician**

All SPs see the physician. The physician measures blood pressure, explains to female SPs how one examination will be completed and explains the meaning of the STD/HIV test results. The physician explains how SPs receive the results of STD/HIV tests so that the results remain totally confidential to the SP. The physician must be present on the MEC before any exams can be conducted, and the physician is in charge of any medical emergency that occurs on the MEC.

■ **Vision**

This examination will consist of a near and distance vision acuity test, eyeglass prescription determination when appropriate, and an automated refraction measurement. It will be given to SPs aged 12 and older.

Eye diseases cause suffering, disability, and loss of productivity for millions of people in the United States. In economic terms, eye disease and blindness are estimated to cost the U.S. in excess of \$22 billion each year. No high-quality, up-to-date information exists on the prevalence of visual impairment and the major causes of visual impairment in the general population. These data are needed in planning health services, in monitoring changes in eye disease prevalence, in research program planning, in developing and testing hypotheses about eye disease etiology.

Data collected more than 20 years ago in the NHANES I (self-reported history questions and full-vision examination with dilation) continue to be the only source of national prevalence data on eye disease and visual acuity impairment and there are no data on visual field impairment. Changes in disease definitions, population demographics, diagnostic capabilities, and treatments for eye diseases make it important to obtain new national data about eye disease. The absence of such data has forced researchers to use blindness registry data that are almost 25 years old. These studies select mostly white populations or non-nationally representative populations.

- **Volatile Organic Compounds (VOC) Special Study**

Information on levels of exposure to a selected group of volatile organic compounds is collected on a subsample of the survey population to assist in determining whether regulatory mechanisms are needed to reduce the levels of hazardous air pollutants to which the general population is exposed.

1.7.4 Sample Person Remuneration

All examinees receive remuneration for the MEC visit as well as payment for transportation expenses. The MEC visit remuneration is age-related and may include an extra fasting incentive if the SP is eligible. SPs who return the physical activity monitor, and SPs who complete the dietary phone interview and the Food Frequency Questionnaire, also receive an incentive.

1.7.5 Report of Exam Findings

Examinees receive the results of many of the tests and exams conducted in the MEC, though some results are used only for research and are not reported.

One report, a Preliminary Report of Findings, is produced on the day of the SP's examination and includes results that are immediately available and require no further evaluation or interpretation. Before the examinee's departure from the MEC, the coordinator prints a report that can include height, weight, complete blood count, blood pressure, and results from the audiometry and cardiovascular fitness examinations. The MEC physician reviews the blood pressure and complete blood count test results for abnormalities and discusses any problems with the SP (or his or her parent.) Approximately 12-16 weeks after the exam, NCHS mails the remainder of the examination results to the SP after appropriate clinical or quality reviews are completed. Seriously abnormal results are reported to the SP via telephone by NCHS before the remaining findings are mailed.

Certain tests, such as those for sexually transmitted diseases (Chlamydia, gonorrhea, herpes simplex, and human papillomavirus) and human immunodeficiency virus (HIV) are released only to the sample person using a specially devised procedure requiring a unique password.

To further assist sample persons, an in-house NCHS survey response team is available to answer calls from NHANES participants regarding the results from the Report of Finding System. The response team effort works both as a triage mechanism and a surveillance system. A receipt and control record is kept on all sample person inquiries. Also available at no cost to sample persons is an 800 toll-free telephone number that can be accessed during regular scheduled business hours. The response team members include a physician, a nurse with a doctorate degree, and other staff who are trained to answer specific questions.

Tests and procedures conducted in the MEC are not considered diagnostic exams and are not a substitute for an evaluation by a medical professional. No clinical treatments or health interventions of any type are performed in the MEC. If a health problem is discovered during the course of the MEC exam, the physician offers to contact the examinee's personal healthcare provider or recommend a local physician or clinic for follow-up care. If a sample person is found to have a serious condition requiring immediate attention, the local rescue squad may be summoned or the SP will be advised to seek immediate medical treatment.

1.7.6 Dry Run Day

At the beginning of the examination period, one-half day is devoted to calibrating instruments, practicing MEC procedures, and collecting biological specimens that serve as blind quality control samples. A dry run day is scheduled immediately before the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. All procedures in the dry run are completed as though the actual exam session was being conducted. The only difference is that the examinees are volunteers who are not part of the sample for the survey. Volunteers may include local residents, local officials, or field employees or guests of NCHS.

1.8 Integrated Survey Information System (ISIS)

The Integrated Survey Information System (ISIS) is a computer-based infrastructure designed to support all survey operations including sample management, data collection, data editing, quality control, analysis, and delivery of NHANES data. With a collection of customized subsystems, the ISIS links the field office, mobile examination center, Westat home office, and NCHS during field operations. Each component in NHANES such as Dietary Interview has a computer application for direct data entry. Data collected in the Dietary Interview room of the mobile examination center is directly entered in the ISIS system computers. In addition, data from biomedical equipment such as the blood pressure monitor in the CV Fitness room is directly downloaded to the ISIS system where it is displayed on the computer screen and stored in the system database.

1.9 Confidentiality and Professional Ethics

All information regarding this study must be kept strictly confidential except as required by law. This includes location of survey sites. Since this study is being conducted under a contract with the National Center for Health Statistics, the privacy of all information collected is protected by two public laws: Section 308(d) of the Public Health Service Act (42 U.S.C.242m) and the Privacy Act of 1974 (5 U.S.C. 552a).

Each person working on the study must be continuously aware of the responsibility to safeguard the rights of all the individuals participating in the study. Each participant should be treated courteously, not as a sample number. Never divulge names or any other information about study participants except to the research team. Refrain from any discussions about study participants, in or out of the MEC, which might be overheard by people not on the survey staff. All of the members of the research team are under the same legal, moral, and ethical obligations to protect the privacy of the SPs participating in the survey. No participant names will be included in any reports prepared about the survey and neither NCHS nor the contractor is allowed to release information that would identify study participants without the consent of the participants.

Cooperation from the public is essential to the success of survey research. A great deal of effort is expended in obtaining cooperation from many national, regional, state, and local officials and the general public. It is the responsibility of every field employee to build on the integrity of the survey to

encourage continued access to study participants during current and future surveys. Professional conduct, both on and off the job, is extremely important.

Each staff member has a responsibility for promoting good public relations. The Public Health Service and the contractor will be judged by the actions of the staff both on and off duty; consequently staff must be discreet in speech and action. Personal appearance and behavior must be governed by these same considerations. Please be aware of the audience at all times and avoid statements or actions that could shed an unfavorable light on the survey.

Staff will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that they are prohibited by law from disclosing any information while working on the survey to anyone except authorized staff of NCHS and the contractor, and that they agree to abide by the contractor's Assurance of Confidentiality.

2. OVERVIEW AND LABORATORY TEAM RESPONSIBILITIES

2.1 Overview

The laboratory component of NHANES includes the collection, processing, storage, and shipping of blood, urine, and other biological and environmental specimens. Collectively, these specimens provide data about the health status of the U.S. population.

The blood collection (venipuncture) procedure consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw. The phlebotomist also collects one additional blood tube from SPs selected for the VOC (volatile organic compounds) special study and administers a dextrose solution (Trutol) to and collects an additional 2-mL gray top tube from SPs selected for the glucose tolerance (GT) component.

The purpose of urine collection and processing is to collect sufficient urine from participants aged 6 years and older to be able to (1) perform a pregnancy test on selected females aged 8 to 17 years and all females aged 18 to 59 years to exclude pregnant participants from other components that could put the participant at risk; (2) allocate urine into vessels for storage and transport to multiple government and contact laboratories for analysis; (3) allocate urine into vessels for future studies; and (4) hold and process urine as a backup for the HIV blood test when the amount of blood collected was insufficient.

The purpose of blood processing is to (1) perform a complete blood count; (2) allocate blood (whole blood, plasma, packed cells, and serum) into vessels for transport to multiple government and contact laboratories for analysis; (3) allocate plasma and serum into vessels for future studies, and (4) process serum and water for environmental testing.

The purpose of collecting and processing one vaginal swab is to be able to store and transport the samples to a laboratory for HPV (human papilloma virus) analysis.

The purpose of performing a complete blood count on blood specimens is to provide a study of blood cells and coagulation.

The purpose of pregnancy testing is to exclude pregnant women aged 18-59 years from participating in the dual-energy x-ray absorptiometry (DXA) section of the body composition component of the MEC exam.

The purpose of conducting the special volatile organic compounds (VOCs) study is to collect blood and a tap water sample to determine the prevalence of exposures to certain chemicals.

2.2 The Laboratory Team

Each laboratory team includes three ASCP (American Society of Clinical Pathologists) certified medical technologists or medical laboratory technologists who have experience in all aspects of laboratory practice and a certified phlebotomist who has experience in venipuncture.

The chief medical technologist is the most senior member of the team. The chief medical technologist is responsible for overseeing all the activities of the medical technologists and phlebotomist in the MEC, and also quality control, equipment calibration, and maintenance. On a routine basis, the chief medical technologist performs the same duties as the other medical technologists.

2.3 Tasks

The phlebotomist's primary tasks include conducting the venipuncture, administering the Trutol solution, conducting a second venipuncture 2 hours after the Trutol solution has been consumed, assisting the medical technologists as needed, managing the component inventory, performing MEC equipment QC activities and recording the results, printing laboratory labels, and labeling blood processing racks. In addition, the phlebotomist acts as a backup examiner for the body measures exam, which includes recruiting SPs to participate in the physical activity monitor study.

The medical technologist's tasks include printing labels and labeling vessels; performing complete blood counts (CBCs); conducting pregnancy tests; processing blood, urine, vaginal swabs and tap water samples, performing MEC equipment QC activities and recording the results; and shipping specimens to contact laboratories. On a routine basis the medical technologists assist the phlebotomist as needed and manage the component inventory.

2.4 Organization of the Laboratory

The laboratory consists of three areas—the phlebotomy room, the laboratory (biological and environmental sample processing/hematology/pregnancy testing) area, and the label/shipping area. The phlebotomy room and laboratory area are located in the back half of trailer #3. The label/shipping area is located in part of the front section of trailer 3. Figure 2-1 illustrates the trailer 3 layout.

The phlebotomist performs the following activities in the phlebotomy room: collects blood, administers the Trutol solution, and collects a second blood sample on SPs who consumed the Trutol.

The medical technologist processes, stores, and ships biological and environmental samples, runs CBCs, and performs pregnancy testing in the laboratory area. They print labels, label blood processing racks, and prepare shipping documents in the label/shipping area.

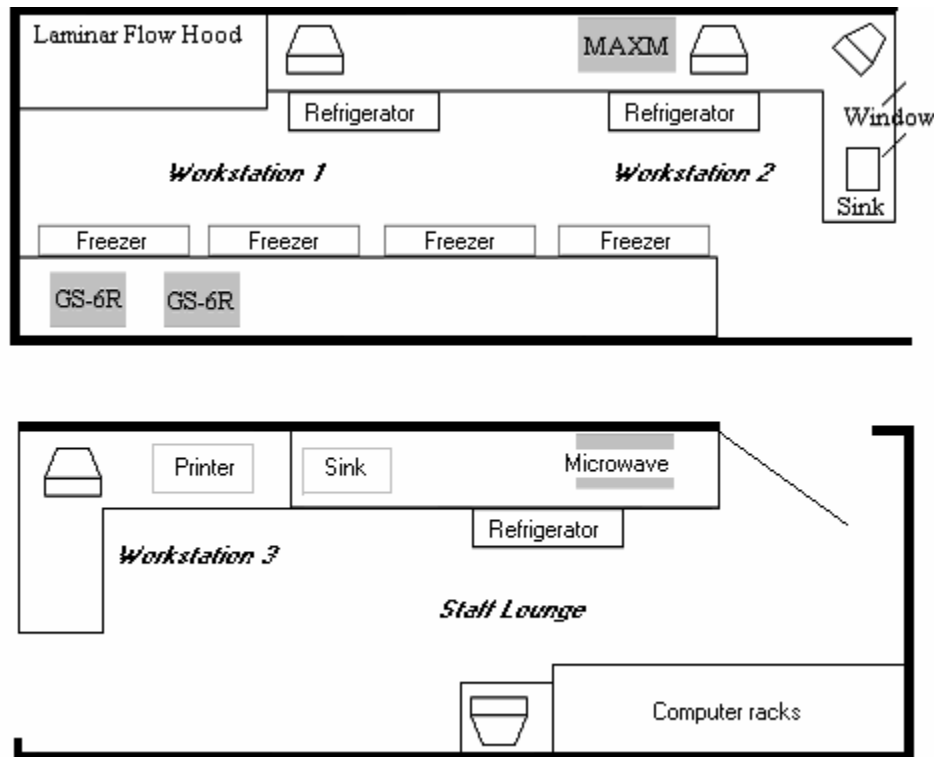


Figure 2-1. Trailer 3 layout

Laboratory Area Floor Plan

The laboratory area contains two workstations designated workstation 1 and workstation 2. Blood processing, storage, and HIV urine processing occurs at workstation 1. Urine collection, urine processing and storage, pregnancy testing, running CBCs, VOC/perchlorate specimen processing, vaginal swab specimen processing, and routine quality control activities occur at workstation 2.

Workstation 3 is located in the label/ship area of the laboratory. Printing labels, labeling vials for each SP's blood-processing rack, and shipping activities occur at this workstation. Packing specimens in shippers may also occur at workstations 1 and 2.

2.5 Tasks – Phlebotomy Room

- Set up supplies and check expiration dates of all items with lot numbers, such as the Vacutainer® tubes.
- Enter lot numbers and expiration dates into the automated Supply Use Control Log.
- Complete the phlebotomy examination, including conducting the venipuncture interview, administering the fasting questionnaire, and performing the venipuncture.
- Complete the OGTT examination, including administering the Trutol solution on assigned SPs and performing the blood draw on all GT eligible SPs.
- Label and transfer all blood tubes to the laboratory area.
- Disinfect all the counters at the beginning and end of each day.
- Take and record the QC readings.
- Maintain the appearance of the venipuncture area and the equipment.
- Monitor the inventory and restock supplies.
- Conduct the start and end of stand inventory counts.
- Clean the phlebotomy room, including the equipment, at the start and end of each stand.
- Assist in printing laboratory labels and label and assemble blood-processing racks.
- Serve as the backup examiner for body measures.

2.6

Tasks – Workstation 1

- Stock blood processing and storage supplies.
- Receive blood specimens.
- Select the correct pre-labeled rack and age appropriate template.
- Set the red top blood tubes aside to clot.
- Pipette whole blood into separate 2-mL cryovials for vessel 1 (Lead/Cad/HG), vessel 2 (Ery Proto), vessel 3 (RBC Folate), vessel 4 (Glycohem), vessel 5 (Mercury), and vessel 6 (CD4) from the 3-mL or 4-mL lavender tube.
- Transfer the 3-mL or 4-mL lavender tube to the workstation 2 technologists for hematology.
- Make the dilution for vessel 3 (RBC Folate).
- Centrifuge the remaining whole blood in the 3-mL lavender tube on SP age 3-5 and centrifuge the 4-mL lavender tube on SPs age 6+ in the refrigerated centrifuge.
- Pipette the plasma from the 3-mL or 4-mL lavender tube into 2-mL cryovials for vessel 7 (Homocys), and vessel 8 (Xtra Plasma).
- Wash and lyse the packed cells from the EDTA tube(s) and transfer into a 2-mL cryovial for vessel 88 (Acrylamide).
- Centrifuge the 2-mL gray tube.
- Pipette the plasma from the 2-mL gray tube into a 2-mL cryovial for vessel 9 (Glucose).
- Centrifuge the red top tubes.
- Pool the serum from the 3-mL, 7-mL, and 15-mL red top tubes for each SP and mix well.
- Aliquot serum into separate 2-mL cryovials for the serum vessels according to the age-specific protocols.
- Make the dilution for vessel 79 (Vitamin C).
- Pour serum from one of the 10-mL red tubes into a 5-mL cryovial for vessel 29/90/92 and the serum from the second 10-mL red tube into a 5-mL cryovial for vessel 89/91/93.
- Enter the blood processing results.

- Centrifuge the second 2-mL gray tube.
- Pipette the plasma from the second 2-mL gray tube into a 2-mL cryovial for vessel 98 (OGTT).
- Enter the blood processing results.
- Refrigerate or freeze the processed vessels.
- Access the HIV urine processing module and record HIV urine (vessel 53) processing results.
- Check contents of blood and HIV urine storage boxes (containers) using the container map module at the end of each session.
- Disinfect all the counters and the laminar flow hood at the beginning and end of each session.
- Maintain appearance of the blood processing area and the equipment.
- Monitor the inventory and restock supplies.
- Conduct the start and end of stand inventory counts.
- Clean the laboratory at the start and end of each stand.
- Assist in printing laboratory labels and label and assemble blood-processing racks.

2.7 Tasks – Workstation 2

- Perform start of stand, start of session, end of session, weekly, and end of stand quality control checks on laboratory equipment and record results.
- Prepare the ascorbic acid.
- Prepare the 6% MPA (metaphosphoric acid).
- Enter the Ascorbic and MPA dates in the Supply Use Control Log.
- Stock supplies for urine processing, hematology, and pregnancy testing.
- Enter the urine collection results.
- Label urine vessels and aliquot urine into 2 or 5-mL cryovials or 14-mL Falcon snap cap according to the processing protocol.
- Enter the urine processing results.

- Store the urine vessels.
- Run the pregnancy test controls.
- Conduct the pregnancy test and enter results.
- Perform startup procedures and run quality control materials on Coulter® MAXM.
- Run specimens on the Coulter® MAXM and enter results.
- Process vaginal swab and VOC (blood and water) specimens.
- Process VOC (blood and VOC water for VOCs (vessel 56) and perchlorate (vessel 103).
- Check contents of urine, vaginal swab and VOC storage boxes and bags using the container maps module at the end of each session.
- Disinfect all counters at the beginning and end of each session.
- Maintain the appearance of the urine processing/hematology area and the equipment.
- Monitor the inventory and restock supplies.
- Assist the phlebotomist with venipuncture.
- Conduct the start and end of stand inventory counts.
- Clean the laboratory at the start and end of each stand.
- Assist in printing laboratory labels and label and assemble blood-processing racks.

2.8 Tasks – Workstation 3

- Print blood, urine, and pregnancy testing labels.
- Prelabel the vials for each SP's blood-processing rack.
- Generate container IDs at the start of stand.
- Assign a container ID number to one container for each vessel.
- Close all open containers, create air bills, and assign containers to shippers.
- Prepare shipping manifests and send electronic files.

- Prepare blood (whole blood, serum, packed cells, and plasma), urine, vaginal swab, and VOC/perchlorate samples for shipping.
- Pack, weigh, label, and ship shippers.
- Open all new containers after shipping.
- Maintain appearance of the label/ship area and the equipment.
- Monitor inventory and restock supplies.
- Assist phlebotomist with venipuncture.
- Conduct start and end of stand inventory counts.
- Clean the laboratory at the start and end of each stand.

3. LABORATORY ISIS FUNCTIONALITY

3.1. Laboratory-Specific Functionality

While MEC applications are custom built for each specific component they share a common design. This commonality provides all component applications the same “look and feel” which minimizes reorienting technologists who rotate from component to component. A complete ISIS overview and these features and characteristics are described in the *ISIS User Guide*. The laboratory application has additional functionality that has been developed to accommodate and facilitate processing specimens and reporting results. This chapter describes the laboratory-specific functionality.

3.2 Laboratory Heads-up Display

Use the laboratory heads-up display to view the SPs scheduled into the session, the modules for which they are eligible, and their current process status. Use the heads-up display to access modules and print additional labels.

| Appointments for Session: 410260 | | | | | | | Process Status | | | | | | | | | |
|----------------------------------|-----------|--------|------|--------|-----|-------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| SP ID | Sample ID | status | type | gender | age | name | UC | B | CB | U | P | HPV | hiv | V | gtt | PW |
| 200594 | 200594 | SC | P | F | 51 | DOE, JANE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 323798 | 323798 | BE | P | M | 40 | PITT, BRAD | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 351499 | 351499 | BE | P | F | 15 | MEYERS, JESSICA | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 420341 | 420341 | SC | P | F | 15 | MEYERS, MICHELLE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 425408 | 425408 | CI | P | F | 19 | CALHOUN, JAMES | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 565634 | 565634 | SC | P | F | 35 | SHEFFIELD, MOLLY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 576133 | 576133 | SC | P | F | 39 | COX, COURTNEY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695392 | 695392 | BE | P | M | 38 | MEYERS, RICHARD | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 721250 | 721250 | SC | P | M | 42 | ARQUETTE, DAVID | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 762833 | 762833 | CI | P | F | 35 | ANISTON, JENNIFER | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 808590 | 808590 | SC | P | F | 44 | JONES, JANET | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, LI=Logged-in, CI=checked-in, BE=being examined, EX=exited), Appointment Type (P=primary, G=guest, VIP=VIP guest, S=surplus, D=dry run), Gender (M=male, F=female), Age, and Name (last, first.)

The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), HPV (HPV swab processing), hiv (HIV urine processing), V (VOC processing), gtt (glucose tolerance test or vessel 98 processing), and PW (perchlorate water processing.) The SP is ineligible for a module when the process status is ◦. The SP is eligible for a module but no results have been recorded when the process status is O. The SP is eligible for a module and some results have been recorded when the process status is ⊙. The SP is eligible for a module, all results have been recorded, and the module is complete when the process status is ●.

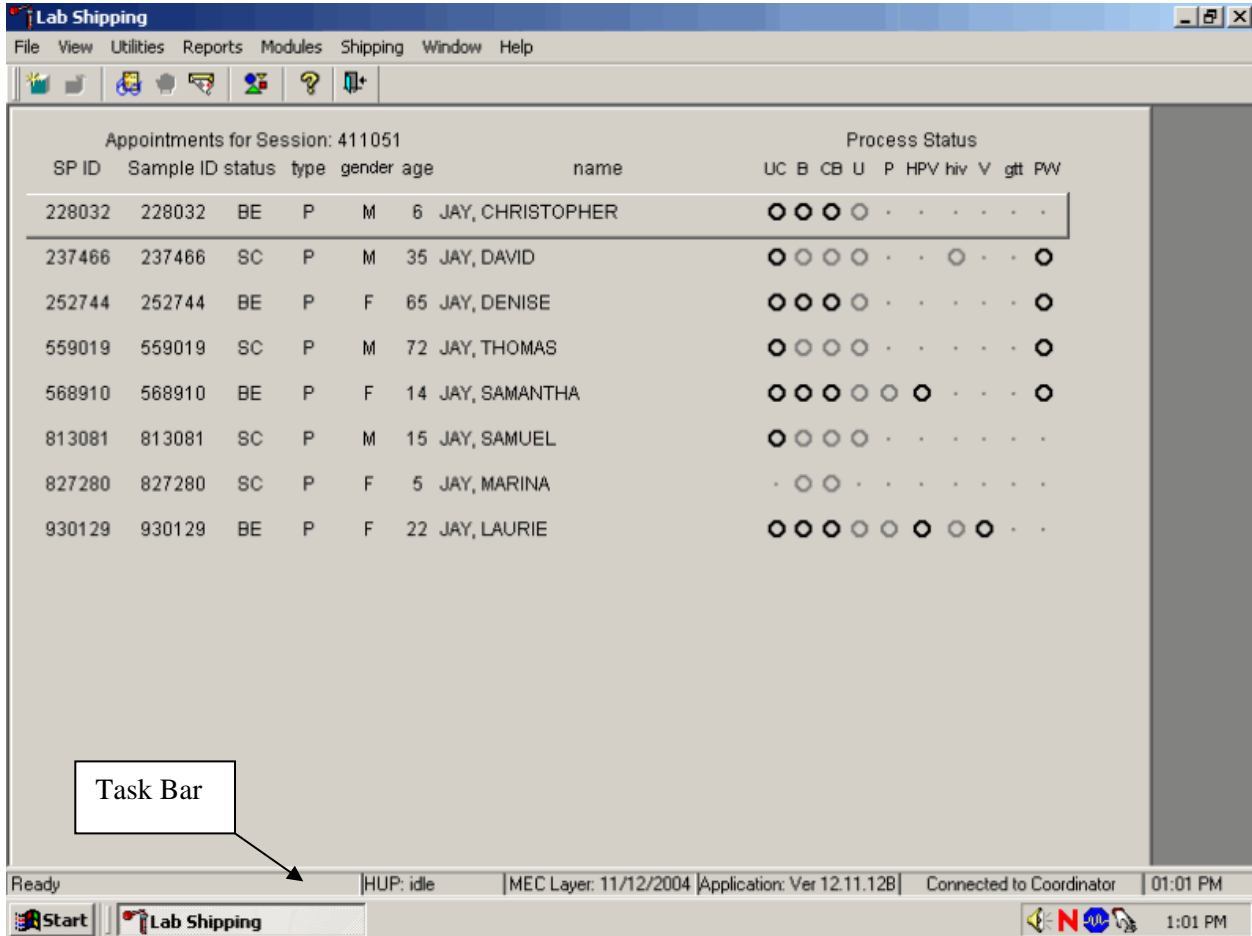
The SP is eligible for a module (O) but the process status for blood processing (B) and the complete blood count (CB) will not enable until the blood tubes are recorded as collected in the phlebotomy component. The process status is O for urine processing (U) and pregnancy testing (P) until the SP's urine is marked as collected in the UC module. Once these samples are collected, the process status changes from O to ●. The SP is eligible for the hiv module but the status is O until the SP's blood processing HIV result is recorded. If the HIV serum vessel (#21) is marked as "not filled" because the quantity of HIV serum is insufficient, the status changes from O to ●. The gtt module will enable as soon as one SP has the OGTT blood tube drawn in phlebotomy. The process status regularly updates and changes after each result is saved.

The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if active SP is not the SP of choice.

To view all SPs, the modules for which they are eligible, and their process status use the mouse to direct the mouse arrow to the vertical scroll bar, left click, and drag the bar up or down.

3.3 Laboratory Task Bar

Monitor the activity in the laboratory task bar.



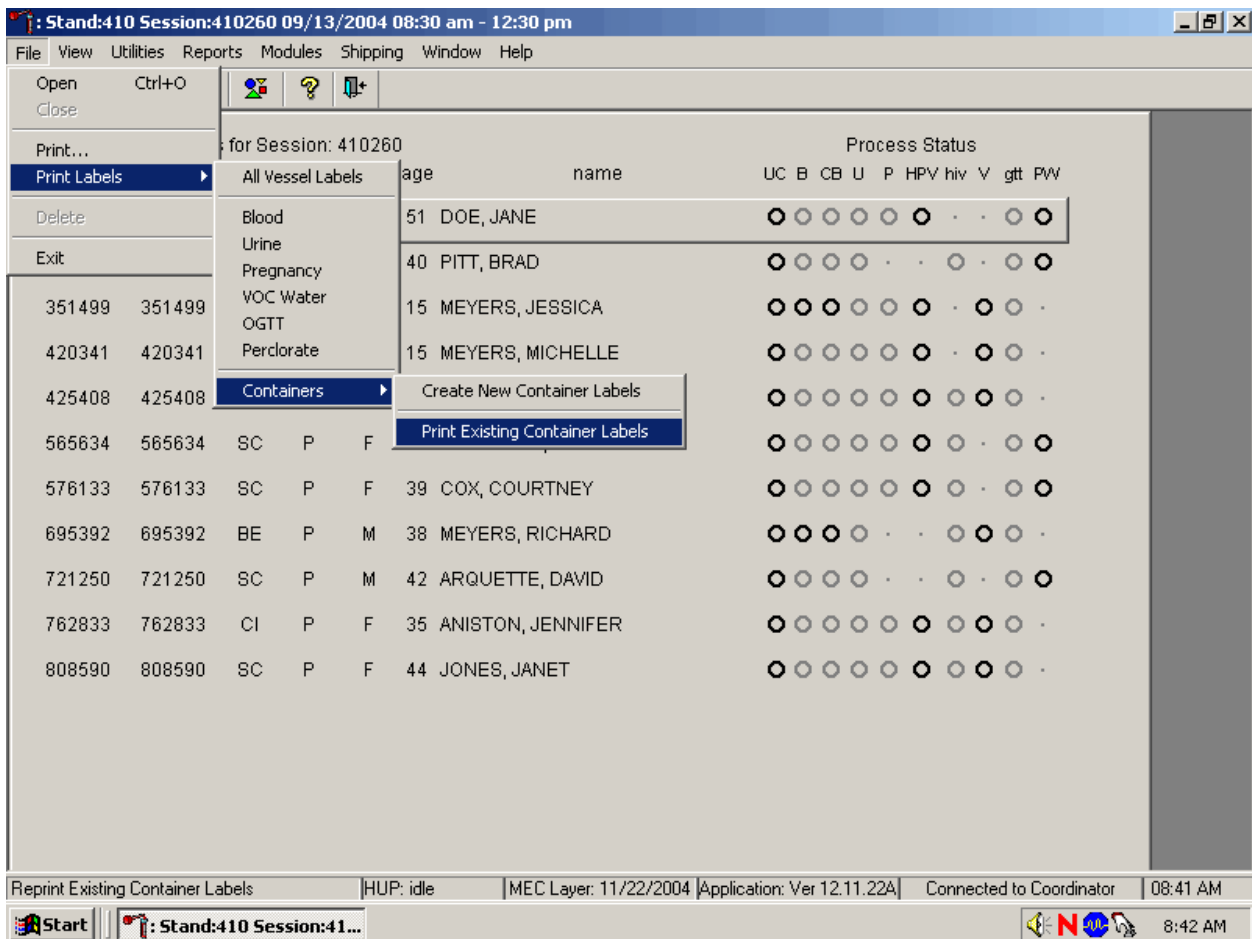
The laboratory task bar displays the following information:

- The status of the refresh routine such as when the labels are printing or the data are updating;
- The status of the heads-up display (HUP) such as when it is “idle;”
- The current version of the MEC Layer;
- The current version of the application;
- The status of the connection to the coordinator; and
- The current time.

3.4 Menu Bar Options

Each MEC application has tailored menu options to support the specific examination. The menu options below list all available options. The options marked with an asterisk appear on all MEC examination programs. Options are grayed (inverted) or not present when they are not available for a specific subsystem.

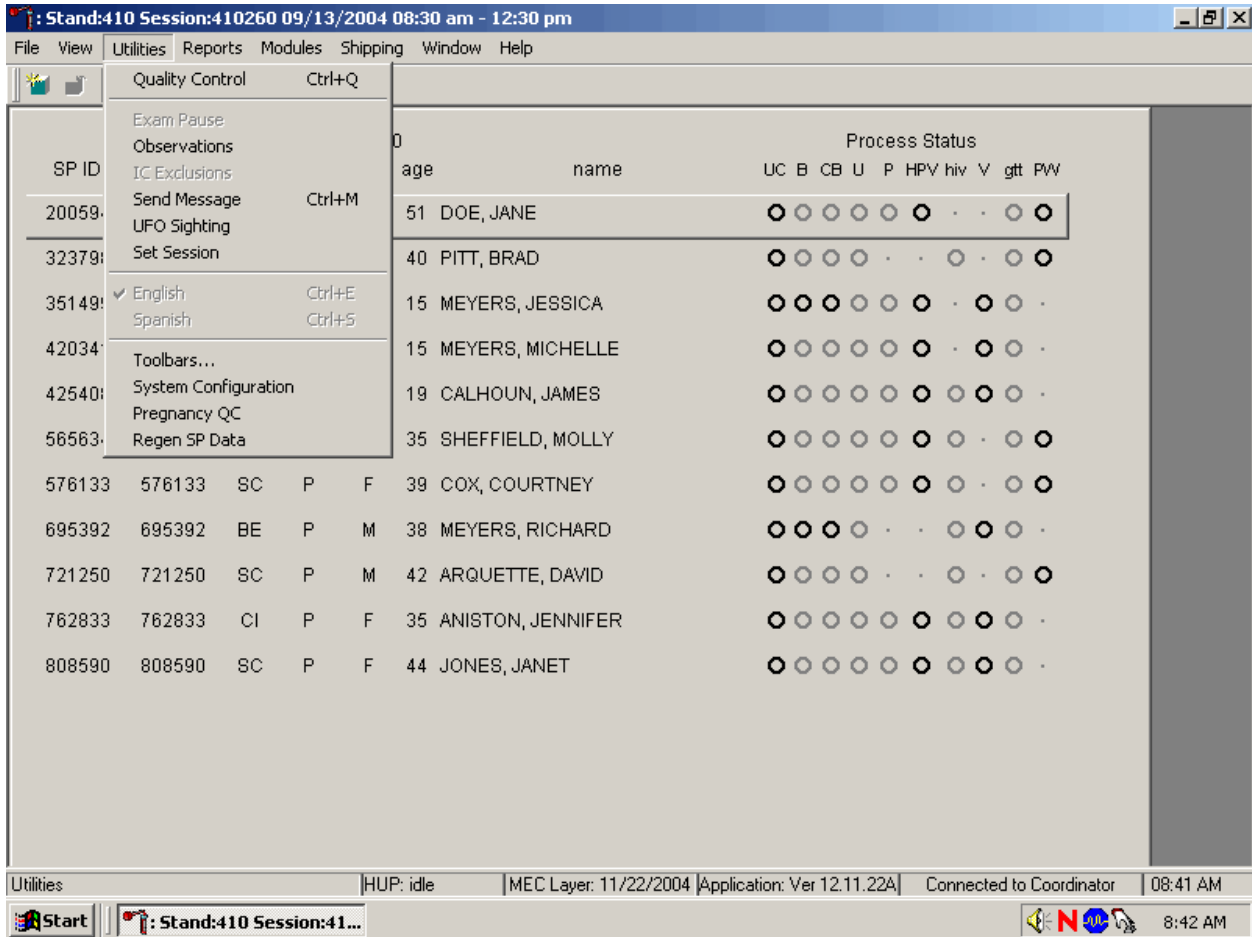
3.4.1 File Menu Options



Asterisks (*) denote menu options common to all MEC examination components.

| *File | |
|---------------------------------|--|
| * <u>O</u> pen <i>Ctrl+O</i> | Opens a new, partial, or not done SP exam; the SP must be assigned by coordinator if the application is not in standalone mode. |
| * <u>C</u> lose | Closes the current examination. |
| * <u>P</u> rint | Prints the current examination screen or report. |
| Print <u>L</u> abels | <p>Allows the laboratory medical technologist to:</p> <p>ALL VESSEL LABELS</p> <ol style="list-style-type: none"> 1. Print laboratory labels for all modules an SP or for all SPs in a session. 2. Print laboratory labels for one module for an SP or for all SPs in a session. 3. Print labels using filters such as previously printed or not previously printed. <p>A complete description of this functionality is described in Section 9.3.1.</p> <p>CONTAINERS</p> <p>Create New Container Labels</p> <ol style="list-style-type: none"> 1. Print and assign container labels. A complete description of this functionality is described in Section 9.5. 2. Reprint existing container label(s). A complete description of this functionality is described in Section 9.6. |
| * <u>D</u> elete | Deletes current exam and any associated references. Used primarily to delete an examination that clearly is in error, such as the wrong SP. Only enabled if it is a new exam and the status is not done or partial. |
| * <u>E</u> xit | Exits the application. |

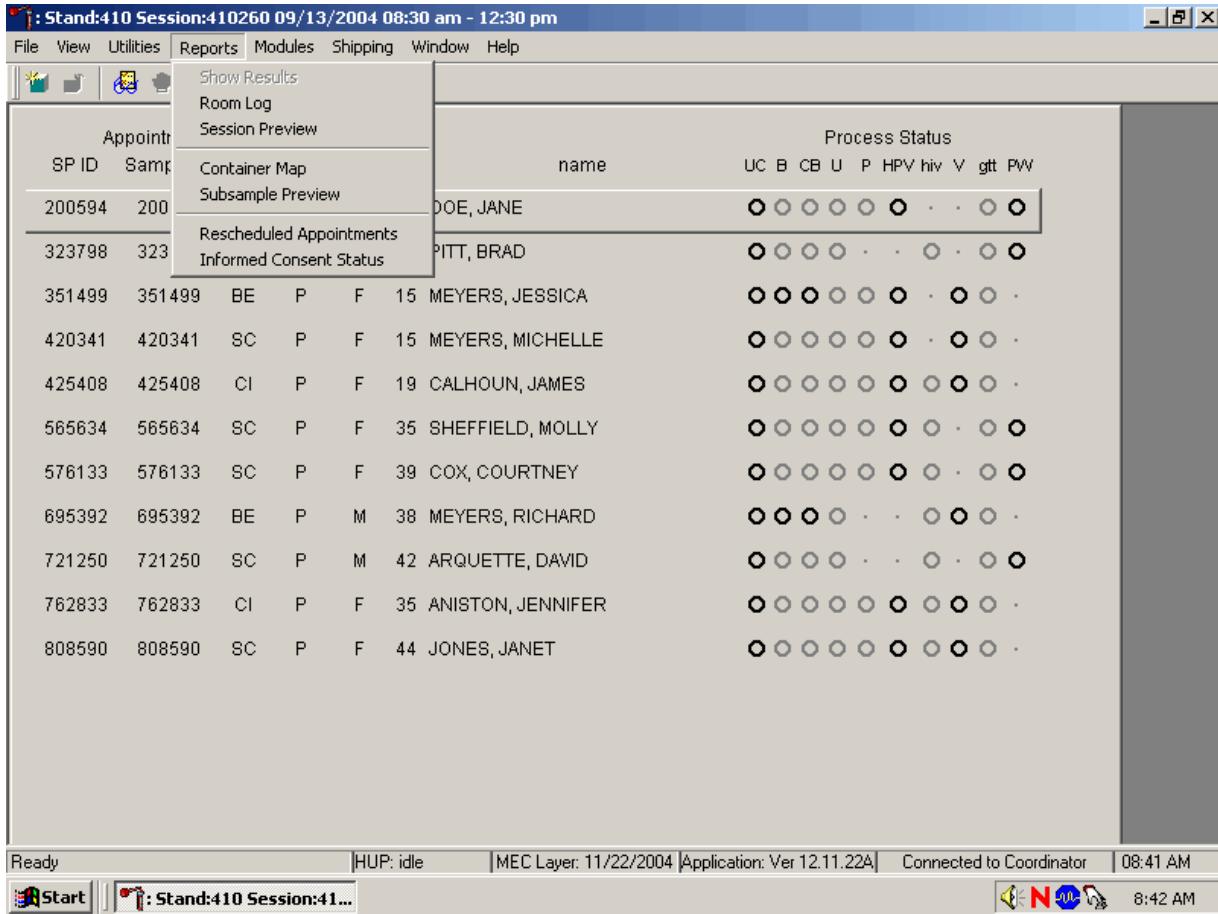
3.4.2 Utilities Menu Options



| *Utilities | |
|----------------------------------|--|
| Quality Control <i>Ctrl+Q</i> | Opens the quality control dialog box to initiate quality control procedures. A complete description of this functionality is described for phlebotomy is located in Section 4.14 and for lab in Section 11.9. |
| *Exam <u>P</u> ause | Used in case of an emergency in the MEC, such as an ill SP. Pauses the exam temporarily to stop the exam timer (in NH_Exam); sends “Exam paused” message to coordinator. |
| * <u>O</u> bservation | Submits an observation to the physician for possible referral. |
| IC <u>E</u> xclusions | Posts an exclusion record for those SPs who do not want HIV, STD, PSA or HPV tests performed or samples stored for future research; this utility is available only for coordinator, physician, and phlebotomy. A complete description of this functionality is described in Section 3.5. |

| *Utilities | |
|--|---|
| *Send <u>M</u> essage <i>Ctrl+M</i> | Opens a dialog box to send messages to the coordinator. |
| *UFO Sighting | Opens the Unusual Field Occurrence utility to document unusual equipment, SP, protocol, trailer, or supply issues. |
| Set Session <u>u</u> | Allows the laboratory medical technologist to change the current session in the laboratory application. A complete description of this functionality is described in Section 3.6. |
| English <i>Ctrl+E</i> | Toggle option to set exam language to English. |
| <u>S</u> panish <i>Ctrl+S</i> | Toggle option to set exam language to Spanish. |
| * <u>T</u> oolbars | Configures placement of toolbars. |
| System <u>C</u> onfiguration | |
| Pregnancy QC | Allows the laboratory medical technologist to access the Pregnancy QC module. A complete description of this functionality is described in Section 6.X. |
| Regen SP Data | Allows the laboratory medical technologists to regenerate or recalculate a new profile for an SP. A complete description of this functionality is described in Section 9.4. |

3.4.3 Report Menu Options



| *Reports | |
|----------------------------------|---|
| <u>Show Results</u> | |
| *Room <u>L</u> og | Lists the SPs who have completed the component, including appt/exam and component status. |
| * <u>S</u> ession Preview* | Lists all SPs in current session. |
| <u>C</u> ontainer Map | Displays a list of laboratory containers and a graphic description of the contents. A complete description of this functionality is described in Section 3.7. |
| Subsample Preview | List the SPs who are eligible for the various subsamples. A complete description of this functionality is described in Section 3.8. |
| <u>R</u> escheduled Appointments | Lists the SPs who have rescheduled from a previous session into the current session. A complete description of this functionality is described in Section 9.3.3. |
| <u>I</u> nformed Consent Status | Lists the various modules that require consent and displays the result of the consent – excluded or not excluded. A complete description of this functionality is described in Section 3.9. |

3.4.4 Modules

Appointments for Session: 410260

| SP ID | Sample ID | status | type | gender | age | name | Process Status | | | | | | | | | |
|--------|-----------|--------|------|--------|-----|-------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| | | | | | | | UC | B | CB | U | P | HPV | hiv | V | gtt | PW |
| 200594 | 200594 | SC | P | F | 51 | DOE, JANE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 323798 | 323798 | BE | P | M | 40 | PITT, BRAD | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 351499 | 351499 | BE | P | F | 15 | MEYERS, JESSICA | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 420341 | 420341 | SC | P | F | 15 | MEYERS, MICHELLE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 425408 | 425408 | CI | P | F | 19 | CALHOUN, JAMES | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 565634 | 565634 | SC | P | F | 35 | SHEFFIELD, MOLLY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 576133 | 576133 | SC | P | F | 39 | COX, COURTNEY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695392 | 695392 | BE | P | M | 38 | MEYERS, RICHARD | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 721250 | 721250 | SC | P | M | 42 | ARQUETTE, DAVID | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 762833 | 762833 | CI | P | F | 35 | ANISTON, JENNIFER | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 808590 | 808590 | SC | P | F | 44 | JONES, JANET | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Ready | HUP: idle | MEC Layer: 11/22/2004 | Application: Ver 12.11.22A | Connected to Coordinator | 08:42 AM

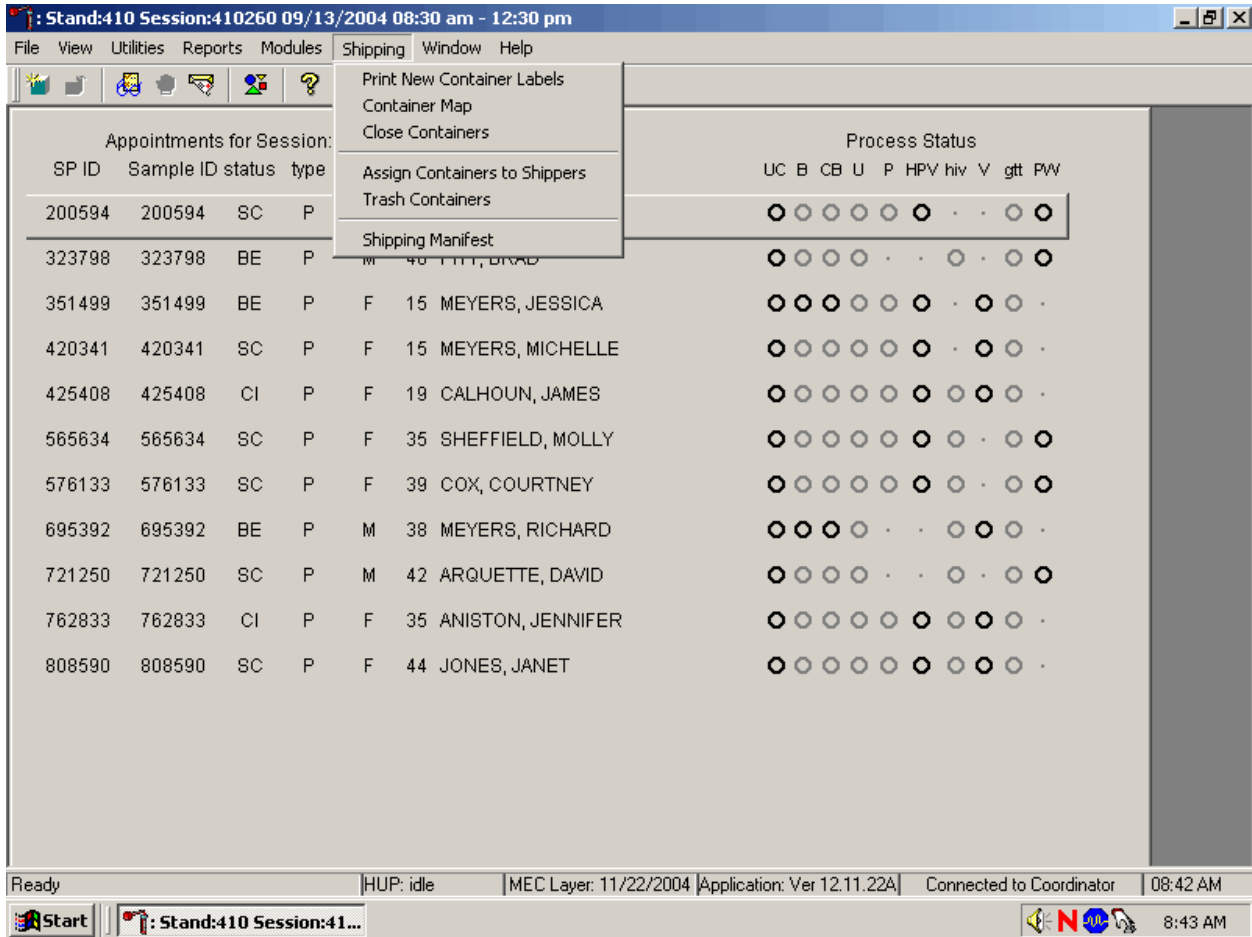
Start | Stand:410 Session:41... | 8:42 AM

Modules

Hematology

Opens the laboratory hematology module. A complete description of this functionality is described in Section 7.XI.

3.4.5 Shipping



Shipping

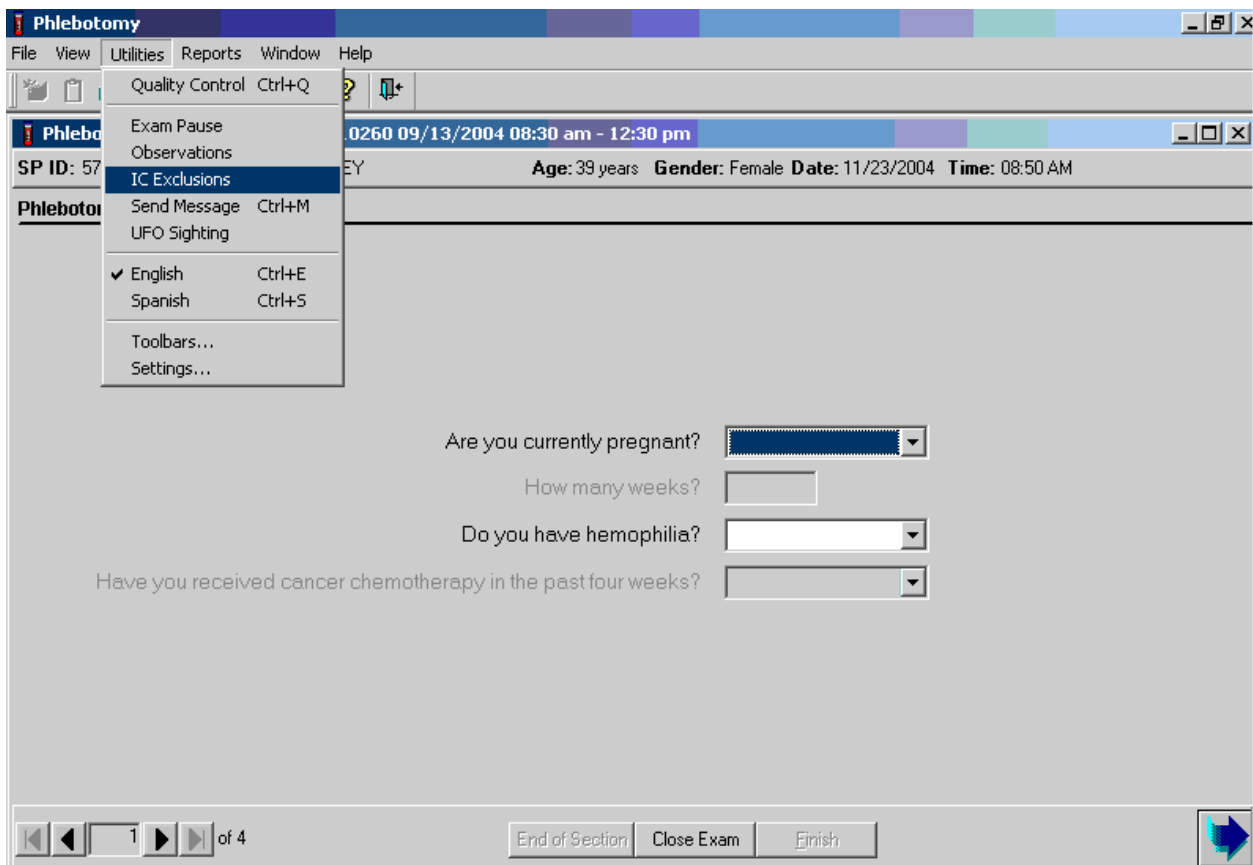
| | |
|---------------------------------------|---|
| Print <u>N</u> ew Container Labels | Allows the medical technologist to print labels for containers such as a 5-inch box with 9 x 9 grid. A complete description of this functionality is described in Section 9.5. |
| <u>C</u> ontainer Map | Allows the medical technologist to view a list of all containers with a graphic representation of the samples assigned to that container. A complete description of this functionality is described in Section 3.7. |
| <u>C</u> lose Containers | Allows the medical technologist to “close” active containers that have been previously opened. A complete description of this functionality is described in Section 9.9. |
| Assign Containers to <u>S</u> hippers | Allows the medical technologist to assign or associate a closed container with a FedEx airbill number. A complete description of this functionality is described in Section 9.10. |

| | |
|-------------------------|---|
| <u>Trash Containers</u> | Allows the medical technologist to delete container label numbers in the database for labels that are damaged. A complete description of this functionality is described in Section 9.6. |
| Shipping Manifest | Allows the medical technologist to print hard copy manifests and electronically send email files to the contract laboratories. A complete description of this functionality is described in Section 9.11. |

3.5 Informed Consent Exclusions

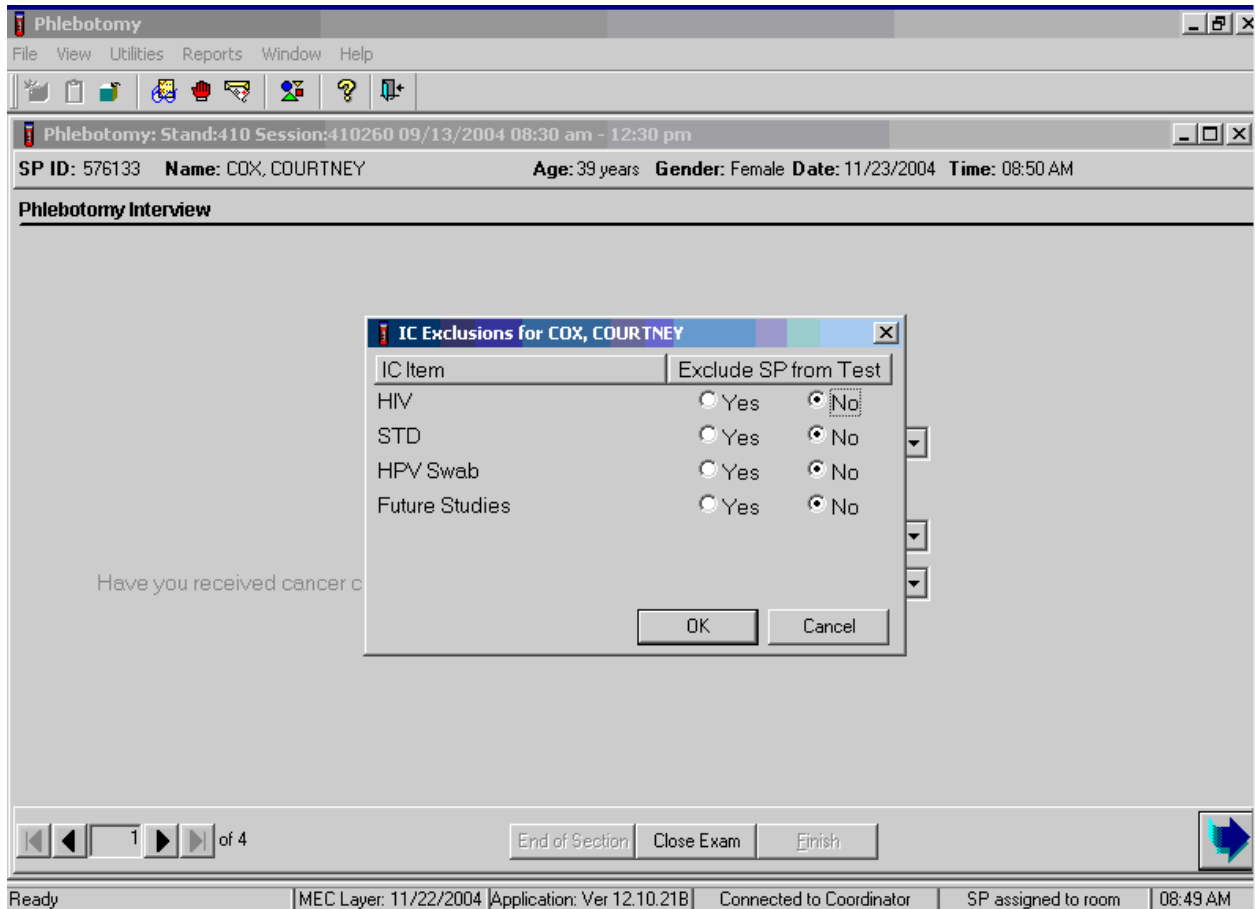
If at any time during the phlebotomy or physician exam the SP indicates they do not want their blood or urine tested for HIV (AIDS), STD (sexually transmitted diseases include chlamydia, gonorrhea, and herpes) or future studies, then enter this information using the IC Exclusions module.

Access the IC Exclusions module.



To access the IC (informed consent) Exclusions module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {IC Exclusions}, and left click, or type [Alt] [U/i], [X/x].

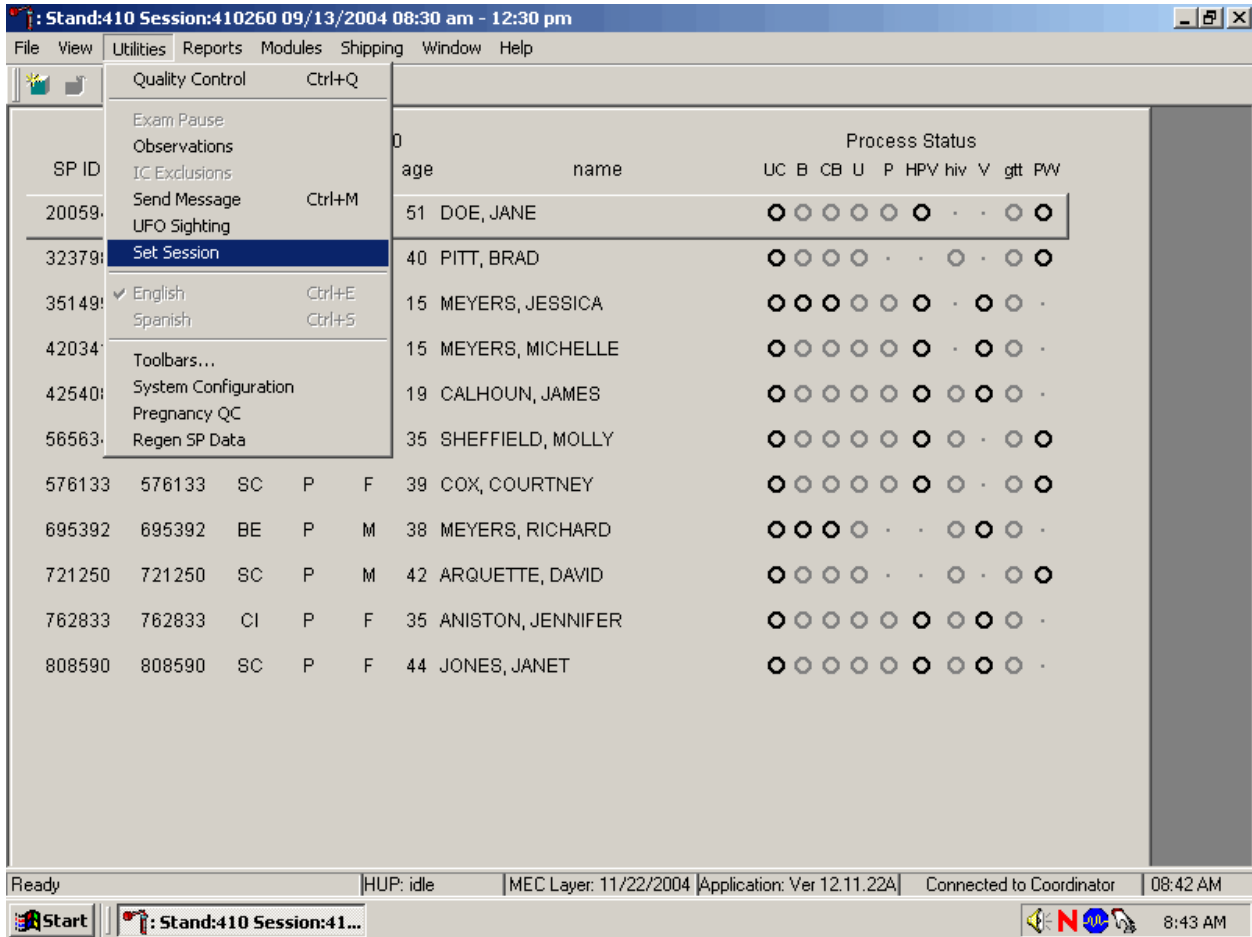
The IC Exclusions window displays all the specific exclusion item tests or groups of tests for which the SP is eligible and the status for each exclusion item.



Record each item as directed by the SP. To mark each item, use the mouse to direct the mouse arrow to the “Yes” or “No” radio button and left click. To record these actions and save them to the database, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions without saving the data to the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

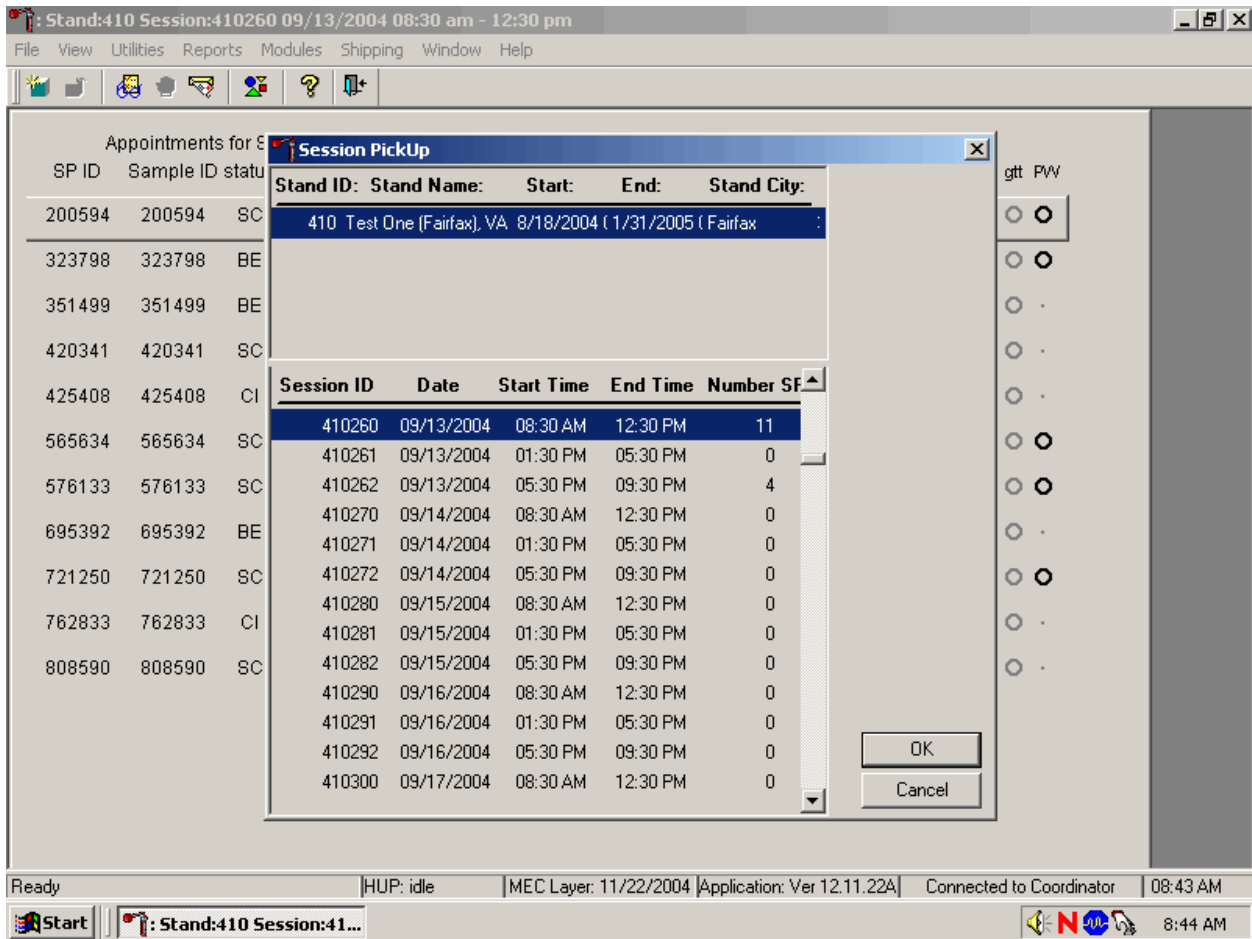
3.6 Set Session Utility

Sign onto the computer terminal. Open the laboratory application. If the laboratory is conducting a MEC session, the heads-up display will default to the current session. Use the Set Session utility to access a session.



To access the Set Session utility, use the mouse to direct the mouse arrow to {Utility} in the menu bar, drag the arrow to {Set Session}, and left click or type [Alt] [U/u] [N/n].

The Session PickUp list displays. Select the correct session from the pick list.



The Session PickUp window displays. The current stand is displayed in the top section of the window. To select or highlight the correct MEC session, use the mouse to direct the mouse arrow to the correct session, date, and time and right click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

After selecting a session from the Session PickUp list and selecting OK, the laboratory heads-up screen displays.

Stand:410 Session:410800 11/06/2004 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 410800

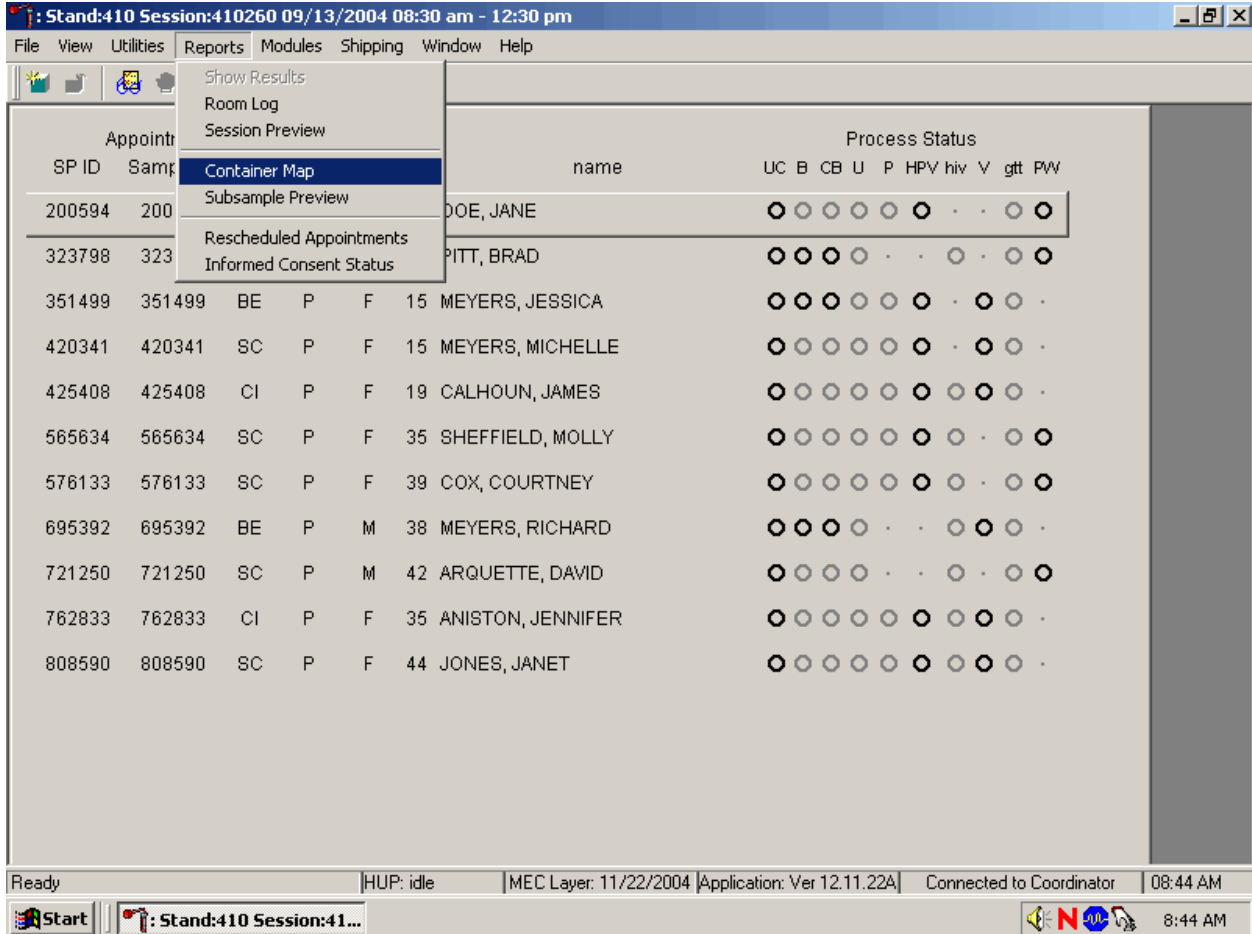
| SP ID | Sample ID | status | type | gender | age | name | Process Status | | | | | | | | | | | | | |
|--------|-----------|--------|------|--------|-----|------------------|----------------|---|----|---|---|-----|-----|---|-----|----|---|---|---|---|
| | | | | | | | UC | B | CB | U | P | HPV | hiv | V | gtt | PW | | | | |
| 346047 | 346047 | SC | P | M | 16 | GOLDSTEIN, RANDY | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 377570 | 377570 | SC | P | F | 13 | SCHRIFT, JOY | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 476384 | 476384 | SC | P | M | 41 | SOCCER, MICHAEL | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 487583 | 487583 | SC | P | M | 60 | O'NEILL, TONY | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 754967 | 754967 | SC | P | M | 13 | COLIGIANT, PAT | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 898895 | 898895 | SC | P | F | 16 | SUE, SARA | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 979907 | 979907 | SC | P | M | 60 | RITTER, ERIC K | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Ready | HUP: idle | MEC Layer: 11/12/2004 | Application: Ver 12.11.19B | Connected to Coordinator | 10:01 AM

Start | Stand:410 Session:41... | 10:01 AM

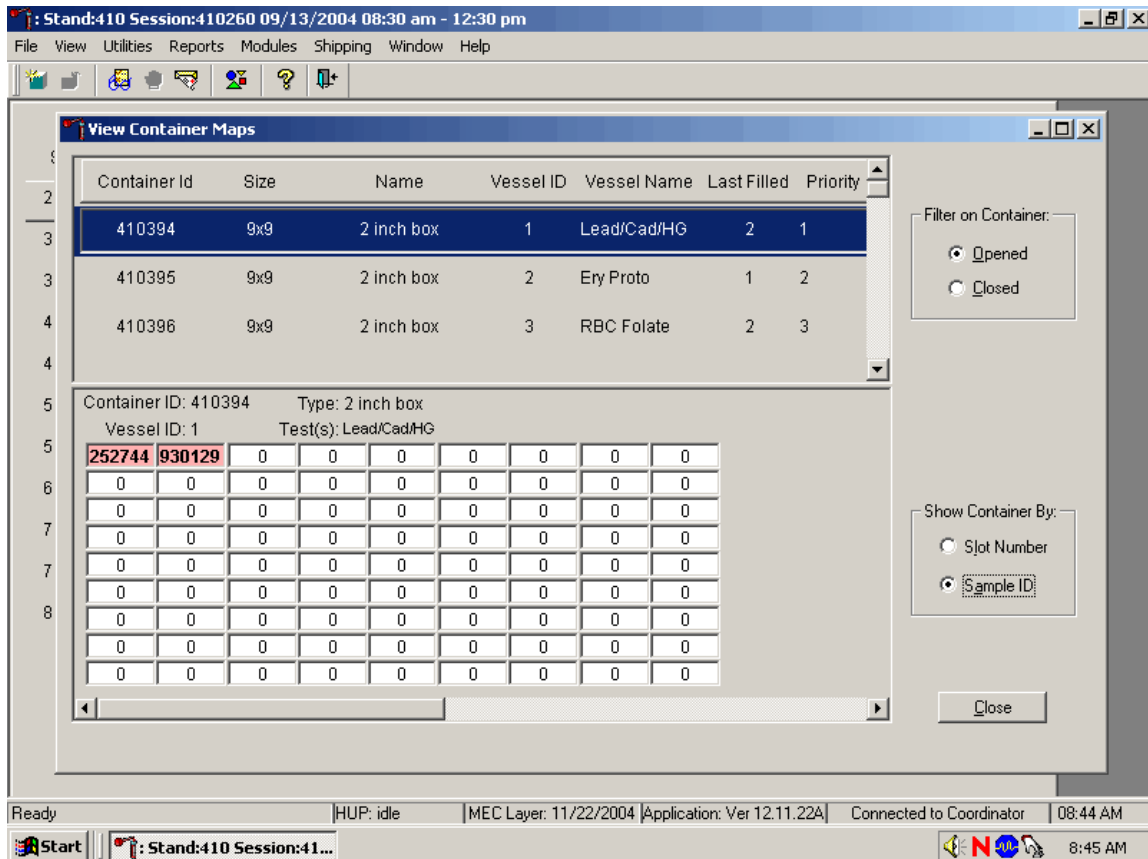
3.7 Container Map

Check the slot assignment of all containers at the end of each session. Access the Container Map report.



To access the Container Map report, use the mouse to direct the mouse arrow to {Reports} or {Shipping} in the menu bar, drag the arrow to {Container Map}, and left click or type [Alt] [R/r] [C/c] or [Alt] [S/s], [C/c].

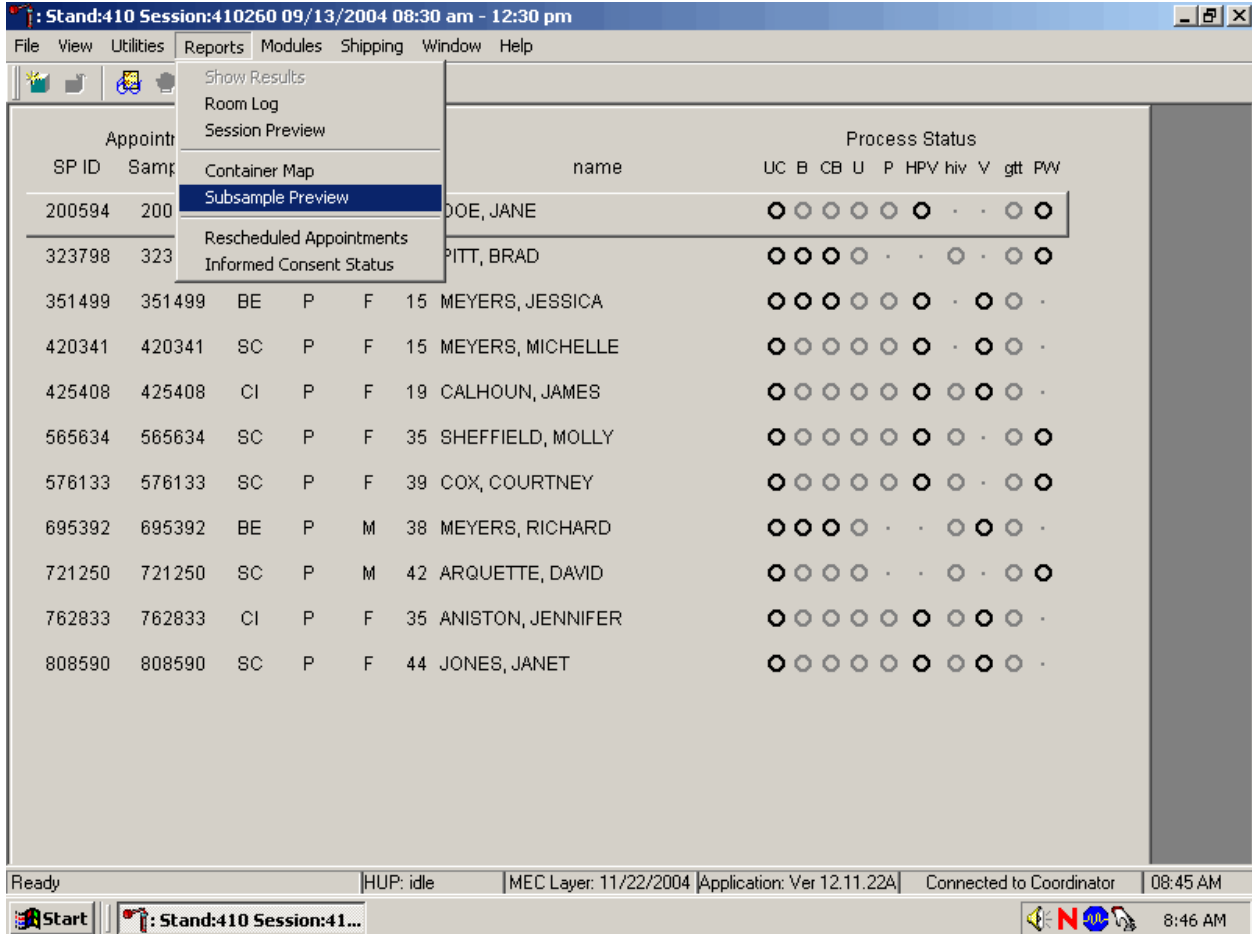
Verify the contents of each container against the container map.



- Set the Filter on Container to “Opened” by using the mouse to direct the mouse arrow to “Opened” and left click.
- Set the Show Container By to “Sample ID” by using the mouse to direct the mouse arrow to “Sample ID” and left click.
- Highlight or select the first container ID for the first vessel by using the up and down keys to move up and down the list of Container IDs. Alternatively, use the mouse to direct the mouse arrow to the scroll bar to the right of the row and drag the bar up or down to find the correct vessel ID.
- Verify the container ID on the box against the container ID listed on the screen and verify each vessel sample ID against its location in the map.
- Segregate (separate out) the specimens that have been checked. When subsequently checking the Container Map Report for this container, begin checking specimens that are not segregated.
- Continue checking each container map report for the remaining vessels.
- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

3.8 Subsample Preview

Access the Subsample Preview to view all SPs in the current session and the selected subsamples for which they are eligible.



To access the Subsample Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Subsample Preview}, and left click.

Review the Subsample Preview.

SPs Selected for Subsamples in Session 410260

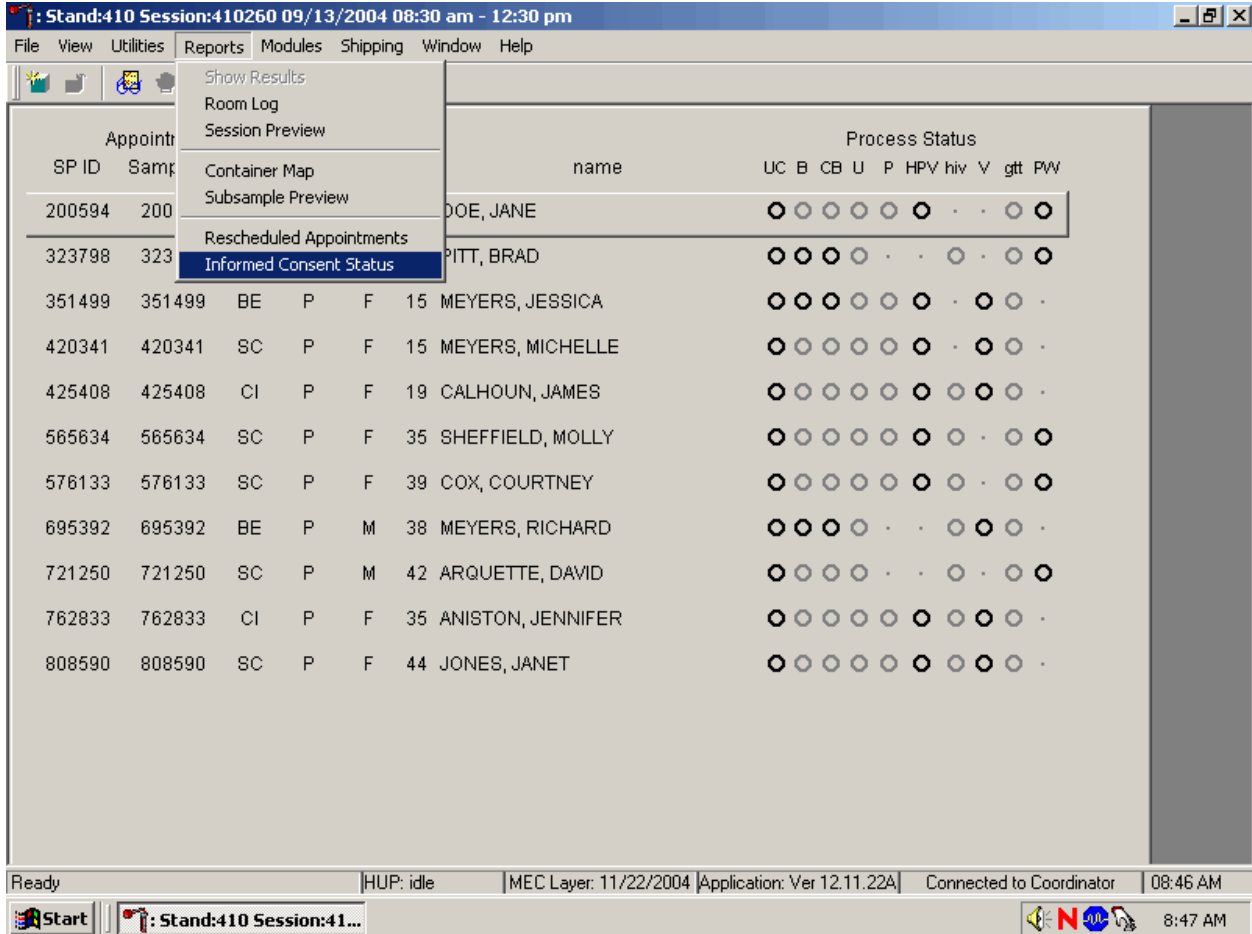
| Appt.ID | SP ID | Person Name | Gender | Age | Type | Subsample Description |
|---------|--------|--------------|--------|-----|------|----------------------------------|
| 4102083 | 808590 | JONES, JANET | F | 44 | 1 | Volatile Organic Compounds (VC) |
| | | | | | 1 | Persistent Pesticide and Dioxins |
| | | | | | 1 | EPA Priority Pesticide |
| | | | | | 1 | Organophosphate Pesticide |
| | | | | | 1 | Urinary Iodine |
| | | | | | 1 | Persistent Pesticides 2 |
| 4102084 | 200594 | DOE, JANE | F | 51 | 1 | Heavy Metals |
| | | | | | 1 | Speciated Arsenic |
| | | | | | 1 | Urine Mercury |
| | | | | | 1 | Perfluor1 |
| | | | | | 1 | Srm Pest |
| | | | | | 1 | Perchlorates Water (H2O) |

11/23/2004 Page 1 of 6

The Subsample Preview report includes all SPs assigned to the current session and the subsamples for which they are eligible. This report contains the appointment ID, SP ID, person name, gender, age, appointment type, and subsample description. Only SPs selected for inclusion in specific subsamples are eligible to have the related vessel filled. To view the entire report, use the mouse to direct the mouse arrow to the right scroll bar, and drag the arrow up or down. To print a copy of the report, use the mouse to direct the mouse arrow to the Print button and left click. To exit and close the report, use the mouse to direct the mouse arrow to the Close button and left click.

3.9 Informed Consent Status

Access the Informed Consent Status report to view SPs and the status of the informed consent result for various tests and/or groups of tests.



To access the Informed Consent Status report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Informed Consent Status} and left click or type [Alt] [R/r], [I/i].

Review the SPs scheduled into the current session and the status of their informed consent by using the Informed Consent Status report.

| Appt Id | Sp Id | Hiv | Std | Future Research | HPV | PSA |
|---------|--------|-----|-----|-----------------|-----|-----|
| 4102085 | 323798 | N | N | N | - | N |
| 4102086 | 351499 | - | N | N | N | - |
| 4102087 | 420341 | - | N | Y | N | - |
| 4102088 | 425408 | N | N | N | N | - |
| 4102089 | 565634 | N | N | Y | N | - |
| 4102090 | 576133 | N | N | Y | N | - |
| 4102091 | 695392 | N | N | N | - | - |
| 4102092 | 721250 | N | N | Y | - | N |
| 4102093 | 762833 | N | N | N | N | - |

'Y' = SP Excluded
 'N' = SP Not Excluded
 '-' = Not Applicable

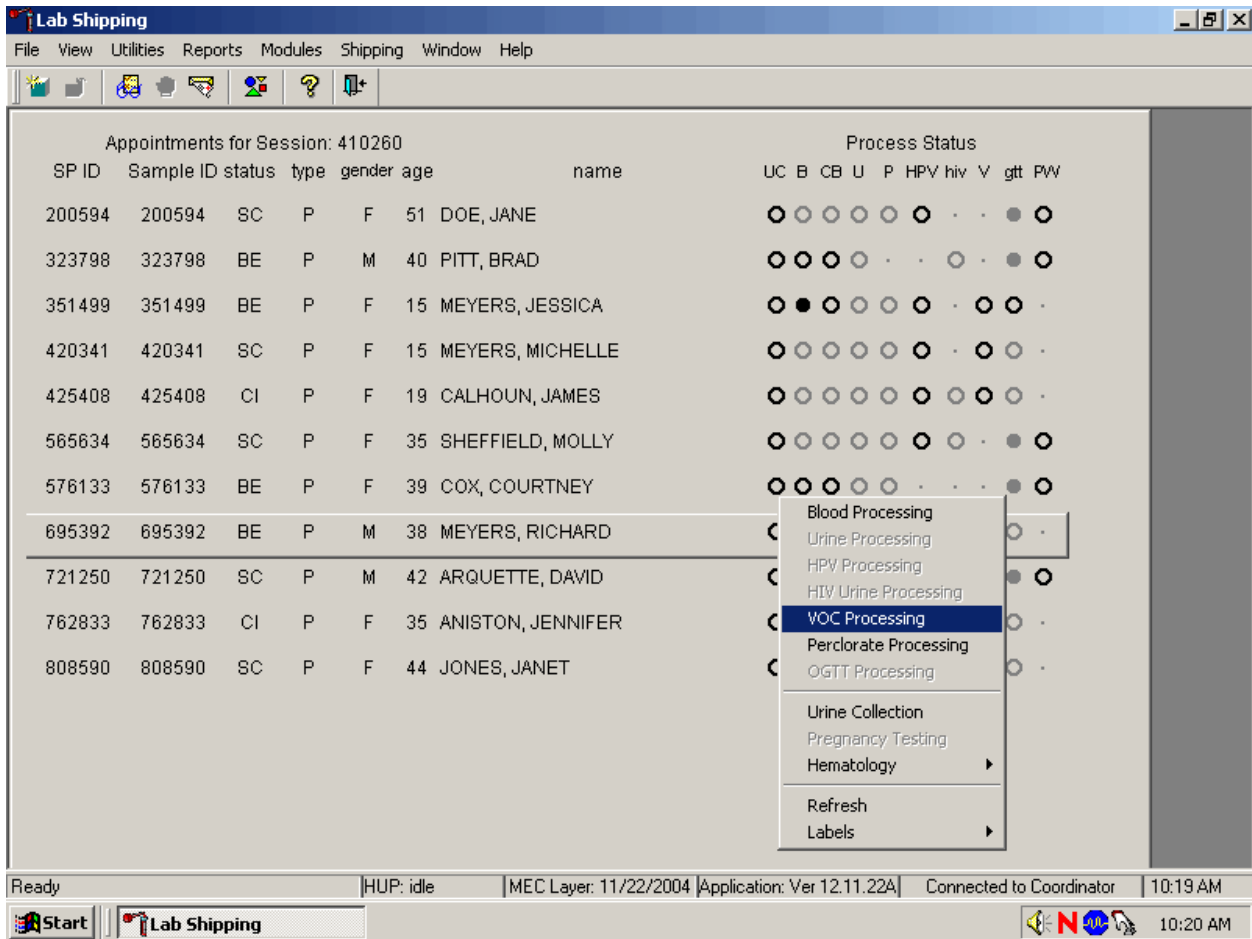
The consent report lists all SPs scheduled into the current session, their appointment and SP IDs, and the exclusion status for the following tests or groups of tests:

- HIV (vessels 22 – serum, 53 - urine)
- STD (vessels 24 – HSV, 46 – Chlam/GC)
- Future research (vessels 8 – plasma, 32-40 – serum, 52 – urine)
- HPV (vessel 78 – HPV swab)
- PSA (vessel 75)

The status is “Y” or “Yes” if the SP is excluded and “N” if the SP is not excluded.

3.10 Access a Processing Module

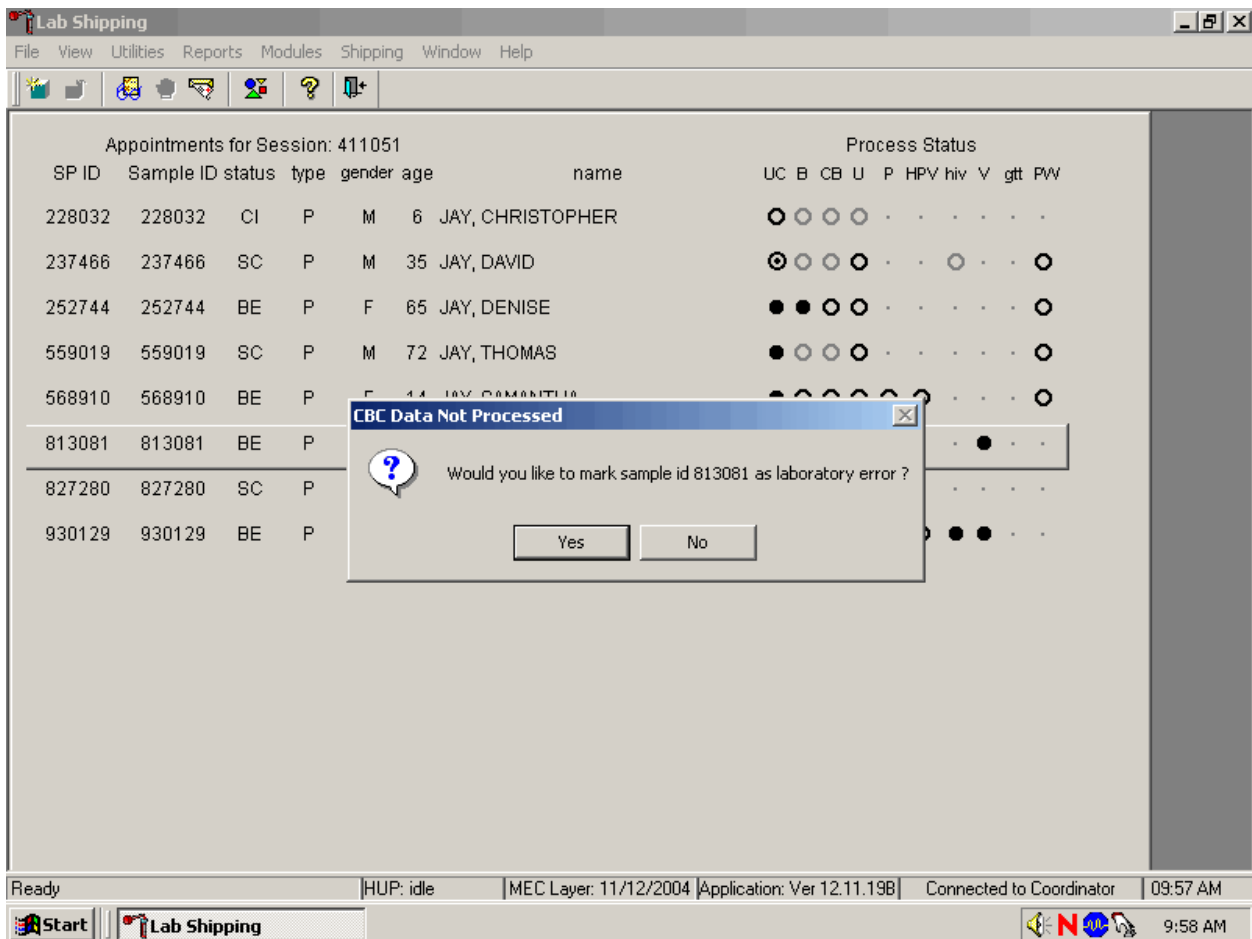
Select the correct SP and access the module of interest. Use the scroll bar to view all SPs scheduled into the session. The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.



To select an SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access a specific processing module, drag the mouse arrow to {Blood Processing}, {Urine Processing}, {HPV Processing}, {HIV Urine Processing}, {VOC Processing}, {Perchlorate Processing}, {OGTT Processing}, {Urine Collection}, {Pregnancy Testing}, or {Hematology} and left click or right click. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to correct module and left click.

3.11 Warning and Error Messages

Throughout the course of an examination, warning and error messages may appear when an attempt is made to perform an action the program cannot execute or requires confirmation to continue the action. The message normally appears with statements explaining the error condition. Complying with the error message statement will normally remedy the error. When required to confirm an action, such as deleting records, be sure the action is necessary because in most cases the action is irreversible.



For example, if the Sample Person ID is incorrect in the SP Logon window a warning message box displays indicating the problem and remedial instructions. To remove the warning message box, use the mouse to direct the mouse arrow to the OK button and left click.

3.11.1 Check-in Status of SP

Only SPs who have checked into the MEC session are available for processing.

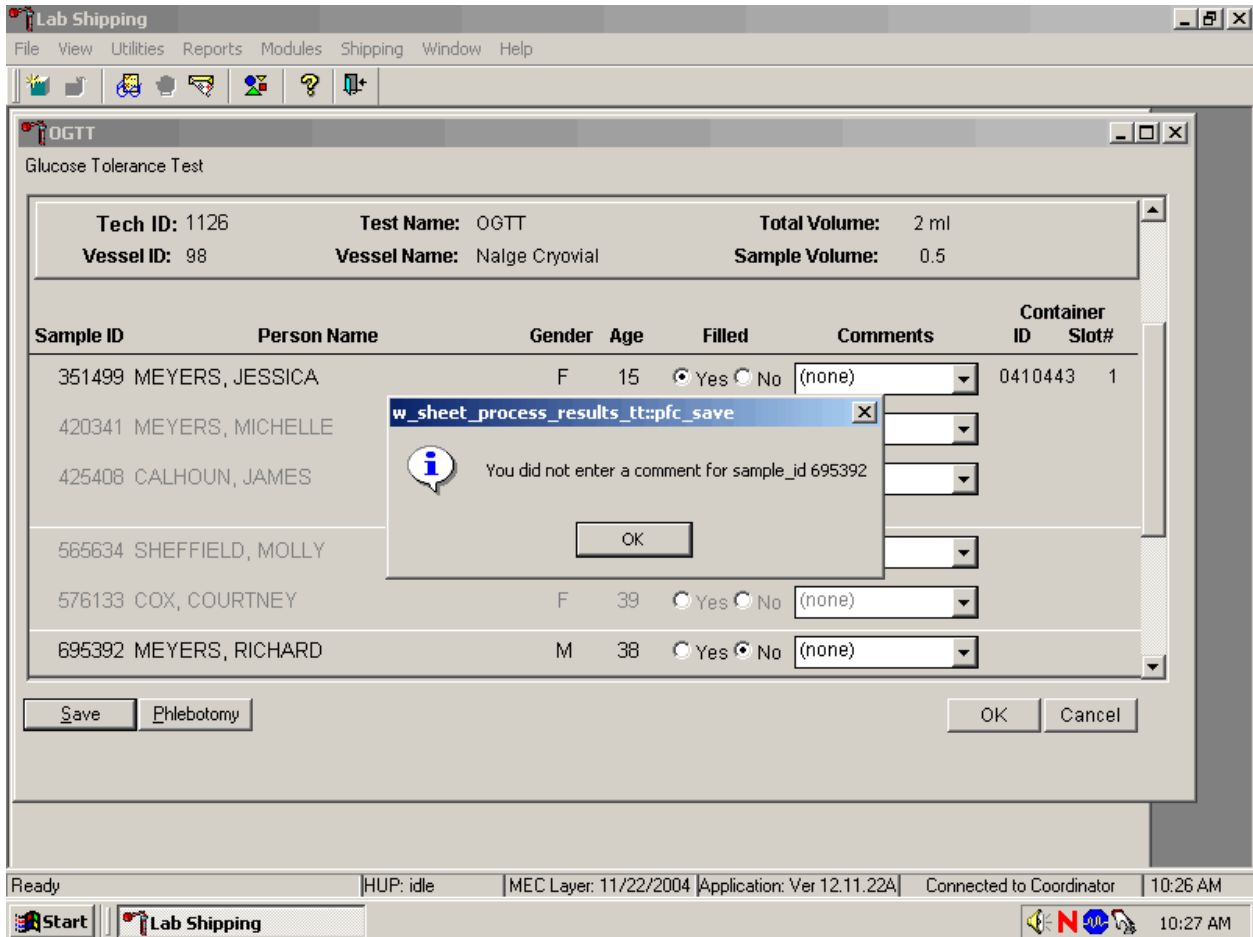
The screenshot shows a software window titled "LAB: Stand:200 Session:200490 05/29/2001 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main area displays a table titled "Appointments for Session: 200490". The table has columns for "SP ID", "Sample ID", "status", "type", "gender", "age", "name", and "Process Status". The "Process Status" column contains a series of radio buttons for each appointment. A warning dialog box titled "Urine Collection" is overlaid on the table, containing a yellow warning icon and the text: "* WARNING * Sample_ID 152478 has not checked-in with the Coordinator." Below the text is an "OK" button. The status bar at the bottom of the window shows "Ready", "HUP: idle", "MEC Layer: 6/20/02", "Application: Ver 10.11.21B", "Connected to Coordinator", and "10:46 AM".

| Appointments for Session: 200490 | | | | | | | Process Status | | | | | | | | |
|----------------------------------|-----------|--------|------|--------|-----|---------------------|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| SP ID | Sample ID | status | type | gender | age | name | UC | B | CB | U | P | VS | hiv | V | N |
| 152478 | 152478 | SC | P | F | 30 | BUTTERCUP, PRINCESS | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 253884 | 253884 | SC | P | M | 82 | GOLDMAN, WILLIAM | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 517668 | 517668 | SC | P | M | 46 | THEGIANT, ANDRE | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 569291 | 569291 | SC | P | F | 53 | WRIGHT, ROBIN | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 710428 | 710428 | SC | P | M | 87 | MONTOYA, INIGO | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

To remove the message box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

3.11.2 Not Filled Require a Comment

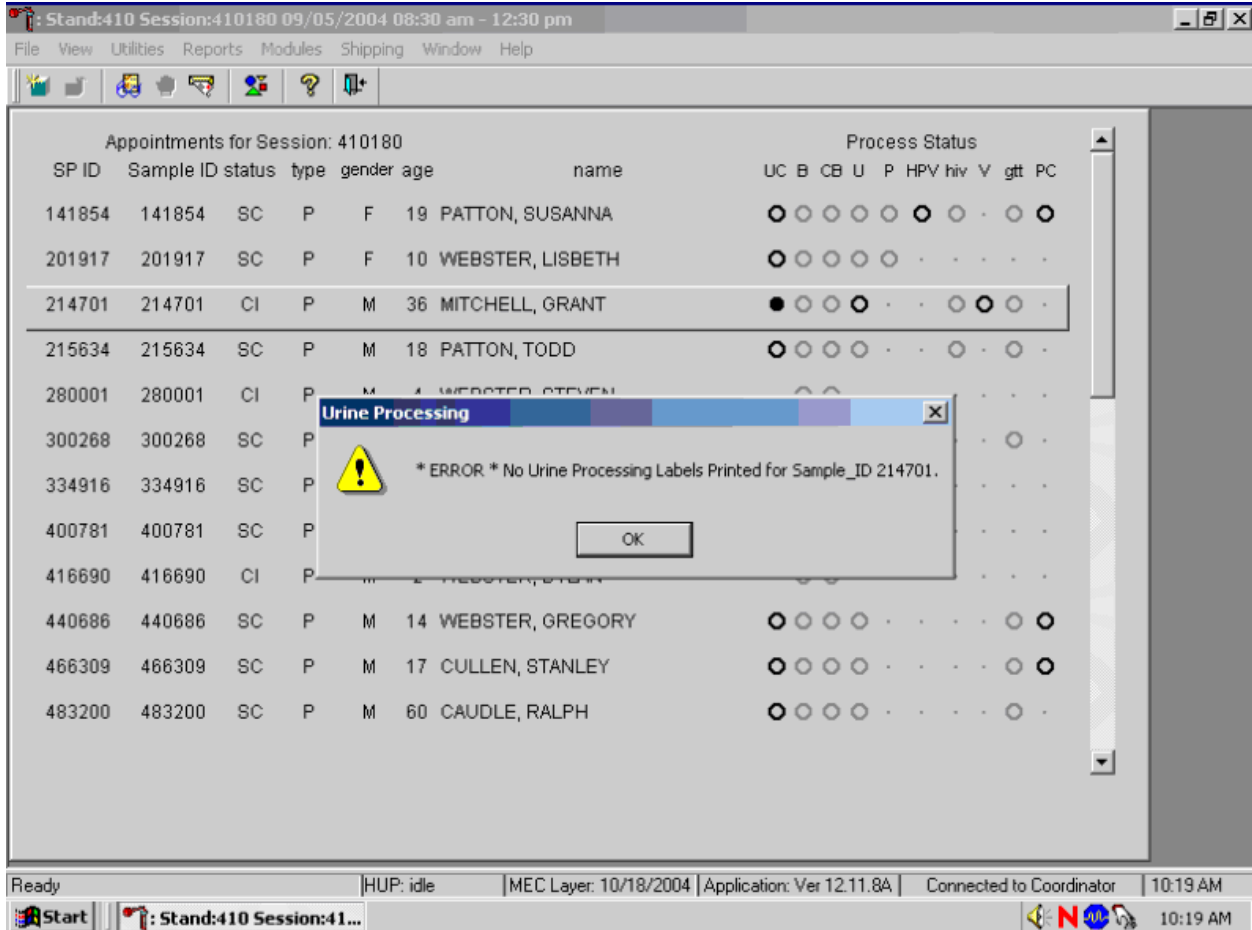
Data cannot be saved until all vessels marked as Filled–“No” are assigned a comment.



If the Save or the OK button is selected and all vessels are not marked as either Filled–“Yes” or Filled–“No,” a warning message box displays requesting a comment for each unfilled vessel. To remove the warning message box, use the mouse to direct the mouse arrow to the OK button and left click.

3.11.3 Labels Must be Printed in Advance

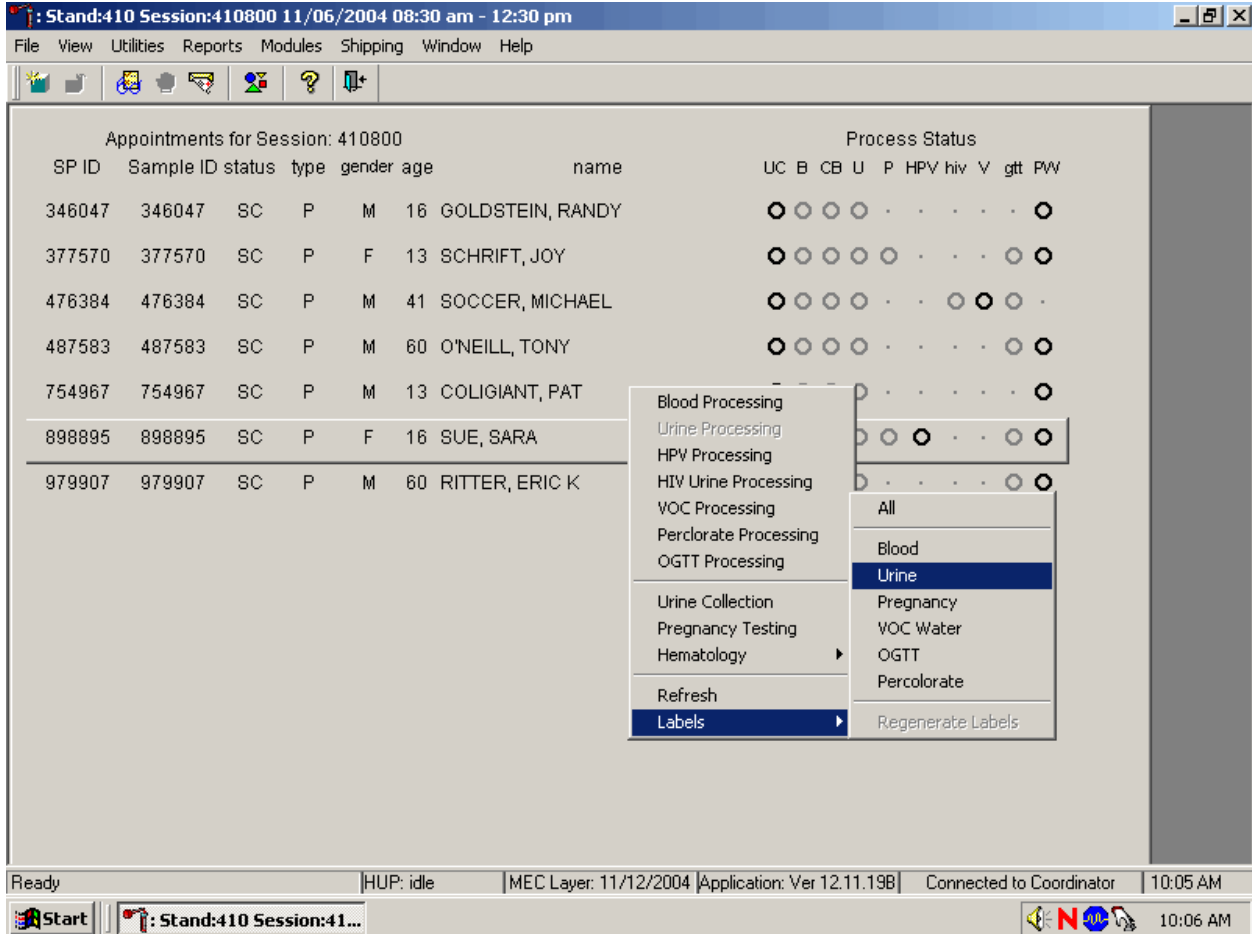
If labels have not been printed in advance, a module-specific processing message box displays.



Specimen processing cannot occur unless labels have been printed in advance. To remove the Sample Processing message box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. Reprint the labels for all SPs or an individual SP in a session.

3.12 Printing Additional Labels

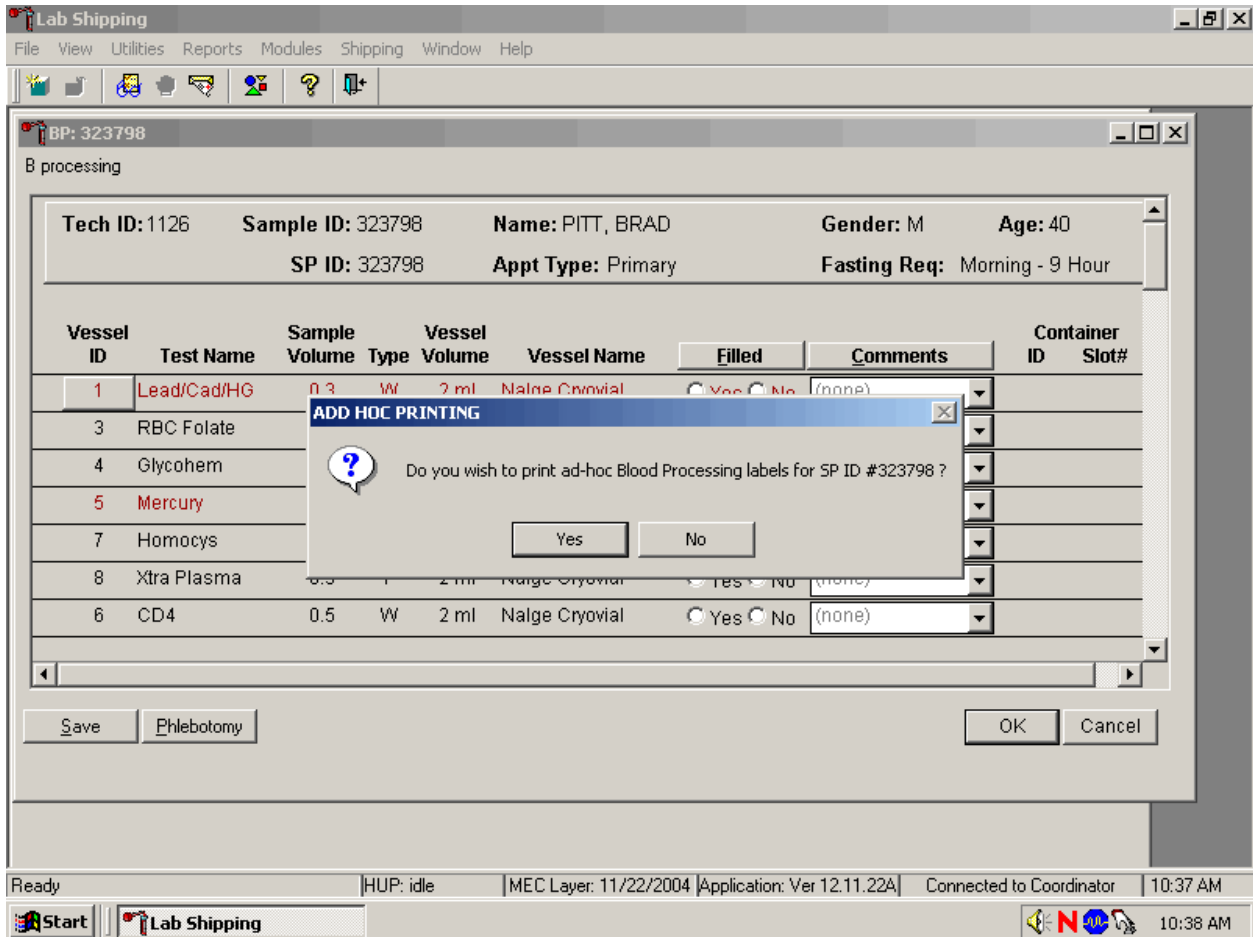
Print additional labels for a particular SP using the heads-up display.



To print additional labels for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then drag the arrow to {All}, {Blood}, {Urine}, {Pregnancy}, {VOC Water}, {OGTT}, or {Perchlorate} and right click. Labels print for the SP in the Label/Ship area.

3.13 Print an Ad Hoc Label

Print an ad hoc label for a single vessel.



To print one ad hoc label for any one vessel in any of the processing modules, use the mouse to direct the mouse arrow to the Vessel ID button and right click. An ADD HOC PRINTING message text box displays. Respond to the message text box request. To print the label and remove the message text box, use the mouse to direct the mouse arrow to the Yes button and left click, or select [Enter]. To remove the message text box without printing a label, use the mouse to direct the mouse arrow to the No button and left click or type [N/n].

4. VENIPUNCTURE

4.1 Introduction

The blood collection procedure consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw. The phlebotomist also collects one additional blood tube from SPs selected for the VOC (volatile organic compounds) special study and administers a dextrose solution (Trutol) to and collects an additional 2-mL gray top tube from SPs selected for the Glucose Tolerance (GT) component.

The phlebotomist conducts an interview to screen SPs for conditions that exclude them from the blood draw. The phlebotomist also administers a fasting questionnaire to determine fasting compliance. The venipuncture protocol is dependent on the SP's age, appointment type, and session time. Exhibits 4-1 through 4-3 illustrate the various venipuncture protocols. These protocols indicate the types and numbers of tubes in priority order for each age group and person type. A chart located on the wall in the phlebotomy room also illustrates this information. It is extremely important to perform the venipuncture protocol as described for each SP. Use comments to describe differences between the actual tubes drawn and the established protocol. After the results of the blood draw are entered, labels automatically print for the blood tubes. The phlebotomist immediately labels collected tubes, places them through the pass-through window to the laboratory, and escorts the SP to the coordinator area. The phlebotomist may offer juice and crackers to SPs under 12 years of age and SPs not selected for the GT component.

Exhibit 4-1. Venipuncture protocol – primary

| Age in Years | 1-2 | 3-5 | 6-11 | 12+ |
|---------------------------------------|-----|-----|------|-----|
| 3-mL Lavender | 1 | 2 | 1 | 1 |
| 4-mL Lavender | | | 1 | 2 |
| 2-mL Gray (Morning sessions only) | | | | 1 |
| 3-mL Red | 2 | | | |
| 7-mL Red | | 2 | 1 | |
| 15-mL Red | | | | 4 |
| 10-mL Red | | | 2 | 2 |
| *10-mL Gray (12+) | | | | 1 |
| **2-mL Gray (GTT morning sessions) | | | | 1 |

* SPs selected for inclusion in the VOC subsample

** Glucose tolerance test

Exhibit 4-2. Venipuncture protocol – VIP guest

| Age in Years | 1-2 | 3-5 | 6-11 | 12+ |
|--------------------------------------|-----|-----|------|-----|
| 3-mL Lavender | 1 | 1 | 1 | |
| 4-mL Lavender | | | | 1 |
| 2-mL Gray (Morning sessions only) | | | | |
| 3-mL Red | 1 | | 1 | |
| 7-mL Red | | 1 | 1 | |
| 15-mL Red | | | | 2 |
| 10-mL Red | | | | |

Exhibit 4-3. Venipuncture protocol – guest and surplus

| Age in Years | 1-11 | 12+ |
|---------------|------|-----|
| 3-mL Lavender | 1 | 1 |
| 3-mL Red | | 1 |

If the veins of an SP appear too fragile to accommodate the size of the large red top tubes, substitute smaller red top tubes as an alternative protocol. Exhibit 4-4, Alternative venipuncture protocol – primary, illustrates the alternative size and number of tubes in boldface with the original tube protocol in parentheses. When the alternative protocol is substituted for the original protocol, a comment must be recorded. This protocol constitutes a deviation from the established standard; it should only be used in rare circumstances.

Exhibit 4-4. Alternative venipuncture protocol – primary

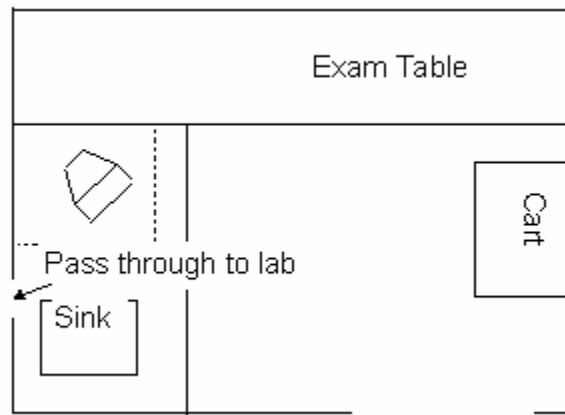
| Age in Years | 3-5 | 6-11 | 12+ |
|--------------|--------------|--------------|--------------|
| 3-mL Red | (1) 5 | | |
| 7-mL Red | (2) | 4 (1) | |
| 15-mL Red | | | (4) |
| 10-mL Red | | (2) | 8 (2) |

NOTE: Alternative venipuncture protocol tubes are shown in boldface; regular protocol tubes are shown in parentheses.

4.2 Equipment and Supplies

The phlebotomy room contains an exam table, a sink, data terminal, Dymo direct thermal label printer, refrigerator, supply cart, and cabinets. Figure 4-1 illustrates the floor plan for the phlebotomy room.

Figure 4-1. Floor plan for phlebotomy room



At the start and end of each stand, take a complete inventory using procedures described in Chapter 11, Section 11.3.

The equipment and supplies used in venipuncture are listed in Exhibit 4-5.

Exhibit 4-5. Equipment and supplies - phlebotomy

| | |
|--|------------------------------------|
| BD Hemogard Vacutainer® 3-mL EDTA | Stretch disposable tourniquet |
| BD Hemogard Vacutainer® 4-mL EDTA | Latex tourniquet |
| BD Hemogard Vacutainer® 2-mL Gray | Alcohol wipe |
| BD Hemogard Vacutainer® 3-mL Red | 2 x 2 gauze square |
| BD Hemogard Vacutainer® 7-mL Red | Co-Flex NL cohesive bandage |
| BD Vacutainer® 15-mL Red | Adhesive bandage |
| BD Vacutainer® 10-mL Red | Adhesive bandage – children |
| BD Vacutainer® 7-mL Gray (VOC) | Transpore tape |
| BD Saf-T EZ® set 19 gauge | Surgical paper tape |
| BD Luer adapter for use with the 19 gauge Saf- T EZ® set | Cartoon stickers |
| BD Vacutainer Push Button™ 21 gauge with adapter | Kleenex |
| BD Vacutainer Push Button™ 23 gauge with adapter | Antibacterial hand soap |
| BD Vacutainer® multiple Eclipse 21 gauge needle | Hand cream |
| BD Vacutainer® needle holder – single use | Ammonia inhalant packet |
| Air sickness bag | Sharps container 8 gallon |
| Heel warmer | Biohazard bags 19 x 23 |
| Labels for Dymo printer | Pillow and disposable pillow cover |
| Nonsterile, powder-free, nonlatex gloves -- small, medium, large | Squeeze ball |
| Juice and crackers | Tube racks |
| List of reportable tests (handout) | Phlebotomy cart |
| Bleach bottle | Floor mat |
| Step stool | Solar wall thermometer |
| Towelettes | CPR mask |
| Liquid Band-Aid | Baby oil |

For each SP, the phlebotomist routinely requires the following materials:

- Alcohol wipes
- 2”x 2” gauze squares
- Vacutainer® tubes of the appropriate size and type
- Disposable tourniquet
- Needle assembly
- Bandage

4.3 Overview

The coordinator tracks each SP through the MEC using the coordinator system. This system tracks the SP throughout the exam, including arrival, location during the session, and exit. The coordinator uses this system to direct the SP to the appropriate workstations in the MEC and to determine if all the appropriate examinations are complete. The MEC coordinator monitors exam component status using responses from examination stations.

It is critical to assign SPs age 12+ to phlebotomy as soon as possible at the start of a session, especially a morning session. It is also important to assess the fasting status of SPs age 12+ assigned to a morning session because they are not eligible for the GT examination if they have not met their 9-hour fast requirement. The coordinator gives each SP a hard copy verification form as part of the check-in process. For SPs age 12+ who are examined during a morning session, it includes the question, “Did you eat or drink anything, other than plain water, after 11:30 last night?” The SP records “yes” or “no” in a checkbox and the coordinator enters this information into the coordinator application. The coordinator application then highlights (hot pink) the names of SPs who responded “Yes” since they have not met the 9-hour fast requirement. The coordinator uses the highlighted names to aid in prioritizing SPs for the phlebotomy component; SPs who are not highlighted are assigned to phlebotomy before SPs whose names are highlighted.

Each SP receives a bar-coded ID bracelet upon arrival at the MEC. The bracelet remains on the SP throughout the session. This bracelet contains the SP’s ID number in bar code and eye-readable format. The phlebotomist “wands” the bracelet bar code with a bar code scanner (wand) to log the SP into the phlebotomy component. If necessary, the ID number can be entered manually by reading it from the bracelet and typing the numbers using the keyboard.

The phlebotomist is responsible for completing the venipuncture section of the phlebotomy exam.

Set up the appropriate blood collection cart in advance, making sure there are sufficient supplies for all SPs in the session. Access the phlebotomy application and open the phlebotomy exam. Log the SP into phlebotomy by scanning the bar code on the SP ID bracelet or manually typing the SP ID when the SP arrives in phlebotomy.

Conduct the phlebotomy interview and administer the fasting questionnaire. The phlebotomy protocol screen displays. Draw the appropriate tubes, and enter the number of tubes collected next to the expected values. Labels generate automatically. Enter the appropriate comment(s) for any tube that was not collected. Label the blood tubes. Verify that the phlebotomy completion status is correct. The phlebotomy section status is “Complete” if all blood tubes are collected, “Partial” if some, but not all blood tubes are collected, and “Not Done” if no blood tubes are collected.

4.4 Gaining Cooperation

The coordinator will introduce the SP to the examination and briefly explain the examination process. The coordinator can answer any general questions the SP has about venipuncture. However, the phlebotomist must be prepared to answer all the questions the SP poses about the venipuncture procedure. In addition, the phlebotomist must convince the SP of the importance of cooperation in the venipuncture component of the examination.

Prepare to answer questions about the rationale for the venipuncture, the discomfort involved, the amount of blood being drawn, and the possibility of contracting an infectious disease from the process. To address SPs’ concerns effectively, know the following information about the procedures used for the study:

- **Rationale**

Although the SP has provided much useful information in the household and individual interviews, the successful completion of the venipuncture component of NHANES is critical to the success of the study. Using the various specimens, researchers and laboratories are able to perform over 250 different biochemical tests (SPs 12+), which provide detailed information about the SP’s health and nutritional status. NHANES data produce descriptive statistics that measure and monitor the health of the U.S. population. Much of this information would not be available in any other way. The laboratories that conduct the analysis are considered the “gold standard” for their particular analyte(s).

- **Discomfort**

Venipuncture causes only minimal discomfort. A certified, experienced, phlebotomist performs venipunctures. A variety of blood collection needles are available so that the most appropriate size can be selected for each SP.

- **Amount**

Phlebotomists draw the following amount of blood:

1-2 years primary SP, 9-mL (0.3 ounces), 0.6 tablespoons

3-5 years primary SP, 20-mL (0.7 ounces), 1.3 tablespoons

6-11 years primary SP, 34-mL (1.1 ounces), 2.3 tablespoons

12+ years primary SP, 105-mL (3.5 ounces), 7.0 tablespoons

1-2 years VIP guest, 6-mL (0.2 ounces), 0.4 tablespoons

3-5 years VIP guest, 10-mL (0.4 ounces), 0.8 tablespoons

6-11 years VIP guest, 13-mL (0.4 ounces), 0.9 tablespoons

12+ years VIP guest, 24-mL (0.8 ounces), 1.6 tablespoons

1-11 years guest and surplus, 3-mL (0.1 ounces), 0.2 tablespoons

12+ years guest and surplus, 6-mL (0.2 ounces), 0.4 tablespoons

An average adult male has 12 pints of blood and an average female has 9 pints. The Red Cross routinely draws 450-mL (or one pint) during a routine donation. Their requirements limit donation to every 8 weeks. The Red Cross does allow autologous donations where an individual can donate his or her own blood before surgery. This consists of one unit per week for up to 6 consecutive weeks. The maximum volume drawn during a MEC exam amounts to less than 25 percent (102-mL) of the amount drawn from regular donors by the Red Cross. The body manufactures blood daily and replaces this volume of blood within 24 hours.

- **Infection control**

The supplies used for venipuncture are completely sterile and are used only once. There is absolutely no possibility of the SPs being infected by any blood-borne disease, such as hepatitis or AIDS, because of participation in the venipuncture component of the NHANES exam.

Gaining the cooperation of an SP is easier if the atmosphere in the phlebotomy room is pleasant and makes the SP feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere in the phlebotomy room.

- Maintain a clean and uncluttered work area. This is especially important because of today's concern with blood-borne infectious diseases, such as hepatitis and AIDS.

- Be aware of body image; a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a smile.
- Speak face to face with the subject and maintain eye contact. Staring at other areas in the room may cause the SP some uneasiness since it implies that he or she is not important. It also implies disinterest.
- Avoid nervous behaviors, such as squirming and tapping that can be distracting. The SP may begin to feel nervous, hurried, and anxious because of such behaviors.

4.4.1 Refusal Conversion

The coordinator should notify the phlebotomist of all venipuncture refusals so that the phlebotomist can attempt a refusal conversion.

The phlebotomist should discuss the condition of the SP's refusal with the coordinator before he or she attempts a conversion. If the coordinator indicates that the SP is an adamant refusal, the phlebotomist should not attempt to approach the SP or conduct the phlebotomy interview. If, however, the coordinator and the phlebotomist decide that the SP is a good candidate for a refusal conversion attempt, the phlebotomist may conduct the phlebotomy interview as part of the conversion attempt. If appropriate, the phlebotomist should enlist the help of the coordinator, the health technologist, and/or the MEC physician when attempting to convert refusals.

4.5 Performing the Venipuncture on SPs who do not Speak English

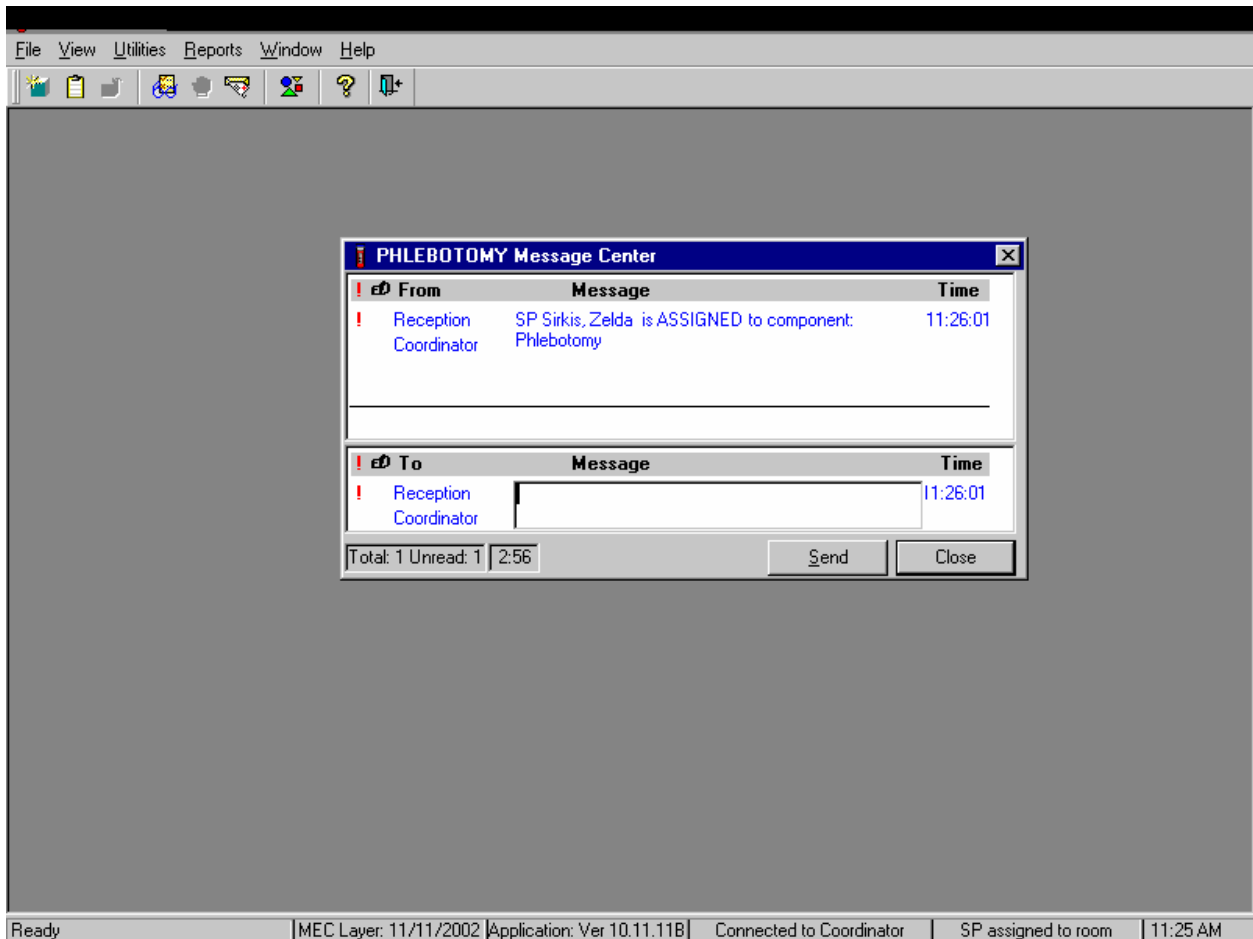
When the phlebotomist must administer the venipuncture procedure to an SP who does not speak English and the phlebotomist does not speak the language of the SP, a translator who does speak the language of the SP assists the phlebotomist.

The translator stays with the phlebotomist and the SP for the entire procedure. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the venipuncture.

4.6 Open the Exam and Log the SP into the Exam

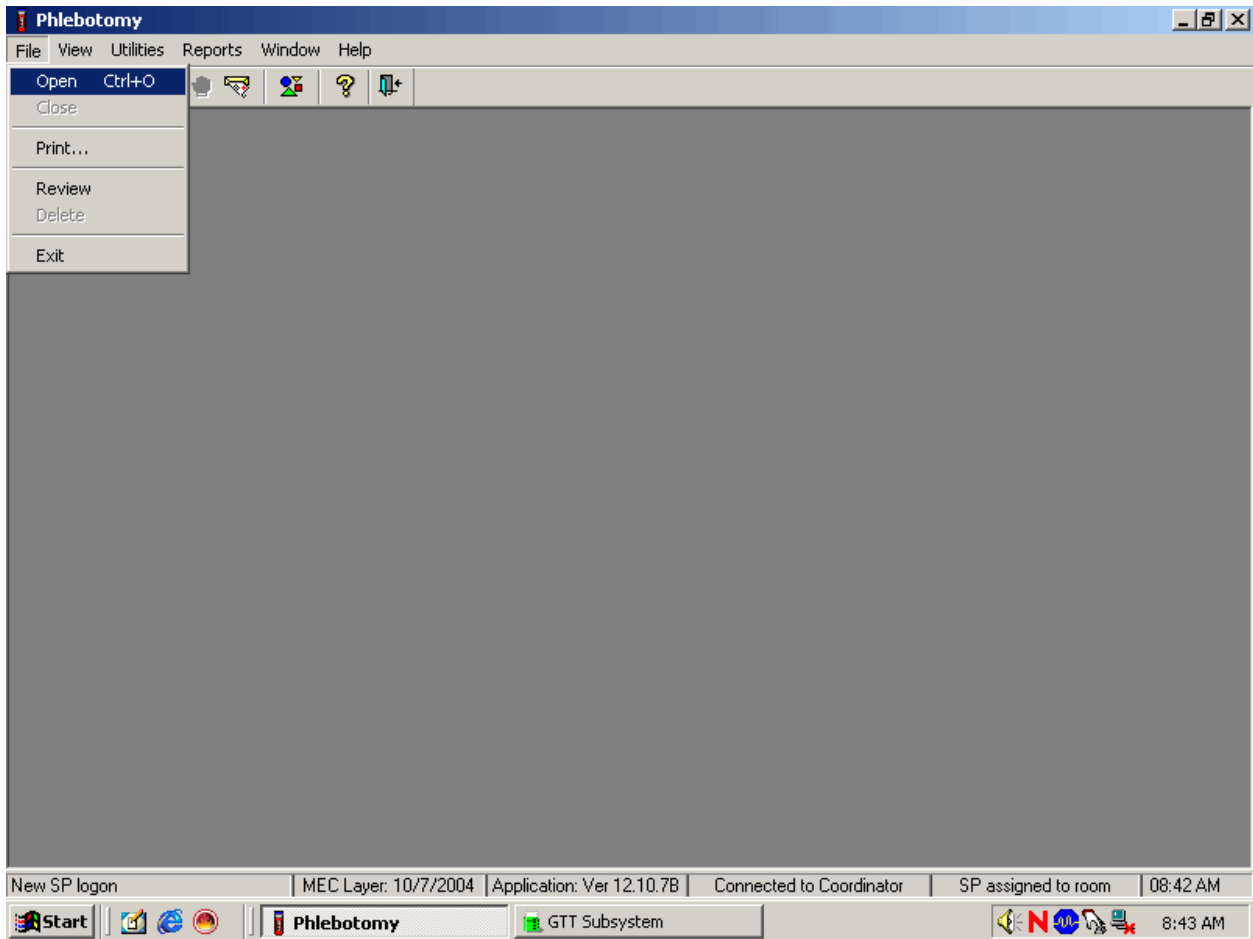
Open and log onto the Phlebotomy application.

The message center window identifies the SP assigned to phlebotomy.



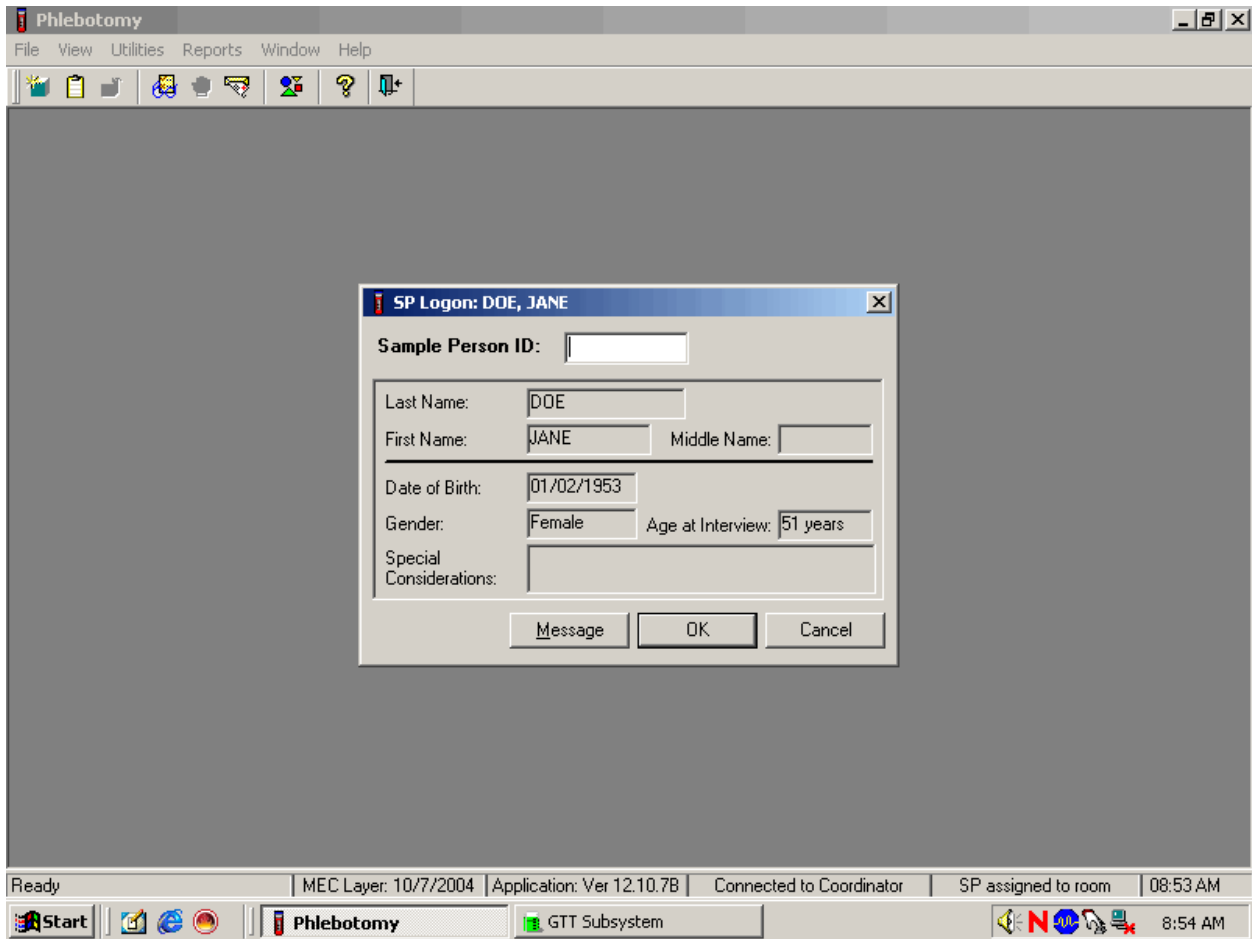
A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the Send button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the “Close” button and left click, or select [Enter].

Open the Phlebotomy exam.



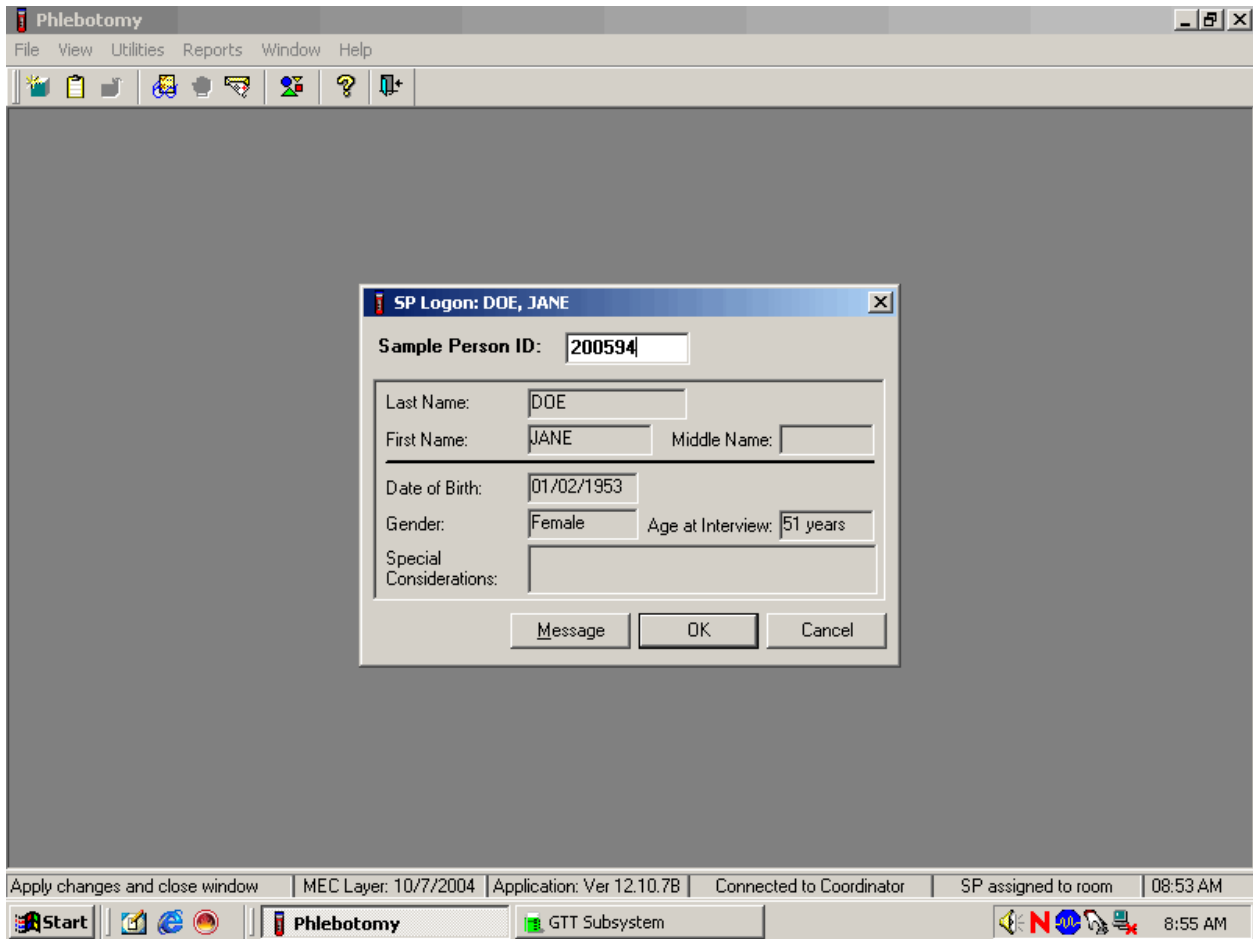
To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o].

The SP Logon window displays.



The SP Logon window displays for the SP assigned to the component.

Log the SP into the component.



To log the SP into the component, either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the "OK" button and left click. To cancel the Logon process and to remove the window, use the mouse to direct the mouse arrow to the "Cancel" button and left click.

Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

4.7 The Phlebotomy Interview

The phlebotomy interview screen includes a shared exclusion pregnancy question for females ages 16-59 and two safety exclusion questions. There are only two reasons to exclude an SP from venipuncture—hemophilia, and having received chemotherapy within the past 4 weeks. Administer the interview (and fasting questionnaire) directly to SPs over the age of 16 or administer the interview questions (and fasting questionnaire) to the SP’s parent or guardian for SPs under age 16.

Administer the phlebotomy interview immediately before performing the venipuncture. Read the text exactly and record the responses.

The screenshot shows a Windows-style application window titled "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window title bar reads "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM". The main content area is titled "Phlebotomy Interview" and contains four questions with corresponding input fields:

- Are you currently pregnant? (Dropdown menu)
- How many weeks? (Text input field)
- Do you have hemophilia? (Dropdown menu)
- Have you received cancer chemotherapy in the past four weeks? (Dropdown menu)

At the bottom of the main area, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "MEC Layer: 10/7/2004", "Application: Ver 12.10.7B", "Connected to Coordinator", "SP assigned to room", and "08:55 AM". The Windows taskbar at the bottom includes the Start button, system tray icons, and the application name "Phlebotomy".

4.7.1 Pregnancy Shared Exclusion Question

For female SPs aged 16-59, the shared exclusion pregnancy questions are enabled and are asked during the MEC examination in the first examination where shared exclusions are asked. Each question is asked only once, even when the question is relevant for more than one component. Some examinations, like phlebotomy, do not require all the shared exclusions to be asked. In this situation, there may be some questions answered in one examination and then disabled in the remaining examinations. Shared exclusion questions are component specific. Answers provided during previous components appear on the screen for the next examiner to see, but the text box for data entry is disabled. Only shared exclusion questions relevant to the age and component that have not been answered are enabled. Example: If the SP goes to the physician component before phlebotomy, the questions about “pregnancy” and “how many weeks” would be asked by the physician. The “pregnancy” question would be disabled in the phlebotomy component.

- If the SP is a male, a female less than 15 years, or a female older than 60 years, the shared exclusion pregnancy questions will not be displayed.
- If the response to the pregnancy status question is “No,” or “Don't know” the question “How many weeks?” is not enabled.
- If the SP is a female aged 16-59, the first shared exclusion pregnancy question is displayed and enabled.

Record the response to the shared exclusion question.

The screenshot displays the Phlebotomy software interface. At the top, the window title is "Phlebotomy". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". A toolbar contains various icons for navigation and actions. The main content area is titled "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM". The section is titled "Phlebotomy Interview". The form contains four questions, each with a corresponding input field:

- Are you currently pregnant? (Drop-down menu)
- How many weeks? (Text input field)
- Do you have hemophilia? (Drop-down menu)
- Have you received cancer chemotherapy in the past four weeks? (Drop-down menu)

The first drop-down menu is open, showing the options "Yes", "No", and "Don't Know". At the bottom of the form, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom of the window shows "Ready", "MEC Layer: 10/7/2004", "Application: Ver 12.10.7B", "Connected to Coordinator", "SP assigned to room", and "08:55 AM". The taskbar at the very bottom shows the Start button, several icons, and the taskbar title "Phlebotomy" with a "GTT Subsystem" window open. The system clock shows "8:55 AM".

Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” or “Don’t Know” and left click. Select [TAB] to move to the next textbox.

If the response to the question “Are you currently pregnant?” is “Yes,” the SP is excluded from GTT due to pregnancy status. If the response to the pregnancy question is “Yes,” ask “How many weeks?” At the coordinator application, the component status for GT defaults to “Not Done” with the comment “Blocked: Not Done [SP pregnant].”

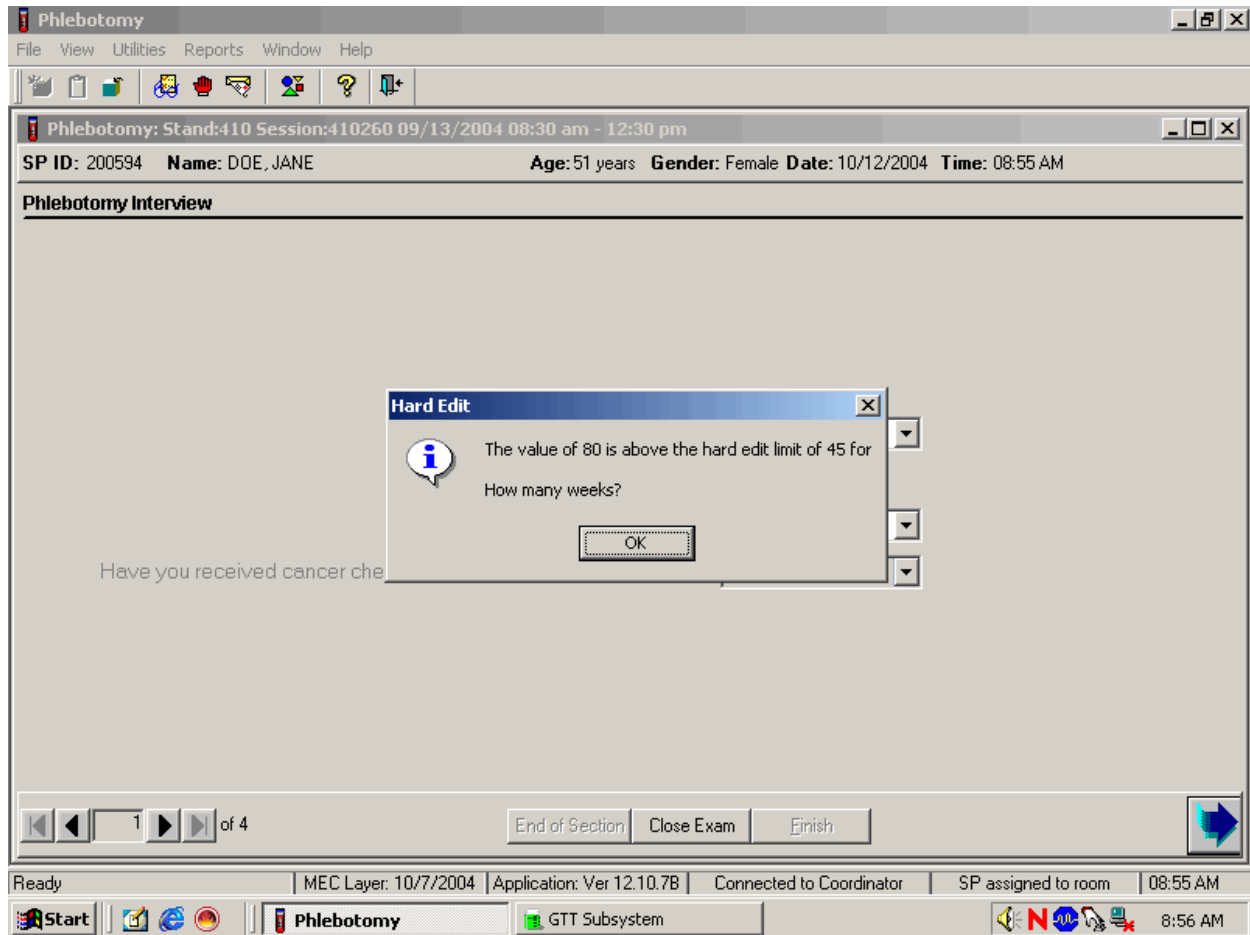
The screenshot displays the Phlebotomy application window. The title bar reads "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and help. The main window title is "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM". The section is titled "Phlebotomy Interview". The form contains the following questions and input fields:

- Are you currently pregnant? Yes (dropdown menu)
- How many weeks? (text input field)
- Do you have hemophilia? (dropdown menu)
- Have you received cancer chemotherapy in the past four weeks? (dropdown menu)

At the bottom of the form, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the bottom of the application shows "Ready", "MEC Layer: 10/7/2004", "Application: Ver 12.10.7B", "Connected to Coordinator", "SP assigned to room", and "08:55 AM". The Windows taskbar at the very bottom shows the Start button, several application icons, and the system tray with the time "8:56 AM".

Record the number of weeks reported by the SP. If the number of weeks is less than 1, enter 0. Since SPs are required to answer this question, get the SP’s best estimate. To enter the number, use the keyboard keys to type the number into the text box.

This number of weeks cannot be greater than 45.



To remove the Hard Edit message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

If the response to the question “Are you currently pregnant?” is “No” or “Don’t Know,” the SP is not excluded from the GTT. Ask the phlebotomy safety exclusion questions.

The screenshot displays the 'Phlebotomy' software interface. The title bar reads 'Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm'. Below the title bar, patient information is shown: 'SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM'. The main area is titled 'Phlebotomy Interview' and contains the following questions and input fields:

- Are you currently pregnant? [No] (dropdown menu)
- How many weeks? [] (text input field)
- Do you have hemophilia? [] (dropdown menu)
- Have you received cancer chemotherapy in the past four weeks? [] (dropdown menu)

At the bottom of the interview area, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. The Windows taskbar at the bottom shows the system tray with the time 8:56 AM and the taskbar with 'Phlebotomy' and 'GTT Subsystem' open.

If the answer to the shared exclusion pregnancy question is “No” or “Don’t know,” then select [TAB] to proceed to the first safety exclusion question, “Do you have hemophilia?”

4.7.2 Safety Exclusion Questions

Continue to conduct the phlebotomy interview by asking the question displayed on the screen, “Do you have hemophilia?”

Q1: Do you have hemophilia?

| | |
|--|---|
| <p>Q1: This question asks whether the SP has hemophilia, which is an exclusion criterion for this procedure.</p> | <p>Explain that we cannot perform phlebotomy on participants who have hemophilia. Hemophilia is a rare disease where an individual’s blood does not clot. If an SP’s relative has hemophilia but the SP does not, the SP is not excluded. If the SP is excluded, the Blood Draw Exclusion box displays. Read the text in the box to the SP and escort the SP back to the coordinator station.</p> |
|--|---|

Record the exact response.

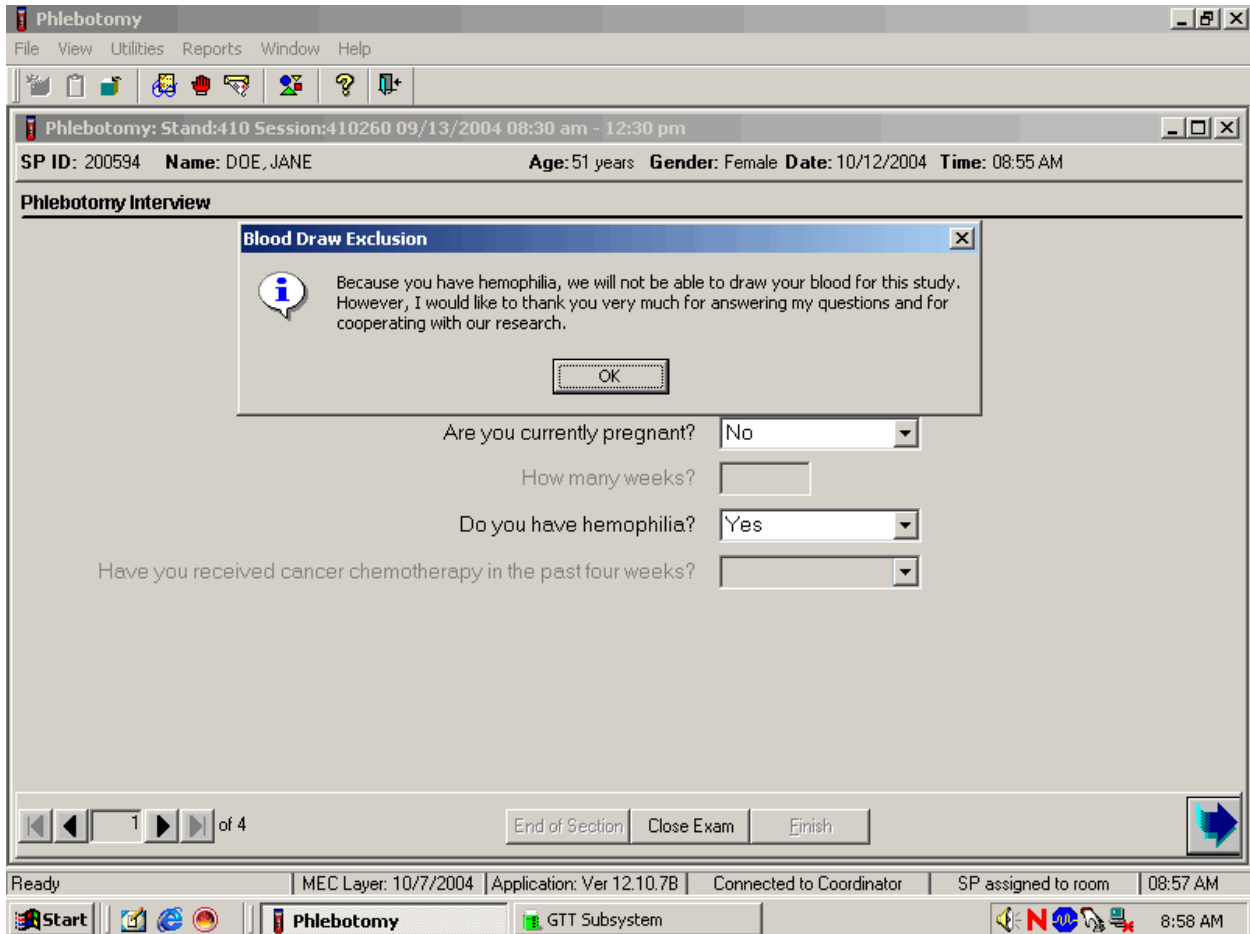
The screenshot displays the 'Phlebotomy' software interface. The main window title is 'Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm'. Below the title bar, patient information is shown: 'SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM'. The section is titled 'Phlebotomy Interview'. The form contains the following questions and input fields:

- 'Are you currently pregnant?' with a dropdown menu showing 'No'.
- 'How many weeks?' with an empty text input field.
- 'Do you have hemophilia?' with a dropdown menu.
- 'Have you received cancer chemotherapy in the past four weeks?' with a dropdown menu showing 'Yes', 'No', 'Refused', and 'Don't Know'.

At the bottom of the form, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. A status bar at the bottom of the window shows 'Ready', 'MEC Layer: 10/7/2004', 'Application: Ver 12.10.7B', 'Connected to Coordinator', 'SP assigned to room', and '08:57 AM'. The Windows taskbar at the very bottom shows the Start button, several icons, and the system tray with the time '8:57 AM'.

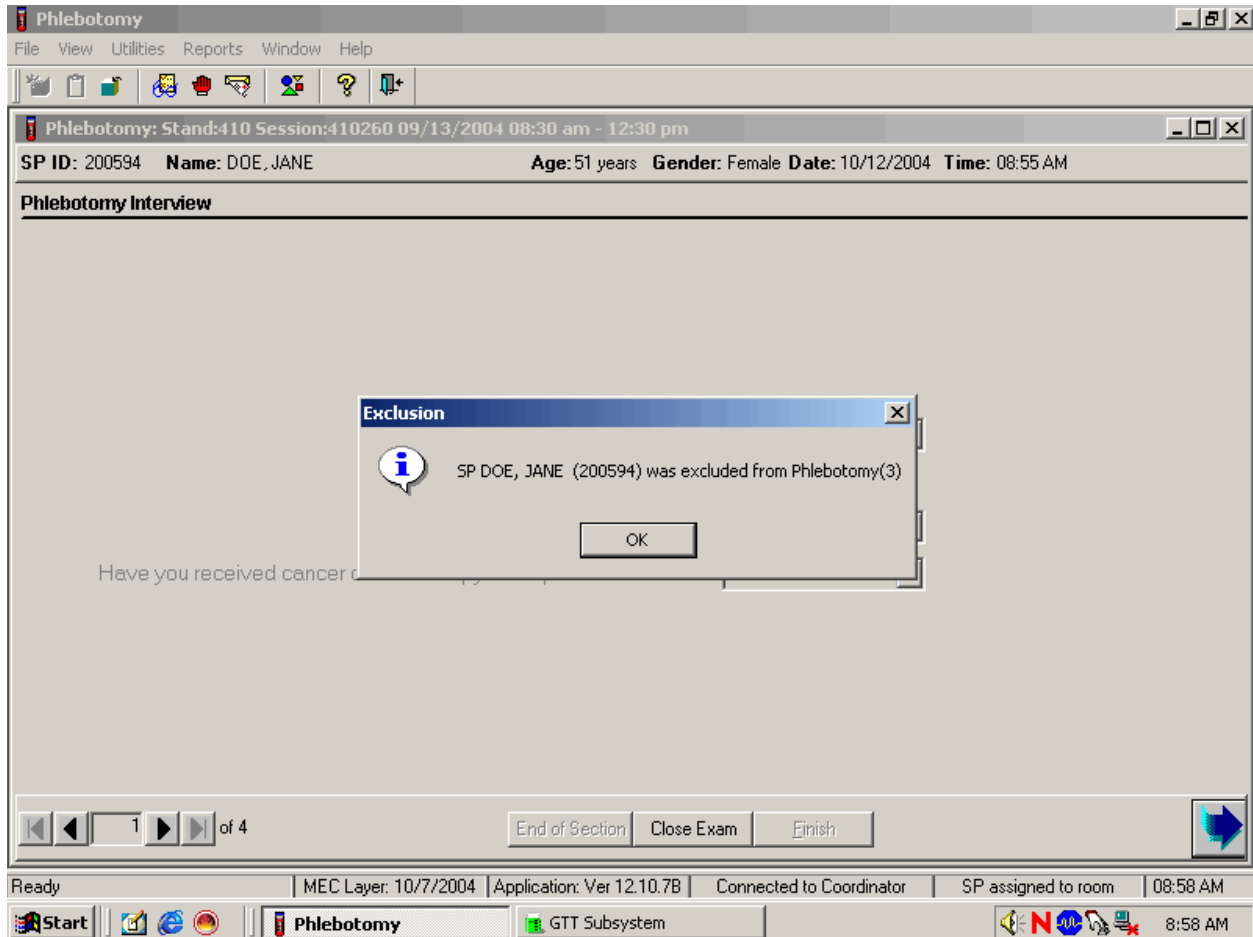
Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” “Refused,” or “Don’t Know,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].

If the SP is excluded from the phlebotomy exam due to hemophilia, the Blood Draw Exclusion informational message text box displays.



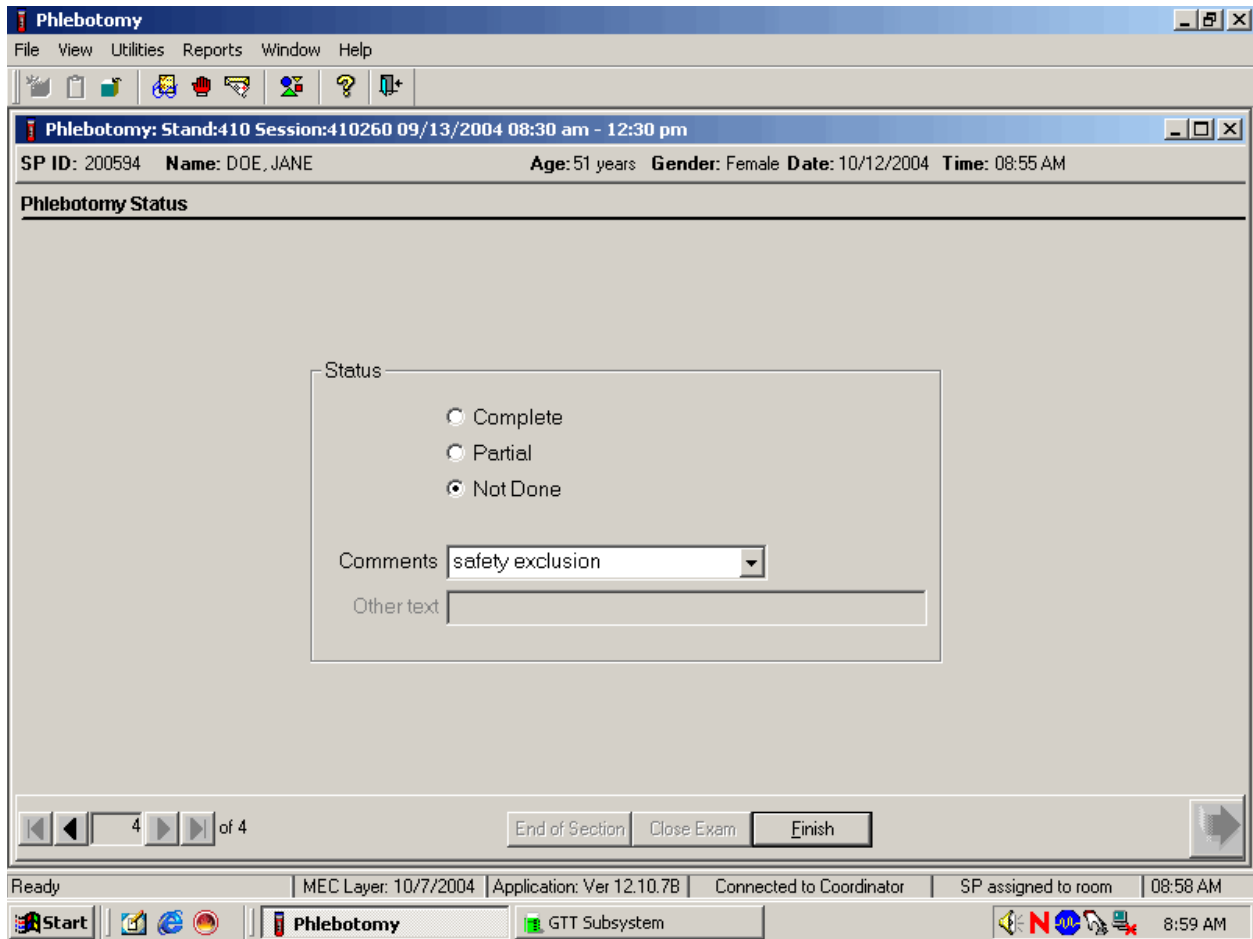
Read the script to the SP. To remove the Blood Draw Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

If the SP is excluded from the phlebotomy component due to hemophilia, an informational Exclusion message text box displays. In some cases more than one Exclusion message box will display, one after the other.



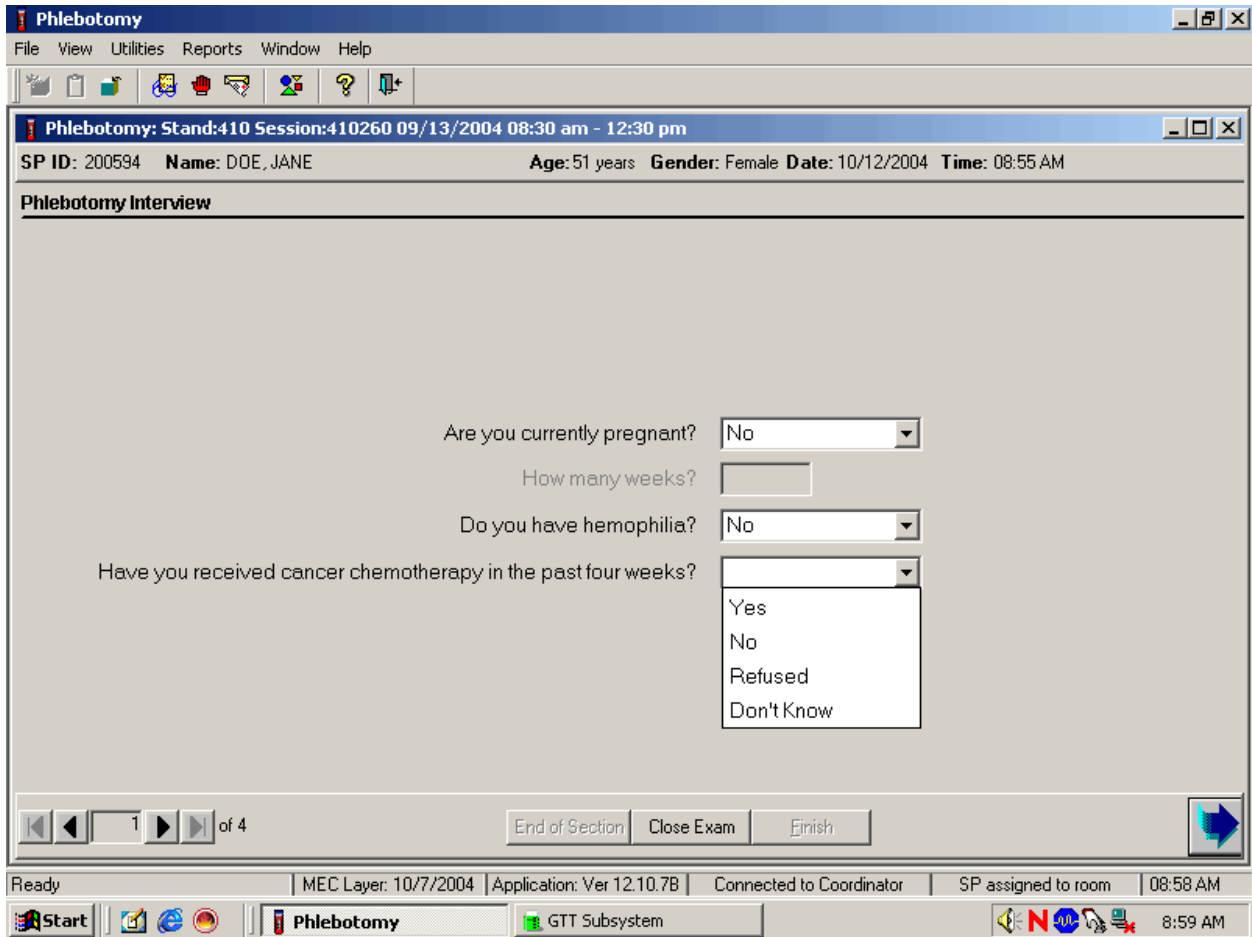
To remove the Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

Verify the status.



SPs excluded due to hemophilia are automatically coded by the application as “safety exclusion.” Escort the SP back to the coordinator or to the next component as directed by the Message Center.

If the SP has not been excluded due to hemophilia, continue the phlebotomy interview by asking the second question displayed on the screen, “Have you received cancer chemotherapy in the past four weeks?”

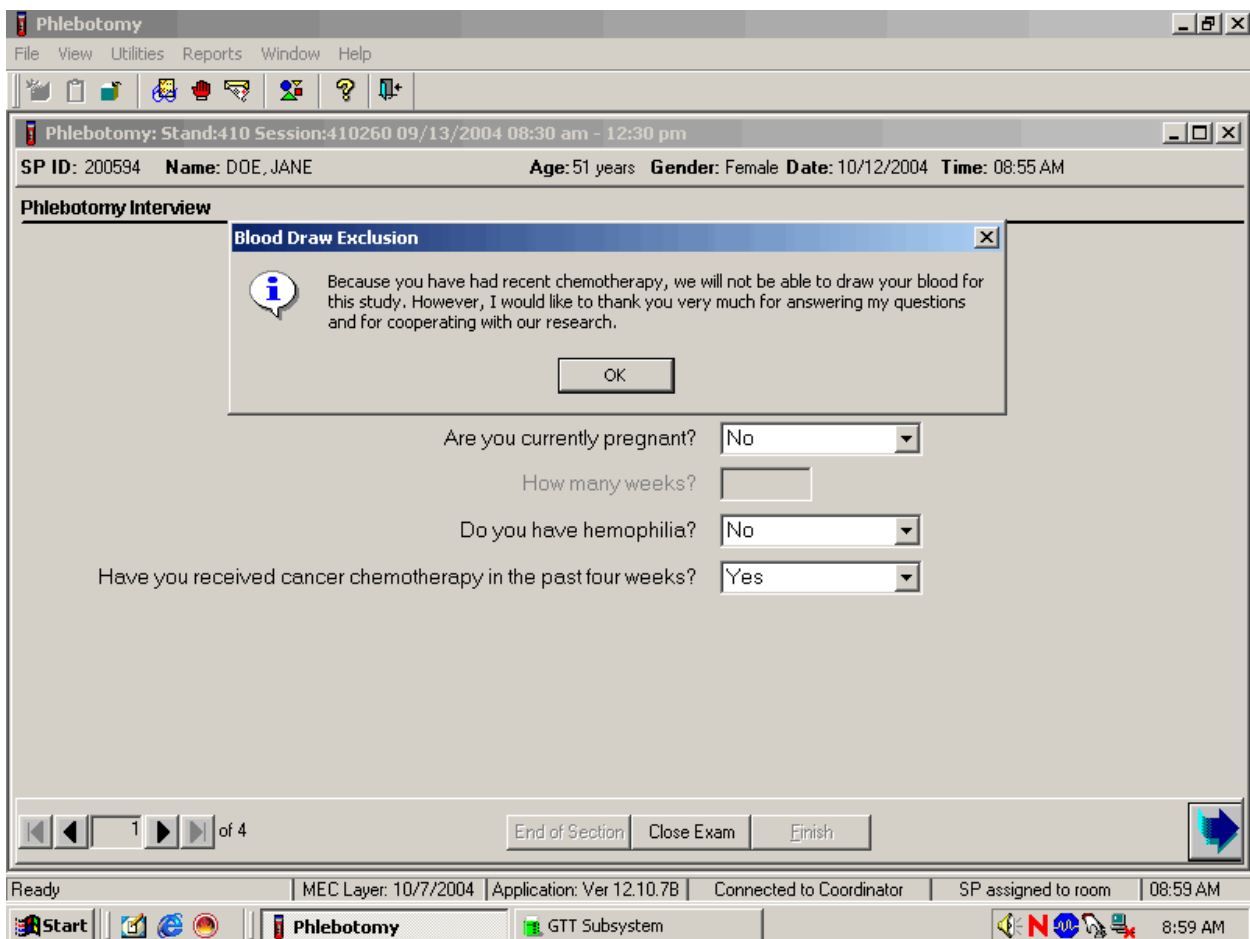


Q2: Have you received cancer chemotherapy in the past four weeks?

| | |
|---|---|
| <p>Q2: This question asks whether the SP has received chemotherapy in the past 4 weeks. This situation excludes the SP from this procedure.</p> | <p>Explain that we cannot perform phlebotomy on participants who have received cancer chemotherapy within the past 4 weeks. If the SP is excluded, the Blood Draw Exclusion box is displayed. Read the text in the box to the SP and escort him or her back to the coordinator station.</p> |
|---|---|

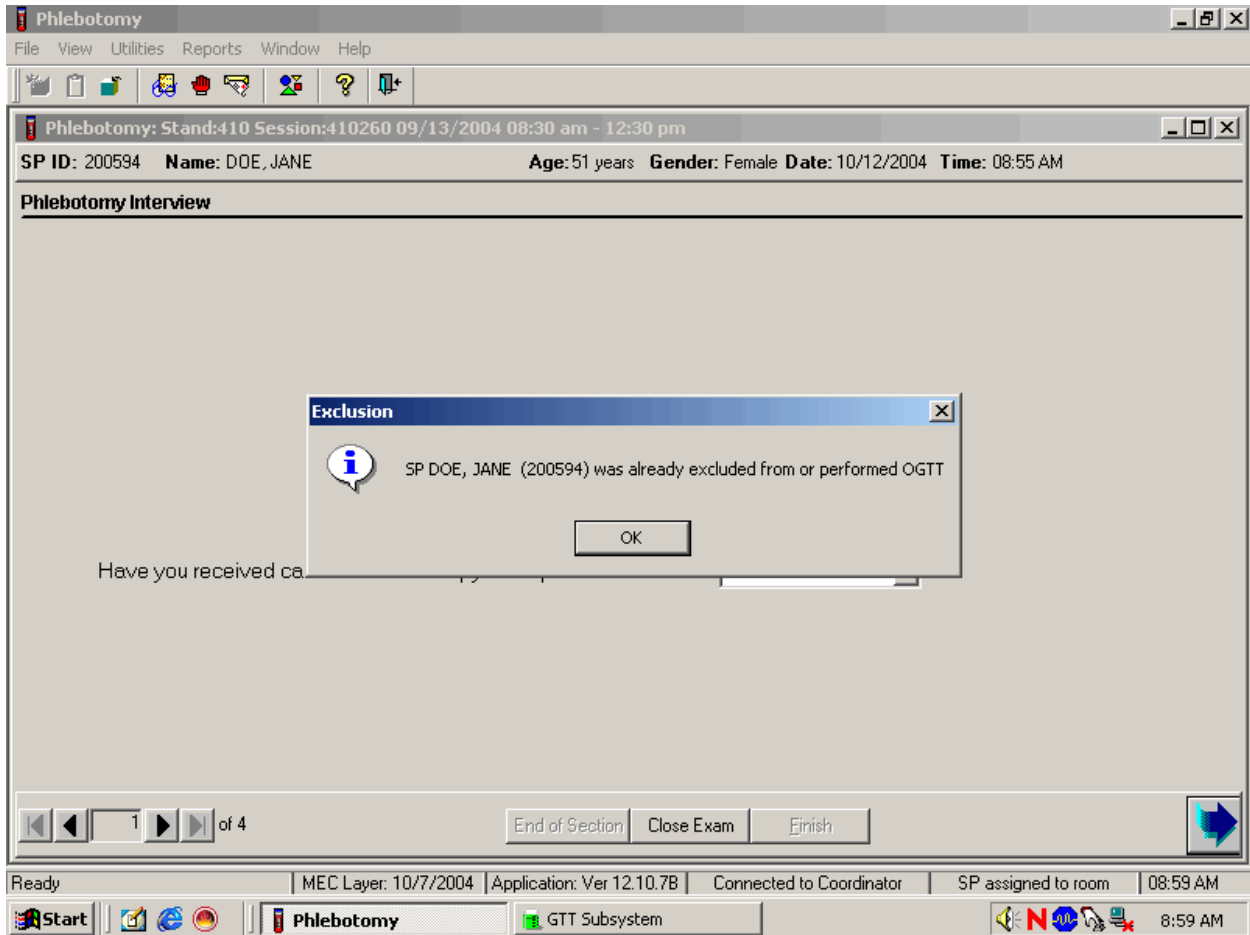
Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” “Refused,” or “Don’t Know,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click.

If the SP is excluded from the phlebotomy exam due to cancer chemotherapy, the Blood Draw Exclusion informational message text box displays.



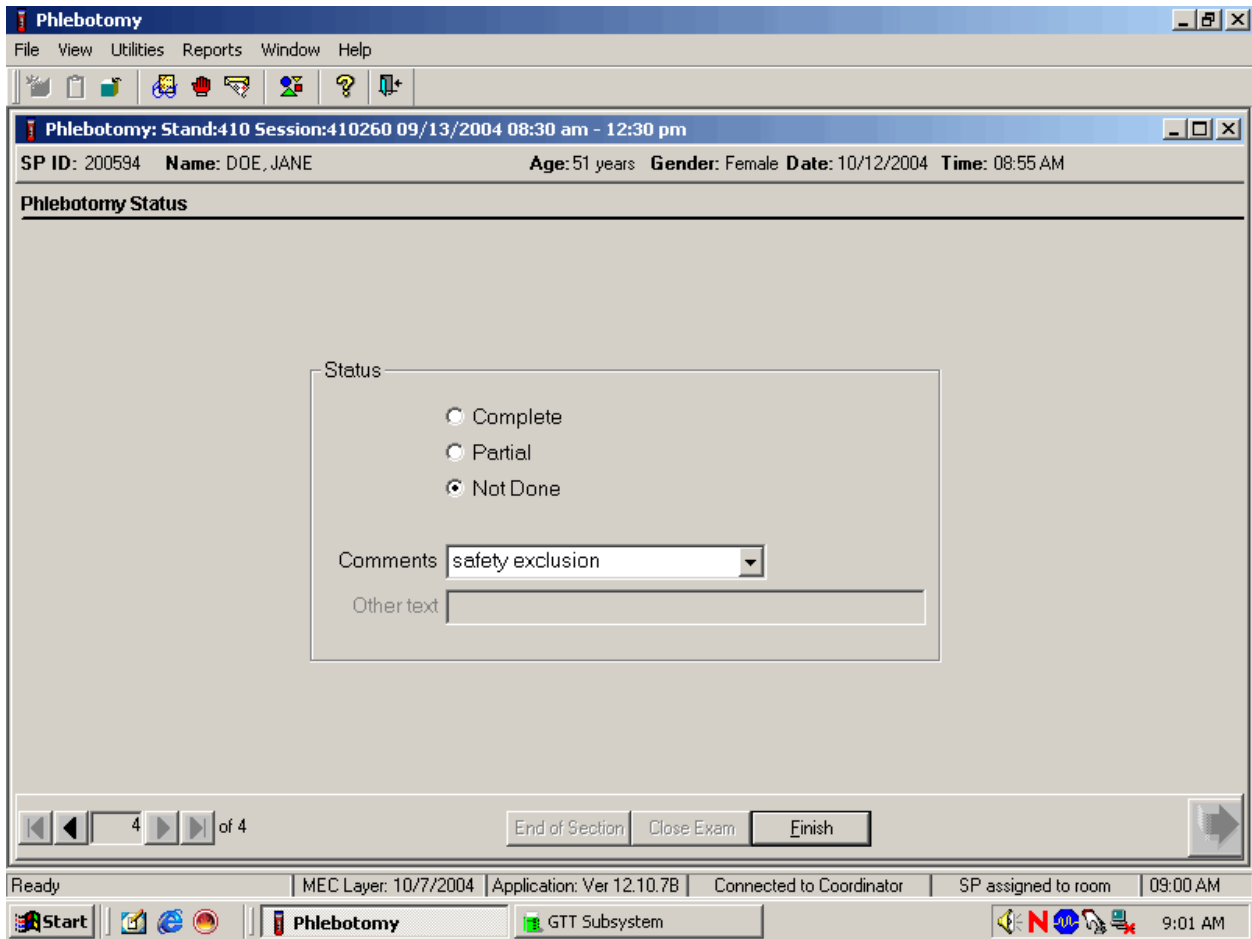
Read the script to the SP. To remove the Blood Draw Exclusion message box, use the mouse to direct the mouse arrow to the OK button and left click.

If the SP is excluded from the phlebotomy component due to chemotherapy, an informational Exclusion message text box displays. In some cases more than one Exclusion message box will display, one after the other.



To remove the Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To progress to the component status screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

Review the Status.



SPs excluded due to chemotherapy are automatically coded by the application as “safety exclusion.” Escort the SP back to the coordinator or to the next component as directed by the Message Center.

If the response to both exclusion questions is “No,” continue to the next screen.

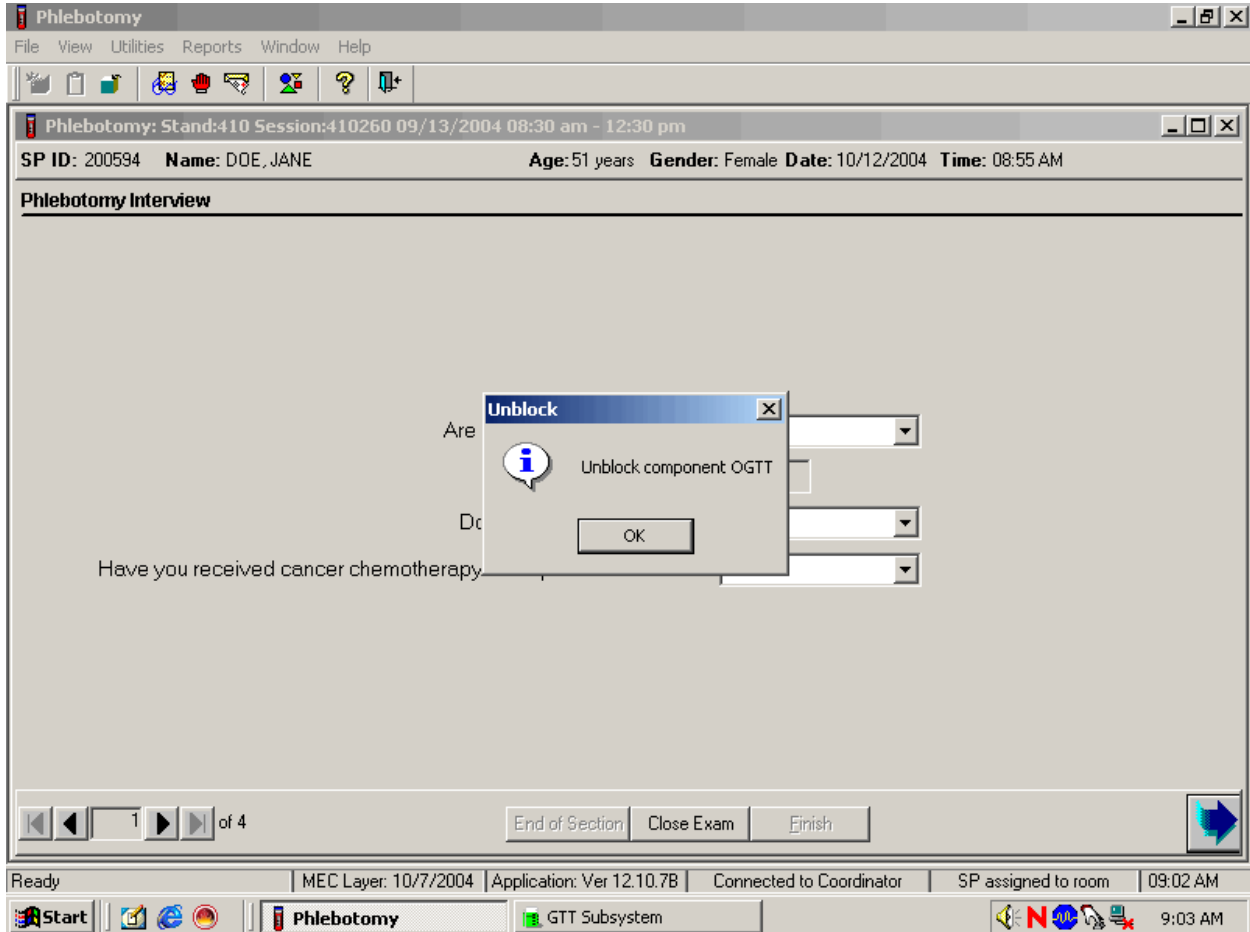
The screenshot displays the 'Phlebotomy' software interface. The main window title is 'Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm'. Below the title bar, patient information is shown: 'SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM'. The section is titled 'Phlebotomy Interview'. The form contains four questions with corresponding input fields:

- Are you currently pregnant?
- How many weeks?
- Do you have hemophilia?
- Have you received cancer chemotherapy in the past four weeks?

At the bottom of the form, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. A blue arrow icon is located in the bottom right corner of the form area. The Windows taskbar at the bottom shows the system tray with the time '9:02 AM' and various icons.

To progress to the fasting questionnaire screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

An informational Unblock message text box may display indicating that the SP has been unblocked from other components.



To remove the Unblock message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To progress to the Fasting Questionnaire screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

4.8 Administering the Fasting Questionnaire

Fasting status is critical to many of the laboratory analytes, and fasting data are required for correct interpretation of laboratory results. Fasting is especially critical because only SPs who have met the fast are eligible for the GT component. No primary SPs aged 1-11 or SPs assigned to afternoon or evening sessions are asked to fast. All other primary SPs aged 12+ appointed to a morning session are asked to fast for 9 hours. This includes diabetics taking insulin, although these SPs are always given the highest priority so the venipuncture can be completed as soon as possible after the SP checks in to the MEC.

The phlebotomist administers the fasting questionnaire to all SPs, and the application calculates and displays the fasting time in number of hours and minutes. The phlebotomist then performs the venipuncture.

The overall objective is to perform phlebotomy on all eligible SPs. The coordinator must base the decision to assign an SP to phlebotomy on the greater goal of completing as many components as possible within the time constraints of the session, with phlebotomy as the highest priority component. Sometimes an SP insists on leaving the MEC before he or she has been assigned to phlebotomy. It is always preferable to get blood from this SP before he or she leaves the MEC. The coordinator and MEC manager are able to provide the best overall assessment of the status of a particular SP.

Guest, dry run, VIP guests, and surplus participants do not have a fasting requirement, even during morning sessions.

SPs may opt to return to the MEC to complete exams that were missed or to complete exams that were begun but not finished. These SPs are designated as “Partial” SPs. When the SP returns to the phlebotomy component, ask and record the fasting questions a second time so that the data are accurate. Delete any data in the text boxes (previous responses from the initial visit) and enter the new responses.

Read the text exactly and record the time.

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm

SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.]

Have you had any of the following since

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]

Alcohol, such as beer, wine, or liquor?

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies?

Antacids, laxatives, or anti-diarrheals?

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

Fasting Hours Minutes

2 of 4

End of Section Close Exam Finish

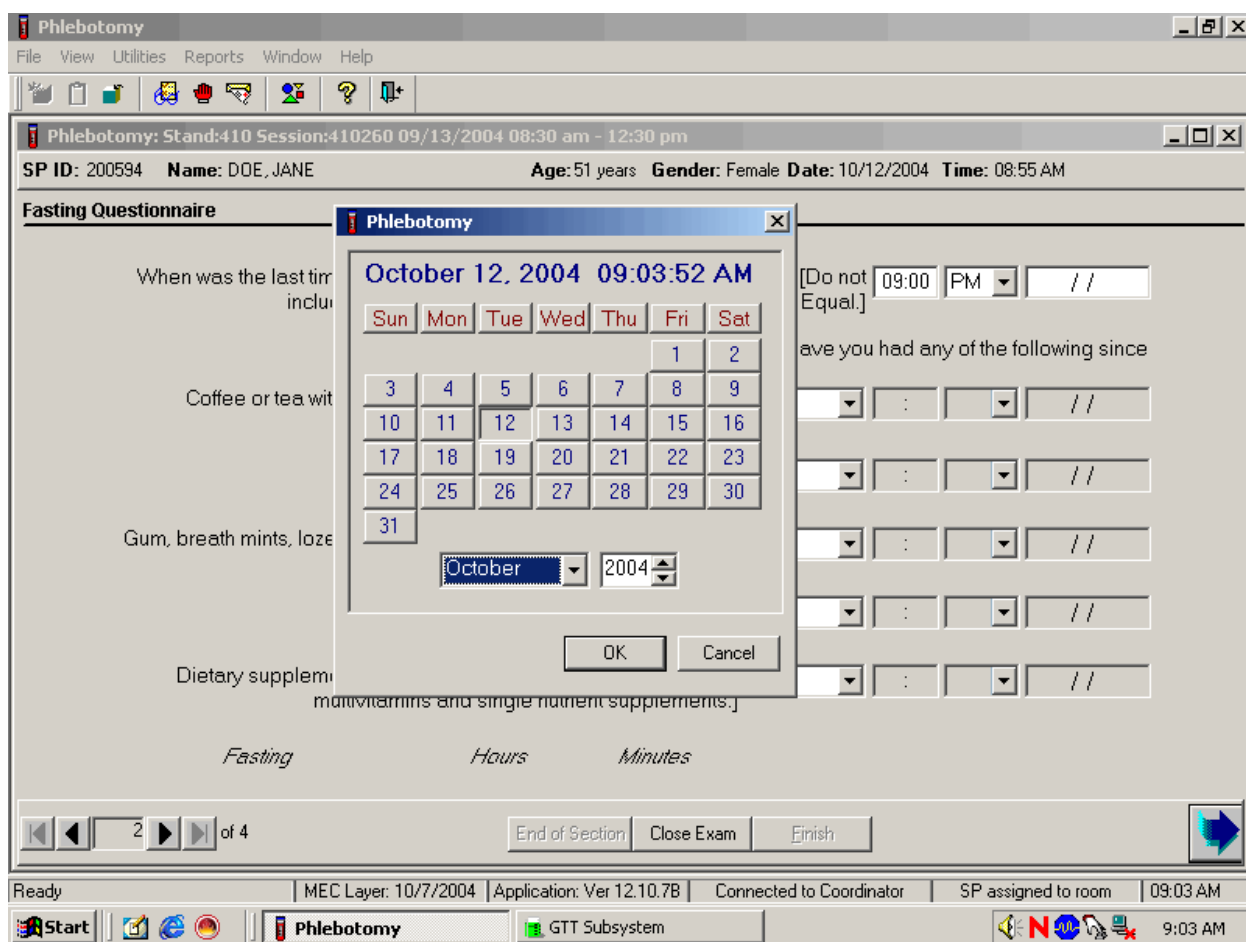
Ready MEC Layer: 10/7/2004 Application: Ver 12.10.7B Connected to Coordinator SP assigned to room 09:02 AM

Start Phlebotomy GTT Subsystem 9:03 AM

Q1: When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.]

| | |
|--|---|
| <p>Q1: This question elicits the last time the SP ate or drank anything and determines fasting time.</p> | <p>SPs are allowed to consume diet soda, black coffee or tea with saccharine or Equal since these have no effect on study analytes. Do not include flavored waters.</p> |
|--|---|

Enter the response.



Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to “AM,” or “PM” and left click.

Type in the date using the keyboard’s numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary), and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse

to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Continue administering the questionnaire. Verify the initial time response by asking the remaining questions.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main window displays patient information: "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm", "SP ID: 200594 Name: DOE, JANE", "Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM". The section is titled "Fasting Questionnaire".

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.] 09:00 PM 10/11/2004

Have you had any of the following since yesterday at 9:00 PM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] Yes

Alcohol, such as beer, wine, or liquor? No

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies?

Antacids, laxatives, or anti-diarrheals?

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

Fasting 12 Hours 4 Minutes

Navigation: 2 of 4, End of Section, Close Exam, Finish

System tray: Ready, MEC Layer: 10/7/2004, Application: Ver 12.10.7B, Connected to Coordinator, SP assigned to room, 09:03 AM. Taskbar: Start, Phlebotomy, GTT Subsystem, 9:04 AM.

Q2: Have you had any of the following since (time from question 1 inserted here)?

| | |
|--|---|
| <p>Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]</p> | <p>Black coffee is acceptable but coffee with any additives other than saccharine or Equal is unacceptable. Include all milk products such as half-and-half, light cream, non-fat milk, and all other non-dairy creamers like Cremora or Coffee-Mate.</p> |
| <p>Alcohol, such as beer, wine, or liquor?</p> | <p>Alcohol includes all types of spirits including light beer and wine. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed, and the correct time.</p> |
| <p>Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?</p> | <p>Include sugar-free gum and mints in this category. Give the SP the laminated card that lists common over-the-counter cough drops and cough and cold remedies to refresh his or her memory if he or she appears unsure about these items. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed, and the correct time.</p> |
| <p>Antacids, laxatives, or anti-diarrheals?</p> | <p>Antacids neutralize stomach acids. Laxatives stimulate evacuation of the bowels. Anti-diarrheals relieve diarrhea and cramping. Include all over-the-counter antacids, laxatives, and anti-diarrheals. Give the SP the laminated card that lists all over-the-counter antacids, laxatives, and anti-diarrheals to refresh his or her memory if he or she appears unsure about these items. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed, and the correct time.</p> |
| <p>Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]</p> | <p>Vitamins refer to various relatively complex organic substances occurring naturally in plant and animal tissue. They are essential in small amounts for the control of metabolic processes. Many are available over the counter as multivitamin-multimineral or single-nutrient supplements like Vitamin C. Include all of these when clarifying the response to this question. Give the SP the laminated card that lists all over-the-counter vitamins, antioxidants, multivitamins, multivitamins with minerals, and therapeutics to refresh his or her memory if he or she appears unsure about these items. If the answer is “Yes,” clarify the response. Ask the SP to describe the activity, item consumed and the correct time.</p> |

To enter a “Yes” or “No” response, type [Y/y] for “Yes” and [N/n] for “No.” Use the up and down arrow keys to toggle between the two choices. Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the response text box, select “Yes” or “No” and left click. If “No” is entered, the next response box is highlighted. If “Yes” is entered, the time and date text boxes are highlighted. Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the drop-down arrow on the right side of the text box, left click, drag the mouse arrow to “AM,” or “PM,” and left click.

Type in the date using the keyboard’s numeric keys and the mm/dd/yyyy format and select [Tab], or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary), and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Review the data in the Fasting Questionnaire.

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm

SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.] 09:00 PM 10/11/2004

Have you had any of the following since yesterday at 9:00 PM?

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] No : //

Alcohol, such as beer, wine, or liquor? No : //

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? No : //

Antacids, laxatives, or anti-diarrheals? No : //

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] Yes 08:10 AM 10/12/2004

Fasting 12 Hours 4 Minutes

2 of 4 End of Section Close Exam Finish

Close the exam MEC Layer: 10/7/2004 Application: Ver 12.10.7B Connected to Coordinator SP assigned to room 09:04 AM

Start Phlebotomy GTT Subsystem 9:05 AM

To progress to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter].

4.9 Venipuncture Procedures

Venipuncture should generally be performed using the median cubital, cephalic, or basilic veins in the left arm unless this arm is unsuitable. If the veins in the left arm are unsuitable, look for suitable veins on the right arm. If the veins in the antecubital space on both arms are not suitable, then look for veins in the forearm or dorsal side of the hand on the left arm/hand and then the right arm/hand.

The Vacutainer® system of blood collection consists of glass or plastic tubes with color-coded stoppers containing a premeasured vacuum that provides a controlled draw. Some tubes may contain additives to prohibit coagulation or inhibit glycolysis of blood cells. Draw the tubes in the order designated by the venipuncture protocol.

The exact quantity of blood drawn into each tube varies slightly with altitude, ambient temperature, and venous pressure. Fill tubes with additives completely to ensure proper ratio of blood to additive. Thoroughly mix the lavender and 2-mL and 10-mL gray top tubes immediately after drawing the tubes and place them on the specimen rocker until the tubes are labeled and passed through to the window to the laboratory.

Use Vacutainer® tubes at room temperature. Protect tubes from extreme temperatures and store in a cool place. It is important to note the expiration date printed on Vacutainer® tubes. Do not use expired tubes unless they are the only tubes available and they still contain a vacuum. Indicate if using expired tubes by using the “Other, specify” comment option on the venipuncture status screen.

Document the use of each Vacutainer® type in the automated Supply Use Control Log. When opening a new box, record the date, the lot number of the box, date in use, the expiration date, and tech ID number.

Allow two venipuncture attempts with the SP’s verbal consent or with the parent’s consent if an SP is a child or an infant.

If an SP faints or becomes ill causing the termination of procedure without collecting all of the blood, repeat the procedure with the SP’s consent after the SP has recovered.

4.9.1 Preparation of the Puncture Site

It is extremely important that the anticipated puncture site is thoroughly cleaned and all necessary equipment, including needles and tubes, are kept sterile and free from contamination.

Follow the steps outlined below to prepare the puncture site.

- Place venipuncture equipment where it is readily available but not in danger of being upset. Keep extra equipment within easy reach.
- Thoroughly wash hands.
- Put on gloves.
- Place appropriate blood collection tubes in a test tube rack in the order dictated by the venipuncture protocol. If an SP exhibits nervousness, keep the tubes covered.
- Instruct the SP to sit on the exam table. **Never** attempt a venipuncture on a standing subject. Having the subject sit helps guard against any injury that might result if the subject faints. Place the SP in a supine position if it is impossible for the SP to sit upright during the procedure. Instruct the SP to extend the arm palm up and straight at the elbow. If the SP is a child or infant, have a medical technologist hold the SP in the proper position.
- Position the SP's arm on the armrest or a pillow so that the veins are readily accessible and you are able to work in a comfortable position. Be sure that the arm is in a downward position with the elbow lower than the heart to prevent backflow. Dispose of the pillow weekly for hygienic purposes. Change the pillowcase daily.
- Inspect the arm. Use the left arm unless unsuitable. The veins of choice are the cephalic, basilic, and median cubital veins located in the antecubital fossa area.
- If the veins in the antecubital space are not suitable, look for suitable veins on the forearm or on the dorsal side of the hand.
- Apply the tourniquet several inches above the selected site.
- Select a vein that is palpable and well fixed to surrounding tissue. Palpate even when the vein is visible. Use the following techniques if the veins do not distend quickly.
 1. Massage the arm from wrist to elbow to force blood into the veins.
 2. Tap the area sharply with the index and second finger two or three times to cause the veins to dilate.
 3. Allow the arm to hang at the SP's side without a tourniquet to allow the veins to fill to their capacity.
 4. Examine the SP's other arm; sometimes the veins in one arm are larger than in the other.
 5. Check carefully for scar tissue or tendons near the vein.

Apply the tourniquet for no more than 1 minute while searching for a vein and then release the tourniquet for 2 to 3 minutes. Avoid prolonged obstruction of blood flow by the tourniquet because it is uncomfortable for the SP and may alter certain results (e.g., cholesterol).

- Reapply the tourniquet when ready to perform the venipuncture.
- Cleanse the area with an alcohol wipe. Do not touch the side of the alcohol wipe that is in contact with the puncture site. Cleanse the area using a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleansed.
- Repeat with a second alcohol wipe. Dry the cleansed area using a 2x2 gauze pad. The area should be completely dry before performing the venipuncture to reduce the burning sensation caused by alcohol penetrating the skin.
- Determine the correct needle size. Use a 19g, 21g, or 23g butterfly or a 21g multisample needle depending on the condition of the SP's veins. The 19g butterfly should be suitable for most SPs. If the SP's veins appear fragile or small, use a 21g or 23g butterfly. If the SP is obese, use a 21g multisample needle.

4.9.2 Venipuncture Technique for the BD Saf-T EZ® Blood Collection Set (19 Gauge)

1. Prepare the blood collection set. Obtain one blood collection set and one luer adapter. Open the blood collection package and inspect the unit. Open the blue adapter cover by twisting the two ends at the seal. Push the male luer adapter firmly and securely into the female end of the needle assembly. Attach a yellow tube holder onto the adapter.
2. Ask the SP to make a fist. Do not have the SP pump his/her fist since this action may alter certain results.
3. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of your less dominant hand.
4. Approach the vein in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
5. Remove the needle cover. Grasp the wings and push the needle firmly and deliberately into the vein. Do not grasp the translucent needle shield to insert. If the needle is in the vein, a small amount of blood will appear in the butterfly tubing. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the butterfly tubing. If no blood enters the tube and no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for 3 minutes.

Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again if using the same arm for a second try.

6. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.
7. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the dominant hand free to pick up and change the tubes. If left-handed, do the reverse.
8. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
9. Immediately invert the lavender and gray tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender and gray tubes on the rocker. Do not invert or agitate the red top tubes.
10. Insert the next tube and push it down gently onto the adapter.
11. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
12. Fill tubes in the proper order, according to the protocol.
13. When the last tube has filled, remove the needle in a smooth quick motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. To activate the shielding mechanism, either grab the tubing and hold the needle guard at the end closest to the tubing and pull the tubing until the needle guard locks in place or hold the needle guard at the end closest to the tubing, grab the wings and slide the wings back until the needle guard locks in place.
14. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

4.9.3 Venipuncture Technique for the BD PushButton™ Blood Collection Set (21 and 23 Gauge)

The BD Vacutainer™ Push Button Blood Collection Set provides immediate protection against needle stick injury when properly activated within the vein, and in accordance with package insert directions.

1. Prepare the blood collection set. Open the package and inspect the unit. Check to ensure that the female luer adapter is firmly and securing attached on the male luer.

2. Ask the SP to make a fist. Do not have the SP pump his/her fist since this action may alter certain results.
3. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of your less dominant hand.
4. Approach the vein in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
5. Remove the needle sheath. With thumb and index finger, grasp wings together and access vein using standard needle insertion technique. If the needle is in the vein, a small amount of blood will appear in the butterfly tubing. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the butterfly tubing. If no blood enters the tube and no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for 3 minutes. Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again if using the same arm for a second try.
6. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.
7. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the dominant hand free to pick up and change the tubes. If left-handed, do the reverse.
8. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
9. Immediately invert the lavender and gray tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender and gray tubes on the rocker.
10. Insert the next tube and push it down gently onto the adapter.
11. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.
12. Fill tubes in the proper order, according to the protocol.
13. When the last tube has filled, ***and while the needle is still in the vein, activate the safety shield by*** pushing the button to retract the needle into the hub of the device.
14. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

4.9.4 Venipuncture Technique for the Eclipse Multisample Needle

1. Prepare the needle. Holding both colored shields, twist and remove the white shield. Screw the needle onto the holder. Rotate safety shield back. Twist and pull needle shield straight off.
2. Place the first tube into the holder, securing it slightly, but not penetrating the stopper.
3. Ask the SP to make a fist. Do not have the SP pump his/her fist since this may alter certain results.
4. Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of your less dominant hand.
5. Approach the veins in the same direction that the vein runs, holding the needle with bevel up and at a 15-degree angle to the SP's arm.
6. Push the needle firmly and deliberately into the vein. Quickly push the first Vacutainer® tube down on the needle. If the needle is in the vein, blood will flow freely into the Vacutainer® tube. If no blood enters the tube but no bruise is forming, probe the vein until blood begins flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place gauze squares over the puncture site and apply firm pressure to the puncture site for 3 minutes. Switch to the other arm using a new needle. Wait 10 minutes before beginning the procedure again, if using the same arm for a second try.
7. Hold the tube with the tube stopper uppermost and with the tube lower than the needle to prevent backflow through the tube. It is very important to prevent possible backflow because of the possibility of adverse reactions to the SP.
8. As the Vacutainer® tube is filling, transfer the tube holder to the left (less dominant) hand, leaving the right (dominant) hand free to pick up and change the tubes. If left-handed, do the reverse.
9. Fill all tubes completely. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.
10. Immediately invert the lavender and gray tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender and gray tubes on the rocker.
11. Insert the next tube and push it down gently onto the adapter.
12. Because prolonged application causes vasoconstriction, remove the tourniquet after 2 minutes to ensure valid test results. If necessary (that is, if the blood flows more slowly), reapply the tourniquet after 2 minutes. If this is the last tube to fill, loosen the tourniquet when the tube begins filling and remove it as the last tube fills.

13. Fill tubes in the proper order, according to the protocol.
14. When the last tube has filled, remove the needle in a quick, smooth motion. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein. Firmly push forward on the safety shield, lock into place, and inspect. After withdrawing the needle, immediately press clean gauze squares over the venipuncture site.
15. Discard the entire blood collection set, including the needle and adapter, in the sharps needle disposal unit. Do not recap the needle. Discard tourniquet in trash.

4.9.5 Concluding the Venipuncture

1. Have the SP place two fingers on the gauze to hold it in place, then ask the SP to raise the arm straight up, elevating the arm above the level of the heart, without bending the elbow. The SP should remain in this position for 2 to 3 minutes to help prevent hematomas.
2. Corresponding computer-generated bar code labels print automatically for the tubes drawn. Label the 10-mL gray top tube with the label containing the Vessel ID - 54. Label all other tubes with bar-coded labels with the bar code vertical on the tube. The time prints on the label.
3. Place the rack containing the blood collection tubes in the pass-through window located over the sink. Alternatively, deliver the rack to the laboratory, and distribute as described below:
 - Place the lavender and gray tubes on the rocker located next to the centrifuge.
 - Place the red top tubes upright in the test tube rack located next to the centrifuges in the laboratory.
4. Place all used needles in a sharps container and dispose of all visibly contaminated waste in a biohazard bag.
5. Check the venipuncture site for clotting.

Venipuncture should generally be performed using the median cubital, cephalic, or basilic veins in the left arm unless this arm is unsuitable. If the veins in the left arm are unsuitable, look for suitable veins on the right arm. If the veins in the antecubital space on both arms are not suitable, then look for veins in the forearm or dorsal side of the hand on the left arm/hand and then the right arm/hand.

Use judgment when applying any bandage to elderly SPs. The skin of the elderly can be very thin and fragile and the Liquid Band-Aid® may irritate the skin when it is removed.

If the venipuncture is performed on a vein in the antecubital space of the right arm:

Apply Liquid Band-Aid to the puncture site. (If the SP is eligible for the GTT, remove the Liquid Band-Aid before the GTT venipuncture. After the GTT venipuncture is complete, reapply Liquid Band-Aid.)

If the venipuncture site is in the left arm:

For all SPs age 1-11 and SPs not eligible for GTT - Apply an adhesive bandage over the gauze pad. Instruct the SP to remove it in no less than 45 minutes if the bleeding has stopped. Also, suggest that the SP sit quietly for a few minutes. If bleeding continues, keep direct pressure on the site for 5 minutes or more.

For all SPs age 12+ who are eligible for the GTT- Apply Liquid Band-Aid® to the puncture site in place of the regular adhesive bandage or CoFlex dressing. Liquid Band-Aid stops minor bleeding, reduces minor pain, and promotes fast healing on contact. It forms a clear, flexible, breathable seal. Apply once. Make sure puncture site has stopped bleeding.

To apply Liquid Band-Aid:

- Dry any excess blood.
- Open the Activator package; hold the activator at the end of the stick. Do not touch the foam pad.
- Invert the liquid bandage bottle four times. Remove the cap. Squeeze four (4) drops of Liquid Band-Aid onto foam pad end of one activator.
- Allow the liquid to drop onto activator without touching the tip of the bottle to the foam end of the activator. Note: Activator must be used to apply Liquid Band-Aid or product will not work.
- Immediately apply Liquid Band-Aid with the activator, covering the entire puncture site. Discard activator after use.
- Close bottle tightly after use.
- Do not touch the area for at least 1 minute until the seal forms.
- Apply once – do not repeat.

As the puncture site heals, liquid Band-Aid will naturally slough off.

To Remove:

- Pour enough baby oil onto the Liquid Band-Aid seal to cover the area.
 - Wait at least 1 minute.
 - Wipe the area with a towelette.
6. Report any adverse reaction to the venipuncture to the physician immediately and document the event by using the automated Unusual Field Occurrence utility.
 7. If the SP has been fasting and is eligible for the GTT, then do not offer him or her a snack and juice. If the SP has not been fasting or is not eligible for the GTT, then offer him or her juice and crackers.
 8. Escort the SP back to the coordinator.
 9. If blood has spilled on the table or the arm board, wash the area with a 10 percent solution of bleach and water, then prepare the workstation for the next SP. Routinely disinfect the table or arm board with 10 percent bleach solution.
 10. Wash hands and change gloves before approaching the next SP.

4.10 Pediatric Venipuncture

Pediatric venipuncture requires special techniques. Because you will be dealing with children of different age ranges and levels of understanding, it is important to be able to recognize at what stage a child is in early in the venipuncture process.

Infants and toddlers, aged 1 to 2 years, experience the world through their senses and do not have much of a language base. Therefore, verbal explanations are virtually meaningless. Expect crying and resistance from the start, even at the first touch. Restrain children of this age by enlisting the assistance of a medical technologist. The best techniques to use with these children are to maintain a reassuring tone, to reinforce that the child is a good boy or girl, and to draw the blood quickly. Be sure to reassure the child after the procedure and to use cartoon adhesive bandages and stickers when finished.

Preschoolers, aged 2 to 6 years, think concretely and in absolute terms; things are good or bad, right or wrong, painful or not painful. For these children, use simple, concrete terms when describing the procedure and its consequences. Always be honest. Try to avoid the word “take” which implies remove, “test” that implies pass or fail, and “fix” which implies broken. With children of this age, it is

still important to emphasize that the child is a good boy or girl and to use colorful adhesive bandages and stickers. Try using distractions, such as holding something, counting things in the room, and breathing deeply. These techniques may work with the older children in this age group. The phlebotomist may have a medical technologist assist with most of these children.

School-aged children, 7 to 12 years, have a better grasp of language and view the world more realistically. They understand past and future, that is, “this will be over soon,” and relative terms, such as “this will hurt a little or a lot.” Detailed explanations of the procedure are extremely effective. Again, always be honest. Include demonstrations, with a doll for example, whenever possible. Having the child help during the procedure distracts the child as well as letting him or her have some control. Be sure to reinforce how big a help he or she was after the draw. Give the child realistic choices, such as which arm to choose. You may need to consider having a medical technologist assist with some children even at this stage. Adhesive bandages continue to be important.

Although adolescents ages 12 to 18 years are beginning to think abstractly, they often regress when placed in stressful situations. It is best to assume that they will act younger than their chronological age. However, it is still very important to address the adolescent as an adult and not as a child. Provide detailed explanations and inform him or her that the best technique is being used. It is very important that the adolescent maintain control of the situation; therefore, give him or her some choices, as well as allowing him or her to help if offered. Be very clear about rules, such as remaining motionless, but do not restrain the adolescent.

Pediatric venipunctures are most successful when children are immobile, the veins are maximally distended, and all supplies are handy. Many children prefer a cloth or gauze under the tourniquet to prevent pinching of skin.

The usual site for pediatric venipunctures is the antecubital fossa. Most venipunctures in children are successful using a 23-gauge butterfly needle. Follow the general guidelines in Section 4.9 for performing venipunctures.

4.10.1 Age-Specific Techniques in Phlebotomy Competency

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The Learning Scope:

Understanding and incorporating age-specific competence in evaluating the phlebotomist's performance

By Donna R. Kirven, BA, BPPVE, PBT(ASCP), CLA

Learning Objectives

At the conclusion of this article the participant will be able to:

State the importance of communicating and incorporating techniques in the performance of phlebotomy procedures based on the physical age and developmental stage of the patient.

Identify at least three major developmental considerations in the performance of phlebotomy procedures for each age-specific group.

Formulate an age-specific competency that can be used as part of the phlebotomy evaluation process.

All health care professions that involve direct patient contact require certain specialized techniques and competencies that are based on characteristics of the patient receiving service. The invasive procedures of phlebotomy are no exception.

Traditionally for some phlebotomists, the majority of their patients could be categorized in one or two age groups, while the experience of others includes all age groups. Age-specific concerns are age, growth, development and safety considerations that must be assessed and incorporated into phlebotomy practices for successful outcomes with all patient age groups.

Simply defined, age-specific competence is the knowledge, skills, ability and behaviors essential for providing care to specific populations of patients and their families. These considerations require expanded knowledge and an increased experience level of physical, psychological and interpersonal assessment skills. The newly certified (or trained) phlebotomist should begin using that training on older children, and as confidence and technical skills are attained, progress to performing venipunctures on younger children and, subsequently, infants.¹ Performing a venipuncture on pediatric patients can present a greater technical and emotional challenge to the phlebotomist, and without proper age-specific techniques can result in an unnecessarily unpleasant experience for the child, the parents and the phlebotomist.

To make quality health care services available to communities served by acute care facilities, age-specific phlebotomy techniques are now becoming a standard part of the phlebotomy training curriculum and annual competencies.

Factors in Age-Specific Techniques

Age-specific techniques in phlebotomy involve much more than simply using a smaller tourniquet and collecting a minimum volume of blood. Considerations for motor skills, communication skills development, social needs, and physical and learning disabilities also are a part of the age-specific assessment. The rationale for age-specific techniques is based on the fact that different age groups of patients have special physical and psychosocial needs. Knowledge of the basic nutritional and social needs such as feeding, sucking and physical affection in the infant patient can exemplify professionalism and confidence to anxious parents. Recognition of the increased potential for diminished hearing, vision and mobilization can dispel feelings of embarrassment and frustration in the elderly patient.

Safety is also an age-specific criteria issue. While the phlebotomist should exercise safe practices with all patients, it is important to be aware of the special safety precautions that should be used with pediatric, elderly and disabled patients that are specifically attributable to age. Communication skills on the part of the patient as well as the phlebotomist are also important factors. When performing phlebotomy procedures on an infant, informing the parent or guardian of the details of the procedure in addition to reassurance can alleviate anxiety and build their trust before attempting the procedure. Becoming a highly qualified, experienced phlebotomist skilled in age-specific techniques requires good interpersonal skills such as integrity, effective communication and confidence, as well as demonstrated technical skill.

By incorporating awareness growth and development theories into phlebotomy training, the phlebotomist can provide service and perform procedures in a manner that meets the practical (quality specimen collection) and personal (trust, reassurance, respect) needs of patients and their family members. Table 1 shows six stages of development and the corresponding age divisions.

The Neonate/Infant

Venipunctures should not be performed on children under the age of 6 months unless the test ordered requires the volume and type of specimen that can only be obtained by a needle stick. Nonetheless, heel sticks, the most frequently used method performed for mandatory newborn screens that test for phenylketonuria (PKU), galactosemia, hypothyroidism, primary congenital hypothyroidism and several other hemoglobinopathies,² are performed on a routine basis and require highly specialized skills and age-specific techniques.

The phlebotomist must select the appropriate method of obtaining a blood sample after considering two factors: the patient's age and sample requirements for the test ordered. The novice phlebotomist must study anatomy and physiology, become familiar with special types of equipment specifically designed for the pediatric patient, observe various techniques as performed by experienced phlebotomists or nurses, and practice the techniques themselves to develop the necessary skills. They must make every attempt to collect the minimum amount of blood required for testing because of the small blood volume of infants. Removal of more than 10 percent of an infant's blood volume at one time can lead to cardiac arrest,¹ while removal of large amounts of blood over an extended period of time can lead to anemia, possibly requiring the infant to undergo a blood transfusion. Improperly performing a heel incision, or using a safety lancet that is not of appropriate pediatric size on small children, can lead to puncture of the calcaneus bone, infection and osteomyelitis.

Specific guidelines for performing a heel stick include:

Refrain from puncturing the anteromedial aspect or the posterior curve of the heel to avoid puncturing the underlying calcaneus.

Hold the infant's foot securely but gently so as not to bruise his/her delicate tissue or restrict blood flow.

Avoid milking or squeezing the foot, which can dilute the blood with interstitial (tissue) fluid or cause hemolysis of the specimen.

Refrain from covering the puncture site with adhesive bandages that can macerate the infant's fragile skin underneath.

The emotional challenge of performing phlebotomy procedures on neonates requires that the phlebotomist be prepared to handle not only the infant's reaction to the procedure, but also the parent or guardian who may be present. It is important that the experienced phlebotomist build trust with the parent by communicating in a warm, compassionate manner while displaying a calm and confident approach. These types of interpersonal skills, in addition to requesting the parent's assistance in comforting the infant, can help calm parental anxiety and foster trust in the phlebotomist, allowing her to perform the procedure in a less frenzied environment. Consider the following:

Case Study

Jordan Smith is a 9-month old boy who has been brought to the outpatient laboratory by his parents for some lab work ordered by Jordan's pediatrician. Aside from the newborn screening performed shortly after his birth, Jordan has never had a blood test. His pediatrician has ordered electrolytes and a complete blood count.

Once Jordan's parents have completed the necessary laboratory registration, Monica, a phlebotomist with 15 years experience, having reviewed the requisition and assembled her phlebotomy supplies beforehand, calls Jordan and his parents into the outpatient drawing room. After introducing herself and completing the patient identification procedure with Jordan's mother, Monica greets Jordan and notices that Jordan's father appears to be frozen with fear, hasn't spoken a word and has large beads of perspiration covering his forehead. Jordan's mother, on the other hand, appears significantly less nervous and is engaged in physically and verbally comforting him. Her years of experience have taught Monica that she should address these observations before beginning the procedure. The dialogue proceeds as follows:

Monica: Mr. and Mrs. Smith, has Jordan ever had a blood test performed?

Mother: No.

Father: (*Shakes his head designating "No"*)

Monica: I'd like to take a minute or two to explain the procedure to you, but first I'd like to reassure you that I will do my best to perform this procedure with as little discomfort as possible for Jordan and for you.

Mother: Thank you.

Father: (*Mumbles "Thank you"*)

Monica: Mr. Smith, you appear to be a little nervous, and that's quite understandable. Our phlebotomy staff here have an average of 10 years experience in performing these procedures on patients who are Jordan's age and younger. I understand your hesitation and respect your concern. If you feel that observing the procedure may be a bit too upsetting for you, you're welcome to have a seat in our waiting area while your wife remains here with us during the procedure, but if you prefer to stay that's fine too.

Father: Well, it's just that he's so small—and do you really have to stick him with a needle to get blood, can't you just prick his foot or something like they did when he was born?

Monica: Children who are Jordan's age have usually begun to stand or walk, and in preparation for this, the skin of the foot has grown thicker and more resilient. To incise or cut the heel at his age and size, in the same method as that for newborns, would not allow sufficient blood flow required to complete the tests that his physician has ordered. Our standard practice for a patient Jordan's age is to obtain a blood specimen from a vein in the arm, which is believed to be a more efficient and less traumatic method of performing a blood test.

Father: How can you find a vein in a little arm like this?

Monica: That's a question that I'm often asked by parents. My training for collecting blood specimens from children required that I learn to feel the veins in little arms just as proficiently as I did in older arms, and after proper training and practice, I did. Sometimes, it's easier to find the veins in someone Jordan's size than it is to find them on an adult.

Father: So you've been doing this a long time?

Monica: I personally have more than 10 years experience drawing infants and children.

Father: Well, that's good to know. I feel a little bit better now so I think I'll stay in here.

Monica: That's great. Mrs. Smith do you have any questions?

Mother: No. I just want this done and over with.

Monica: Great! If I can get you to help me by holding Jordan just this way, it will really help us complete this procedure quickly and ensure that we have collected a quality specimen. Dad, you can help too by giving Jordan lots of encouragement and praise during the procedure.

The Pre-School Child

Although the pre-school aged patient has begun to verbally communicate in small statements, it is important that the phlebotomist explain the intended procedure in terminology appropriate for the child. As this patient age group is heavily engaged in security-seeking behavior, the presence of the phlebotomist—a stranger clad in a white lab coat—can often exacerbate their fear and increase their anxiety level even before they see a needle. Approach them slowly and gain their trust before handling equipment or touching their arms to look for a vein.²

One of the goals of age-specific techniques for this group is to attempt to keep the child calm and reduce crying which, if prolonged, can actually raise the white blood cell count and the blood pH level.³ Several methods can be used to accomplish this, some of which may not work for every child; however, the appropriate choices can be more easily made with the phlebotomist's increasing experience level.

Some of these methods are:

Prepare materials and gather equipment before you encounter the child. Doing this in the child's presence will allow more time for the child's anxiety to build.

Approach the child in a friendly, cheerful and empathetic manner. Speak before you touch the child, even if the child cannot or will not respond. Introduce yourself and address the child by name.

Speak in a soothing, non-threatening tone of voice. Even if the child does not completely understand what you are saying, a calming tone communicates a non-threatening intention.

Explain the procedure in terms that are appropriate for the child's age. This, coupled with a soothing tone of voice, can help to lessen the child's fear.

Do *not* say, "It will not hurt." Explain that some pain will be involved in the procedure, and that it is OK to say "ouch" or cry a bit, but that it is important to keep the arm as still as possible.

During the procedure, keep the child informed of how much longer it will be—"Just one more tube"—while using appropriate praise for the child, even if he/she did not cooperate as much as possible. Phrases such as "You are doing such a good job of helping me. Thank you, (patient's name)" can provide reinforcing recognition that may encourage the child to approach his/her next phlebotomy experience with less anxiety.

The School-Aged Patient

Performing phlebotomy procedures on the 8-12 year old patient can be more of a physical challenge than an emotional one. This age group has mastered the meaning and use of the word "No," and is prepared to defend their fear with it. Proper immobilization of the pediatric patient is necessary to ensure the safety of the child as well as the phlebotomist. Instructing the parent/guardian on the correct "hugging" hold method for a child seated on the parent/guardian's lap, or the appropriate restraint for the prone child can allow the phlebotomist to collect the specimen in a manner that will also ensure accurate test results.

The school-aged patient has moved from security-seeking behavior to independence-seeking behavior and as such can exhibit unceasing curiosity. It is important that all phlebotomy equipment be kept out of reach of the child; however, be sure to respond to the child's inquiries as appropriate. Asking questions is an integral part of the learning process, and responding initiates effective communication skills. These young patients have begun to establish their identities, and the phlebotomist must communicate with them as individuals, in age-appropriate terminology.

Also, most of these children have begun the initial stages of puberty, so the phlebotomist must allow for the privacy of the child in preparation for the phlebotomy procedure. In an outpatient setting, if a urine specimen is ordered, give the child instructions for collection, in age-appropriate terminology, and allow him/her to attempt specimen collection assisted by the parent/ guardian or alone.

The Adolescent Patient

In dealing with the adolescent patient, it is essential for the health care provider to remember the importance of demonstrating an understanding of the significance of peer relationships to the adolescent. Embarrassment can be this age group's mascot. The phlebotomist can implement this understanding by recognizing that some reassuring comments or approaches, if not age-appropriate, can actually instill *more* anxiety for the adolescent patient. Providing age-appropriate praise and positive feedback for this group of patients can lessen their anxiety.

Adolescents in the higher age range are usually engaged in thoughts, goals and behavior that they believe will eliminate the perception of a child, and establish that of an adult. These behaviors can, however, manifest themselves in a sensitivity-heightened and non-interactive manner that can test the communication skills of the phlebotomist, as well as the parent/guardian. It is important to continue to initiate communication with adolescent patients and welcome their limited inquiries.

The older adolescent male, for some unknown cause, possibly hormonal, can demonstrate a greater potential for fainting during a venipuncture procedure. One of the age-specific safety techniques that can be used with this patient age group is to more closely assess the patient before, during and after the procedure. Listen for a previous history of syncope or light-headedness when first encountering the adolescent patient.

During the procedure, periodically check for pre-syncope signs such as profuse perspiration, change in skin pallor, and/or the onset of clammy hands. Another indication of pre-syncope can be the adolescent patient who is suddenly silent in the middle of a conversation or extremely talkative after having been previously silent.

It is important that the phlebotomist be familiar with the department's policy/procedure for dealing with patients who experience syncope, light-headedness or dizziness.

The Adult Patient

Some of the typical conditions that commonly affect the adult patient are stress and depression, which are usually related to pressures of the workplace, marriage, childbearing, parenting and social expectations. Additionally, these roles can induce a stronger identification with their parents or primary caregivers, known as generativity, as well as a closer reflection with their own mortality.

For the average adult, the focus of learning patterns and thinking lies mainly on problem solving. Accordingly, the phlebotomist must use effective communication skills by clearly and honestly informing the adult patient of the procedure while continually maintaining a professional, confident manner. Adult patients are more than willing to cooperate if they are aware of the benefits of their cooperation.

An adult patient can possess the same fear as that of a pediatric patient; however, the adult patient is usually more willing to allow the procedure as long as it is performed in a professional and concise manner. Conditions that may begin to affect the middle-aged adult patient are the onset of cardiovascular disease and menopause, stroke and cancers. On the other hand, a significant percentage of adult patients who are directed toward maintaining good mental and physical health, optimal energy and social activity exists. These patients are usually less stressed about phlebotomy procedures and view them as an integral part of the preventive health care process.

One of the most effective tools of good communication is eye contact. Eye contact promotes a sense of trust and honesty between the patient and phlebotomist; however, if a patient does not return the eye contact when being spoken to, he/she may prefer less direct eye contact due to cultural or modesty reasons. Experienced phlebotomists will take cues from the patient to monitor and satisfy the patient's comfort level needs.

When interacting with adult patients, the phlebotomist should refrain from engaging in negative body language such as crossed arms, wrinkled forehead or frequently glancing at a clock or watch. These behaviors can detract from the professional image when communicating with adult patients.

The Elderly Patient

With the expanding life expectancy tables, many phlebotomists' patients are likely to be elderly.³ As with infants and younger patients, this can present both physical and psychological challenges for the health care professional. Likewise, working with the older adult can be extremely rewarding for the phlebotomist who continues to perfect her technical expertise and take the time to treat the patient with respect and compassion.

Elderly patients may feel that they are in less control of their medical situation than other patients, may feel apprehensive about having the procedure performed and embarrassed about feeling this way about it. As with all patients, elderly patients should be treated with consideration for their special needs and with tender, loving care. However, elderly patients are sometimes under the impression that they are a burden and become anxious about the procedure because they don't wish to be a bother. Phlebotomists can help to ease this anxiety by being friendly and cheerful, and taking the time to not only listen to their patients and talk with them, but also to encourage verbalization of their concerns and fears. This can help establish the patient's trust in the phlebotomist and dispel feelings of being a bother.

As people age, they usually undergo a number of physical changes that can have a significant impact on their safety and the effectiveness of normal collection procedures. The elderly patient experiences skin changes, such as the loss of elasticity and moisture, as well as the thinning of skin layers. Loss of supportive connective tissue can lead to "loosened" skin, and loss of muscle tissue and tone may allow for greater movement of veins.³ The phlebotomist must treat the skin of the elderly patient in a gentle manner. Sometimes the tourniquet that is applied in a tight or rough fashion can easily tear this delicate skin.

In this age group, patients may experience a decrease in peripheral circulation due to narrowed vessels that are the result of atherosclerosis⁴ and, combined with loss of vessel elasticity, become more fragile. Gently massaging the intended site rather than slapping or tapping the arm or hand can effectively increase circulation to the site. As skin layers thin, arteries can lay closer to the skin surface in elderly patients, so the phlebotomist must take care to palpate for the "best" vein, and ensure that it does not have a pulse.

Hearing loss is another disorder that is commonly found in the elderly patient. The phlebotomist should approach a patient who communicates that he/she has a hearing impairment by speaking in a slowed, deliberate and distinct voice to confirm that the patient understands. Some conditions, including Parkinson's disease and stroke, can lead to impaired or unclear speech. This can be a source of frustration for the elderly patient. The phlebotomist must allow the patient to complete his/her statements without being made to feel "rushed," and remember that speech difficulty does not imply difficulty hearing or understanding.

Arthritis also affects a large percentage of the elderly population and may restrict the patient from fully straightening or extending the fingers or arms. The phlebotomist should never force a patient's limb, but should ask the patient whether this action is painful or uncomfortable.

Tremor is also common in advanced aging³ and may present some difficulty for the patient to hold his/her arm steady during the venipuncture procedure.

A large number of adults over the age of 50 begin to experience loss of visual acuity and, as such, it is vitally important that the phlebotomist ensure that the entrance and floor areas are free of any debris that may not be visible to the elderly patient. Clear plastic needle covers and small pieces of tape can be falling hazards. Inpatient beds that are raised should be lowered before leaving the patient's room.

Poor nutrition and chronic degenerative disease may lead to emaciation, which can make the elderly patient more susceptible to infection due to loss of immune function,³ so these potential falling hazards should be eliminated to avoid cuts, lacerations and broken limbs.

Forgetfulness, confusion and dementia are more commonly found in the elderly population.³ Reliability on the inpatient's armband to confirm identification is a must. Some confused patients may not fully understand your intentions and may lash out in defense. If the patient does not demonstrate a clear understanding of the procedure, the phlebotomist should check with the nurse and seek assistance if appropriate.

Summary

Age-specific care techniques are a requirement for all health care professions involving direct patient contact, such as phlebotomy. It is vitally important that these techniques be introduced and incorporated into all phlebotomy training programs, competencies and continuing education. Learning these techniques requires not only a fundamental knowledge of human growth and development, but also the ability to combine technical expertise with age-specific interpersonal skills.

Incorporating the physical, psychological and social needs of patients into the formal phlebotomy training curriculum can provide a vital foundation for all those who aspire to successfully perform phlebotomy procedures. Probationary and annual competencies should specifically address age-specific topics such as tone of voice, eye contact and active listening skills. The implementation of age-specific techniques into the phlebotomy training curriculum and competency format will yield more effective phlebotomy practices and, subsequently, quality patient care.

REFERENCES

1. Garza D, Becan-McBride K. *Phlebotomy Handbook: Blood Collection Essentials*, pediatric procedures, 6th Edition. Upper Saddle River, NJ, Prentice Hall, 2002.
2. McCall R, Tankersley C. Pediatric venipuncture In: *Phlebotomy Essentials*, 2nd Edition. Philadelphia, Lippencott-Raven, 1998.
3. Sommer S, Warekois R. Blood collection in special populations In: *Phlebotomy: Worktext and Procedures Manual*. Philadelphia, W.B. Saunders, 2002.
4. Klosinski D. Collecting specimens from the elderly patient. *Laboratory Medicine*. 1997;28(8): 515-522.

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http://www.advanceformlp.com/common/editorialsearch/viewer.aspx?FN=03mar10_mtp11.html&AD=3/10/2003&FP=mt

1. Which of the following is considered a personal need of the patient?

- a) reassurance
- b) respect
- c) trust
- d) all of the above

2. Which of the following age groups is heavily engaged in security-seeking behavior?

- a) elderly
- b) pre-school
- c) adolescent
- d) school-aged

3. Immobilizing the pediatric patient can allow the phlebotomist to:

- a) collect a specimen in a manner that will ensure accurate results.
- b) build trust.
- c) demonstrate confidence.
- d) facilitate development and growth.

4. Which of the following age groups includes a population that demonstrates a greater potential for fainting during a venipuncture procedure?

- a) elderly
- b) pre-school
- c) adolescent
- d) school-aged

5. To monitor and satisfy the adult patient's comfort level needs, the experienced phlebotomist will take his/her cues from the:

- a) physician.
- b) nurse.
- c) family.
- d) patient.

6. To ease anxiety with the elderly patient, the phlebotomist can:

- a) be friendly and cheerful.
- b) listen and talk with the patient.
- c) encourage verbalization of concerns and fears.
- d) do all of the above.

7. One of the age-specific goals for the school-aged group is to:

- a) facilitate bonding.
- b) satisfy practical needs.
- c) encourage commitment to task and contribution.
- d) assess limiting physical conditions.

8. Infant cardiac arrest can result from removal of:

- a) 10 percent of infant's blood volume over an extended period of time.
- b) small amounts of blood over an extended period of time.
- c) 10 percent of infant's blood volume at one time.
- d) 2 percent of infant's blood volume at one time.

9. When performing venipuncture on the pre-school patient, the phlebotomist should:

- a) say nothing.
- b) say, "it will not hurt."
- c) not say, "it will not hurt."
- d) say none of the above.

10. The experienced phlebotomist must demonstrate an understanding of the importance of peer relationships when performing phlebotomy procedures with patients in the:

- a) elderly age group.
- b) adolescent age group.
- c) adult age group.
- d) pre-school age group.

11. Some of the typical conditions that commonly affect the adult age group are:

- a) diminished hearing.
- b) loss of skin elasticity.
- c) stress and depression.
- d) embarrassment.

12. One of the conditions of advanced aging that can make it difficult for the elderly patient to hold his/her arm steady during the venipuncture procedure is:

- a) skin layer thinning.
- b) loss of visual acuity.
- c) tremor.
- d) poor nutrition.

13. Which of the following is considered one of the basic characteristics of the pre-school aged patient?

- a) feeding
- b) privacy
- c) imagination
- d) generativity

14. Which of the following should be specifically addressed in probationary and annual competencies?

- a) eye contact
- b) tone of voice
- c) active listening skills
- d) all of the above

15. Age, growth and development and safety considerations must be assessed and incorporated into phlebotomy practices for:

- a) increased facility profit.
- b) addressing practical patient needs only.
- c) successful outcomes with all patient age groups.
- d) enhanced interdepartmental communications.

16. In the case study, which of the following is a method that the phlebotomist used to build trust?

- a) taking the time to explain the procedure
- b) asking the parents if the patient had a blood test performed before
- c) explaining the venipuncture procedure
- d) all of the above

17. The phlebotomist in the case study demonstrated professional and timely assessment skills by:

- a) explaining the procedure to the parents before beginning the procedure.
- b) communicating her years of experience before beginning the procedure.
- c) addressing the father's anxiety before beginning the procedure.
- d) assembling the phlebotomy equipment before beginning the procedure.

18. By thoroughly answering the parent's questions and communicating her length of experience, the phlebotomist in the case study demonstrated:

- a) compassion.
- b) proper immobilization technique.
- c) satisfaction of practical needs.
- d) confidence.

19. By explaining why the child was too old to have the specimen collected by skin puncture, the phlebotomist in the case study illustrated:

- a) age appropriate terminology.
- b) non-threatening tone of voice.
- c) knowledge of growth and development.
- d) respect for patient privacy.

20. In the case study, which of the following demonstrates that the phlebotomist addressed the personal needs of the patient and his parents?

- a) explaining the procedure with compassion
- b) reassuring the parents
- c) addressing the father's anxiety
- d) all of the above

http://www.advanceformlp.com/common/editorialsearch/viewer.aspx?FN=03mar10_mtplsanswers.html&AD=3/10/2003&FP=mt

4.11 Hand Venipuncture

It is acceptable to use dorsal hand veins as the venipuncture site. This site should be used only if the antecubital veins are unsuitable, such as when the antecubital area is edematous, burned or scarred areas, there are casts on both arms, or the veins are thrombosed.

- Select a vein that is palpable, lightly brushing a finger across the back of the hand as it is palpated. This helps select the best vein and determines its direction. Palpate even when the vein is visible.
- Use a 21g or 23g butterfly blood collection set depending on the condition of the SP's veins.
- Follow the venipuncture technique described in Section 4.9.3 to draw the blood.

4.12 Recording the Results of the Venipuncture Procedure

The Venipuncture screen displays the tube protocol for the SP.

The screenshot displays the Phlebotomy software interface. The main window title is "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". The patient information is: SP ID: 200594, Name: DOE, JANE, Age: 51 years, Gender: Female, Date: 10/12/2004, Time: 08:55 AM. The section is titled "Venipuncture". The tube protocol is as follows:

| Tube Type | Quantity | Total |
|---------------|----------|-------|
| 3 ml lavender | 0 | of 1 |
| 4 ml lavender | 0 | of 2 |
| 2 ml gray | 0 | of 1 |
| 15 ml red | 0 | of 4 |
| 10 ml red | 0 | of 2 |

There is a checkbox labeled "Obtained all" with the value "200594" next to it. Below the tube list is a "Comment:" field with a dropdown arrow. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom shows: Ready, MEC Layer: 10/7/2004, Application: Ver 12.10.7B, Connected to Coordinator, SP assigned to room, 09:05 AM. The taskbar shows the Start button, Phlebotomy application, and GTT Subsystem.

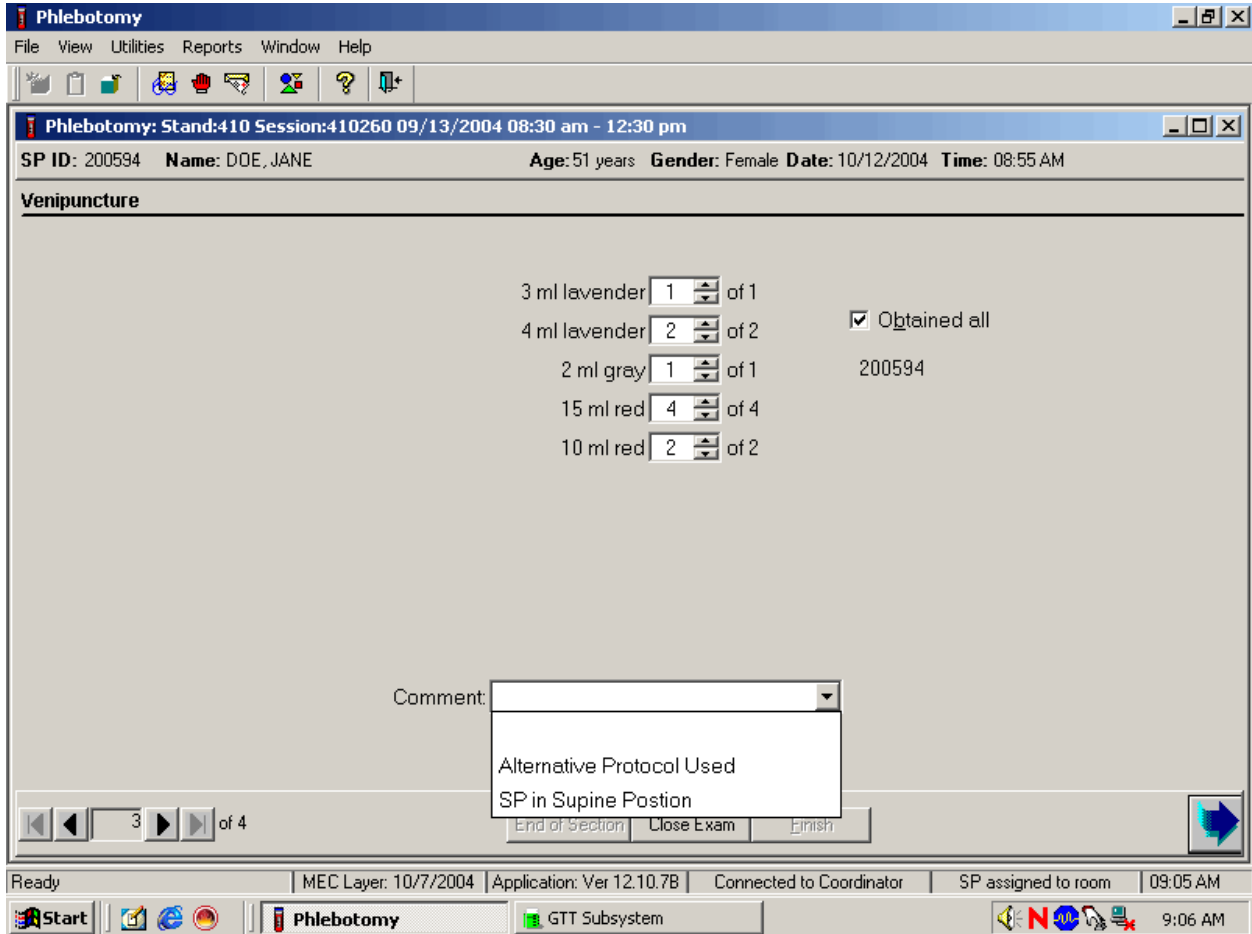
Each SP's profile is dependent on his or her age, appointment type, selection for inclusion into randomly-selected subsamples, and the session time.

Immediately after completing the venipuncture, enter the results of the blood draw, the reasons for a tube not being drawn according to the protocol, and any comments about the venipuncture.

The screenshot shows the Phlebotomy software interface. The title bar reads "Phlebotomy". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and help. The main window title is "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". Below this, patient information is displayed: "SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM". The section is titled "Venipuncture". It lists five tubes with spinners for quantity: "3 ml lavender 1 of 1", "4 ml lavender 2 of 2", "2 ml gray 1 of 1", "15 ml red 4 of 4", and "10 ml red 2 of 2". To the right of these is a checked checkbox labeled "Obtained all" and the SP ID "200594". Below the tube list is a "Comment:" label followed by a text input field. At the bottom of the window are navigation buttons: "End of Section", "Close Exam", "Einish", and a blue arrow button. The status bar at the very bottom shows "Ready", "MEC Layer: 10/7/2004", "Application: Ver 12.10.7B", "Connected to Coordinator", "SP assigned to room", and "09:05 AM". The Windows taskbar at the bottom shows the Start button, several icons, and the taskbar with "Phlebotomy" and "GTT Subsystem" open, along with the system clock showing "9:05 AM".

To record all tubes as filled or obtained, use the mouse to direct the mouse arrow to the “Obtained all” check box and left click, or type [Alt] [B/b]. This records a check mark in the box and marks all tubes as obtained. To mark individual tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number of each tube up or down or type the correct number using the numeric keys.

Document circumstances where the alternative protocol was used or the SP was in the supine position.



To record either “Alternative Protocol Used” or “SP in Supine Position” comments in the Comment text box, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, type [A/a] for “Alternative Protocol Used” or [S/s] for “SP in Supine Position” and [Enter], or use the up and down arrows to toggle between the two choices and [Tab.]

To progress to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

4.13 Venipuncture Status

Verify the venipuncture status.

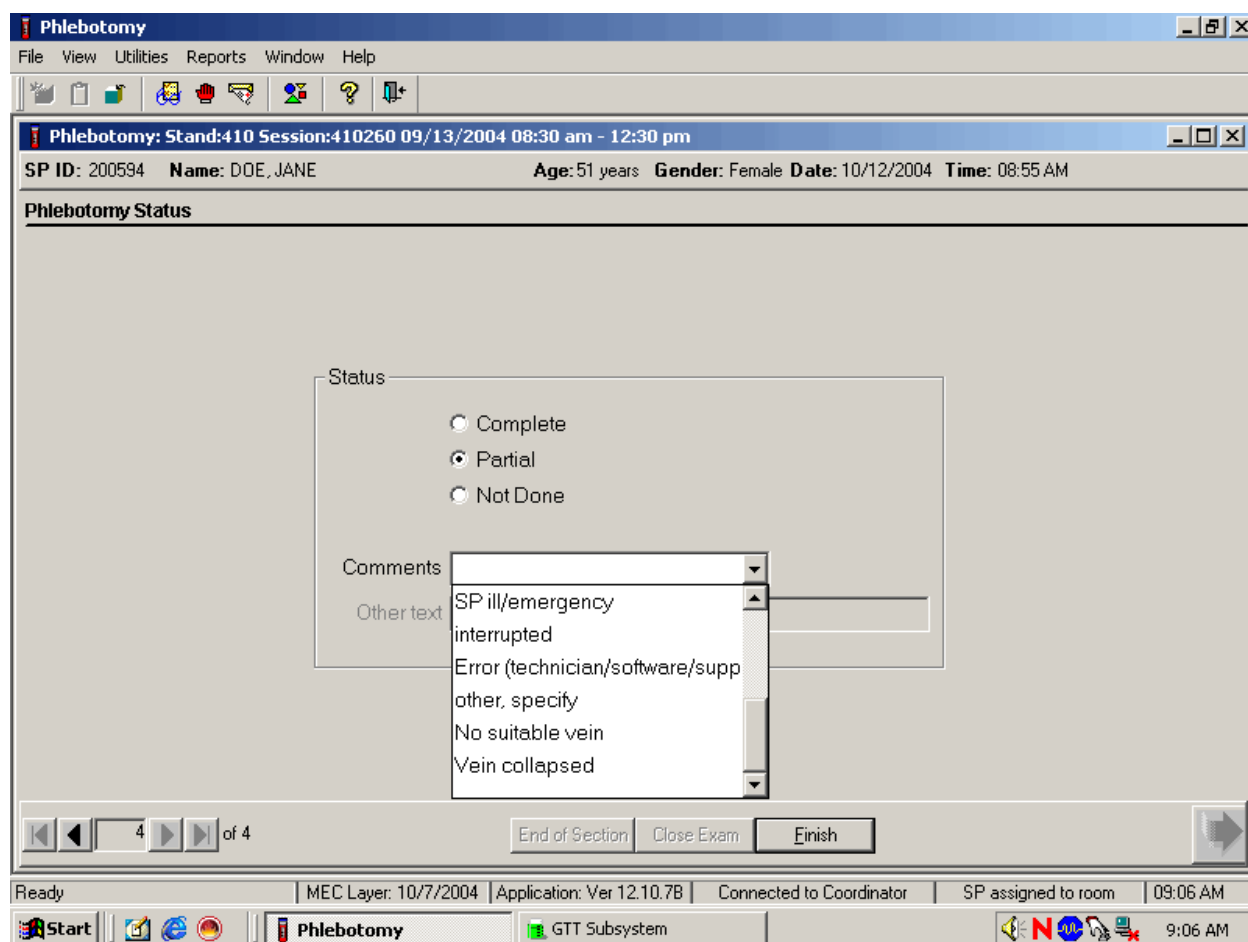
The screenshot displays the Phlebotomy software interface. The main window title is "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". Below the title bar, the patient information is displayed: "SP ID: 200594 Name: DOE, JANE Age: 51 years Gender: Female Date: 10/12/2004 Time: 08:55 AM". The main content area is titled "Phlebotomy Status" and contains a form with the following elements:

- Status:** A group box containing three radio buttons: Complete, Partial, and Not Done.
- Comments:** A text input field with a dropdown arrow on the right.
- Other text:** A larger text input field below the comments field.

At the bottom of the main window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom of the screen shows "Ready", "MEC Layer: 10/7/2004", "Application: Ver 12.10.7B", "Connected to Coordinator", "SP assigned to room", and "09:05 AM". The Windows taskbar at the very bottom shows the Start button, several application icons, and the system tray with the time "9:06 AM".

The venipuncture status is complete if all tubes were collected.

Comment codes are used to explain Partial and Not Done status codes.

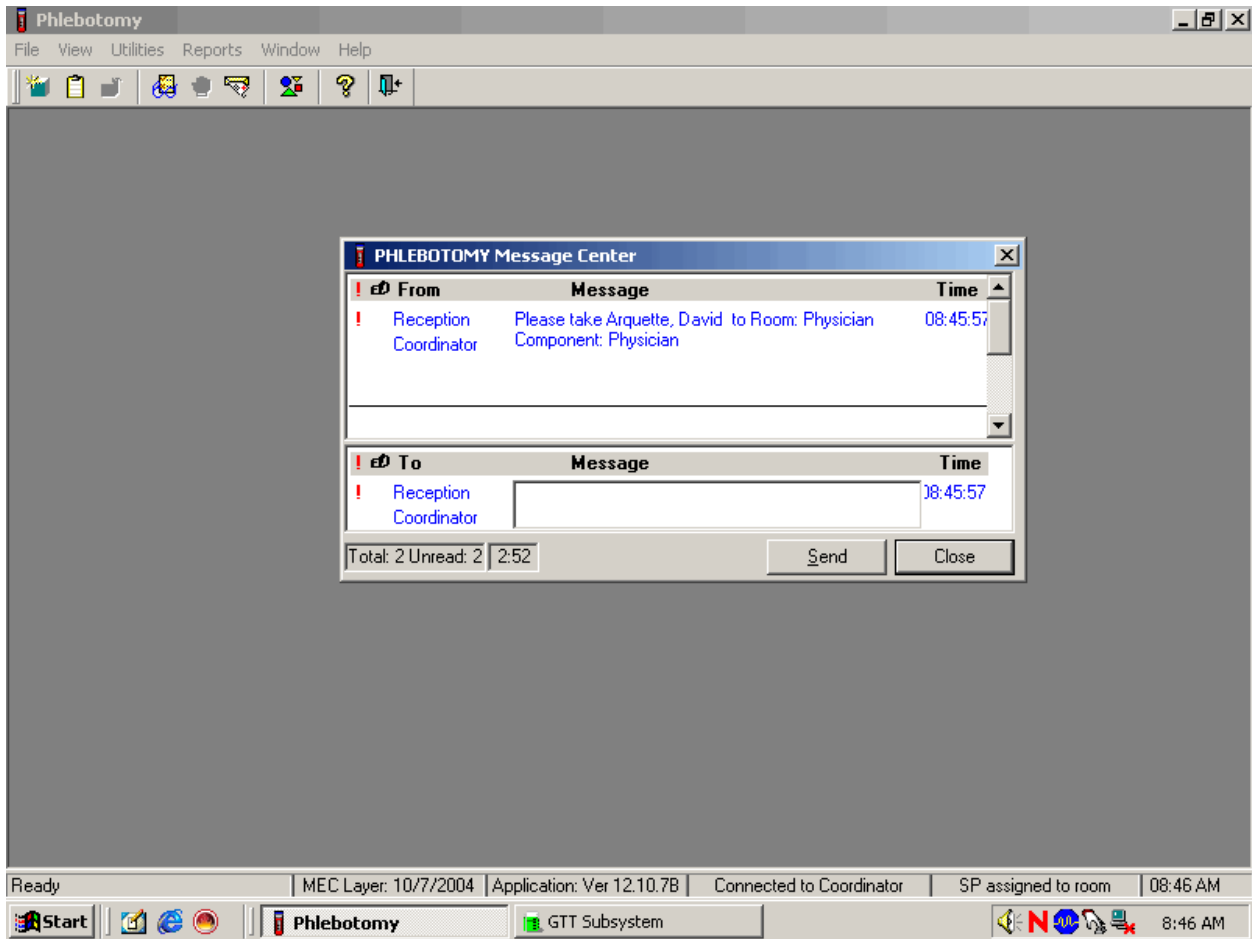


Choose and enter the appropriate comment code when the venipuncture section status is Partial or Not Done. To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

| Comment Code | Use when: |
|------------------------------------|--|
| safety exclusion | Not applicable This is reserved for positive responses to the hemophilia and chemotherapy exclusion questions and it is automatically coded by the application. The coordinator may code exams using this comment. |
| SP refusal | The SP refuses to have his/her blood collected. This is an SP-initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam. Use this comment to code partial exams when the SP refuses after one tube has been drawn, or the blood flow stops after one tube but before all tubes have been successfully drawn. |
| no time | Not applicable. |
| physical limitation | Not applicable. |
| communication problem | Not applicable. |
| equipment failure | Not applicable. |
| SP ill/emergency | Use this comment to code not done or partial when the SP faints or is about to faint or the SP became ill or an emergency occurred and the test could not be performed on the SP. |
| Interrupted | Not applicable. |
| error (technician/software/supply) | Use this comment to code partial and not done exams when there are phlebotomist errors, or software or supply issues. |
| other, specify | If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field. |
| No suitable vein | Use this comment to code exams as not done (no tubes drawn) when the SP does not have an accessible vein, any arms available, casts on both arms, there is a rash over the entire area, or the blood draw was started but there was no blood in the tubing. |
| Vein collapsed | Use this comment to code exams as partial when one or more tubes are successfully drawn but blood flow stops before all tubes are drawn or when the vein collapses. |

When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click to exit or select [Enter] when this blue arrow is highlighted.

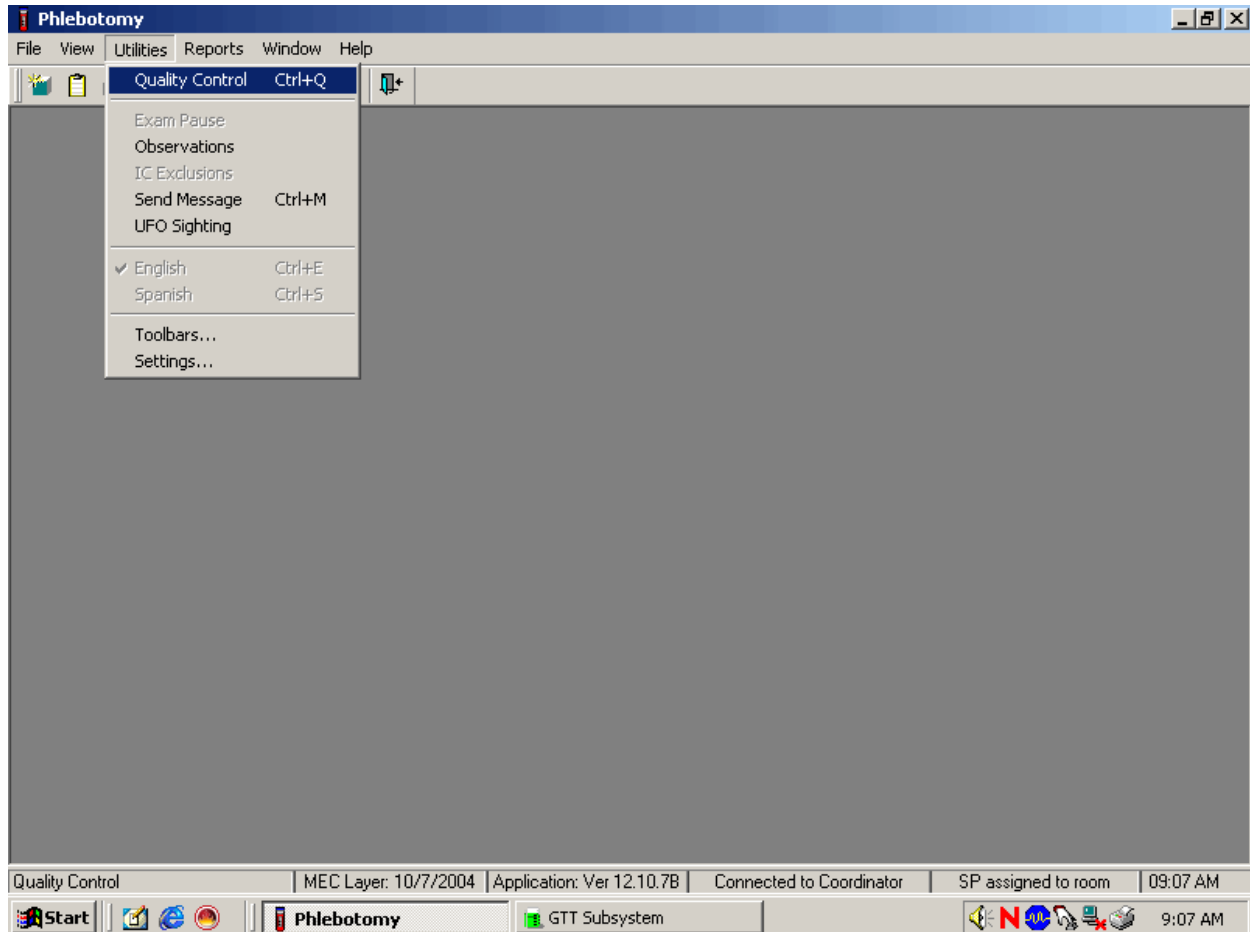
Escort the SP to the location indicated in the Message Center text box.



Review the instructions in the Message Center text box and follow the directions.

4.14 Phlebotomy Quality Control

Perform phlebotomy quality control at the end of each session even if there are no SPs scheduled into the session. Record the room temperature reading and the action that the counters were disinfected using the End of Session tab. Record the supply lot numbers and expiration dates by using the Supply Use tab.



To access the phlebotomy Quality Control module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Quality Control} and left click, or select [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

4.14.1 End of Session QC

Record the End of Session quality control activities. Mark each Done check box with a check mark.

| QC Check | Done | Result | Comment |
|--------------------|--------------------------|-------------|---------|
| Room Temp. Reading | <input type="checkbox"/> | 17°C - 25°C | |
| Disinfect Counters | <input type="checkbox"/> | | |

To record a check mark in the Room Temp. Reading check box, use the mouse to direct the mouse arrow to the check box in the Done column and left click, then select [Tab] to move to the Result text box. Enter the temperature in the Result text box and select [Tab] to move to the Comment text box. If the reading is outside the established range (17-25°C), document the actions taken to resolve the situation in the Comment text box. Select [Tab] to move to the next QC item.

Continue entering the QC.

| QC Check | Done | Result | Comment |
|--------------------|-------------------------------------|-------------------|--|
| Room Temp. Reading | <input checked="" type="checkbox"/> | 26 17°C - 25°C | Notified chief lab tech and MEC manager. |
| Disinfect Counters | <input checked="" type="checkbox"/> | | |

To record a check mark in the Disinfect Counters check box, use the mouse to direct the mouse arrow to the check box and left click, then select [Tab] to move to the Result box. Type “Yes” or “Not Done” in the Disinfect Counters Comment text box and then [Tab] to add free form text explaining why the counters were not disinfected for any “Not done” response.

4.14.2 Supply Use Control Log

Many items have specific lot numbers and expiration dates. Enter the lot numbers and expiration dates in the Supply Use module. This module lists every inventory item associated with the phlebotomy component that includes a lot number and expiration date.

| <i>Item</i> | <i>Lot Number</i> | <i>Expiration Date</i> |
|------------------------------------|-------------------|------------------------|
| Butterfly Needle 19G Saf-T EZ Set | Yes | Yes |
| Luer Adapter | Yes | No |
| Vacutainer 21G Multi Sample Needle | Yes | No |
| Push Button 21G Needle | Yes | Yes |
| Push Button 23G Needle | Yes | Yes |
| Band-Aid Liquid Bandage | Yes | Yes |
| BD Vacutainer 3-mL EDTA Blood Tube | Yes | Yes |
| BD Vacutainer 4-mL EDTA Blood Tube | Yes | Yes |
| BD Vacutainer 2-mL Gray Blood Tube | Yes | Yes |
| BD Vacutainer 3-mL Red Blood Tube | Yes | Yes |
| BD Vacutainer 7-mL Red Blood Tube | Yes | Yes |
| BD Vacutainer 10-mL Red Blood Tube | Yes | Yes |
| BD Vacutainer 15-mL Red Blood Tube | Yes | Yes |
| VOC 10-mL Vacutainer Blood Tube | Yes | Yes |
| Trutol Glucose Drink - Cola | Yes | Yes |
| Trutol Glucose Drink - Lemon/Lime | Yes | Yes |
| Trutol Glucose Drink - Orange | Yes | Yes |
| Apple Juice | No | Yes |
| Orange Juice | No | Yes |
| Peanut Butter Crackers | No | Yes |
| Solar Thermometer | No | Yes |

Use the Supply Use tab to enter lot numbers and expiration dates.

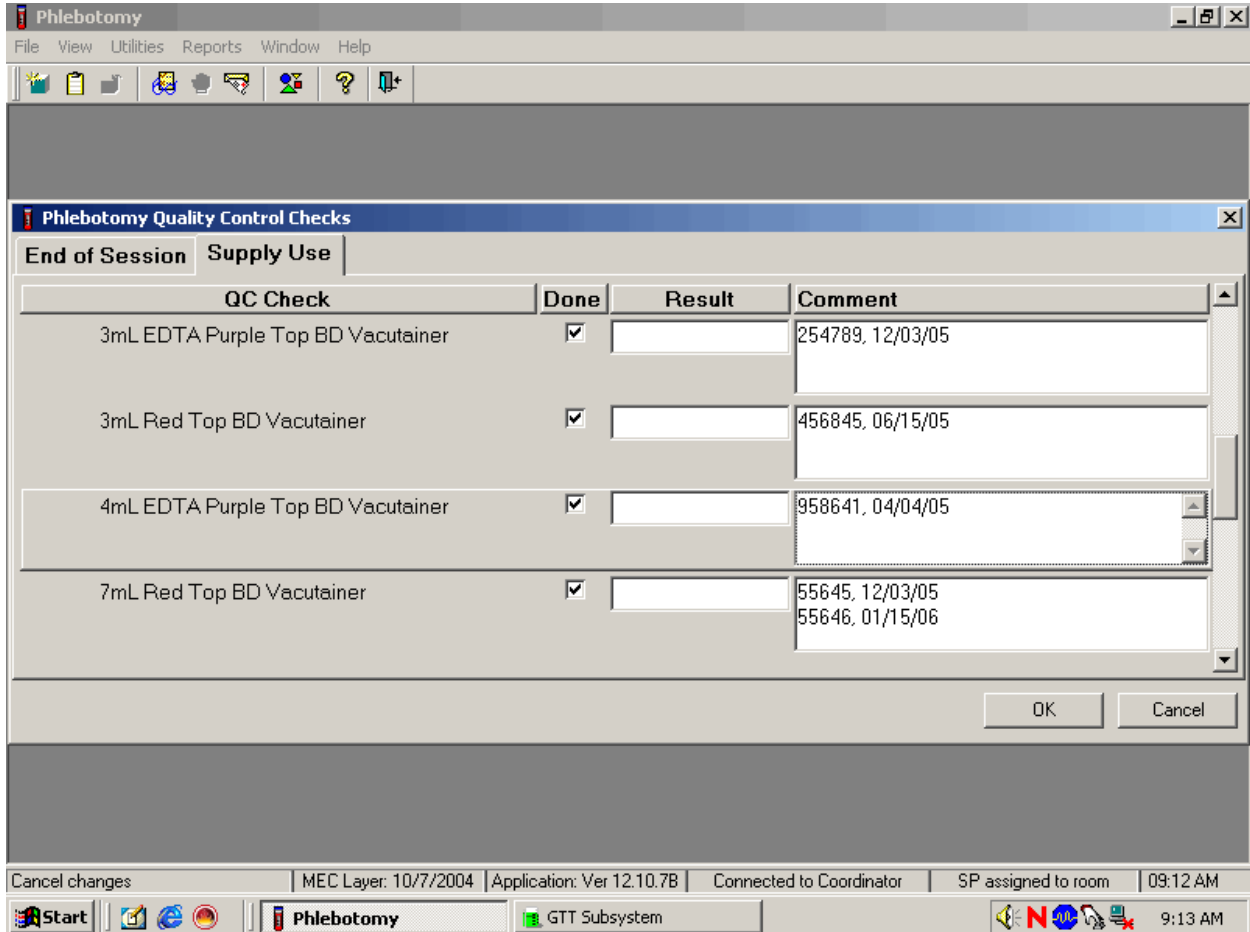
The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. A sub-dialog box titled "Phlebotomy Quality Control Checks" is open, with two tabs: "End of Session" and "Supply Use". The "Supply Use" tab is active and contains a table with the following columns: "QC Check", "Done", "Result", and "Comment".

| QC Check | Done | Result | Comment |
|----------------------------|--------------------------|--------|---------|
| 7mL Red Top BD Vacutainer | <input type="checkbox"/> | | |
| 10mL Red Top BD Vacutainer | <input type="checkbox"/> | | |
| 15mL Red Top BD Vacutainer | <input type="checkbox"/> | | |
| 19 G BD Needle | <input type="checkbox"/> | | |

At the bottom right of the dialog box are "OK" and "Cancel" buttons. The status bar at the bottom of the window displays: "Cancel changes", "MEC Layer: 10/7/2004", "Application: Ver 12.10.7B", "Connected to Coordinator", "SP assigned to room", and "09:12 AM". The Windows taskbar at the very bottom shows the Start button, several icons, and the system tray with the time "9:12 AM".

Select the correct activity (Supply Use) by using the mouse to direct the mouse arrow to the correct heading on the top of the file and left click. **Mark each check box and record the lot and expiration date of each item. Perform this activity at the start of the stand and whenever a new lot is put into use.**

Mark activities as done and enter the lot number and expiration date in the Comment text box.



To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the “Done” column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box. Do not enter the response or reading in the Result text box. Select [Tab] or [Enter] to move to the Comment text box.

For each item:

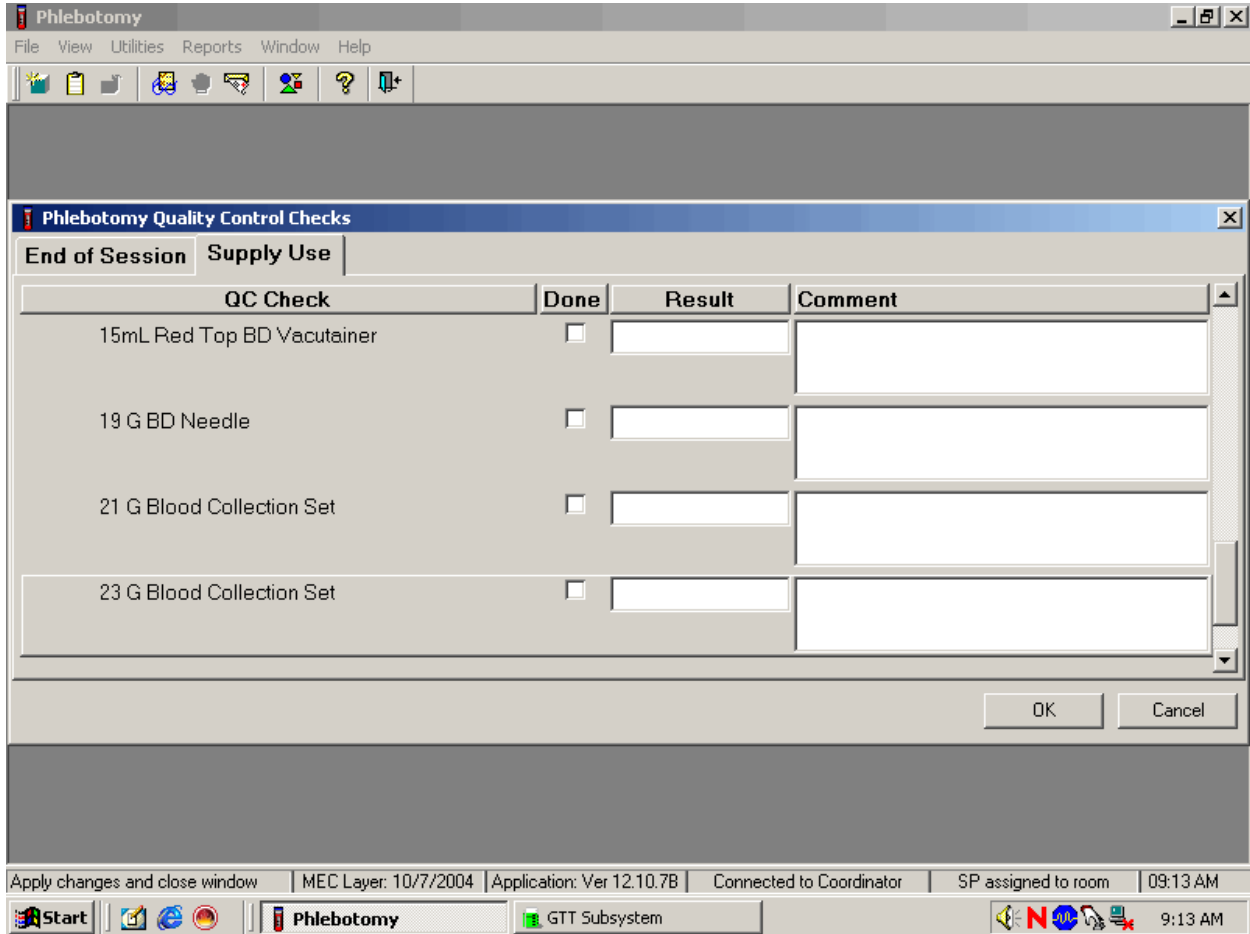
Record the lot number (if the item does not have a lot number, then record “no lot”);

Add a comma;

Add a space; and

Record the expiration date using the MM/DD/YY format.

There is no frequency requirement for this module within the QC application. Update the information each time a new lot is put into use.



To save these results in the database, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the QC module without saving these actions in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

4.15 Red Cross Procedures for Handling Fainting (Syncope)

“Fainting” is a partial or complete loss of consciousness. This is due to a reduced supply of blood to the brain for a short time. Occasionally, a person collapses without warning. Recovery of consciousness usually occurs when the victim falls. Injury may occur from the fall. To prevent a fainting

attack, a person who feels weak and dizzy should lie down or bend over with his or her head at the level of the knees.

- Signs and symptoms include:
 1. Extreme paleness
 2. Sweating
 3. Coldness of the skin
 4. Dizziness
 5. Numbness and tingling of the hands and feet
 6. Nausea
 7. Possible disturbance of vision

If at any time during the venipuncture procedure the SP exhibits any of the manifestations listed above, conclude the venipuncture immediately and perform the first aid procedures listed below.

- Place the SP in a supine position.
- Loosen any tight clothing and keep crowds away.

Provide a disposable airsickness bag if the SP vomits and roll him/her onto his/her side or turn his/her head to the side.

- Maintain an open airway.
- **Do not** pour water over the SP's face because of the danger of aspiration; instead, provide a cool wet cloth to the forehead.
- **Do not** give any liquid unless the SP has revived.
- Examine the SP to determine if he/she has suffered injury from falling.
- Seek medical assistance. Do not leave the SP. Call for assistance or use the intercom to speak to the coordinator. Observe the SP carefully afterward because fainting might be a brief episode in the development of a serious underlying illness.¹

¹ From *Standard First Aid and Personal Safety*, Second Edition, the American Red Cross, New York: Doubleday and Company, Inc., 1981, pp. 173-174.

4.16 How to Deal With System Failure

If the computer system fails, record results on a preprinted Phlebotomy Worksheet (Exhibits 4-6 and 4-7). Complete a Phlebotomy worksheet for each SP while conducting the exam. Enter the results after the system is operational.

Exhibit 4-6. Phlebotomy worksheet – English Primary
PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

PRIMARY SP

SP ID _____

| Phlebotomy Interview | Responses Yes, No, Refused, Don't Know | |
|---|--|-------------------------------------|
| Do you have hemophilia? | | |
| Have you received cancer chemotherapy in the past four weeks? | | |
| Fasting Questionnaire | Record time and date | |
| Q1. When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal] | | |
| Confirmation Question: Q2. Have you had any of the following since {insert time from Q1 here}? | Responses <u>Yes</u> , <u>No</u> | If Yes, record time and date |
| Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] | | |
| Alcohol, such as beer, wine, or liquor? | | |
| Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies? | | |
| Antacids, laxatives, or anti-diarrheals? | | |
| Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] | | |
| Primary SP Protocol | # Filled | Not Filled <input type="checkbox"/> |
| 3 mL lavender (1 age 1-2, 2 age 3-5) | | |
| 4 mL lavender (2 age 6-11, 3 age 12+) | | |
| 2 mL gray (morning only 1 age 12+) | | |
| 3 mL red (2 age 1-2) | | |
| 7 mL red (2 age 3-5, 1 age 6-11) | | |
| 15 mL red (4 age 12+) | | |
| 10 mL red (2 age 6-11, 2 age 12+) | | |
| 10 mL gray (1 age 12+ if eligible for VOC subsample) | | |
| Comments: | | |

Exhibit 4-7. Phlebotomy worksheet – Spanish Primary

PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

PRIMARY SP

SP ID _____

| Phlebotomy Interview | Responses Yes, No, Refused, Don't Know | |
|--|---|-------------------------------------|
| ¿Tiene hemofilia? | | |
| ¿Ha recibido algún tratamiento para el cáncer en las cuatro semanas pasadas?? | | |
| Fasting Questionnaire | Record time and date | |
| Q1. ¿Cuándo fue la última vez que comió o bebió algo que no haya sido agua sola? [No incluya soda de dieta, café sin azúcar ni leche o té con sacarina o “Equal”.] | | |
| Confirmation Question: Q2. ¿Ha tomado o comido algo de lo siguiente desde ayer a las {insert time from Q1 here}? | Responses Yes, No | If Yes, record time and date |
| ¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.] | | |
| ¿Alcohol, tal como cerveza, vino o licor? | | |
| ¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado? | | |
| ¿Antiácidos, laxantes, o antidiarréicos? | | |
| ¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.] | | |
| Primary SP Protocol | # Filled | Not Filled □ |
| 3 mL lavender (1 age 1-2, 2 age 3-5) | | |
| 4 mL lavender (2 age 6-11, 3 age 12+) | | |
| 2 mL gray (morning only 1 age 12+) | | |
| 3 mL red (2 age 1-2) | | |
| 7 mL red (2 age 3-5, 1 age 6-11) | | |
| 15 mL red (4 age 12+) | | |
| 10 mL red (2 age 6-11, 2 age 12+) | | |
| 10 mL gray (1 age 12+ if eligible for VOC subsample) | | |
| Comments: | | |

5. URINE SPECIMEN COLLECTION AND PROCESSING

5.1 Introduction

The purposes of urine collection and processing are to collect sufficient urine from primary SPs aged 6 years and older to be able to (1) perform a pregnancy test for selected females aged 8-11 years and all females aged 12 to 59 years; (2) allocate urine into (processing/storage) vessels for transport to various laboratories for analysis; and (3) process urine on SPs aged 18-49 years for HIV if the phlebotomist is not performing the blood draw or the quantity of serum is insufficient for serum HIV. Collect sufficient urine on VIP guest, guest, and surplus appointment types to be able to (1) perform a pregnancy test on all females aged 12 to 59 years and (2) allocate urine into (processing/storage) vessels for transport to various laboratories for analysis.

Collect a urine specimen from all SPs who are 6 years of age and older. The volume of urine required to complete each SP's protocol is displayed in the urine collection module. Document urine collection, perform pregnancy test if indicated, process urine, and store the vessels. At least 5-mL of urine is required on VIP guest, guest, and surplus appointment types. Document urine collection, perform pregnancy test if indicated, process urine, and store the vessels.

The MEC coordinator instructs each SP aged 6 years and older to provide a urine sample at the same time the SP changes clothes. If the SP cannot provide a urine sample at that time, the coordinator asks the SP to provide the sample as soon as possible. After collection, the coordinator or assistant coordinator transports the urine specimen to the laboratory.

The coordinator explains the following instructions to the subject before urine collection:

- Wash hands with soap and water;
- It is important that the cup and cap not touch or come into contact with any parts of the body, clothing, or external surfaces; and
- Close container to minimize exposure to air.

5.2 Supplies

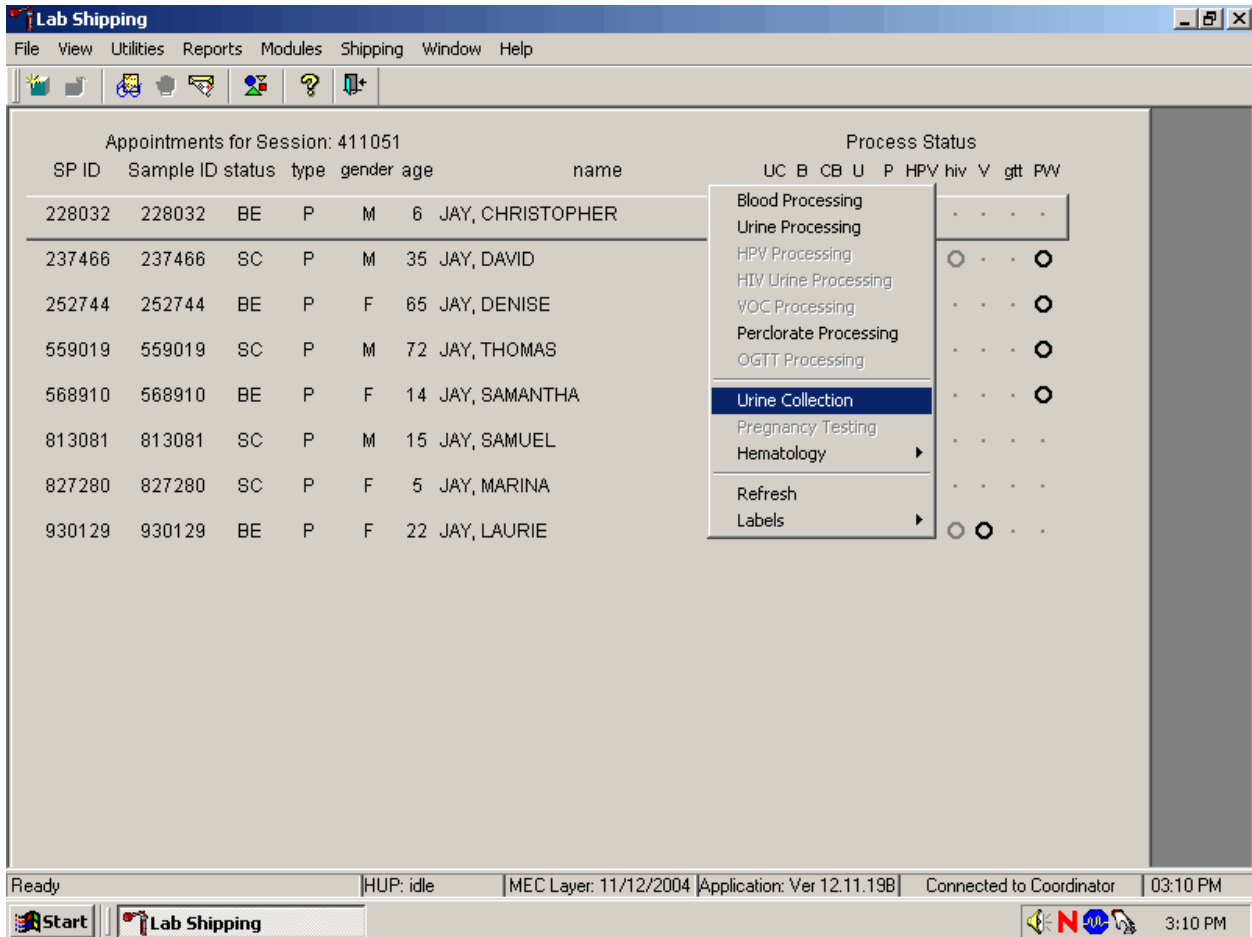
The supplies needed for urine collection and urine processing and storage are listed in Exhibit 5.1.

Exhibit 5-1. Equipment and supplies - urine processing and storage

| | |
|--|--|
| 5-mL cryovial sterile | 14-mL snap cap test tube |
| 14-mL snap cap vial with colored dot (Urn Merc) | Transfer pipette |
| Bench Kote paper | Kimwipes |
| Cube rack – 4 way flipper rack | Nonsterile, powder-free, gloves—small, medium, large |
| 5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid | 5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid |
| 5.25 x 5.25 x 3.0 inch cardboard box without grid | Three inch 5 x 5 cardboard grid |

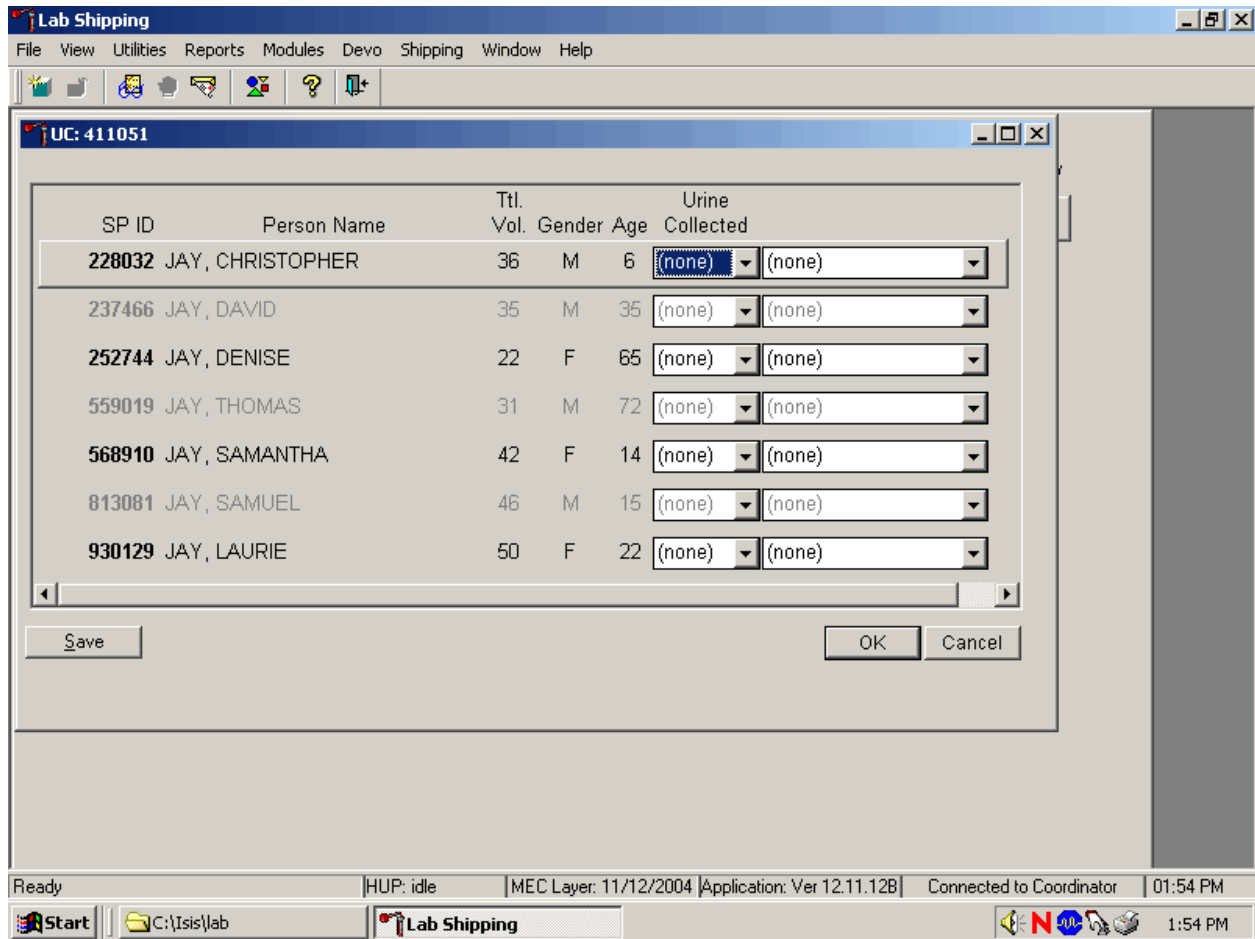
5.3 Document Urine Collection

Select the correct SP and access the Urine Collection module.



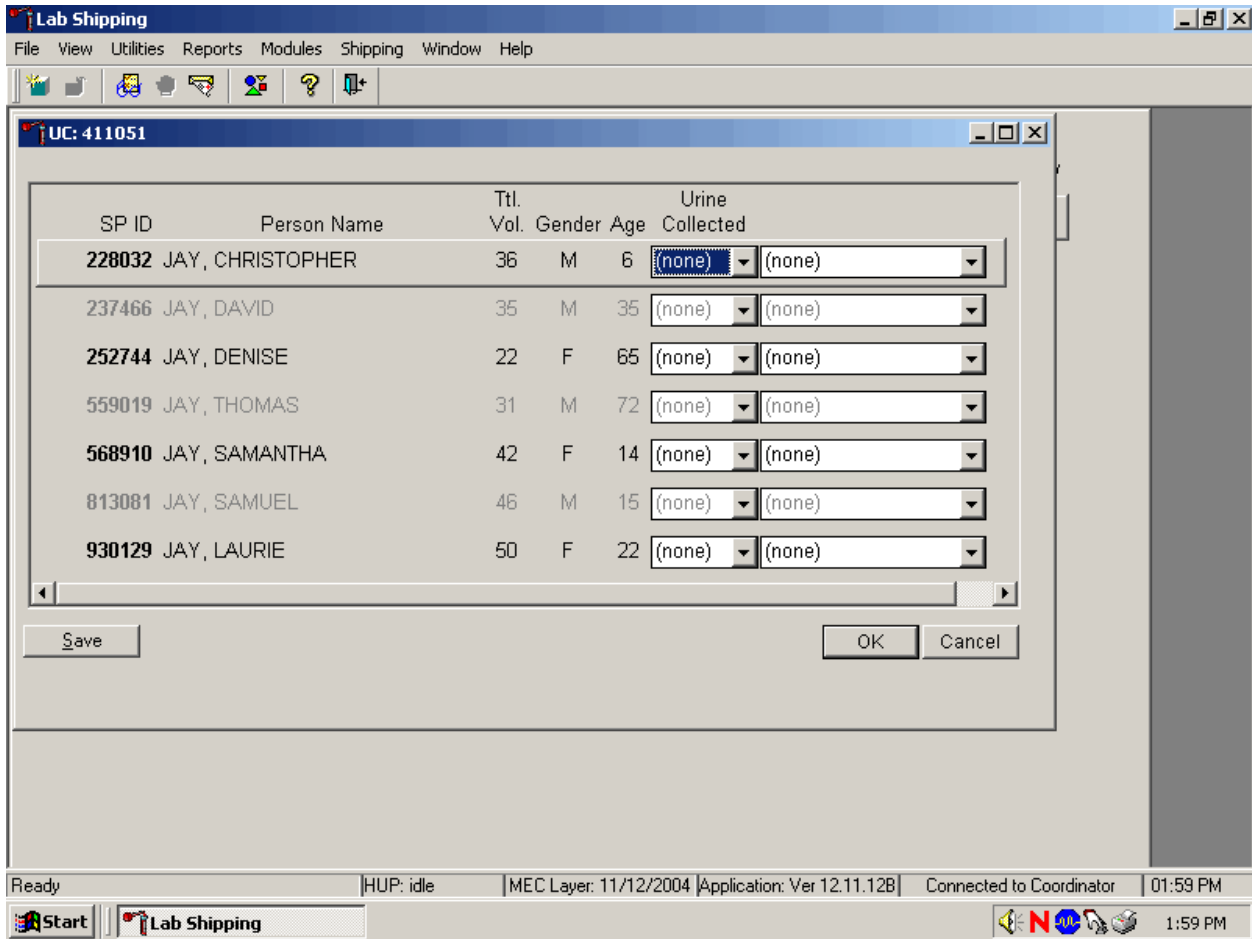
To select a SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the Urine Collection module, drag the mouse arrow to {Urine Collection} and left click or left click and type [C/c].

The urine collection window displays.



The urine collection window contains columns for the SP ID, Person Name (last, first), Ttl Vol (total volume required to complete the protocol), Gender, Age, and Urine Collection and Comment result fields. The total volume includes 1-mL for pregnancy testing.

This result field for checked-in SPs is indicated in black, while the result field for SPs who have not checked into the MEC session is gray. Use the scroll bar to view all SPs scheduled into the session.



Evaluate the sufficiency of the quantity of urine received in the laboratory. Compare the number displayed in the Ttl Vol column and the actual volume of urine (using the gradations on the urine collection cup).

Record the urine collection result for each SP.

The screenshot shows the 'Lab Shipping' application window. The title bar reads 'Lab Shipping'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. The main window displays a table with columns: 'SP ID', 'Person Name', 'Ttl. Vol.', 'Gender', 'Age', and 'Urine Collected'. The table contains seven rows of patient data. The row for SP ID 930129, JAY, LAURIE, is selected. A dropdown menu is open for the 'Urine Collected' column of this row, showing options: '(none)', 'No', 'Yes', and 'Yes/QNS'. Below the table are 'Save', 'OK', and 'Cancel' buttons. The status bar at the bottom shows 'Ready', 'HUP: idle', 'MEC Layer: 11/12/2004', 'Application: Ver 12.11.12B', 'Connected to Coordinator', and '01:59 PM'. The Windows taskbar at the very bottom shows the 'Start' button, the 'Lab Shipping' taskbar icon, and the system tray with the time '1:59 PM'.

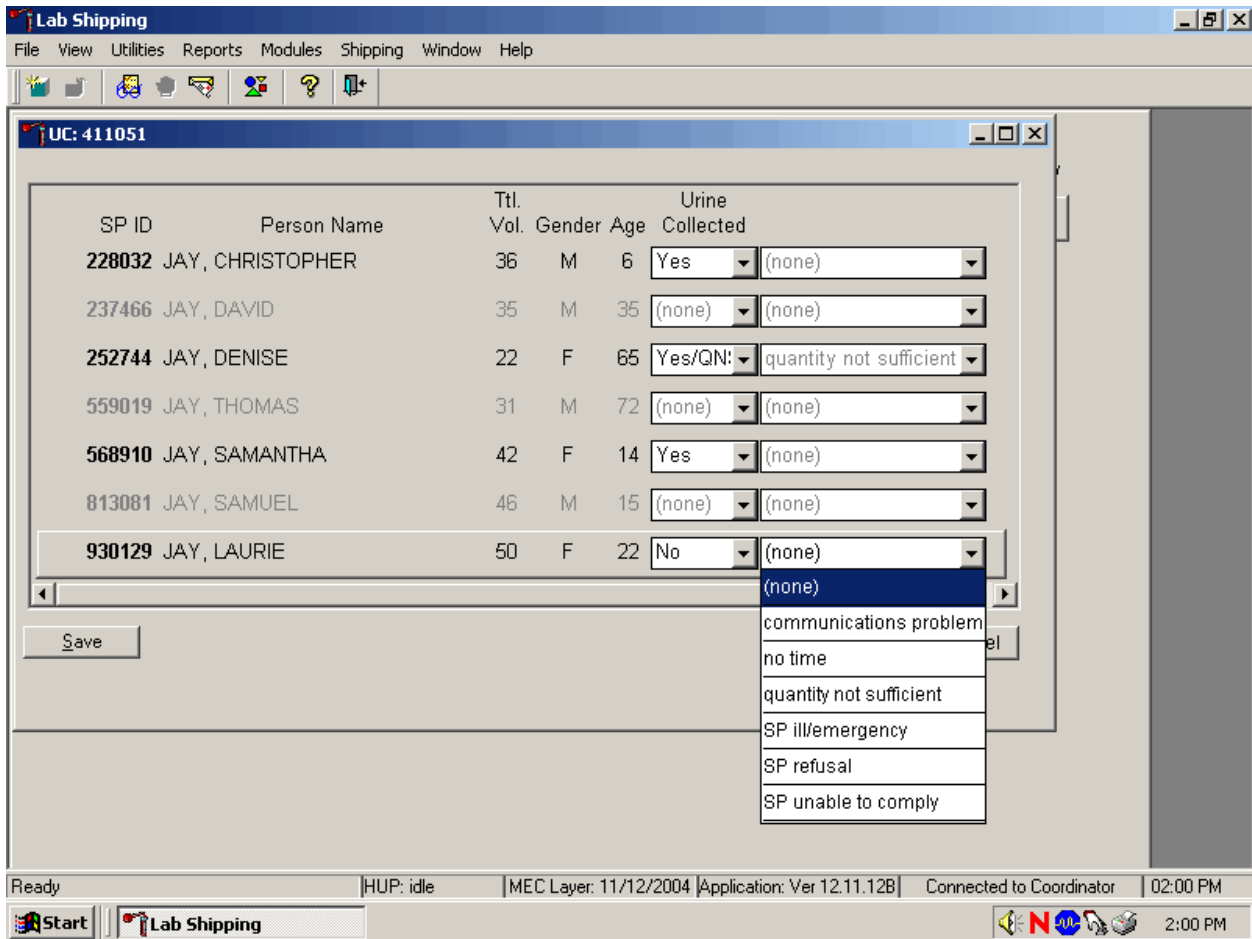
| SP ID | Person Name | Ttl. Vol. | Gender | Age | Urine Collected |
|--------|------------------|-----------|--------|-----|-----------------|
| 228032 | JAY, CHRISTOPHER | 36 | M | 6 | (none) |
| 237466 | JAY, DAVID | 35 | M | 35 | (none) |
| 252744 | JAY, DENISE | 22 | F | 65 | (none) |
| 559019 | JAY, THOMAS | 31 | M | 72 | (none) |
| 568910 | JAY, SAMANTHA | 42 | F | 14 | (none) |
| 813081 | JAY, SAMUEL | 46 | M | 15 | (none) |
| 930129 | JAY, LAURIE | 50 | F | 22 | (none) |

Record the urine collection result for each SP by typing [Y/y] for “Yes,” [N/n] for “No,” or [Y/y] a second time for “Yes/QNS.” Alternatively, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to “Yes,” “No,” or “Yes/QNS” and left click. A “Yes/QNS” result automatically notifies the coordinator, who then asks the SP to provide an additional urine specimen.

Refrigerate all insufficient urine samples. When additional urine is obtained, pool the urine, mix, and process.

Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each SP. Enter “No” in the result field for all SPs who have not produced a urine sample. Record a result other than “(none)” for all SPs.

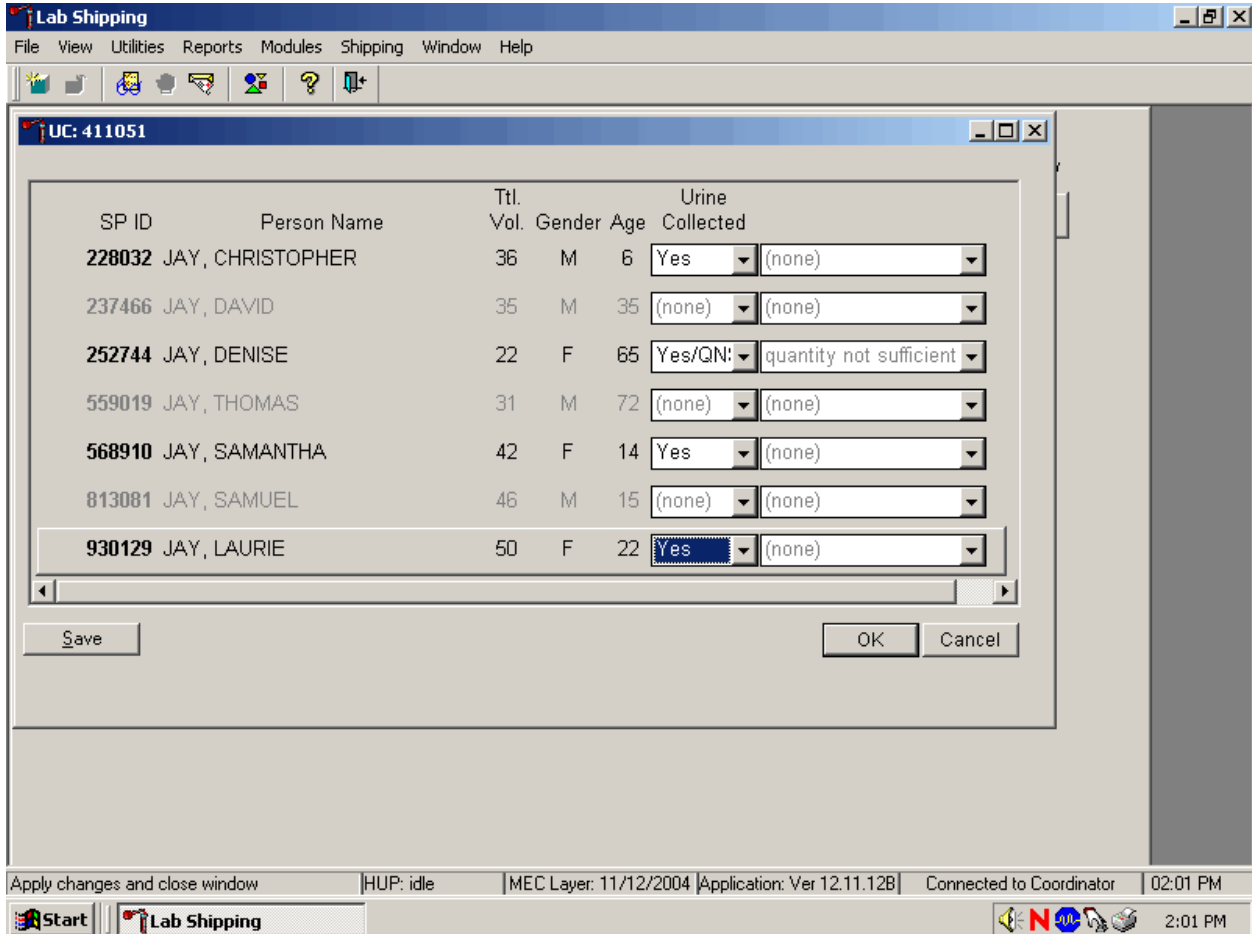
Record a comment for all insufficient urine collections.




To record a comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, and select the most appropriate choice. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code and when the correct choice is highlighted, left click.

| Comment Code | Use when: |
|-------------------------|--|
| communication problem | SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test |
| no time | Not applicable |
| quantity not sufficient | The quantity of urine is insufficient to process any or all urine vessel(s) |
| SP ill/emergency | Not applicable |
| SP refusal | SP refuses to provide urine during the session |
| SP unable to comply | SP has a physical limitation that prohibits them from producing a urine specimen or the SP is unable to produce urine during the session |

Continue recording and updating urine collection results as specimens are delivered to the laboratory.



Make sure to use the scroll bar to view all SPs. Save each result after entering it in the Urine Collected result field. To save a result to the database without exiting the module or removing the window, use the mouse to direct the arrow to the Save button and left click or press [Enter] when it is highlighted. To save a result to the database and exit the module and to remove the window, use the mouse to direct the mouse arrow to the OK button and left click. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to Cancel button and left click. To exit the module or close the window after saving results to the database and without recording any further actions, use the mouse to direct the mouse arrow to the  Close Window button and left click.

5.4 Urine Specimen Assays

Process urine specimens for the following tests:

- Pregnancy test for selected females aged 8-11 and all females aged 12 to 59 years
- Albumin/Creatinine (Alb/Creat) on primary SPs and VIP Guests aged 6+ years old
- Chlamydia/Gonorrhea (Chlam/GC) on primary SPs 14-39 years old
- Urinary Iodine (Urn Iodine) on selected SPs 6+ years old
- Speciated Arsenic (Spc Arsenic) on selected SPs 6+ years old
- Priority Pesticides (Prior Pest) on selected SPs 6+ years old
- Organophosphates (Organophos) on selected SPs 6+ years old
- Urine Mercury (Urn Merc) on selected SPs 6+ years old
- Heavy Metal on selected SPs aged 6+ years old
- Phytoestrogens (Urn Phytoes) on selected SPs aged 6+ years old
- Polyaromatic Hydrocarbons (PAH) on selected SPs aged 6+ years old
- Phthalates on selected SPs aged 6+ years old
- Perchlorate on SPs aged 6+ years old
- Extra urine (Xtra Urine) on SPs aged 6+ years old
- HIV Urine for SPs 18-49 years old if no blood is collected or the quantity of serum is insufficient for serum HIV and the SP has not refused HIV

5.5 Urine Specimen Protocols

Table 5-1 summarizes the urine processing protocol for primary SPs. Process urine in priority order with vessel 45 filled first, 46 second, etc.

Table 5-1. NHANES urine processing protocol – primary

| Vessel No | Assay | Age in years | Sample size mL | Vessel |
|-----------|-------------|--------------|----------------|--------------------------------------|
| 45 | Alb/Creat | 6+ | 3 | 5-mL Cryovial |
| 46 | Chlam/GC | 14-39 | 10 | 14 mL snap cap tube |
| 69 | Urn Iodine | 6+ | 3 | 5-mL Cryovial |
| 86 | Spc Arsenic | 6+ | 3 | 5-mL Cryovial |
| 48 | Prior Pest | 6+ | 10 | 14 mL snap cap tube |
| 49 | Organophos | 6+ | 10 | 14-mL snap cap tube |
| 62 | Urn Merc | 6+ | 5 | 14-mL snap cap tube with colored dot |
| 50 | Heavy Metal | 6+ | 10 | 14-mL snap cap tube |
| 65 | Urn Phytoes | 6+ | 3 | 5-mL Cryovial |
| 66 | PAH | 6+ | 3 | 5-mL Cryovial |
| 67 | Phthalates | 6+ | 3 | 5-mL Cryovial |
| 102 | Perchlorate | 6+ | 5 | 5-mL Cryovial |
| 52 | Xtra Urine | 6+ | 5 | 5-mL Cryovial |
| 53 | HIV | 18-49 | 3 | 5-mL Cryovial |

Table 5-2 summarizes the urine processing protocol for the VIP guest appointment type.

Table 5-2. NHANES urine processing protocol – VIP guest

| Vessel No | Assay | Age in years | Sample size mL | Vessel |
|-----------|-----------|--------------|----------------|---------------|
| 45 | Alb/Creat | 6+ | 3 | 5-mL Cryovial |

5.6 Labeling Urine Processing Vessels

The appropriate bar code labels automatically print for each SP based on the SP's age, sex, appointment type, and subsample selection. The label/ship technologist at workstation 3 prints the labels at least one session in advance. The printing procedure is described in Chapter 9. Place labels at workstation 2.

Process urine on one SP at a time. Set up each urine processing rack using the preprinted labels. Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally making sure the label wraps onto itself. Place the

label so the first digit of the vessel number is at the top of the vessel. Set the vessels in the cube racks in priority order.

One hour into the session, if an SP has not checked in, separate the labels for SPs who have checked in from SPs who have not checked in. Set the labels aside for SPs who have not checked in. If the SP does not show up for the session, then discard the labels at the end of the session.

5.7 Urine Specimen Processing

- Perform pregnancy test and record results before aliquoting the urine specimen.
- Label all urine aliquot vessels for the SP and place in priority order in the rack.

Allocate the urine sample for each of these tests using the following procedure:

45. Pour 3-mL of the specimen for Alb/Creat into a 5-mL vessel.
46. Pour 10-mL of the specimen for Chlam/GC into 14-mL vessel.
69. Pour 3-mL of the specimen for Urn Iodine into a 5-mL vessel.
86. Pour 3-mL of the specimen for Spc Arsenic into a 5-mL vessel.
48. Pour 10-mL of specimen for Prior Pest into 14-mL vessel.
49. Pour 10-mL of specimen for Organophos into 14-mL vessel.
62. Keep vessel 62 upright at all times; do not invert the tube because the preservative could drain into the caps and spill when opened. If the vessel does become inverted, stand it upright for at least several hours or overnight, then open the cap, and pipette the urine into the 14-mL vessel. Tap the bottom of the capped vessel against a hard surface before opening. Use a plastic transfer pipette to transfer exactly 5-mL of urine into the 14-mL snap cap vessel, snap the cap closed, and mix gently. Do not discard the prepared tubes even if the preservative crystallizes. If the preservative crystallizes, add 5-ml of urine with the transfer pipette and mix extremely well. Do not use these tubes for any other purpose since they contain a preservative.
50. Pour 10-mL of the specimen for Heavy Metal into a 14-mL vessel.
65. Pour 3-mL of the specimen for Urn Phytoes into a 5-mL vessel.
66. Pour 3-mL of the specimen for PAH into a 5-mL vessel.

67. Pour 3-mL of the specimen for Phthalates into a 5-mL vessel.
102. Pour 5-mL of the specimen for Perchlorate into a 5-mL vessel.
52. Pour 5-mL of the specimen for Xtra Urine into second 5-mL vessel.
53. Pour 3-mL of specimen for HIV Urine into 5-mL vessel (give this tube to the blood processing technologist).

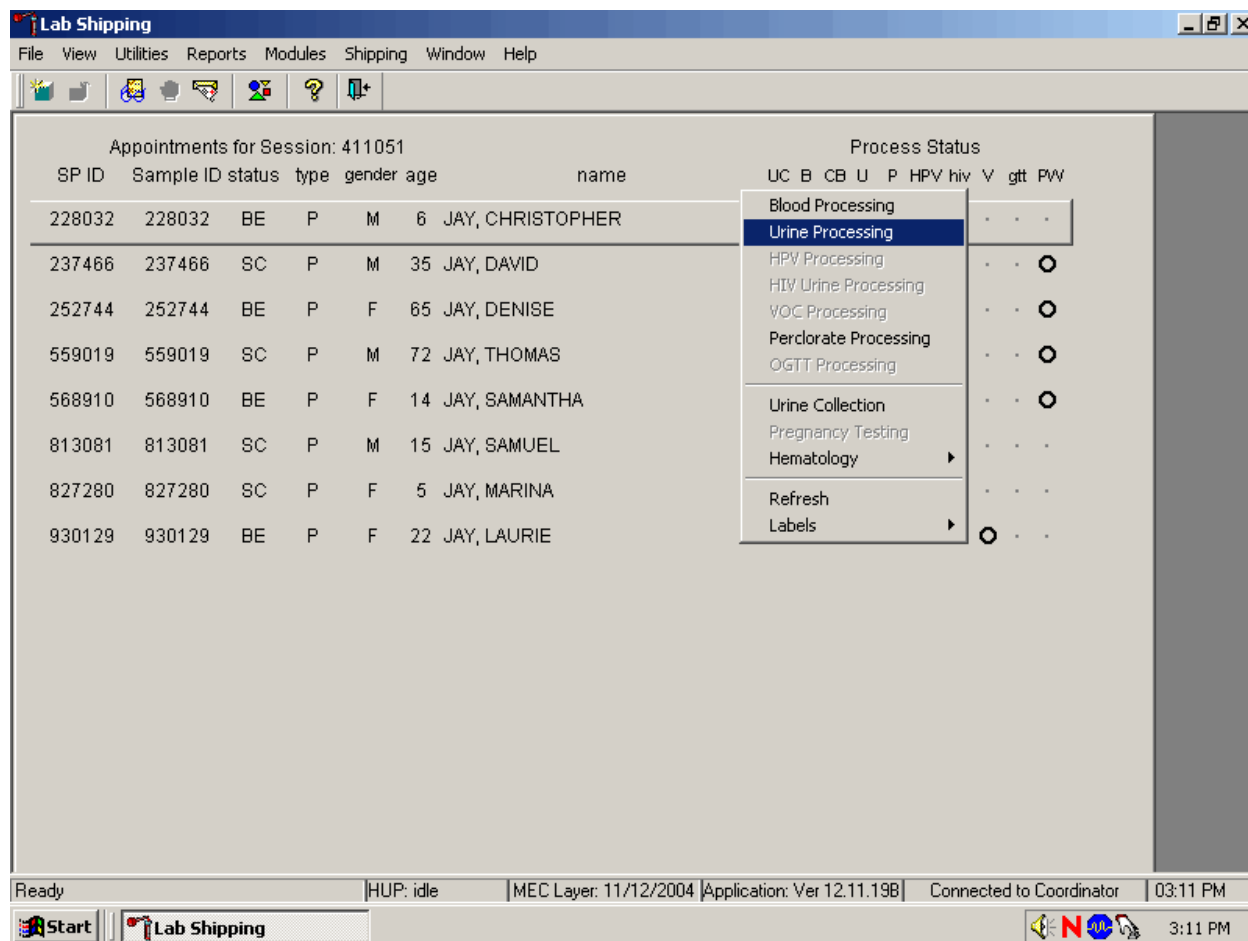
Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink that is connected to the sewer. Flush the sink with water. Discard urine cup in the biohazard trash.

Do not process urine on more than one SP at a time.

5.8 Record the Results of Urine Specimen Processing

After filling the urine specimen vessels for each SP, use the Urine Processing module to enter the results of urine processing.

Access the Urine Processing module.



To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Urine Processing} and right click or right click and type [U/u]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Urine Processing} and right click or right click and type [U/u].

The SP's urine processing window displays.

Lab Shipping
 File View Utilities Reports Modules Shipping Window Help

UR: 228032
 U processing

Tech ID: 1126 **Sample ID:** 228032 **Name:** JAY, CHRISTOPHER **Gender:** M **Age:** 6
SP ID: 228032 **Appt Type:** Primary **Fasting Req:** No Fasting Required

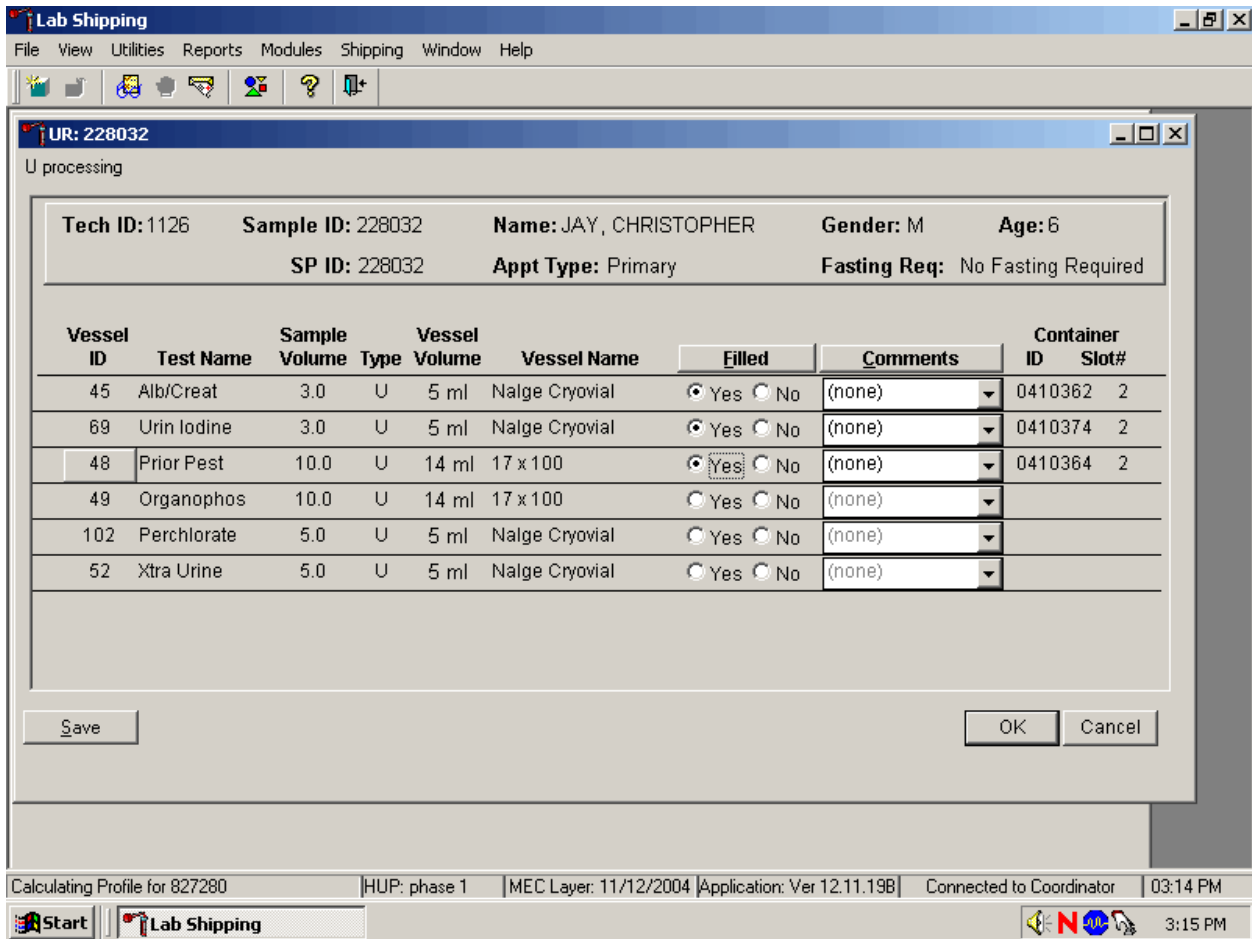
| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|--|----------|--------------|-------|
| 45 | Alb/Creat | 3.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 69 | Urin Iodine | 3.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 48 | Prior Pest | 10.0 | U | 14 ml | 17 x 100 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 49 | Organophos | 10.0 | U | 14 ml | 17 x 100 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 102 | Perchlorate | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 52 | Xtra Urine | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

Ready HUP: idle MEC Layer: 11/12/2004 Application: Ver 12.11.19B Connected to Coordinator 03:14 PM

Start Lab Shipping 3:14 PM

The urine processing window contains the following information for SPs: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) type, and Fasting Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Sample Type (U = urine), Vessel Volume, Vessel Name, Filled (Yes or No) radio buttons, Comment drop-down box, and Container ID and Container Slot# column.

Individually mark each vessel as Filled –“Yes.”



To mark an individual urine vessel as collected or Filled –“Yes” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As each vessel is marked as Filled –“Yes,” it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled –“No.”

The screenshot shows the 'Lab Shipping' application window. At the top, there is a menu bar with 'File', 'View', 'Utilities', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. The main window title is 'UR: 228032' and the status is 'U processing'.

Below the title bar, there is a patient information section with the following details:

- Tech ID: 1126
- Sample ID: 228032
- Name: JAY, CHRISTOPHER
- Gender: M
- Age: 6
- SP ID: 228032
- Appt Type: Primary
- Fasting Req: No Fasting Required

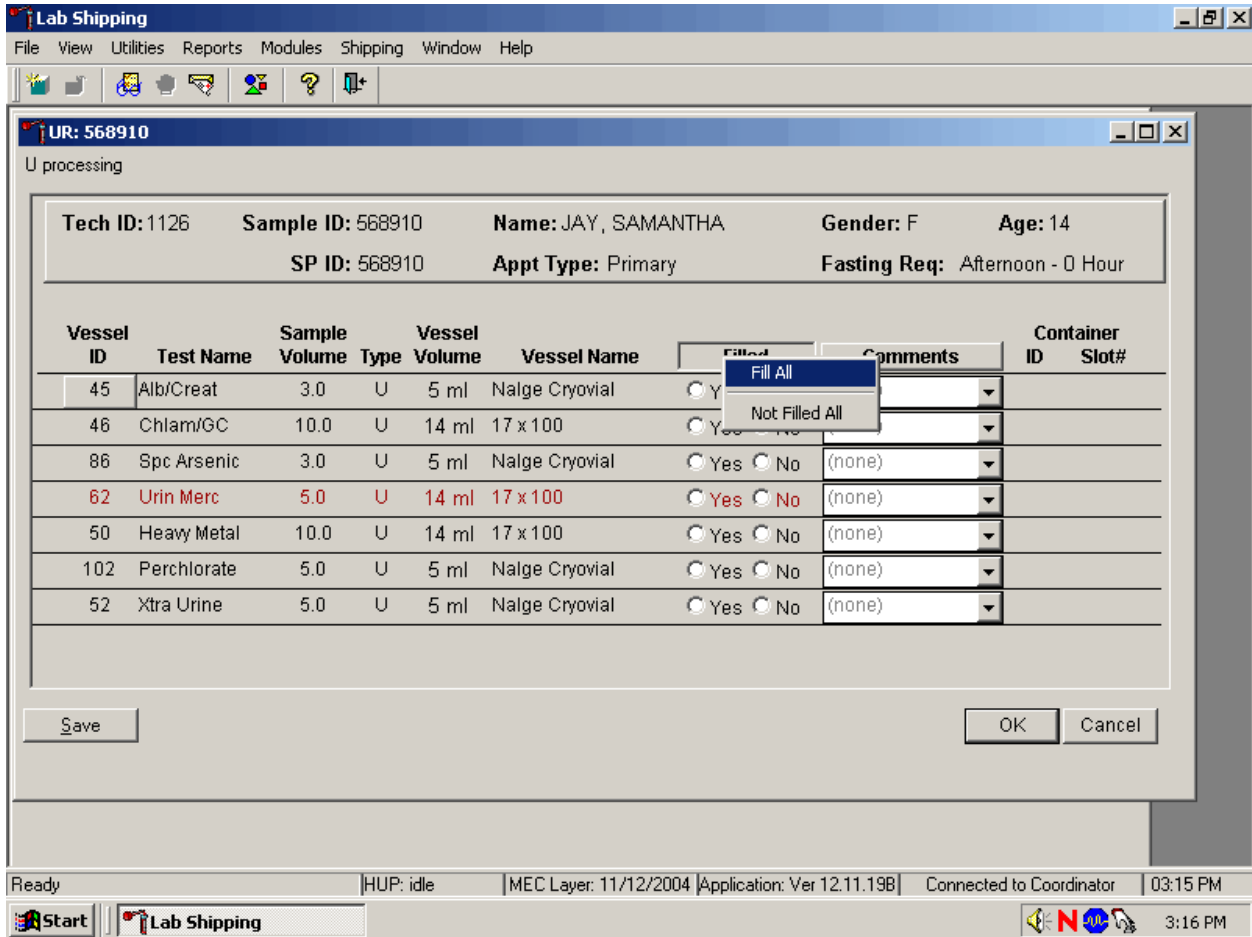
Below the patient information is a table with the following columns: Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Filled, Comments, Container ID, and Slot#. The 'Filled' column contains radio buttons for 'Yes' and 'No'. The 'Comments' column contains a dropdown menu with '(none)' and 'quantity not sufficient'.

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|---------------------|--------------|-------|
| 45 | Alb/Creat | 3.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410362 | 2 |
| 69 | Urin Iodine | 3.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410374 | 2 |
| 48 | Prior Pest | 10.0 | U | 14 ml | 17 x 100 | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410364 | 2 |
| 49 | Organophos | 10.0 | U | 14 ml | 17 x 100 | <input type="radio"/> Yes <input checked="" type="radio"/> No | quantity not suffic | | |
| 102 | Perchlorate | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 52 | Xtra Urine | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

At the bottom of the window, there are three buttons: 'Save', 'OK', and 'Cancel'. The status bar at the bottom of the application shows 'Ready', 'HUP: idle', 'MEC Layer: 11/12/2004', 'Application: Ver 12.11.198', 'Connected to Coordinator', and '03:15 PM'. The Windows taskbar at the very bottom shows the 'Start' button, the 'Lab Shipping' application icon, and the system clock showing '3:15 PM'.

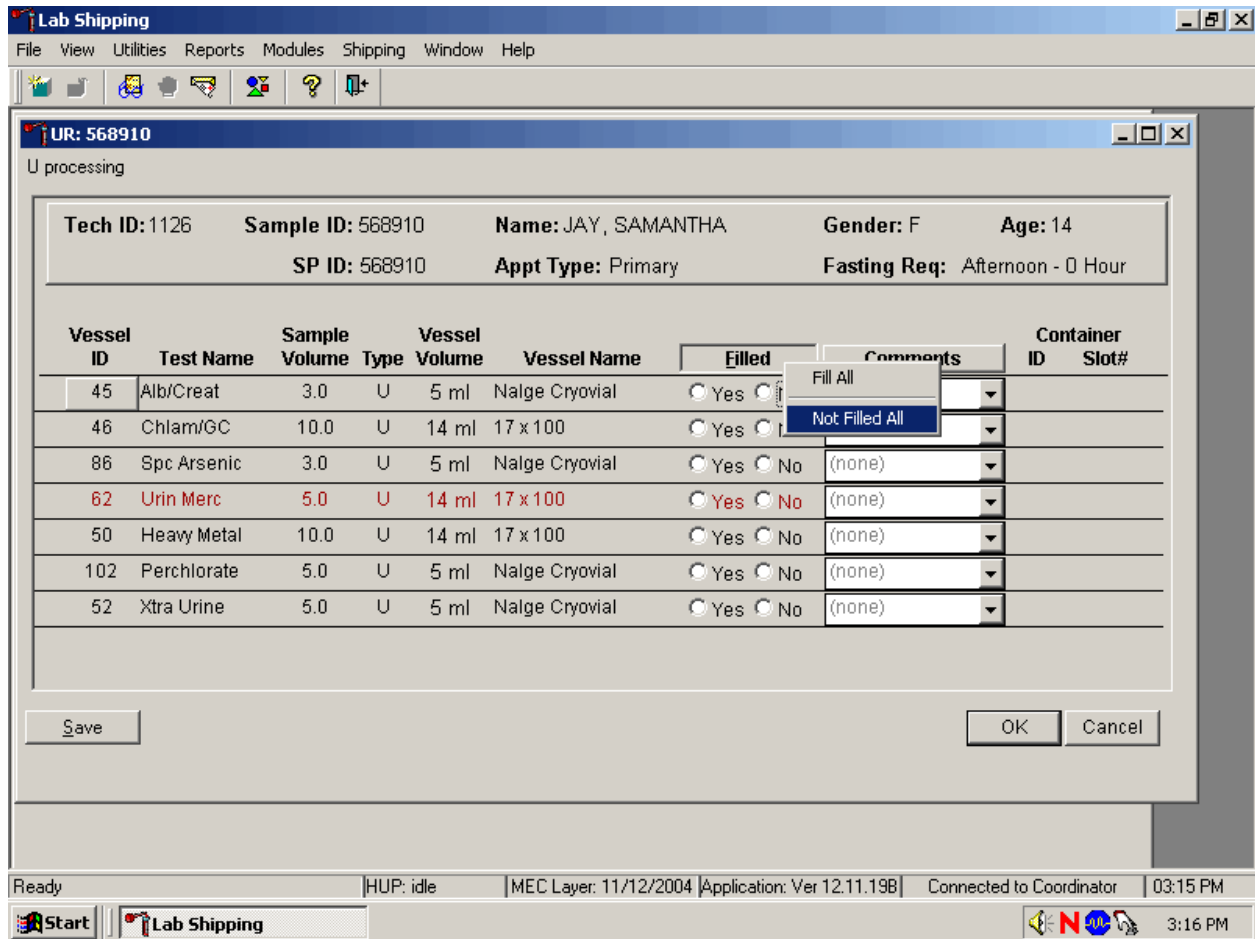
To mark an individual urine vessel as not collected or Filled –“No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. As each vessel is marked as Filled “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column.

Collectively mark all vessels as Filled--“Yes.”



To collectively mark all vessels as Filled --“Yes,” use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, and drag the arrow to {Fill All} and left click or type [Shift] [F/f], [I/i.]

Collectively mark all vessels as Filled –“No.”



To mark all vessels as Filled–“No,” use the mouse to direct the mouse arrow to the Filled box, left click, drag the mouse arrow to {Not Filled All}, and left click or type [Shift] [F/f], [N/n.]

Use the quality comment code to indicate if blood is present.

| | |
|---------------|-----------------------------------|
| Comment Code | Use when: |
| Blood present | Blood is visible in the specimen. |

Attach the quality comment code to indicate if blood is present.

The screenshot shows the 'Lab Shipping' application window. The main window title is 'UR: 568910' and it is in 'U processing' mode. The patient information is as follows:

- Tech ID: 1126
- Sample ID: 568910
- Name: JAY, SAMANTHA
- Gender: F
- Age: 14
- SP ID: 568910
- Appt Type: Primary
- Fasting Req: Afternoon - 0 Hour

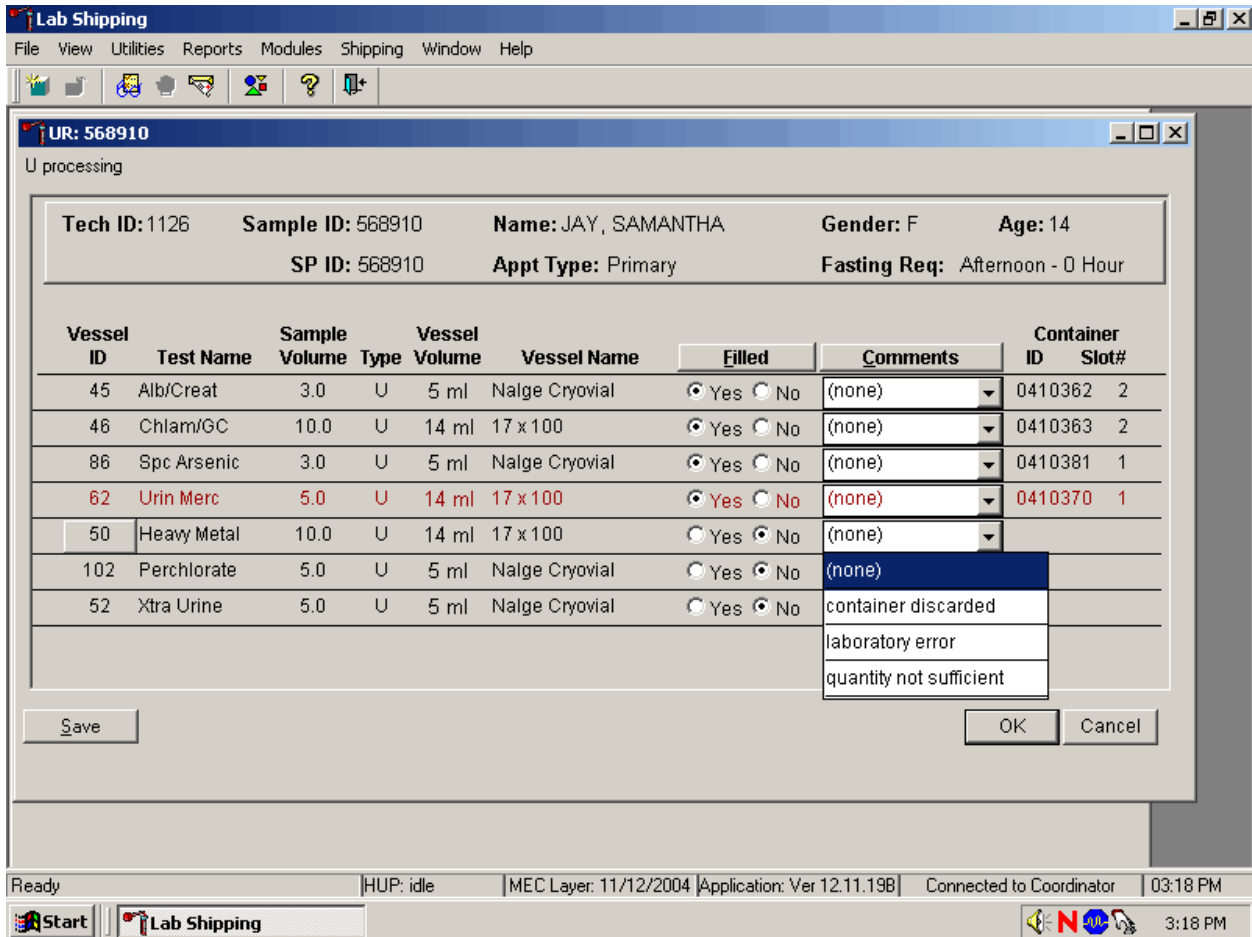
The main data table is as follows:

| Vessel ID | Test Name | Sample Volume | Vessel Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|-------------|---------------|----------------|---|---------------|--------------|-------|
| 45 | Alb/Creat | 3.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410362 | 2 |
| 46 | Chlam/GC | 10.0 | U | 14 ml | 17 x 100 | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0363 | 2 |
| 86 | Spc Arsenic | 3.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | blood present | | |
| 62 | Urin Merc | 5.0 | U | 14 ml | 17 x 100 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 50 | Heavy Metal | 10.0 | U | 14 ml | 17 x 100 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 102 | Perchlorate | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 52 | Xtra Urine | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

At the bottom of the window are buttons for 'Save', 'OK', and 'Cancel'. The system tray at the bottom shows the time as 3:16 PM and the application version as 12.11.19B.

To enter the quality control comment “blood present” for a filled vessel, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {blood present}, and left click.

If a vessel is marked as Filled–“No,” the comment “quantity not sufficient” is automatically entered. Review the comment for all insufficient urine collections and correct the comment, when necessary.



| Comment Code | Use when: |
|-------------------------|---|
| container discarded | Not applicable |
| laboratory error | A technologist makes an inadvertent error when processing |
| quantity not sufficient | The amount of urine received in the lab is insufficient to fill this vessel |

Continue recording and updating urine collection results as specimens are delivered to the laboratory.

Do not use the comment, “container discarded” for Filled –“No” vessels.

Lab Shipping

File View Utilities Reports Modules Shipping Window Help

UR: 568910

U processing

Tech ID: 1126 Sample ID: 568910 Name: JAY, SAMANTHA Gender: F Age: 14
 SP ID: 568910 Appt Type: Primary Fasting Req: Afternoon - 0 Hour

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|---------------------|--------------|-------|
| 45 | Alb/Creat | 3.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410362 | 2 |
| 46 | Chlam/GC | 10.0 | U | 14 ml | 17 x 100 | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410363 | 2 |
| 86 | Spc Arsenic | 3.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410381 | 1 |
| 62 | Urin Merc | 5.0 | U | 14 ml | 17 x 100 | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410370 | 1 |
| 50 | Heavy Metal | 10.0 | U | 14 ml | 17 x 100 | <input type="radio"/> Yes <input checked="" type="radio"/> No | (none) | | |
| 102 | Perchlorate | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | (none) | | |
| 52 | Xtra Urine | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | container discarded | | |

Save OK Cancel

Ready HUP: idle MEC Layer: 11/12/2004 Application: Ver 12.11.19B Connected to Coordinator 03:18 PM

Start Lab Shipping 3:18 PM

The drop-down comment list for Filled–“No” contains {container discarded}. Do not use this comment.

Review the information in the urine-processing window and save the data to the database.

Lab Shipping
 File View Utilities Reports Modules Shipping Window Help

UR: 568910
 U processing

Tech ID: 1126 Sample ID: 568910 Name: JAY, SAMANTHA Gender: F Age: 14
 SP ID: 568910 Appt Type: Primary Fasting Req: Afternoon - 0 Hour

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|---------------------|--------------|-------|
| 45 | Alb/Creat | 3.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410362 | 2 |
| 46 | Chlam/GC | 10.0 | U | 14 ml | 17 x 100 | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410363 | 2 |
| 86 | Spc Arsenic | 3.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410381 | 1 |
| 62 | Urin Merc | 5.0 | U | 14 ml | 17 x 100 | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410370 | 1 |
| 50 | Heavy Metal | 10.0 | U | 14 ml | 17 x 100 | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410366 | 1 |
| 102 | Perchlorate | 5.0 | U | 5 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410391 | 2 |
| 52 | Xtra Urine | 5.0 | U | 5 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | quantity not suffic | | |

Save OK Cancel

Ready HUP: idle MEC Layer: 11/12/2004 Application: Ver 12.11.19B Connected to Coordinator 03:17 PM

Start Lab Shipping 3:18 PM

Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

5.9 Second Urine Samples

If the initial urine sample does not meet the minimum volume requirement, refrigerate the initial urine until enough additional urine is received to meet the minimum requirements to complete the protocol or the session ends. If a subsequent second sample fulfills this requirement, pool the initial and subsequent urine samples, update the Urine Collection module, access the Urine Processing module, fill the vessels, and record the results. If the session ends and no additional urine has been collected, access the Urine Processing module, fill as many vessels as possible (in priority order), mark the remaining vessels as filled “No,” and save the results.

5.10 Specimen Storage

Fill the urine vessels, enter the urine processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Table 5-3. Check the slot assignment of the lead dust container at the end of each processing session by accessing the Container Map Report. Verify the contents of each container against the container map.

At the beginning of each stand, generate and print a series of bar-coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process “opens” a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in containers are assigned according to a standard left to right, top to bottom procedure. Store each vessel in the appropriate slot in the correct container immediately after processing.

Table 5-3. Storage protocol for urine

| Shipping Location | Vessels | Conditions | Frequency | Vessel Storage |
|-------------------------------|-----------------|------------|--------------|----------------------|
| University of Minnesota | 45 Alb/Creat | Frozen | Weekly | 9 x 9 three-inch box |
| CDC NCID NCHSTD | 46 Chlam/GC | Frozen | Weekly | 5 x 5 three-inch box |
| CASPIR | 69 Urn Iodine | Frozen | Weekly | 9 x 9 three-inch box |
| CASPIR | 86 Spc Arsenic | Frozen | Weekly | 9 x 9 three-inch box |
| CDC Dr. Dana Barr | 48 Prior Pest | Frozen | End of stand | 5 x 5 three-inch box |
| CDC Dr. Dana Barr | 49 Organophos | Frozen | End of stand | 5 x 5 three-inch box |
| CASPIR | 62 Urn Merc | Frozen | Weekly | 5 x 5 three-inch box |
| CASPIR | 50 Heavy Metal | Frozen | Weekly | 5 x 5 three-inch box |
| CASPIR/Dr. Christine Pfeiffer | 65 Urn Phytoes | Frozen | End of stand | 9 x 9 three-inch box |
| CASPIR/Dr. Andreas Sjodin | 66 PAH | Frozen | End of stand | 9 x 9 three-inch box |
| CDC Dr. Antonia Calafat | 67 Phthalates | Frozen | End of stand | 9 x 9 three-inch box |
| CDC Air Toxicant Branch | 102 Perchlorate | Frozen | Weekly | 9 x 9 three-inch box |
| CASPIR | 52 Xtra Urine | Frozen | End of stand | 9 x 9 three-inch box |

5.11 How to Deal With System Failure

If the computer system fails, record results on a preprinted workstation 2 processing worksheet (Exhibit 5-2). Complete a workstation 2 worksheet for each SP after performing the pregnancy test, and while processing the urine specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 5-2. Workstation 2 processing worksheet

URINE COLLECTION, PREGNANCY TEST, URINE PROCESSING

SP ID _____

| | Urine Collected Age 6+ | Yes ✓ | Yes/QNS ✓ | No ✓ | Comments: Communication problem No time Quantity not sufficient SP ill/emergency SP refusal SP unable to comply | | |
|--------|-----------------------------|---------------|--------------|---------------|---|--|--------|
| Result | | | | | | | |
| | Pregnancy Test Age 8-17 | Negative ✓ | Invalid ✓ | Positive ✓ | Serum Confirmation Result (Send observation to physician) | | |
| Result | | | | | | | |
| | Pregnancy Test Age 18-59 | Negative ✓ | Invalid ✓ | Positive ✓ | | | |
| Result | | | | | | | |
| ID | Name | Ages | Sample mL | Sample Type | Filled ✓ | Comments <i>ONS</i> <i>Blood Present</i> | Slot # |
| 45 | Alb/Creat | 6+ | 3 | Urine | | | |
| 46 | Chlam/GC | 14-39 | 10 | Urine | | | |
| 69 | Urn Iodine | 6+ | 3 | Urine | | | |
| 86 | Spc Arsenic | 6+ | 3 | Urine | | | |
| 48 | Prior Pest | 6+ | 10 | Urine | | | |
| 49 | Organophos | 6+ | 10 | Urine | | | |
| 62 | Urn Merc | 6+ | 5 | Urine | | | |
| 50 | Heavy Metal | 6+ | 10 | Urine | | | |
| 65 | Urn Phytoes | 6+ | 3 | Urine | | | |
| 66 | PAH | 6+ | 3 | Urine | | | |
| 67 | Phthalates | 6+ | 3 | Urine | | | |
| 102 | Perchlorate | 6+ | 5 | Urine | | | |
| 52 | Xtra Urine | 6+ | 5 | Urine | | | |
| 53 | HIV | 18-49 | 3 | Urine | | | |

**National Health and Nutrition Examination Survey
National Center for Health Statistics
United States Public Health Service
Procedure: Pregnancy Testing
January, 2005**

Prepared by _____

Date Adopted _____

Approved by _____

Director

Signed _____

Director

Dated _____

Director

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

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Date Reviewed _____

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

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6. URINE PREGNANCY TEST

I. Purpose and Principle of the Test

Perform a pregnancy test on females of all appointment types who are aged 12-59 years, and girls 8-11 who report that they are menstruating when asked during the home interview. A positive test result excludes pregnant women aged 8-59 from participating in the dual-energy x-ray absorptiometry (DXA) section of the body composition component of the MEC exam. Report test results immediately since these components are not assigned until the results of the pregnancy test are documented. If a urine pregnancy test is positive on any female SP aged 8-17 years, the result is confirmed using a serum test. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.

Tests for confirming pregnancy are based on detecting elevated levels of human chorionic gonadotropin (hCG), a hormone that the placenta begins to produce in increasing amounts shortly after fertilization. The Icon® 25 hCG (Urine/Serum) test kit is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy.

In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception. The hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period, and peaking in the 100,000 to 200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid raise in concentration during early gestational growth, make an excellent marker for the detection of pregnancy.

The Icon® 25 hCG test is a rapid test that qualitatively detects the presence of hCG in urine or serum sample at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum. At the level of claimed sensitivity, the ICON ® 25 hCG test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH, and hTSH at high physiological levels.

The assay is conducted by adding urine or serum sample to the sample well of the test device. The sample migrates via capillary action along the membrane to react with colored conjugate. Positive samples react with the specific antibody-hCG-colored conjugate to form a colored line at the test region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

II. Special Safety Precautions

ICON® 25 hCG Test (Urine or Serum)

- This test is for professional *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- The test device should remain in the sealed pouch until use.
- Observe standard guidelines for handling biological hazards.
- Wear gloves while handling specimens. After use, dispose of gloves and other contaminated materials appropriately in a proper biohazard container and wash hands.

Sure-Vue™ hCG Urine and Serum Control Sets

- Sure-Vue™ hCG urine and serum controls are intended to be used to monitor the performance and accuracy of pregnancy test kits. These controls are for professional use only.
- The use of known controls in the laboratory is invaluable. It is important to verify testing procedures to confirm the validity of the results reported. Testing Sure-Vue™ hCG Urine and Serum Controls will provide assurance that the pregnancy test kit is performing properly.
- Reagents in these kits contain 0.2 percent of sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide buildup. This reagent is harmful if swallowed. Contact with acids liberates very toxic gas. After contact with skin, wash immediately with plenty of water.
- Do not use the controls beyond the expiration date.

III. Computerization: Integrated Survey and Information System (ISIS)

The MEC-automated ISIS system captures all data and stores it electronically at Westat's home office in Rockville, Maryland. Access the Pregnancy QC module to enter the quality control results. The session number, technologist ID, and run number are automatically captured; enter the kit lot number and expiration date, and the urine and serum control lot and expiration dates. Record control results and save them to the database. All pregnancy quality control results are immediately available electronically at the home office. All data are backed up and stored at Westat's home office.

IV. Specimen Collection and Preparation

Collect a urine specimen on all SPs 6 years and older into a clean and dry plastic container and document the collection in the urine collection module as described in Chapter 5. Perform a urine pregnancy test on females of all person types who are aged 12-59 years and girls aged 8-11 who report that they are menstruating when asked during the home interview. If a urine pregnancy test is positive on any female SP aged 8-17, confirm the result using serum. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function. Assay all specimens immediately and record results in the Laboratory Pregnancy Testing module.

V. Procedure for Microscopic Examination

Not applicable.

VI. Reagents and Supplies

A. Reagents

ICON® 25 hCG Urine/Serum test kit

Product Number 43025 (25)

Beckman Coulter

4300 N. Harbor Blvd

Fullerton, CA 92834-3100

1-800-877-6242 or 650-845-3526

■ Components

- One test device. (25) – Contains anti-hCG particles and anti-hCG coating on the membrane.
- Disposable sample droppers - Plastic pipettes for measuring and dispensing patient samples. (Packaged together with the test device in a white foil pouch.)
- Zip closable bag with two extra sample droppers
- Product instructions

■ Storage and Stability

- Store the ICON 25 hCG test kit at 2 - 30°C, (59 - 83°F). The test device is stable up to the expiration date printed on the sealed pouch. Keep the test device in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond expiration date. Date and initial the kit when putting it into use.

Sure-Vue™ hCG Control Sets – Urine and Serum

Sure-Vue™ hCG Control Sets – Urine

Product Number SA087413-F

Fisher Scientific Company

1-888-727-3315 (Technical assistance)

■ Components - Sure-Vue™ hCG Control Set

- Urine is a stable human urine-based material for use as a quality control material. Use controls in the same manner as SP specimens in accordance with the protocol provided in the Sure-Vue™ hCG Control Sets directional insert.

- Low Positive Control: Human urine containing approximately 25 mIU hCG/mL and 0.2% sodium azide as a preservative. (1 x 5 mL)
- High Positive Control: Human urine containing approximately 250 mIU hCG/mL and 0.2% sodium azide as a preservative. (1 x 5 mL)
- Negative Control: Contains 0.2% sodium azide as a preservative. (1 x 5 mL)
- Storage and Stability - Sure-Vue™ hCG Control Set
 - Store the urine control set between 2 to 8°C (35 to 46°F) at which temperatures these controls are stable until the expiration date printed on the label.

Sure-Vue™ hCG Serum Control Set
 Product Number 087712-F
 Fisher Scientific Company
 1-888-727-3315 (Technical assistance)

- Components - Sure-Vue™ hCG Serum Control
 - The Sure-Vue™ hCG Serum Control is a stable human serum-based material for use as a quality control material. Use controls in the same manner as SP specimens in accordance with the protocol provided in the Sure-Vue™ hCG Control Set directional insert.
 - Low Positive Control: Human serum containing approximately 25 mIU hCG/mL and 0.2% sodium azide as a preservative. (1 x 5 mL)
 - High Positive Control: Human serum containing approximately 250 mIU hCG/mL and 0.2% sodium azide as a preservative. (1 x 5 mL)
 - Negative Control: Contains 0.2% sodium azide as a preservative. (1 x 5 mL)
- Storage and Stability - Sure-Vue™ hCG Serum Control
 - Store the Sure-Vue™ hCG Serum Control Set between 2 to 8°C (35 to 46°F) at which temperatures these controls are stable until the expiration date printed on the label.

B. Supplies

- Timer

VII. Calibration

Not applicable

VIII. Assay Procedure

ICON® 25 hCG Test kit

- Label each test device with the preprinted label or write the SP ID on a clear section of the test device using a felt tip pen.
- Use a new transfer dropper for each specimen.

Sure-Vue™ hCG Urine and Serum Control Sets

- The Sure-Vue™ urine and serum controls have their own droppers. The use of the control droppers to add three drops of sample has been validated; do not use the ICON 25 hCG plastic pipette to add controls.
- Allow controls to reach room temperature before testing. The controls are ready to use. No dilution is required.
- The controls are used in place of the specimen and should be tested according to the ICON® 25 hCG test procedure.
- Discard the high positive urine and serum vials. (250 mIU/mL).

Urine or Serum Testing Procedure

Perform the test procedure for ICON® 25 hCG Urine/Serum test at room temperature (15 - 30°C, 59 - 86°F). Before proceeding, carefully read Section XII. entitled “Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions.”

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer three full drops of urine or serum (approximately 100 µL) to the sample well (S)

of the test device, and then start the timer. Avoid trapping air bubbles in the sample well.

3. Wait for the red line(S) to appear. Read the results at 3 minutes when testing a urine sample or 5 minutes when testing a serum sample. It is important that the background is clear before the result is read.

NOTE: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period; therefore, do not interpret the result after 3 minutes when testing a urine sample or after 5 minutes when testing a serum sample.

IX. Reportable Range of Results

Report test results as Positive, Negative, or Invalid.

X. Quality Control

Run negative and low positive urine controls containing hCG at concentrations of 0 and 25 mIU/mL, respectively, just prior to or concurrently with the first examinee pregnancy test each exam day, and when putting a new lot into use. Run negative and low positive serum controls with each serum pregnancy test. The pregnancy QC module contains the following information:

- The session ID number links to the stand number, stand location, date, including day, month, and year. The technologist ID is automatically captured.
- Kit lot number and expiration date fill in automatically from the prior QC report. Update or manually enter this information if necessary.
- The control lot number and expiration date for both the urine and serum control fills in automatically from the prior QC report. Update or manually enter this information if necessary.
- The Control QC Type is either urine or serum. The default type is set as urine.
- Negative Control result.
- Positive Control result.

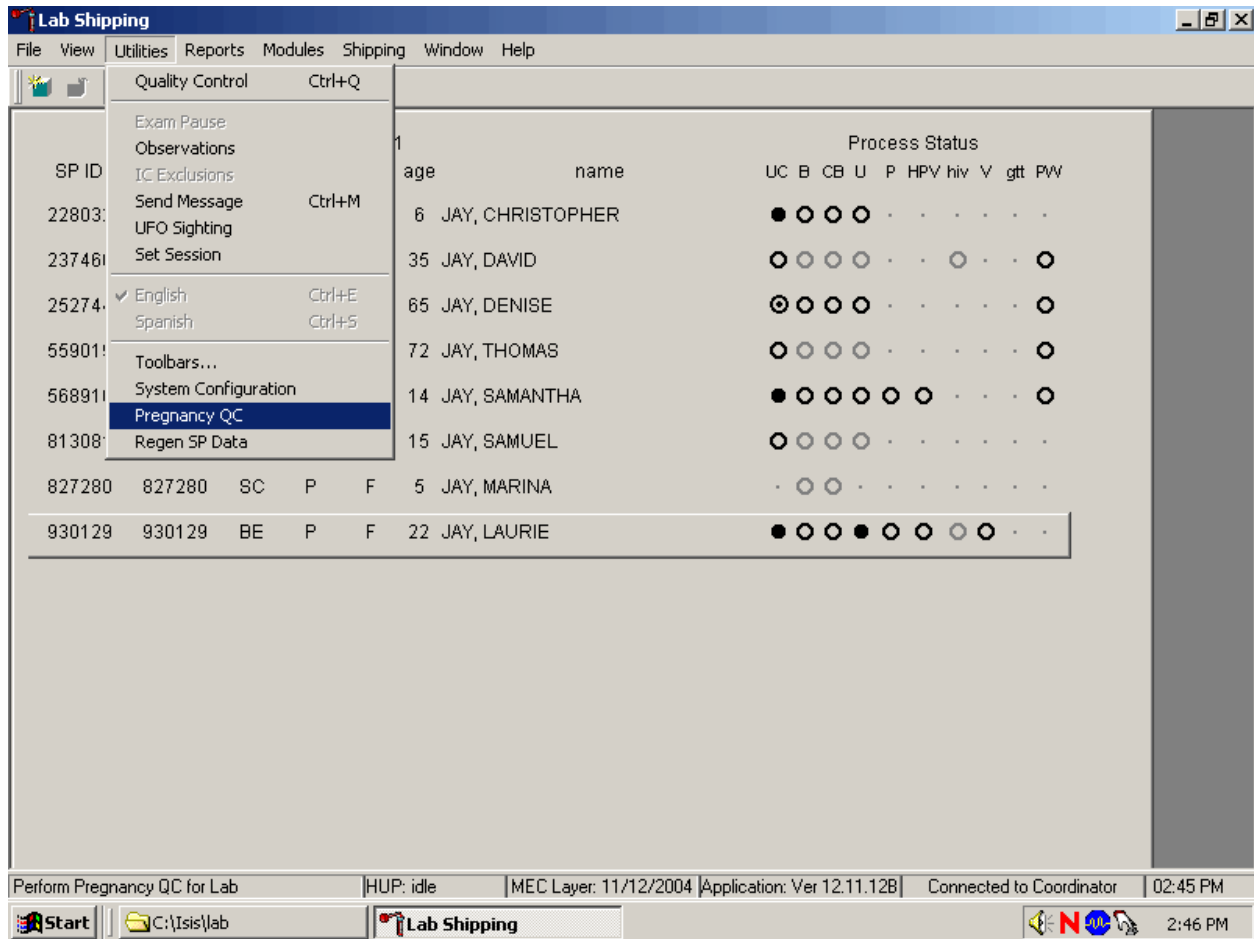
CAP Proficiency Testing

For purposes of this document, proficiency testing is one method of external quality control in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 3 months).

Participation in the College of American Pathologist (CAP) EXCEL proficiency-testing program is part of the comprehensive quality control program. Each MEC submits results for CAP specimens for evaluation. CAP compares the results to established values and issues a report.

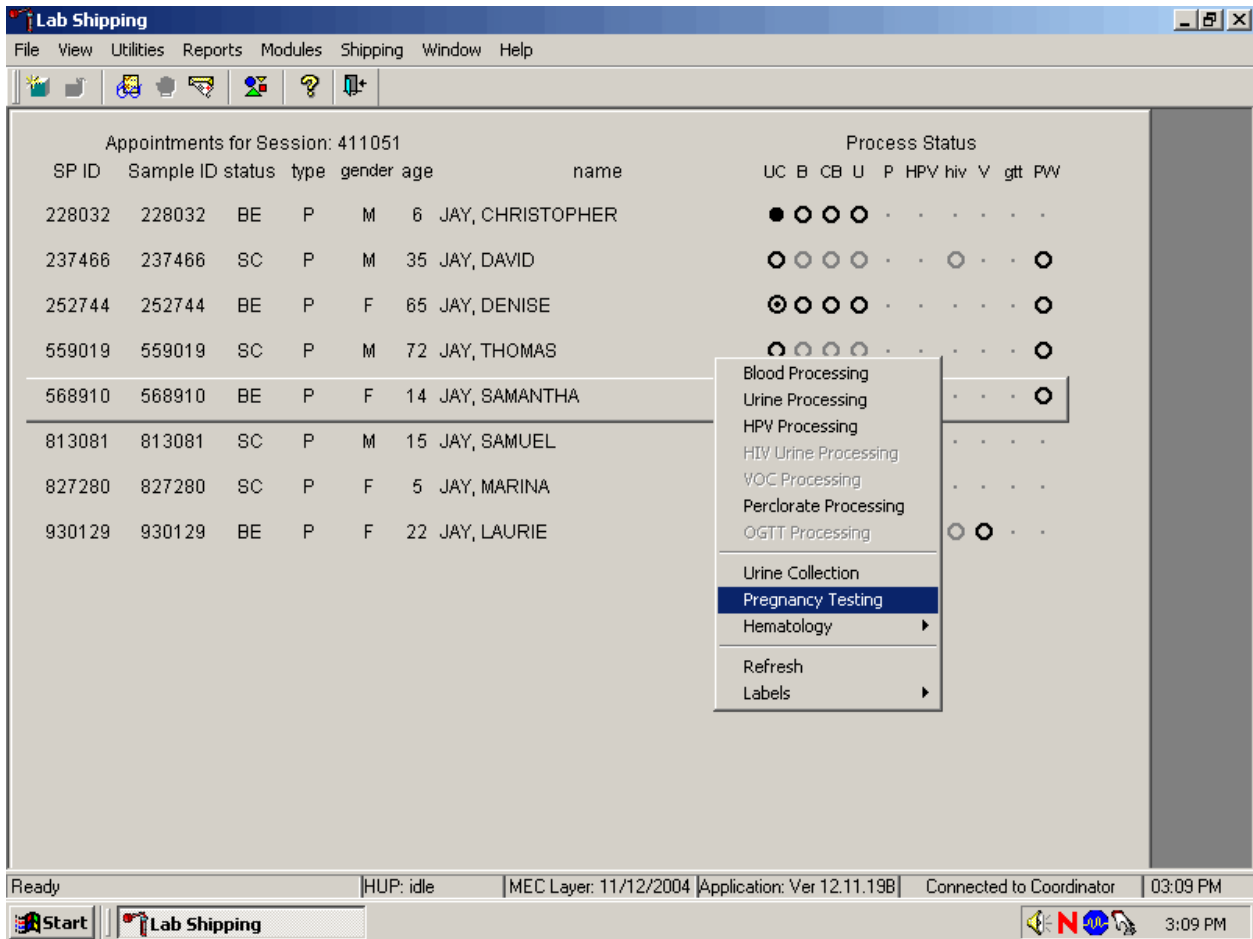
CAP sends samples three times a year for qualitative serum hCG and urine hCG. Each serum survey includes five lyophilized sera specimens and each urine survey includes 5 liquid specimens. Handle and analyze these samples in a manner identical to SP samples. Record results on the CAP forms and send to the address specified by CAP Surveys Program Support. Send a copy of the CAP form to the home office at the end of the stand.

Open the Pregnancy QC module.



To open the pregnancy QC module, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the arrow to {Pregnancy QC}, and left click or type [Alt] [U/u], [R/r].

Alternatively, open the Pregnancy QC module from the heads-up screen.



To access the Pregnancy QC module from the heads-up screen, use the up and down keys to move up and down the list until the correct SP is highlighted or use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing}, and left click or left click and type [P/p].

The pregnancy QC window displays.

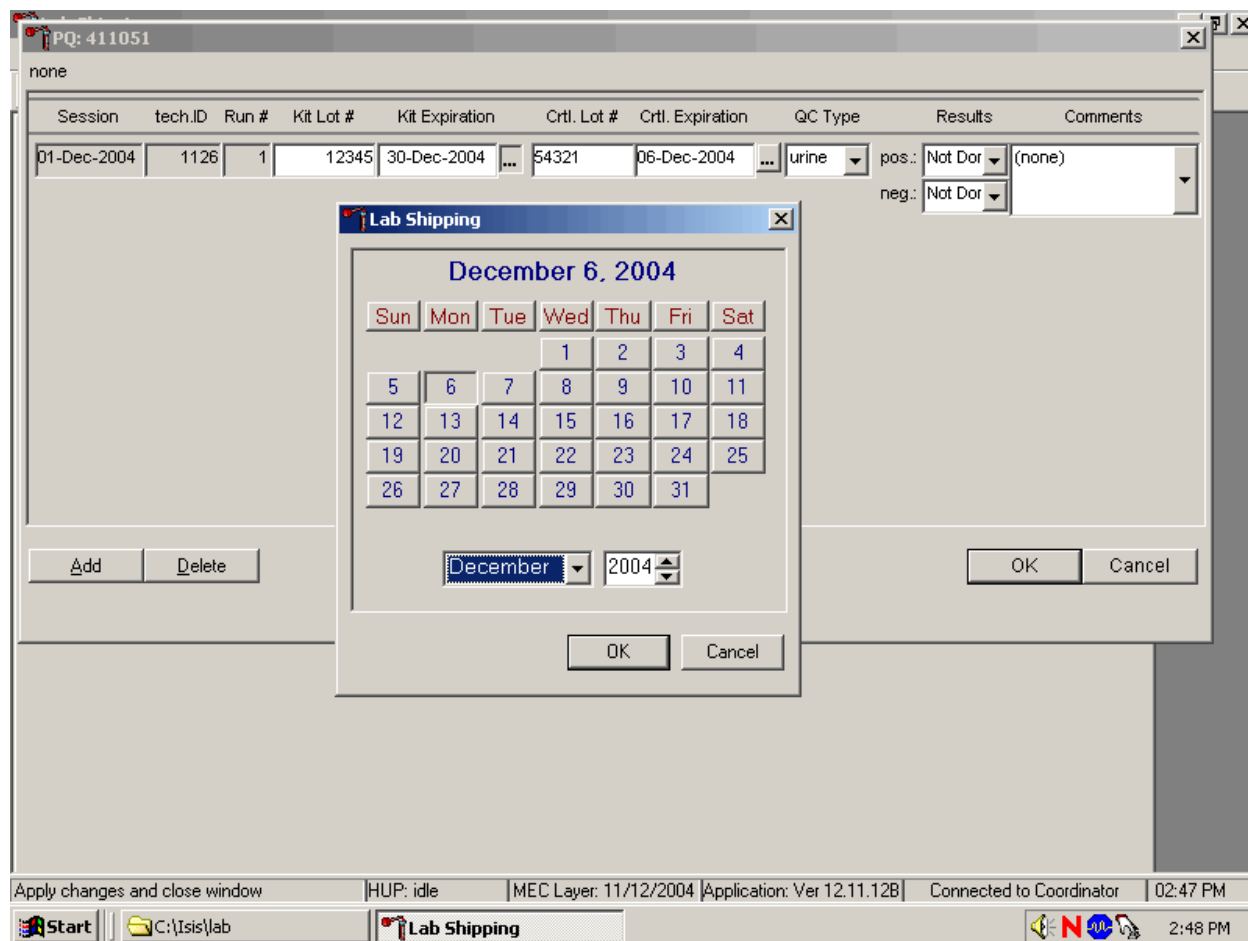
The screenshot shows a software window titled "PQ: 411051" with a "none" label. The window contains a data entry form with the following fields and values:

| Session | tech.ID | Run # | Kit Lot # | Kit Expiration | Ctrl. Lot # | Ctrl. Expiration | QC Type | Results | Comments |
|-------------|---------|-------|-----------|----------------|-------------|------------------|---------|--------------------------------|----------|
| 01-Dec-2004 | 1126 | 1 | 12345 | 30-Dec-2004 | 54321 | 06-Dec-2004 | urine | pos.: Not Dor neg.: Not Dor | (none) |

At the bottom of the window, there are buttons for "Add", "Delete", "OK", and "Cancel". The taskbar at the bottom shows the Start button, the current directory "C:\Isis\lab", a "Lab Shipping" icon, and the system clock showing "2:48 PM".

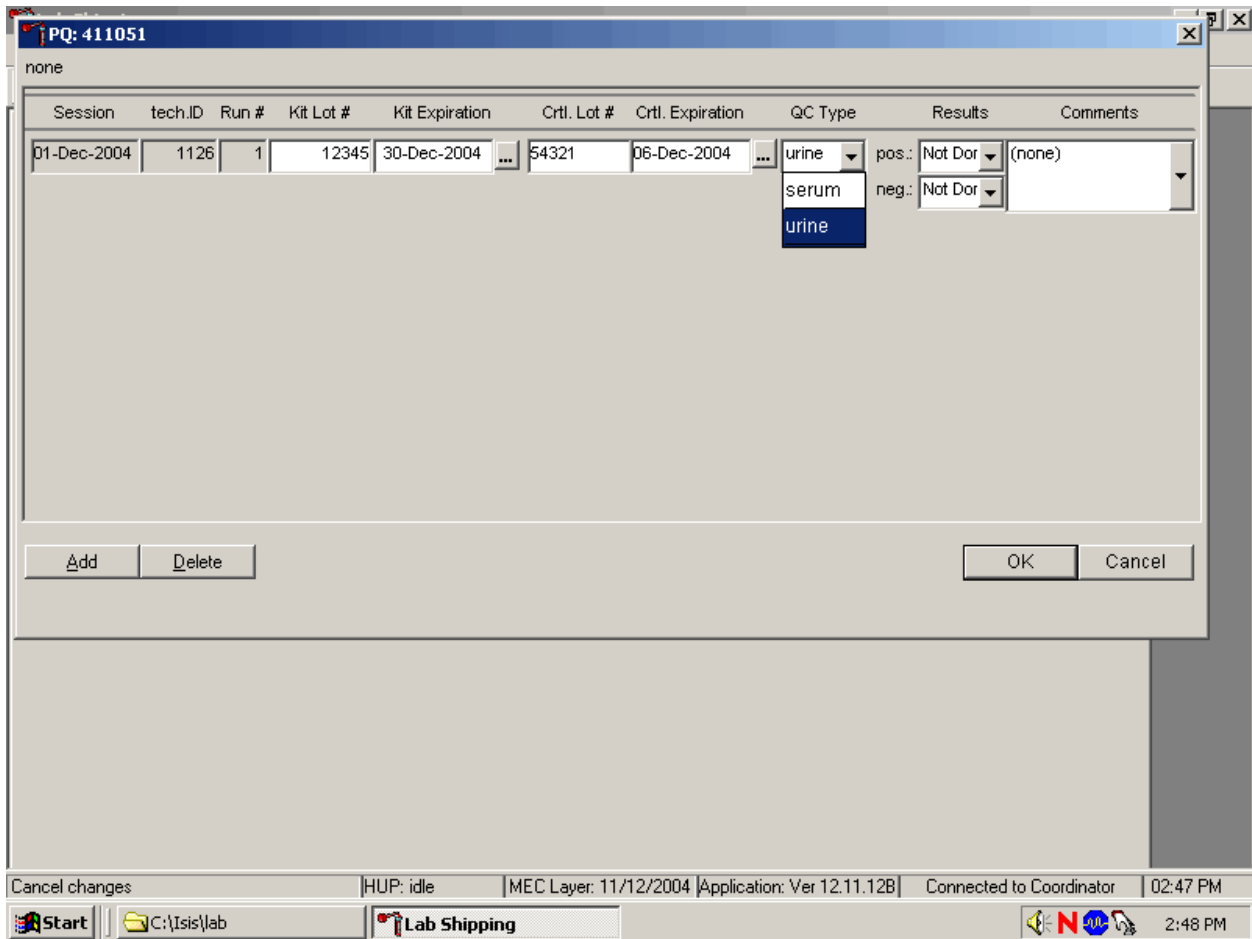
The pregnancy QC module automatically captures the session date and technologist ID and assigns the run number. The module defaults to the last kit lot number, kit expiration date, Ctrl (control) lot number, Ctrl expiration date, and the QC type - urine. Verify the existing kit lot number and expiration date. If the lot number is incorrect, type in the new kit lot number using the keyboard's numeric keys and select [Tab] to progress to the Kit Expiration blank. Use the calendar to correct the Kit Expiration date. If the screen defaults to the current Ctrl lot number, verify the existing lot number and expiration date. If the lot number is incorrect, type in the new control lot number using the keyboard numeric keys and select [Tab] to progress to the Ctrl Expiration blank. Use the calendar to correct either the Kit or the Ctrl Expiration date.

Update the Kit or Ctrl Expiration date using the calendar function.



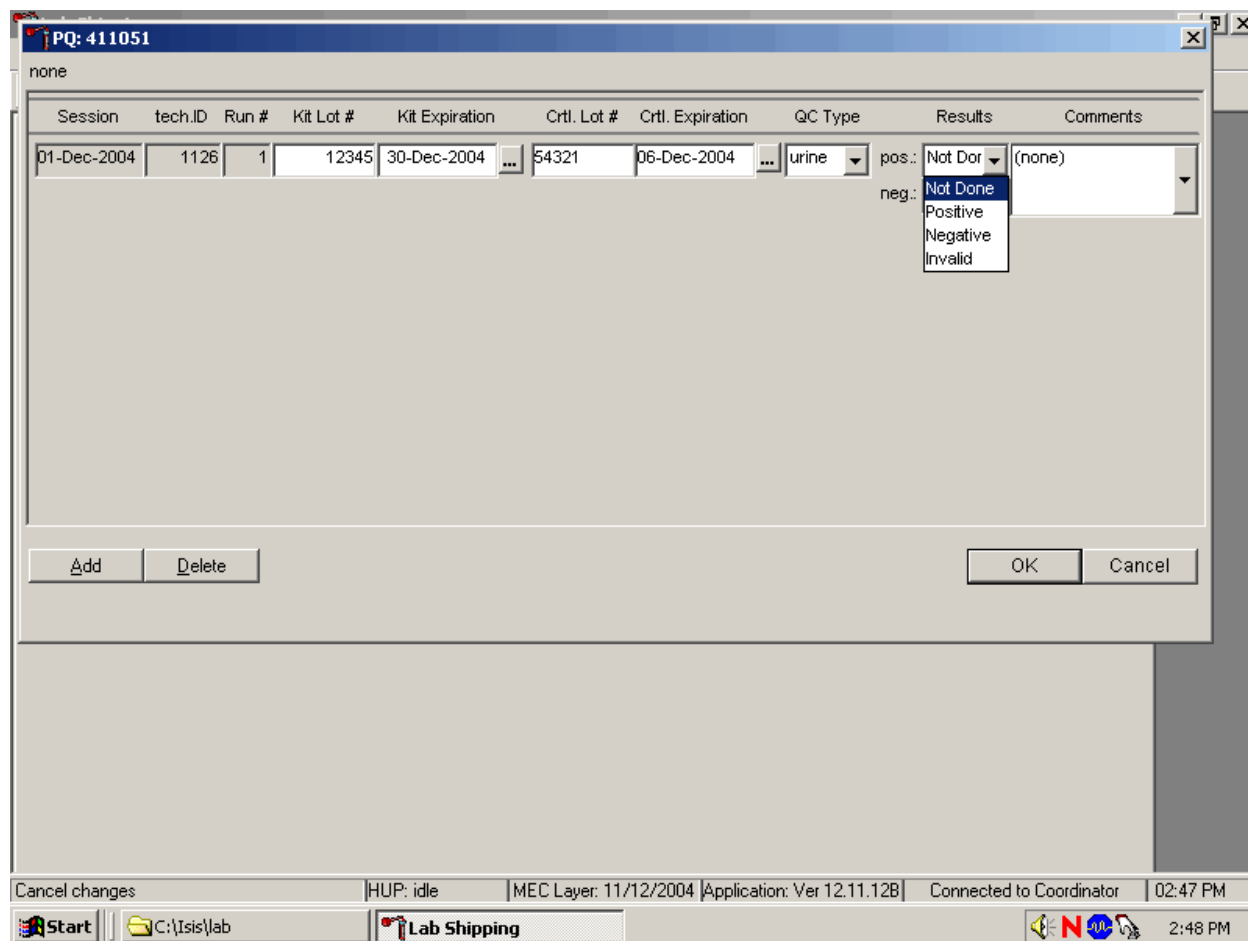
Type in the date using the keyboard's numeric keys and the dd/mm/yyyy format and select [Tab] or use the calendar to enter the date. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis and left click. To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary) and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to up down controls on the spin box and toggle the year up and down. To transfer this date into the text box, use the mouse to direct the mouse arrow to the OK button and left click; to exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Select the control QC type.



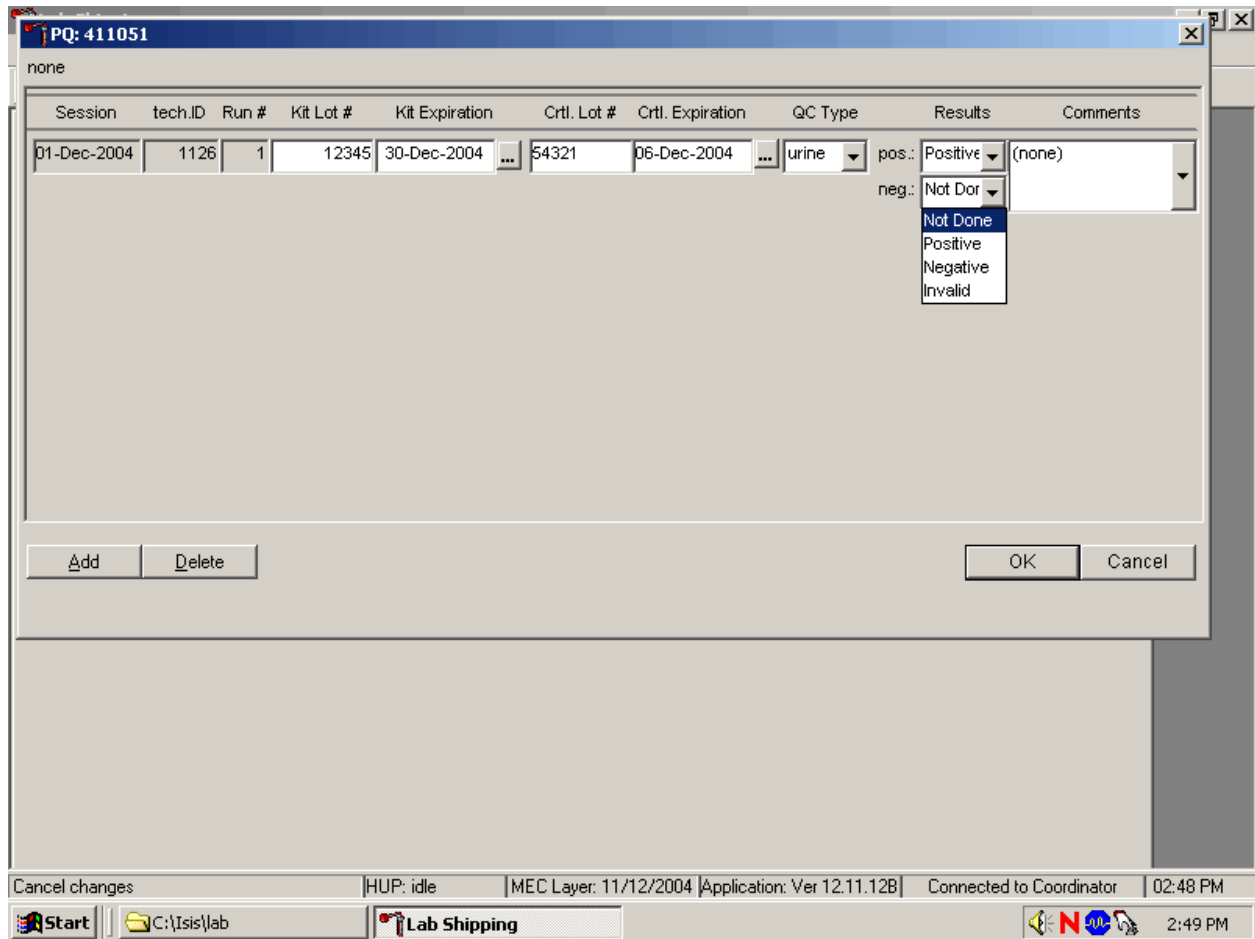
The QC control type default is “Urine.” To change the QC type to serum or to select urine, use the mouse to direct the mouse arrow to the drop-down list, drag the mouse arrow to either serum or urine and left click. Alternatively, highlight the QC type text box and type [S/s] for serum or [U/u] for urine and [Tab] to move to the result test boxes.

Record the positive and negative control results.



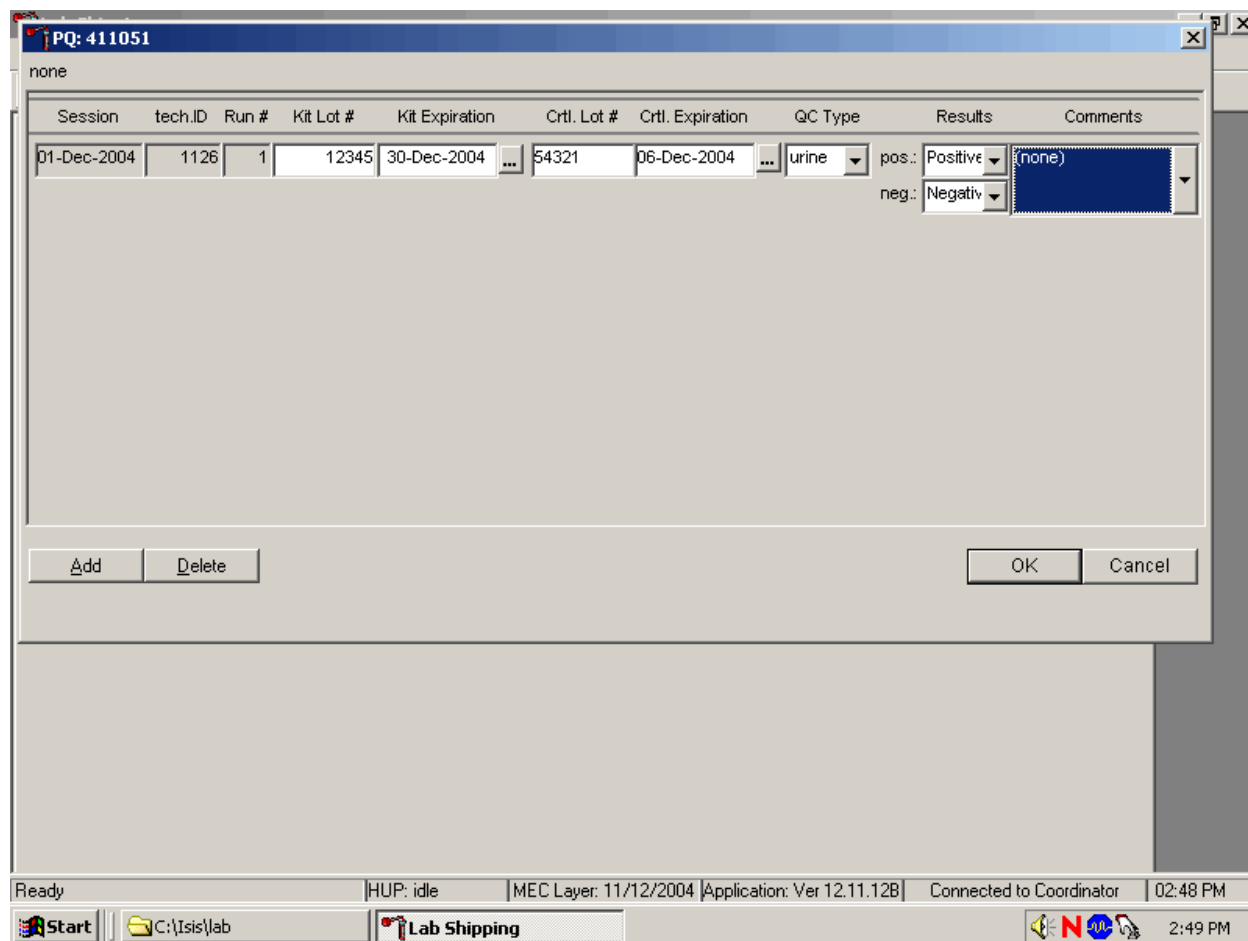
To enter a result in the positive result text box, type [P/p] for “Positive,” [N/n] for “Negative,” or [I/i] for “Invalid” or use the up and down arrow keys to toggle between the three choices: Positive, Negative, and Invalid and select [Tab]. Alternatively, use the mouse to direct the mouse arrow to the drop-down list, drag the mouse arrow to “Positive,” “Negative,” or “Invalid” and left click. If “Positive” is entered, the Negative response box is highlighted. Type [Tab] to move to the negative result text box.

Enter a result in the negative result text box.



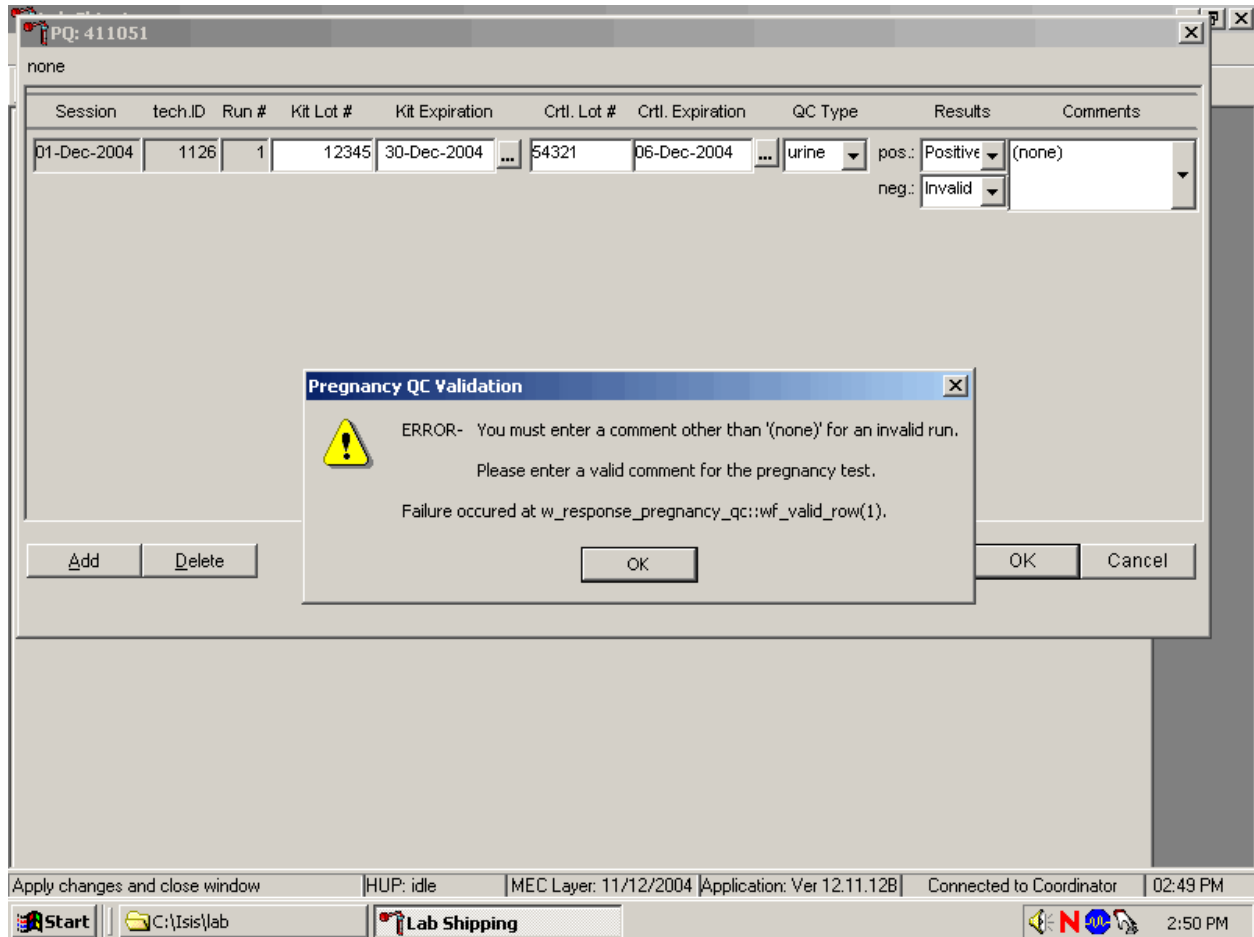
To enter a result in the negative result text box, type [P/p] for “Positive,” [N/n] for “Negative,” or [I/i] for “Invalid” or use the up and down arrow keys to toggle between the three choices: Positive, Negative, and Invalid and [Tab]. Alternatively, use the mouse to direct the mouse arrow to drop-down list, drag the mouse arrow to “Positive,” “Negative,” or “Invalid,” and left click.

Save results when positive and negative controls demonstrate the expected result.



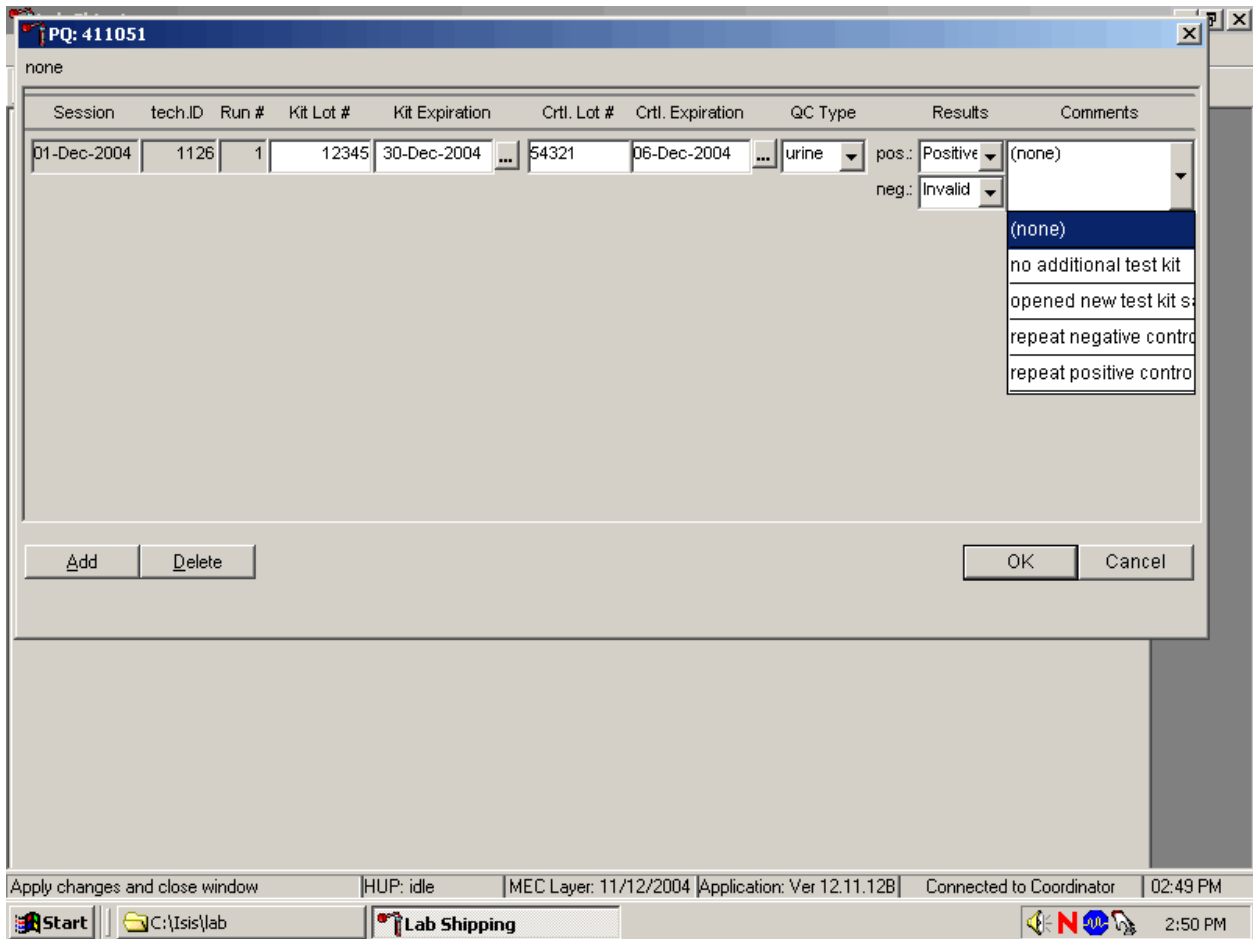
If the positive and negative controls demonstrate the expected result, use the mouse to direct the mouse arrow to the OK button and left click to save these results and to proceed with pregnancy testing. To cancel and exit the module without recording or saving any QC results to the database, use the mouse to direct the mouse arrow to the Cancel button and left click. To delete the information in the window and exit the module without recording or saving any QC results to the database, use the mouse to direct the mouse arrow to the Delete button and left click or type [Shift] [D/d].

Enter a comment for any result that is inconsistent with expected results. If the OK button is selected before a comment is entered, the ERROR informational message box displays. Review the text in this box.



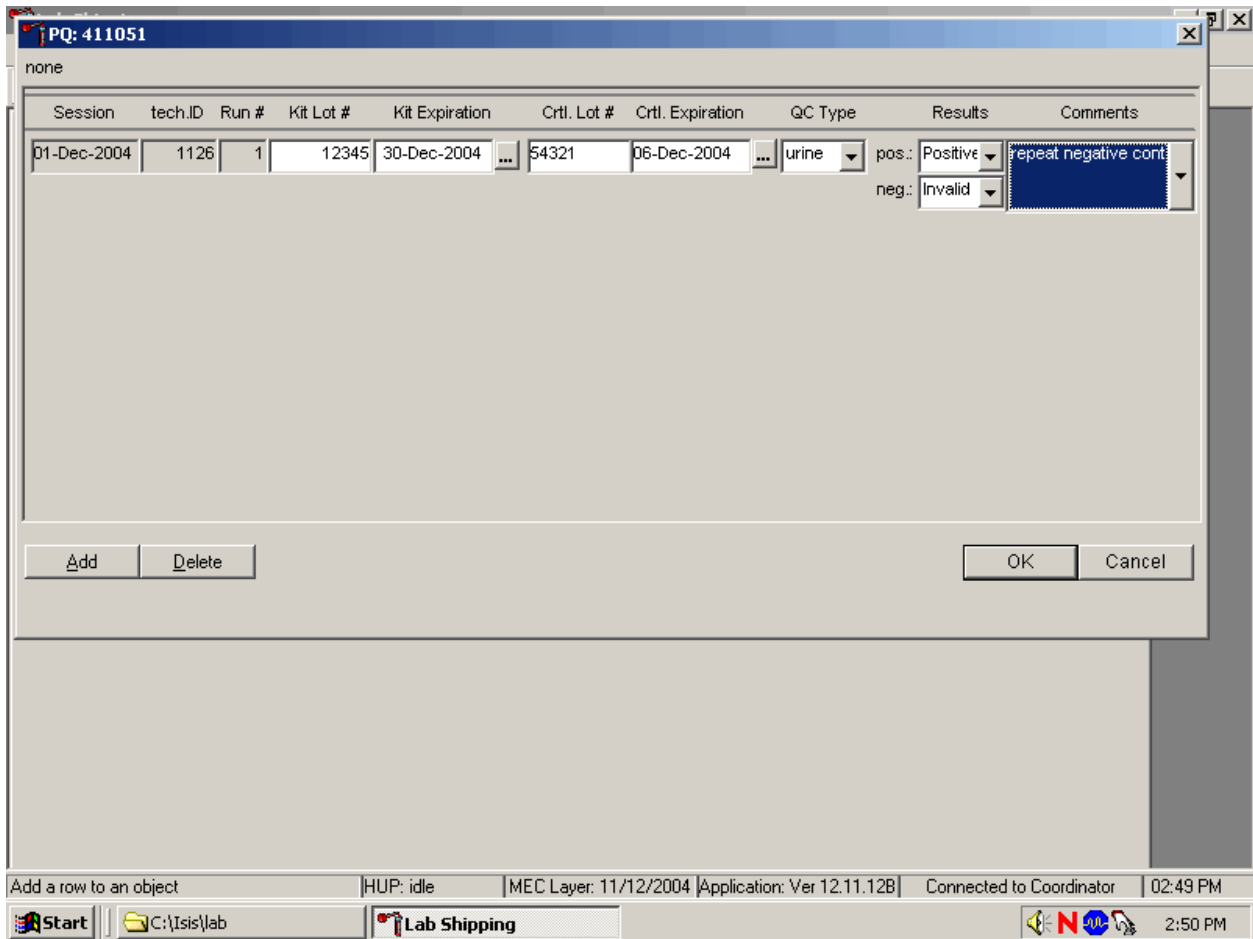
To close the box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

Enter a comment for any result that is inconsistent with expected results.



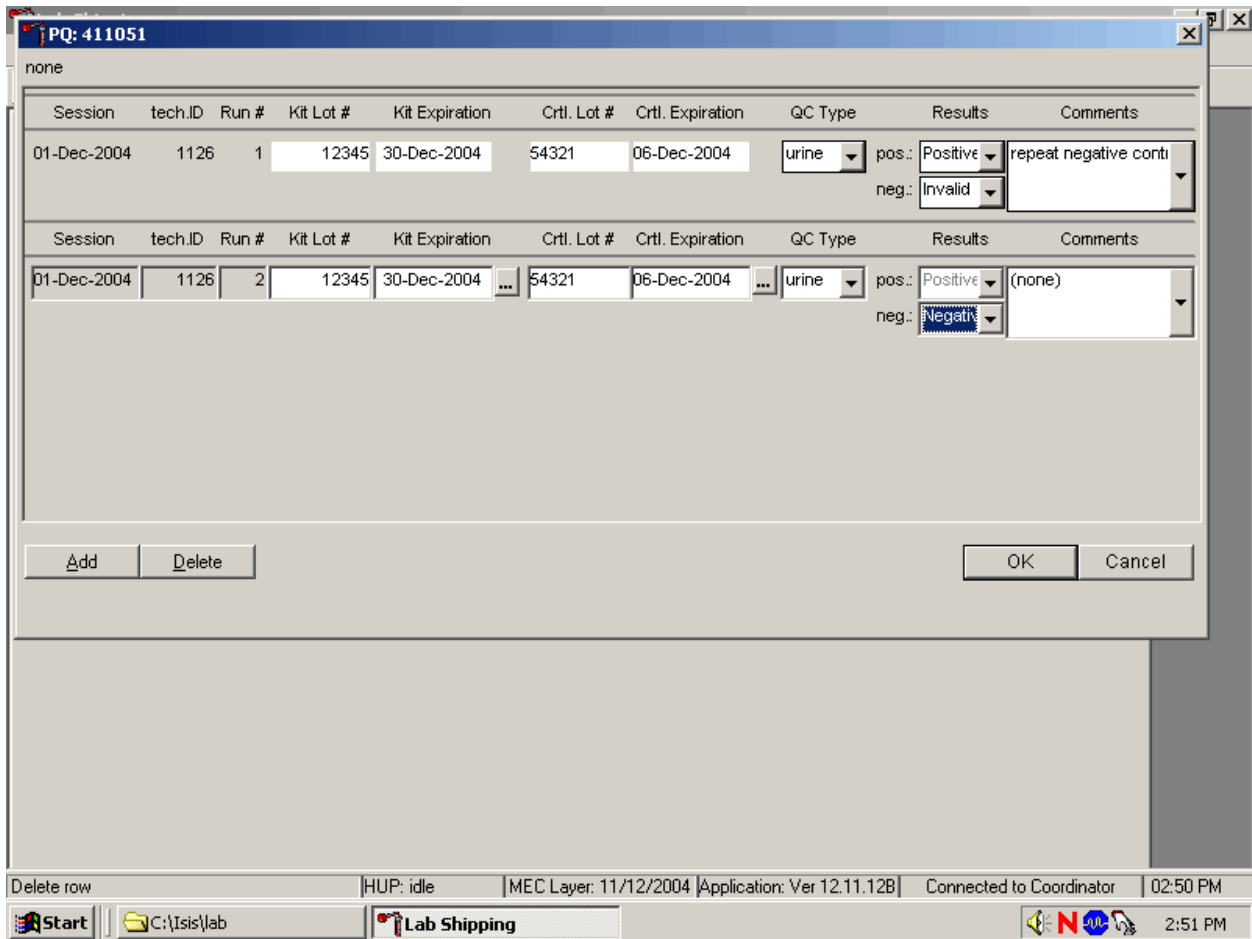
Enter the appropriate comment in the "Comments" column by using the mouse to direct the mouse arrow to the drop-down list, left click to display the choices, drag the mouse arrow to the most appropriate choice, and left click when the correct choice is highlighted. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

Review the comment.



Review all the information in the QC window to verify its accuracy.

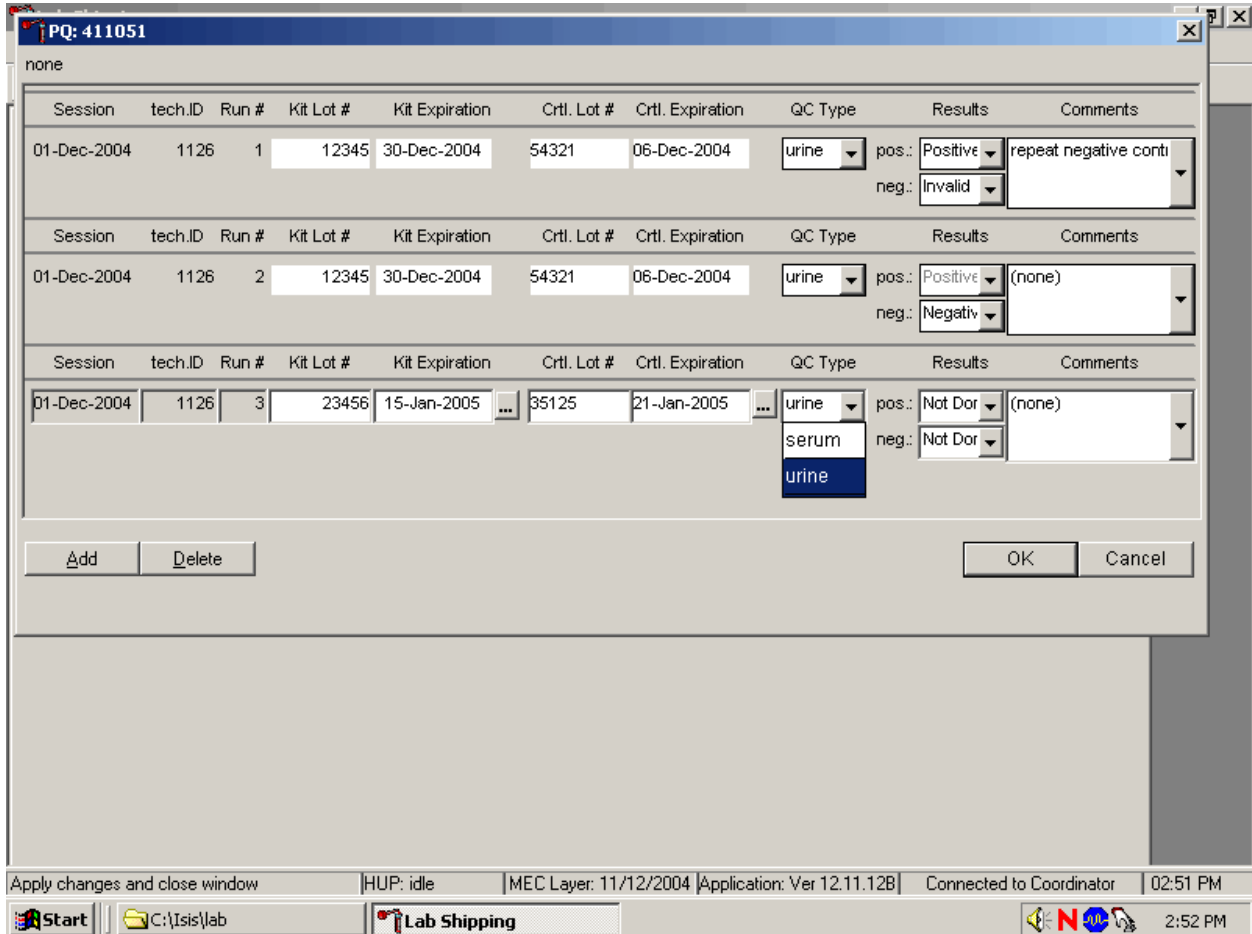
Add a new QC record and repeat the control for invalid or unexpected results.



Rerun or repeat the control that demonstrated the unexpected result. Add a new test line to record the new control results. To add a new QC test line, use the mouse to direct the mouse arrow to the Add button and left click or type [Shift] [A/a]. Record the new results. If this resolves the inconsistency, use the mouse to direct the mouse arrow to the OK button and left click to save these results and to proceed with pregnancy testing.

If this does not resolve the situation, repeat the procedure with a different lot of controls. If this fails to resolve the problem, discard the entire lot of pregnancy test kits and test a new lot.

Add a new test line each time a control is run and remember to record the serum QC each time it is performed.



To add a new QC test line, use the mouse to direct the mouse arrow to the Add button and left click or type [Shift] [A/a]. The QC Type defaults to “Urine.” Correct the control lot number and expiration date. To change the QC type to serum, use the mouse to direct the mouse arrow to the drop-down list, drag the mouse arrow to serum and left click.

Record the serum control results.

| Session | tech.ID | Run # | Kit Lot # | Kit Expiration | Crtl. Lot # | Crtl. Expiration | QC Type | Results | Comments |
|-------------|---------|-------|-----------|----------------|-------------|------------------|---------|----------------------------------|-----------------------|
| 01-Dec-2004 | 1126 | 1 | 12345 | 30-Dec-2004 | 54321 | 06-Dec-2004 | urine | pos.: Positive neg.: Invalid | repeat negative conti |
| 01-Dec-2004 | 1126 | 2 | 12345 | 30-Dec-2004 | 54321 | 06-Dec-2004 | urine | pos.: Positive neg.: Negative | (none) |
| 01-Dec-2004 | 1126 | 3 | 23456 | 15-Jan-2005 | 35125 | 21-Jan-2005 | urine | pos.: Positive neg.: Negative | (none) |

Buttons: Add, Delete, OK, Cancel

Taskbar: Start, C:\Isis\lab, Lab Shipping, 2:52 PM, 11/12/2004

If the positive and negative serum controls demonstrate the expected result, use the mouse to direct the mouse arrow to the OK button and left click to save these results and to proceed with pregnancy testing. If the positive and/or the negative serum controls fail to demonstrate the expected result(s), add a new QC record, and repeat the control.

XI. Interpretation of Results and Remedial Action

ICON® 25 hCG Test

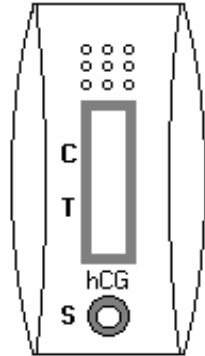


Figure 1
ICON 25 test device

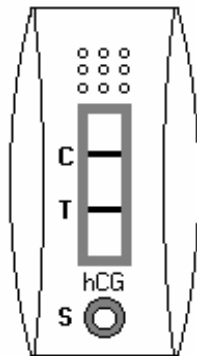


Figure 2
Positive Result
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

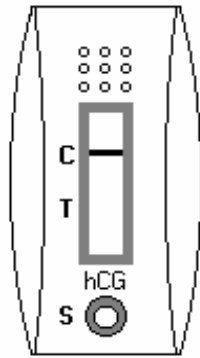


Figure 3
Negative Result
One red line appears in the control region (C). No apparent red or pink line appears in the test region.

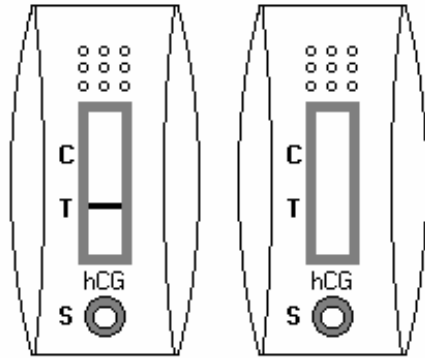


Figure 4
Invalid Result
Control line fails to appear.

Positive Result:

A specimen that produces two distinct red lines is positive for the presence of hCG. One line should be in the control region (C) and another line should be in the test region (T).

Negative Result:

A specimen that does produce a red line appears in the control region (C) or no apparent red or pink line in the test region is negative for the presence of hCG.

Invalid Result (any of the following):

For the test to be valid, a red line must appear in the control region (C). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit and immediately contact the technical supervisor.

If an invalid test result occurs repeatedly, or for technical assistance, contact the Technical Support Department, 1-800-877-6242.

Sure-Vue™ hCG Urine and Serum Control Sets

Positive Result:

The 25 mIU/mL hCG positive urine and serum controls should produce positive results.

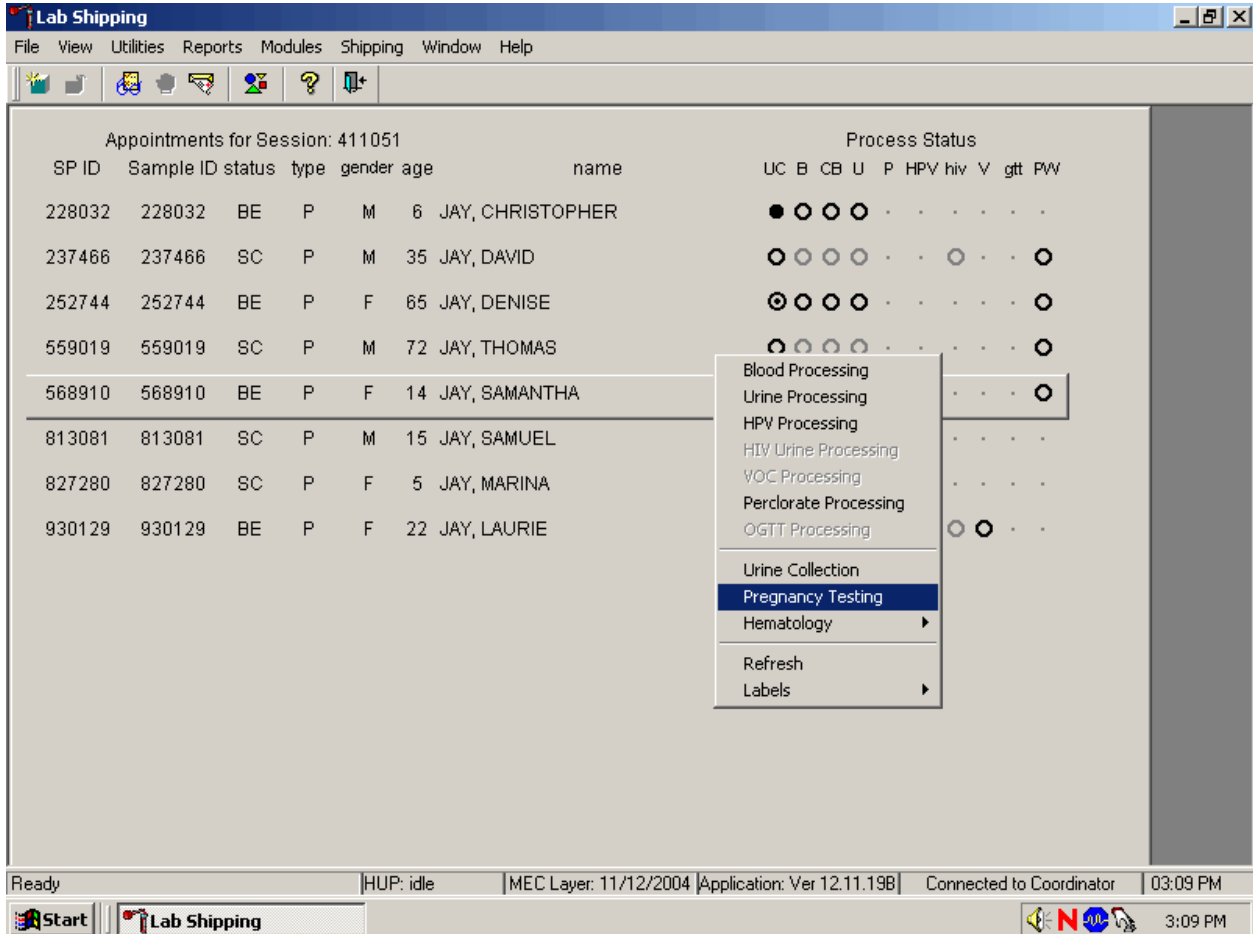
Negative Result:

The negative urine and serum control should produce a negative result.

XII. Record Results

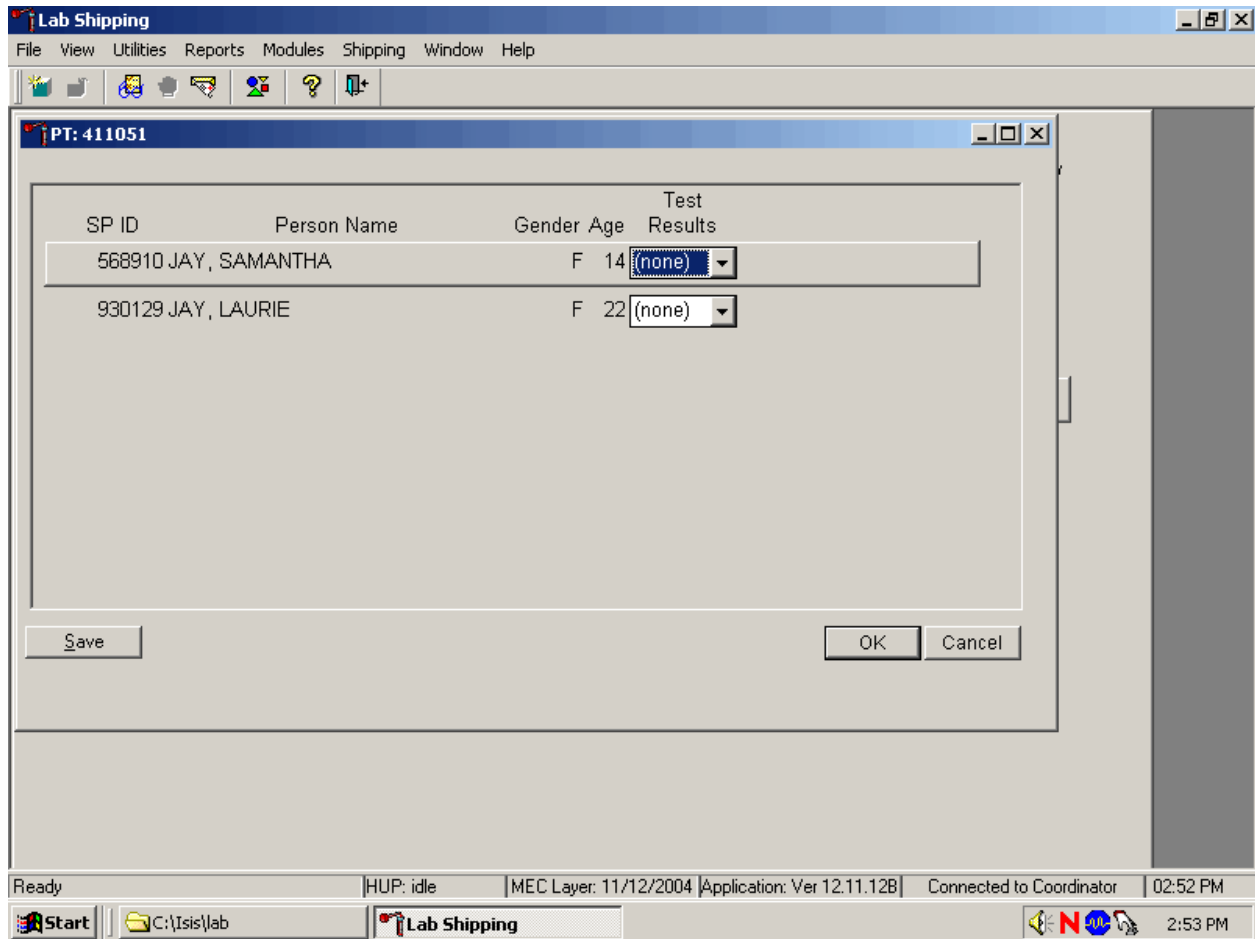
Use the heads-up display and the Pregnancy Testing module to enter the results of the ICON® 25 hCG test kit pregnancy test result for each SP.

Use the heads-up display to access the Pregnancy Testing module.



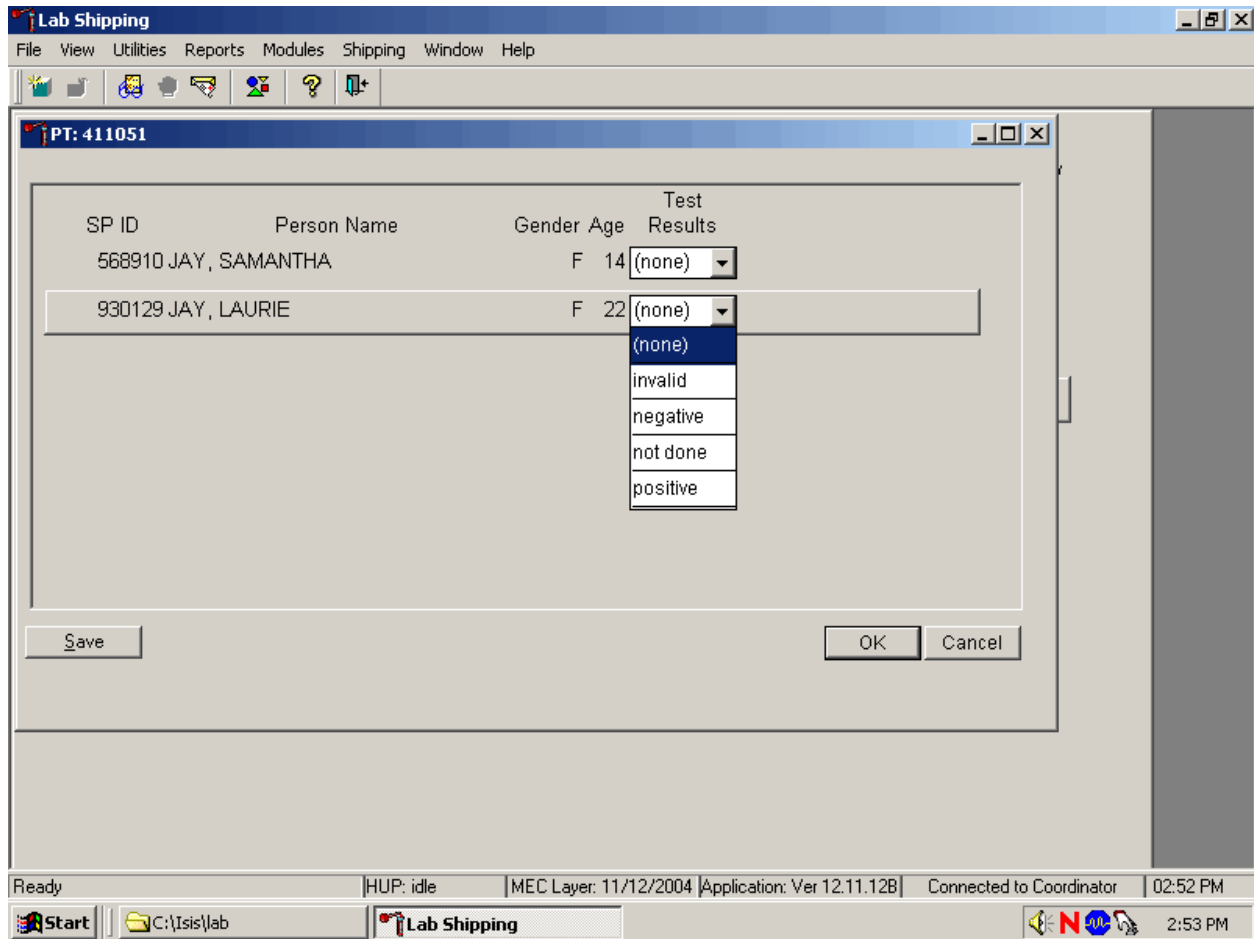
To access the Pregnancy Testing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing}, and left click, or left click and type [P/p]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to {Pregnancy Testing}, and left click, or left click and type [P/p].

The Pregnancy Testing window displays.



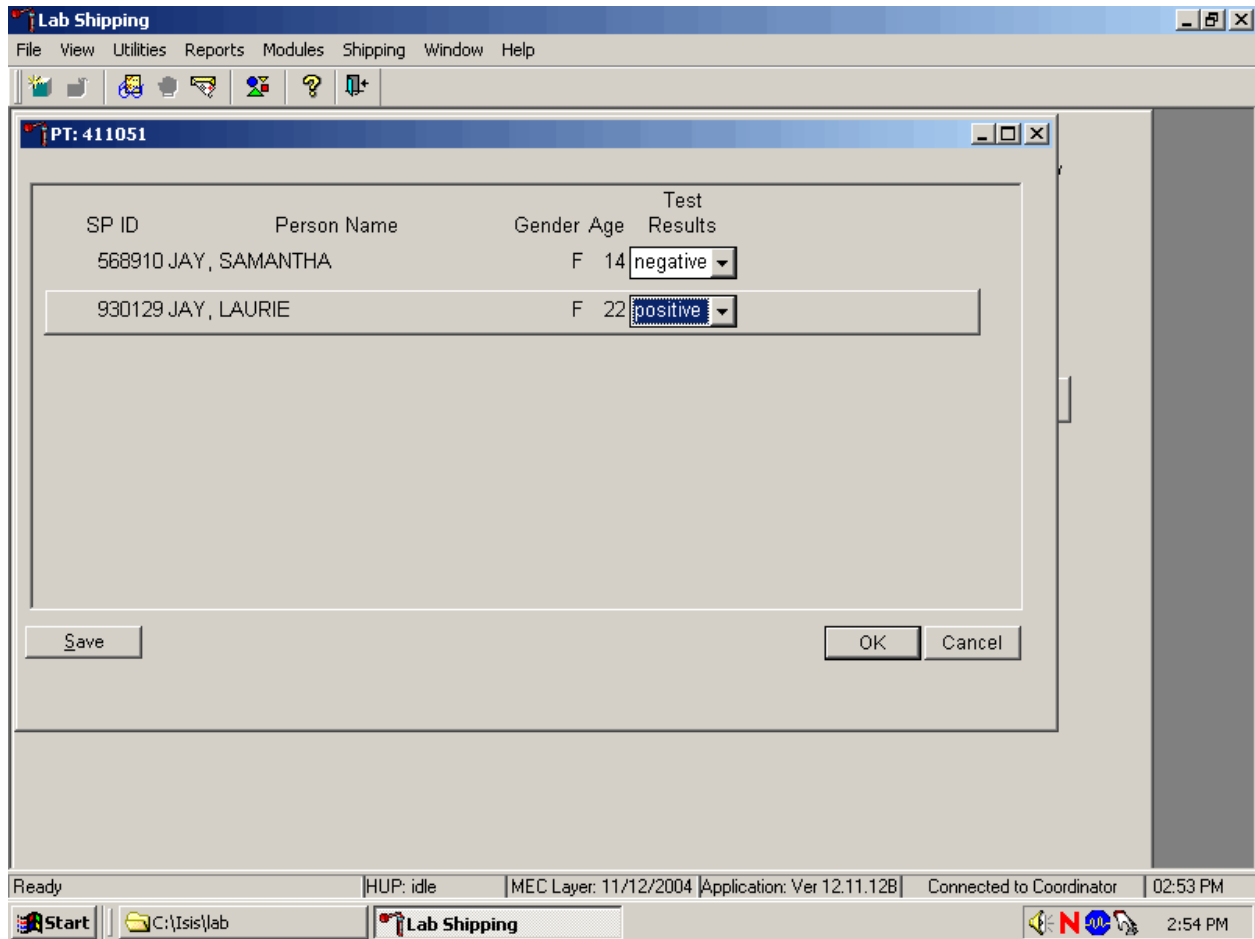
The text is black for SPs who have urine collection results recorded as “yes” or “yes/QNS.” The text is gray for SPs who do not have urine collection results recorded. The window lists the SP ID, Person Name, Gender, Age, and includes a Test Results column (text box).

Report the results for each SP as positive, negative, or invalid.



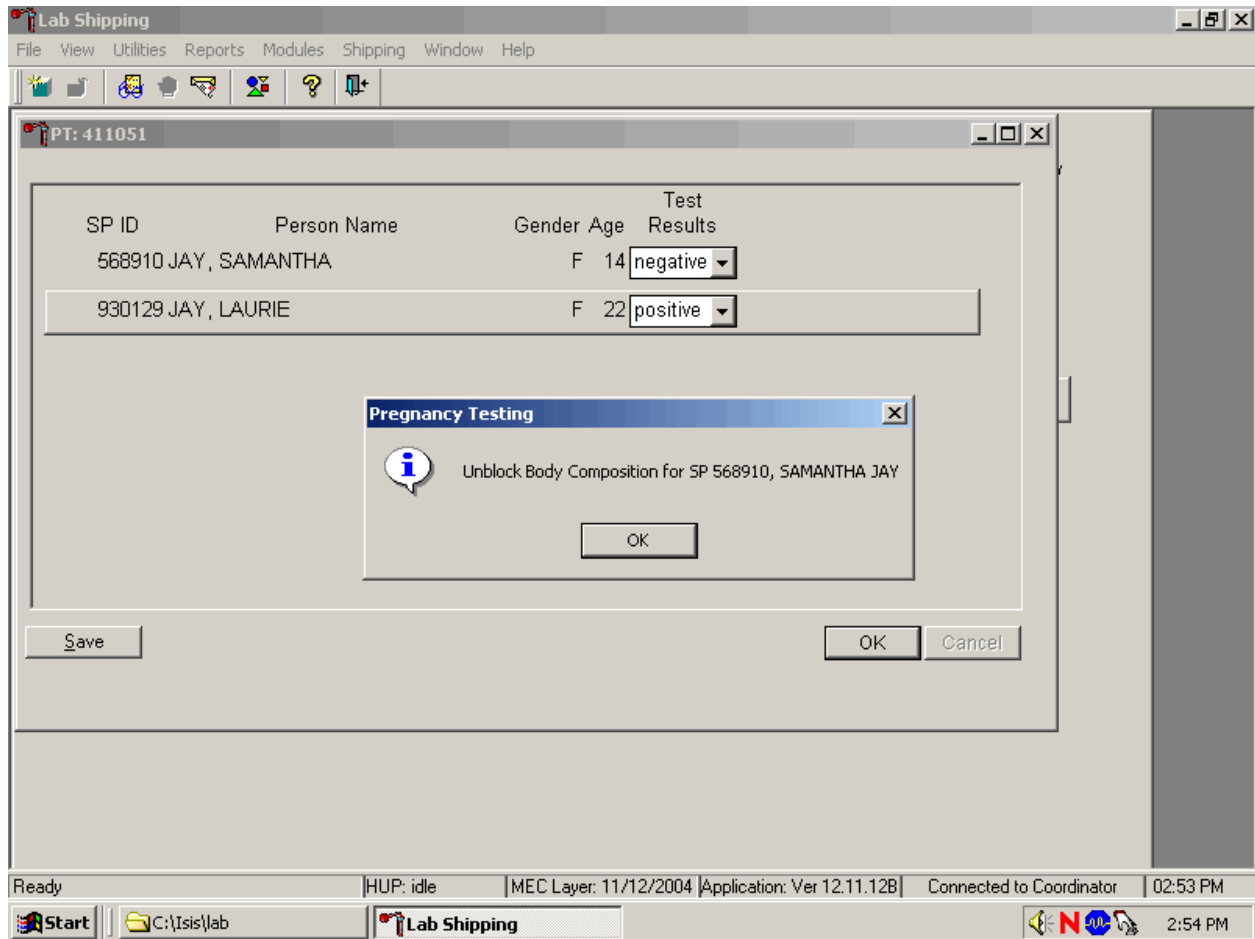
If the Test Result field is black or highlighted, record the result by typing [P/p] for positive, [N/n] for negative, or [I/i] for an invalid result. Alternatively, to record a result, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct choice and left click. To update the results without exiting the window, use the mouse to direct the mouse arrow to the Save button and left click or type [ALT] [S/s]. To update the results and exit the window, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit the module without saving any result, use the mouse to direct the mouse arrow to the Cancel button and left click.

Continue performing pregnancy tests and recording the results.



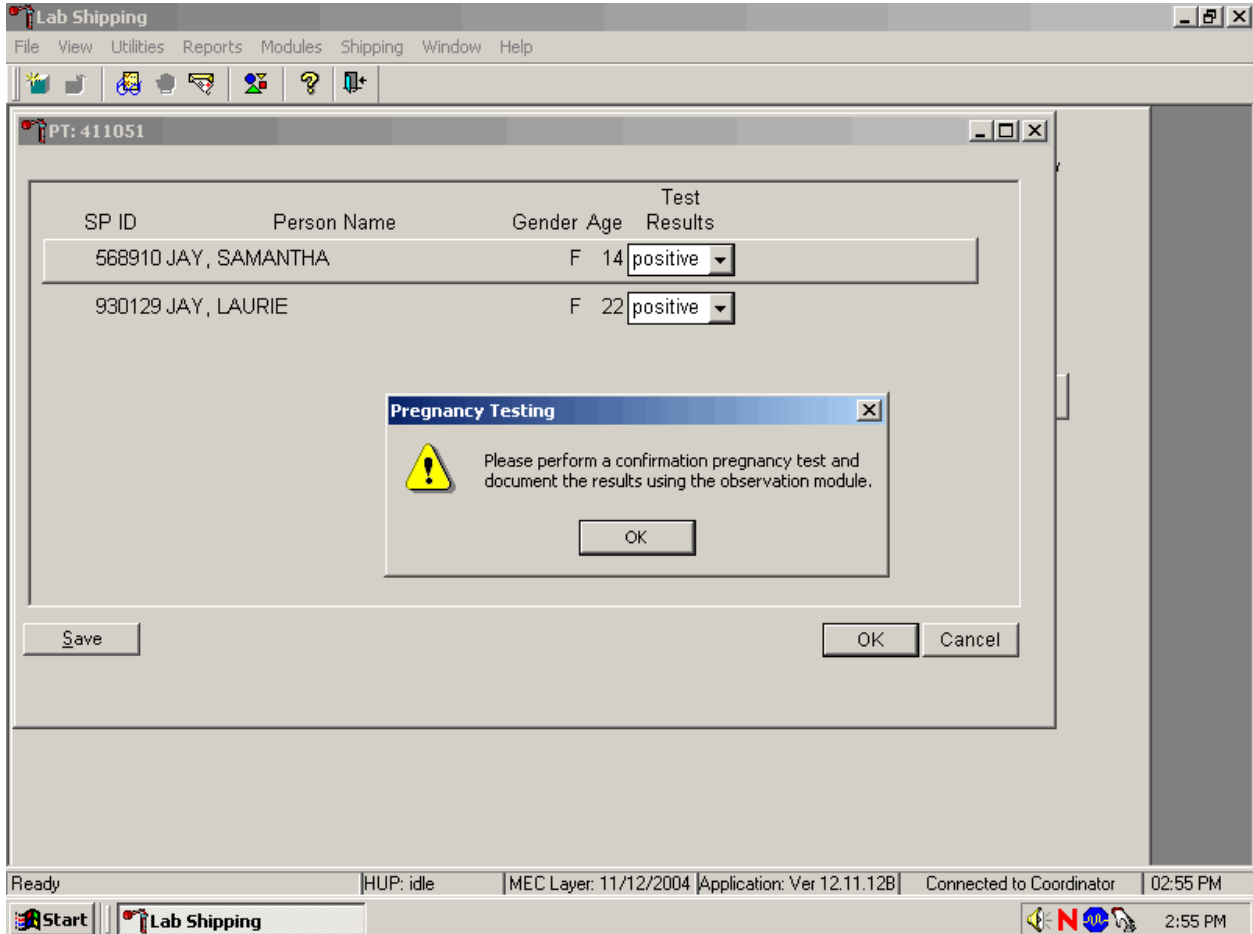
Save the test results after entering each positive, negative, or invalid result. To update the results without exiting the window, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To update the results and exit the window, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit the module without saving any result, use the mouse to direct the mouse arrow to the Cancel button and left click.

After each negative result is saved to the database, an unblocking message box displays.



To remove the informational message box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

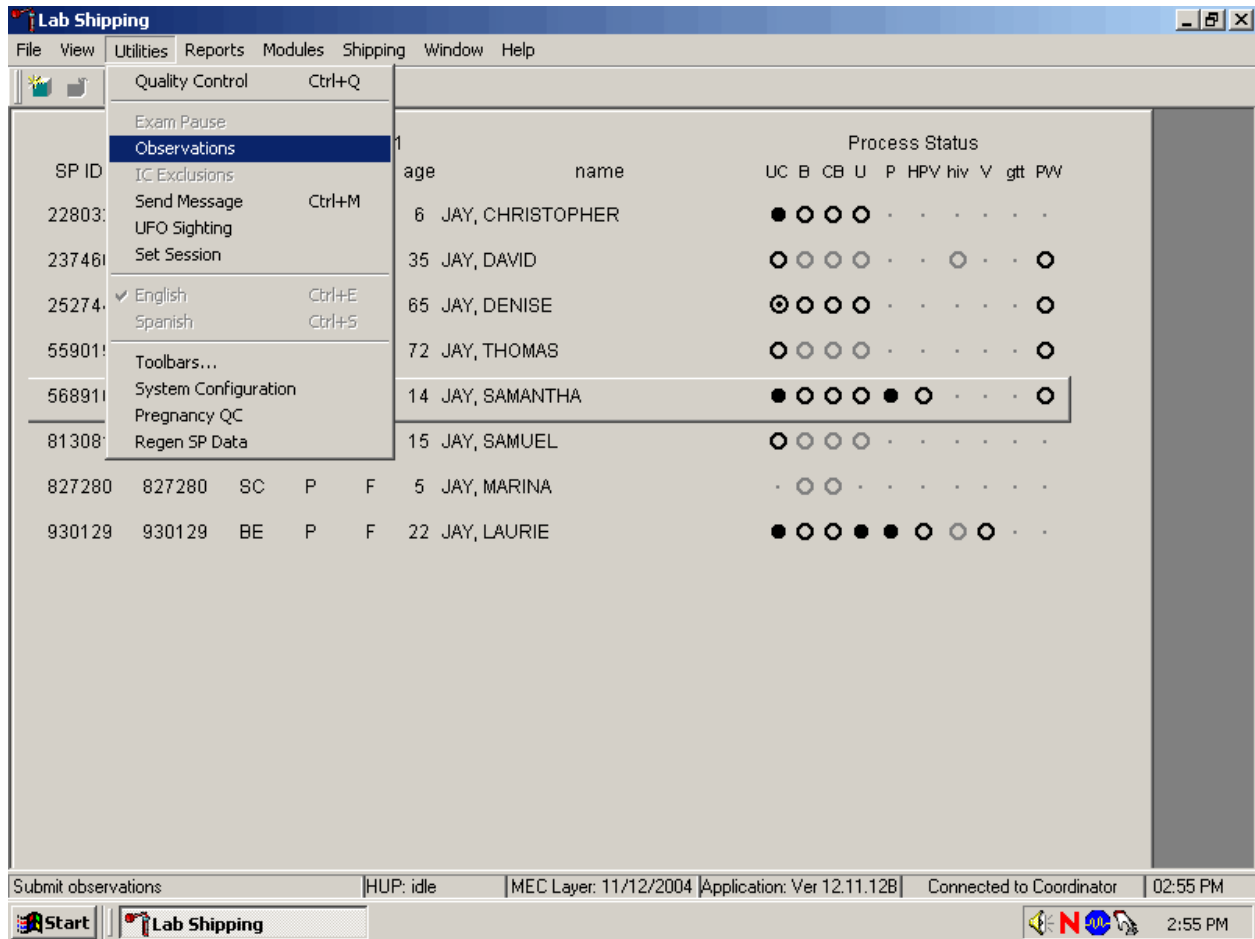
If a urine pregnancy test is positive on any female SPs aged 8-17 years, confirm the result using serum. An informational pop-up box displays as a reminder to perform the confirmation test.



To remove the informational message box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

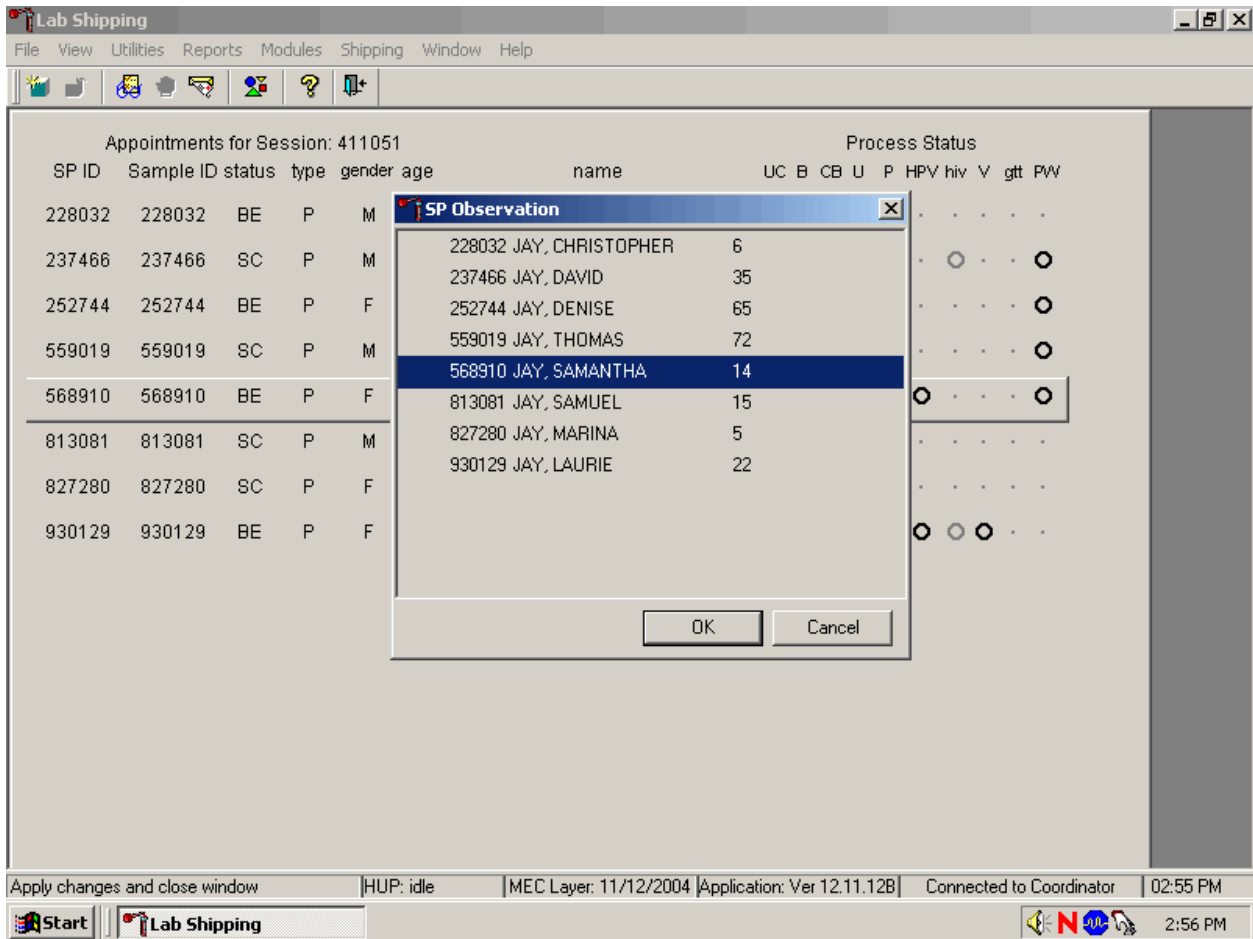
If no blood is drawn, repeat the urine test. **Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.**

Access the observation function to send an observation to the physician.



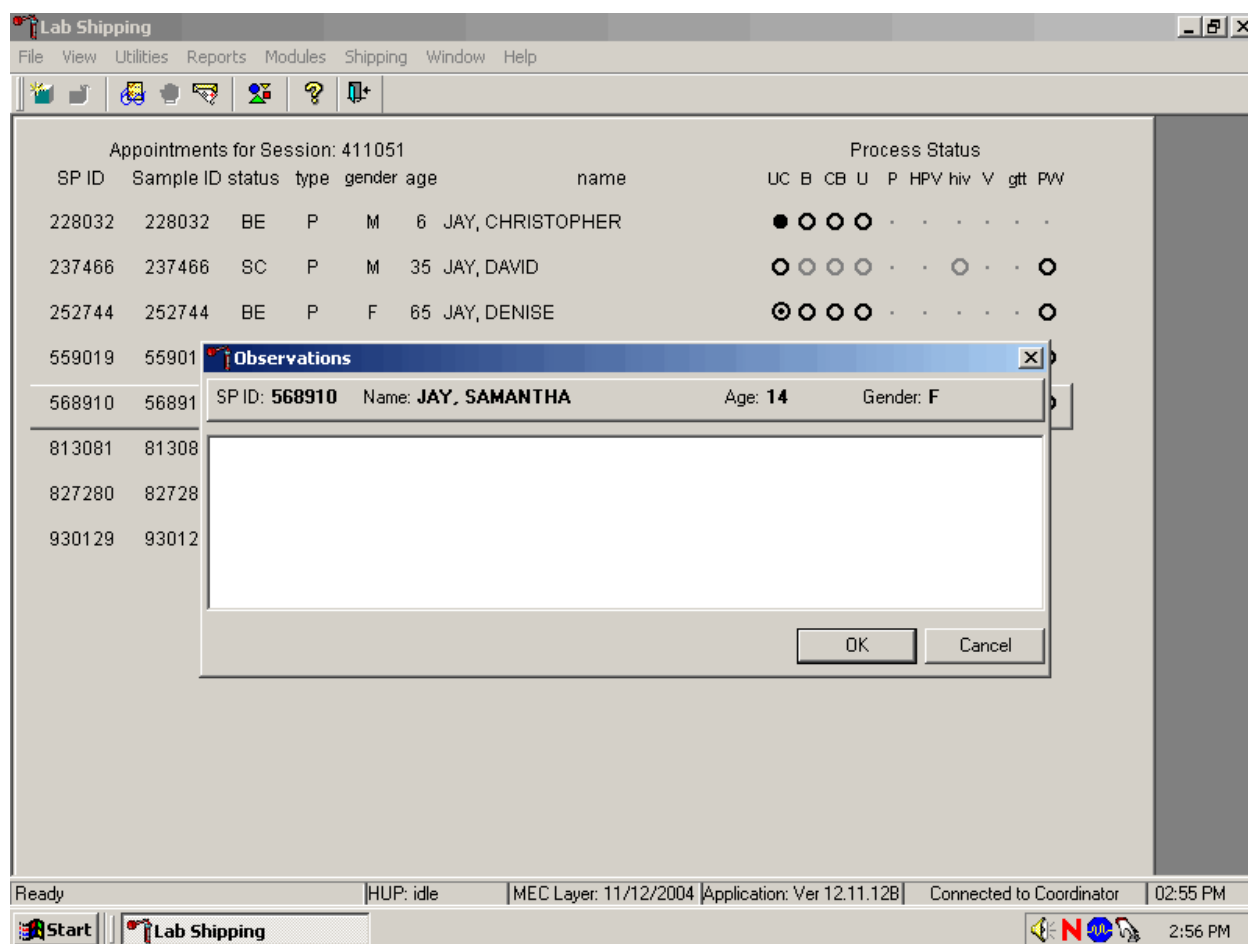
To send an observation to the physician, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the mouse arrow to {Observations} and left click or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



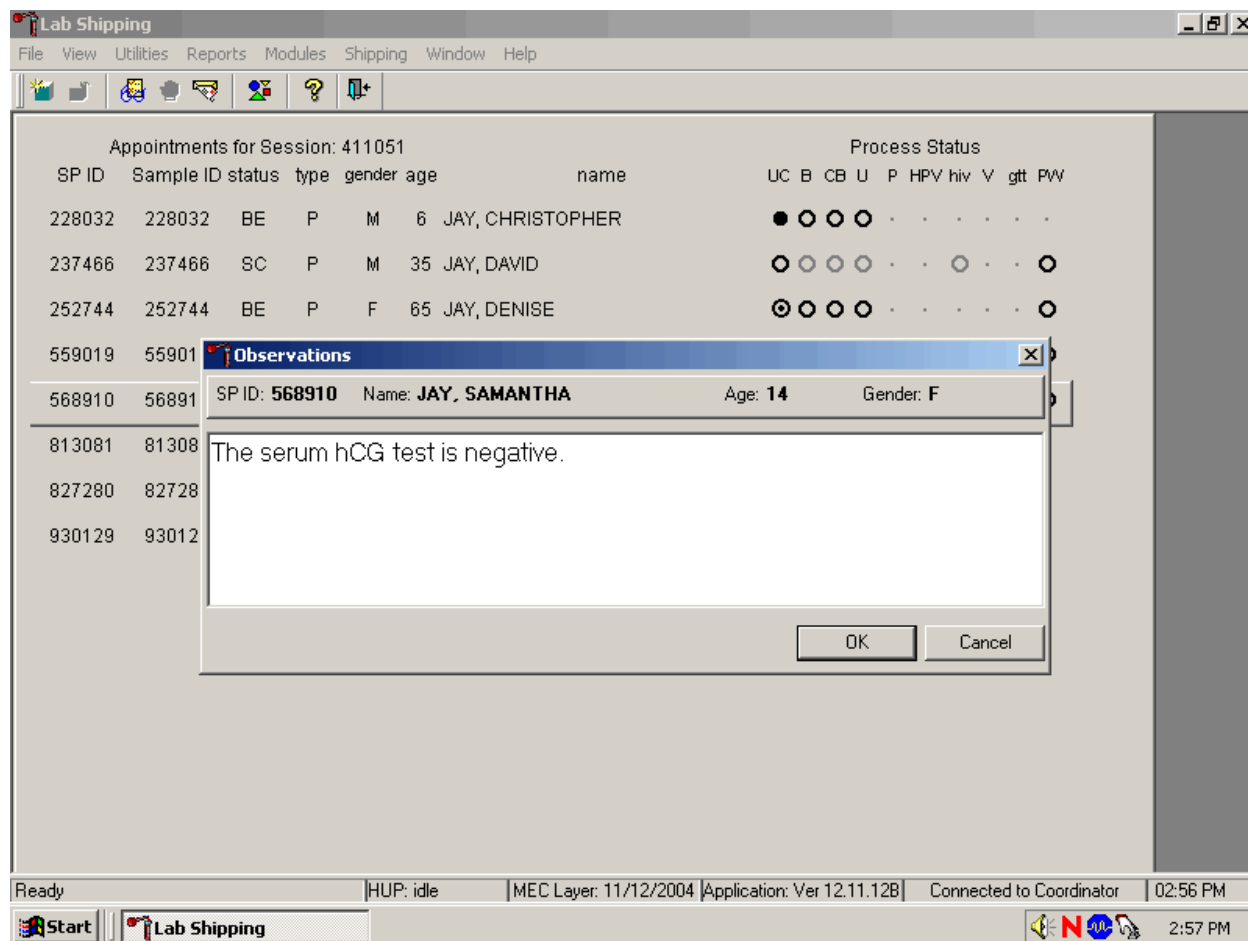
To select or highlight an SP, drag the mouse arrow to the correct SP and left click. Verify that the SP ID, name, and age are correct. Use the vertical scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the Cancel button and left click.

The observation text window displays.



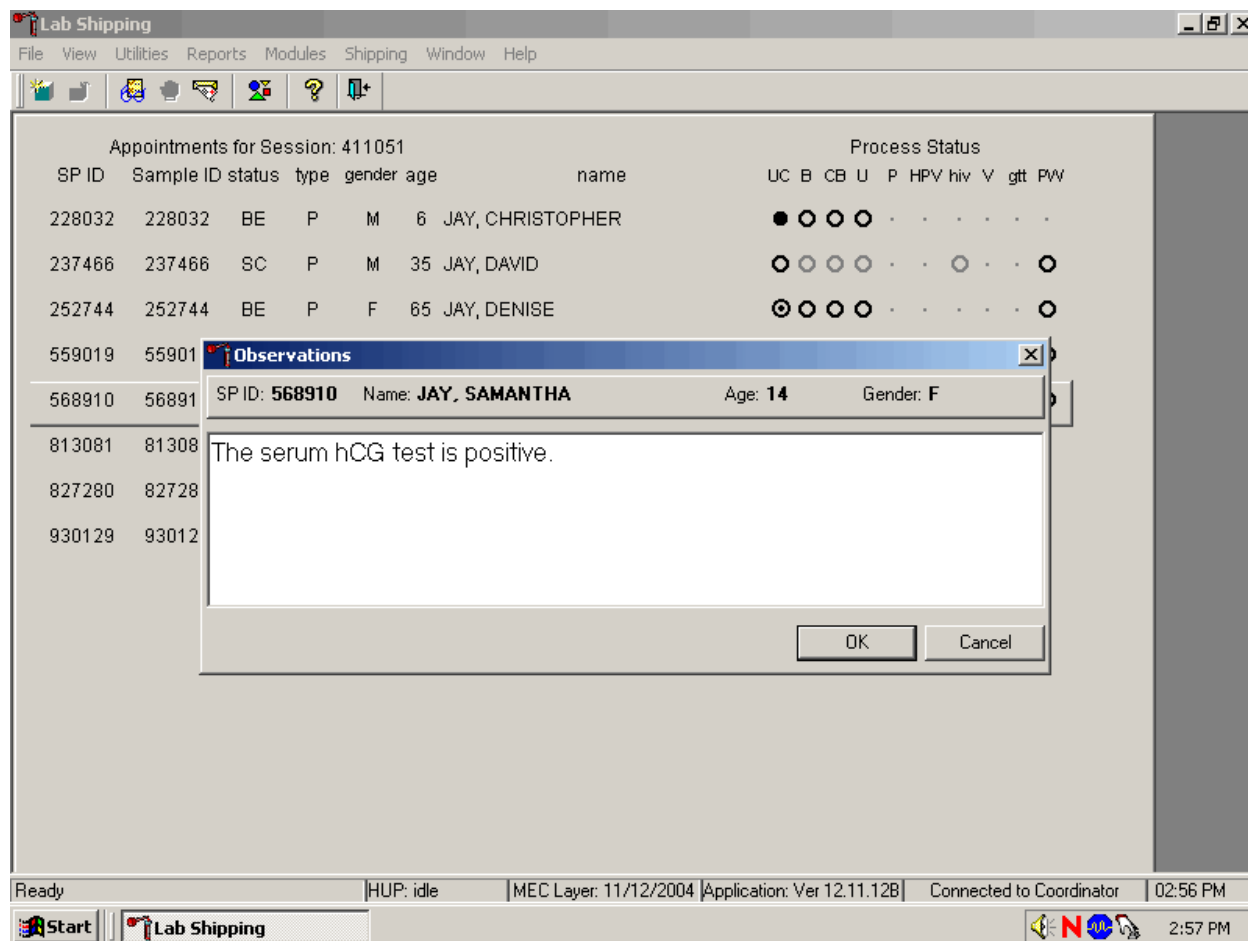
The observation text window contains the SP ID, name, age, and gender. Type the observation using the keyboard's keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report a negative serum test result on SPs aged 8-17 years.



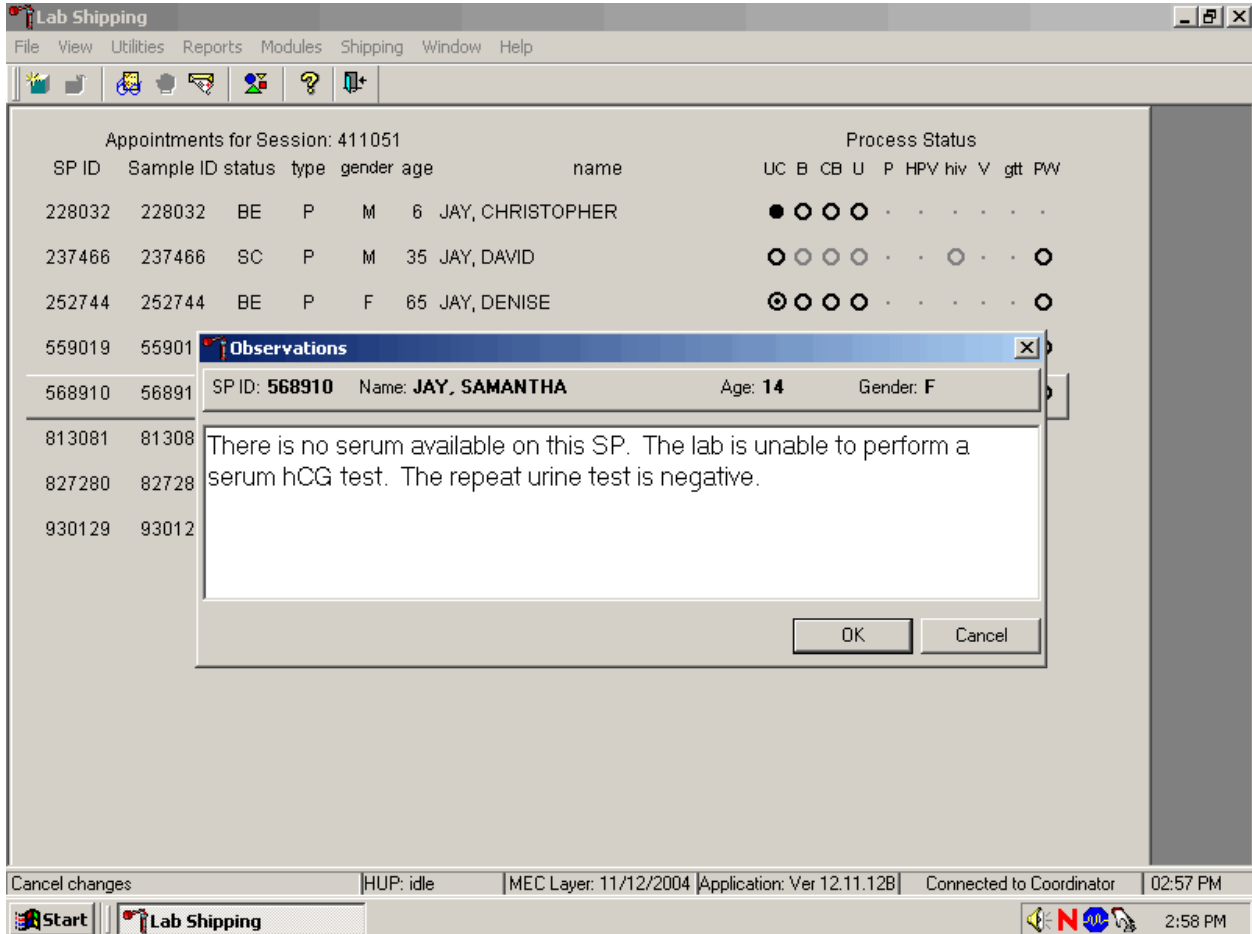
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum hCG test is negative” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report a positive serum test result on SPs aged 8-17 years.



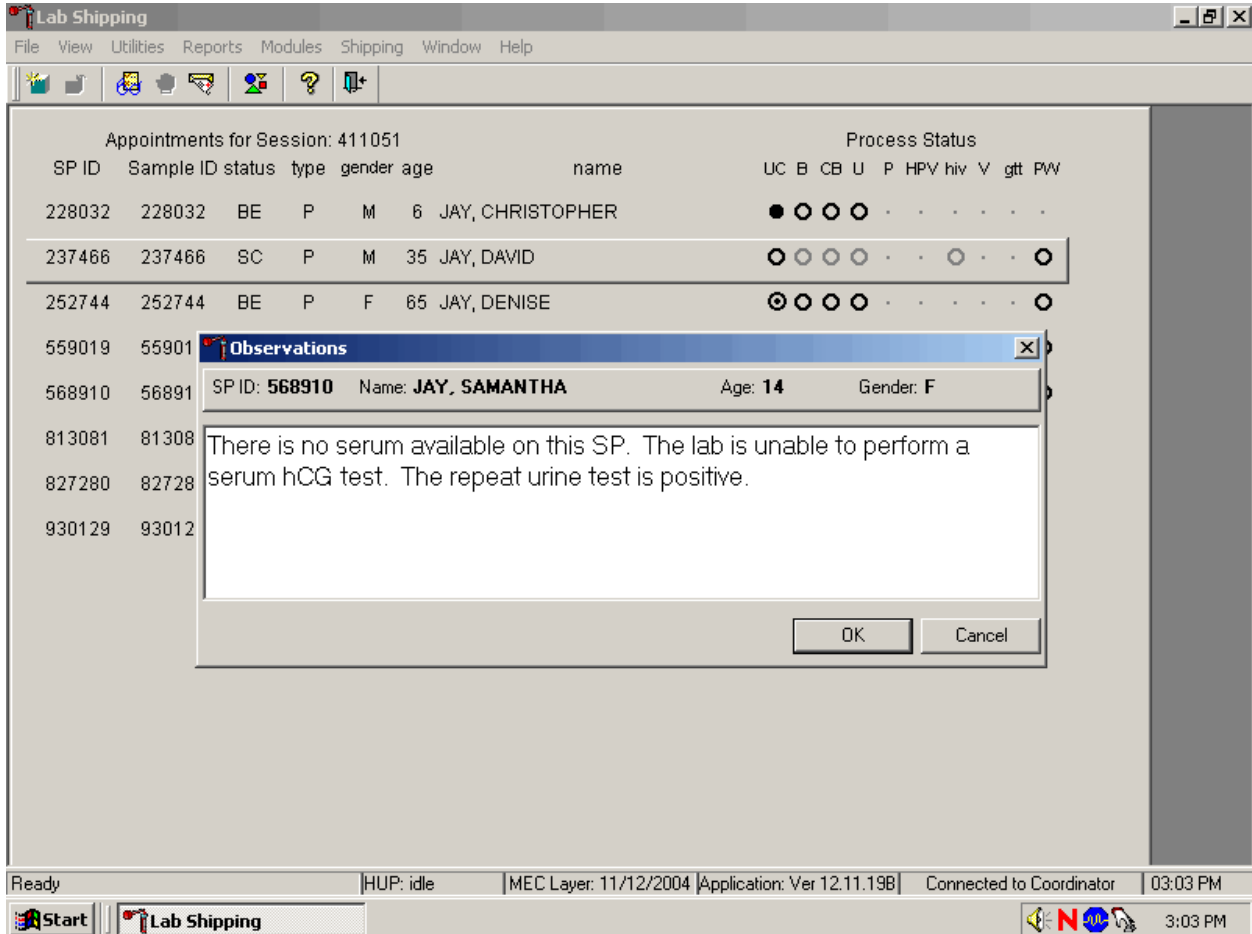
The observation window contains the SP ID, name, age, and gender. Type the observation, “The serum hCG test is positive” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report the inability to perform the serum confirmation test and to report the results of a repeat negative urine test on female SPs aged 8-17 years.



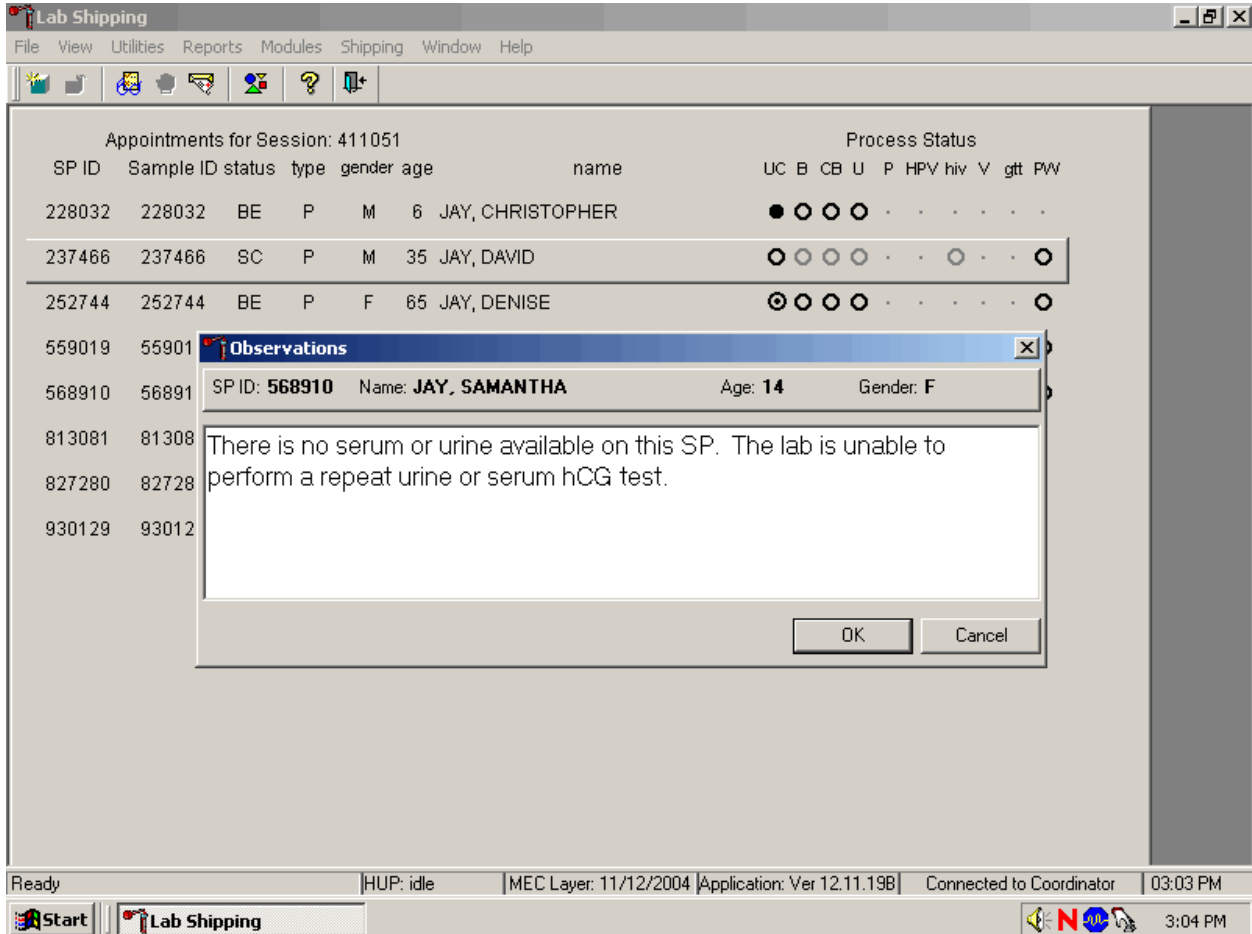
The observation window contains the SP ID, name, age, and gender. Type the observation, “There is no serum available on this SP. The lab is unable to perform a serum hCG test. The repeat urine hCG test is negative.” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report the inability to perform the serum confirmation test and to report the results of a repeat positive urine test on female SPs aged 8-17 years.



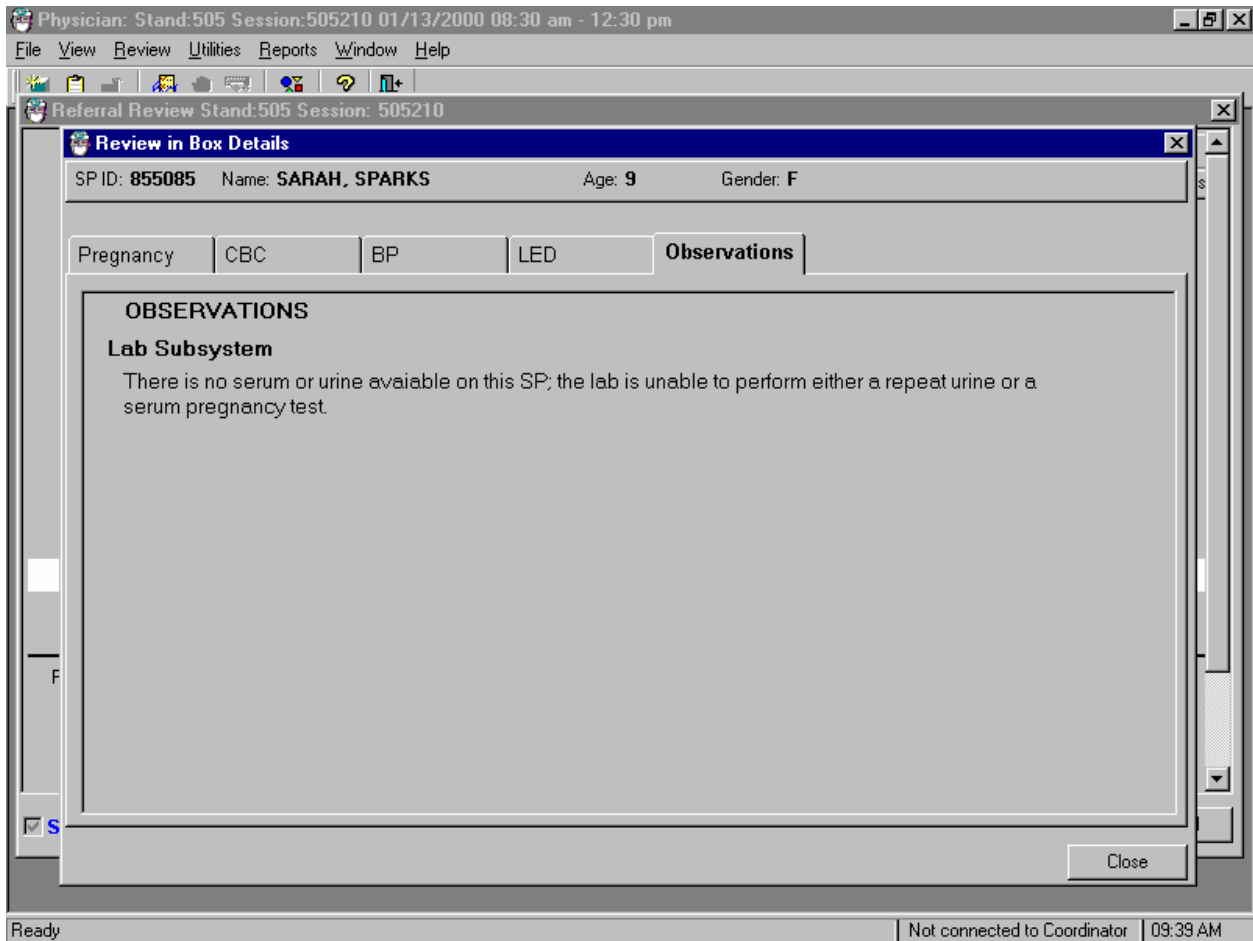
The observation window contains the SP ID, name, age, and gender. Type the observation, “There is no serum available on this SP. The lab is unable to perform a serum hCG test. The repeat urine test is positive.” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Send an observation to report the inability either to perform the serum confirmation test or to repeat the urine test on female SPs aged 8-17 years.



The observation window contains the SP ID, name, age, and gender. Type the observation, “There is no serum or urine on this SP. The lab is unable to perform either a repeat urine or serum hCG test.” using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

The physician reviews all observations.



The physician accesses the observations using the Review in Box Details.

XIII. Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions

Read the following procedural notes to ensure the best results with the ICON 25 hCG test kit.

ICON® 25 hCG Test

- Dispensing Specimen – Do not reuse a test device or use a test device for multiple patient samples or controls, as this will produce inaccurate results.
- Incubation Times – The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the sample. However, neither the qualitative value nor the rate of increase in hCG can be determined by this qualitative test.
- Batch Processing – If several specimens are to be tested during one run, perform each test step for all specimens and controls at timed intervals before proceeding to the next test step. It is recommended that no more than ten (10) test devices be run in one batch.
- Specimens Containing Particulate Matter – Urine samples exhibiting visible precipitates should be centrifuged or allowed to settle to obtain a clear sample for testing.
- Very dilute urine samples, as indicated by a low specific gravity, may not contain representative levels of hCG.
- False negative results may occur when the levels of hCG are below the sensitivity level of the test.
- Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum samples shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed.

- A number of conditions other than pregnancy, including trophoblastic disease and certain nontrophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine or serum should not be used to diagnose pregnancy unless these conditions have been ruled out.
- This test provides a presumptive diagnosis for pregnancy. A physician should only make a confirmed pregnancy diagnosis after all clinical and laboratory findings have been evaluated.
- Negative results are expected in healthy nonpregnant women and healthy men. Healthy pregnant women have hCG in their urine and serum samples. The amount of hCG will vary greatly with gestational age and between individuals. Concentrations of hCG in pregnant women are generally between 10 and 30 mIU hCG/mL in the 7-10 days following implantation or 3 weeks after the last menstrual period (LMP). During the latter part of the first trimester of pregnancy, the hCG concentration reaches a maximum level of greater than 100,000 mIU/mL.
- The ICON 25 hCG test has a stated sensitivity of 25 mIU/mL and is capable of detecting pregnancy as early as 1 day after the first missed menses.
- Do not use urine samples containing grossly hemolyzed blood since they may give inaccurate or erratic results.

Sure-View™ hCG Urine and Serum Control Sets

- These controls are formulated for use as quality control specimens in the reagent verification of pregnancy test kits.

Sensitivity and Specificity

ICON® 25 hCG Test

Accuracy

A multicenter clinical evaluation was conducted comparing the results obtained using the ICON® 25 hCG test and another commercially available urine/serum membrane hCG test. The urine study included 159 samples and both tests identified 88 negative and 71 positive results. The serum study included 73 samples and both assays identified 51 negative and 21 positive and 1 inconclusive results. The results demonstrated a 100 percent overall agreement (for an accuracy of >99%) of the ICON® 25 hCG test when compared to the other urine/serum membrane hCG test.

| | | Commercially Available Test | |
|-----------------------|---|-----------------------------|----|
| | | + | - |
| ICON® 25 hCG Urine | + | 71 | 0 |
| | - | 0 | 88 |

| | | Commercially Available Test | |
|-----------------------|---|-----------------------------|----|
| | | + | - |
| ICON® 25 hCG Serum | + | 21 | 0 |
| | - | 0 | 51 |

Sensitivity

- The ICON® 25 hCG test detects hCG at concentrations of 25 mIU hCG/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of 300 mIU/mL of luteinizing hormone, (LH), 1000 mIU/mL of follicle stimulating hormone (FSH), and 1000 mIU/mL of thyroid stimulating hormone (TSH) to negative (0 mIU/mL hCG) urine/serum specimens and to positive (25mIU/mL hCG) urine/serum specimens did not exhibit cross-reactivity in the assay.

Specificity

- The following potentially interfering substances were added to hCG negative and positive samples.
- None of the substances at the concentrations tested interfered in the test.

Interfering Substances

| Substance Added | Concentration |
|------------------------|----------------------|
| Acetaminophen | 20 mg/dL |
| Ascorbic Acid | 20 mg/dL |
| Caffeine | 20 mg/dL |
| Gentisic Acid | 20 mg/dL |
| Acetylsalicylic Acid | 20 mg/dL |
| Atropine | 20 mg/dL |
| Bilirubin (serum) | 40 mg/dL |
| Glucose | 2 g/dL |
| Hemoglobin | 1 mg/dL |
| Bilirubin (Urine) | 2 mg/dL |
| Triglycerides | 1200 mg/dL |

Sure-Vue™ hCG urine and Serum Controls

These controls have been designed to produce correct results in pregnancy test kits. These controls have been tested with the ICON® 25 hCG test and were found to produce satisfactory results.

XIV. Reference Ranges

Not applicable.

XV. Action Limits

Not applicable.

XVI. Specimen Storage and Handling During Testing

Serum

Serum is required; do not use plasma. Specimens may be stored for 48 hours at 2°C - 8°C (36°F - 46°F) before testing. Specimens held for longer times should be frozen at -20°C (-4°F) before testing. Bring all specimens to room temperature before beginning the assay procedure and mix before testing. Use clear nonhemolyzed samples when possible.

Urine

A urine sample must be collected in a clean and dry container. Centrifuge very turbid urine specimens at 2500 RPM for 5 minutes before use. Do not shake or disturb specimens containing particulate matter, such as salts that have settled out of solution; pipette samples from the clear supernatant of such specimens.

XVII. Alternative Method for Performing Test or Storing Specimens if Test System Fails

There is no alternative method for testing.

XVIII. Test Results Reporting System Protocol for Reporting Action Limits

Not applicable.

XIX. Specimen Accountability and Tracking

All records, including QA/QC data are maintained for 6 years. Use only numerical identifiers for SP results.

XX. Quality Control Summary Statistics and Graphs

Quality control reports are monitored by stand and maintained for 6 years.

XXI. References

Batzer, F.R. (1980). Hormonal evaluation of early pregnancy, *Fertility & Sterility*, 34(1), 1-13.

Catt, K.J., Dafau, M.L., and Vaitukaitis, J.L. (1975). Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte, *J. Clin. Endocrinol. Metab.*, 40(3), 537-540.

Braunstein, G.D., Rasor, J., Adler, J., and Danzer, H. (1976). ME Wade Serum human chorionic gonadotropin levels throughout normal pregnancy, *AM. J. Obstet. Gynecol.*, 126(6), 678-681.

Lenton, E.A., Neal, L.M., and Sulaiman, R. (1982). Plasma concentrations of human chorionic gonadotropin from the time of implantation until the second week of pregnancy, *Fertil. Steril.*, 37(6), 773-778.

Steier, J.A., Bergsjö, P., and Myking, O.L. (1984). Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy, *Obstet. Gynecol.*, 64(3), 391-394.

Dawood, M.Y., Saxeba, B.B., and Landersman, R. (1977). Human chorionic gonadotropin and its subunits in hydatiform mole and choriocarcinoma, *Obstet. Gynecol.*, 5(2), 172-181.

Braunstein, G.D., Vaitukaitis, J.L., Carbone, P.P., and Ross, G.T. (1973). Ectopic production of human chorionic gonadotropin by neoplasms, *Ann. Intern. Med.*, 78(1), 39-45.

**National Health and Nutrition Examination Survey
National Center for Health Statistics
United States Public Health Service
Procedure: Complete Blood Count (CBC)
January, 2005**

Prepared by _____

Date Adopted _____

Approved by _____

Director

Signed _____

Director

Dated _____

Director

Reviewed by _____

Date Reviewed _____

Reviewed by _____

Date Reviewed _____

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7. COMPLETE BLOOD COUNT (CBC)

Introduction

Perform a complete blood count (CBC) in duplicate on all Sample Persons (SPs) age 1 and older. Perform the CBC on the Beckman Coulter® MAXM. Run a CBC on the SP's EDTA blood tubes.

The three Coulter MAXMs serial numbers and system IDs are:

| | | |
|---------|------------------|-------------------|
| MAXM #1 | Serial # AA06042 | System ID # 13017 |
| MAXM #2 | Serial # AA31227 | System ID # 29894 |
| MAXM #3 | Serial # AB08075 | System ID # 31831 |

I. Purpose and Principle of Test

The Beckman Coulter® method of sizing and counting particles uses measurable changes in electrical resistance produced by nonconductive particles suspended in an electrolyte.

A suspension of blood cells passes through a small orifice simultaneously with an electric current. A small opening (aperture) between electrodes is the sensing zone through which suspended particles pass. In the sensing zone, each particle displaces its volume of electrolyte. Beckman Coulter® measures the displaced volume as a voltage pulse, the height of each pulse being proportional to the volume of the particle.

The quantity of suspension drawn through the aperture is for an exact reproducible volume. Beckman Coulter® counts and sizes individual particles at a rate of several thousand per second. This method is independent of particle shape, color, and density.

The MAXM is a quantitative, automated, differential cell counter for *in vitro* diagnostic use.

The MAXM measures these parameters in whole blood:

| Cell | Parameter | Measured | Pulse size Wavelength Calculation | Reported Units |
|------|---------------------------|----------|---|------------------------------|
| WBC | White Blood Cell Count | WBC bath | ≥35 fL | n x 10 ³ cells/μL |
| RBC | Red Blood Cell Count | RBC bath | 36 to 360 fL | n x 10 ⁶ cells/μL |

| | | | | |
|----------|---------------------------------------|-------------------------------|--|------------------------------------|
| Hgb | Hemoglobin Concentration | WBC bath | 525 nm | g/dL |
| Hct | Hematocrit | Computed | RBC x MCV/10 | % Percent |
| MCV | Mean Cell Volume | Derived from RBC histogram | # x size of RBC/ Total RBC | fL |
| MCH | Mean Cell Hemoglobin | Computer | Hgb/RBC x 10 | pg |
| MCH C | Mean Cell Hemoglobin Concentration | Computed | Hgb/Hct x 100 | g/dL |
| RDW | Red Cell Distribution Width | Derived from RBC histogram | CV expressed in % of the RBC size distribution | % Percent |
| Plt | Platelet Count | RBC bath | 2 to 20 fL | n x 10 ³ cells/ μ L |
| MPV | Mean Platelet Volume | Derived from Plt histogram | Mean volume of Plt population under the fitted curve x constant | fL |
| NE% | Neutrophil Percent | Derived from scatterplot | # cells inside NE area/# cells inside total cell area x 100 | % Percent |
| NE # | Neutrophil Number | Absolute number | NE%/100 x WBC Count | 10 ³ cells/ μ L |
| LY% | Lymphocyte Percent | Derived from scatterplot | # cells inside LY area/# cells inside total cell area x 100 | % Percent |
| LY# | Lymphocyte Number | Absolute number | Ly%/100 x WBC Count | 10 ³ cells/ μ L |
| MO% | Monocyte Percent | Derived from scatterplot | # cells inside MO area/# cells inside total cell area x 100 | % Percent |
| MO# | Monocyte Number | Absolute number | MO%/100 x WBC Count | 10 ³ cells/ μ L |

| | | | | |
|-----|--------------------|--------------------------|---|--------------------------|
| EO% | Eosinophil Percent | Derived from scatterplot | # cells inside EO area/# cells inside total cell area x 100 | % Percent |
| EO# | Eosinophil Number | Absolute number | EO%/100 x WBC Count | 10 ³ cells/μL |
| BA% | Basophil Percent | Derived from scatterplot | # cells inside BA area/# cells inside total cell area x 100 | % Percent |
| BA# | Basophil Number | Absolute number | BA%/100 x WBC Count | 10 ³ cells/μL |

***PDW -- Platelet Distribution Width and Pct -- Platelet Crit are NOT for diagnostic use and do not print. Coulter uses the value for PDW as an internal check on the reported platelet parameters, Pct and MPV.**

Methodology: The methods used to derive CBC parameters are based on the Beckman Coulter® method of counting and sizing, in combination with an automatic diluting and mixing device for sample processing, and a single beam photometer for hemoglobinometry. The WBC differential uses VCS technology. Analysis and classification of WBCs use three simultaneous measurements of individual cell volume (V), high frequency conductivity (C), and laser light scatter (S). The scattergram plots the cells based upon the measurements of these three parameters.

II. Special Safety Precautions

All specimens may be potentially positive for infectious agents including HIV and the hepatitis B and C viruses. Observe universal precautions. It is mandatory to wear gloves and lab coat when handling all human blood products and Beckman Coulter® controls. Wear safety glasses whenever operating the instrument in SECONDARY mode. Dispose of all biological samples in a biohazard container and wipe down all work surfaces with 10% bleach solution at the end of each session.

The mobile examination center (MEC) *Working Safely with Hazardous Chemicals* manual contains all Coulter material safety data sheets (MSDS).

III. Computerization: Integrated Survey and Information System (ISIS)

The MAXM Data Management System (DMS) transmits individual SP results to the MEC automated ISIS system. Review all SP results at the Coulter DMS monitor. The hematology module in the laboratory application automatically receives the results or transmits them manually to the hematology module. The laboratory application evaluates the data for completeness and accuracy. The final decision to accept or reject a result is the responsibility of the medical technologist.

All data are backed up and stored at Westat's home office.

IV. Specimen Collection and Preparation

A. Specimen collection

1. The phlebotomist collects a 3 or 4-mL K₃ EDTA tube on all SP's age 1+ following established venipuncture protocol and procedures. (A 1-2% dilution effect occurs in this liquid EDTA tube.)

B. Specimen preparation

1. The blood specimen-processing technologist initially processes the tube by taking off whole blood for various tests. The blood specimen-processing technologist places the specimen on a rocker until the hematology technologist can perform the CBC. Run the CBC as soon as possible; there is no requirement to wait any length of time between drawing the blood and running the CBC.

V. Procedure for Microscopic Examination

Not Applicable - Do not prepare differential microscopic slides.

VI. Reagents and Supplies

The MAXM DMS stores and maintains the lot numbers and expiration dates.

A. Reagents, controls and calibrators

1. Isoton III® -- PN 8546733 (20 L) -- an isotonic electrolyte
 - Expires on expiration date printed on container.
2. Beckman Coulter® Clenz -- PN 8546930 (5L) -- a cleaning agent that cleans and rinses diluter parts
 - Expires 90 days after being opened and installed on the instrument.
3. Lyse-S III® diff lytic reagent- PN 8546983 (1L) -- a lytic reagent used for the CBC mode
 - Expires 60 days after being opened and installed on the instrument.
4. Scatter Pak® -- PN 8546917
 - Diff Lytic Reagent -- Erythrolyse II® erythrocyte lytic reagent
 - Diff Leukocyte Preservative -- StabiLyse® leukocyte preservative
 - Expires 60 days after being opened and installed on the instrument.
5. Latron® Controls - PN 7546914 (5 x 16-mL)
 - Expires 30 days after being opened.
6. Latron® Primer - PN 7546915 (5 x 16-mL)
 - Expires 30 days after being opened.

7. 5C® Cell Controls Tri Pack contains Normal, Abnormal I, Abnormal II - PN 7547001 (9 x 3.3-mL)
 - Expires 13 days or 13 events after being opened.
8. Calibration S-CAL® - PN 7546808 (2 x 6-mL) (With Lin-C PN 6605374)
 - Use at the start of each stand. Expires 1 hour after being opened.
9. 5C® Cell Control Normal - PN 7546923 (9 x 3.3-mL)
 - Use when calibrating with S-CAL for reproducibility study.

B. Supplies

1. 3-mL K₂EDTA Becton Dickinson Hemogard Vacutainer® tube (367856)
2. 4-mL K₂EDTA Becton Dickinson Hemogard Vacutainer® tube (367861)
3. Tube rocker
4. Bleach, 5.25% Sodium Hypochlorite
5. Bottled distilled water
6. Three 30 mL plastic containers with lid
7. Two 1-liter containers with lid
8. Plastic squirt bottle
9. Cotton gauze pads
10. Three-hole paper punch
11. Notebook
12. Fujitsu printer ribbon

13. Flashlight
14. 10-mL syringe with plastic tubing
15. Precision screwdriver set
16. Distilled water bottle
17. Disposable lab jacket – 48 inches long

C. Notes

1. If reagents become frozen in transit, mix thoroughly by inversion and let bubbles settle before use.
2. Do not place reagents on or near electric cords or lines to avoid electrical interference.

VII. Calibration

S-CAL® (PN 7546808 - 2 x 6-mL) The S-CAL® calibrator kit determines the adjustment factors for the calibration of the Beckman Coulter® MAXM. Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. Perform calibration in the close-vial mode, at ambient room temperature range (16-32°C, 60-90°F), using S-CAL® as an alternative to whole blood.

A. Perform calibration:

- At the beginning of each stand;
- After replacing any component dealing with dilution preparation, such as BSV or primary measurement, such as an aperture;
- If the Beckman Coulter® representative suggests calibration;
- If controls show unusual trends or are outside limits; and
- When room temperature varies more than 10°F (5.5°C) from the room temperature during the last calibration.

1. Principle - The MAXM uses the S-CAL® kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. S-CAL® calibrates the **WBC, RBC, Hgb, MCV, Plt, and MPV** parameters. It is a stabilized human-blood preparation. S-CAL® is an acceptable alternative to whole blood calibration.

The calibration procedure uses replicate measurements of S-CAL® calibrator. The S-CAL® divides the average result into the calibrator Assigned Value to give the Adjustment Factor. Then, it obtains and adjusts an instrument reading according to the Adjustment Factor.

Hct, MCH, MCHC, RDW, and the DIFF parameters do not require calibration.

2. Reagents - S-CAL® consists of treated, stabilized, human erythrocytes and platelet sized components in an isotonic bacteriostatic medium. Fixed erythrocytes simulate leukocytes.

Materials required -- Before calibrating, assemble the following materials: S-CAL® kit containing two 6-mL vials of S-CAL® calibrator, one plastic pipette, and two empty glass-mixing tubes with pierceable caps.

3. Storage, handling and stability -- Sealed vials are stable through the expiration date when stored at 2-8°C (35-46°F). Open and/or pooled vials are stable for 1 hour.

Potential biohazard – Each human donor used in preparation of this material was tested by an FDA-approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV), as well as for hepatitis B surface antigen, and found to be negative (were not repeatedly reactive). Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- The supernatant should show no gross turbidity and be light red in color. Significant darkening of the supernatant might indicate hemolysis and a reduction of the red cell count.

B. Pre-calibration, reproducibility, and carryover check

Perform a calibration after the instrument has been "Shut Down" (Section VIII D.) for at least 30 minutes. Select **DILUTER FUNCTIONS, START-UP.**

1. Pre-calibration procedure

Bleach the aspiration system using the Clean Needle procedure.

- a) Prepare a fresh bleach solution. Put one-mL bleach and one-mL distilled water into 5-mL lavender top Vacutainer® tube.
- b) Stop the system before it performs the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE, [F3], Run. Press [F9] Stop.**
- c) Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, FLUIDIC TESTS, and CLEAN NEEDLE.** Press [Enter] and follow the screen instructions. Wait for green light before placing tube into the carousel.

To rinse the system, perform daily Start Up. Select **DILUTOR FUNCTIONS; START UP [Enter].**

Run 5C® cell controls.

2. Reproducibility check

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Select [F5] to access options. Change [F5] Print: to none and [F6] Host to Off.
- b) Use an unopened, normal-level, 5C®-cell control for reproducibility studies. Label the control vial with date and initial. Use of expired controls for this procedure is acceptable.
- c) Select **SPECIAL FUNCTIONS, CALIBRATION, REPRODUCIBILITY** [Enter].
- d) Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop.
- e) Press [F6]. Press space bar to turn the DIFF ON. Press [Enter]. Press [F2] *START PRIMARY*.
- f) Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "YES." Press [Enter]. This deletes the old data.

If there are runs present in the table and the message does not appear, press [F8] Delete. Press the space bar to answer "YES." Press [Enter]. This deletes the old data.

- (1) Follow the directions listed in Section X for preparation and mixing the 5C®-cell control.
- (2) Cycle the sample 11 times. Do not use the bar code reader. Mix gently before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.

(3) Check the results. Verify the average %CV does not exceed these limits:

- WBC 2.5%
- RBC 2.0%
- Hgb 1.5%
- MCV 2.0%
- Plt 5.0%
- MPV 3.0%

Check the low to high difference (bottom line, right hand side) for the diff parameters with these limits:

- LY% ≤ 4.8
- MO% ≤ 3.2
- NE% ≤ 4.8
- EO% ≤ 1.6
- BA% ≤ 1.6

If the results are outside the limits, call the Beckman Coulter® representative.

(4) Press [F4] to print the screen for the logbook. Press [F3] Run [F9] STOP. Press [Esc]. Proceed with a Carryover Check.

g) Notes

(1) Be sure the PR↓ is on the status line before starting the reproducibility study.

(2) Be sure to delete any data on the reproducibility screen before starting a new study.

(3) On the reproducibility screen, use the %CV line for CBC parameters only and the Diff line for the DIFF parameters only.

3. Carryover check (Draw two 4-mL EDTA tubes of normal blood.)
- a) Select **SPECIAL FUNCTIONS, CALIBRATION, and CARRYOVER**. Press [F2] *START PRIMARY*. Does the following message appear? "MODE REQUIRES EXISTING RUNS TO BE DELETED. ARE YOU SURE?: NO." If the message appears, press the space bar to answer "yes." Press [Enter]. This deletes the old data.
- (1) Use a routine 4-mL Vacutainer® EDTA for the carryover check clean vials. Fill three separate vials with diluent, then cap.
 - (2) Follow the screen directions. Cycle two vials of normal blood and three vials of diluent. Do not use the bar code reader. Insert the tube into the carousel when the green light appears.
 - (3) Check the lower right corner of the screen for CARRYOVER ACCEPTABLE. If the result is not acceptable and the H flags appear next to the carryover value results, repeat the procedure. If results are still OUT, call the Beckman Coulter® representative.
 - (4) Press [F4] to print the carryover screen for the logbook. Press [F9] to return to the main menu.
- b) Notes
- (1) Choose a sample with a WBC count of $10,000 \pm 1,000$ if possible. All other parameters should be within normal ranges.
 - (2) Ignore count period (CP) voteouts on diluent runs.
 - (3) Percent carryover is calculated by the formula.

(4)
$$\frac{\text{1st diluent sample} - \text{3rd diluent sample}}{\text{2nd sample}} \times 100 = \% \text{ carryover}$$

C. CBC calibration with S-CAL® calibrator

Take the S-CAL® calibrator from the refrigerator. Let it warm to ambient temperature for 20 minutes. Meanwhile, continue with the following steps:

1. Select **SPECIAL FUNCTIONS, CALIBRATION, and CBC CALIBRATION**. Press [F2] START PRIMARY. Delete any data in the table. Press [F8]. Press the space bar to answer "YES." Press [Enter].
2. Prepare the CBC calibration screen.
 - a) Enter the S-CAL® calibrator assigned values from the Table of Assigned Values on the package insert on the REF: VALUES line at the cursor. The Hct is not calibrated although the value is listed on the package insert.
 - b) Enter the expiration date and the lot number.

3. Prepare and cycle the calibrator

- a) Mix by hand as follows: Roll the tube slowly between the palms of the hands eight times in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.
- b) Determine that all cells are uniformly distributed by inspecting the vial contents. If the cells are not totally distributed, repeat the mixing procedure. Use cotton gauze pads to remove the rubber stopper from the vial. Absorb any spray produced by pressure within the vial by using the gauze pads, avoiding accidental contact with the product.
- c) With the pipette, fill each of two mixing tubes to within 1/4 inch of the top. Dispose of extra S-Cal. Set one of these tubes aside in a test tube rack. Do not refrigerate or place on rocker. Use Tube #1 for calibration and tube #2 for verification if needed.
- d) Cycle the first cap-pierceable calibrator 11 times. Do not use the bar code reader. Invert the vial and mix the S-CAL® calibrator before each cycle. Insert the tube into the carousel when the green light appears. The first sample is automatically marked DEL and its results are not included in the calculations.
- e) After the cycles are complete, press [F4] Print to print the screen for the logbook. Press [F3] Run, [F9] STOP. Press [Esc.]

4. Assess the run

- a) Check for trending. If trending is present, stop and contact a Beckman Coulter® representative.

- b) Check the %CV values against these precision %CV limits. If any parameter exceeds the limit, STOP and contact a Beckman Coulter® representative.

| Parameter | Precision (CV%) |
|-----------|-----------------|
| WBC | ≤2.5 |
| RBC | ≤2.0 |
| Hgb | ≤1.5 |
| MCV | ≤2.0 |
| Plt | ≤5.0 |
| MPV | ≤3.0 |

- c) FAC %DIFF values against these limits (disregard minus signs. The values are absolute numbers). If any parameter exceeds its limit, STOP and call a Beckman Coulter® representative.

| Parameter | Acceptable FAC %DIFF |
|-----------|----------------------|
| WBC | ≤5.0 |
| RBC | ≤2.0 |
| Hgb | ≤3.0 |
| MCV | ≤2.5 |
| Plt | ≤9.0 |
| MPV | ≤20.0 |

- d) Determine the need for calibration. Check the FAC %DIFF and DELTA DIFF values against these limits (disregard minus signs. The values are absolute numbers).

| Parameter | Do not calibrate if FAC %DIFF is: | Do not calibrate if DELTA DIFF is: |
|-----------|-----------------------------------|------------------------------------|
| WBC | ≤1.25 | ≤0.10 |
| RBC | ≤0.70 | ≤0.03 |
| Hgb | ≤0.78 | ≤0.10 |
| MCV | ≤1.18 | ≤1.00 |
| Plt | ≤2.70 | ≤6.0 |
| MPV | ≤5.00 | ≤0.50 |

- e) If both the FAC %DIFF and DELTA DIFF values for all parameters are less than or equal to these limits, DO NOT calibrate: Press [F4] to print the screen for the logbook.
- f) If the FAC %DIFF or DELTA DIFF value of any of these parameters is greater than these limits continue with the next steps to verify the calibration.

5. To verify calibration:

- a) Determine which calibration factors to change. Check the FAC % DIFF and DELTA DIFF values against these ranges.

| Parameter | Calibrate if FAC %DIFF is: | Calibrate if DELTA DIFF is: |
|-----------|----------------------------|-----------------------------|
| WBC | >1.25 but ≤5.00 | >0.10 but ≤0.40 |
| RBC | >0.70 but ≤2.00 | >0.03 but ≤0.09 |
| Hgb | >0.78 but ≤3.00 | >0.10 but ≤0.40 |
| MCV | >1.18 but ≤2.50 | >1.00 but ≤2.00 |
| Plt | >2.70 but ≤9.00 | >6.0 but ≤20.0 |
| MPV | >5.00 but ≤20.00 | >0.50 but ≤2.00 |

- b) If any value is outside these ranges, then, is *Select Function* displayed? If NO, press [F3] Run [F9] STOP [Esc]. If YES, Press [F5]. Choose SELECT PARAMETERS. Press [Enter]. Use the space bar to select YES for parameters that need adjusting, NO for others. Press [Esc]. Select TRANSMIT FACTORS. Press [Enter]. The following message appears: "WARNING -- DATA WILL BE CLEARED AFTER TRANSMISSION. DO YOU WANT TO PRINT DATA? Y/N" Select N since the values have already been printed.
- c) Press [F3] Run [F2] START PRIMARY. Gently invert the second cap-pierceable vial of S-CAL® calibrator 8-10 times. Cycle the S-CAL® calibrator 11 times. Before each cycle, invert the vial and mix the S-CAL® calibrator. Check the FAC %DIFF and DELTA DIFF values

results for all parameters against these limits (disregard minus signs) to be sure that they are below the lower limit.

| Parameter | FAC %DIFF | DELTA DIFF |
|-----------|-----------|------------|
| WBC | ≤1.25 | ≤0.10 |
| RBC | ≤0.70 | ≤0.03 |
| Hgb | ≤0.78 | ≤0.10 |
| MCV | ≤1.18 | ≤1.00 |
| Plt | ≤2.70 | ≤6.0 |
| MPV | ≤5.00 | ≤0.50 |

- d) If any value is above these limits, call a Beckman Coulter® representative. Turn the printer back on using Options. Press [F4] to print the screen for the logbook. Rerun controls.

6. Calibration terms and formulas

a) MEAN

- The average of the 10 S-CAL calibrator runs

b) NEW CAL FAC

- The calibration factor needed to obtain the S-CAL Calibrator Reference value. The instrument calculates and displays it whether or not it needs to be changed.
- Reference Value x Old Cal Factor = NEW CAL FAC
S-CAL mean value (n=10)

c) OLD CAL FAC

- The current calibration factor

d) %CV

- Indicates the reproducibility of the S-CAL calibrator run. Check to ensure that the data being used is valid when making decisions to recalibrate or not.

e) FAC % DIFF

- The difference between the OLD CAL FAC and the NEW CAL FAC expressed as a percentage.
- $$\frac{\text{NEW CAL FAC} - \text{OLD CAL FAC}}{\text{OLD CAL FAC}} \times 100 = \text{FAC \% DIFF}$$

f) DELTA DIFF

- The absolute difference between the reference value and the S-CAL calibrator MEAN.

g) REF VALUES.

- The assigned value for each parameter.

VIII. Assay Procedure

A. Run Start Up at the beginning of the first session each operational day.

1. Leave the instrument on and operate the MAXM with all panels closed. Check to make sure the date and time displayed are correct. To set date and time select **SPECIAL FUNCTIONS, SET UP, SYSTEM SET UP, SET DATE/TIME**. Move the cursor and enter the correct date or time and press [Enter] or the arrow keys. Press [F10] to save and exit.
2. To begin Start Up, select **DILUTER FUNCTIONS, and START UP**. Press [Enter]. Follow the instructions on the screen.
3. After Start Up is complete, evaluate the display. Expired reagents and failed checks appear in red. Press [F2] to view detailed results. Make sure the Background and other Start Up results are within limits. Results outside limits turn red. Results automatically print. File in the logbook.
4. Review and verify sample analysis set up.
 - a) Select **SAMPLE ANALYSIS, RUN SAMPLE** [F3]. Sample mode? Press [F5] for options. Press the corresponding function key to enter specific options. Use [F6] to turn the Diff ON. Use [F5] to change XB to OFF and DB to ON, Print to NONE, Host to ON, and Display Only to OFF. Press [Esc] to exit.

B. Run controls

Run Beckman Coulter® LATRON primer and latex control, and all three levels, normal (blue), abnormal I (yellow), and abnormal II (pink), of Beckman Coulter® 5C® cell control daily at the beginning of the first session. Run all three levels (normal, abnormal I, and abnormal II) of Beckman Coulter® 5C® cell control at the beginning of the second session.

C. Run Sample Persons

1. Review the placement of the bar code on the sample tube to make sure it is parallel to the stopper and does not cover the bottom of the tube.
2. Run all samples in duplicate.
3. Run samples in the primary mode.

Check to verify connection and working order of the printer.

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].
 - b) Is Sample Mode? Displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.
 - c) Press [F2] START PRIMARY.
 - d) Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep; place the tube in the carousel. If the red light appears, wait and try reading the bar code label again.
4. Alternatively, cycle samples in the SECONDARY mode.

Blood detectors are inactive in the SECONDARY mode. This mode does not check sample and aspiration integrity. Run samples in the SECONDARY mode only if the primary mode is unavailable.

- a) Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter].
- b) Is Sample Mode? displayed? If no, press [F9] STOP. Use [F6] to turn Diff ON.

- c) Press [F3] SECONDARY.
 - d) Identify the sample by holding the bar code label on the tube in front of the reader. Green light will beep. If the red light appears, wait and try reading the bar code label again.
 - e) Cycle the sample in the SECONDARY mode:
 - (1) Mix the sample gently.
 - (2) Open the tube and immerse the aspirator tip in the sample.
 - (3) Press and release the sample bar.
 - (4) Remove the sample when the instrument beeps.
 - (5) Monitor the aperture-viewing screens for debris during the COUNT period.
5. Review data and transmit
- a) Review the data using the criteria described in Section X.
 - b) Set host computer to ↑. Data from the Coulter DMS is automatically transmitted to the ISIS system.

D. Daily Shut Down

1. Shut down the instrument at the end of each day. Shut down the instrument for at least 30 minutes but less than 48 hours.
2. To begin shut down make sure the status line displays *Select Function*. Select **DILUTER FUNCTIONS** and **SHUT DOWN**. Press [Enter].

3. When it is time to use the instrument, perform Start Up. Results must be within tolerance.
4. Perform daily QC and operate as usual.

E. Prolonged Shut Down

1. If the instrument is going to be shut down for 48-72 hours, perform the following steps:
 - a) Perform daily Shut Down. Let cleaning agent remain in the instrument for at least 30 minutes.
 - b) Perform Start Up to put diluent in the system.
 - c) Turn off the power.
 - d) When it is time to use the instrument, turn power on, and perform a Start Up. Results must be within tolerance.
 - e) Perform daily QC and operate as usual.
2. If the instrument is going to be shut down for more than 72 hours, perform the following steps:
 - a) Place all reagent pickup tubes into distilled water.
 - b) Repeatedly perform Shut Down and Start Up procedures throughout the day.
 - c) Let distilled water remain in the reagent lines.
 - d) Turn off the power.

- e) Place reagent caps on all open containers.
- f) When it is time to use the instrument, turn on the power and place the reagent pickup tubes into the reagent containers, prime all reagents, perform a shut down and then perform a Start Up. Results must be within tolerance.
- g) Perform daily QC and operate as usual.

F. Beginning and end of stand operations

1. Beginning of stand

- a) Obtain one urine collection container or a 50-mL conical tube, seven 3 or 4-mL EDTA tubes (1 clean aspiration system, 3 reproducibility, 3 carryover), enough supplies to draw two 4-mL EDTA blood tubes, and a few plastic transfer pipettes.
- b) Using all new containers of reagents, carefully unwrap and place all reagent pickup tubes in their appropriate container after pouring 30-mL Isoton® III into 30-mL plastic container. Use the Isoton® when performing the calibration carryover check. Handle reagent tubes by the collar only to avoid contamination. Turn the power ON. Prime reagents through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS**, and choose **ALL**.
- c) Perform the Start Up procedure. This should take approximately 5-6 minutes. Results should be within tolerance.
- d) Contact the local Beckman Coulter® representative to perform an instrument verification procedure on setup day or as soon as possible.
- e) Calibrate, perform, and verify QC checks according to procedure.

f) Review and verify system set up. Select **SPECIAL FUNCTIONS, SET UP, SYSTEM SET UP:**

(1) Select **SHIFT**

- (a) Move the cursor and set up the starting times for each shift and press [Enter] or the arrow keys. The system automatically calculates the end of the shift to prevent overlap.
- (b) Set shift 1 "Time" at 0800.
Set shift 2 "Time" at 1230.
Set shift 3 "Time" at 2230.
- (c) Press [F10] to save and return to the previous screen.

(2) Select **REAGENTS** - Update reagent logs

- (a) To record new reagent information: Key in the new reagent information: lot number, date reagent opened (pressing [Enter] automatically gives today's date), and the expiration date. Do not forget to enter revised expiration dates where appropriate. Press [Enter] after each item. Press [F10] to save the data and leave the reagent screen.

(3) Select **INSTITUTION.**

- (a) Enter the "SUPER" password. Type in:
Name, NHANES
Lab Director, Brenda Lewis
Address, NCHS
Maryland
Telephone, 301-436-7080
(Default) Instrument, AA06042
AA31227
AB08075

Use space bar to choose YES for Name Printed on Graphic Printer and NO for all other information. Press [F10] to save.

(4) Select **COMMUNICATION DEF.** Enter the **SUPERVISOR PASSWORD, "super."** Select, **HOST COMPUTER DEFINITION.**

- (a) Use [Enter] or arrow keys to move to the appropriate field.
- (b) Type in the following information where necessary and use the space bar to choose between the responses.

| | | | |
|----------------------|------|--------------------|-----|
| STKS 2A Host Mode | No | Enable Spooler | Yes |
| | | Replace Null by SP | No |
| Timeout (secs) | 8 | | |
| Baud rate | 9600 | | |
| Parity | none | | |
| Stop bits | 1 | | |
| Handshake | Yes | | |
| Block size | 256 | | |
| Graphic transmission | | | |
| DF1 | No | | |
| DF2 | No | | |
| CVS histograms | No | | |
| RBC histograms | No | | |
| PLT histograms | No | | |

- (c) Press [F10] to save and [Esc] to return to previous screen.

(5) Select **Language.**
Ensure the default is "ENG." Press [F10] to save and exit.

(6) Select **IQAP ID#.**
Type in the IQAP number.
Enter 32979 1 T1 for instrument AA06042
32979 1 T2 for instrument AA31227
32979 1 T3 for instrument AB08075
Press [F10] to save and exit.

(7) Select **SET DATE/TIME**.
Move the cursor and enter the correct date or time and press [Enter] or use the arrow keys. Press [F10] to save and exit.

(8) Select **LYSE VOLUME**.
Press space bar to choose 1 L. Press [F10] to save and exit.

(9) Select **OPTIMIZE HARD DISK**.
Type in the password "super" at the prompt and then press [Enter]. Use the spacebar to select YES. Press [F10] to save. Press [F9] to return to the main menu.

g) Review sample analysis set up. Select **SPECIAL FUNCTIONS, SET UP, and SAMPLE ANALYSIS SET UP**. Type in the password "super."

(1) Select **DISPLAY FORMATS, REPORTING UNITS**.
Use the space bar to toggle to US 1. Press [F10] to save and [F9] to return to main menu.

(2) Select **PRINT OPTIONS**.
Auto Print Format
Select [**GRAPHIC FORMAT**]

Ticket Options

Verify the following settings.

| | |
|---------------------------|----------|
| PRINT UNITS: | Y |
| PRINT NORMAL RANGES: | Y |
| PRINT PARAMETER LABELS: | Y |
| TICKET PRINTER CONNECTED: | N |
| S/D FLAGS: | Y |
| DIFF ORDER: | Standard |
| AUTO-TICKET PRINT: | N |

TICKET FORMAT START OF
NEXT FORM Continuous

Spooler Priority

Leave [AUTO PRINT] as the default.

Graphic Options

Verify the following settings.

| | |
|-------------|------------|
| | Width/Font |
| Page Format | Wide/Large |

| | | |
|---------------------|---|-----|
| DF 1. RBC, PLT | : | Yes |
| DF2, DF3 | : | No |
| VCS Histograms | : | No |
| Demographics | : | No |
| S/D flags | : | Yes |
| Print Units | : | No |
| Print Diff Box | : | No |
| Print Normal Ranges | : | No |

Optional Printer

Select "N."

- (3) Select **ACTION LIMITS** [Enter], **DEFINITIVE FLAG LIMITS** [Enter].

Disable definitive flag limits. Set low limit for all parameter values to zero except for PCT. Set lower limit for PCT to 0.000. Set high limit to 99.9 for all parameters except RBC, PLT, and PCT. Set RBC upper limit to 9.9, PLT to 999 (with no decimal) and PCT to 0.990. Press [F10] and [Enter] to save and exit.

- (4) Select **ACTION LIMITS** [Enter], **HIGH/LOW FLAG LIMITS** [Enter].

Disable High/Low flag limits. Set low limit for all parameter values to zero except for PCT. Set lower limit for PCT to 0.000. Set high limit to 99.9 for all parameters except RBC, PLT, and PCT. Set RBC upper limit to 9.9, PLT to 999 (with no decimal) and PCT to 0.990. Press [F10] and [Enter] to save and exit.

(5) Select **XB LIMITS**.

Enter target and limit percent values.

XB Limits

| | Target | Limit % |
|------|--------|---------|
| MCV | 88.5 | 3 |
| MCH | 29.5 | 3 |
| MCHC | 33.5 | 3 |

Press [F10] to save and exit.

2. End of stand

a) Obtain three urine collection cups and three 4-mL EDTA blood tubes.

b) Review, print, and clear error file.

(1) Select **SPECIAL FUNCTIONS, ERROR FILE** [Enter]. Review data and print [F4]. Document any relevant information on the print out and file in the logbook. Delete file [F8] -- "Do you want to delete error file; NO" message will appear. Use the space bar to change NO to YES [Enter]. Return to main menu [F9].

c) Download IQAP files to diskette following procedure in Section X.D.1.

d) Perform daily Shut Down. Let cleaning agent remain in the instrument for at least 30 minutes.

e) Perform Start-up.

- f) Disable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTIONS, FLUIDIC TESTS,** and **DISABLE REAGENT SENSORS.** Toggle through each reagent line using the space bar to change "ON" to "OFF."
- g) Bleach the reagent lines.
- (1) Remove all reagent pickup tubes from the reagent containers. Dispose of all open containers. Wash and save the reagent collars.
 - (2) Prepare a 25% solution of bleach (250-mL) and distilled water (750-mL) in one liter bottle. Place all reagent pickup tubes into the 25% bleach/distilled water solution. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL.** Press [Enter]. Repeat this procedure two more times.
- h) Place all reagent pickup tubes into containers of distilled water.
- i) Bleach the apertures and flow cell.
- (1) Mix 15-mL bleach and 15-mL distilled water in a plastic container.
 - (2) Put 30-mL of distilled water in a second plastic container.
 - (3) Open the front panel.
 - (4) Select **DILUTER FUNCTIONS,** and **DISINFECT.** Press [Enter].
 - (5) The instrument defaults to 15 minutes; stop the procedure after 3 minutes. Press [Enter].

- (6) Immerse the bleach probe in the bleach solution when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE BLEACH." Press any key. Aspirate all the bleach solution.
 - (7) Immerse the bleach probe in the distilled water when the screen displays, "PRESS ANY KEY WHEN READY TO ASPIRATE WATER." Press any key. Aspirate all the distilled water. Stop the cycle after 3 minutes by pressing [F4].
 - (8) Wait until the screen displays *Select Function* before touching any keys. When *Select Function* is displayed, continue with the following procedure.
- j) Disinfect the needle. Bleach the aspiration system using the Clean Needle procedure.
- (1) Prepare a fresh bleach solution. Put 1-mL bleach and 1-mL distilled water into 4-mL lavender top Vacutainer® tube.
 - (2) Stop the system before beginning the Clean Needle procedure. If status message is not *Select Function* or *Compressor Off*, go to **SAMPLE ANALYSIS, RUN SAMPLE**, [F3], Run. Press [F9] Stop.
 - (3) Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, FLUIDIC TESTS, and CLEAN NEEDLE**. Press [Enter] and follow the screen instructions. Wait for green light before placing tube into the carousel.
- k) Perform reproducibility in Primary and Secondary mode using this 1% bleach solution. Prepare a 1% bleach solution and fill one 4-mL EDTA blood tube with this solution. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START*

PRIMARY. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY.** Select Primary and aspirate three samples of 1% bleach. Enter [F3]; sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of 1% bleach solution.

- l) Rinse the reagent lines. Make sure all reagent lines are immersed in containers of distilled water. Select **DILUTER FUNCTIONS, PRIME, PRIME ALL.** Press [Enter]. Repeat this procedure two more times.
- m) Perform a Start Up. Make sure containers are full.
- n) Perform reproducibility in Primary and Secondary mode by using distilled water. Fill one 4-mL EDTA blood tube with this distilled water. Turn the diff off. Is *Sample Mode?* displayed? If YES, go to step 3. If NO, press [F9] Stop. Press [F6]. Press space bar to turn the DIFF OFF. Press [Enter]. Press [F2] *START PRIMARY.* Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY.** Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY.** Select Primary and aspirate three samples of distilled water. Enter [F3], sample mode. Enter [F9] Stop. Select Secondary mode and aspirate three samples of distilled water. Press [Enter].
- o) Select **DILUTER FUNCTIONS, START-UP.** Press [Enter]. Perform one additional Start-Up procedure with the lines in the distilled water containers.
- p) Cycle the instrument dry.
 - (1) Remove all reagent pickup tubes from the distilled water containers.

- (2) Continue to cycle the instrument dry by priming air through all the lines by selecting **DILUTER FUNCTIONS, PRIME REAGENTS** and choose **ALL**. Repeat these actions at least three times.
 - (3) Open front cover. Using hemostats, seal tubing with check valve coming out of the bottom of the sheath tank. Loosen the four large screws that hold the panel containing the sheath tank. Gently pull panel away from instrument. Trace two red wires from top of sheath tank to plastic electrical connection. Disconnect the junction. Insert paper clip into junction so that a circuit is formed on the instrument side of the connector. Do this by bending paper clip into a U and placing one end of paper clip into each of the open sockets on the instrument side of the junction. This will allow the instrument to Drain, Vent, and Shut Down without reagent. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, OPERATOR OPTION, and DRAIN AND VENT**. Press [Enter.]
 - (4) Select **DILUTER FUNCTIONS, and SHUT DOWN**. Press [Enter].
 - (5) After cycles are complete, remove paper clip, reconnect junction, put panel back into instrument and tighten screws, then remove hemostats.
- q) Enable the reagent sensors. Select **SPECIAL FUNCTIONS, DIAGNOSTIC, FLUIDIC TESTS, and DISABLE REAGENT SENSORS**. Toggle through each reagent line using the space bar to change "No" to "Yes."
- r) To protect the reagent pickup tubes from contamination, wrap them securely in paper towels. Allow air to continue to dry the tubes.

- s) Turn off the power.
- t) Rinse exterior of BSV with distilled water to remove built up Isoton and blue Clenz agent. Blot the BSV dry with lint free tissue. Do not use gauze.
- u) Wash exterior of instrument with distilled water.
- v) Empty waste and rinse container.
- w) Blow air through the flow cell at the end of each stand. This is referred to as the Triple Transducer Module (TTM). Address questions to the service representative at 1-800-526-7694. Remove the 6-inch sample line to the flow cell at the mixing chamber. Connect a 10-mL syringe with tubing to the 6-inch line and force air into the line to remove ALL remaining liquid from the flow cell and the 6-inch sample line. Reconnect the sample line.

IX. Beckman Coulter® Reportable Range of Results

| Parameter | Linearity | Limits: The greater of |
|--------------------------------|---------------|------------------------|
| WBC x 10 ³ cells/μL | 0 to 99.9 | 0.2 or 3.0% |
| RBC x 10 ⁶ cells/μL | 0 to 7.00 | 0.05 or 2.0% |
| Hgb g/dL | 0 to 25.0 | 0.2 or 3.0% |
| MCV fL | 50.0 to 150.0 | 2.0 or 3.0% |
| Plt x 10 ³ cells/μL | 0 to 999 | 10.0 or 7.0% |
| MPV fL | 5.0 to 20.0 | 5.0% |

X. Quality Control

A. Latron® latex controls (PN 7546914 - 5 x 16-mL) The Latron® control is for use in monitoring the volume, conductivity, and light scatter (VCS) parameters on the MAXM. Use the Latron® control immediately following the Latron® primer. Run this control at the beginning of each day. Date and initial the vials when opened.

1. Principle -- The Latron® control is a ready-to-use suspension of latex particles. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter.
2. Reagents -- Latex particles suspended in a buffered bacteriostatic and fungistatic medium containing a surfactant.
3. Storage, handling, and stability -- Sealed vials are stable until their expiration date when stored and used at 2-30°C (35-86°F). Once open, date, and initial vials. Opened vials are stable for 30 days when stored at recommended temperatures. Keep vials tightly capped when not in use.
4. Indications of instability or deterioration -- Inability to recover expected results might indicate product instability or deterioration due to improper storage, handling, or contamination. Discard vial if debris is visible and put new vial into use.
5. Instructions for use -- Before running control, verify that a Startup has been performed.
 - a) Run Latron® primer in the secondary mode. Select **CONTROLS**, then **CONTROL RUN** and press [Enter]. If the **LATEX FILE** does not appear, press [F2] File. Select the **LATEX FILE**. Press [Enter]. Press [F3] Run [F4] Primer. Cycle the primer by immersing the aspirator tip completely in the primer. Press and release the sample bar. The aspirate

probe for open vials will begin to aspirate the primer. Remove vial when the audible "beep" occurs. Evaluate primer results. Results should be less than 500. Press [Esc] to remove the primer run.

- b) Run the latex control. Mix a room-temperature control vial gently by inverting five (5) to eight (8) times. Be careful to avoid foaming. When *Select Function* appears on the status line, press [F3] Run, [F3] Control (SECONDARY). Cycle the control by immersing the aspirator tip completely in the vial. Press and release the sample bar. The aspirate probe for open vials will begin to aspirate the control. Remove vial when the audible "beep" occurs.
- c) Examine the Mean Channel and Coefficient of Variation for volume, conductivity, and light scatter for the Diff Mode only. Compare the results to the Assigned Mean Values and Expected Coefficient of Variation. Check for **H** (high) or **L** (low) beside the results. If there are no H's or L's, results are within range. Press [F4] to print results for the logbook. If a H or L displays, do the following:
- (1) Bubbles in the flow cell or improper vial handling -- Rerun the primer and control.
 - (2) Contaminated control, improperly mixed, or past open vial expiration date -- Wipe the aspirator tip. Try a new vial of Latron® control. Mix gently according to directions.
 - (3) ":::::" System detects a clog in the flow cell -- Press [F3]. Press [F7] to PURGE the flow cell. Press [F4]. Cycle the Latron® primer again. Press [Esc] [F3] [F3]. Cycle the Latron® latex control again. If the control is still "out" of range, repeat the actions 2 or 3 more times. If the problem remains, perform a ShutDown and Start Up procedure. If problem continues, call a Beckman Coulter® representative for assistance.

- (4) Assigned value or range is incorrect -- Be sure the assigned values and ranges match the ones on the Latron® package insert. If in error, correct them by selecting **SPECIAL FUNCTIONS, SET-UP, CONTROL SET UP.**

6. Setting up a Latex control file

Set up a file each time a new lot number is received. Assigned channel, expected range, and %CV are automatically entered; change them to assigned values on assay sheet, if necessary.

Choose **SPECIAL FUNCTIONS, SET UP, CONTROL SET-UP, LATEX FILE.** Select a NOT SET-UP or an inactive file. Enter the name of the file, (Latex), Lot #, expiration date, and technician initials. Check entries. Press [F10] to save and exit.

B. 5C® Cell Controls Tri Pack contains Normal (blue), Abnormal I (yellow), Abnormal II (pink) (PN 7547001 - 9 x 3.3 mL.) The 5C®-cell control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. Run this control at the beginning of each session. Date and initial the open vials.

1. Principle -- The 5C® cell control consists of human blood so repeated measurements to monitor daily performance of the instrument system is possible.
2. Reagents -- 5C®-cell control consists of treated, stabilized human erythrocytes in an isotonic bacteriostatic medium. 5C®-cell control also contains a stabilized, platelet-sized component, and fixed erythrocytes to simulate leukocytes.
3. Storage, handling, and stability -- Store 5C®-cell control at 2-8°C. When stored at 2-8°C, sealed vials are stable at least until the expiration date shown on the Table of Expected Results. NOTE: The MCV and/or RDW parameters may show trending through the shelf life of the product. This is inherent to the

product and is not an indicator of product stability. Date and initial open vials. Opened vials are stable for 13 days or 13 events when stored at 2-8°C.

Potential biohazard -- Each human donor used in preparation of this material was tested by an FDA-approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) as well as for hepatitis B surface antigen and found to be negative (were not repeatedly reactive). Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (darkly colored supernatant) indicate product deterioration. However, a slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.
5. Instructions for use -- Remove 5C® cell control tubes from refrigerator and warm to ambient temperature for 10-15 minutes. After warming, mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again.

- a) Run the 5C®-cell control in the Primary Mode of the instrument. Select **SAMPLE ANALYSIS, RUN SAMPLES**. Press [Enter]. Is **SAMPLE MODE** displayed? If no, press [F9] **STOP**. Make sure the **DIFF** is on. If it is off, press [F6]. Press [F2] **START PRIMARY**. Complete the entire procedure and return the controls to the refrigerator within 30 minutes.
- b) Identify the sample by holding the bar code label in front of the reader. Place the control in the carousel. Repeat for other levels of controls.

c) Check the results of each control. Select **CONTROLS, REVIEW, OR REPORT** and [F2] to select a file for review. Choose one control file and [Enter]. Check for **H** (high) or **L** (low) beside the results. If there are no H's or L's, results are within range. To print results for the logbook for the last control run, press [F4] Print. Use [F2] to select another file and repeat actions. Review and print reports for all three controls and file in the logbook. If a **H** or **L** displays, consider the following reasons and perform and document the following actions:

- (1) Improper mixing -- Follow instructions and rerun control.
- (2) Control files set-up incorrectly -- Make sure the assigned values and ranges match those on the control package insert. If in error, correct them by selecting, **SPECIAL FUNCTIONS, SET UP, CONTROL SET UP.**
- (3) Chance (statistical outlier) -- Rerun the control. If it is still out, continue with the following actions.
- (4) Change in the control -- Try another vial or level of control.
- (5) Instrument change -- Watch for normal sample flow. Call Beckman Coulter® representative to help troubleshoot abnormal operation.

6. Setting up a CBC/Diff control file

Set up a file whenever receiving a new lot number of control. Enter control package insert information for control with differential. Enter information using the bar code wand. Enter information manually if necessary.

Choose **SPECIAL FUNCTIONS, SET UP, and CONTROL SET-UP.** Select **CBC DIFF/FILE.** Select a NOT SET-UP or an inactive file.

a) Using bar code scanner

Scanning bar code units -- Choose the correct section of the package insert to scan making sure to select the part with the correct Unit Format (US), for the correct instrument (MAXM).

- (1) Hold the wand like a pencil.
- (2) Place the wand in section 1, Lot No. Read this section first.
- (3) Gently slide the wand back and forth over the bar code until the instrument beeps. The lot number is now entered. Start and end each scan in the white space.
- (4) Beckman Coulter®'s expected ranges appear automatically when the control lot number is entered in an empty file.
- (5) Follow the same procedure for the expiration date and assigned values. (Values 2-10)
- (6) Manually select and enter Shift and Operator ID.
Check all entries to make sure they are correct. Press [F10] to save and exit.

b) Manual entry

Enter lot number. This enters the IQAP number automatically. Enter the expiration date, shift, and operator code. Continue to enter the package insert data. Press [Enter] after each entry. Press [↓] at the end of each row. The system automatically enters the level and default ranges based on the first two digits of the lot number. Check to make sure all entries are correct. Press [F10] to save and return to the previous screen.

C. Control statistics and graphs

1. Use to review and print:

Control results, cumulative statistics and graphs for CBC/DIFF files; or
Control results, cumulative statistics and histograms for LATEX Files; or
Check cumulative results for trends or shifts as necessary for troubleshooting.

Print, review, and delete cumulative statistics and graphs for all CBC/DIFF and LATEX files at the end of each stand after transferring information to the IQAP disk and file in the logbook.

2. CBC/DIFF control review and report

- a) Use this report to review and print control results and cumulative statistics for CBC files. Select **CONTROLS, REVIEW OR REPORT**, and [Enter]. Press [F2] to select one of the following files, Normal, Abnormal I, Abnormal II, and Latex [Enter]. Press [F4] to print. Review and file in logbook. Continue to select each file in turn, print, and file.

Screen-specific function keys:

[F2] File Displays all available files. Use ↓ and ↑ to select the correct file. Press [Enter].

[F4] Print Prints the entire control file in a line list format on 8.5 x 11 in paper.

[F6] Remove/Restore

Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] restores the run and original statistics.

[F8] Delete File

Deletes the current control file. Displays a message "*You have asked to delete ENTIRE control file. Are you sure you want to delete?*" No. Press the space bar to select Yes or No.

[←] [→] Press [←] or [→] to see parameters not currently displayed on the screen.

[F9] Menu Displays the main menu.

3. Latex control review and report

a) Use this report to review and print control results and cumulative statistics and histograms for LATEX files. Check cumulative results to look for trends, shifts, or, if necessary, troubleshooting.

b) Screen-specific function keys:

Press [←] To go back to DIFF Latex Control Review

[F2] File Displays all available files. Use ↓ and ↑ to select the correct file. Press [Enter].

[F4] Print Prints the entire control on a graphic printer.

[F6] Remove/Restore

Removes a highlighted run from the calculations. A DEL appears in place of the run number. The statistics recalculate. Pressing [F6] again restores the run and original statistics.

[F8] Delete File

Deletes the current control file. Displays a message "*You have asked to delete ENTIRE control file. Are you sure you want to delete?*" No. Press the space bar to select Yes or No

[←] [→] Press [←] or [→] to see parameters not currently display on the screen.

[F9] Menu Displays the main menu.

D. Interlaboratory Quality Assurance Program (IQAP)

All instruments participate in Beckman Coulter®'s IQAP program. The IQAP program includes saving results of 5C® Cell controls, transferring them to a disk, and sending them to Beckman Coulter® who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. Perform this procedure at the end of each stand, or when a lot expires.

Follow procedure for CBC/DIFF and Latex control review and report. After downloading and printing results, delete control files [F8].

1. Procedure to download IQAP files to diskette.
 - a) Slide the diskette into the drive with the arrow side up and pointed toward the drive in the Beckman Coulter® Data Management System. Gently push the diskette until it clicks into place.
 - b) Turn the computer OFF. Wait 15 seconds, and then turn the computer back ON. A screen will appear showing the Beckman Coulter® Corporation logo. To exit this screen, follow the instructions on the bottom left portion of the screen, and press [Esc].
 - c) The screen will indicate the process the system is performing. Read the instructions on the screen. When the process is complete, the DMS displays the list of possible files on the screen for review and selection. If some of the values are incorrect, edit or delete the fields on this screen. Any alteration to this screen will affect only data on the IQAP diskette, not in the MAXM computer.

- d) FILE_NAME indicates the files by file number for downloading to the diskette.
- LOT_# indicates the type of control. Prefixes 86, 87, and 88 refer to 5C® Cell Controls.
 - SHIFT refers to the shift designation selected for running the controls. Edit this field if necessary. Use arrow keys to position.
 - START and END indicate beginning and end dates for each file. These fields are not editable.
 - REPORT indicates whether IQAP will issue a report on the lot number.
 - N_REC indicates the number of records found in the file.
- e) Press [Esc] to leave this screen. If the IQAP# and Serial# are present and valid, the following screen message will appear, "Updating the IQAP Disk." After writing the control files to the diskette, a screen message will give instructions to follow. Follow these instructions and the computer will reboot to the routine program. To remove the diskette, press the eject button on the lower right of the diskette drive opening. Do not remove the diskette until the drive indicator light is off.
- f) Label the diskette with the supplied IQAP ID label. Place the diskette in the preaddressed mailer provided and mail. Do not place the label over the drive spindle or high-density hole.

E. X_B analysis

1. X_B analysis is a QC method monitoring instrument performance by tracking the MCV, MCH, and MCHC parameters of SP samples. These indices are very stable and show little variance between SP samples. This method displays the moving average of SP samples and compares it to established target values. Target values are MCV = 88.5, MCH = 29.5, and MCHC = 33.5. Given that the instrument will run no more than 30 unique samples per day, is this not a valid indicator. Coulter indicated that only medium to large institutions use this

measure. Because our population is small and samples are run more than once, the data are overweighted. Disable this option.

2. X_B batch means

Not applicable

To change the status of X_B , select [F5] Optns on the **RUN SAMPLES** screen.

3. X_B Graphs

Not applicable

F. Proficiency testing

Evaluation and participation in the College of American Pathologist (CAP) proficiency-testing program is part of the comprehensive quality control program. These survey materials are shipped three times per year and consist of 5 3-mL whole blood specimens. Follow all CAP instruction in preparing the materials before performing the test. Run specimens in a manner identical to routine specimens. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

G. Linearity for WBC, RBC, Hgb and Plt parameters

Lin-C™ (PN 7547065 - 5 x 3.3-mL) The Lin-C™ linearity controls verifies the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent.

OR

CAP Hematology Calibration Verification/Linearity Survey (LN9) - These materials are shipped twice per year and consist of 18 3-mL liquid specimens. Follow all CAP instruction in preparing and running the materials before performing the test. Fill out the CAP result form, make a copy for the logbook, and send results to CAP.

Run either the Lin-C™ or CAP LN9 survey material:

- At installation
- At least yearly
- Whenever experiencing an altitude change of 1 mile or more between stands

1. Principle - Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems. Controls contain one each of Ultra Low Range, Low Range, Mid Range, High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt.

To ensure the accuracy of linearity control ranges, Beckman Coulter® system calibrates with S-CAL® calibrator.

2. Reagents -- Lin-C™ controls consist of treated, stabilized, human erythrocytes in an isotonic bacteriostatic medium. Linearity controls also contain a stabilized platelet-sized component, and fixed erythrocytes to simulate leukocytes.
3. Storage, handling, and stability -- Ship Lin-C™ controls in thermally insulated containers designed to keep kits cool. Store Lin-C™ linearity controls between 2-8°C (35-46°F). Store vials in an upright position to achieve maximum product yield. Storage of the control product in a cap down position might require additional mixing or complete resuspension of cellular components.

Potential biohazard -- Each human donor used in preparation of this material was tested by an FDA approved method for the presence of the antibodies to Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) as well as for hepatitis B surface antigen and found to be negative (were not repeatedly reactive.) Handle these reagents at Biosafety Level 2 because no test method can offer complete assurance that these and other infectious agents are absent.

4. Indications of instability or deterioration -- Inability to obtain expected values without known instrument problems or gross hemolysis (dark colored supernatant) indicates product deterioration. A slight pink color to the supernatant is normal. Do not confuse this pink color with deterioration of the product.

5. Instructions for use -- Remove Lin-C™ controls from refrigerator and warm to ambient temperature for 10-15 minutes. After warming, mix by hand as follows:

Do not use a rotator, rocker, or mechanical mixer. Roll the tube slowly between the palms of the hands eight full rotations in an upright position. Invert the tube and slowly roll it again eight times. Gently invert the tube eight times. Repeat these actions again. Controls expire 7 days after opening.

a) Turn the blood detectors off to analyze the Ultra Low Range. Select **SPECIAL FUNCTIONS, DIAGNOSTICS, OPERATOR OPTIONS, BSV TESTS, and BLOOD DETECTOR ON/OFF.** Press [Enter]. Use space bar to select On or OFF. Press [Enter].

b) Disable the differential before analyzing Lin-C™ linearity controls. Is SAMPLE MODE displayed? If no, press [F9] STOP. Make sure the DIFF is off. If it is on, press [F6].

c) When analyzing Lin-C™ linearity controls, flags such as L, LL, H, HH, R, RR, *, *R, and *V will occur. Ignore these flags if a numerical result is obtained. When ---- (voteout), (incomplete computation) or ++++ (over range) flags occur, the sample should be repeated. Ignore Beckman Coulter® histogram differential flags and results.

d) Run the Lin-C™ controls in the Primary Mode of the instrument. Select **SPECIAL FUNCTIONS, CALIBRATION, and REPRODUCIBILITY.** Press [Enter]. Press [F2] START PRIMARY. Analyze controls six times and record the results for WBC, RBC, Hgb, and Plt

parameters for each sample on the worksheet. Repeat flagged samples with non-numeric results.

- e) Beckman Coulter® recommends that five sample results should be used to calculate the mean value. Use a minimum of three samples to calculate the mean when repetitive results with non-numeric values occur. Delete the first sample result. Plot mean recovered values on the Lin-C™ linearity control graphs.
- f) Compare the mean value to the linearity control ranges listed on the Table of Expected Results on the package insert. Mean values should recover within the ranges. Use the ranges established by Beckman Coulter® Corporation as a guideline.
- g) Plot the instrument background count as a zero value to extend the reportable range. Beckman Coulter® will prepare tabular summaries and graphic presentations of the data. Submit the top copy of the worksheet to IQAP at the following address:

Beckman Coulter Corporation
IQAP (M/C 31 B04)
PO BOX 169015
Miami, FL 33116-9015

XI. Interpretation of Results and Remedial Action

A. Sample Person hemoglobin and hematocrit review and remedial actions.

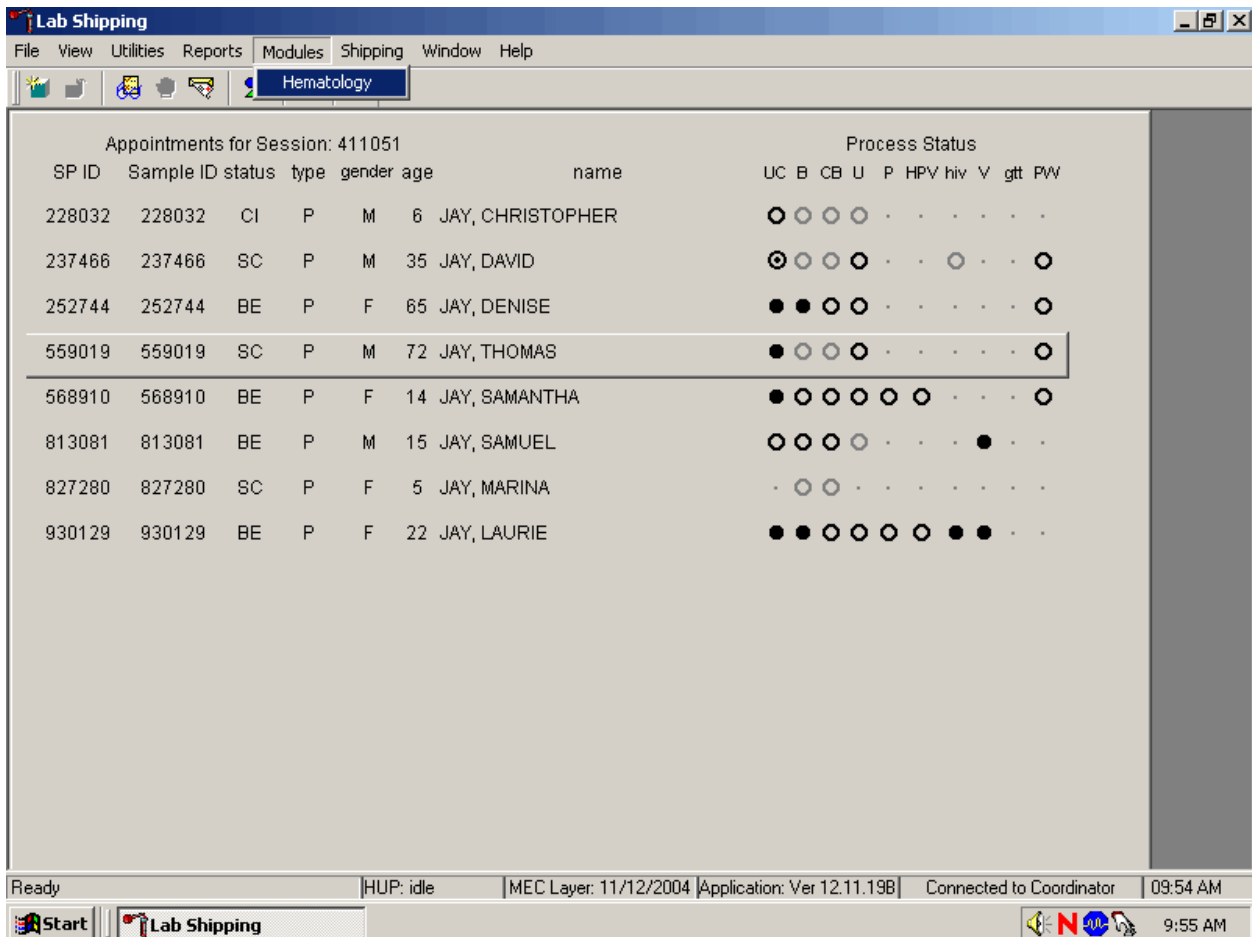
1. Review all results to make sure the hemoglobin and hematocrit are acceptable. The hematocrit should be approximately three times the hemoglobin.

B. Sample person parameter value review and remedial actions.

1. Access the Hematology module or reject a clotted blood tube.

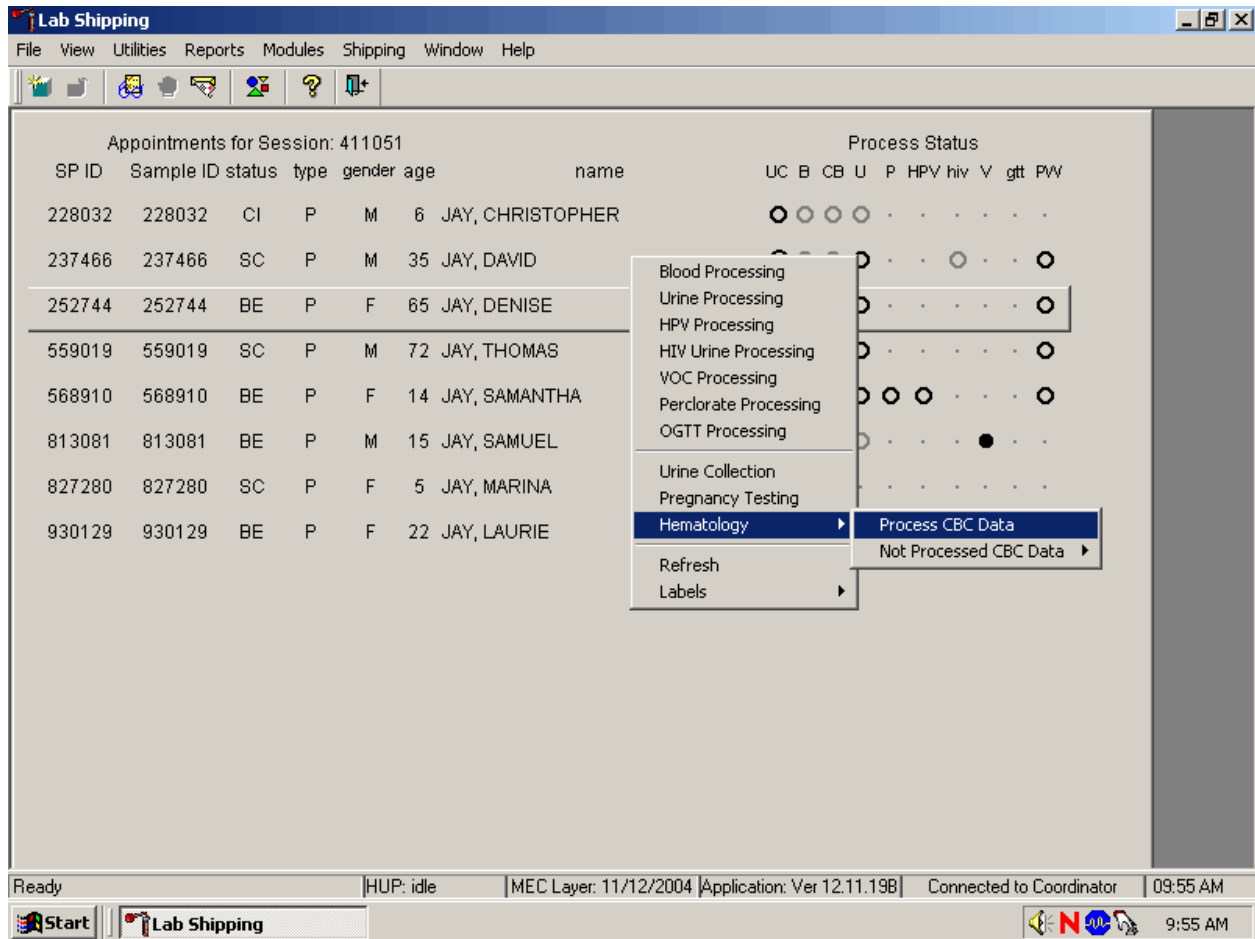
Make sure the Hematology module is open before running SP samples on the MAXM.

Open the Hematology module.



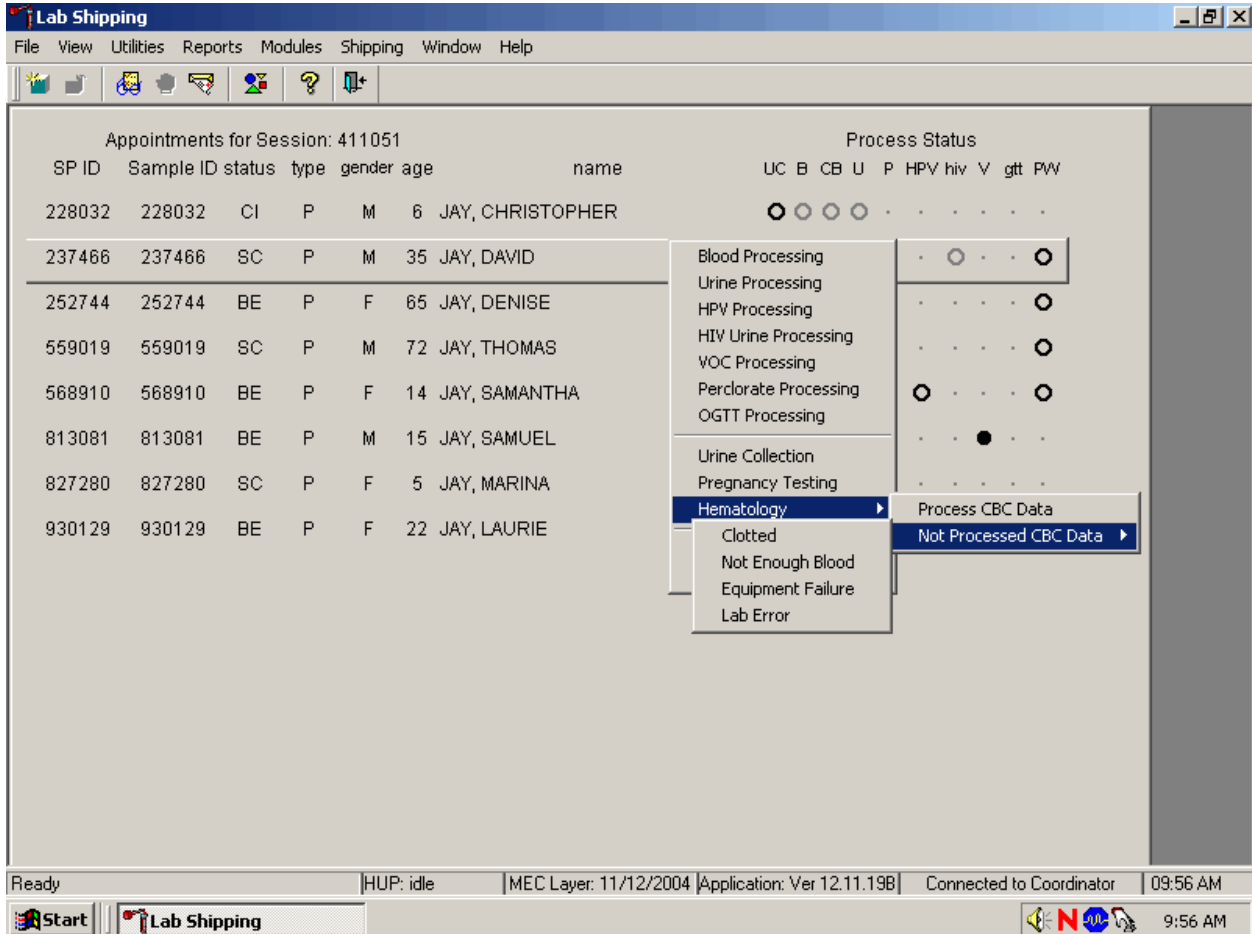
To open the Hematology module, use the mouse to direct the mouse arrow to {Modules}, in the top menu bar, left click, drag the mouse arrow to {Hematology}, and right click, or type [Alt][M/m], [H/h].

Alternatively, open the Hematology module from the heads-up display.



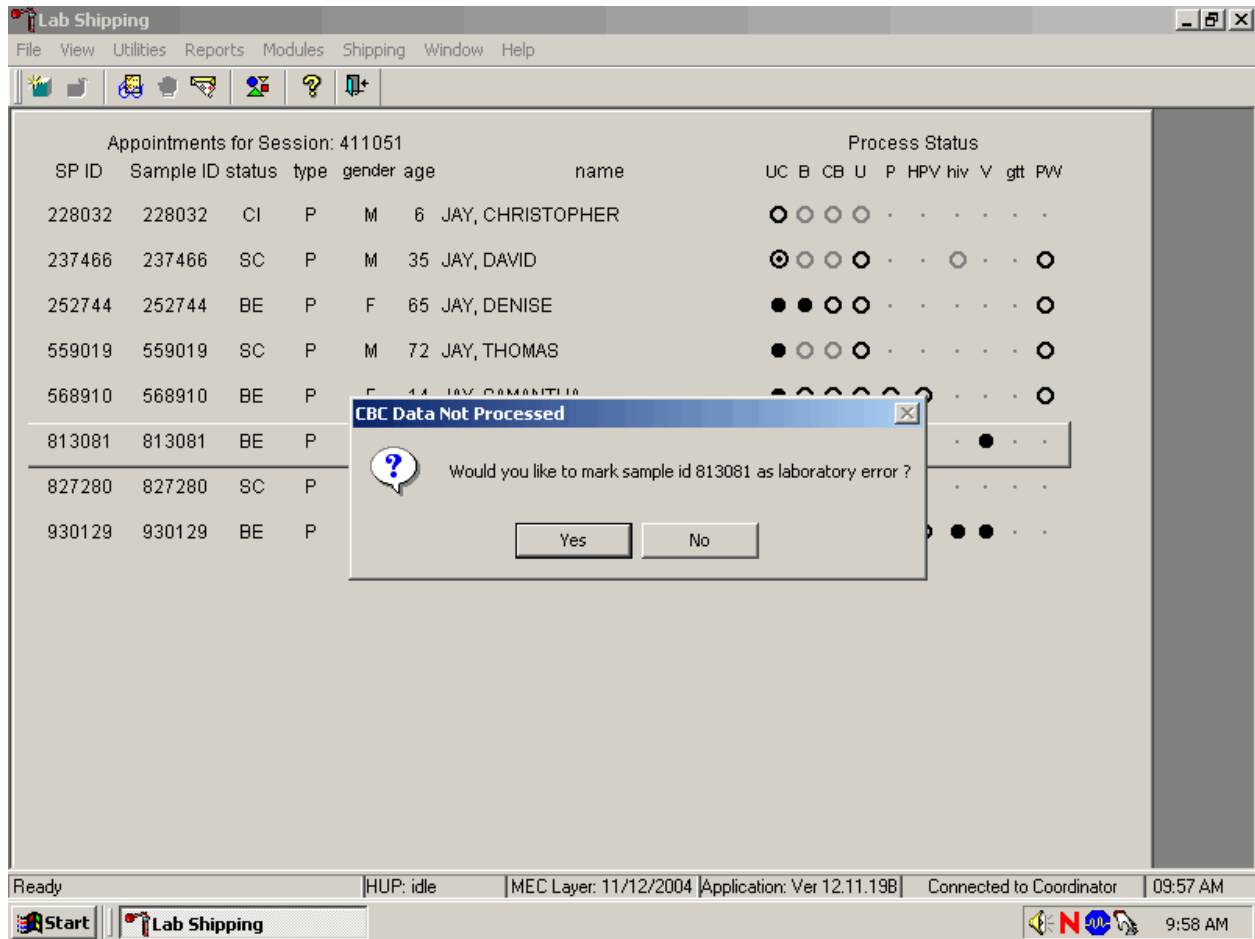
To access the Hematology module, use the mouse to direct the mouse arrow to any SP, right click, drag the mouse arrow to {Hematology} then to {Process CBC Data}, and right click or right click and type [Shift] [E/e] [P/p]. Alternatively, use the up and down keys to move up and down the list until a particular SP is highlighted, right click, drag the mouse arrow to {Hematology} then to {Process CBC Data}, and right click or right click and type [Shift] [E/e] [P/p].

Either open the module or reject the specimen and add a reason or comment for every CB record where blood was drawn in phlebotomy AND there are no CBC results.



Open the module {Process CBC Data} or record a reason why the CBC is not being run {Not Processed CBC Data}. Select or record a comment for every CBC that is not run. To complete opening or accessing the Hematology module, use the mouse to direct the mouse arrow to {Process CBC Data} and right click or type [P/p.] To record a reason why a CBC is not being run, use the mouse to direct the mouse arrow to the exact SP's line on the heads-up display, right click, drag the mouse arrow to {Not Processed CBC Data}, and drag the mouse arrow to the correct reason and right click. Alternatively, type [Shift] [E/e] [N/n] and [C/c] for Clotted, [N/n] for Not Enough Blood, [E/e] for Equipment Failure, or [L/l] for Lab Error.

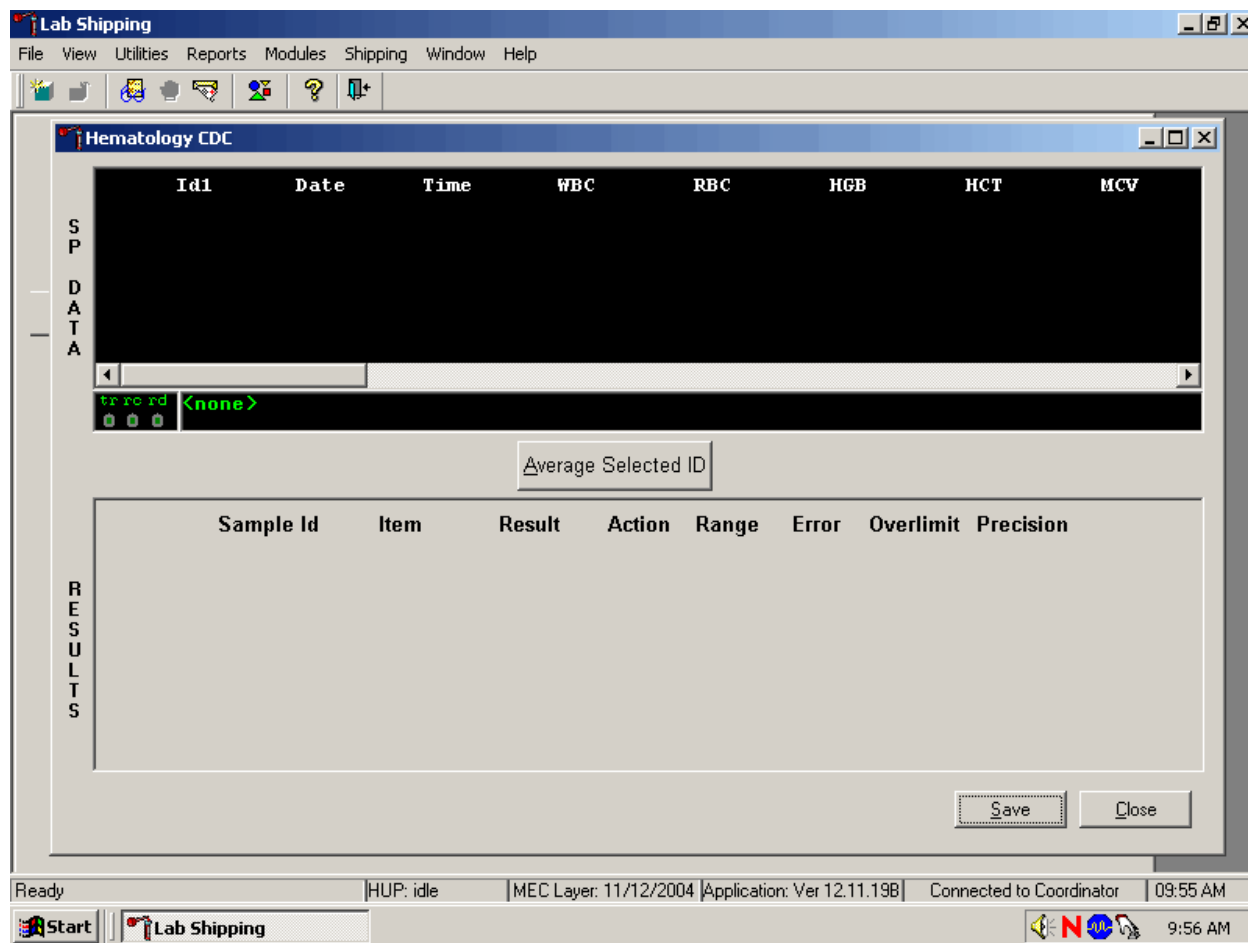
A pop-up window will display. Confirm the selection.



A CBC Data Not Processed message text box displays that asks, "Would you like to mark sample id XXXXXX as Clotted/Not Enough Blood/Equipment Failure/Lab Error?" To record a "Yes" response, use the mouse to direct the mouse arrow to the Yes button and left click, type [Y/y], or press [Enter]. To record a "No" response, use the mouse to direct the mouse arrow to the No button and left click, or type [N/n]. If a Yes response is recorded, the comment is saved to the database. If a No response is recorded, no comment is saved to the database. If the record is marked with the selection in the database, then the heads-up display updates to complete (the CB circle fills in).

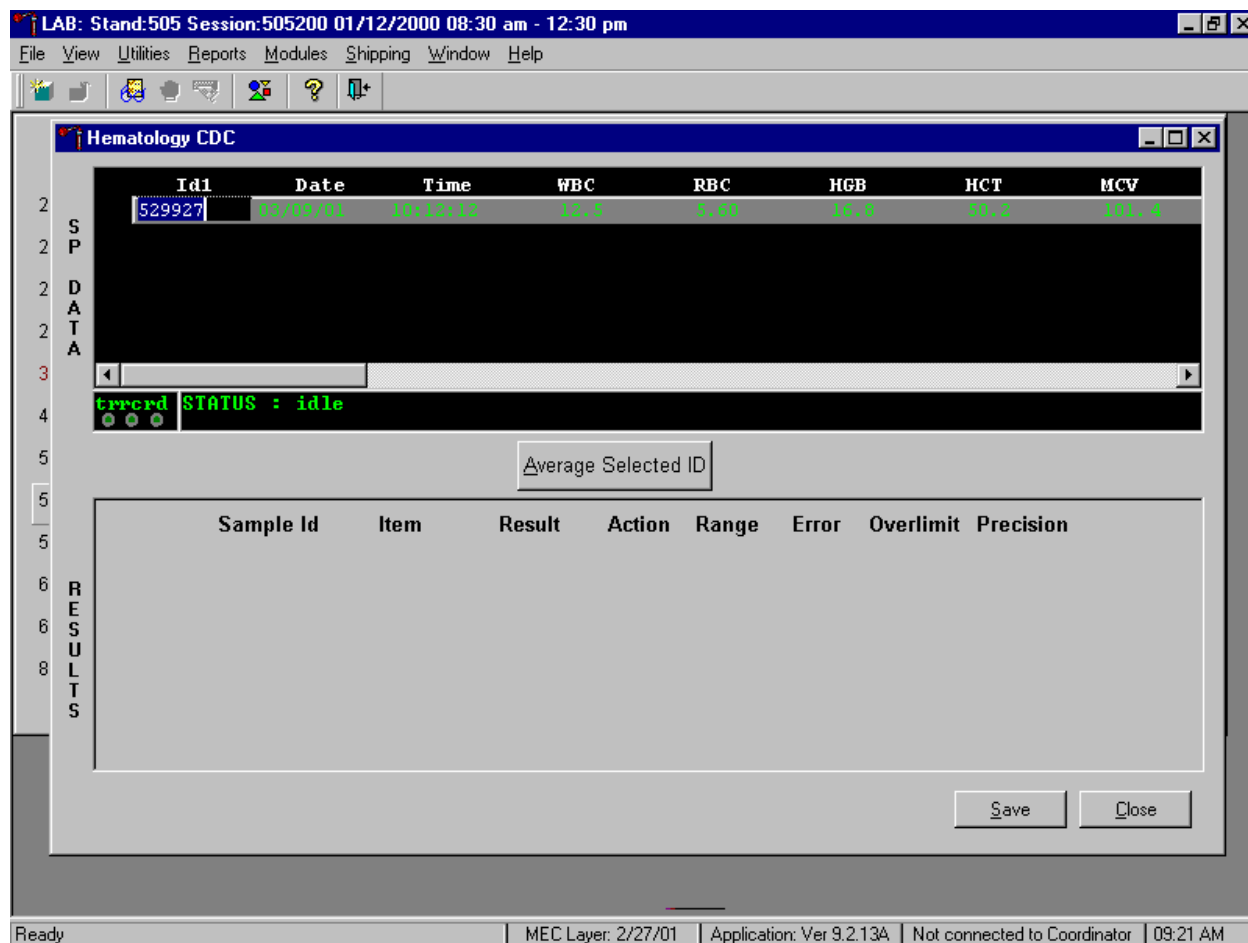
2. Hematology module overview.

Coulter automatically transmits results to the Laboratory application. Make sure the Beckman Coulter DMS host computer icon (HC) is displaying an up arrow (↑) in the DMS bottom tile bar.



SP data transmits to the Hematology module and displays it in the top portion of the window, the SP Data section. This section includes the SP ID, the date and time the CBC was run, and columns for each individual parameter. The bottom portion of the window is the Results section. Results display after the Average Selected ID button is selected.

Review all Coulter data in the SP Data section after transmission.



To view SP data for all parameters, use the mouse to direct the mouse arrow to the horizontal scroll bar at the bottom of the SP Data section and drag the scroll bar to the left or right. Alternatively, to view the SP data for all parameters, use the mouse to direct the mouse arrow to the small scroll arrows on the left and right edges of the horizontal scroll bar, and left click.

The Hematology Results section overview.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The main window is titled "Hematology CDC".

On the left side, there are vertical labels: "S P" (rows 2-3), "D A T A" (rows 4-5), and "R E S U L T S" (rows 6-8). The "S P" section shows a summary table with the following data:

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 529927 | 05/05/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |

Below the summary table, there is a status bar showing "ERROR STATUS : idle".

The "R E S U L T S" section contains a table with the following data:

| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 529927 | CBC_WBC | 12.5 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 529927 | CBC_RBC | 5.6 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 529927 | CBC_HGB | 16.8 | H | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 529927 | CBC_HCT | 50.2 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

At the bottom of the results table, there is a comment field for Sample Id# 529927 with the text "result based on single run". There are "Save" and "Close" buttons to the right of the comment field.

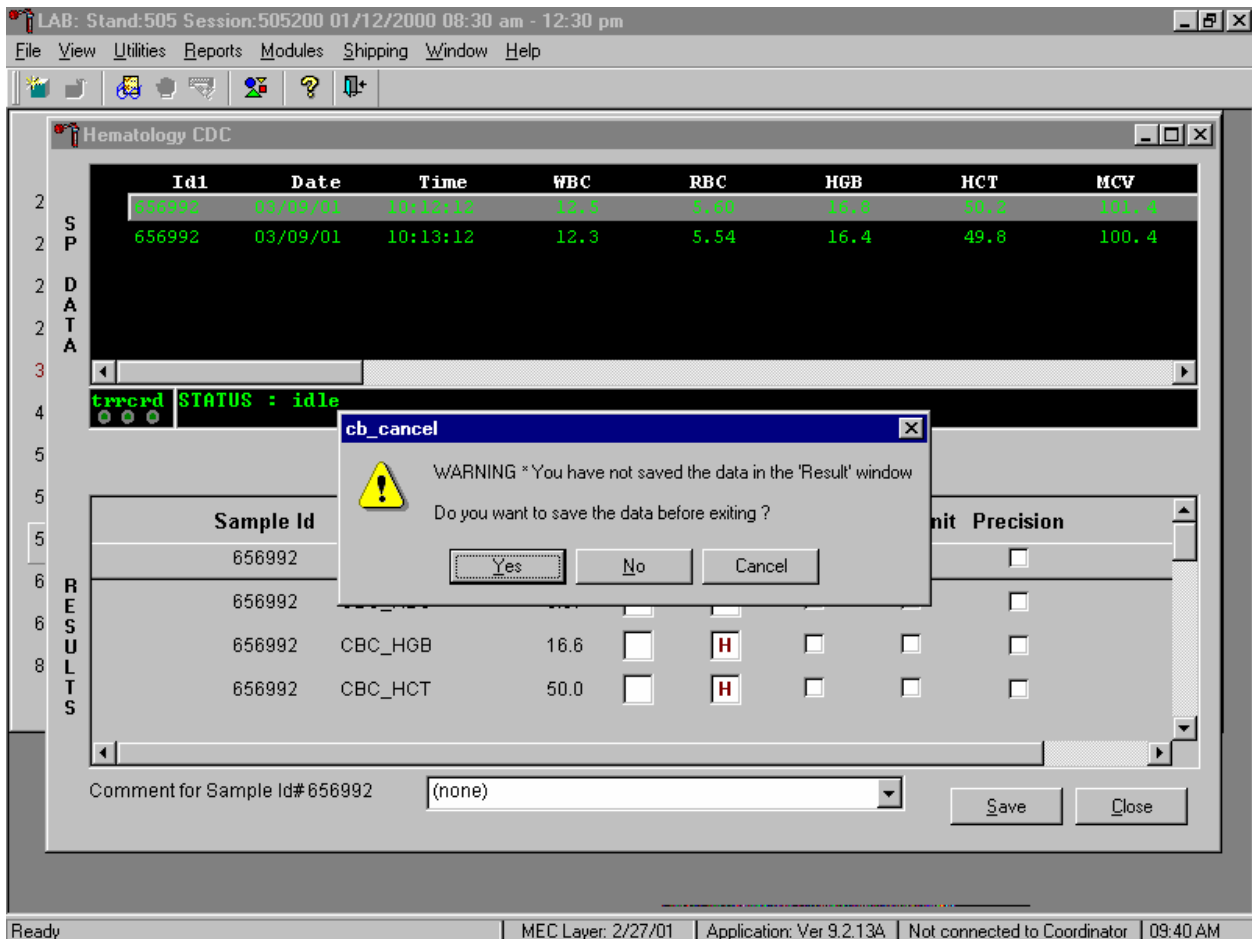
The status bar at the bottom of the window shows: Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:23 AM

The Result columns include: Sample ID, Item (CBC parameter), Result (Coulter data for a single run or the ISIS averaged result for multiple runs), Action (CDC established critical limits), Range (CDC established reference ranges for both genders and four age groups), Error (Coulter transmitted instrument errors), Overlimit (Coulter transmitted result that exceeds the instrument's linearity limit), and Precision (CDC established values for the difference between any two runs.) Checkmarks display in boxes for parameters that have errors, are overlimit, or for those that exceed precision limits. An "H" for "high" and "L" for "low" display for parameters that exceed action limits or reference ranges.

Average, evaluate, and save results for all parameters. The SP's results display in the bottom portion of the window after the Average Selected ID button is selected. To view results for all parameters, use the mouse to direct the mouse arrow to the vertical scroll bar at the right side of the

Results section and drag the bar up or down. Alternatively, to view all the results, use the mouse to direct the mouse arrow to the small scroll arrows on the top and bottom edges of the vertical scroll bar, and left click. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. To save the result to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Cancel button and left click or type [Shift] [C/c].

A warning text box displays if the Close button is selected before the results have been saved.

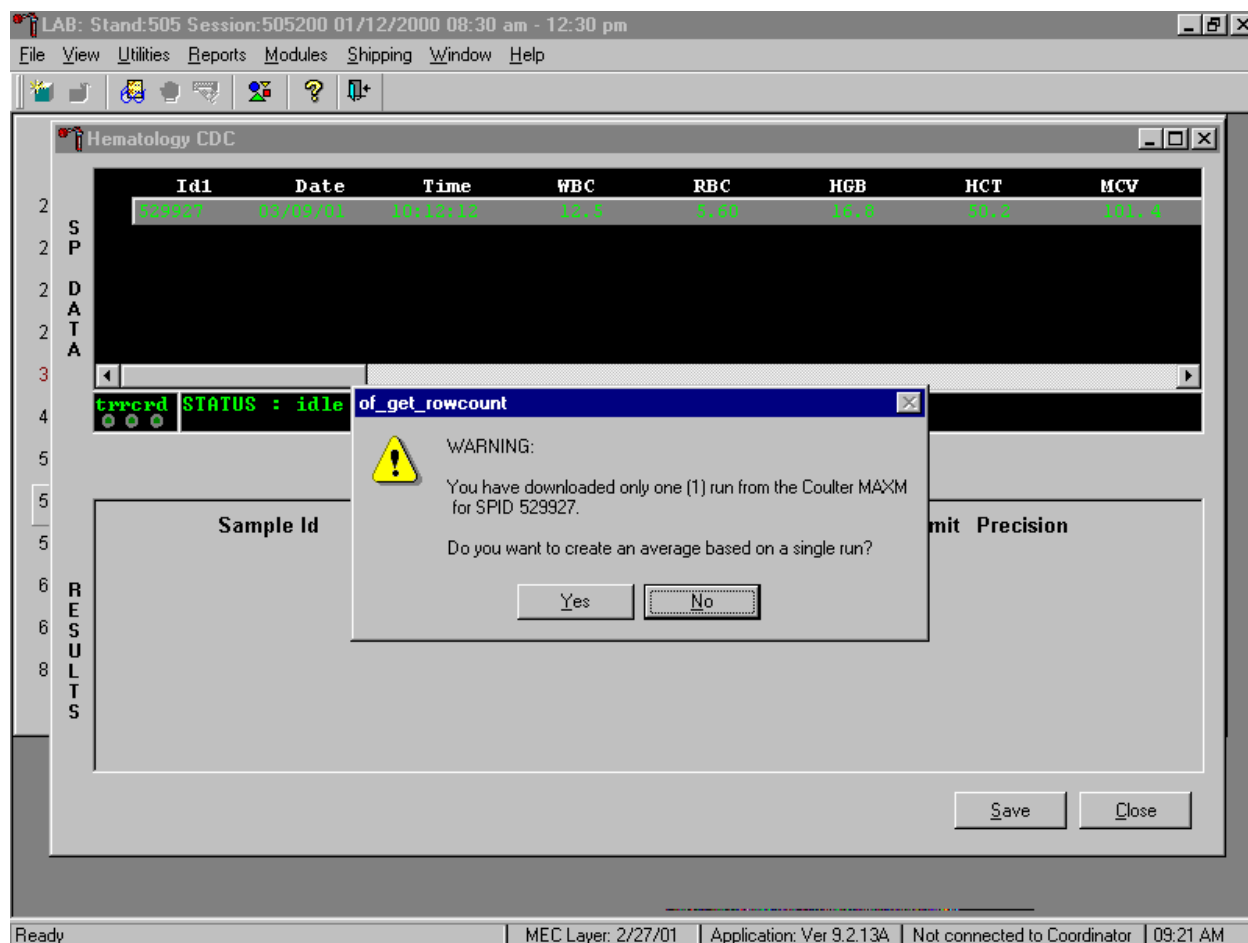


If the Close button is selected before the results are saved to the database, a warning message text box displays that states, "WARNING *You have not saved the data in the 'Result' window" and asks,

"Do you want to save the data before exiting?" To record a "Yes" response, use the mouse to direct the mouse arrow to the Yes button and left click, type [Y/y], or press [Enter]. To record a "No" response, use the mouse to direct the mouse arrow to the No button and left click, or type [N/n]. To cancel the action, use the mouse to direct the mouse arrow to the Cancel button and left click. If a Yes response is recorded, the CBC results are saved to the database and erased. If a No response is recorded, no results are saved to the database and the data in the Results section is erased. A Cancel response returns the screen to its previous state.

3. Running samples when only one run is possible.

Save results where only one run was possible.

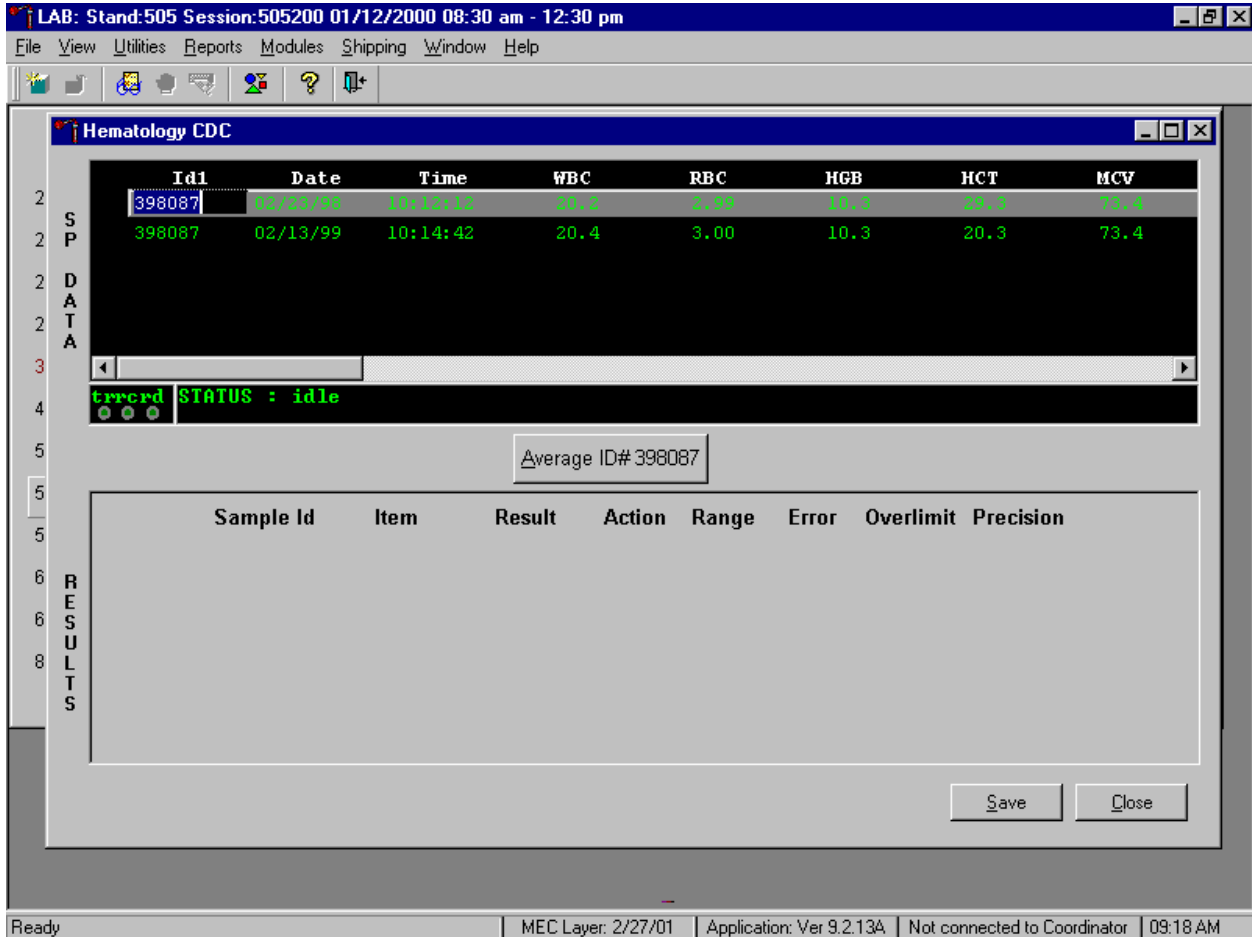


Run samples in duplicate whenever possible. If the whole blood is insufficient, it is acceptable to average and save only one run. To save results where only one run is possible, use the mouse to direct the mouse arrow to the Average Selected ID box and left click. A warning message text box displays that states, "You have downloaded only one (1) run from the Coulter MAXM for SPID XXXXXX" and asks, "Do you want to create an average based on a single run?" To record a "Yes" response, use the mouse to direct the mouse arrow to the Yes button and left click or type [Y/y]. To record a "No" response, use the mouse to direct the mouse arrow to the No button and left click, or type [N/n], or press [Enter]. If a Yes response is recorded, the CBC results display in the bottom Results section of the window. A "No" response cancels the action and returns the window to its previous state.

For results where only one run was possible, the Comment box at the bottom of the window defaults to "result based on single run."

4. Running samples in duplicate.

Run all samples in duplicate and average the data.



Whenever a sample is run in duplicate, both results display in the SP Data section. To average these two results, use the mouse to direct the mouse arrow to Average ID#XXXXXX button and left click.

Results display in the lower section of the window.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Hematology CDC

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 656992 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 656992 | 03/09/01 | 10:13:12 | 12.3 | 5.54 | 16.4 | 49.8 | 100.4 |

errord STATUS : idle

Average ID# 656992

| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------|--------------------------|-------|--------------------------|--------------------------|--------------------------|
| 656992 | CBC_WBC | 12.4 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 656992 | CBC_RBC | 5.57 | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 656992 | CBC_HGB | 16.6 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 656992 | CBC_HCT | 50.0 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comment for Sample Id# 656992 (none) Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:40 AM

The difference between duplicate values for WBC, RBC, Hgb, MCV, Plt, NE#, LY#, MO#, EO# and BA# are calculated and evaluated to determine if the differences are within the following CDC established precision limits.

CDC established precision limits:

| Test | Precision Limits |
|------|-------------------|
| WBC | 0.4×10^3 |
| RBC | 0.1×10^6 |
| Hgb | 0.4 g/dL |
| MCV | 2.2 fL |
| Plt | 23×10^3 |
| NE# | 0.4×10^3 |
| LY# | 0.2×10^3 |
| MO# | 0.2×10^3 |
| EO# | 0.2×10^3 |
| BA# | 0.2×10^3 |

If RBC parameters are out of range, evaluate the data for drift. If drift is evident, evaluate the possibility of an instrument malfunction. If any WBC differential absolute number is out of range, check the WBC scattergram for abnormal cell population(s).

Evaluate and save results when precision limits are not exceeded.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The main window is titled "Hematology CDC" and contains a data table with the following columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. The data rows are:

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 656992 | 03/08/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 656992 | 03/09/01 | 10:13:12 | 12.3 | 5.54 | 16.4 | 49.8 | 100.4 |

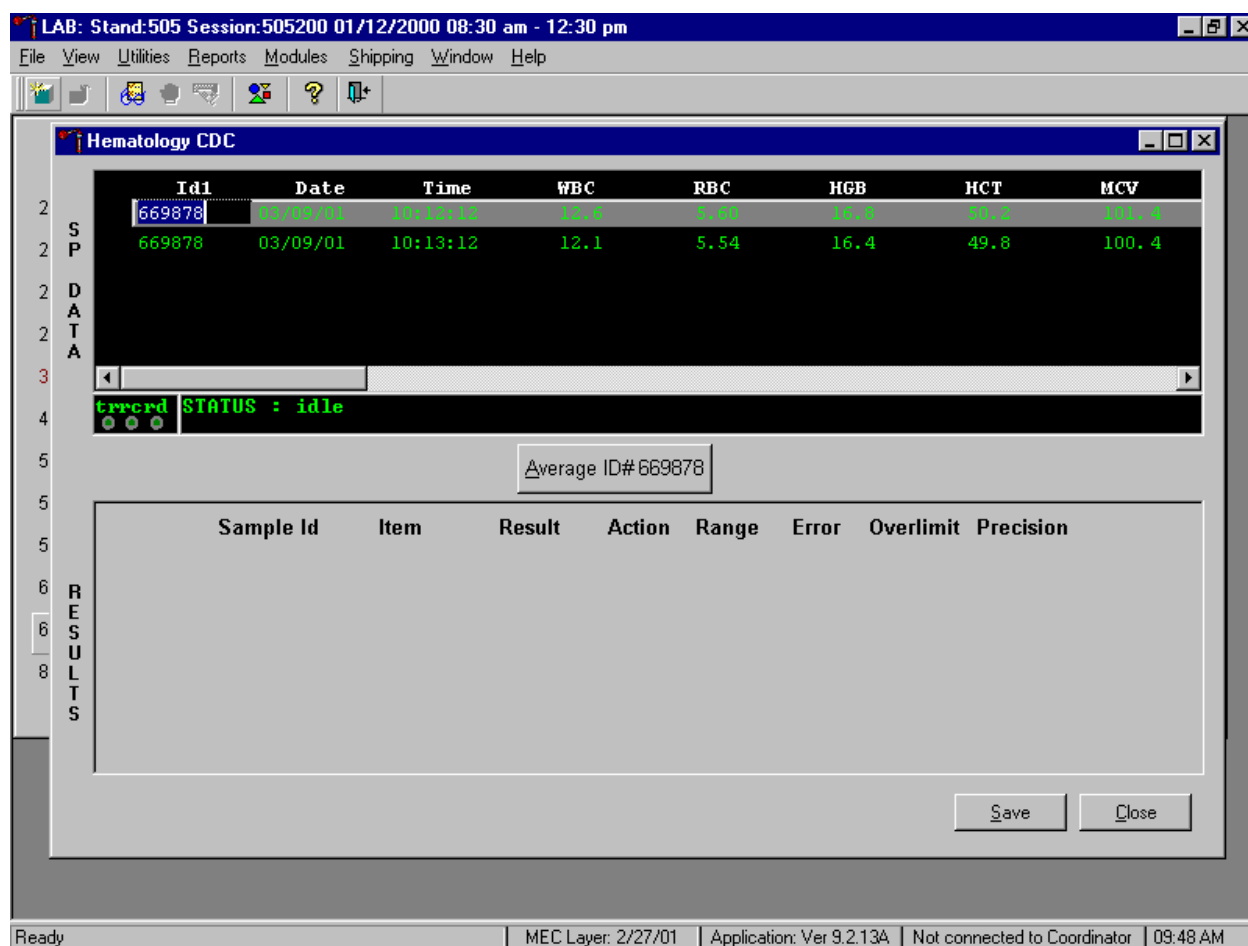
Below the data table, there is a status bar showing "errord STATUS : idle". A text box contains "Average ID# 656992". The "RESULTS" section contains a table with the following columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The data rows are:

| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------|--------------------------|-------|--------------------------|--------------------------|--------------------------|
| 656992 | CBC_WBC | 12.4 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 656992 | CBC_RBC | 5.57 | <input type="checkbox"/> | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 656992 | CBC_HGB | 16.6 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 656992 | CBC_HCT | 50.0 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

At the bottom of the results section, there is a text box for "Comment for Sample Id# 656992" with the value "(none)", and "Save" and "Close" buttons.

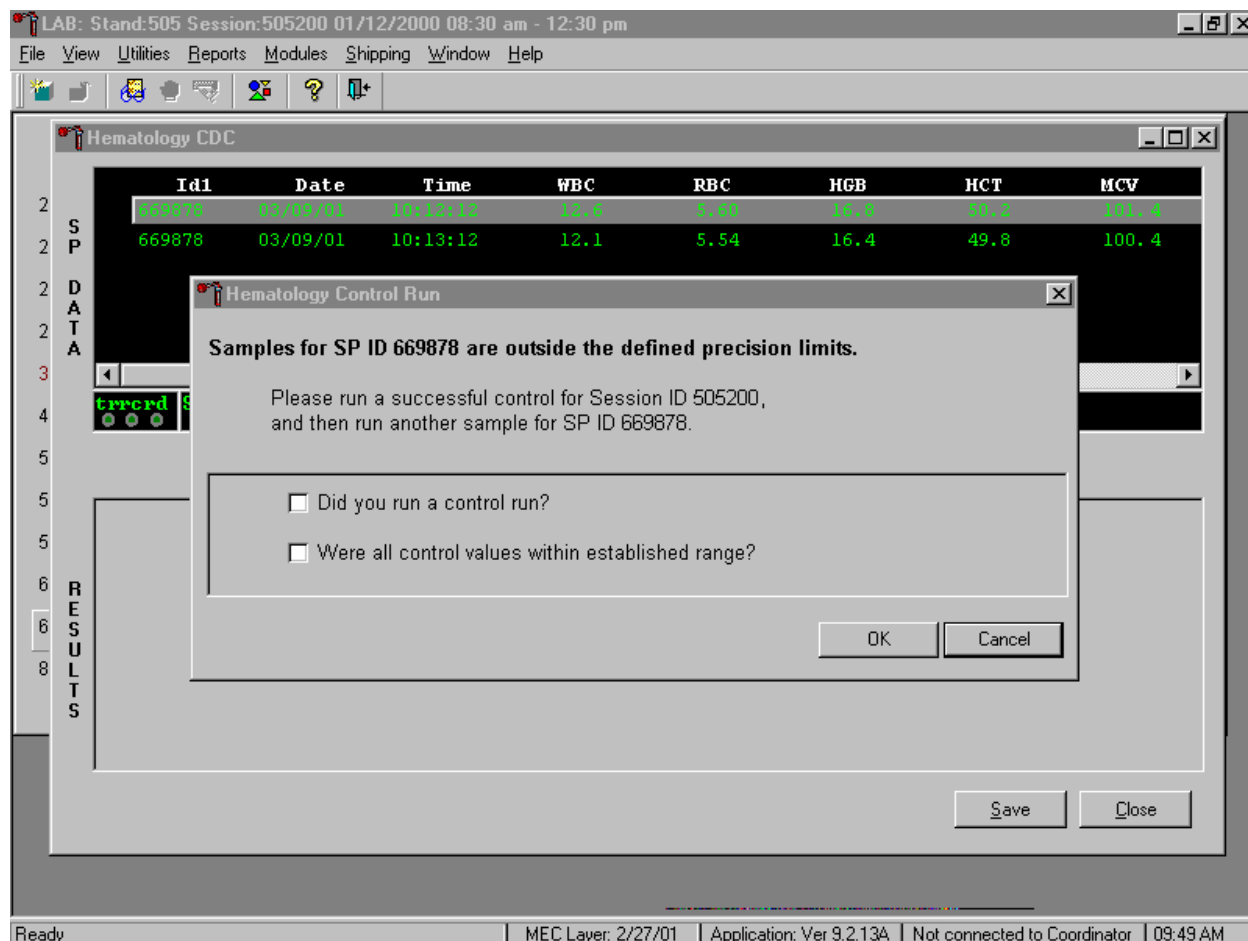
Evaluate results for all parameters. Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the results to the database. To save the results to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

Average, evaluate, and rerun specimens that exceed precision limits.



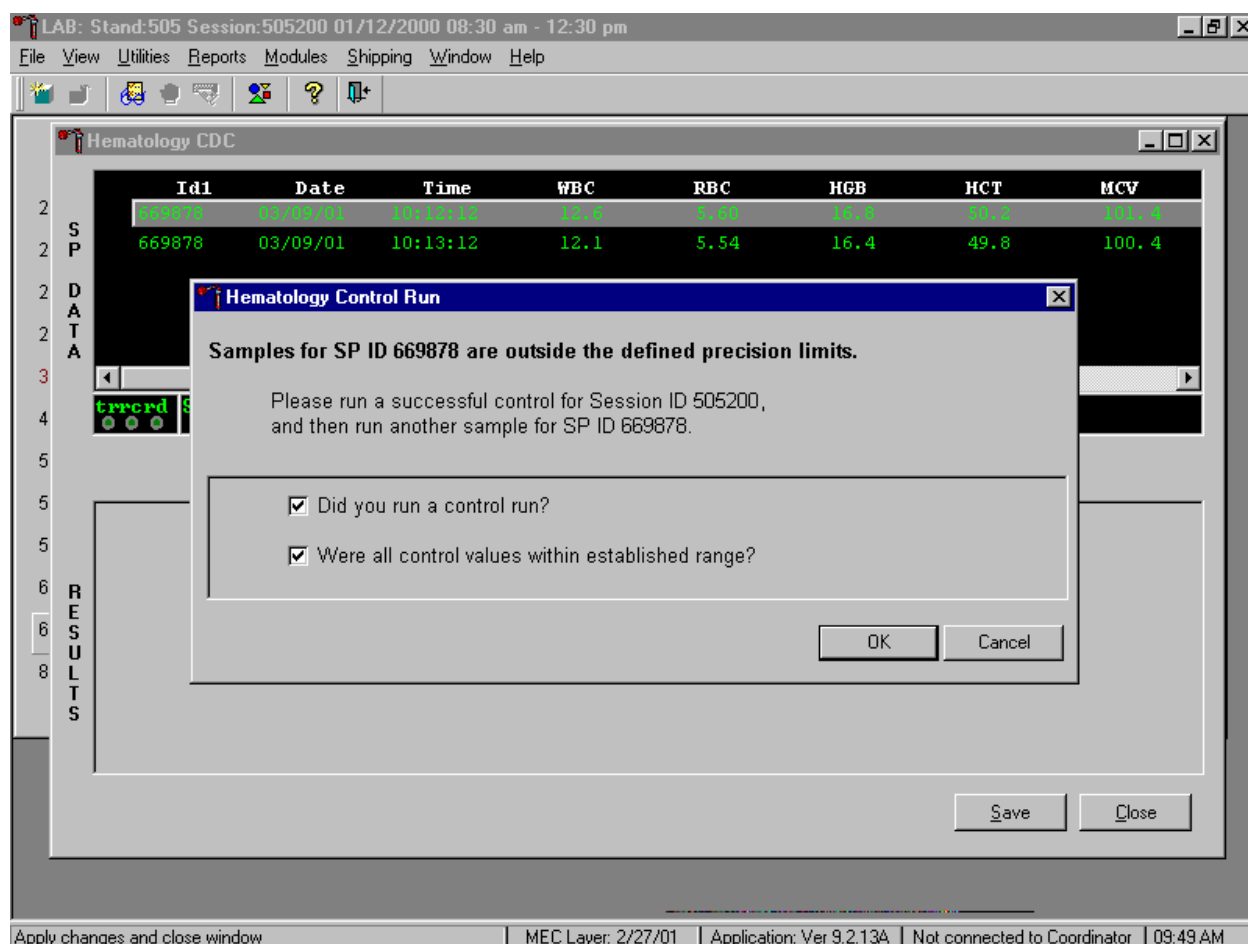
Average the two results by using the mouse to direct the mouse arrow to the Average ID#XXXXXX button and left click. If at this point, precision limits are exceeded for any individual parameter, the technologist is prompted to run a control and evaluate the control to determine if all control values fall within the control's established range.

If any parameter exceeds its precision limit, the Hematology Control Run window displays.



The Hematology Control Run window indicates that the "Samples for SP ID XXXXXX are outside the defined precision limits." It instructs the technologist to "Please run a successful control for Session ID XXXXXX, and then run another sample for SP ID XXXXXX." Run any one level of 5C Cell control and evaluate the results. Respond to the two questions, "Did you run a control run?" and "Were all control values within established range?" To confirm these actions, use the mouse to direct the mouse arrow to each of the two check boxes and left click to record the check marks.

Save the responses to the check box questions.



To save these responses to the database, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter], or to exit the Hematology Control Run window without saving the responses, use the mouse to direct the mouse arrow to the Cancel button and left click. As soon as the OK button is selected, the averages display in the Results section of the window.

Evaluate the results displayed in the Results section of the window.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". A toolbar contains various icons. The main window is titled "Hematology CDC" and is divided into several sections:

- DATA:** A table with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. It contains two rows of data for sample IDs 669876 and 669878.
- STATUS:** A section showing "Average ID# 669878" and a status indicator "STATUS : idle".
- RESULTS:** A table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. It lists results for WBC, RBC, HGB, and HCT for sample ID 669878. The RBC, HGB, and HCT results have "H" flags in the Action column, indicating high values.
- Comment:** A text field for "Comment for Sample Id# 669878" with the value "(none)".
- Buttons:** "Save" and "Close" buttons are located at the bottom right of the results section.

The status bar at the bottom of the window displays: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:50 AM".

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. Use the scroll bar to view all results. When there are checkmarks in any of the Precision columns, meaning that the precision limit was exceeded, rerun the blood sample a third time. If there is insufficient blood to run the CBC a third time, save the result to the database. To save the results to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

Run the specimen a third time when any precision limit is exceeded.

The screenshot shows a software window titled "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Inside, there is a "Hematology CDC" window and a "RESULTS" window.

Hematology CDC Data:

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 669878 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 669878 | 03/09/01 | 10:13:12 | 12.0 | 5.54 | 16.4 | 49.8 | 100.4 |
| 669878 | 03/09/01 | 10:16:45 | 12.3 | 5.57 | 16.8 | 50.0 | 100.4 |

Below the table, it says "errord STATUS : idle".

RESULTS Data:

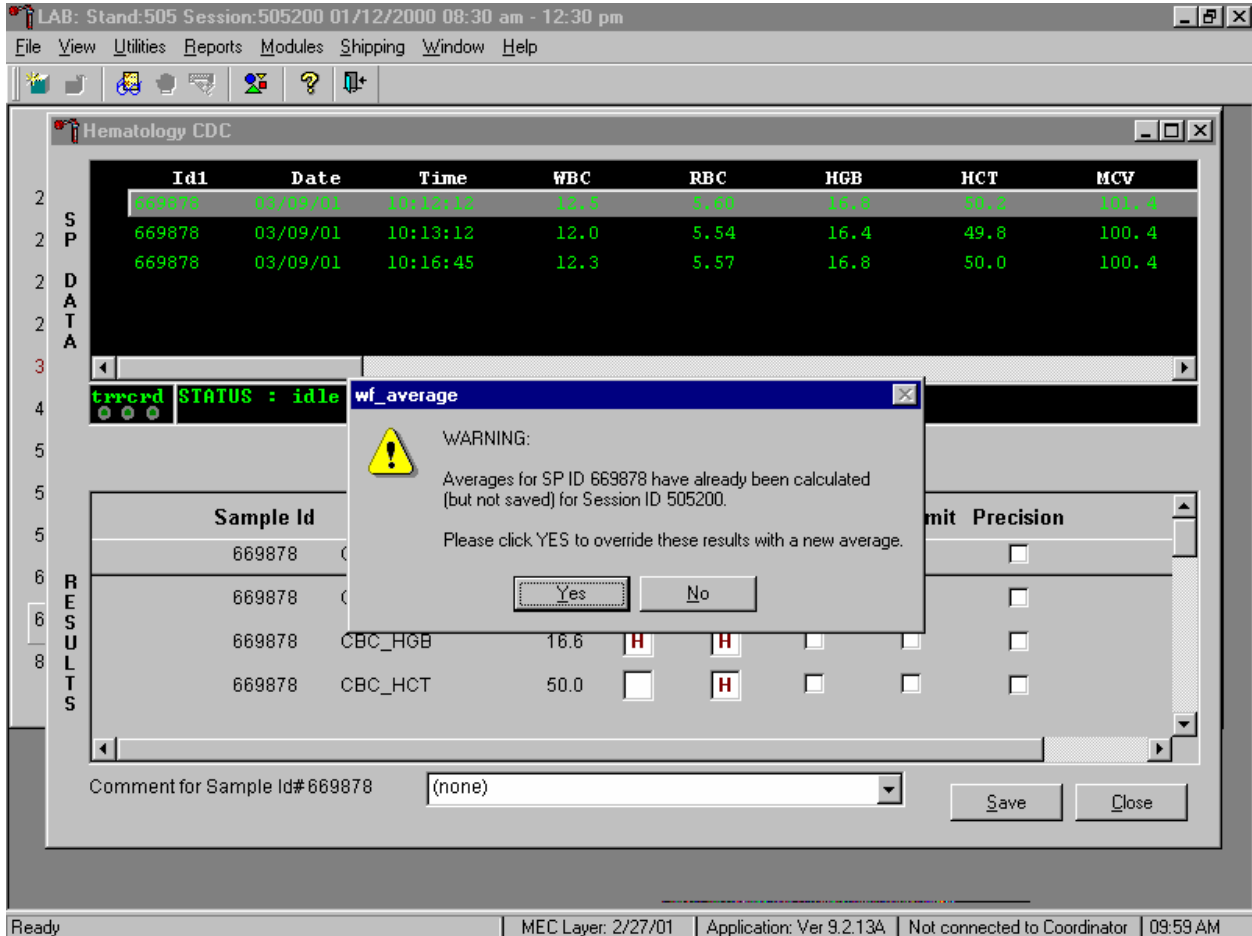
| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 669878 | CBC_WBC | 12.4 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_RBC | 5.57 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HGB | 16.6 | H | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HCT | 50.0 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

At the bottom of the RESULTS window, there is a "Comment for Sample Id#669878" field with "(none)" selected, and "Save" and "Close" buttons.

The status bar at the bottom shows: Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:58 AM

Run the blood sample a third time. Whenever a sample is run more than once, all results in the SP Data section are displayed. To re-average these results, use the mouse to direct the mouse arrow to Average ID#XXXXXX button and left click. The initial averaged result for parameters that do not exceed precision limits are fixed and are not recalculated.

Override the current averaged results for parameters that exceeded the precision limit with a new average.



Whenever a sample has previously been averaged, and a new average is calculated, a Warning message text box displays stating, "Averages for SP ID XXXXXX have already been calculated (but not saved) for session ID XXXXXX." The text box instructs, "Please click YES to override these results with a new average." To override the current average with a new average (but for only those parameters that exceeded precision limits), use the mouse to direct the mouse arrow to the Yes button and left click or type [Shift] [Y/y], or press [Enter]. To exit or return to the previous screen containing the previous averages, use the mouse to direct the mouse arrow to the No button and left click, or type [Shift] [N/n].

Evaluate the new results.

LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Hematology CDC

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 669878 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 669878 | 03/09/01 | 10:13:12 | 12.0 | 5.54 | 16.4 | 49.8 | 100.4 |
| 669878 | 03/09/01 | 10:16:45 | 12.3 | 5.57 | 16.8 | 50.0 | 100.4 |

errord STATUS : idle

Average ID# 669878

| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 669878 | CBC_WBC | 12.4 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_RBC | 5.57 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HGB | 16.6 | H | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HCT | 50.0 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comment for Sample Id# 669878 (none)

Save Close

Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:59 AM

The first three runs are recalculated to find the closest two results for parameters where the difference between any two results exceeded its precision limits. If all parameters now meet precision limits (there are no checkmarks in the Precision column), save the results to the database. To save the result to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. After results are saved, they are erased from the screen. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

If necessary, run the specimen a fourth time and evaluate.

If precision limits are still not met for any parameter, run the blood tube a fourth time. Re-average, evaluate, and save the results. If after four runs precision limits are still not met for any parameter, a comment is automatically attached to the results. Do not run a specimen more than four times.

5. Attaching comments to the results.

Enter a comment for any run where results were repeated and confirmed, the equipment failed, or there was a laboratory error.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". A toolbar with various icons is located below the menu bar.

The main window is titled "Hematology CDC" and contains a table of data. The table has columns: Id1, Date, Time, WBC, RBC, HGB, HCT, and MCV. The data rows are:

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 669878 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 669878 | 03/09/01 | 10:13:12 | 12.0 | 5.54 | 16.4 | 49.8 | 100.4 |
| 669878 | 03/09/01 | 10:16:45 | 12.3 | 5.57 | 16.8 | 50.0 | 100.4 |

Below the table, there is a status bar that says "errord STATUS : idle". A button labeled "Average ID# 669878" is visible.

The "RESULTS" section contains a table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The data rows are:

| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 669878 | CBC_WBC | 12.4 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_RBC | 5.57 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HGE | (none) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HCT | results repeated and confirmed | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

A dropdown menu is open over the "results repeated and confirmed" row, showing options: "results repeated and confirmed", "laboratory error", "result based on single run", and "(none)". Below the table is a "Comment for Sample Id# 669878" field with a dropdown menu showing "(none)". "Save" and "Close" buttons are at the bottom right.

The status bar at the bottom of the window displays: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 09:59 AM".

To attach a comment to the results in the database, use the mouse to direct the mouse arrow to the drop-down list on the Comment box, left click to display the codes, drag the mouse arrow to the most appropriate choice, and left click. Alternatively, to record a comment, use the mouse to direct the

mouse arrow to the drop-down list on the Comment box, click to display the codes, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code, and when the correct choice is highlighted, left click.

| Comment | Use when: |
|--------------------------------|---|
| results repeated and confirmed | Any parameter exceeded an action, range or precision limit and the specimen (blood tube) was run more than once. |
| equipment failure | The Coulter malfunctioned. |
| laboratory error | There was a technologist error. |
| result based on single run | The quantity of specimen is insufficient to run it more than once. |
| no diff results/diff voteout | The Coulter does not report parameter results for any part of the differential or the instrument reported a voteout for any of the differential parameters. |

Save the result after attaching a comment.

The screenshot shows the Hematology CDC software interface. At the top, the window title is "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The main window is titled "Hematology CDC".

On the left side, there are vertical labels: "S P" (rows 2-3), "D A T A" (rows 4-5), and "R E S U L T S" (rows 6-8). The "D A T A" section contains a table with the following data:

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 669878 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 669878 | 03/09/01 | 10:13:12 | 12.0 | 5.54 | 16.4 | 49.8 | 100.4 |
| 669878 | 03/09/01 | 10:16:45 | 12.3 | 5.57 | 16.8 | 50.0 | 100.4 |

Below the data table, there is a status bar showing "errord STATUS : idle". A button labeled "Average ID#669878" is visible. The "R E S U L T S" section contains a table with the following data:

| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 669878 | CBC_WBC | 12.4 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_RBC | 5.57 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HGB | 16.6 | H | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 669878 | CBC_HCT | 50.0 | <input type="checkbox"/> | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

At the bottom, there is a comment field for "Sample Id#669878" with the text "results repeated and confirmed". There are "Save" and "Close" buttons. The status bar at the very bottom shows "Save changes", "MEC Layer: 2/27/01", "Application: Ver 9.2.13A", "Not connected to Coordinator", and "09:59 AM".

Save the averaged result and update the comment, by using the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To exit without saving any data to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

6. Using alternative data manipulation choices.

Retain data for multiple SPs in the SP Data section of the window.



In general, run one SP in duplicate through the Coulter, average the result, and save the data to the database. The Hematology module will display data for multiple SPs in the SP Data section. Each individual SP's results or pairs of results are displayed in a different color. To select or highlight any one SP, use the mouse to direct the mouse arrow to the row containing the correct SP ID and left click.

Average the results for one SP at a time.

The screenshot shows a software window titled "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Inside, there is a "Hematology CDC" window with a table of data and a "RESULTS" section.

Hematology CDC Data Table:

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|-------|
| 529927 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 565368 | 03/09/01 | 10:12:13 | 16.2 | 3.99 | 10.3 | 29.3 | 73.4 |
| 565368 | 03/09/01 | 10:13:13 | 16.2 | 3.29 | 10.3 | 29.3 | 63.4 |
| 656992 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 656992 | 03/09/01 | 10:13:12 | 12.3 | 5.54 | 16.4 | 49.8 | 100.4 |

Below the table, it says "Average ID# 565368".

RESULTS Table:

| Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|-----------|---------|--------|--------|-------|--------------------------|--------------------------|-------------------------------------|
| 565368 | CBC_WBC | 16.2 | H | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 565368 | CBC_RBC | 3.64 | | L | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 565368 | CBC_HGB | 10.3 | | L | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 565368 | CBC_HCT | 29.3 | | L | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

At the bottom, there is a "Comment for Sample Id# 565368" field with "(none)" selected, and "Save" and "Close" buttons.

Evaluate each parameter for error, overlimit, and precision checkmarks, and "H" or "L" action limit and reference range flags. If there are no checkmarks in the Precision column (no precision limit was exceeded), save the result to the database. To save the result to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To exit without saving the result to the database, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c]. If there are any Precision checkmarks, run a 5C Cell control, evaluate the control results, rerun the blood tube a third time, re-average, evaluate, and save the results.

Use alternative data manipulation choices as desired.

Use the "Clear All Downloads" function to delete all data for all SPs in the SP Data section.

The screenshot shows the Hematology CDC software interface. At the top, the title bar reads "LAB: Stand:505 Session:505200 01/12/2000 08:30 am - 12:30 pm". Below the title bar is a menu bar with "File", "View", "Utilities", "Reports", "Modules", "Shipping", "Window", and "Help". The main window is titled "Hematology CDC" and contains several sections:

- SP DATA:** A table with columns: Id#, Date, Time, WBC, RBC, HGB, HCT, and MCV. The data is as follows:

| SP DATA | Id# | Date | Time | WBC | RBC | HGB | HCT | MCV |
|---------|--------|----------|----------|------|------|------|------|-------|
| 2 | 529927 | 03/09/01 | 10:12:12 | 12.5 | 5.60 | 16.8 | 50.2 | 101.4 |
| 2 | 565368 | 03/09/01 | 10:12:13 | 16.2 | 3.99 | 10.3 | 29.3 | 73.4 |
| 2 | 565368 | 03/09/01 | 10:13:1 | | | 10.3 | 29.3 | 63.4 |
| 2 | 656992 | 03/09/01 | 10:12:1 | | | 16.8 | 50.2 | 101.4 |
| 2 | 656992 | 03/09/01 | 10:13:1 | | | 16.4 | 49.8 | 100.4 |
- STATUS:** A section showing "STATUS : idle".
- RESULTS:** A table with columns: Sample Id, Item, Result, Action, Range, Error, Overlimit, and Precision. The data is as follows:

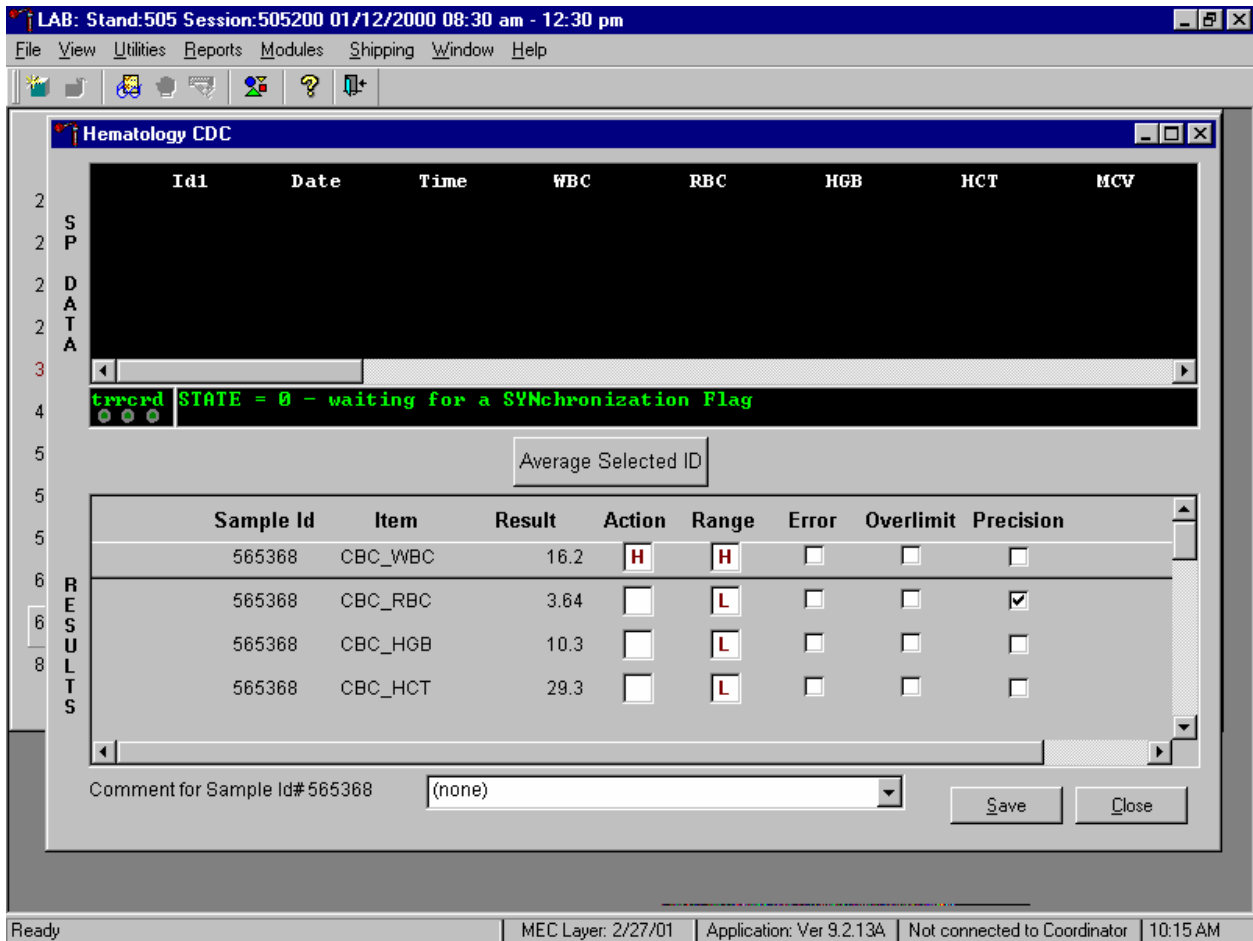
| RESULTS | Sample Id | Item | Result | Action | Range | Error | Overlimit | Precision |
|---------|-----------|---------|--------|--------|-------|--------------------------|--------------------------|-------------------------------------|
| 5 | 565368 | CBC_WBC | 16.2 | H | H | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6 | 565368 | CBC_RBC | 3.64 | | L | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6 | 565368 | CBC_HGB | 10.3 | | L | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8 | 565368 | CBC_HCT | 29.3 | | L | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
- Comment for Sample Id#565368:** A dropdown menu showing "(none)".
- Buttons:** "Save" and "Close" buttons.

A context menu is open over the row with Id# 565368, showing options: "Clear ID# 565368", "Clear All Downloads", "View Log For ID# 565368", "Save Averages", "Clear Averages", "Save & Exit", and "Clear & Exit".

At the bottom of the window, the status bar shows: "Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:14 AM".

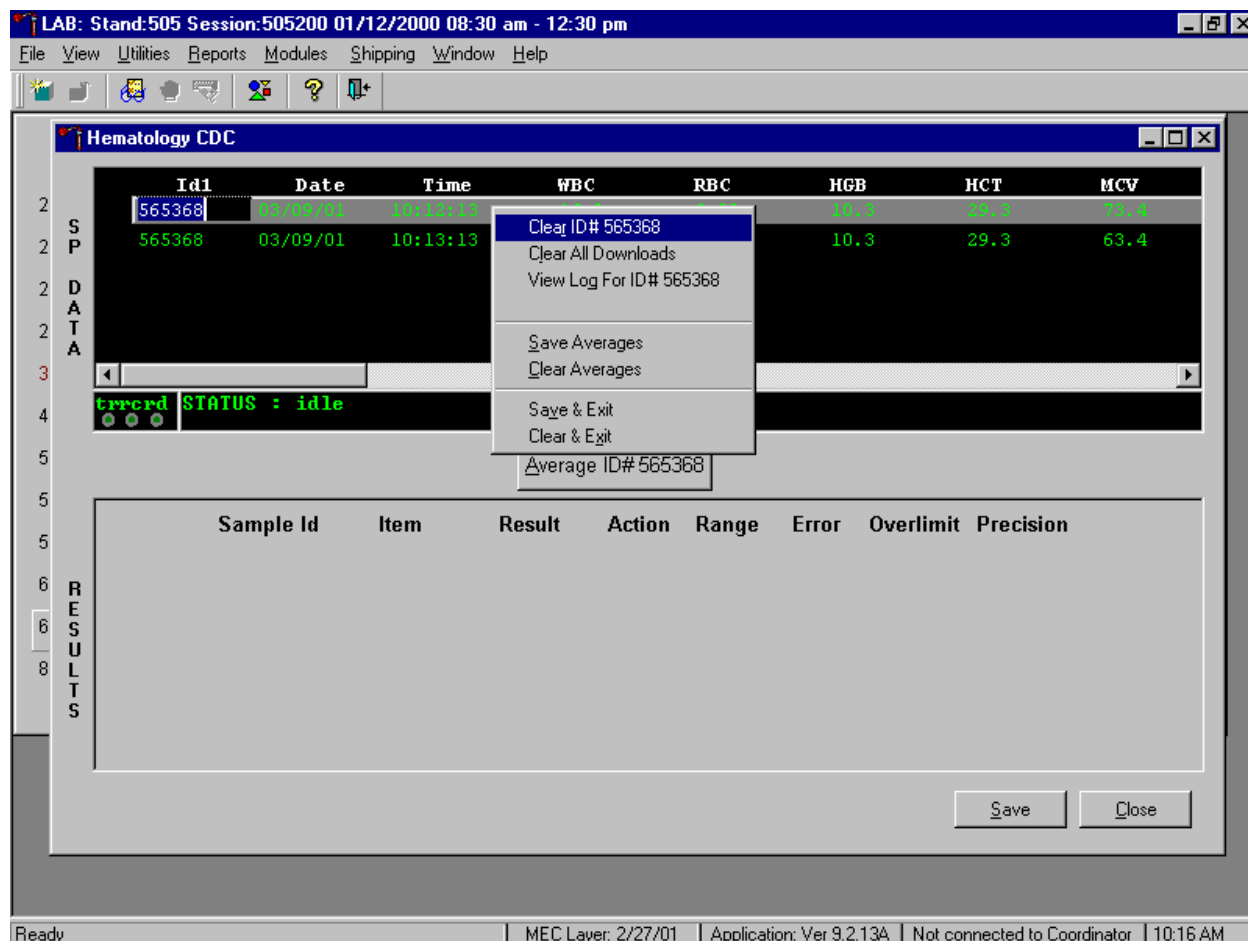
To clear all downloads from the SP Data section, use the mouse to direct the mouse arrow to any individual row in the SP Data section and right click to display the alternative data manipulation choices. To select "Clear All Downloads," drag the mouse arrow to {Clear All Downloads} and left click or type [Shift] [L/I].

Release the mouse button to clear all downloads.



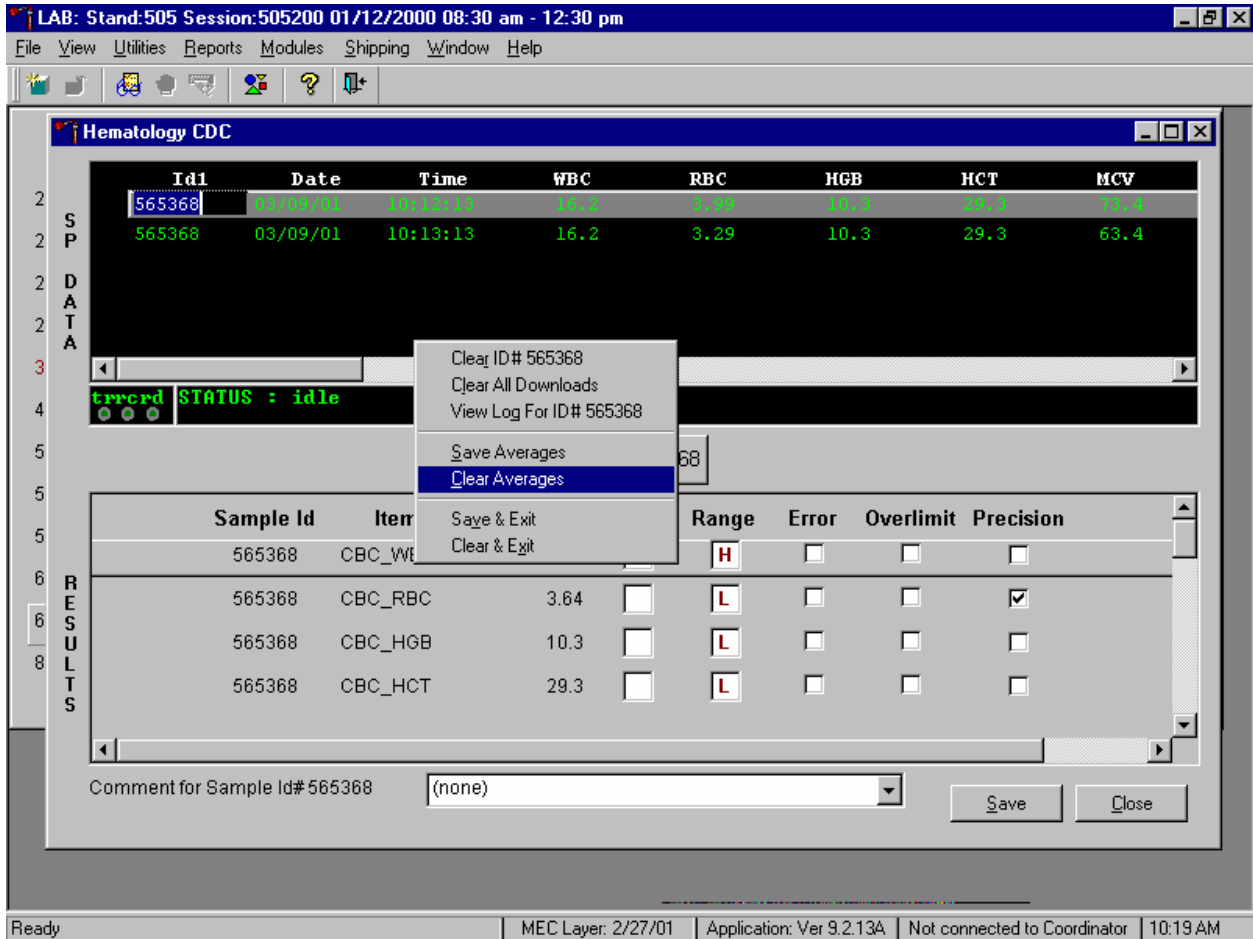
All data in the SP Data section is erased but the last averaged result remains in the Results section of the window. To clear the result section, close the Hematology module. To close the hematology module, use the mouse to direct the mouse arrow to the Close button and left click or type [Shift] [C/c].

Use the data manipulation functions to erase or delete one SP's data in the SP Data section.



To clear the Coulter downloads for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to {Clear ID#XXXXXX }, and right or left click or type [Shift] [R/r]. Release the mouse button to clear this download. Retransmit, average, and save the data.

Clear only the averaged results for any SP using data manipulation choices.



To clear the averaged results for any one SP, use the mouse to direct the mouse arrow to the individual row in the SP Data section, right click to display the alternative data manipulation choices, drag the mouse arrow to {Clear Averages}, and right or left click or type [Shift] [C/c].

Release the mouse button to clear the results.

The screenshot shows the Hematology CDC software interface. The main window has a menu bar with 'File', 'View', 'Utilities', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. The main content area is divided into several sections:

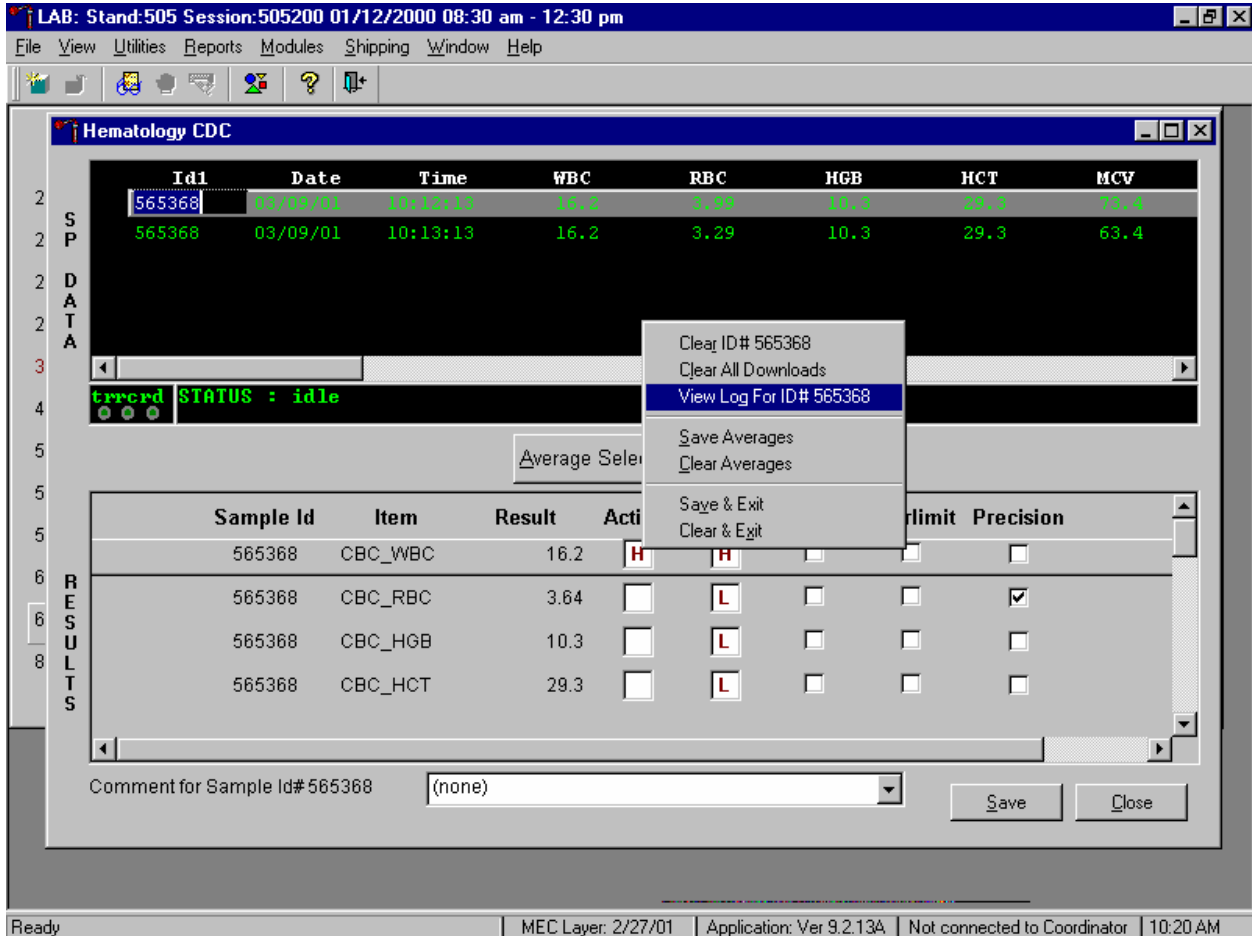
- DATA:** A table with columns: Id1, Date, Time, WBC, RBC, HGB, HCT, MCV. The data is as follows:

| Id1 | Date | Time | WBC | RBC | HGB | HCT | MCV |
|--------|----------|----------|------|------|------|------|------|
| 565368 | 03/09/01 | 10:12:13 | 16.2 | 3.99 | 10.3 | 29.3 | 75.4 |
| 565368 | 03/09/01 | 10:13:13 | 16.2 | 3.29 | 10.3 | 29.3 | 63.4 |
- STATUS:** A text field showing 'errord STATUS : idle'.
- Average Selected ID:** A button labeled 'Average Selected ID'.
- RESULTS:** A section with a table header: 'Sample Id', 'Item', 'Result', 'Action', 'Range', 'Error', 'Overlimit', 'Precision'. The table body is currently empty.
- Buttons:** 'Save' and 'Close' buttons are located at the bottom right of the RESULTS section.

The status bar at the bottom of the window displays: 'Ready | MEC Layer: 2/27/01 | Application: Ver 9.2.13A | Not connected to Coordinator | 10:19 AM'.

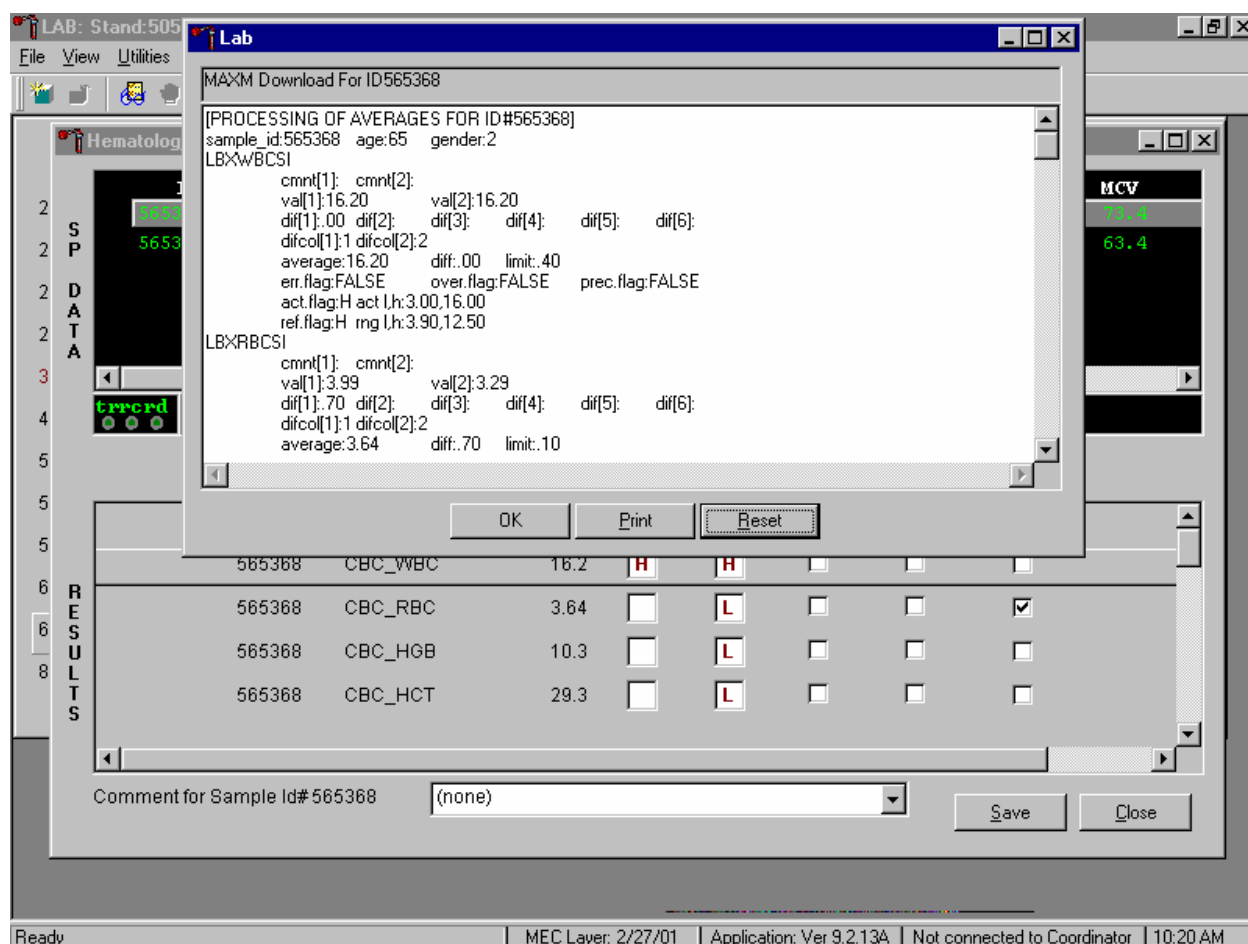
All results in the Results section of the window are erased. Re-average and save the data.

Use the "View Log for ID# XXXXXX" choice to view all Coulter data, averages, and precision limit values for any SP.



To view the detailed log for any one SP's result, use the mouse to direct the mouse arrow to the individual row in the SP Data section and right click to display the alternative data manipulation choices. Drag the mouse arrow to {View Log for IDXXXXXX} and release the mouse button to view the detailed log for this SP's results.

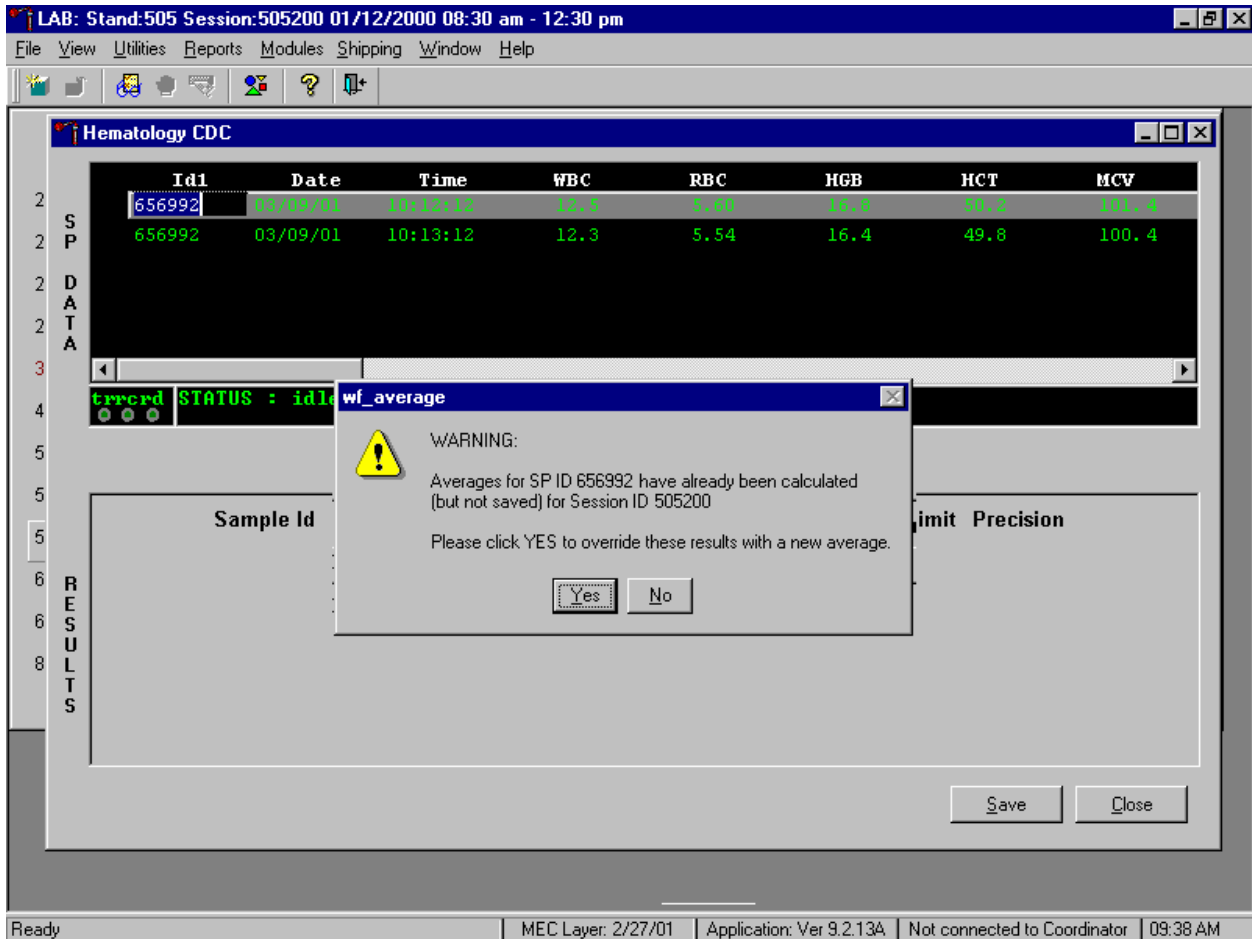
Review the SP's log.



The SP's log contains detailed information for each parameter and each run. When finished reviewing the information, use the mouse to direct the mouse arrow to the OK button to close the window. To print the log, drag the mouse arrow to the Print button and left click or type [Shift] [P/p]. To clear the log and close the screen, use the mouse to direct the mouse arrow to the Reset button and left click, or type [Shift] [R/r], or select [Enter].

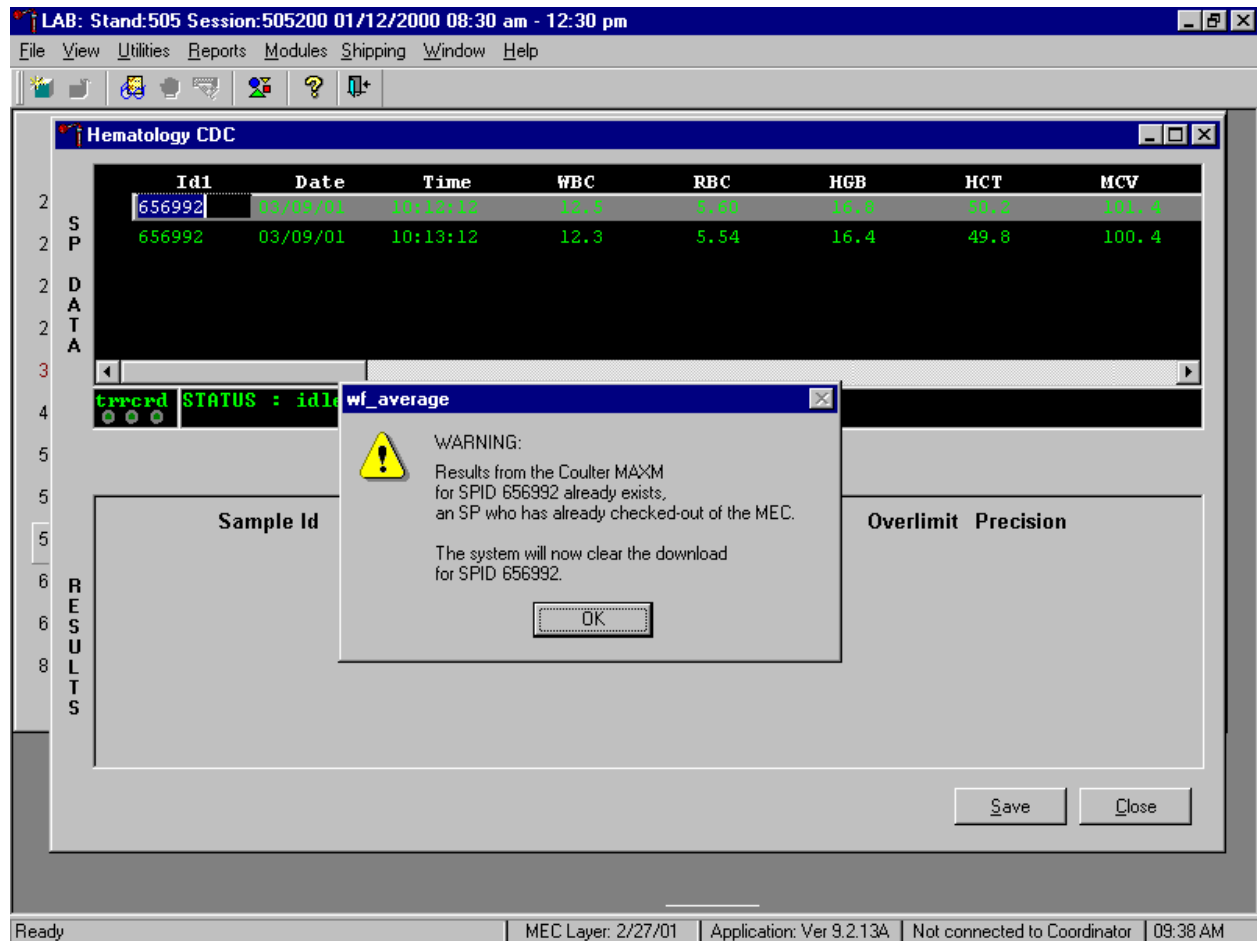
7. Re-averaging results.

Re-average a result that has or has not previously been saved to the database.



If a SP has not exited the MEC and the Report of Findings has not been printed, it is possible to retransmit and re-average the results for a SP and overwrite (save) the results in the database. A warning message text box displays when an attempt is made to save the data on a SP who has not exited the MEC or for whom a Report of Findings has not been printed. This text states, "Averages for SP ID XXXXXX have already been calculated (but not saved) for session XXXXX. Please click yes to override these results with a new average." To override the previous results, use the mouse to direct the mouse arrow to the Yes button and left click or select [Enter] or type [Shift] [Y.] To remove the text box without overriding the previous results, use the mouse to direct the mouse arrow to the No button and left click, or type [Shift] [N].

If the SP has exited the MEC or the Report of Findings has been printed, it is impossible to overwrite (save) the results in the database.



A warning message text box displays when an attempt is made to save the data on a SP either who has exited the MEC or for whom a Report of Findings has been printed. This text states, "Results from the Coulter MAXM for SPID XXXXXX already exist for an SP who has already checked out of the MEC. The system will now clear the download for SP ID XXXXXX." To remove the text box, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter]. The downloaded data, including the results, are automatically erased.

C. MAXM parameter codes

1. Review the message

The Beckman Coulter® MAXM uses triplicate counting with strict voting criteria. It has proprietary flagging algorithms to confirm parameter results before reporting. The instrument may not detect a transient or partial aperture blockage by any of these processes. A partial aperture blockage may cause erroneous results, such as WBC count lower than what is present. Monitor the aperture-viewing screen when cycling specimens that are likely to contain fibrin or debris.

The MAXM displays abnormal parameter results for all cell populations and values. The following table describes the display and cause for the parameter codes.

| Display | Cause |
|---|--|
| All Parameters | |
| "●●●●" for a single parameter result | Incomplete or abnormal computation. |
| "●●●●" for all parameter results and PART.ASP message displayed | Sample integrity check failed, short sample or clot. |
| "-----" for CBC parameter results, and no average histogram for the affected parameter If WBC is "-----", then LY#, MO#, NE#, EO# and BA# are "●●●●" If RBC is "-----", then MCH, MCHC, Hct are "-----" | Total voteout (none of the three counts agreed); Diff parameters do not vote out. |
| "*V" | Single-count period voteout; May indicate an erroneous result due to aperture blockage or lack of mixing bubble. |

| | |
|---|---|
| "V" | Appears next to parameter derived from the parameter with the single count period voteout. |
| <p>"+++++" for parameter results</p> <p style="text-align: center;">IMPORTANT</p> <p>If the WBC, RBC, Hgb, or Plt result is +++++, run a blank cycle to prevent carryover to the next sample.</p> | <p>Result exceeds:</p> <p>WBC $\geq 100.0 \times 10^3$ cells/μL</p> <p>RBC $\geq 10.00 \times 10^6$ cells/μL</p> <p>Plt $\geq 1000 \times 10^3$ cells/μL</p> <p>MCV ≥ 1000</p> <p>If WBC is over range an R appears next to the RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, MPV, Plt and Diff % results. Results for Diff% are dots (.....).</p> <p>If RBC is over range an R appears next to Hct, MCH, and MCHC results.</p> <p>If Hgb is over range an R appears next to MCH, and MCHC results.</p> <p>If MCV is over range an R appears next to Hct, MCHC, and RDW results.</p> <p>If Plt is over range an R appears next to WBC, Hgb, MCH, MCHC, diff# and Pct results.</p> <p>Data Base Query displays average values for over range WBC, RBC, or Plt. [F3] Results or [F3] Edit, beneath the definitive flag section. These values are for review only; do not report them.</p> |

| | |
|--|---|
| | <p style="text-align: center;">IMPORTANT</p> <p>Sample dilution may result in erroneous differential results.</p> <p>Set DIFF to OFF before cycling the diluted sample when WBC is over range.</p> |
| "???" for Diff results | Questionable data |
| Plt Parameter | |
| "R" next to Plt and MPV result | <p>PDW >20% mode not between 3 and 15 fL, or non-positive curve detected, or</p> <p>Plt <20,000, or</p> <p>Total voteout of fitted curve, or WBC is over range.</p> |
| RBC Parameters | |
| "R" next to RDW result | Excessive asymmetry in RBC histogram, or WBC or MCV over range. |
| "*R" next to MCV; also "R" next to RBC, Hct, MCH, MCH, RDW, Plt, and MPV | MCV below lower limit of <50 fL. |
| WBC Parameters | |
| "*R" next to WBC; also "R" next to Diff numbers | <p>Check of WBC lower threshold failed.</p> <p>Particles are present at the 35 fL threshold (Plt clump, giant Plt, nrbc, lyse resistant RBC, malarial parasites).</p> |
| "R" next to Diff percentages and numbers | <p>Low differential count statistics. These messages occur also:</p> <p style="padding-left: 40px;">Population message: ABNORMAL WBC POP</p> <p style="padding-left: 40px;">Suspect message: REVIEW SLIDE</p> |
| ":::" for Diff results | <p>System detects a clog in the flow cell. There are three types of clogs:</p> <p style="padding-left: 40px;">FC = Full Clog</p> <p style="padding-left: 40px;">PC1 = Partial Clog 1 (partial clog in the flow cell or sample line)</p> <p style="padding-left: 40px;">PC2 = Partial Clog 2 (partial clog in the sheath system)</p> |

2. Remedial action

Review the result for the affected parameter. Rerun the specimen if any of the parameter flags occurs.

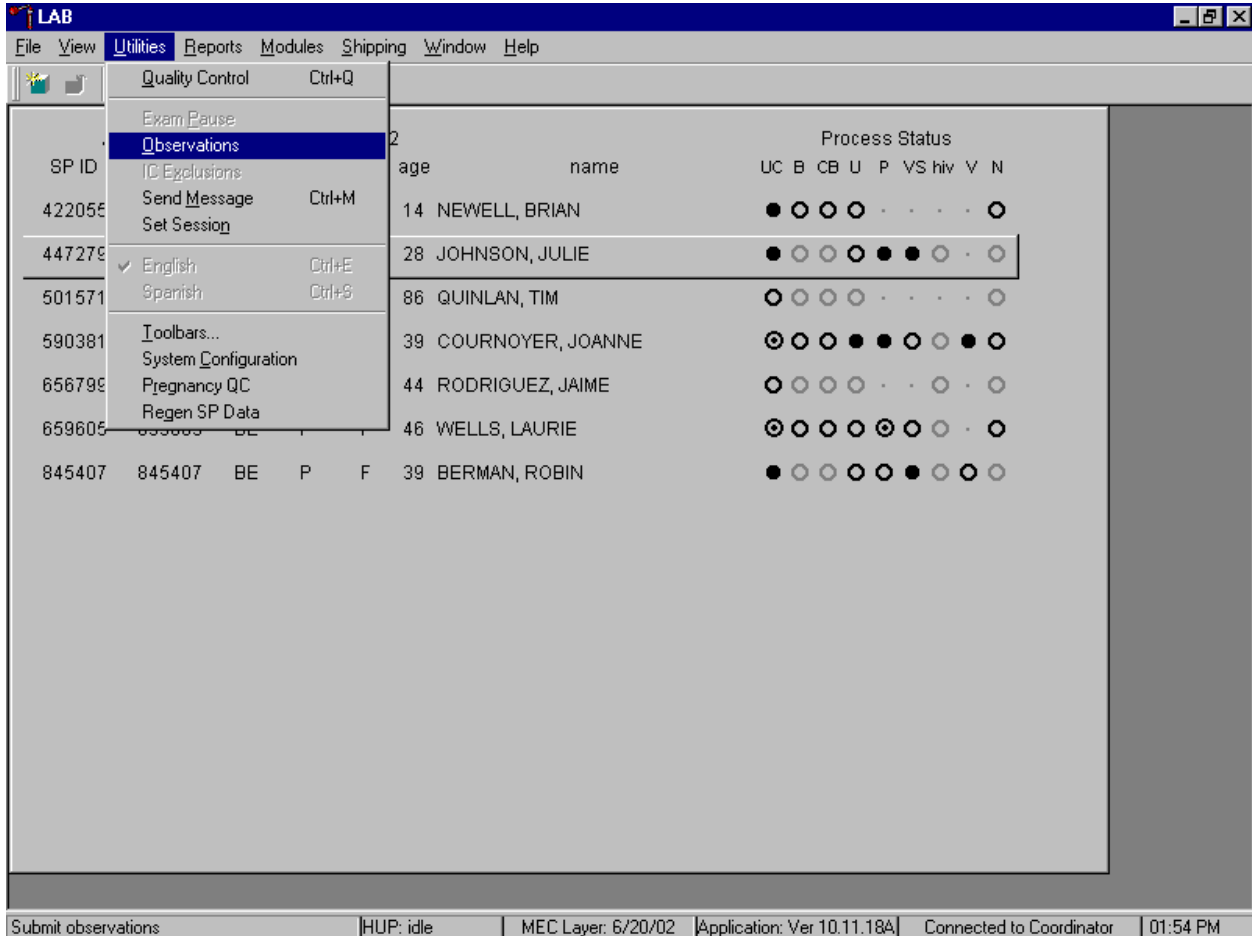
D. MAXM suspect messages

1. Suspect messages flag an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. Specific suspect messages indicate some abnormalities that exhibit characteristic cluster patterns. Suspect messages indicate the possibility of a particular abnormality. Not every atypical scatterplot has a corresponding suspect message.
2. Remedial action -- Rerun the specimen.

E. Physician review

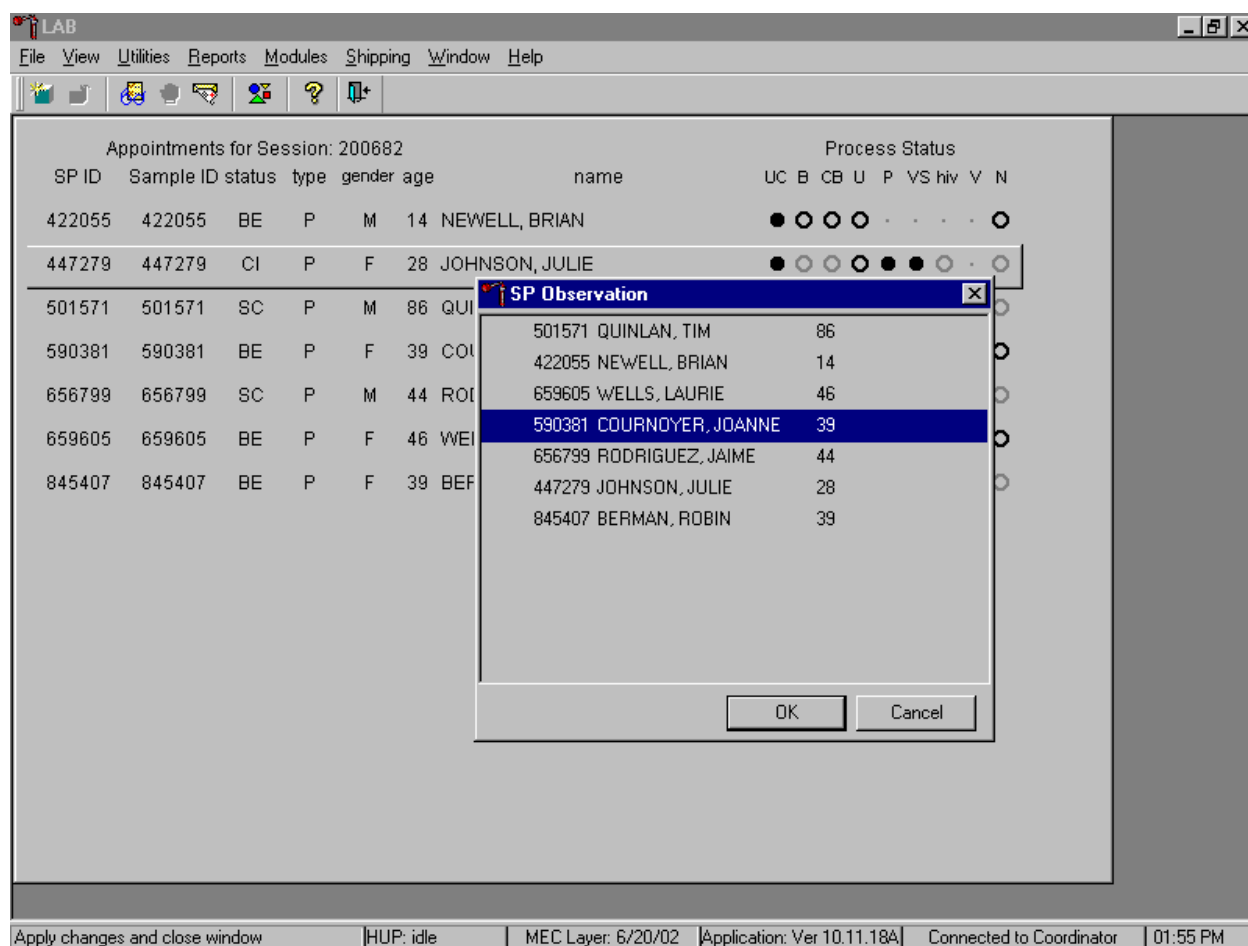
1. The MEC physician reviews and interprets all CBC results. Results outside action limits flash and transmit to the physician immediately. The physician determines if referral for the SP for treatment is necessary.
2. The medical technologist sends an observation to the physician whenever a critical or action limit is detected for any CBC parameter. This observation includes the date, time, responsible laboratory individual, person notified, and test results.

Send an observation on any SP scheduled into the MEC session. Access the observation function.



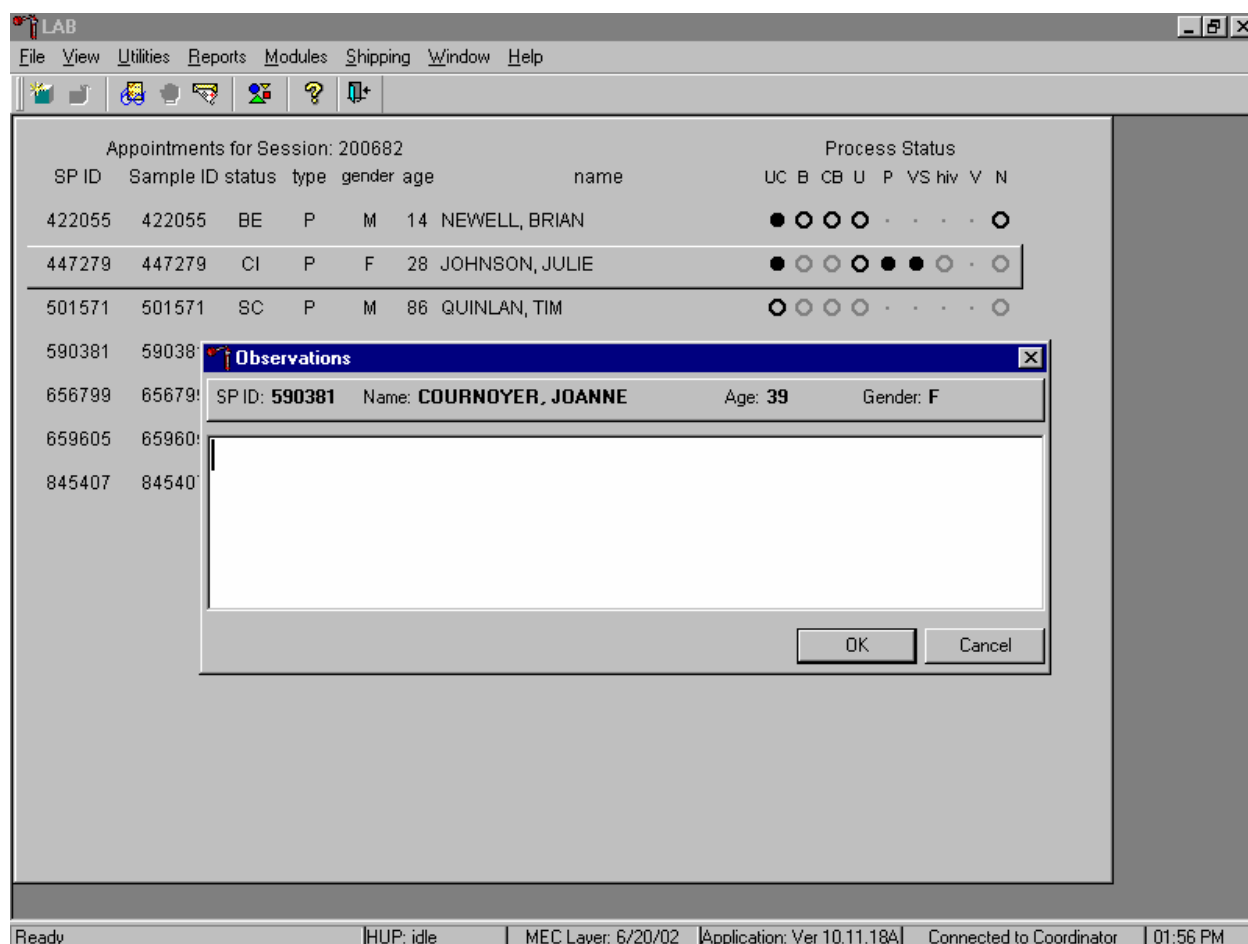
To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations}, and left click, or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



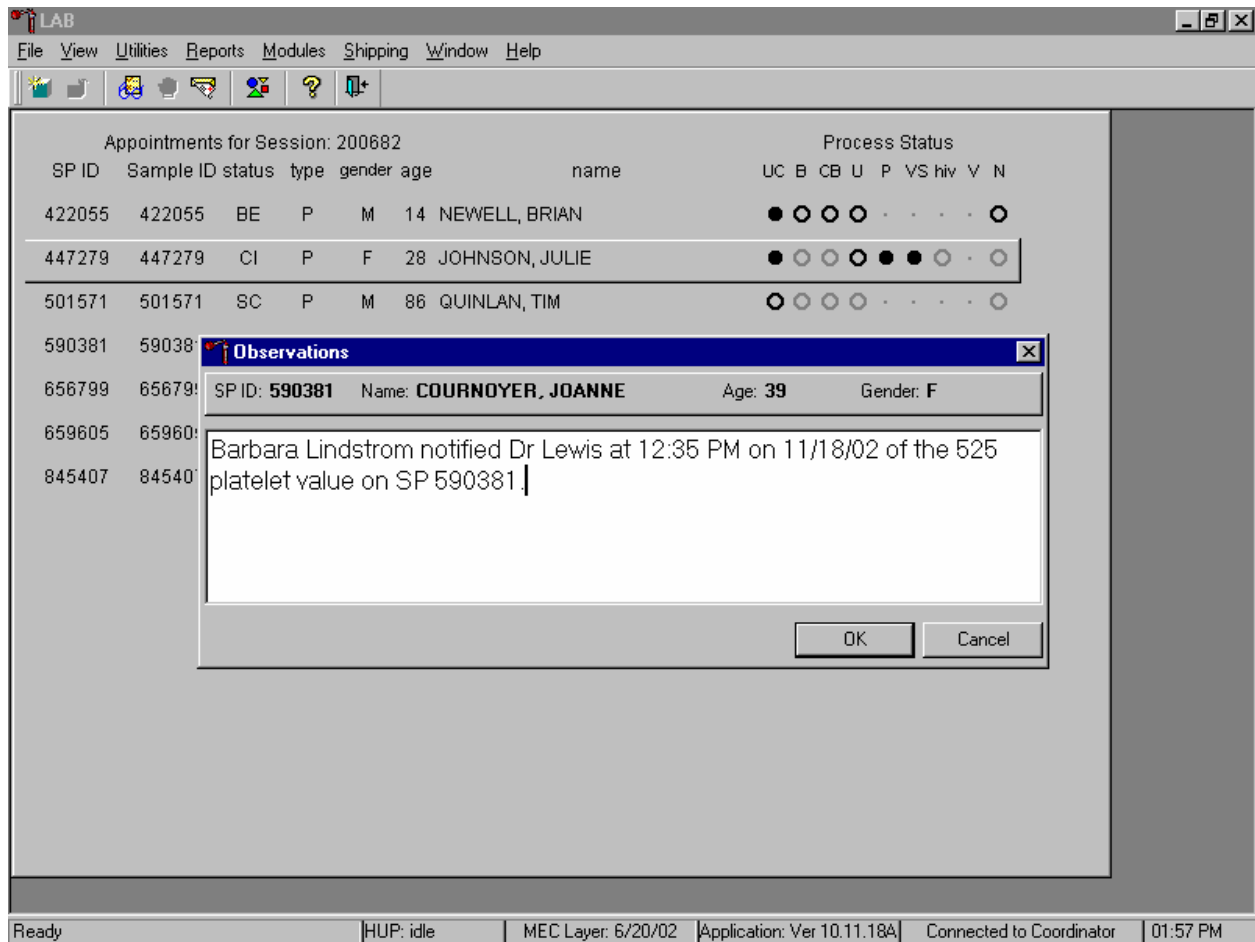
To select or highlight an SP, drag the mouse arrow to the correct SP and left click or use the up and down arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions and exit the observation function, use the mouse to direct the mouse arrow to the Cancel button and left click.

The observation window displays.



The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions or to exit the observation window without entering an observation, use the mouse to direct the mouse arrow to the Cancel button and left click.

Enter the observation on a SP.



Document the date, time, responsible laboratory individual, person notified, and test results, including the parameter.

XII. Limitations of Method: Specimen Rejection, Interfering Substances and Conditions

This method limits samples to human whole blood.

A. Specimen rejection

1. Reject clotted specimens and recollect.

B. Interfering Substances and Conditions

Because the Coulter directly measures RBC, WBC, Hgb, and Diff %, it is most important to concentrate on analytes and substances that interfere with these parameters. The Coulter calculates HCT, MCH, MCHC, and DIFF # parameters. The Coulter derives MCV, RDW, PLT, and MPV from RBC or platelet histograms. The following are possible interfering substances or conditions:

- Abnormal BUN, glucose, or sodium levels could affect the MCV.
- Abnormal WBCs could affect lymphocytes, monocytes, and granulocytes.
- Abnormally small WBCs could affect white count, lymphocytes, monocytes, and granulocytes.
- Clumped platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Cryofibrinogen and cryoglobulin crystals could affect white count, lymphocytes, monocytes, granulocytes, RBC, hemoglobin, platelet count, and MPV.
- An elevated WBC count could affect RBC, hemoglobin, MCV, RDW, platelet count, and MPV parameters.
- Fragile WBCs could affect white count, lymphocytes, monocytes, granulocytes, platelet count, and MPV.
- Giant platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Hemolyzed specimens could affect RBC, hemoglobin, platelet count, and MPV.
- Lipemic specimens could affect MCV.
- Severely icteric plasma causes increased hemoglobin. Evaluate CBC result carefully and report all parameters except the hemoglobin result
- Nucleated RBCs could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.

XIII. Reference Ranges

1. Males

| Age in Years | 1-5 | 6-18 | 19-65 | 66+ |
|----------------------------|-------------|-----------|-----------|------------|
| WBC (x 10 ³ μL) | 4.3-14.1 | 3.7-11.9 | 3.9-12.1 | 3.9-12.3 |
| RBC (x 10 ⁶ μL) | 4.00 - 5.30 | 4.10-5.60 | 4.10-5.80 | 4.00-5.60 |
| Hgb (g/dL) | 10.5-13.7 | 11.5-16.3 | 12.7-17.1 | 11.0-16.8 |
| HCT (%) | 31.8-40.8 | 34.4-48.3 | 38.0-50.3 | 33.1-50.2 |
| MCV (fL) | 67.6-88.2 | 74.3-93.0 | 78.1-99.2 | 78.9-101.4 |
| MCH (pg) | 21.7-29.8 | 24.3-31.7 | 25.7-33.8 | 25.6-34.4 |
| MCHC (g/dL) | 31.5-35.0 | 31.9-35.1 | 32.0-35.3 | 31.8-35.1 |
| RDW (%) | 11.7-16.5 | 11.7-14.3 | 11.8-15.3 | 12.1-16.6 |
| Plt (x 10 ³ μL) | 224-568 | 194-477 | 157-414 | 138-407 |
| MPV (fL) | 6.3-9.3 | 6.6-9.9 | 6.8-10.4 | 6.7-10.6 |
| LY (%) | 24.5-70.0 | 20.0-56.6 | 17.8-51.8 | 13.0-48.3 |
| MONO (%) | 0-12 | 0-12 | 0-12 | 0-13 |
| NE (%) | 21.4-70.5 | 33.2-74.7 | 39.7-77.3 | 44.7-81.9 |
| EO (%) | 0-10 | 0-11 | 0-8 | 0-8 |
| BA (%) | 0-2 | 0-2 | 0-2 | 0-2 |

2. Females

| Age in Years | 1-5 | 6-18 | 19-65 | 66+ |
|----------------------------|-------------|-----------|-----------|------------|
| WBC (x 10 ³ μL) | 4.2-13.6 | 4.0-12.4 | 3.9-12.5 | 4.0-12.3 |
| RBC (x 10 ⁶ μL) | 3.90 - 5.20 | 3.90-5.20 | 3.70-5.20 | 3.50-5.20 |
| Hgb (g/dL) | 10.5-13.7 | 11.1-14.7 | 10.4-15.2 | 10.5-15.5 |
| HCT (%) | 32.0-40.6 | 33.4-43.4 | 32.0-45.0 | 32.0-46.0 |
| MCV (fL) | 69.0-88.6 | 74.5-93.9 | 73.4-98.3 | 79.7-100.2 |
| MCH (pg) | 22.3-30.1 | 24.2-31.8 | 23.2-33.3 | 25.9-33.8 |
| MCHC (g/dL) | 31.8-35.1 | 31.7-35.0 | 31.4-35.1 | 31.6-35.0 |
| RDW (%) | 11.4-15.4 | 11.6-14.8 | 11.8-16.6 | 12.0-16.1 |
| Plt (x 10 ³ μL) | 229-581 | 202-476 | 172-453 | 147-440 |
| MPV (fL) | 6.3-9.2 | 6.7-10.0 | 6.9-10.7 | 6.8-10.8 |
| LY (%) | 24.9-70.5 | 18.7-58.5 | 17.8-52.8 | 15.7-51.1 |
| MONO (%) | 0-12 | 0-12 | 0-12 | 0-13 |
| NE (%) | 21.3-69.3 | 32.9-77.2 | 39.6-77.8 | 42.0-79.8 |
| EO (%) | 0-10 | 0-11 | 0-8 | 0-8 |
| BA (%) | 0-2 | 0-2 | 0-2 | 0-2 |

3. Reference ranges for normal values were calculated from the NHANES III data set using 95% reference interval(s) determined nonparametrically, through ranking the observations and determining the lower (2.5th percentile) and the upper (97.5th percentile) reference limits. The nonparametric (ranking) method was used because most measured hematology parameters have a skewed, non-Gaussian distribution.

XIV. Action Limits

Action limits are a guide to inform the physician that a CBC result(s) is/are abnormal. Since all specimens are run in duplicate, there is no reason to retest the sample.

- WBC male and female (all ages) < or = to 3 x 10³ μL or > or = to 16.0 x 10³ μL
- Hgb male and female (<6 years) <6.5 g/dL or >14.5 g/dL
- Hgb female (>6 years) <6.5 g/dL or >16.0 g/dL

- Hgb male (>6 years) <6.5 g/dL or >18.0 g/dL
- PLT male and female (all ages) <50 x 10³ μ L or >800 x 10³ μ L

Possible causes of abnormal parameters:

- High RBC, Hgb, or HCT -- dehydration, polycythemia, shock, chronic hypoxia
- Low RBC, Hgb or HCT -- anemia, thalassemia and other hemoglobinopathies
- Low MCV -- microcytic anemia
- High MCV -- macrocytic anemia, liver disease
- Low WBC -- sepsis, marrow hypoplasia
- High WBC -- acute stress, infection, malignancies
- Low platelets -- risk of bleeding
- High platelets -- risk of thrombosis

XV. Specimen Storage and Handling during Testing

A. Specimen storage

1. Store specimens capped and place on a rocker at room temperature until processed.
2. Run within 24 hours of drawing.

XVI. Alternative Method for Performing Test or Storing Specimens if Test System Fails

There is no alternative method for this test. Store EDTA tube at room temperature for no more than 24 hours. Restore the instrument to functionality and then run the specimen.

XVII. Test Results Reporting System: Protocol for Reporting Action Limits

Results outside the action limits are automatically brought to the physician's attention for a decision as to "course-to-follow."

XVIII. Specimen Accountability and Tracking

All records, including QA/QC data will be maintained for 6 years. Use only numerical identifiers for SP results.

XIX. Quality Control Summary Statistics and Graphs

Chapter 10 includes a separate detailed description of the comprehensive quality control plan. Monitor 5C® Cell control results for bias and maintain results for the entire study period. Compare all three instruments CAP proficiency results.

XX. References

1. Beckman Coulter® MAXM Analyzer Operator's Guide. (1992, January 21). PN 4235935J.
2. Beckman Coulter® MAXM Analyzer Use and Function. (1995, January). PN 4235933H.
3. Beckman Coulter® MAXM Analyzer Special Procedures and Troubleshooting. (1995, December). PN 4235934J.
4. Corash, L. (1983). Platelet Sizing: Techniques, Biological Significance, and Clinical Applications. Current Topics in Hematology. New York: Alan R. Wise, Inc.
5. Geigy Scientific Tables. (1984). Vol. 3, 210.
6. Jones, A.R., Twedl, D., Swaim, W., and Gottfried E. (1996). Diurnal change of blood count analytes in normal subjects. *Am J Clin Path*, 106, 723-7.
7. NCCLS document H15-A. (1984). Reference procedure for the quantitative determination of hemoglobin in blood. National Committee for Clinical Laboratory Standards, Villanova, PA.
8. NCCLS document H7-A. (1985). Procedure for determining packed cell volume by the micro hematocrit method. National Committee for Clinical Laboratory Standards, Villanova, PA.
9. NCCLS document H18-A. (1990). Procedures for the handling and processing of blood specimens. National Committee for Clinical Laboratory Standards, Villanova, PA.
10. NCCLS document H3-A3. (1991). Procedures for the collection of diagnostic blood specimens by venipuncture. National Committee for Clinical Laboratory Standards, Villanova, PA.

11. NCCLS document H4-A3. (1991). Procedures for the collection of diagnostic blood specimens by skin puncture. National Committee for Clinical Laboratory Standards, Villanova, PA.
12. NCCLS document H26-A. (1996). Performance goals for the internal quality control of multichannel hematology analyzers; Approved Standard. NCCLS, Wayne, PA.
13. Standard 493-1211. *Federal Register*, 57: 40, (1992, February 28). Rules and Regulations, p. 7164.
14. Threatte, G.A., Andrados, C., Ebbe, S., and Brecher, G. (1984). Mean platelet volume: The need for a reference method. *AJCP*, 81, 769-772.

8. BLOOD AND HIV URINE PROCESSING

8.1 Introduction

The purpose of blood processing is to (1) perform a complete blood count; (2) allocate blood into 42 vessels for storage and transport to 17 laboratories across the United States for analysis; and (3) allocate plasma and serum into vessels for future studies. Processing includes centrifuging and storing blood collection tubes; aliquoting whole blood into storage vessels; centrifuging, separating, and aliquoting plasma and serum into storage vessels; performing two dilutions; washing and lysing whole blood cells; and storing the specimens.

Process urine for HIV if no blood was collected or the quantity of serum was insufficient for serum HIV (for primary SPs aged 18-49) and the SP has not refused the HIV test.

8.2 Equipment and Supplies

The blood processing area includes two under-counter refrigerators, four under-counter freezers, two refrigerated centrifuges, two data terminals, a laminar flow hood, and two specimen rockers. This area also includes counter space for processing blood. Store extra processing supplies in cabinets and/or the trailer compartments. Store the sterile saline in the refrigerator.

Exhibit 8-1. Nonconsumable supplies for blood processing

| | |
|--|---------------------------------------|
| Blood processing template (12+ and 1-2/3-5/6-11) | Nalge cryovial racks |
| One Eppendorf pipette 100-5000 μ L | Two Eppendorf pipette 50-1000 μ L |
| One Eppendorf pipette 5-100 μ | Pipette charging stand |
| One pipette battery | 50-mL graduated cylinder |
| 13mm half rack | Cube rack – 4-way flipper rack |
| 16mm full rack | Floor mat |
| 16mm half rack | Protective eyewear |
| Deionized water bottle | Saline squeeze bottle |

Exhibit 8-2. Consumable supplies for blood processing

| | |
|--|---|
| Cotton swabs | Eight gallon biohazard sharps container |
| Biohazard bags 25 x 35 | Biohazard bags 19 x 23 |
| Kimwipes | Bench Kote paper |
| Pipette tips 1000 μ L | Pipette tips 200 μ L |
| Pipette tips 5-mL | Wooden applicator sticks |
| Quart size zip closable bags | 3.5-mL transfer pipette nonsterile |
| 5-mL cryovial sterile | 14-mL snap cap test tube |
| Conical tube 50-mL | 2-mL cryovial sterile |
| 2-mL cryovial non-sterile | Caps for 2-mL cryovial |
| Serum filters 13mm x 4 inches | Serum filters 16mm x 6 inches |
| 5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid | 5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid |
| 5.25 x 5.25 x 3.0 inch cardboard box without grid | Three inch 5 x 5 cardboard grid |
| 5.25 x 5.25 x 5.0 inch cardboard box with 5 x 5 foam insert | Nonsterile, powder-free, latex (nonlatex for use by latex allergic staff) gloves—small, medium, large |
| Ascorbic acid 0.5 gm per vessel | Metaphosphoric acid 6% |
| Sterile saline | Deionized water |
| Sharpie pens | Lab marker – fine |

8.3 Protocols

Exhibits 8-3 through 8-6 illustrate the primary SP's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-3. Primary SP's whole blood processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|-------------|--------------|-------------|-------------|-----------------|-------------|---------------------|
| 1 | Lead/Cad/HG | 1+ | 0.3 | Whole blood | EDTA | 2-mL | |
| 2 | Ery Proto | 3-5 12-49 | 0.4 0.4 | Whole blood | EDTA | 2-mL | 12-49 Females only |
| 3 | RBC Folate | 1+ | 0.1 | Whole blood | EDTA | 2-mL | Dilute with 1-mL AA |
| 4 | Glycohem | 12+ | 0.4 | Whole blood | EDTA | 2-mL | |
| 5 | Mercury | 1+ | 0.5 | Whole blood | EDTA | 2-mL | |
| 6 | CD4 | 18-49 | 0.5 | Whole blood | EDTA | 2-mL | |

Exhibit 8-4. Primary SP's plasma processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|-------------|------|-------------|-------------|-----------------|-------------|--|
| 7 | Homocys/MMA | 20+ | 1.0 | Plasma | EDTA | 2-mL | Plasma must be off the cells within 30 minutes |
| 8 | Xtra Plasma | 6+ | 0.5 | Plasma | EDTA | 2-mL | |
| 9 | Glucose | 12+ | 0.5 | Plasma | Grey | 2-mL | Morning SPs only |
| 98 | OGTT | 12+ | 0.5 | Plasma | Grey | 2-mL | Morning SPs only |

Exhibit 8-5. Primary SP's packed cells processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|------------|------|-------------|--------------|-----------------|-------------|--------------------|
| 88 | Acrylamide | 3+ | 1.0 | Packed cells | EDTA | 2-mL | Wash 3 times, lyse |

Exhibit 8-6. Primary SP's serum processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|-----|--------------|---------------------|--------------------|-------------|-----------------|-------------|---|
| 100 | IgE | 1-5 6+ | 0.5 1.0 | Serum | Red | 2-mL | |
| 81 | Vitamin B6 | 0.2 0.3 0.5 | 1-2 3-11 12+ | Serum | Red | 2-mL | |
| 70 | Vitamin D | 1-2 3+ | 0.3 0.5 | Serum | Red | 2-mL | |
| 12 | Fol/B12 | 1-2 3-5 6+ | 0.7 0.8 1.0 | Serum | Red | 2-mL | Do not allow protracted exposure to sunlight; sunlight degrades Folate. |
| 13 | CRP | 1-2 3+ | 0.2 0.3 | Serum | Red | 2-mL | |
| 14 | Hep Profile | 6+ | 1.5 | Serum | Red | 2-mL | |
| 87 | Hepatitis ab | 1-2 2-5 | 0.3 0.4 | Serum | Red | 2-mL | |
| 99 | Fer/TfR | 1-2 3-5 12-49 | 0.3 0.5 0.5 | Serum | Red | 2-mL | 12-49 females only |
| 11 | Iron/TIBC | 3-5 12-59 | 1.0 1.0 | Serum | Red | 2-mL | 12-59 females only |
| 17 | Cotinine | 3-5 6-11 12+ | 1.0 1.3 1.8 | Serum | Red | 2-mL | |
| 21 | Lipids | 6+ | 1.5 | Serum | Red | 2-mL | |
| 104 | Lp(a) | 12+ | 0.5 | Serum | Red | 2-mL | Morning SPs only |
| 94 | PTH2 | 6+ | 1.0 | Serum | Red | 2-mL | |
| 77 | HPV Serum | 14-59 | 0.5 | Serum | Red | 2-mL | |
| 79 | Vitamin C | 6+ | 0.1 | Serum | Red | 2-mL | Dilute with 400-µL MPA |
| 18 | Biochem | 12+ | 0.8 | Serum | Red | 2-mL | |
| 23 | Insulin | 12+ | 1.0 | Serum | Red | 2-mL | Morning SPs only |
| 22 | HIV | 18-49 | 0.8 | Serum | Red | 2-mL | |
| 24 | HSV | 14-49 | 0.2 | Serum | Red | 2-mL | |
| 75 | PSA | 40+ | 1.0 | Serum | Red | 2-mL | Males only |
| 15 | Vit A/E/Car | 6-11 12+ | 0.4 0.5 | Serum | Red | 2-mL | |
| 29 | Persis Pest | 12+ | 4.0 | Serum | 10-mL Red | 5-mL | Process separately. Decant this aliquot. |
| 89 | Persis Pest2 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL | Process separately. Decant this aliquot. |

Exhibit 8-6. Primary SP's serum processing protocol (continued)

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|------------|------|-------------|-------------|-----------------|-------------|--|
| 90 | Perfluor1 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL | Process separately. Decant this aliquot. |
| 91 | Srm Pest | 12+ | 4.0 | Serum | 10-mL Red | 5-mL | Process separately. Decant this aliquot. |
| 92 | BFR1 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL | Process separately. Decant this aliquot. |
| 93 | BFR2 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL | Process separately. Decant this aliquot. |
| 32 | Xtra Serum | 3+ | 0.5 | Serum | Red | 2-mL | |
| 33 | Xtra Serum | 6+ | 0.5 | Serum | Red | 2-mL | |
| 34 | Xtra Serum | 6+ | 0.5 | Serum | Red | 2-mL | |
| 35 | Xtra Serum | 6+ | 0.5 | Serum | Red | 2-mL | |
| 36 | Xtra Serum | 12+ | 0.5 | Serum | Red | 2-mL | |
| 37 | Xtra Serum | 12+ | 0.5 | Serum | Red | 2-mL | |
| 38 | Xtra Serum | 12+ | 1.0 | Serum | Red | 2-mL | |
| 39 | Xtra Serum | 12+ | 1.0 | Serum | Red | 2-mL | |
| 40 | Xtra Serum | 12+ | 1.0 | Serum | Red | 2-mL | |

Exhibits 8-7 through 8-8 illustrate the VIP guest's protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-7. VIP Guest's blood whole blood processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|-------------|--------------|-------------|-------------|-----------------|-------------|-------------------|
| 1 | Lead/Cad/HG | 1+ | 0.3 | Whole blood | EDTA | 2-mL | |
| 2 | Ery Proto | 3-5 12-49 | 0.4 0.4 | Whole blood | EDTA | 2-mL | 2-49 females only |
| 3 | RBC Folate | 1+ | 0.1 | Whole blood | EDTA | 2-mL | |
| 4 | Glycohem | 12+ | 0.4 | Whole blood | EDTA | 2-mL | |
| 5 | Mercury | 1+ | 0.5 | Whole blood | EDTA | 2-mL | |

Exhibit 8-8. VIP Guest's serum processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|-------------|---------------------|-------------------|-------------|-----------------|-------------|---|
| 81 | Vitamin B6 | 1-2 3-11 12+ | 0.2 0.3 0.5 | Serum | Red | 2-mL | |
| 12 | Fol/B12 | 1-5 6+ | 0.7 1.0 | Serum | Red | 2-mL | Do not allow protracted exposure to sunlight; sunlight degrades Folate. |
| 99 | Fer/TfR | 1-2 3-5 12-49 | 0.3 0.5 0.5 | Serum | Red | 2-mL | 12-49 females only |
| 11 | Iron/TIBC | 3-5 12-59 | 1.0 1.0 | Serum | Red | 2-mL | 12-59 females only |
| 21 | Lipids | 6+ | 1.5 | Serum | Red | 2-mL | |
| 94 | PTH2 | 6+ | 1.0 | Serum | Red | 2-mL | |
| 79 | Vitamin C | 6+ | 0.1 | Serum | Red | 2-mL | Dilute with 400- μ L MPA |
| 23 | Biochem | 12+ | 0.8 | Serum | Red | 2-mL | |
| 15 | Vit A/E/Car | 6-11 12+ | 0.4 0.5 | Serum | Red | 2-mL | |

Exhibit 8-9 illustrates the guest and surplus protocol for blood processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 8-9. Guest and surplus serum processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|-----------|------|-------------|-------------|-----------------|-------------|---------|
| 18 | Biochem | 12+ | 0.8 | Serum | Red | 2-mL | |

8.4 Blood Processing Age Specific Protocols

Exhibits 8-10 through 8-13 illustrate the blood processing vessels for each primary SP by age group.

Exhibit 8-10. Blood processing protocol for primary SPs aged 1-2 years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|-----|--------------|------|-------------|-------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 1-2 | 0.3 | Whole blood | 3-mL EDTA | 2-mL |
| 3 | RBC Folate | 1-2 | 0.1 | Whole blood | 3-mL EDTA | 2-mL |
| 5 | Mercury | 1-2 | 0.5 | Whole blood | 3-mL EDTA | 2-mL |
| 100 | IgE | 1-2 | 0.5 | Serum | 3-mL Red | 2-mL |
| 81 | Vitamin B6 | 1-2 | 0.2 | Serum | 3-mL Red | 2-mL |
| 70 | Vitamin D | 1-2 | 0.3 | Serum | 3-mL Red | 2-mL |
| 12 | Fol/B12 | 1-2 | 0.7 | Serum | 3-mL Red | 2-mL |
| 13 | CRP | 1-2 | 0.2 | Serum | 3-mL Red | 2-mL |
| 87 | Hepatitis ab | 2 | 0.3 | Serum | 3-mL Red | 2-mL |
| 99 | Fer/TfR | 1-2 | 0.3 | Serum | 3-mL Red | 2-mL |

Exhibit 8-11. Blood processing protocol for primary SPs aged 3-5 years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|-----|--------------|------|-------------|--------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 3-5 | 0.3 | Whole blood | 3-mL EDTA | 2-mL |
| 2 | Ery Proto | 3-5 | 0.4 | Whole blood | 3-mL EDTA | 2-mL |
| 3 | RBC Folate | 3-5 | 0.1 | Whole blood | 3-mL EDTA | 2-mL |
| 5 | Mercury | 3-5 | 0.5 | Whole blood | 3-mL EDTA | 2-mL |
| 88 | Acrylamide | 3-5 | 1.0 | Packed cells | 3-mL EDTA | 2-mL |
| 100 | IgE | 3-5 | 0.5 | Serum | 7-mL Red | 2-mL |
| 81 | Vitamin B6 | 3-5 | 0.3 | Serum | 7-mL Red | 2-mL |
| 70 | Vitamin D | 3-5 | 0.5 | Serum | 7-mL Red | 2-mL |
| 12 | Fol/B12 | 3-5 | 0.8 | Serum | 7-mL Red | 2-mL |
| 13 | CRP | 3-5 | 0.3 | Serum | 7-mL Red | 2-mL |
| 87 | Hepatitis ab | 3-5 | 0.4 | Serum | 7-mL Red | 2-mL |
| 99 | Fer/TfR | 3-5 | 0.5 | Serum | 7-mL Red | 2-mL |
| 11 | Iron/TIBC | 3-5 | 1.0 | Serum | 7-mL Red | 2-mL |
| 17 | Cotinine | 3-5 | 1.0 | Serum | 7-mL Red | 2-mL |
| 32 | Extra Serum | 3-5 | 0.5 | Serum | 7-mL Red | 2-mL |

Exhibit 8-12. Blood processing protocol for primary SPs aged 6-11 years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|-----|-------------|------|-------------|--------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 6-11 | 0.3 | Whole blood | 3-mL EDTA | 2-mL |
| 3 | RBC Folate | 6-11 | 0.1 | Whole blood | 3-mL EDTA | 2-mL |
| 5 | Mercury | 6-11 | 0.5 | Whole blood | 3-mL EDTA | 2-mL |
| 88 | Acrylamide | 6-11 | 1.0 | Packed cells | 4-mL EDTA | 2-mL |
| 8 | Xtra Plasma | 6-11 | 0.5 | Plasma | 4-mL EDTA | 2-mL |
| 100 | IgE | 6-11 | 1.0 | Serum | 7 or 10-mL Red | 2-mL |
| 81 | Vitamin B6 | 6-11 | 0.5 | Plasma | 7 or 10-mL Red | 2-mL |
| 70 | Vitamin D | 6-11 | 0.5 | Serum | 7 or 10-mL Red | 2-mL |
| 12 | Fol/B12 | 6-11 | 1.0 | Serum | 7 or 10-mL Red | 2-mL |
| 13 | CRP | 6-11 | 0.3 | Serum | 7 or 10-mL Red | 2-mL |
| 14 | Hep Profile | 6-11 | 1.5 | Serum | 7 or 10-mL Red | 2-mL |
| 17 | Cotinine | 6-11 | 1.3 | Serum | 7 or 10-mL Red | 2-mL |
| 21 | Lipids | 6-11 | 1.5 | Serum | 7 or 10-mL Red | 2-mL |
| 94 | PTH2 | 6-11 | 1.0 | Serum | 7 or 10-mL Red | 2-mL |
| 79 | Vitamin C | 6-11 | 0.1 | Serum | 7 or 10-mL Red | 2-mL |
| 15 | Vit A/E/Car | 6-11 | 0.4 | Serum | 7 or 10-mL Red | 2-mL |
| 32 | Xtra Sera | 6-11 | 0.5 | Serum | 7 or 10-mL Red | 2-mL |
| 33 | Xtra Sera | 6-11 | 0.5 | Serum | 7 or 10-mL Red | 2-mL |
| 34 | Xtra Sera | 6-11 | 0.5 | Serum | 7 or 10-mL Red | 2-mL |
| 35 | Xtra Sera | 6-11 | 0.5 | Serum | 7 or 10-mL Red | 2-mL |

Exhibit 8-13. Blood processing protocol for primary SPs aged 12+ years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|-----|-------------|-------|-------------|--------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 12+ | 0.3 | Whole blood | 4-mL EDTA | 2-mL |
| 2 | Ery Proto | 12-49 | 0.4 | Whole blood | 4-mL EDTA | 2-mL |
| 3 | RBC Folate | 12+ | 0.1 | Whole blood | 4-mL EDTA | 2-mL |
| 4 | Glycohem | 12+ | 0.4 | Whole blood | 4-mL EDTA | 2-mL |
| 5 | Mercury | 12+ | 0.5 | Whole blood | 4-mL EDTA | 2-mL |
| 6 | CD4 | 18-49 | 0.5 | Whole blood | 4-mL EDTA | 2-mL |
| 88 | Acrylamide | 12+ | 1.0 | Packed cells | 3-mL EDTA | 2-mL |
| 7 | Homocys/MMA | 20+ | 1.0 | Plasma | 4-mL EDTA | 2-mL |
| 8 | Xtra Plasma | 12+ | 0.5 | Plasma | 4-mL EDTA | 2-mL |
| 9 | Glucose | 12+ | 0.5 | Plasma | 2-mL Gray | 2-mL |
| 98 | OGTT | 12+ | 0.5 | Plasma | 2-mL Gray | 2-mL |
| 100 | IgE | 12+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 81 | Vitamin B6 | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 70 | Vitamin D | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 12 | Fol/B12 | 12+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 13 | CRP | 12+ | 0.3 | Serum | 15-mL Red | 2-mL |
| 14 | Hep Profile | 12+ | 1.5 | Serum | 15-mL Red | 2-mL |

Exhibit 8-13. Blood processing protocol for primary SPs aged 12+ years (continued)

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|-----|--------------|-------|-------------|-------------|-----------------|-------------|
| 99 | Fer/TfR | 12-49 | 0.5 | Serum | 15-mL Red | 2-mL |
| 11 | Iron/TIBC | 12-59 | 1.0 | Serum | 15-mL Red | 2-mL |
| 17 | Cotinine | 12+ | 1.8 | Serum | 15-mL Red | 2-mL |
| 21 | Lipids | 12+ | 1.5 | Serum | 15-mL Red | 2-mL |
| 104 | Lp(a) | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 94 | PTH2 | 12+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 77 | HPV Serum | 14-59 | 0.5 | Serum | 15-mL Red | 2-mL |
| 79 | Vitamin C | 12+ | 0.1 | Serum | 15-mL Red | 2-mL |
| 18 | Biochem | 12+ | 0.8 | Serum | 15-mL Red | 2-mL |
| 23 | Insulin | 12+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 22 | HIV | 18-49 | 0.8 | Serum | 15-mL Red | 2-mL |
| 24 | HSV | 14-49 | 0.2 | Serum | 15-mL Red | 2-mL |
| 75 | PSA | 40+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 15 | Vit A/E/CAR | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 32 | Xtra Serum | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 33 | Xtra Serum | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 34 | Xtra Serum | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 35 | Xtra Serum | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 36 | Xtra Serum | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 37 | Xtra Serum | 12+ | 0.5 | Serum | 15-mL Red | 2-mL |
| 38 | Xtra Serum | 12+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 39 | Xtra Serum | 12+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 40 | Xtra Serum | 12+ | 1.0 | Serum | 15-mL Red | 2-mL |
| 29 | Persis Pest | 12+ | 4.0 | Serum | 10-mL Red | 5-mL |
| 89 | Persis Pest2 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL |
| 90 | Perflour1 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL |
| 91 | Srm Pest | 12+ | 4.0 | Serum | 10-mL Red | 5-mL |
| 92 | BFR1 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL |
| 93 | BFR2 | 12+ | 4.0 | Serum | 10-mL Red | 5-mL |

Exhibits 8-14 through 8-17 illustrate the blood processing vessels for each VIP guest.

Exhibit 8-14. Blood processing protocol for VIP guest aged 1-2 years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|----|-------------|------|-------------|-------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 1-2 | 0.3 | Whole blood | 3-mL EDTA | 2-mL |
| 3 | RBC Folate | 1-2 | 0.1 | Whole blood | 3-mL EDTA | 2-mL |
| 5 | Mercury | 1-2 | 0.5 | Whole blood | 3-mL EDTA | 2-mL |
| 81 | Vitamin B6 | 1-2 | 0.2 | Serum | 3-mL Red | 2-mL |
| 12 | Fol/B12 | 1-2 | 0.7 | Serum | 3-mL Red | 2-mL |
| 99 | Fer/TfR | 1-2 | 0.3 | Serum | 3-mL Red | 2-mL |

Exhibit 8-15. Blood processing protocol for VIP guest aged 3-5 years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|----|-------------|------|-------------|-------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 3-5 | 0.3 | Whole blood | 3-mL EDTA | 2-mL |
| 2 | Ery Proto | 3-5 | 0.4 | Whole blood | 3-mL EDTA | 2-mL |
| 3 | RBC Folate | 3-5 | 0.1 | Whole blood | 3-mL EDTA | 2-mL |
| 5 | Mercury | 3-5 | 0.5 | Whole blood | 3-mL EDTA | 2-mL |
| 81 | Vitamin B6 | 3-5 | 0.3 | Serum | 7-mL Red | 2-mL |
| 12 | Fol/B12 | 3-5 | 0.7 | Serum | 7-mL Red | 2-mL |
| 99 | Fer/TfR | 3-5 | 0.5 | Serum | 7-mL Red | 2-mL |
| 11 | Iron/TIBC | 3-5 | 1.0 | Serum | 7-mL Red | 2-mL |

Exhibit 8-16. Blood processing protocol for VIP guest aged 6-11 years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|----|-------------|------|-------------|-------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 6-11 | 0.3 | Whole blood | 3-mL EDTA | 2-mL |
| 3 | RBC Folate | 6-11 | 0.1 | Whole blood | 3-mL EDTA | 2-mL |
| 5 | Mercury | 6-11 | 0.5 | Whole blood | 3-mL EDTA | 2-mL |
| 81 | Vitamin B6 | 6-11 | 0.3 | Serum | 3 or 7-mL Red | 2-mL |
| 12 | Fol/B12 | 6-11 | 1.0 | Serum | 3 or 7-mL Red | 2-mL |
| 21 | Lipids | 6-11 | 1.5 | Serum | 3 or 7-mL Red | 2-mL |
| 94 | PTH2 | 6-11 | 1.0 | Serum | 3 or 7-mL Red | 2-mL |
| 79 | Vitamin C | 6-11 | 0.1 | Serum | 3 or 7-mL Red | 2-mL |
| 16 | Vit A/E/Car | 6-11 | 0.4 | Serum | 3 or 7-mL Red | 2-mL |

Exhibit 8-17. Blood processing protocol for VIP guest aged 12+ years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|----|-------------|-------|-------------|-------------|-----------------|-------------|
| 1 | Lead/Cad/HG | 12+ | 0.3 | Whole blood | 4-mL EDTA | 2-mL |
| 2 | Ery Proto | 12-49 | 0.4 | Whole blood | 4-mL EDTA | 2-mL |
| 3 | RBC Folate | 12+ | 0.1 | Whole blood | 4-mL EDTA | 2-mL |
| 4 | Glycohem | 12+ | 0.4 | Whole blood | 4-mL EDTA | 2-mL |
| 5 | Mercury | 12+ | 0.5 | Whole blood | 4-mL EDTA | 2-mL |
| 81 | Vitamin B6 | 12+ | 0.5 | Serum | 10-mL Red | 2-mL |
| 12 | Fol/B12 | 12+ | 1.0 | Serum | 10-mL Red | 2-mL |
| 99 | Fer/TfR | 12-49 | 0.5 | Serum | 10-mL Red | 2-mL |
| 11 | Iron/TIBC | 12-59 | 1.0 | Serum | 10-mL Red | 2-mL |
| 21 | Lipids | 12+ | 1.5 | Serum | 10-mL Red | 2-mL |
| 94 | PTH2 | 12+ | 1.0 | Serum | 10-mL Red | 2-mL |
| 79 | Vitamin C | 12+ | 0.1 | Serum | 10-mL Red | 2-mL |
| 18 | Biochem | 12+ | 0.8 | Serum | 10-mL Red | 2-mL |
| 16 | Vit A/E/Car | 1+2 | 0.5 | Serum | 10-mL Red | 2-mL |

Exhibit 8-18 illustrates the blood-processing vessel for each guest and surplus.

Exhibit 8-18. Blood processing protocol for guest and surplus aged 12+ years

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type |
|----|-----------|------|-------------|-------------|-----------------|-------------|
| 18 | Biochem | 12+ | 0.8 | Serum | 3-mL Red | 2-mL |

8.5 Labeling Vessels

The phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting up the blood processing racks and in labeling the vessels with the appropriate bar code label.

Use the following materials to set up and label blood racks:

- Rack
- Age-appropriate processing template

- Storage vessels of the following sizes
 - 2.0-mL vessel
 - 5.0-mL vessel
 - 14.0-mL tube
 - 50-mL conical tube
- Bar-coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

Prepare one blood processing rack for each SP. The tubes for which each SP is eligible are determined by their sex, appointment type, and inclusion into certain subsamples so each SP's blood processing rack will be unique. When possible, prepare the racks at least 1 day before the SP arrives for the MEC examination.

Before each session, the technologist at workstation 3 prints all labels for all SPs, distributes the labels, and labels the blood processing racks. The correct bar code labels automatically print for each SP based on the SP's unique profile.

While the technologist assigned to shipping is responsible for labeling the vessels and setting up the blood processing racks, it is the blood-processing technologist's responsibility to verify that each vessel has the correct label before filling. Do not rely only upon memory or the positioning of the vessels in a rack to indicate which vessels to fill.

Always double check:

- The SP's ID number on the bar code label;
- The vessel number on the label;
- The adhesion quality of the labels; and
- To ensure that specimens are not missing labels or incorrectly labeled.

Save and recycle unused vessels:

- If the SP does not show up for their MEC exam at the appointed date and time, then it is possible they will reschedule;

- Store the SPs labeled vials in a zip closable bag until the end of the stand; and
- If the SP has not shown up by the end of the stand, discard the unused vessels.

8.6 Equipment

8.6.1 Benchtop Centrifuges

Each laboratory contains two benchtop refrigerated Beckman GS-6R centrifuges.

The centrifuge has the following safety features:

- An imbalance detector triggers an automatic shutdown if rotor loads are severely out of balance.
- A safety-lock mechanism and secondary manual latch prohibit opening the centrifuge door during a run until the rotor is virtually stopped.
- A lockout system requires the door to be closed and latched before the centrifuge will start.
- An anchoring system secures the centrifuge in place. Anchoring systems reduce the possibility of injury or damage that could result from centrifuge movement in case of a major rotor mishap.

The control panel is mounted at an angle on the centrifuge front for easy visibility and access. The control panel has the following features:

- Power – This rocker switch, labeled I (ON), and O (OFF), controls electrical power to the centrifuge. The chamber door cannot be opened unless the power is turned ON.
- Door – When pressed to the OPEN position, this switch releases the latch mechanism and allows the door to be opened when the secondary manual latch lever is switched to UNLOCK (the rotor must be stopped and the power switched on).
- Brake – Use this switch to select the brake mode used during deceleration. Set the position to HIGH or LOW. The HIGH break position activates the dynamic and the electromechanical disk breaking. Dynamic breaking starts immediately after the timer turns the rotor off. At 1600 rpm the disk break engages and remains on until the speed reaches 400 rpm, followed by dynamic breaking alone to 50 RPM. At 50 rpm, all breaking stops and the rotor coasts to a stop.

- Time – This knob may be set for any run time between 2 and 30 minutes in 1-minute increments. During a run, the timer rotates back to zero, at which point the centrifuge begins deceleration. A HOLD setting enables longer-duration runs – the centrifuge will run until turned off. Stop runs at any time by turning the knob to OFF.

For plasma and serum – set appropriate time and temperature for each tube as follows:

- 3 or 4-mL EDTA 10 minutes 4-8°C
- 2-mL gray 10 minutes 17-25°C or 4-8°C
- 3-mL, 7-mL, 10-mL or 15-mL red 15 minutes 17-25°C

For packed cells – set appropriate time and temperature for each tube as follows:

- 3 or 4-mL EDTA 5 minutes 4-8°C

- Speed and ACCU-SET – Use this knob to set the drive speed, in 200-rpm increments, up to 8000 rpm. For precise adjustments, the ACCU-SET button can be pressed as the speed knob is turned until the desired speed appears on the RPM display. ACCU-SET can be adjusted at any time during a run.

For plasma and serum – set the speed at 2,900 rpm.

For packed cells – set the speed at 1,985 rpm.

- RPM – During the run, the display indicates the actual rotor speed to the nearest increment of 10 rpm.
- Temperature – Use this knob to set operating temperature. The dial is marked from -10 to +40°C in 1°C increments. Set the refrigerated centrifuge at 4°C and the room temperature centrifuge at 22°C. The display indicates the temperature (+/-2°C) within the bowl in increments of 1°C.

Run Procedure:

1. Press the POWER to switch to ON.
2. Move the door latch lever to UNLOCK. Press the DOOR switch to OPEN and lift the centrifuge door up; it will remain in the open positions.
3. Load the Aerosolve canisters symmetrically. If only two canisters are being run, place the canisters in opposite buckets; place two empty buckets for balance in the other two buckets. If only three canisters are required, balance tubes in empty canister across from third canister.

4. Close the centrifuge door and push firmly down on it until hearing a clicking or latching sound. Move the secondary latch lock to LOCK position.
5. Set the TEMPERATURE knob to the required run temperature.
6. Set the run speed using the following procedure:
 - Press the small ACCU-SET button in; rotate the SPEED dial until the required speed shows on the display.
 - While holding the ACCU-SET button in, rotate the SPEED dial until the required speed shows on the display.
 - When the selected speed is displayed, release the ACCU-SET button.
7. Select the HIGH brake position for the EDTA, gray, and blue top tubes and select the LOW brake for the red top tubes.
8. Turn the timer to the required time. The centrifuge will start. As the run begins, acceleration control protects delicate gradients; when the rotor speed reaches about 200 rpm, full acceleration to set speed occurs.
9. To end a run in progress for any reason: Turn the timer knob to OFF. The door interlock system keeps the door latched until the rotor has virtually stopped.
10. After the rotor stops spinning, move the secondary latch lever to UNLOCK and press OPEN switch on the control panel to open the door.
11. After completing a run, unload the canisters.

Leave the door open in order to prevent chamber icing.

8.6.2 Laminar Flow Biological Safety Cabinet Operating Sequence

- Turn on the cabinet blower and lights, and check the air intake and exhaust portals of the cabinet to make sure they are unobstructed.
- Check the pressure on the magnehelic gauge. If the pressure has increased more than 0.1 w.g. since the previous reading, notify the biomedical engineer. Record the pressure reading and any comments in the Laboratory QC module.
- Allow the blowers to operate for a minimum of 15 minutes before beginning work in the cabinet.
- Disinfect the interior of the workspace by wiping it down with a 10% solution of bleach and water (1:10).

- Place a disposable paper blotter on the work surface. Set up the equipment for processing. Do not place any equipment or supplies over the front intake grills.
- Arrange and separate clean and contaminated materials.
- Wait 2 to 3 minutes after placing the materials and supplies in the cabinet before beginning work. This will rid the area of all “loose” contamination.
- Wear a long-sleeved laboratory coat and gloves. This will minimize the shedding of skin flora into the work area and concurrently protect hands and arms from viable agent contamination. Wash hands with soap and water before and after working in the cabinet.
- After completing work, leave the blower on for 2 to 3 minutes to purge the unit.
- Decontaminate interior surfaces after removal of all specimens and biohazard waste by wiping them with a 10% solution of bleach and water (1:10).
- Check the grills and diffuser vents for spills or splashes and clean using appropriate techniques and materials.

8.7 Blood Processing Procedures

Centrifuge all blood specimens unopened, then transport to, and uncap and process in the laminar flow hood. The laminar flow hood provides a HEPA filtered, recirculated mass airflow within the workspace, and protects from any spattering that may occur when opening the Vacutainer® tubes or when pouring or pipetting the specimens. It also prevents drawing contaminated air or dust over the specimens. It is mandatory to use the blower.

Always wear gloves when handling specimens. Check gloves for small holes or tears. Change gloves if they become visibly contaminated with blood. Immediately soak visibly contaminated racks in 1:100 bleach solution.

Decontaminate racks and templates by soaking them in 10% bleach solution at the end of each session. Place on blotter to air dry.

8.7.1 Eppendorf Research Pro Pipettes

Pipette whole blood and pooled serum and make dilutions using the Eppendorf Research pro pipettes. Pipette plasma using plastic transfer pipettes.

The MEC laboratory has four Eppendorf Research pro electronic pipettes: one 5-100 μ L, two 50-1000 μ L, and one 100-5000 μ L. The lab also uses 100 μ L and 1000 μ L Biopur pipette tips and 5-mL bulk pipette tips. Charge the pipettes in the 4-stand charger.

- Use the one 5-100 μ L pipette in the standard (PIP) mode and set the volume to 100 μ L. Use this dedicated pipette to aliquot the whole blood for the RBC folate, vessel 3, and Vitamin C, vessel 79.
- Use one of the two 50-1000 μ L pipettes in the standard (PIP) mode and set the volume to 1000 μ L. Use this dedicated pipette to aliquot the ascorbic acid for RBC folate, vessel 3.
- Use the second 50-1000 μ L pipette in the FIX mode. Set the five fixed volumes to 300 μ L, 400 μ L, 500 μ L, 600 μ L, and 1000 μ L. Use this pipette to aliquot all whole blood tests, except the RBC folate, and pooled serum volumes that match the five volume settings. Use this pipette to dilute 100- μ L serum with 400- μ L MPA for the Vitamin C assay, vessel 79.
- Use the second 50-1000 μ L pipette and the 100-5000 μ L pipette in the DIS mode. Set the DIS volume on the 50-1000 μ L to 100 μ L. Set the DIS volume on the 100-5000 μ L to 500 μ L. Use these pipettes to aliquot pooled serum.
- Use the 100-5000 μ L pipette in the FIX mode. Set the five fixed volumes to 1000 μ L, 2000 μ L, 3000 μ L, 4000 μ L, and 5000 μ L. Use this pipette to aliquot pooled serum volumes that match the five volume settings.
- Use the 100-5000 μ L pipette in the ADS mode. Program this mode in slot 2. Set the volume to 500 μ L and the interval to 1 second. Use this pipette to aliquot pooled serum.

- Use the 100-5000 μL pipette in the SD mode. Set the volumes to match the age-specific processing protocols. Set program 1 to match the adult profile for vessels 11-70. Set program 3 to match the child's profile age 1-2. Set program 4 to match the child's profile age 3-5. Set program 5 to match the child's profile age 6-11. Use this pipette to aliquot pooled serum.

| Pipette | Tip | Mode | Volume | Matrix |
|--|--------------------------------------|------------|--|---|
| <i>*5-100 μL</i> | <i>200 μL</i> | <i>PIP</i> | <i>100 μL</i> | <i>Whole blood</i> |
| <i>*50-1000 μL</i> | <i>1000 μL</i> | <i>PIP</i> | <i>1000 μL</i> | <i>Ascorbic acid</i> |
| <i>50-1000 μL</i> | <i>1000 μL</i> | <i>FIX</i> | <i>300 μL 400 μL 500 μL 600 μL 1000 μL</i> | <i>Whole blood Pooled serum MPA</i> |
| <i>50-1000 μL</i> | <i>1000 μL</i> | <i>DIS</i> | <i>100 μL</i> | <i>Whole blood Pooled serum</i> |
| <i>100-5000 μL</i> | <i>5000 μL</i> | <i>FIX</i> | <i>1000 μL 2000 μL 3000 μL 4000 μL 5000 μL</i> | <i>Pooled serum</i> |
| <i>100-5000 μL</i> | <i>5000 μL</i> | <i>DIS</i> | <i>500 μL</i> | <i>Pooled serum</i> |
| <i>100-5000 μL</i> | <i>5000 μL</i> | <i>ADS</i> | <i>500 μL 1 second</i> | <i>Pooled serum</i> |
| <i>100-5000 μL</i> | <i>5000 μL</i> | <i>SD</i> | <i>Program 1 – 12+ Program 3 – Child 1-2 Program 4 – Child 3-5 Program 5 – Child 6-11</i> | <i>Pooled serum</i> |

Italic = Pipette's primary program

* Dedicated pipette for RBC Folate, vessel 3 and Vitamin C, vessel 79 dilutions

8.7.1.1 Safety Precautions, Handling, Care, Maintenance, and Battery for the Research Pro

Before using the Research pro for the first time, please read the entire *Eppendorf Research pro Instruction Manual*. Observe the following points:

Handling

- Use the Research pro only when a pipette tip is attached.
- Do not lay down the Research pro when a filled pipette tip is attached.
- After liquid has been aspirated, press the Actuate key only when you are sure the liquid shall be dispensed correctly.
- When the pipette is switched on and when the Reset key is pressed, the piston may move. Please ensure beforehand that the liquid in the pipette tip shall be dispensed correctly.
- Emergency stop: pressing the Reset key can stop a moving piston.
- Operate the Research pro at temperatures between 15°C and 40°C. Operate at a maximum humidity of 80% at a temperature up to 31°C.

Care and Maintenance

- Do not clean the display or any of the labeling using acetone or aggressive solutions.
- Do not allow any liquid to enter the device.
- Authorized service personnel may carry out repairs only.
- Use original spare parts and accessories (battery, pipette tips) only.

Battery

- Charge the battery before operating the device for the first time.
- Charge the battery in the pipette only, using the charging stand and the original power unit.

- If a flashing battery symbol appears in the display, stop dispensing and charge the battery.
- When charging the battery, do not allow the battery to be exposed to any metallic surfaces.
- Dispose of used batteries as special waste.
- Never charge the Research pro without a battery.
- Before storing the Research pro for a long period, remove the battery.

8.7.1.2 Technical Data for the Research Pro

Single Channel Pipette

| Volume Range μL | Step size μL | Color code | Pipette tip | Test volume | Inaccuracy % | Imprecision % |
|----------------------------|-------------------------|------------|--------------------|---|------------------------|---------------------------|
| 5-100 | 0.1 | Yellow | 200 μL | 100 μL | ± 0.8 | ≤ 0.2 |
| 50-1000 | 1 | Blue | 1000 μL | 1000 μL | ± 0.6 | ≤ 0.2 |
| 100-5000 | 10 | Violet | 5-mL | 500 μL 5000 μL | ± 3.0 ± 0.6 | ≤ 0.6 ≤ 0.15 |

The technical data are valid only when the Research pro is used with Eppendorf pipette tips.

- Test conditions in accordance with DIN 12650 for piston-stroke pipettes with an air cushion by means of a standardized fine balance with a moisture trap
- Number of determination: 10
- Degassed distilled water, $20^{\circ}\text{C} - 25^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$
- Maximum speed
- Standard operation
- Prewetted pipette tip, dispensing onto inside of tube due to possible evaporation
- Check volumes $\leq 10 \mu\text{L}$ immediately after aspiration

Battery

- Nickel-metal hydride battery pack, 1,200 mAh/2.4 V with reversible overcurrent and overtemperature protection
- Charging time: approximately 9.5 hours for a fully discharged battery; overcharging protection with the pipette

Power Unit

- Input voltage, country-specific: 230 V \pm 10%, 50/60 Hz; 115 V \pm 10%, 60 Hz; 100 V \pm 10%, 50/60 Hz.
- Output voltage: 9 V DC; 200 mA (1.8 VA)

Delivery Package

The Research pro is supplied as a single-channel pipette for different volume ranges. The pipette is delivered without a charging adapter, but each lab is supplied with a charging stand. Each package contains:

- Charging stand with separate power unit;
- Special tool(s) according to pipette type;
- Operating manual with measuring protocol and CE conformity assurance document; and
- Ni-MH battery pack.

Inserting the Battery

Charge the battery in the pipette. Charging may only be carried out using the charging stand with the original power unit. Do not try to recharge a pipette if the battery is not installed. A new battery does not attain its full capacity until two or three complete charging/discharging cycles have been completed.

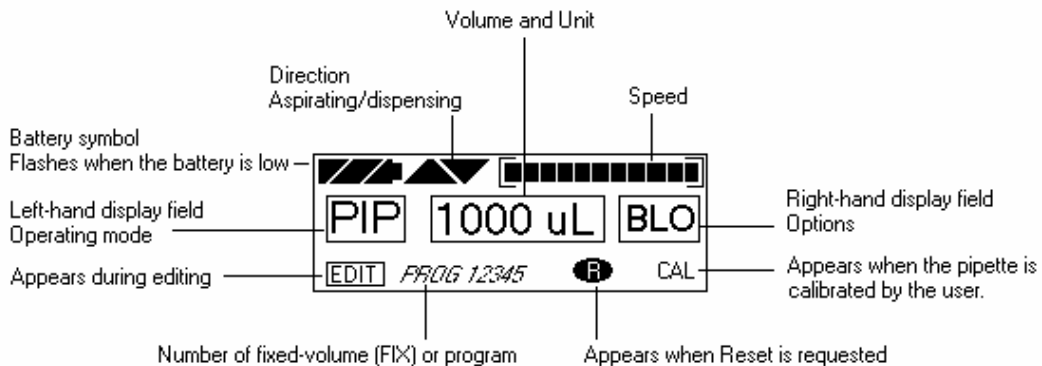
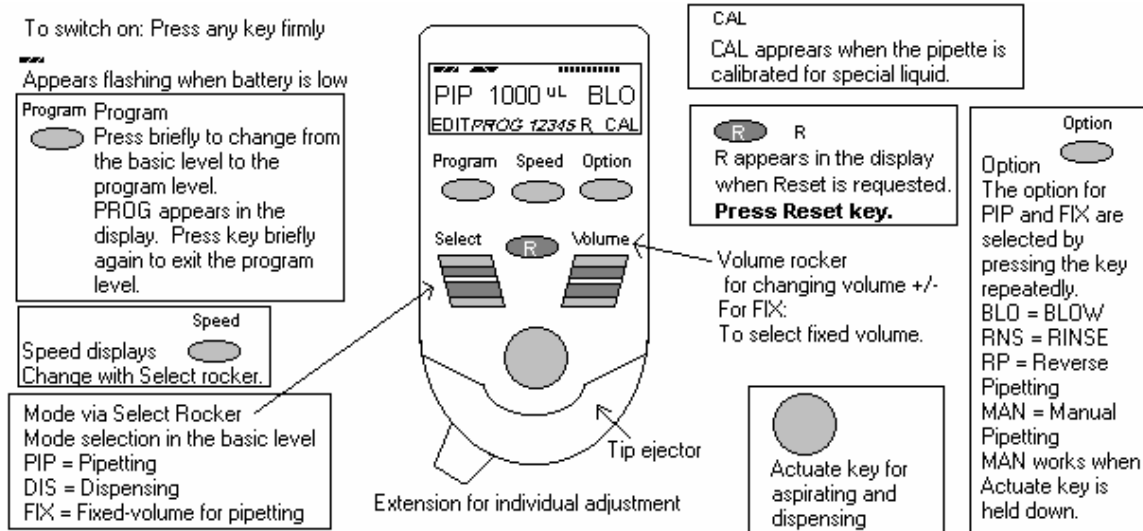
For charging purposes, place the pipette in the charging stand.

During the start and termination of the charging process, “CON” appears briefly on the left-hand side of the display. The display is switched on during the charging process. The battery symbol appears in a rolling form. During charging, the dispensing function is frozen. When the charging process has finished, the battery symbol appears in the display without moving. When the pipette has been fully charged, it may remain in the charging stand. To increase the charging capacity, the battery should be discharged until the flashing battery symbol appears. To avoid accidental discharge, remove the battery from the Research pro during extended periods of nonuse. In this case, all data remains stored.

8.7.1.3 Operating Principle

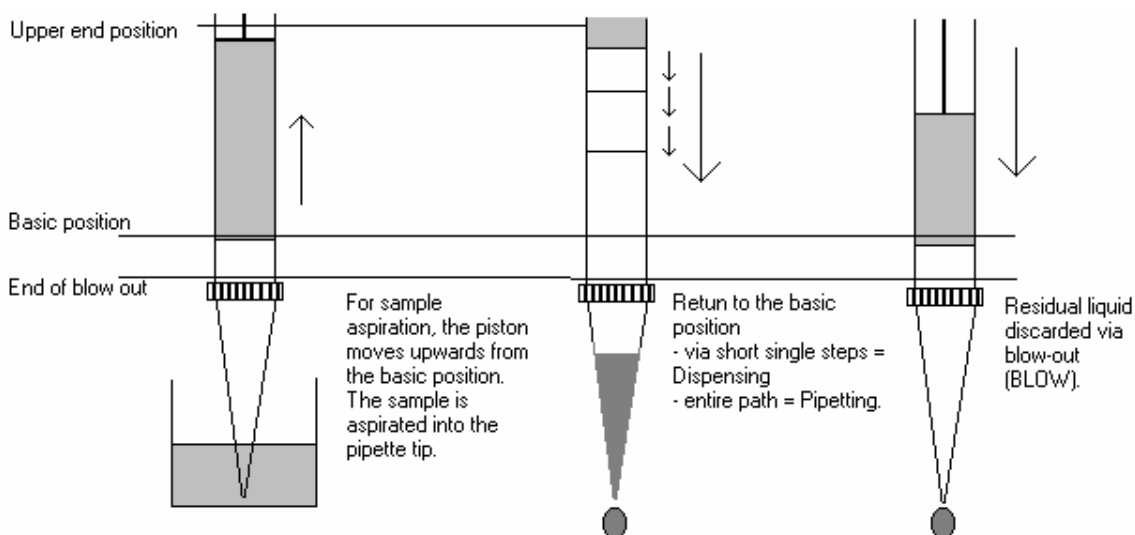
Display and Keypad

- To switch on: Press any key firmly.
- To switch off: Unit does this automatically after 10 minutes of nonuse.



8.7.1.4 Functions of the Unit

The Research pro is a microprocessor-controlled pipette, which executes the piston movement with the aid of a stepper motor. The power supply is a rechargeable nickel-metal hydride battery.



Dispensing and reverse pipetting require a different basic position than that for pipetting. *The request to change the basic position is accomplished by selecting the Reset button.*

Ejector with Extension

The force translation of the ejector for pipette tips ensures that the tips are ejected very easily. The extension can be individually adjusted to accommodate left- and right-handed users as well as different hand sizes. *Select the desired setting by simply sliding the extension into the position as required.*

Hook on the Hand Rest

Loosening the screw enables the hook on the rear of the pipette to be adjusted to suit all hand sizes. This can be done easily with a small Phillips screwdriver.

Contact Surface on the Read of the Pipette

Both upper surfaces are required for charging the nickel-metal hydride battery.

The lower surfaces are the data interfaces for the service department.

The contact to the charging adapter or the charging stand cannot be confused with any other contacts.

Acoustic Signals

Certain signals assist the user for different operations:

- Short signal to acknowledge that the keypad has been pressed;
- Slightly higher tone to indicate that the function for which the key has been pressed cannot be executed;
- Louder tone to indicate that the piston movement has ended;
- Louder tone to indicate that a specific sequence of steps (e.g. Dispensing) has ended; and
- Louder tone to indicate an error message.

The acoustic signals are a great help when you are familiarizing yourself with the operating procedure of the Research pro. They can be switched off if required.

8.7.1.5 Mode of Operation

If the display of the Research pro is dark, activate the pipette by pressing any key firmly. If the pipette has not been used for a long period, a motor reset is executed after it has been activated.

- Attach an Eppendorf pipette tip to the Research pro. The color-coding of the Actuate key corresponds to the color code of the racks for the pipette tips. The dispensing liquid is aspirated into the tip.
- When aspirating liquid, immerse the pipette tip vertically – and as little as possible into the liquid. Following aspiration, remove the pipette tip from the liquid after the acoustic signal has been emitted. If the air bubbles have been aspirated, repeat this process.
- Never lay the pipette down when the tip is filled.
- To dispense the liquid, position the pipette tip against the side of the aspirating vessel.
- Discard the pipette tip by pressing the Eject key, attach a new tip, and reaspirate liquid.

Essential Operating Information

The following sections contain systematic explanations of the operating procedure. It is essential to work through these sections with the pipette in your hand.

Reset



If a Reset is requested in the display, a piston movement always accompanies this Reset request. For this reason, please ensure that any residual liquid in the pipette tip is dispensed beforehand. A Reset can also be used to empty the pipette tip and to end an operating process. If you quit an input field during programming (e.g., changing the speed) using Reset, the changes that have been made are not stored. The Reset button can also act as an emergency stop function.

Motor
reset

If the Reset key (**R**) is held down until the piston movement begins and R appears in the display, a motor reset is carried out. This motor reset guarantees that the piston movement is correct. This reset lasts for approximately 10 seconds.

Please refer to the following illustrations when going through each operation.



The Research pro has two operating levels. The basic modes for pipetting (PIP and FIX) and (DIS) are accessed in the first level by pressing the Select rocker. **PROG** appears in the display by pressing the “Program” key. You are now in the second level. Using the Select rocker, select from the five available program slots. To quit this level, press the “Program” key briefly and PROG will disappear from the display.



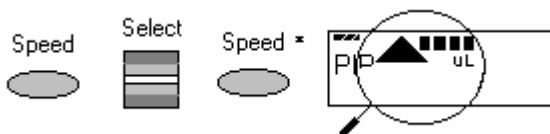
If the piston movements appear in the display without any volumes, this indicates a process that is not connected to liquid aspiration or dispensing.

Aspirating and Dispensing Speeds

The selected speed can be viewed by pressing the Speed key several times. The speed is changed as follows:



Display and selection of aspirating speed.



Display and selection of dispensing speed.

- This procedure does not have to be completed using the Speed key. Any key, with the exception of Reset, may be used. At the same time, pressing the key executes the respective key function.
- The direction of the arrow for speed flashes in this input field.

- The speed can be altered before every dispensing or aspiration.
- Important – High speeds have a much lower current consumption than low speeds.

8.7.1.6 Pipetting in the Standard Mode (PIP) *(Use this mode for whole blood RBC folate and Vitamin C [5-100 μ L pipette] and ascorbic acid [50-1000 μ L pipette].)*

In the standard mode, blowout is executed automatically when liquid is dispensed. The standard mode is recommended for rapid series pipetting with aqueous solutions.

| Programming – PIP | |
|---------------------|---|
| Step 1 | Select the pipetting mode “PIP.” Use the Select rocker switch to move up and down through the three modes (PIP, DIS, and FIX) until the “PIP” choice appears in the left-hand side of the display. <i>(If PROG appears in the display: Press the Program key briefly until PROG disappears.)</i> |
| Step 2 | Select the volume. Use the Volume rocker to move the number up or down until the number (volume) 100 for the 5-100- μ L pipette and 1000 μ L for the 50-1000- μ L pipette is reached. If necessary, press the Option key several times until the right-hand side of the display is blank. (Do not use the BLO, RNS, RP, or MAN options.) |
| Pipetting Procedure | |
| Step 1 | Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip. |
| Step 2 | Place the pipette tip against the side of the receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the liquid with a blowout, press the Aspirate button. |
| Step 3 | The pipette is ready to aspirate again if the Aspirating arrow in the display points up. |

8.7.1.7 Pipetting with a Preselected Fixed (FIX) Volume (*Use this mode for aliquoting whole blood volumes 300, 400, 500, 600, and 1000 μL and for 400 μL MPA – 50-1000 μL pipette, and for pipetting pooled serum volumes 1000, 2000, 3000, 4000, and 5,000 μL – 100-5000 μL .)*)

FIX is used to rapidly set and recall five frequently used pipette volumes. Five FIX volumes are predefined in the pipette. FIX volumes can be changed via programming.

| Programming FIX fixed volumes | |
|-------------------------------|---|
| Step 1 | Select the pipetting mode “FIX.” Use the Select rocker switch to move up and down through the three modes (PIP, DIS, FIX) until the “FIX” choice appears in the display. <i>(If PROG appears in the display: Press the Program key briefly until PROG disappears.)</i> |
| Step 2 | Hold down the Program key until EDIT appears in the lower left hand corner of the display. The volume flashes. |
| Step 3 | Select the first memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #1 is displayed. |
| Step 4 | Select the volume for memory slot #1. Use the Volume rocker to move the number (volume) up and down until the number (volume) 300 μL for the 5-1000- μL pipette or 1000 μL for the 100-5000 μL pipette is reached. |
| Step 5 | Select the next (second) memory slot for purposes of changing the volume. Select the second memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #2 is displayed. |
| Step 6 | Select the volume for memory slot #2. Use the Volume rocker to move the number (volume) up and down until the number (volume) 400 μL for the 5-1000- μL pipette or 2000 μL for the 100-5000 μL pipette is reached. |

| | |
|---------------------|---|
| Step 7 | Select the next (third) memory slot for purposes of changing the volume. Select the third memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #3 is displayed. |
| Step 8 | Select the volume for memory slot #3. Use the Volume rocker to move the number (volume) up and down until the number (volume) 500 μL for the 5-1000- μL pipette or 3000 μL for the 100-5000 μL pipette is reached. |
| Step 9 | Select the next (fourth) memory slot for purposes of changing the volume. Select the fourth memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #4 is displayed. |
| Step 10 | Select the volume for memory slot #4. Use the Volume rocker to move the number (volume) up and down until the number (volume) 600 μL for the 5-1000- μL pipette or 4000 μL for the 100-5000 μL pipette is reached. |
| Step 11 | Select the next (fifth) memory slot for purposes of changing the volume. Select the fifth memory slot using the Select rocker. Use the Select rocker to move the memory slot number up and down until the #5 is displayed. |
| Step 12 | Select the volume for memory slot #5. Use the Volume rocker to move the number (volume) up and down until the number (volume) 1000 μL for the 5-1000- μL pipette or 5000 μL for the 100-5000 μL pipette is reached. |
| Step 13 | End the programming. Press the Program key to stop programming. Alternatively, to stop programming and aspirate the volume of liquid in the display, press the Aspirate button. EDIT and the flashing volume disappear from the display. |
| Pipetting Procedure | |
| Step 1 | Select the correct mode. Use the Select rocker to move up and down through the three mode choices (PIP, DIS, FIX) until FIX displays. |
| Step 2 | Select one of the five programmed fixed volumes. Select the correct memory slot. Use the Volume rocker to move the volume number up and down until the correct choice displays. |

| | |
|--------|---|
| Step 3 | Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip. |
| Step 4 | Place the pipette tip against the side of the receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the liquid with a blowout, press the Aspirate button. |
| Step 5 | The pipette is ready to aspirate again if the Aspirating arrow in the display points up. |

8.7.1.8 Dispensing (DIS) *(use this mode to pipette 100 µL whole blood and/or pooled serum – 50-1000 µL pipette and 500 µL pooled serum 100-5000 µL pipette)*

During this procedure, the aspirating liquid is dispensed in partial steps. As with “Reverse Pipetting,” slightly more liquid is aspirated than is necessary for the sum of the dispensing steps. The maximum number of dispensing steps per filling of the pipette tip is displayed in the right hand side of the display. The maximum number of dispensing steps is calculated by the pipette and is based on the dispensing volume and the pipette tip. For example, if the dispensing volume is set at 100 µL and the pipette tip is 1000 µL then there are 10 dispensing steps. If the dispensing volume is set at 500 µL and the pipette tip is 5000 µL, then there are also 10 dispensing steps.

| | |
|------------------------|---|
| Programming DIS | |
| Step 1 | Select the pipetting mode “DIS.” Use the Select rocker switch to move up and down through the three modes (PIP, DIS, FIX) until the “DIS” choice appears in the display. <i>(If PROG appears in the display: Press the Program key briefly until PROG disappears.)</i> |
| Step 2 | Select the volume per dispensing step. Use the Volume rocker to move the number up or down until the number (volume) 100 for the 50-1000-µL pipette or 500 µL for the 100-5000 µL pipette is reached. |

| | |
|----------------------------|---|
| Step 3 | Select the aspirating speed using the Speed key and the Select rocker. Press the Speed key, then use the Select rocker to move the speed indicator all the way to the right. When finished, press the Speed key. The pipette is ready for entry of the dispensing speed. |
| Step 4 | Select the dispensing speed. Use the Select rocker to move the speed indicator all the way to the right. Press the Speed key to exit. |
| Pipetting Procedure | |
| Step 1 | Select the correct mode. Use the Select rocker to move up and down through the three mode choices (PIP, DIS, FIX) until DIS displays. |
| Step 2 | Aspirate the liquid. Make sure the Aspirating arrow in the display points up. Immerse the tip of the pipette tip into the liquid and press the Actuate key to draw the liquid into the pipette tip. (If \mathbb{R} appears in the display: Press the R key briefly.) |
| Step 3 | Place the pipette tip against the side of the first receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the first aliquot, press the Aspirate button. The dispensing step counter (number) on the right-hand side of the display counts down one number. |
| Step 4 | Place the pipette tip against the side of the second receiving vessel. Make sure the Dispensing arrow in the display points down. To dispense the second aliquot, press the Aspirate button. The dispensing step counter (number) on the right-hand side of the display counts down one more number. |
| Step 5 | Continue dispensing until the dispensing step number reaches 0. A special acoustic signal is emitted. |
| Step 6 | Complete the “blank” step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted. |
| Step 7 | Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released. |

| | |
|--------|--|
| Step 8 | The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display. |
|--------|--|

8.7.1.9 Notes on the Programs

- To reach the programming level, press the Program key briefly.
- PROG appears in the display together with a memory slot number from 1 to 5.
- With the aid of the Select rocker, five programs can be shown in the left-hand side of the display.
- To program the five memory slots, it is possible to select from seven different program sequences:
 1. PIP = Pipetting

As per PIP outside program level. The complete sequence with volume, option, and speeds is programmed in one memory slot.
 2. SP = Sequential Pipetting

Up to five different pipette steps can be linked to each other. Volume, option, and speeds are defined for each pipetting sequence.
 3. DIS = Dispensing

As per DIS outside the program level. The complete procedure is programmed in one memory slot with dispensing volume, dispensing steps, and speeds.
 4. SD = Sequential Dispensing

Up to 20 dispensing steps can be defined. Each dispensing step may have a different partial volume. The total volume may exceed the filling level of a pipette tip. This means that new liquid for the pipette tip must be aspirated during the dispensing procedure. Only one aspirating and dispensing speed is defined for all dispensing steps.
 5. ADS = Automatic Dispensing

With the Actuate key held down, all dispensing strokes are executed automatically with the same volume and in a user-defined rhythm (.01-10.0 seconds). Automatic dispensing may be interrupted by releasing the Actuate key. Apart from this, the procedure is identical to the DIS function.

6. DIL = Diluting

During the diluting process, a diluent, then an air bubble, and finally a sample are aspirated into the pipette tip. The user defines the diluent volume and the sample volume. The air bubble is dependent on the sample volume and is always specified by the program. Selecting a pipetting option can dispense the entire contents of the pipette tip. Depending on the pipette used, the dilution ratio is between approximately 1:2 and approximately 1:20.

7. SDI = Serial Diluting

For serial diluting, a defined volume of liquid is aspirated into the pipette tip. This liquid is dispensed and then mixed with a specific liquid volume by means of a programmable mixing process (volume, mixing cycles). Pressing the Actuate key separately starts the mixing process (MIX).

EDIT

1. If PROG is in the display, holding down the Program key can open the programming level. The Program key must be held down until the word EDIT appears in the display in front of PROG 1-5. Systematically programming is explained in the following subsection.
2. If the programming of a program sequence is quit by pressing Reset, the entries for the program sequence are not stored.
3. The same program sequence – with, for example, different volumes or options – can be stored in several memory slots. It would, therefore, be possible for different pipetting sequences to be stored permanently in the program level.
4. Programming sequences can be overwritten at any time under EDIT (Hold down the Program key). During the programming process, the entry that is to be defined flashes in the display. Selections are made using the Select rocker. Volumes are selected using the Volume rocker.
5. Data is stored by pressing the Actuate key (ENTER function).
6. Options and speeds can be selected in the programming level by using the Select rocker or by using the Option and Speed key. We recommend that you read these sections before you start programming. The following sections on programming for pipetting contain only a description of operations using the rockers. Programming and execution of the other programs are contained in Part B of the Research pro manual.

8.7.1.10 Introduction – Additional Program Sequences

During programming (EDIT and PROG in display), the Speed and Option keys and the Volume rocker can also be used. This enables users to skip backwards and forwards during the program sequence.

When the programs are executed (only PROG is in the display), the Speed and Option keys and the Volume rocker are blocked.

If only parts of the program have been changed, programming can be ended prematurely by pressing the Program key briefly.

If a memory slot is quit using Reset before programming has been completed, the changes that have not been carried out for this memory slot are not saved. EDIT disappears from the display.

8.7.1.11 SD = Sequential Dispensing (*Use this mode to pipette the 4 age-specific (1-2, 3-5, 6-11 and 12+) serum protocols – 100-5000 μ L pipette.*)

The sequential dispensing program can be used when different volumes of a solution have to be dispensed consecutively. Up to 20 steps can be defined. If the sum of the dispensing steps is larger than the volume of the pipette tip, the procedure for normal dispensing is applicable when a liquid is aspirated repeatedly.

| Programming SD | |
|----------------|--|
| Step 1 | Select the programming mode. Press the Program key. PROG appears in the display. |
| Step 2 | Select the memory slot number 1. Use the Select rocker to move up and down through the 5 program numbers until “1” is selected. |
| Step 3 | Hold down the Program key until EDIT appears in the display. |
| Step 4 | Select the SD program. Use the Select rocker to move through the programming choices until “SD” appears in the display. Press the Actuate key. |

| | |
|----------------------------|--|
| Step 5 | Determine the dispensing steps 1-20. Use the Select rocker to move the number up or down until the number 19 is displayed. Press the Actuate key to store the number of steps in the program. |
| Step 6 | Select and store the volume for the first dispensing step. Use the Select or Volume rocker to move the number up or down until the number 1000 is displayed. Press the Actuate key to store the volume for step 1. |
| Step 7 | Continuing programming the remaining 18 steps and volumes for the 12+ protocol. |
| Step 8 | Select the aspirating and dispensing speed using the Speed key and the Select rocker. Press the Speed key then use the Select rocker to move the speed indicator all the way to the right. Press the Actuate key to store the speed in the program. |
| Step 9 | Programming is complete. The display should show: “SD 500 μ L 19” |
| Pipetting Procedure | |
| Step 1 | The necessary or largest possible amount of serum is aspirated. Aspirate the serum. Make sure the direction of the aspirating arrow is pointed up. Press the Actuate key once. The pipette will aspirate 1000 μ L. |
| Step 2 | Dispense the serum. Make sure the direction of the aspirating arrow is pointed downward. |
| Step 3 | Place the pipette tip against the side of the first receiving vessel. To dispense the first aliquot, press the Actuate key once to dispense one 1000 μ L aliquot. The dispensing step counter (number) on the right-hand side of the display counts down one number. |
| Step 4 | Place the pipette tip against the side of the second receiving vessel. |
| Step 5 | Continue dispensing the remaining aliquots until the (number) on the right-hand side of the display reaches 0. If a slot in the processing rack is empty, dispense the aliquot back into the pooled serum vessel. |
| Step 6 | Complete the “blank” step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted. |

| | |
|--------|---|
| Step 7 | Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released. |
| Step 8 | The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display. |

Continue programming the remaining program slots, age-specific protocols, and volumes.

8.7.1.12 ADS = Automatic Dispensing (*Use this mode to repetitively pipette 500 μ L pooled serum – 100-5000 μ L pipette.*)

The automatic dispensing function allows a single volume to be dispensed repetitively with a predetermined time interval of between 0 and 10 seconds.

| Programming ADS | |
|-----------------|--|
| Step 1 | Select the programming mode. Press the Program key. PROG appears in the display. |
| Step 2 | Select the memory slot number 2. Use the Select rocker to move up and down through the 5 program numbers until “2” is selected. |
| Step 3 | Hold down the Program key until EDIT appears in the display. |
| Step 4 | Select the ADS program. Use the Select rocker to move through the programming choices until “ADS” appears in the display. Press the Actuate key. |
| Step 5 | Select and store the dispensing volume. Use the Select or Volume rocker to move the number until 500 is displayed. Press the Actuate key to store the volume in the program. |
| Step 6 | Select the aspirating and dispensing speed using the Speed key and the Select rocker. Press the Speed key, and then use the Select rocker to move the speed indicator all the way to the right. Press the Actuate key to store the speed in the program. |

| | |
|---------------------|---|
| Step 7 | Reduction of the dispensing steps. The total number of dispensing steps displays in the right-hand side of the display. Do not use the Select rocker to change this number. The pipette has calculated the number of dispensing steps based on the aspirating volume and the size of the pipette tip. Press the Actuate key to store the number of calculated dispensing steps and to move to the final programming step, setting the dispensing frequency. |
| Step 8 | Set the dispensing frequency. Use the Select rocker to move the number of seconds (SEC) up or down until 1 is displayed before SEC in the display. Press the Actuate key to store this frequency in the program. |
| Step 9 | Programming is complete. The display should show: “ADS 500 μ L 10” |
| Pipetting Procedure | |
| Step 1 | Aspirate the serum. Make sure the direction of the aspirating arrow is pointed upward. Press the Actuate key once. The pipette will aspirate 5000 μ L. |
| Step 2 | Dispense the serum. Make sure the direction of the aspirating arrow is pointed downward. Press the Actuate key once. Dispensing is carried out while the Actuate key is held down. An acoustic signal is emitted after the dispensing step. To interrupt the action, release the Actuate key. |
| Step 3 | Place the pipette tip against the side of the first receiving vessel. To dispense the first aliquot, press the Actuate key once to dispense one 500 μ L aliquot or to automatically pipette sequential 500 μ L aliquots, <u>hold the actuate key down</u> . The dispensing step counter (number) on the right-hand side of the display counts down one number. As soon as you hear the acoustic signal, move the pipette tip to the next vessel. |
| Step 4 | Place the pipette tip against the side of the second receiving vessel. |
| Step 5 | Continue dispensing 500 μ L aliquots until the (number) on the right-hand side of the display reaches 0. |

| | |
|--------|---|
| Step 6 | Complete the “blank” step. Press the Actuate key to perform the blank step. This is not a dispensing step. A special acoustic signal is emitted. |
| Step 7 | Discard the last drop. Press the Actuate key to blow out the last drop. This is not a dispensing step. Dashes replace the volume number in the display. If the Actuate key is held down during the final blowout, the device does not return the Aspiration arrow to the up position until the key is released. |
| Step 8 | The pipette is ready to aspirate again if the Aspirating arrow in the display points up and the volume number and dispensing step display. |

8.7.1.13 Device Parameters

Trained personnel may change device parameters only after a thorough inspection.

Device parameters are made up of the following:

- BE1 To switch on/off the acoustic signal for the keypad (short beep).
- BE2 To switch on/off the second acoustic signal for the end position of the dispensing piston, for warning and for confirmation (different beeps).
- CAL To alter the calibration data μL , axle section (b) and gradient (m).
- OPT Option for volume restriction.
When the 200 μL tips are used with the 300- μL pipettes (limit: 200 μL).
With “RP” and “DIS” when filtertips are used.
- INI To initialize the original pipette data upon delivery.

The device parameters can all be found on one list. The Actuate key functions as an Enter key. After Enter has been pressed, the next line appears in the display.

| | |
|---|---|
| To access the device parameters | With the pipette switched on, press both the Speed and Option keys briefly at the same time. |
| To switch off/on acoustic signal for the keypad | Use the Select rocker to move through the selections until “BE 1” is displayed in the left side of the display window. Press the Actuate key. |
| To switch on/off (on), second acoustic signal | Use the Select rocker to move through the selections until “BE 2” is displayed in the left side of the display window. Press the Actuate key. |
| To exit the device parameters | Press the Actuate key when “INI” is displayed in the left side of the display window. |
| To initialize the pipette and to erase all settings | Using “ENTER,” access “INI” in device parameters. Hold down the Program key. Initialization is completed when the device parameter “INI” disappears from the display. |

8.7.1.14 Care, Sterilization, Maintenance, and Ordering Information

The outside of the pipette can be wiped with a moist cloth. The use of water with wetting agent is also permitted.

DO NOT ALLOW ANY LIQUID TO ENTER THE PIPETTE.

Only the lower part of the pipette should be rinsed with distilled water and dried. The pipette may be wiped clean with 60% Isopropanol.

If the pipette is very contaminated or if very aggressive chemicals are dispensed, the lower half of the Research pro should be disassembled. The individual parts are rinsed in distilled water and then dried. The piston is then lightly lubricated using silicone grease.

After opening the pipette, please check that the piston is correctly positioned. A motor reset must also be executed. The motor reset is triggered by holding down the Reset key until **R** appears in the display.

Sterilization

Only the lower half of the pipette can be disassembled. The individual parts of the lower part must be disassembled as separate pieces. Please review the diagrams on page 27 of the *Eppendorf Research pro Instruction Manual* before attempting to disassemble any pipette.

To loosen the lower part of the pipette for all pipettes except the 5,000 μL :

1. Hold down the ejector and pull off the ejector sleeve. Force may be required.
2. Unscrew the lower part using the key. During disassembly, do not damage the piston!
3. Unscrew the piston. If necessary, first loosen the piston at the upper end using flat nose pliers. The piston is moved to the lowest position.

To loosen the lower part of the 5,000 μL pipette:

1. Hold down the ejector and pull off the ejector sleeve. Force may be required.
2. Unscrew the cylinder. The piston is held in place magnetically. During reassembly, do not damage the piston!
3. Pull the piston out of the upper part.

Assemble in reverse order. Engage the magnetic coupling of the 5,000 μL piston as shown in the diagram on page 27 of the instruction manual. Check that the dispensing function of the pipette is working correctly.

Maintenance

Apart from general care and occasional discharging (when the battery symbol starts flashing) and recharging of the pipette, no special maintenance is necessary if the pipette is used correctly. The lower part of the pipette may be replaced completely. The process for replacing the seals in the lower part is described in Part B of the Research pro manual: “Ordering information/service parts.” The Service Department may carry out maintenance on the Research pro. Contact Brinkmann Instruments at 800-645-3050 Ext. 404.

A complete list of troubleshooting information is included on pages 28 and 29 of the *Eppendorf Research pro Instruction Manual*.

Ordering information

| Item | Size | Part number |
|---|------------------------|-------------|
| Eppendorf Research pro | 5-100 μL | 2246-136-2 |
| Eppendorf Research pro | 50-1000 μL | 2246-138-9 |
| Eppendorf Research pro | 100-5000 μL | 2246-139-7 |
| Charging stand | Four pipettes | 2246-155-9 |
| Pipette Tips | | |
| Bulk-packaged, in bags | 5-mL | 2235-081-1 |
| Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips | 200 μL | 2249-002-8 |
| Eppendorf Biopur, colorless, sterile, pyrogen-free, DNA-free, Rnase-free In Boxes 5 x 96 = 480 tips | 1000 μL | 2249-006-1 |
| Additional accessories | | |
| Spare Ni-MH battery, 1,200 mAh | | 2246-701-8 |

Page 102 in the instruction manual contains a complete list of additional parts and accessories.

- Use the dedicated 5-100 μL and the dedicated 50-1000 μL Eppendorf Research pro pipettes and trace metal free pipette tips to aliquot whole blood and perform the dilution for RBC Folate using 1.0-uL ascorbic acid.

Pipetting Procedure

1. Using the pipette tip dispenser tray, press the pipette nozzle firmly into a fresh tip.
2. Aspirate and dispense the whole blood, serum, and ascorbic acid using procedures described in Section 8.7.
3. Place the tip against the inner wall of the cryovial as close to the bottom as possible.
4. Discard the tip in the sharps container.
5. Cover the pipette tips at the end of each session to prevent contamination.

8.7.2 Process the 3-mL and 4-mL EDTA Tubes

Use the well-mixed lavender 3-mL and 4-mL EDTA tubes for the hematology profile (CBC) and certain blood tests. The EDTA (tripotassium salts of ethylene diamine-tetracetic acid) acts as a chelating agent to combine with calcium in the blood to prevent coagulation.

8.7.2.1 Process the 3-mL or 4-mL EDTA Tube for Lead/Cad/HG, Ery Proto, RBC Folate, Glycohem, Mercury, and CD4

The hematology technologist runs the CBC on the room temperature 3-mL or 4-mL EDTA tube after the blood-processing technologist verifies proper identification and labeling, and processes the tube for the Lead/Cad/HG, Ery Proto, RBC Folate, Glycohem, Mercury, and CD4. If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad/HG), vessel 3 (RBC Folate), vessel 4 (Glycohem), or vessel 5 (Mercury); process vessel 2 (Ery Proto) and vessel 6 (CD4) and attach the comment, "Clotted." If the CBC was accidentally run before the whole blood for vessels 1 (Lead/Cad/HG) and 5 (Mercury) was

pipetted, do not process these two vessels and add the comment “empty vial” to vessel 1 and “laboratory error” to vessel 5. Continue to pipette the whole blood for vessels 2, 3, 4, and 6 even if the CBC was run before the whole blood was pipetted.

Complete the following process for all SPs. Use the following tubes for the CBC and whole blood protocol:

- ✓ Process the single 3-mL EDTA tube for primary SPs aged 1-2 for CBC and whole blood.
- ✓ Process the first of two 3-mL EDTA tubes for primary SPs aged 3-5 for CBC and whole blood.
- ✓ Process the single 3-mL EDTA tube for primary SPs aged 6-11 for CBC and whole blood.
- ✓ Process the first of two 4-mL EDTA for primary SPs aged 12+ for CBC and whole blood.
- ✓ Process the single 3-mL EDTA tube for VIP guests aged 1-11 for CBC and whole blood.
- ✓ Process the single 4-mL EDTA tube for VIP guests aged 12+ for CBC and whole blood.
- The blood-processing technologist initially processes the 3-mL or 4-mL EDTA tube.
 - Invert the appropriate EDTA tube several times to remix contents thoroughly.

Vessel 1

- Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.3-mL whole blood for vessel 1 (Lead/Cad/HG) on primary SPs and VIP guests aged 1+ into a 2-mL vessel.

Vessel 2

- Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 2 (Ery Proto) on primary SPs and VIP guests ages 3-5 and female primary SPs and VIP guests aged 12-49 into a 2-mL vessel.

Vessel 3

- Use trace metal free pipette tips and the dedicated 5-100 μ L Eppendorf pipette to pipette 0.1-mL whole blood for vessel 3 (RBC Folate) on primary SPs and

VIP guests aged 1+ into a 2-mL vessel. Do not prewet the pipette tips. Dilute the whole blood with ascorbic acid. Use trace metal free pipette tips and the dedicated 50-1000 μ L Eppendorf pipette to immediately pipette 1.0-mL ascorbic acid into the 2-mL vessel. Mix well. Refrigerate L-ascorbic acid diluent when not in use. Discard unused diluent at end of each stand.

Vessel 4

- Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.4-mL whole blood for vessel 4 (Glycohem) on primary SPs and VIP guests aged 12+ into a 2-mL vessel.

Vessel 5

- Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.5-mL whole blood for vessel 5 (Mercury) on primary SPs and VIP guests aged 1+ into a 2-mL vessel.

Vessel 6

- Use trace metal free pipette tips and the 50-1000 μ L Eppendorf pipette to aliquot 0.5-mL whole blood for vessel 6 (CD4) on primary SPs aged 18-49 into a 2-mL vessel.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.
- Place the EDTA tube on a hematology rocker until the hematology technologist performs the CBC.

Run the CBC within 2 hours. If unable to run the CBC within 2 hours, store the 2-mL EDTA blood tube at room temperature for no more than 24 hours. After 24 hours, the blood will undergo changes that will render the WBC, RBC, HgB, and HCT results inaccurate.

8.7.2.2 Process the 4-mL EDTA Tube for Plasma for Homocys/MMA and Xtra Plasma

Process the EDTA tube for Homocys/MMA and Xtra Plasma immediately and centrifuge at 4-8°C or refrigerate the tube until it can be centrifuged. Remove the plasma from the cells within 30 minutes. Red blood cells synthesize Homocysteine, which results in a 10 percent increase after

30 minutes. After 1 hour, the increase in Homocysteine is 2-16 percent, after 2 hours 11-30 percent, after 4 hours 23-35 percent, and after 6 hours 22-42 percent.

Use the following tubes for the plasma protocol:

- ✓ Process the 4-mL EDTA tube on SPs age 6+ (save any remaining plasma and the cells from the 4-mL EDTA tube on SPs age 6-11.)

Complete the following process for all SPs:

- Place the tube in the centrifuge carrier of the refrigerated tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Immediately centrifuge the whole blood from the 4-mL EDTA tube in the at 4-8°C centrifuge at 2,900 rpm for 10 minutes to yield plasma for vessel 7 (Homocys/MMA) and vessel 8 (Xtra Plasma.)

Vessel 7

- Use a calibrated plastic transfer pipette to aliquot at least 1.0-mL plasma for vessel 7 (Homocys/MMA) on primary SPs aged 20+ into a 2-mL vessel.

Vessel 8

- Use a calibrated plastic transfer pipette to aliquot at least 0.5-mL plasma for vessel 8 (Xtra Plasma) on primary SPs aged 6+ into a 2-mL vessel.
- If there is any excess plasma remaining after pipetting the protocol then add 1.0-mL to vessel 7 and any remainder to vessel 8. Save the cells from the 4-mL EDTA tube processed on SPs age 6-11.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Securely close all vessels to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.2.3 Process the 3 or 4-mL EDTA Tube for Packed Cells for Acrylamide

Centrifuge the EDTA tube and remove the plasma. Leave the cells in the original blood collection tube. Wash the remaining red blood cells (erythrocytes) with sterile saline three times and then

lyse the cells with distilled water. Store the saline in the refrigerator and use it cold. Pour saline and deionized water into squeeze bottles. It is acceptable to batch the samples as long as the samples and reagents are refrigerated.

Use the following tubes for the packed cells protocol:

- ✓ Process the dedicated second 3-mL EDTA tube on SPs aged 3-5.
- ✓ Process any remaining plasma and the cells from the 3 or 4-mL EDTA tube on SPs aged 6-11.
- ✓ Process the dedicated 3-mL EDTA tube on SPs aged 12+.
- Place the tube(s) in the centrifuge carrier of the refrigerated tabletop centrifuge. Balance the tube(s) in the centrifuge by using water-filled tubes if necessary. Take care not to disturb the pellet of red blood cells when removing the plasma.

Vessel 88

1. Centrifuge the 3 or 4-mL EDTA tube at 4-8°C and 1,985 rpm for 5 minutes to separate the plasma from the cells.
2. Use a disposable transfer pipette to remove the plasma, which is the upper clear layer, and add it to vessel 8.
3. Use the refrigerated squeeze bottle of saline to add an equal amount (to the packed cells) of 0.9 % cold saline to the packed cells.
4. Close vial and mix by gently shaking.
5. Centrifuge at 1,985 rpm and 4°C for 5 min.
6. Remove and discard the clear upper layer.
7. Repeat step 3 to 6 two more times (total of 3 wash cycles).
8. After the last wash cycle use the squeeze bottle of deionized water to add an equal amount of deionized water to the packed cells. (The final volume should be at least 1.0-mL of washed lysed packed cells.)
9. Close vial and mix by gently shaking.
10. Transfer the lysed cells to a 2-mL cryovial.

- Close all vessels secured to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.3 Process the 2-mL Gray Tube for Glucose and OGTT

Centrifuge and separate the plasma from the 2-mL gray top tube as soon as possible. Process the specimen even if the contents of the gray tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 2-mL gray tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 9 (Glucose) or vessel 98 (OGTT.)

Vessel 9

- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 9 (Glucose) or vessel 98 (OGTT) on primary SPs aged 12+ into a 2-mL vessel.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Close all vessels secured to prevent leakage and evaporation.
- Record results using the blood-processing module as described in Section 8.8.
- Store all specimens immediately as outlined in Section 8.10.

8.7.4 Process the 3-mL, 7-mL, 10-mL, and 15-mL Red Top Tubes for Pooled Sera

- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in each 3-mL, 7-mL, 10-mL, and 15-mL red top tube to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.

- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.
 - Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.

If the serum in any one red top tube from a SP is grossly hemolyzed, do not pool it with serum from the remaining tubes. Reserve it for the storage vessels 32-37.

If the serum in all red top tubes for a SP is turbid, lipemic, or icteric, pool it and allocate as usual.

- **Vessels 100, 81, 70, 12, 13, 14, 87, 99, 11, 17, 21, 104, 94, 77, 79, 18, 23, 22, 24, 75, 15, 32-40**
 - Use a serum separator to remove serum from all the red top tubes by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard. Do not touch the serum separator to the clot barrier.
 - Label the 50-mL conical tube with SP ID # label. Pool all clear sera. For each SP pool the serum from all red top tubes by decanting the separated serum into the 50-mL polypropylene tube. Hold the tube and the separator level while decanting the serum. Be careful to avoid introducing any cellular debris. Discard all tubes and separators in a sharps container.
 - Securely close the 50-mL polypropylene tube and mix its contents by gentle inversion.
 - Confirm that all vessels have the correct information with the appropriate SP's bar code ID label before filling them.
 - Use a trace metal free pipette tip and the dedicated 5-100µL Eppendorf pipette to aliquot 0.1-mL serum for vessel 79 (Vitamin C) on primary SPs aged 6+ into a 2-mL vessel. Do not prewet the pipette tips. Invert the container with the 6%MPA for 30 seconds every 10 minutes or before each use. Use the Eppendorf pipette to immediately pipette 400-µL 6%MPA into the 2-mL vessel. Cap and vigorously shake the vial for 15-20 seconds or vortex on high for 15 seconds. Refrigerate MPA diluent when not in use. Discard unused diluent at end of each stand.
 - Use the 100-5000 Eppendorf® pipette and 5-mL pipette tips to aliquot the serum for all vessels except vessel 79.

- Using clear serum only, fill as many vessels as possible in the priority order shown in Section 8.3. Exhibits 8.10 – 8.18 describe the order of allocation and specific procedures to follow for each person type and vessel.
 - If excess serum remains after completing the entire protocol, add an additional 1.5-mL serum beginning with vessel 32 and continuing through vessel 37 until the serum is exhausted. If extra serum remains, continue to top off the other serum vessels beginning with vessel 11 until the serum is exhausted.
- Securely close all vessels to prevent leakage and evaporation.
 - Record results using the blood-processing module as described in Section 8.8.
 - Store all specimens immediately as outlined in Section 8.10.
 - If the serum cannot be aliquoted immediately, refrigerate it at 4°C for no more than 4 hours.

8.7.5 Process the 10-mL Red Top Tubes for Environmental Subsamples

The environmental subsamples represent a 1/3 nonoverlapping sample of SPs aged 12+. An SP is eligible for vessels 29 and 89 or vessels 90 and 91 or vessels 92 and 93.

- Do not substitute any other red top tube for these vessels; the 10-ml red top tube is prescreened by the CDC for these tests.
- Gently invert the tubes 5-6 times as soon as possible after receiving them in the laboratory.
- Allow the blood in the 10-mL red top tubes to clot for 30-45 minutes at room temperature. Do not let clot for more than 1 hour.
- Place the tubes in the room temperature centrifuge carrier of either tabletop centrifuge. Balance the tubes in the centrifuge by using water-filled tubes if necessary. Centrifuge the red top tubes at 17-25°C and 2,900 rpm for 15 minutes to yield serum.

Vessel 29/Vessel 90/Vessel 92

- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.
- Use a serum separator to carefully remove serum from the first 10-mL red top tube by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard or some flow through may occur. Do not touch the serum separator to the clot barrier.

- Aliquot the serum immediately by pouring the serum for vessel 29 (Persis Pest), vessel 90 (Perfluor1) or vessel 92 (BFR1) on primary SPs age 12+ into a 5.0-mL vessel.

Vessel 89/Vessel 91/Vessel 93

- Determine if the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the serum when entering the processing results.
- Use a serum separator to carefully remove serum from the second 10-mL red top tube by pushing the serum separator to the clot barrier gently to ensure cell-free separation. Do not push the separator too hard or some flow through may occur. Do not touch the serum separator to the clot barrier.
- Aliquot the serum immediately by pouring the serum for vessel 89 (Persis Pest2), vessel 91 (Srm Pest), or vessel 93 (BFR2) on primary SPs age 12+ into a 5.0-mL vessel.
 - Securely close all vessels to prevent leakage and evaporation.
 - Record results using the blood-processing module described in Section 8.8.
 - Store all specimens immediately as outlined in Section 8.10.

8.7.6 Reagent Processing and Preparation

The Centers for Disease Control and Prevention supplies premeasured 1% ascorbic acid (AA) for the RBC Folate assay. Prepare this reagent before processing the blood samples. Allow the reagent to equilibrate to room temperature before pipetting and performing the dilution. Use the Eppendorf Research pro pipettes to make the dilution. Add 1.0-mL ascorbic acid to 0.1-mL whole blood for the RBC Folate assay. Mix by gentle inversion.

- The ascorbic acid powder is in a 50-mL Falcon tube. Dissolve the powder in 50-mL of distilled water using a graduated cylinder to measure the water and mix gently. Prepare this reagent weekly. Date and label the Falcon tube. If the powder appears discolored or the solution appears cloudy, discard and prepare fresh reagent. If no bottled distilled water is available, use tap water. Record the reagent in the Supply Use Control Log each time it is prepared.
- Refrigerate the prepared reagent at the end of each day to maintain its stability and bring the reagent back to room temperature the next day.

The Centers for Disease Control and Prevention supplies premeasured 6% metaphosphoric acid (MPA) for the Vitamin C assay. Prepare this reagent before processing the blood samples. Allow the reagent to equilibrate to room temperature before pipetting and performing the dilution. Use calibrated Eppendorf Research Pro pipettes to make the dilution. Add 400- μ L MPA to 0.1-mL or 100- μ L serum for the Vitamin C assay. Do not add the serum to the MPA; the MPA should be added to the serum. Mix vigorously for 15-20 seconds. Invert every 10 minutes until dissolved. It is normal for the MPA crystals to take about 15 to 30 minutes to dissolve while gently mixing the 50 cc tube of water. It is acceptable to warm it by placing it between the hands while mixing it gently back and forth.

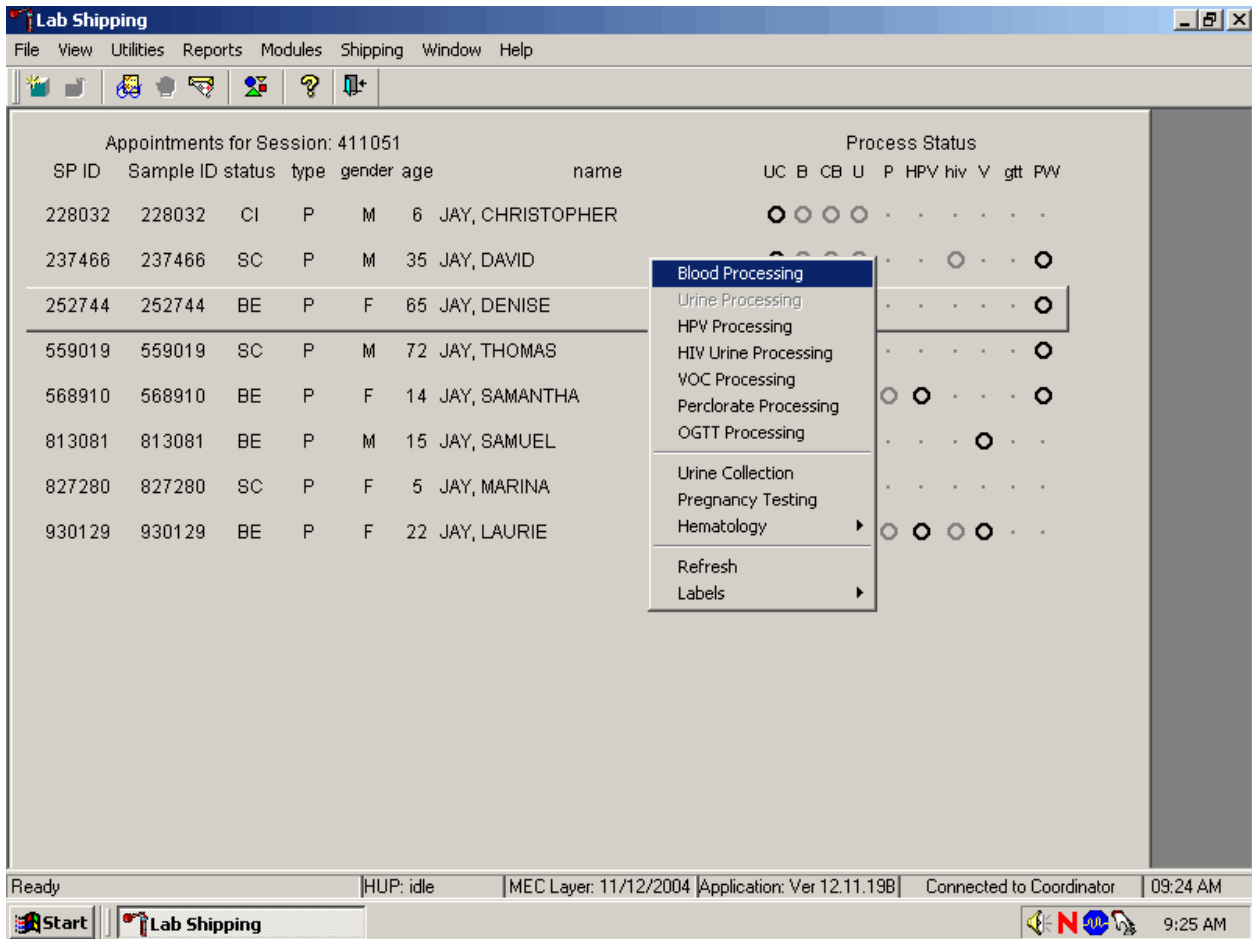
- The premeasured MPA crystals are supplied in glass vials. Dump the crystals into a clean 50-mL Falcon tube. Add exactly 50-mL of distilled water to the MPA crystals. It is acceptable to rinse the glass vial with a portion of the 50-mL distilled water and pour this into the 50-mL conical tube. It takes about 30 minutes for the crystals to go into the solution. Mix gently every 10 minutes. Prepare this reagent weekly. Date and label the Falcon tube. If no bottled distilled water is available, use tap water. Record the reagent in the Supply Use Control Log each time it is prepared.
- Transfer 8-mL from the 50-mL Falcon tube to a 14-mL Falcon snap cap tube at the start of each exam day. Discard any MPA remaining in the 14-mL Falcon snap cap tube at the end of each exam day. Keep the remainder of the solution in the 50-mL Falcon tube refrigerated. Always allow the reagent to warm up to room temperature before dispensing.
- This is a very strong acid; be very careful not to get it on the skin or in the eyes.

8.8 Record the Results of Specimen Processing

After filling or processing the whole blood, plasma, serum, clots, and/or the EDTA tubes for each SP, use the Blood Processing module to enter the blood processing results.

Open and log onto the Laboratory application. Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status.

Select the correct SP and access the Blood Processing module.



If labels have not been printed in advance, a Blood Processing message text box displays. To access the blood processing module, highlight the SP, right click, drag the mouse arrow to {Blood Processing}, and left click or type [Alt] [B/b].

The SP's blood processing screen displays.

Lab Shipping
 File View Utilities Reports Modules Shipping Window Help

BP: 252744
 B processing

Tech ID: 1126 Sample ID: 252744 Name: JAY, DENISE Gender: F Age: 65
 SP ID: 252744 Appt Type: Primary Fasting Req: Afternoon - 0 Hour

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|--|----------|--------------|-------|
| 1 | Lead/Cad/HG | 0.3 | W | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 3 | RBC Folate | 0.1 | W | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 4 | Glycohem | 0.4 | W | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 5 | Mercury | 0.5 | W | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 7 | Homocys | 1.0 | P | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 88 | Acrylamide | 1.0 | PC | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 100 | IgE | 1.0 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

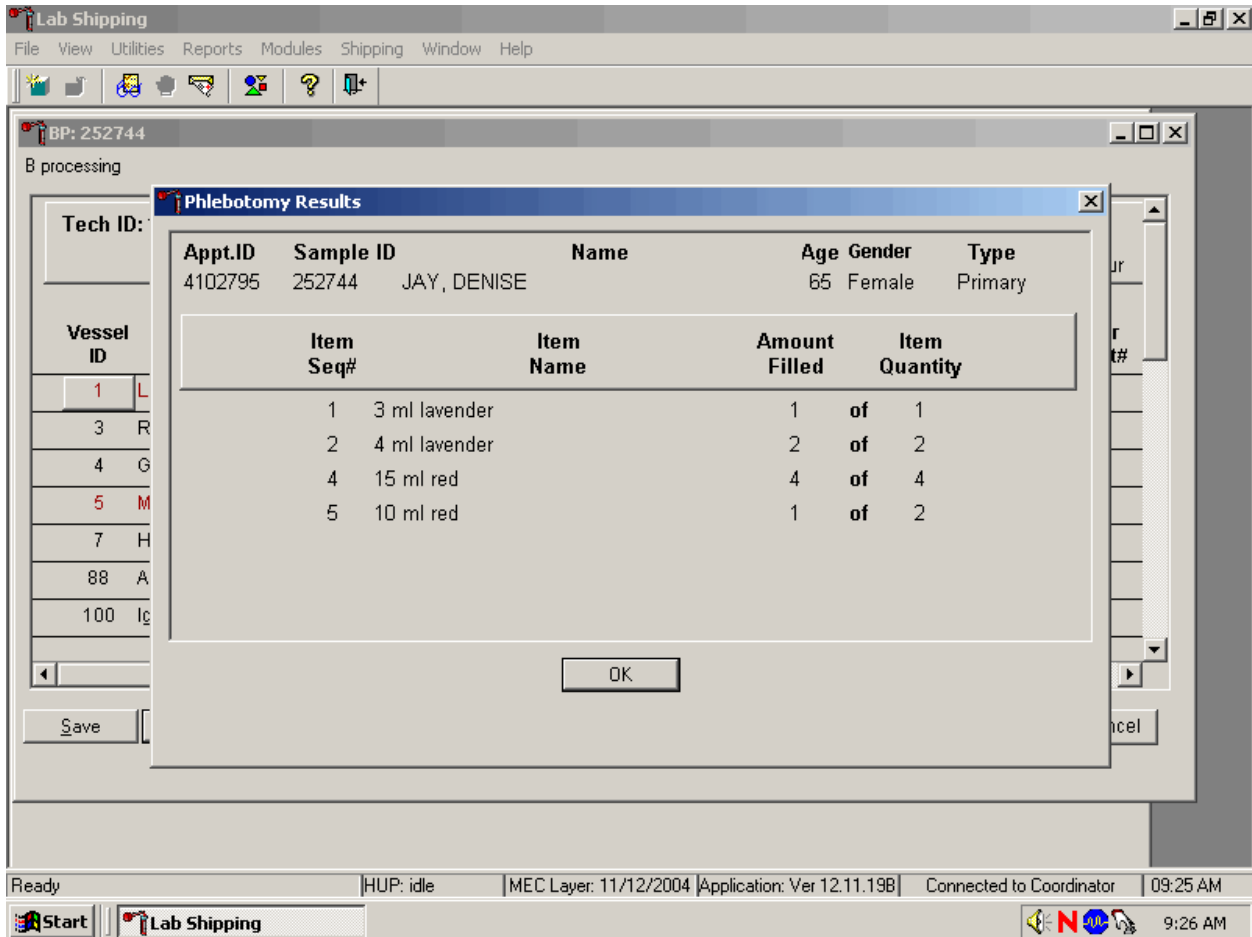
Save Phlebotomy OK Cancel

Cancel changes HUP: idle MEC Layer: 11/12/2004 Application: Ver 12.11.198 Connected to Coordinator 09:25 AM

Start Lab Shipping 9:26 AM

The blood processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, Fasting Req, columns for Vessel ID, Test Name, Sample Volume, Type (whole blood, plasma, serum, packed cells), Vessel Volume, Vessel Name, Filled radio buttons, Comments text box, and a Container ID/Slot# column. Vessels that require sterile 2-mL cryovials are displayed in red.

Inspect the SPs Vacutainer® tubes. Compare the Sample ID on the tubes to the bar code label on the vessels. Verify that the number of tubes and the recorded amount of blood collected are correct.



To review the phlebotomy results, use the mouse to direct the mouse arrow to the Phlebotomy button on the blood processing screen and left click or type [Shift] [P/p.] The phlebotomy protocol and number of tubes successfully collected displays. To close this screen, use the mouse to direct the mouse arrow to the OK button and left click.

Record blood processing results for each SP. Individually mark each vessel as Filled--"Yes."

BP: 252744
B processing

Tech ID: 1126 Sample ID: 252744 Name: JAY, DENISE Gender: F Age: 65
 SP ID: 252744 Appt Type: Primary Fasting Req: Afternoon - 0 Hour

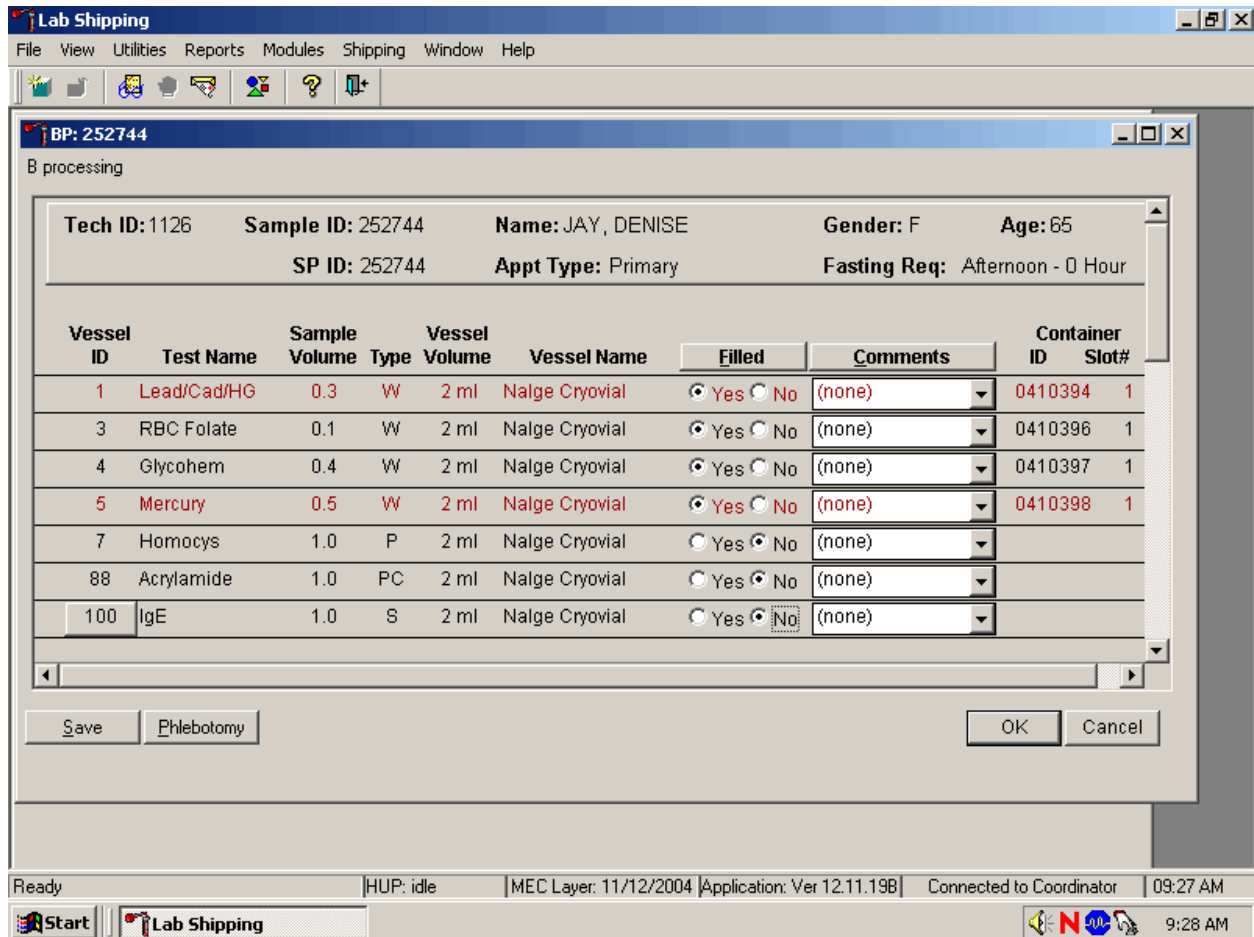
| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|----------|--------------|-------|
| 1 | Lead/Cad/HG | 0.3 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410394 | 1 |
| 3 | RBC Folate | 0.1 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410396 | 1 |
| 4 | Glycohem | 0.4 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410397 | 1 |
| 5 | Mercury | 0.5 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410398 | 1 |
| 7 | Homocys | 1.0 | P | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 88 | Acrylamide | 1.0 | PC | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 100 | IgE | 1.0 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

Buttons: Save, Phlebotomy, OK, Cancel

Ready | HUP: idle | MEC Layer: 11/12/2004 | Application: Ver 12.11.19B | Connected to Coordinator | 09:27 AM

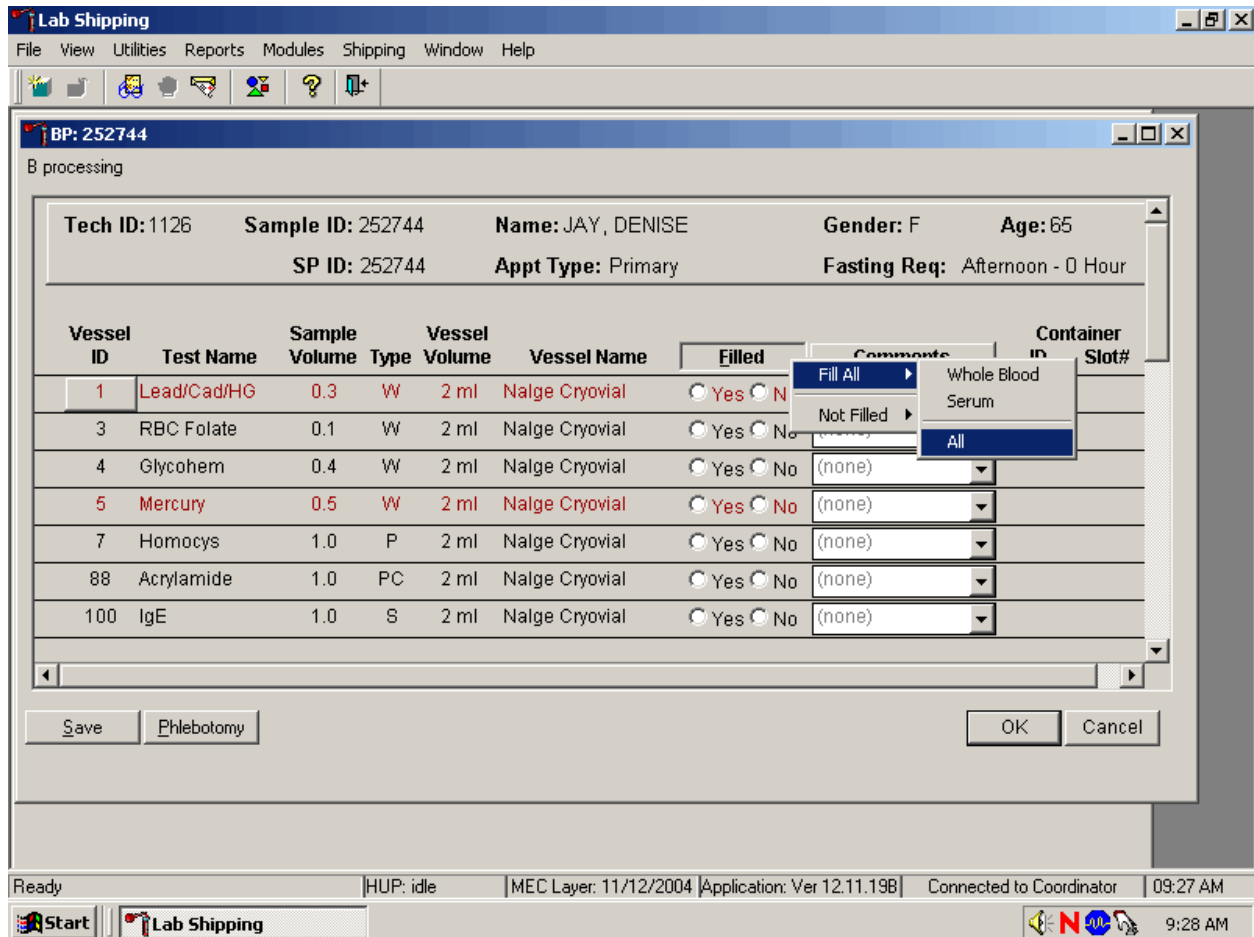
To mark an individual blood vessel as collected or Filled--"Yes" use the mouse to direct the mouse arrow to the center of the "Yes" radio button and left click. As each vessel is marked as Filled--"Yes," it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled—"No."



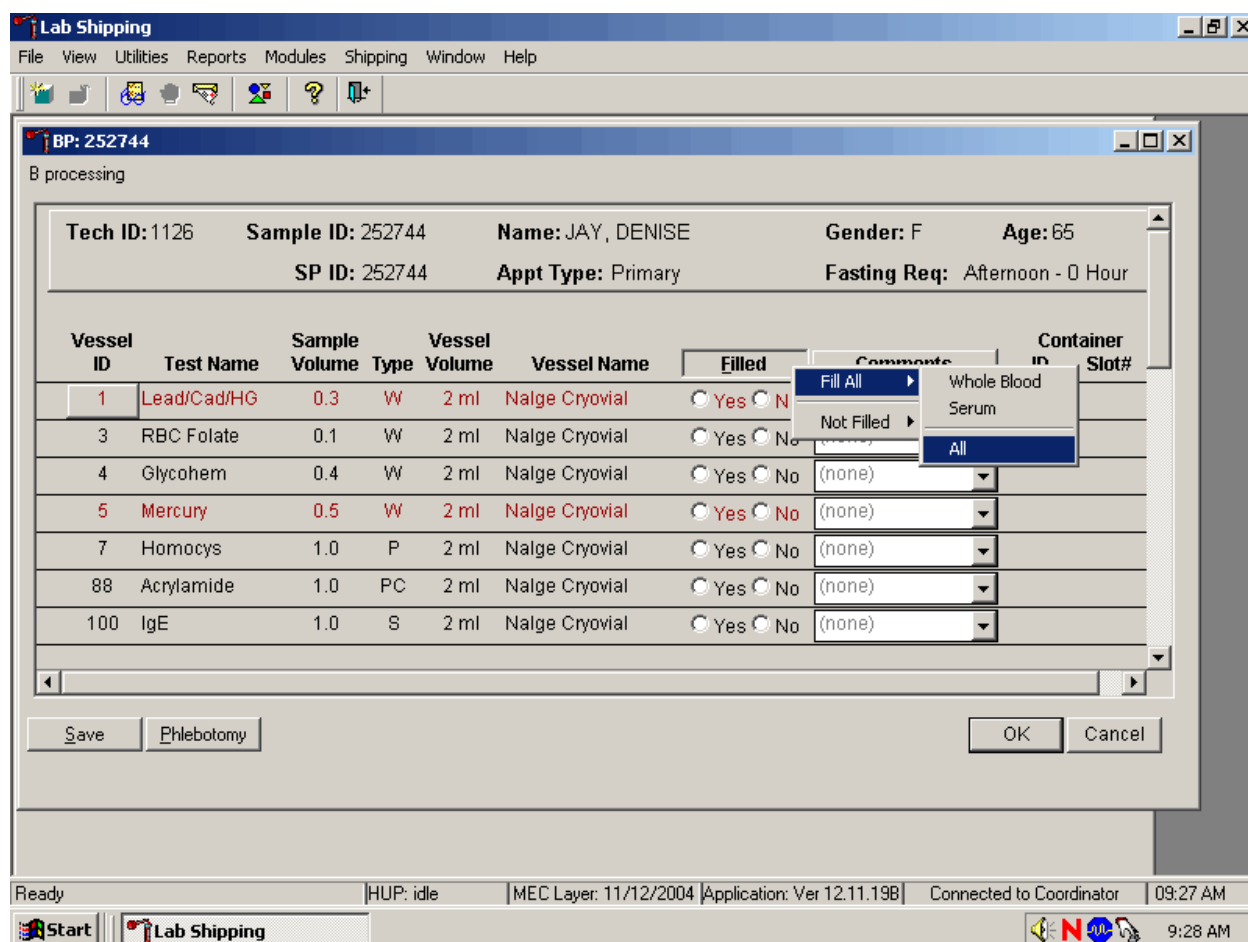
To mark an individual blood vessel as not collected or Filled—"No," use the mouse to direct the mouse arrow to the center of the "No" radio button and left click. Vessels marked as "No" require a comment.

Collectively mark all vessels as Filled—"Yes."



To collectively mark all vessels as Filled—"Yes," use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {All}, and left click. Alternatively, to collectively mark all vessels as Filled—"Yes," type [Shift] [F/f], [I/i], and [A/a.]

Selectively mark all whole blood or serum vessels as Filled—"Yes."

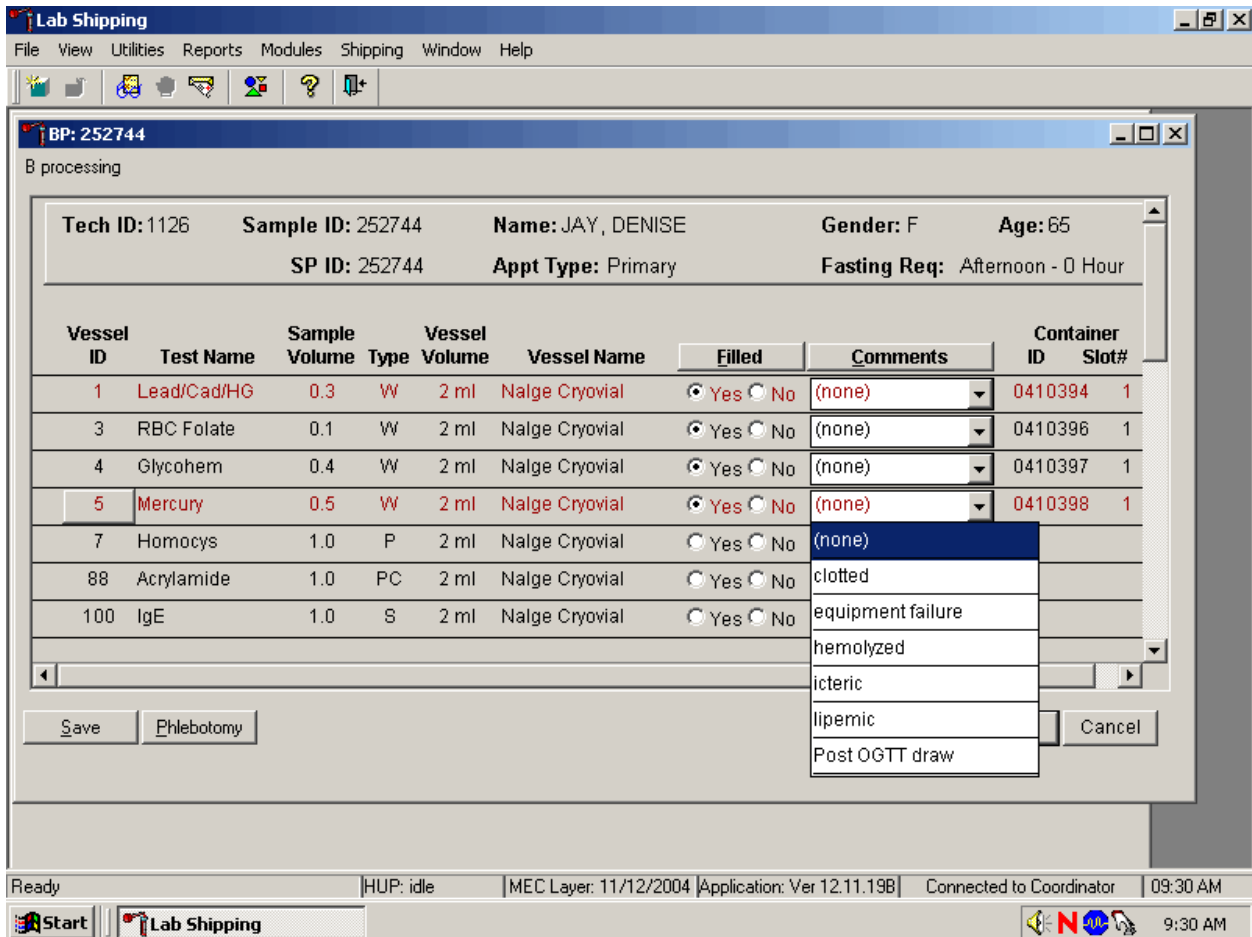


To collectively mark all whole blood vessels as Filled—"Yes," use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {Whole Blood}, and left click. To collectively mark all serum vessels as Filled—"Yes," use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Fill All}, drag the mouse arrow to {Serum}, and left click. As each vessel is marked as "Filled," it is automatically assigned to a slot in an existing (open) container. Alternatively, to collectively mark all whole blood vessels as Filled—"Yes," type [Shift] [F/f], [I/i] and [W/w] and to collectively mark all serum vessels as Filled—"Yes," type [Shift] [F/f], [I/i], and [S/s].

Quality comment codes are available to describe the quality of the specimen.

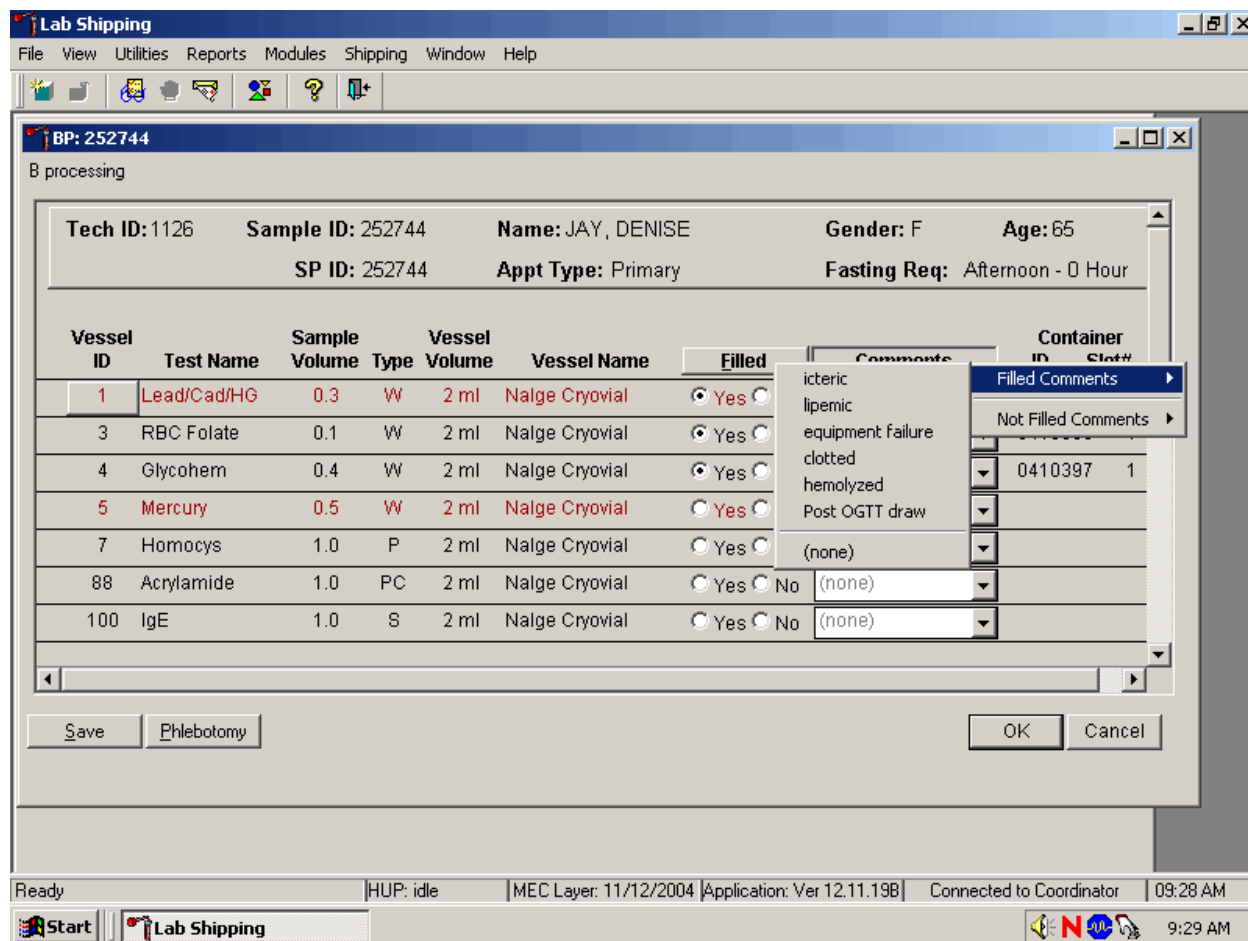
| Comment for filled vessels | Use when: |
|----------------------------|---|
| clotted | The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting. |
| equipment failure | Pipettes are malfunctioning. |
| hemolyzed | There is red appearance to the serum or plasma. Hemolysis refers to the abnormal lysis of erythrocytes. Hemolysis can occur before venipuncture (<i>in vivo</i> hemolysis) or during the analytic procedure (<i>in vitro</i> hemolysis). If <i>in vivo</i> , hemolysis will give plasma a red color. Use when describing visible hemolysis, which occurs when the concentration of hemoglobin exceeds 200 mg/L. |
| icteric | There is visible orange color to the serum or plasma. Icteric refers to orange color imparted to a sample because of the presence of bilirubin. Bilirubin present in serum results in visible “jaundice” color when the concentration of bilirubin is above 430 umol/L. |
| lipemic | There is turbid appearance to the serum or plasma. Lipemia refers to the presence of lipid particles (usually very low-density lipoprotein) in a sample, which gives the sample a turbid appearance. Plasma appears visibly lactescent or lipemic when the concentration of triglycerides exceeds 4.6 mmol/L. |
| Post OGTT draw | During the OGTT blood draw (two hours after the initial venipuncture and after the SP has consumed the Trutol), the phlebotomist will draw any tubes that were missed during the first venipuncture. If any vessel is filled from one of the tubes drawn during the OGTT blood draw, then add this comment. |

Attach a comment to an individual filled vessel.



To attach a quality control comment to an individual filled vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (c, e, h, i, l, p.)

Use the following procedure when all filled vessels require the same comment.



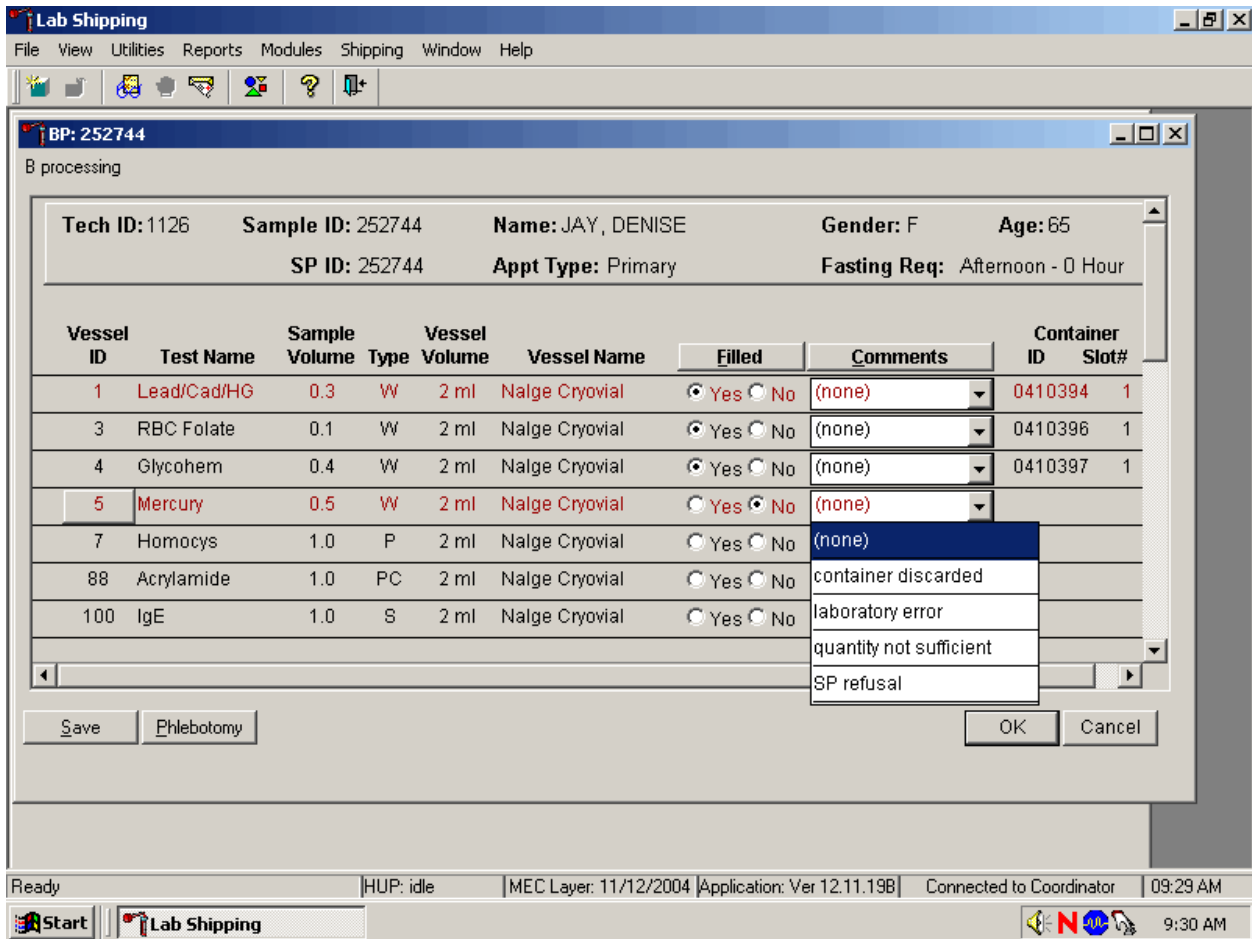
To collectively assign the same comment to all vessels, use the mouse to direct the mouse arrow to the Comments button on the top of the radio buttons, left click, drag the arrow to {Filled Comments}, drag the mouse arrow to the correct choice, and left click. Alternatively, to assign the same comment to all filled vessels type [Shift] [C/c], and the first letter of the correct choice (i, l, e, c, h, p.)

All plasma vessels must be marked individually. All vessels marked as Filled–"No" require a comment or explanation.

Enter comment codes to describe the reasons why a vessel is marked as Filled–"No," or why the protocol is incomplete.

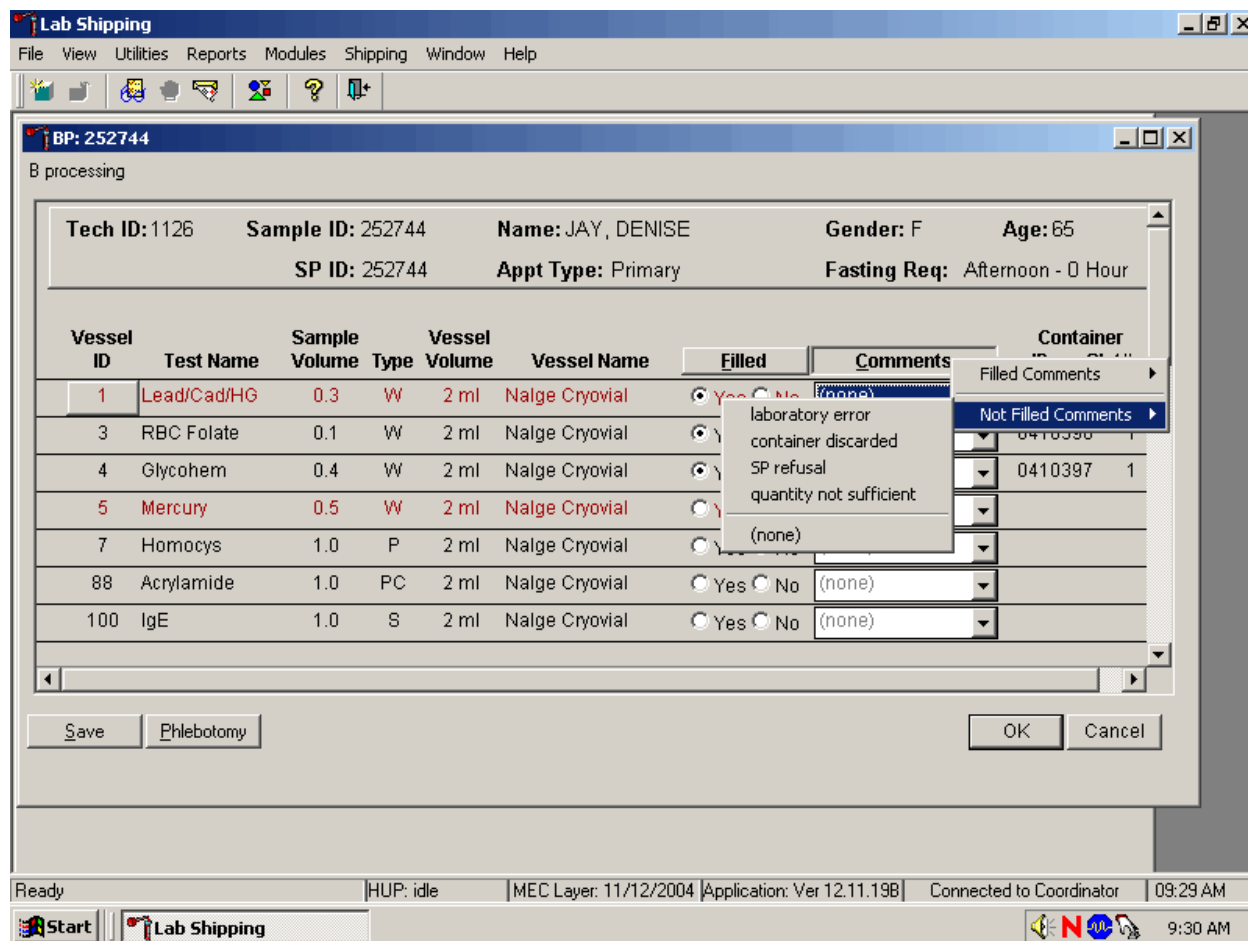
| Comment for not filled vessels | Use when: |
|--------------------------------|---|
| container discarded | Do not use this comment. |
| laboratory error | A tube breaks in the centrifuge, contents spill, or other technologist error. |
| quantity not sufficient | Quantity of blood is not sufficient to complete the protocol. |
| SP refusal | The SP does not provide consent and consequently, excluded from HIV. |

Attach a comment to an individual Filled–"No" vessel.



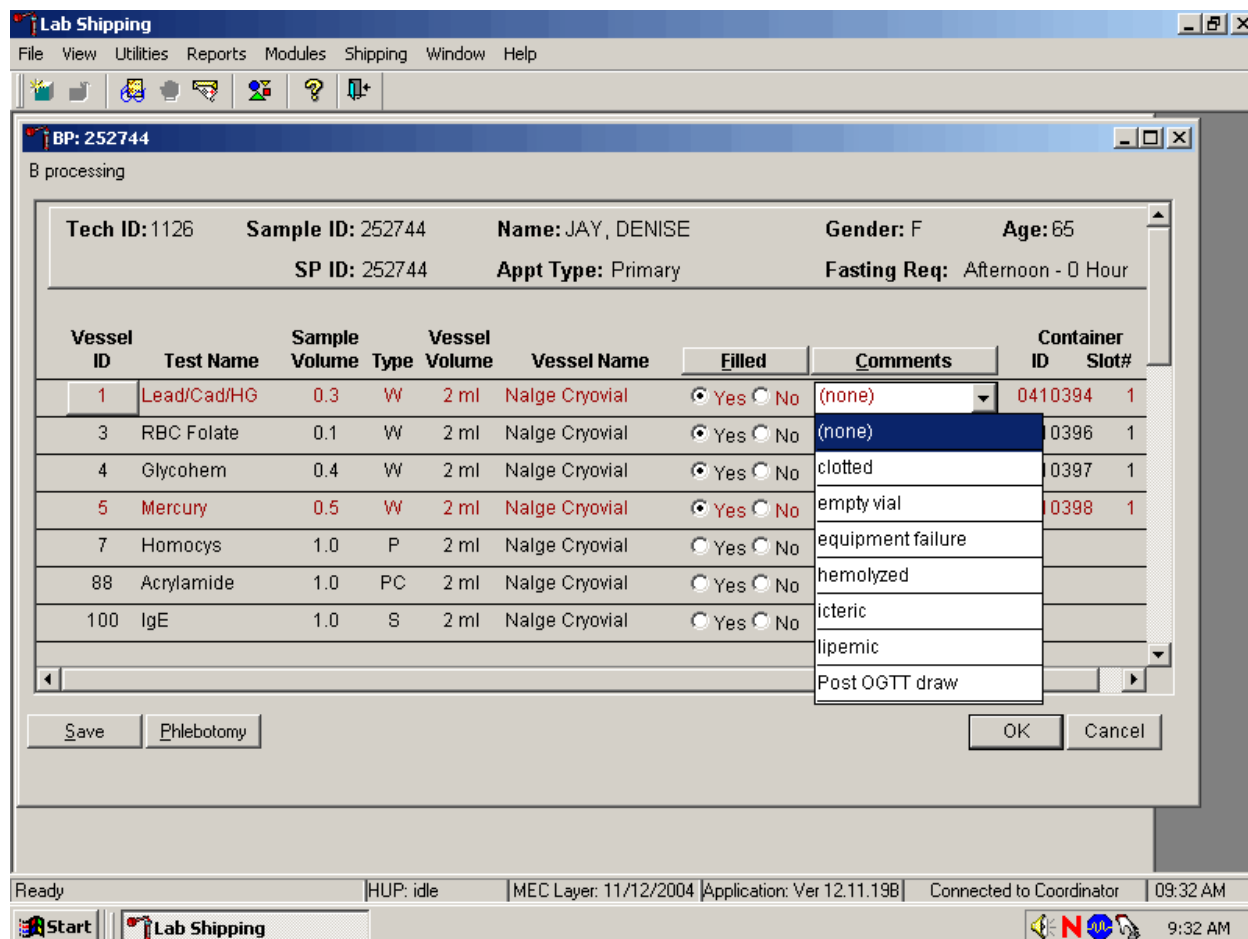
To attach a Filled–"No" comment to an individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

Use the following procedure when all Filled – “No” vessels require the same comment.



To collectively attach the same comment to all Filled–“No” vessels, use the mouse to direct the mouse arrow to the Filled button on the top of the radio buttons, left click, drag the arrow to {Not Filled All}, drag the mouse arrow to the desired choice, and left click. Alternatively, to collectively attach the same comment to all vessels marked as Filled – “No” type [Shift] [C/c], [N/n], and the first letter of the desired choice (l=laboratory error, s= SP refusal, q=quantity not sufficient.).

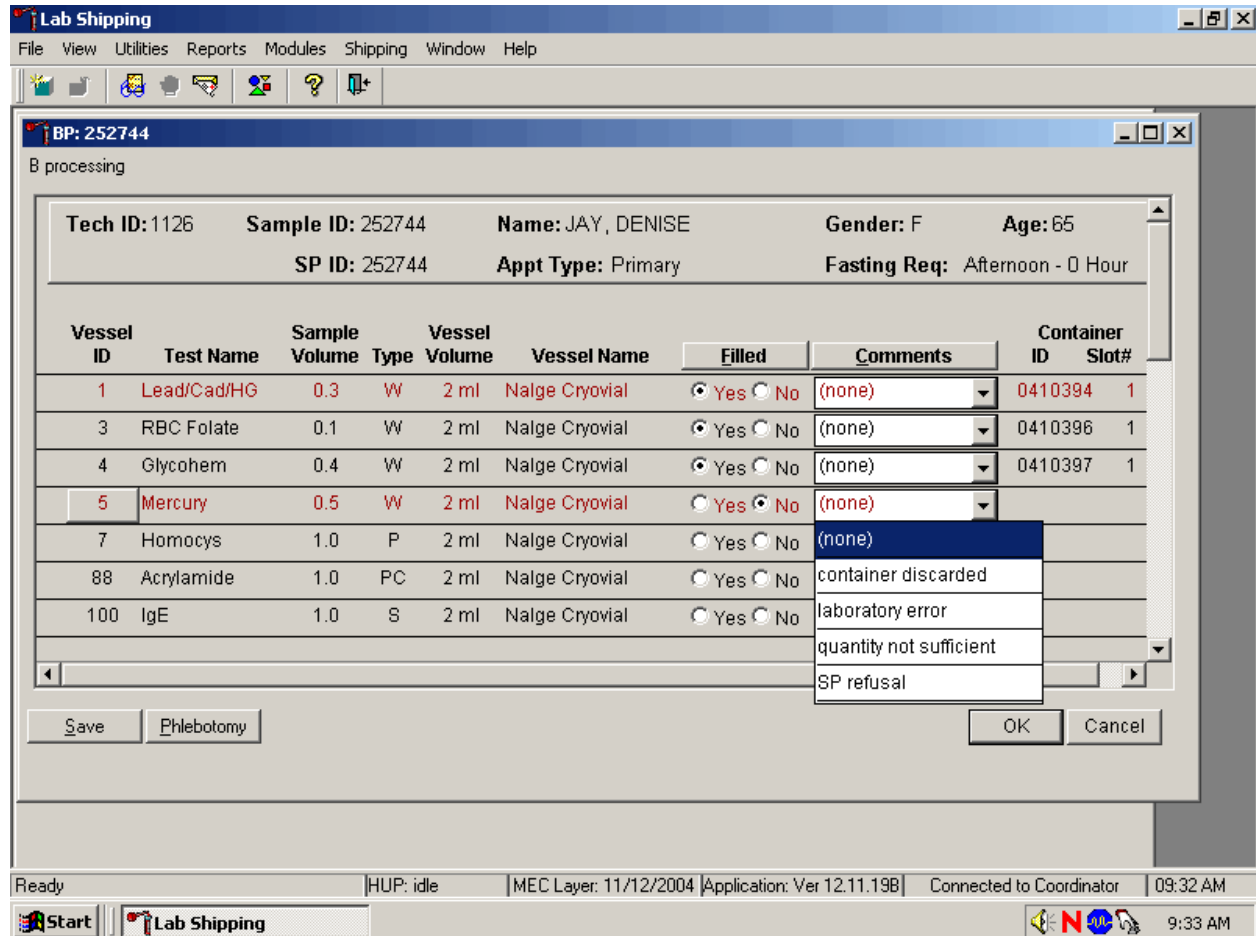
Every SP who has any vessel filled must have vessel 1 marked as filled.



Mark vessel 1 as Filled—"Yes," even if the blood is clotted, but do not fill the vessel. Attach the comment, "empty vial" to this vessel. To attach the comment "empty vial" to this individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to {empty vial}, and left click.

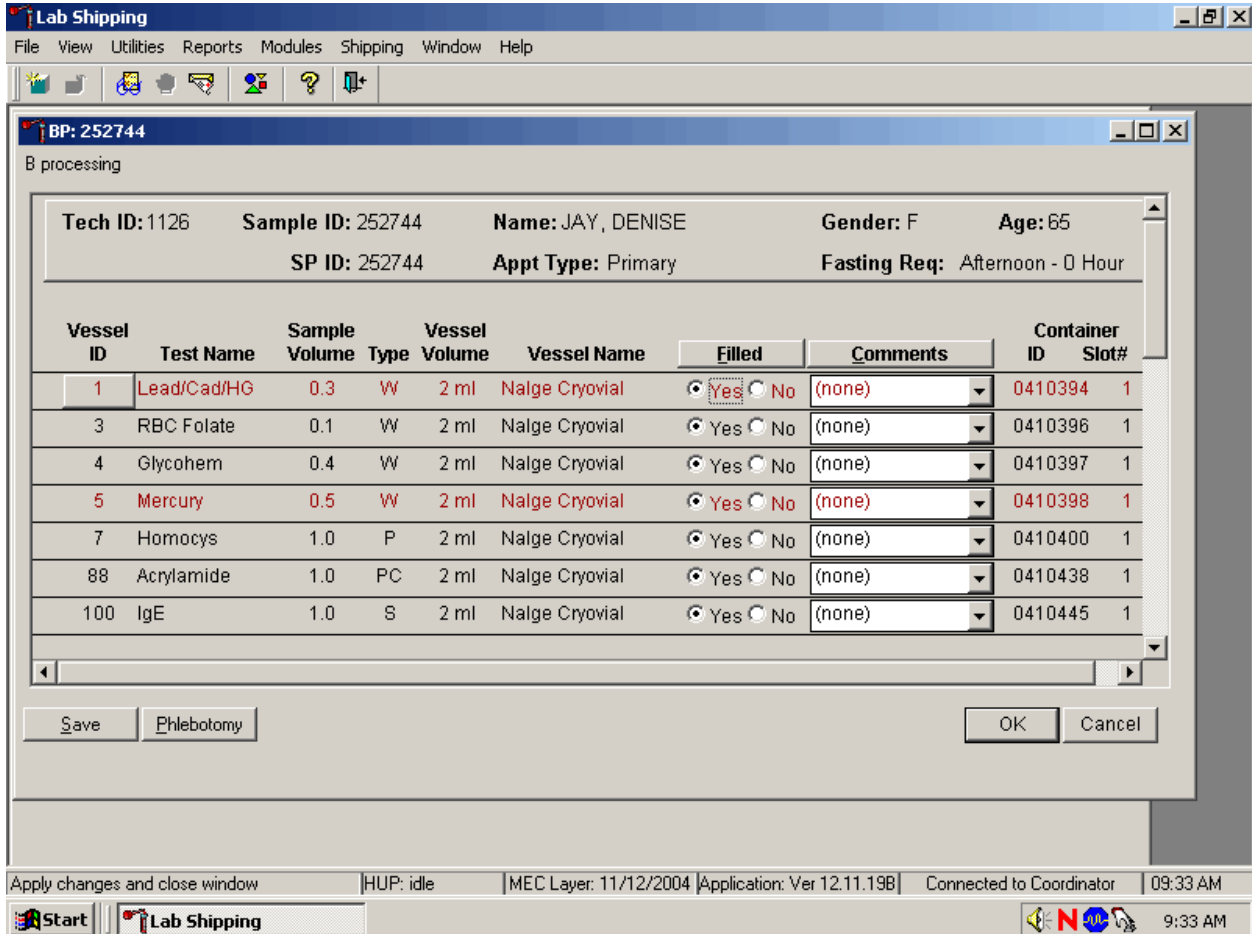
If the EDTA tube is clotted, do not process vessel 1 (Lead/Cad), vessel 3 (RBC Folate), vessel 4 (Glycohem) or vessel 5 (Mercury). Process vessel 2 (Ery Proto) and vessel 6 (CD4) but attach the comment, "Clotted."

Attach the “Laboratory error” comment to a Filled-No result for vessels 1 and 5, if the CBC was run before the vessels were processed.



If the CBC was accidentally run before the whole blood for vessels 1 (Lead/Cad) and 5 (Mercury) was pipetted, then do not process these two vessels. Mark vessel 1 as Filled–”Yes” and attach the comment “empty vial.” Mark vessel 5 as Filled–”No” and attach the comment “laboratory error.” Continue to pipette the whole blood for vessels 2, 3 4, and 6 even if the CBC was run before the whole blood was pipetted.

Continue to enter results as vessels are processed. Review the information in the blood-processing window and save the data to the database.



Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

8.9 Process HIV Urine

At the end of each session, process urine for HIV if no blood was collected or the quantity of serum was insufficient for serum HIV (for SPs 18-49) and the primary SP has not refused the HIV test. Record the HIV vessel 22 result to the database.

If the quantity of serum is insufficient and the SP has not refused the test, mark vessel 22 as Filled—"No."

Lab Shipping

File View Utilities Reports Modules Shipping Window Help

BP: 930129

B processing

Tech ID: 1126 Sample ID: 930129 Name: JAY, LAURIE Gender: F Age: 22
 SP ID: 930129 Appt Type: Primary Fasting Req: Afternoon - 0 Hour

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|----------------------|--------------|-------|
| 79 | Vitamin C | 0.1 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410434 | 2 |
| 18 | Biochem | 0.8 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410409 | 2 |
| 22 | HIV | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | quantity not suffici | | |
| 24 | HSV | 0.2 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | quantity not suffici | | |
| 15 | Vit A/E/Car | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | quantity not suffici | | |
| 32 | Xtra Sera | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | quantity not suffici | | |
| 33 | Xtra Sera | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | quantity not suffici | | |

Save Phlebotomy OK Cancel

Ready HUP: idle MEC Layer: 11/12/2004 Application: Ver 12.11.19B Connected to Coordinator 09:37 AM

Start Lab Shipping 9:38 AM

Once the blood processing result for vessel #22 (HIV) is Filled—"No" and the result is saved to the database, the HIV Urine Processing module becomes enabled.

Select the correct SP from the heads-up display.

The screenshot shows the 'Lab Shipping' application window. The main area displays a table of appointments for session 411051. A context menu is open over the row for SP ID 930129, with 'HIV Urine Processing' selected. The status bar at the bottom shows system information and the time 9:40 AM.

| Appointments for Session: 411051 | | | | | | | Process Status | | | | | | | | | |
|----------------------------------|-----------|--------|------|--------|-----|------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| SP ID | Sample ID | status | type | gender | age | name | UC | B | CB | U | P | HPV | hiv | V | glt | PW |
| 228032 | 228032 | CI | P | M | 6 | JAY, CHRISTOPHER | ○ | ○ | ○ | ○ | . | . | . | . | . | . |
| 237466 | 237466 | SC | P | M | 35 | JAY, DAVID | ⊙ | ○ | ○ | ○ | . | . | ○ | . | . | ○ |
| 252744 | 252744 | BE | P | F | 65 | JAY, DENISE | ● | ● | ○ | ○ | . | . | . | . | . | ○ |
| 559019 | 559019 | SC | P | M | 72 | JAY, THOMAS | ● | ○ | ○ | ○ | . | . | . | . | . | ○ |
| 568910 | 568910 | BE | P | F | 14 | JAY, SAMANTHA | ● | ○ | ○ | ○ | ○ | ○ | . | . | . | ○ |
| 813081 | 813081 | BE | P | M | 15 | JAY, SAMUEL | ○ | ○ | ○ | ○ | . | . | . | ○ | . | . |
| 827280 | 827280 | SC | P | F | 5 | JAY, MARINA | . | ○ | ○ | ○ | . | . | . | . | . | . |
| 930129 | 930129 | BE | P | F | 22 | JAY, LAURIE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | . | . |

The process status HIV circle changes from gray to black when an SP is eligible for the HIV urine vessel. Access the HIV Urine Processing module.

The HIV Urine Processing screen displays.

The screenshot shows a software window titled "Lab Shipping" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. A sub-window titled "HIV: 930129" is open, displaying "I processing".

At the top of the sub-window, there is a summary section with the following fields:

- Tech ID: 1126
- Sample ID: 930129
- Name: JAY, LAURIE
- Gender: F
- Age: 22
- SP ID: 930129
- Appt Type: Primary
- Fasting Req: Afternoon - 0 Hour

Below this is a table with the following columns: Vessel ID, Test Name, Vessel Type, Vessel Volume, Vessel Name, Filled, Comments, Container ID, and Container Slot#. The table contains one row of data:

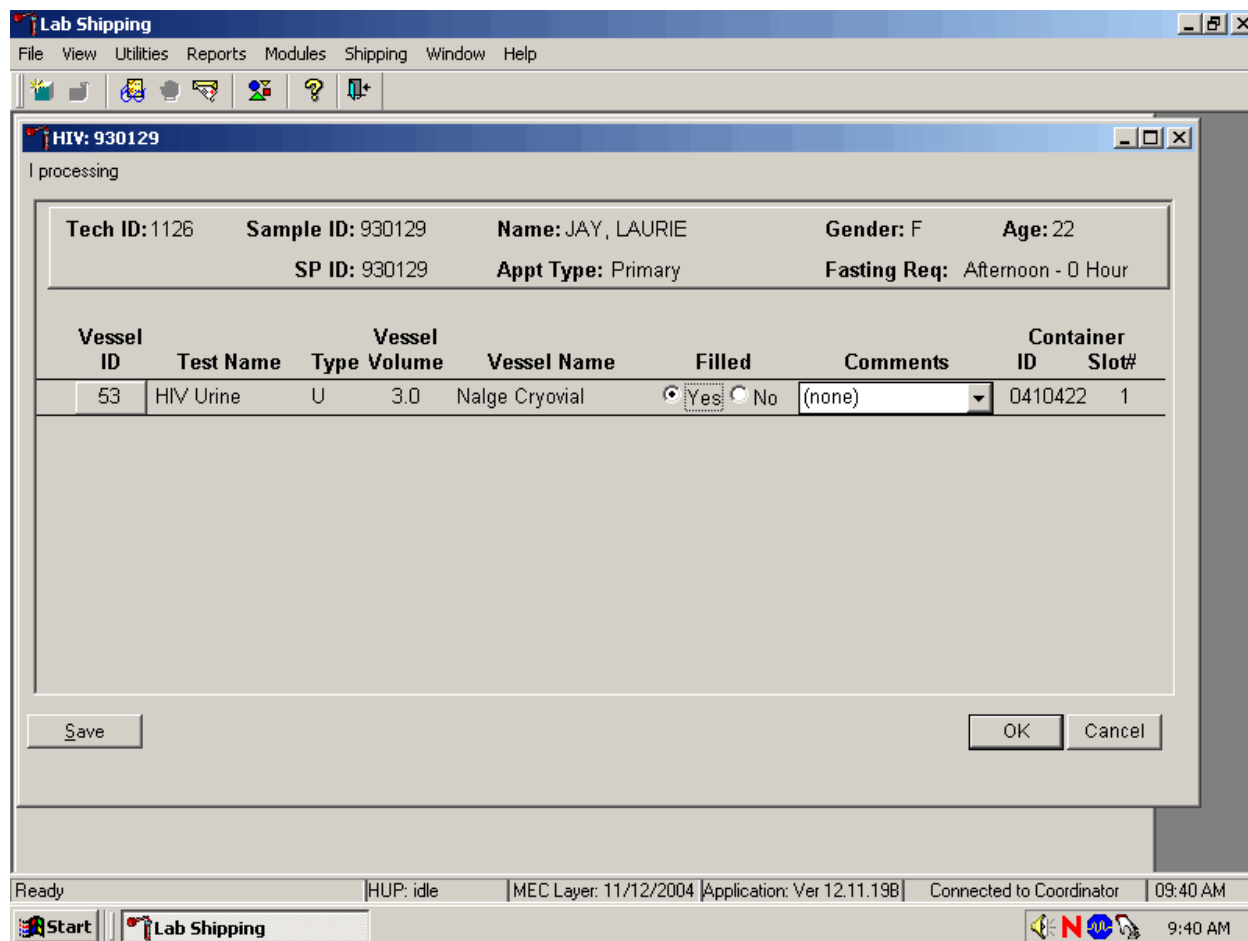
| Vessel ID | Test Name | Vessel Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Container Slot# |
|-----------|-----------|-------------|---------------|----------------|--|----------|--------------|-----------------|
| 53 | HIV Urine | U | 3.0 | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

At the bottom of the sub-window, there are three buttons: "Save", "OK", and "Cancel".

The Windows taskbar at the bottom shows the system tray with the following information: Ready, HUP: idle, MEC Layer: 11/12/2004, Application: Ver 12.11.198, Connected to Coordinator, 09:39 AM. The taskbar also shows the Start button, the Lab Shipping application icon, and the system clock showing 9:40 AM.

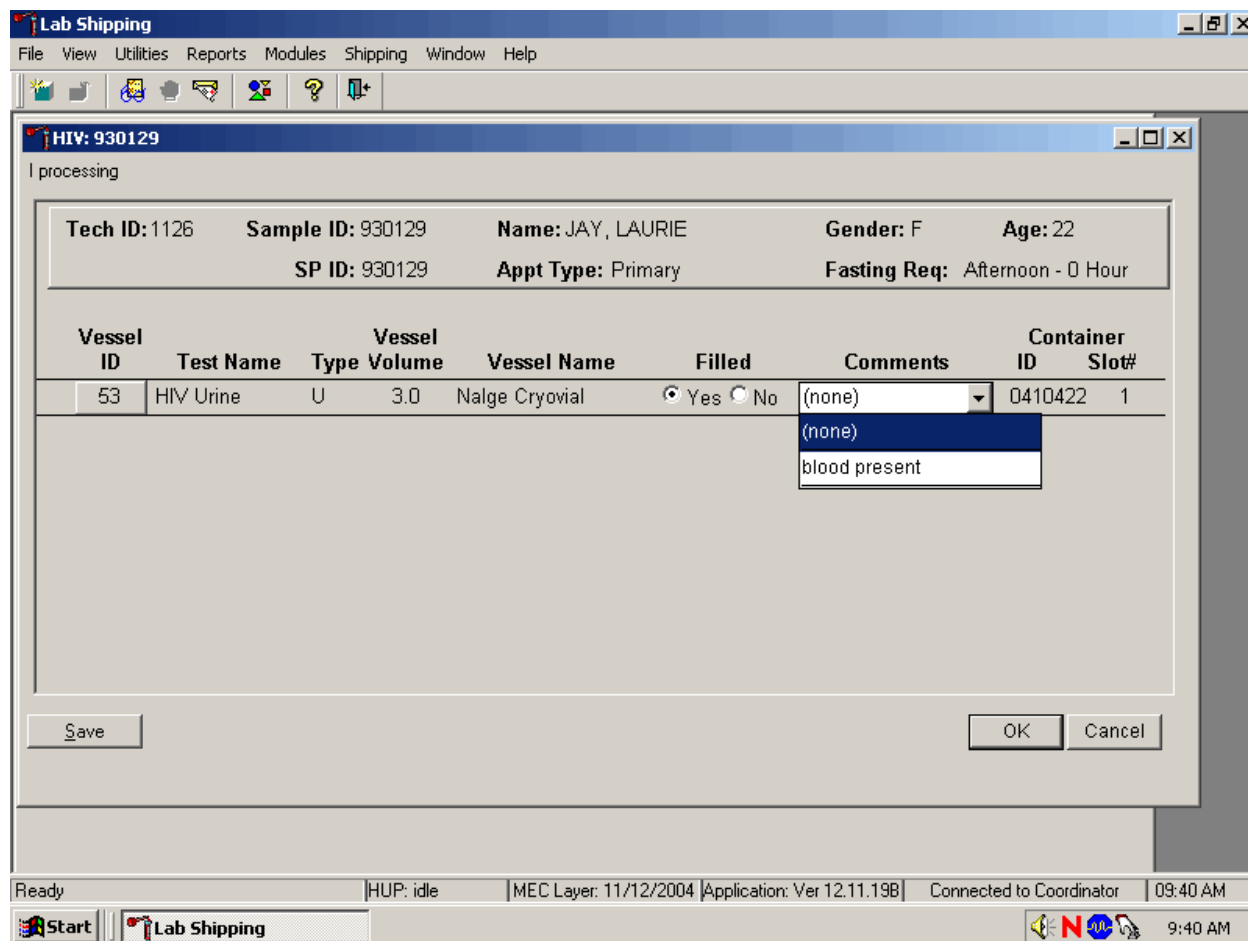
The HIV processing window contains the following information for SPs: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) type, and Fasting Req. There are columns that list the Vessel ID, Test Name, Sample Type (U = urine), Vessel Volume, Vessel Name, Filled (Yes or No) radio buttons, Comment drop-down box, and a Container ID and Container Slot# column.

Mark the vessel as Filled—"Yes" or Filled—"No."



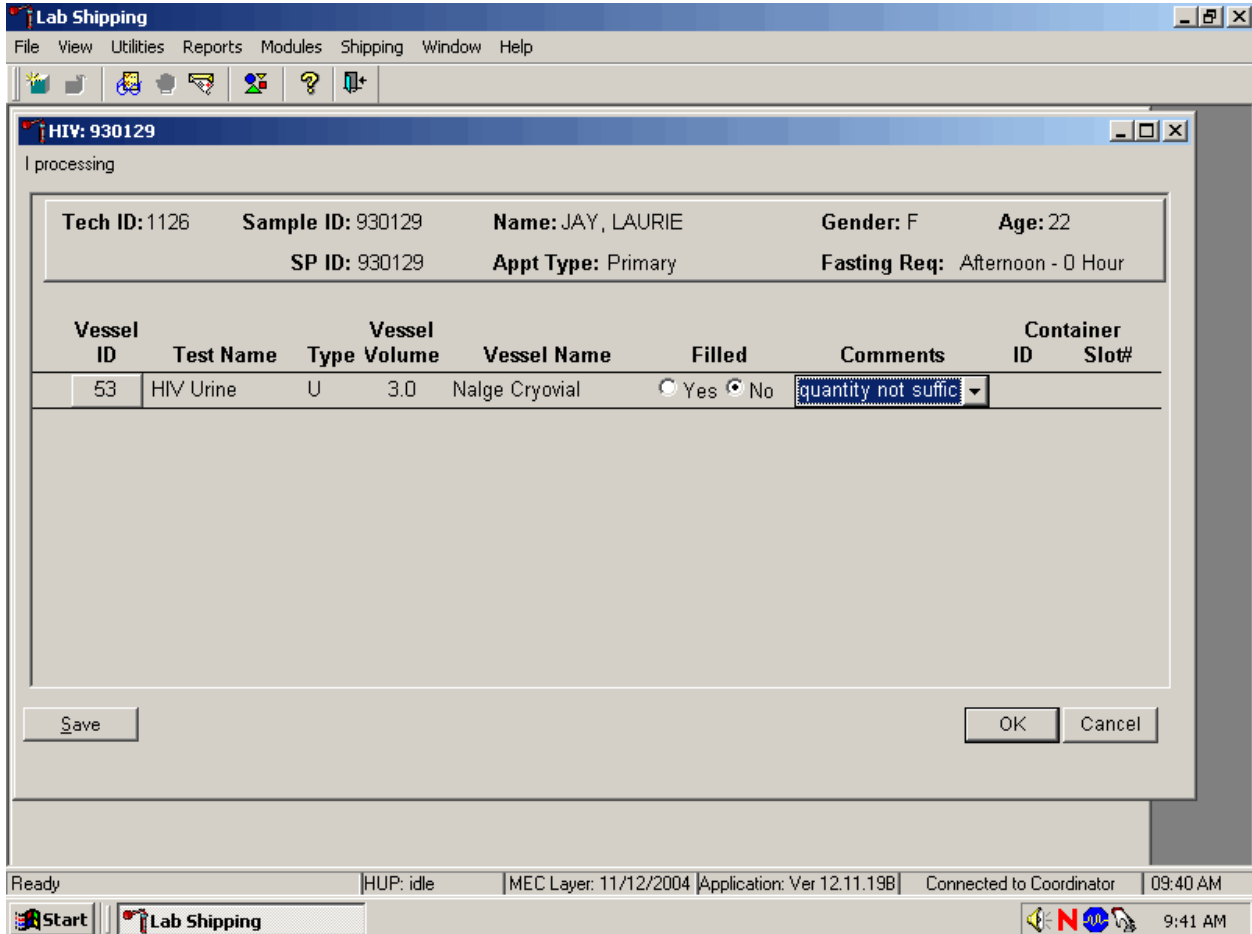
To mark the HIV urine vessel as collected or Filled—"Yes," use the mouse to direct the mouse arrow to the center of the "Yes" radio button and left click. As this vessel is marked as Filled—"Yes," it is automatically assigned to a slot in an existing (open) container. To mark the HIV urine vessel as not collected or Filled—"No," use the mouse to direct the mouse arrow to the center of the "No" radio button and left click.

Use the quality comment code to indicate if blood is present.



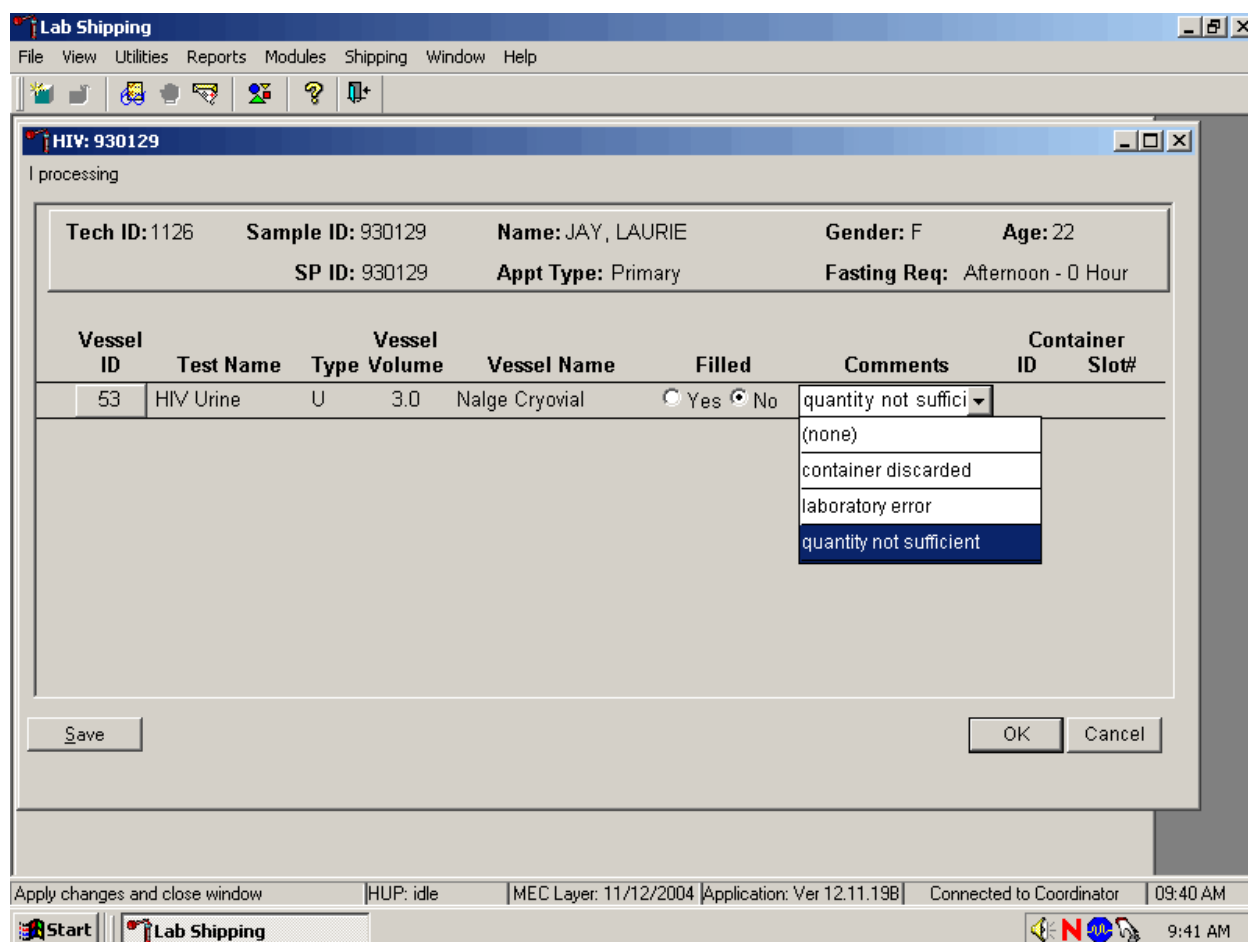
To enter the quality control comment “blood present” for a filled vessel, use the mouse to direct the mouse arrow to the drop-down list in the Comment column, left click to display the choices, drag the mouse arrow to {blood present}, and left click.

If this vessel is marked as Filled—"No," the comment, "quantity not sufficient" is automatically entered in the Comments column.



The other comment options are "container discarded" and "lab error."

Change the comment from “quantity not sufficient,” when necessary.



To select a different comment, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

Review the information in the urine-processing window and save the data to the database. Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

8.10 Blood Specimen Storage

8.10.1 Blood Specimen Storage Protocol

Fill the blood vessels, enter the blood and HIV urine processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Table 8-1.

At the beginning of each stand, generate and print a series of bar-coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process “opens” a storage box. Each vessel is assigned to a specific slot in a specific container as processing results are entered. Slots in containers are assigned according to a standard left to right, top to bottom procedure. Store each vessel in the appropriate slot in the correct container immediately after processing.

Table 8-1. Storage protocol for blood and HIV urine

| Shipping Location | Vessels | Conditions | Vessel Storage | Ship Frequency |
|-----------------------------------|------------------|--------------|----------------------|----------------|
| CASPIR | 1 Lead/Cad/HG | Frozen | 9 x 9 two inch box | Weekly |
| NYS DOH/Wadsworth CTR | 2 Ery Proto | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 3 RBC Folate | Frozen | 9 x 9 two inch box | Weekly |
| NHANES Diabetes Laboratory | 4 Glycohem | Refrigerated | 9 x 9 two inch box | Weekly |
| CASPIR | 5 Mercury | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 6 CD4 | Frozen | 9 x 9 two inch box | End of stand |
| CASPIR | 7 Homocys/MMA | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 8 Xtra Plasma | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 88 Acrylamide | Frozen | 9 x 9 two inch box | Weekly |
| National Diabetes Laboratory | 9 Glucose | Frozen | 9 x 9 two inch box | Weekly |
| National Diabetes Laboratory | 98 OGTT | Frozen | 9 x 9 two inch box | Weekly |
| TBD | 100 IgE | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 81 Vitamin B6 | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 70 Vitamin D | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 12 Fol/B12 | Frozen | 9 x 9 two inch box | Weekly |
| Univ of Washington | 13 CRP | Frozen | 9 x 9 two inch box | Weekly |
| CDC NCID Hepatitis Ref Lab | 14 Hep Profile | Frozen | 9 x 9 two inch box | Weekly |
| CDC NCID Hepatitis Ref Lab | 87 Hepatitis ab | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 99 Fer/TfR | Frozen | 9 x 9 two inch box | Weekly |
| Collaborative Laboratory Services | 11 Iron/TIBC | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 17 Cotinine | Frozen | 9 x 9 two inch box | Weekly |
| Lipoprotein Analytical Lab/JHU | 21 Lipids | Frozen | 9 x 9 two inch box | Weekly |
| U of Washington – Michelle Mehan | 104 Lp(a) | Frozen | 9 x 9 two inch box | Weekly |
| Univ of Washington | 94 PTH2 | Frozen | 9 x 9 two inch box | Weekly |
| CDC Kristi Singletary Meadows | 77 HPV Serum | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 79 Vitamin C | Frozen | 9 x 9 two inch box | Weekly |
| Collorative Laboratory Services | 18 Biochem | Refrigerated | 9 x 9 two inch box | Weekly |
| NHANES Diabetes Laboratory | 23 Insulin | Frozen | 9 x 9 two inch box | Weekly |
| CDC NCID AIDS Division | 22 HIV | Frozen | 9 x 9 two inch box | Weekly |
| Emory University | 24 HSV | Frozen | 9 x 9 two inch box | Weekly |
| Univ of Washington | 75 PSA | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 15 Vit A/E/Car | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR | 32-40 Xtra Serum | Frozen | 9 x 9 two inch box | End of stand |
| CDC NCID AIDS Division | 53 HIV Urine | Frozen | 9 x 9 three inch box | Weekly |
| CASPIR/Dr. Wayman Turner | 29 Persis Pest | Frozen | 9 x 9 three inch box | End of stand |
| CASPIR/Dr. Wayman Turner | 89 Persis Pest2 | | | |
| CDC Dr. Antonia Carafat | 90 Perfluor | Frozen | 9 x 9 three inch box | End of stand |
| CDC Dr. Dana Barr | 91 Srm Pest | Frozen | 9 x 9 three inch box | End of stand |
| CASPIR/Dr. Wayman Turner | 92 BFR 1 | Frozen | 9 x 9 three inch box | End of stand |
| CASPIR/Dr. Wayman Turner | 93 BFR 2 | | | |

8.11 How to Deal With System Failure

If the computer system fails, record results on a preprinted Workstation 1 processing worksheet (Exhibit 8-19). Complete a Blood Processing and HIV Urine Processing worksheet for each SP while processing the blood and HIV urine specimens. Enter the results after the system is operational.

Exhibit 8-19. Workstation 1 processing worksheet

BLOOD PROCESSING AND HIV URINE PROCESSING

SP ID _____

| ID | Name | Ages | Sample mL | Sample Type | Filled ✓ | Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i> | Not Filled Comments <i>ONS</i> <i>SP Refusal</i> <i>Lab Error</i> | Slot # |
|-----|--------------|---------------------|-------------------|-------------|-------------|---|--|--------|
| 1 | Lead/Cad/HG | 1+ | 0.3 | WB | | | | |
| 2 | Ery Proto | 3-5 12-49 | 0.4 0.4 | WB | | | | |
| 3 | RBC Folate | 1+ | 0.1 | WB | | | | |
| 4 | Glycohem | 12+ | 0.4 | WB | | | | |
| 5 | Mercury | 1+ | 0.5 | WB | | | | |
| 6 | CD4 | 18-49 | 0.5 | WB | | | | |
| 7 | Homocys/MMA | 20+ | 1.0 | P | | | | |
| 8 | Xtra Plasma | 6+ | 0.5 | P | | | | |
| 9 | Glucose | 12+ | 0.5 | P | | | | |
| 98 | OGTT | 12+ | 05 | P | | | | |
| 88 | Acrylamide | 3+ | 1.0 | PC | | | | |
| 100 | IgE | 1-5 6+ | 0.5 1.0 | S | | | | |
| 81 | Vitamin B6 | 1-2 3-11 12+ | 0.2 0.3 0.5 | S | | | | |
| 70 | Vitamin D | 1-2 3+ | 0.3 0.5 | S | | | | |
| 12 | Fol/B12 | 1-2 3-5 6+ | 0.7 0.8 1.0 | S | | | | |
| 13 | CRP | 1-2 3+ | 0.2 0.3 | S | | | | |
| 14 | Hep Profile | 6+ | 1.5 | S | | | | |
| 87 | Hepatitis ab | 2 3-5 | 0.3 0.4 | | | | | |
| 99 | Fer/TfR | 1-2 3-5 12-49 | 0.3 0.5 0.5 | S | | | | |
| 11 | Iron/TIBC | 3-5 12-59 | 1.0 1.0 | S | | | | |
| 17 | Cotinine | 3-5 6-11 12+ | 1.0 1.3 1.8 | S | | | | |
| 21 | Lipids | 6+ | 1.5 | S | | | | |
| 104 | Lp(a) | 12+ | 0.5 | S | | | | |
| 94 | PTH2 | 6+ | 1.0 | S | | | | |
| 77 | HPV Serum | 14-59 | 0.5 | S | | | | |
| 79 | Vitamin C | 6+ | 0.1 | S | | | | |
| 18 | Biochem | 12+ | 0.8 | S | | | | |

Exhibit 8-19. Workstation 1 processing worksheet (continued)

| ID | Name | Ages | Sample mL | Sample Type | Filled ✓ | Filled Comments <i>Icteric</i> <i>Lipemic</i> <i>Equip Failure</i> <i>Clotted</i> <i>Hemolyzed</i> <i>Blood Present</i> | Not Filled Comments <i>ONS</i> <i>SP Refusal</i> <i>Lab Error</i> | Slot # |
|----|--------------|-------------|--------------|----------------|-------------|--|---|-----------|
| 23 | Insulin | 12+ | 1.0 | S | | | | |
| 22 | HIV | 18-49 | 0.8 | S | | | | |
| 24 | HSV | 14-49 | 0.2 | S | | | | |
| 75 | PSA | 40+ | 1.0 | S | | | | |
| 15 | Vit A/E/CAR | 6-11 12+ | 0.4 0.5 | S | | | | |
| 32 | Xtra Serum | 3+ | 0.5 | S | | | | |
| 33 | Xtra Serum | 6+ | 0.5 | S | | | | |
| 34 | Xtra Serum | 6+ | 0.5 | S | | | | |
| 35 | Xtra Serum | 6+ | 0.5 | S | | | | |
| 36 | Xtra Serum | 12+ | 0.5 | S | | | | |
| 37 | Xtra Serum | 12+ | 0.5 | S | | | | |
| 38 | Xtra Serum | 12+ | 1.0 | S | | | | |
| 39 | Xtra Serum | 12+ | 1.0 | S | | | | |
| 40 | Xtra Serum | 12+ | 1.0 | S | | | | |
| 53 | HIV Urine | 18-49 | 5.0 | U | | | | |
| 29 | Persis Pest | 12+ | 4.0 | S | | | | |
| 89 | Persis Pest2 | 12+ | 4.0 | S | | | | |
| 90 | Perfluor1 | 12+ | 4.0 | S | | | | |
| 91 | Srm Pest | 12+ | 4.0 | S | | | | |
| 92 | BFR1 | 12+ | 4.0 | S | | | | |
| 93 | BFR2 | 12+ | 4.0 | S | | | | |

WB = Whole Blood

P = Plasma

PC=Packed cells

S = Serum

U = Urine

9. PRINTING LABELS AND SPECIMEN SHIPMENT

9.1 Introduction

Labels are essential to the laboratory component. Labels support each sample person's (SP's) unique processing protocol. The laboratory record is created when the medical technologist accesses a session for the first time. This record forms the basis for each SP's data in the database. Container labels are generated and assigned to vessel storage containers and allow a processed sample to be tracked from mobile examination center (MEC) processing through contract laboratory receipt.

Ship biological specimens to a variety of contract laboratories in double-sided Styrofoam and corrugated cardboard shippers or hard-sided shippers with Styrofoam inserts using dry ice or wet ice (refrigerant packs). Include a copy of a shipping manifest with each shipment that contains a list of the items contained in the shipment and certain demographic information. Exhibit 9-1, the Blood and urine shipping protocol, illustrates the specifications for the shipment of blood and urine specimens to each contract laboratory.

Ship packages using FedEx. The chief medical technologist is responsible for contacting FedEx at the start of each stand to determine availability. The MEC manager contacts the dry ice company at the start of each stand to establish a contact but the chief medical technologist arranges for the delivery of dry ice on shipping days. It is the chief medical technologist's responsibility to confirm the arrangements for shipping and dry ice delivery with the MEC manager at the beginning of each stand.

The chief medical technologist works with the MEC manager and the home office to determine exactly which days to ship specimens to the contract laboratories. As a rule, pack and ship most specimens once a week during MEC split examination sessions. The exceptions are vessels 6, 8, 32-40, 29/89, 90, 91, 92/93, 48, 49, 65, 66, 67, and 52. Hold these containers and ship once they are full or hold and ship at the end of the stand. All specimens should arrive at the destination the day after shipping. The next-day limitation may conflict with off days, holidays, and vacations. If a conflict with the shipping schedule, working schedule, or the contract laboratory schedule occurs, consult the MEC manager and the home office technical supervisor.

Exhibit 9-1. Blood and urine shipping protocol

| Location | Vessels | Conditions | Vessel storage | Shipping frequency |
|---|-----------------|--------------|--------------------|-------------------------|
| Blood | | | | |
| CASPIR Vessel 1 | Lead/Cad/HG | Frozen | 9 x 9 two inch box | Weekly |
| NYS DOH/ Wadsworth CTR Vessel 2 | Ery Proto | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 3 | RBC Folate | Frozen | 9 x 9 two inch box | Weekly |
| NHANES Diabetes Laboratory Vessel 4 | Glycohem | Refrigerated | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 5 | Mercury | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 6 | CD4 | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 7 | Homocys/MM A | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 8 | Xtra Plasma | Frozen | 9 x 9 two inch box | Full or end of stand |
| CASPIR Vessel 88 | Acrylamide | Frozen | 9 x 9 two inch box | Weekly |
| NHANES Diabetes Laboratory Vessel 9 | Glucose | Frozen | 9 x 9 two inch box | Weekly |
| NHANES Diabetes Laboratory Vessel 98 | OGTT | Frozen | 9 x 9 two inch box | Weekly |
| TBD Vessel 100 | IgE | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 81 | Vitamin B6 | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 70 | Vitamin D | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 12 | Fol/B12 | Frozen | 9 x 9 two inch box | Weekly |
| Univ of Washington Vessel 13 | CRP | Frozen | 9 x 9 two inch box | Weekly |
| CDC NCID Hepatitis Ref Lab Vessel 14 | Hep Profile | Frozen | 9 x 9 two inch box | Weekly |
| CDC NCID Hepatitis Ref Lab Vessel 87 | Hepatitis ab | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 99 | Fer/TfR | Frozen | 9 x 9 two inch box | Weekly |
| Collaborative Laboratory Services Vessel 11 | Iron/TIBC | Frozen | 9 x 9 two inch box | Weekly |

Exhibit 9-1. Blood and urine shipping protocol (continued)

| Location | Vessels | Conditions | Vessel storage | Shipping frequency |
|--|-----------------------------|--------------|----------------------|-------------------------|
| CASPIR Vessel 17 | Cotinine | Frozen | 9 x 9 two inch box | Weekly |
| Lipoprotein Analytical Lab/JHU Vessel 21 | Lipids | Frozen | 9 x 9 two inch box | Weekly |
| Univ of Washington – Michelle Mehan Vessel 104 | Lp(a) | Frozen | 9 x 9 two inch box | Weekly |
| Univ of Washington Vessel 94 | PTH2 | Frozen | 9 x 9 two inch box | Weekly |
| CDC Kristi Singletary Meadows Vessel 77 | HPV Serum | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 79 | Vitamin C | Frozen | 9 x 9 two inch box | Weekly |
| Collaborative Laboratory Services Vessel 18 | Biochem | Refrigerated | 9 x 9 two inch box | Weekly |
| NHANES Diabetes Laboratory Vessel 23 | Insulin | Frozen | 9 x 9 two inch box | Weekly |
| CDC NCID AIDS Division Vessel 22 | HIV | Frozen | 9 x 9 two inch box | Weekly |
| Emory University Vessel 24 | HSV | Frozen | 9 x 9 two inch box | Weekly |
| Univ of Washington Vessel 75 | PSA | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessel 15 | Vit A/E/Car | Frozen | 9 x 9 two inch box | Weekly |
| CASPIR Vessels 32-40 | Xtra Serum | Frozen | 9 x 9 two inch box | Full or end of stand |
| CASPIR/Dr. Wayman Turner Vessels 29 and 89 | Persis Pest Persis Pest2 | Frozen | 9 x 9 three inch box | Full or end of stand |
| CASPIR/Dr. Antonia Carafat Vessels 90 | Perfluor1 | Frozen | 9 x 9 three inch box | Full or end of stand |
| CDC/Dr. Dana Barr Vessels 91 | Srm Pest | Frozen | 9 x 9 three inch box | Full or end of stand |
| CASPIR/Dr. Wayman Turner Vessels 92 and 93 | BFR1 BFR2 | Frozen | 9 x 9 three inch box | Full or end of stand |

Exhibit 9-1. Blood and urine shipping protocol (continued)

| Location | Vessels | Conditions | Vessel storage | Shipping frequency |
|--|-------------|--------------|----------------------|----------------------|
| Urine | | | | |
| Univ of Minnesota Vessel 45 | Alb/Creat | Frozen | 9 x 9 three inch box | Weekly |
| CDC NCID NCHSTD Vessel 46 | Chlam/GC | Frozen | 5 x 5 three inch box | Weekly |
| CASPIR Vessel 69 | Urn Iodine | Frozen | 9 x 9 three inch box | Weekly |
| CASPIR Vessel 86 | Spc Arsenic | Frozen | 9 x 9 three inch box | Weekly |
| CDC Dr. Dana Barr Vessel 48 | Prior Pest | Frozen | 5 x 5 three inch box | Full or end of stand |
| CDC Dr. Dana Barr Vessel 49 | Organophos | Frozen | 5 x 5 three inch box | Full or end of stand |
| CASPIR Vessel 62 | Urn Merc | Frozen | 9 x 9 three inch box | Weekly |
| CASPIR Vessel 50 | Heavy Metal | Frozen | 5 x 5 three inch box | Weekly |
| CASPIR/Dr. Christine Pfeiffer Vessel 65 | Urn Phytoes | Frozen | 5 x 5 three inch box | Full or end of stand |
| CASPIR/Dr. Andreas Sjodin Vessel 66 | PAH | Frozen | 9 x 9 three inch box | Full or end of stand |
| CDC Dr. Antonia Calafat Vessel 67 | Phthalates | Frozen | 9 x 9 three inch box | Full or end of stand |
| CDC Air Toxicant Branch Vessel 102 | Perchlorate | Frozen | 9 x 9 three inch box | Weekly |
| CASPIR Vessel 52 | Xtra Urine | Frozen | 9 x 9 three inch box | Full or end of stand |
| CDC NCID AIDS Division Vessel 53 | HIV | Refrigerated | 9 x 9 three inch box | Weekly |

9.2 Equipment and Supplies

Exhibit 9-2 contains a list of label/shipping supplies.

Exhibit 9-2. Supplies for labels/shipping

| | |
|--|--|
| Small Styrofoam shipper (14 x 14 x 12) | Medium Styrofoam shippers (16 x16 x 15.5) |
| 5-mL cryovial sterile | 2-mL cryovial sterile |
| 14-mL snap cap test tube | 2-mL cryovial nonsterile |
| Conical tube 50-mL | Caps for 2-mL cryovial |
| 5.25 x 5.25 x 2.0 inch cardboard box with 9 x 9 cardboard grid | 5.25 x 5.25 x 3.0 inch cardboard box with 9 x 9 cardboard grid |
| 5.25 x 5.25 x 5.0 inch cardboard box with 5 x 5 foam insert | Three-inch 5 x 5 cardboard grid |
| 5.25 x 5.25 x 3.0 inch cardboard box without grid | Scale |
| STP-710 Pressure vessel | STP-310 Pressure vessel |
| STP-740 Pressure vessel | U-TEK Reusable Refrigerant Packs Large |
| Plastic bag 9 x 12 | Zip closable bags – quart size |
| Absorbent sheets (2 x 2) | Rubber bands |
| Large padded envelope | Newsprint paper |
| Cryo gloves | Full face shield |
| Hammer | Dry ice scoop |
| Tape gun | Packaging tape 2” |
| Overpack label | DIAGNOSTIC SPECIMENS label |
| UN 3373 label | Refrigerate Do Not Freeze label |
| Keep Frozen label | Avery 5160 labels |
| Label Datamax (1.125”) | Printer ribbon, Datamax (thermal transfer) |
| Sheet-fed laser labels | Wipes, Terri 13” x 18” |
| FedEx large boxes | FedEx Class 9 label |
| Clear FedEx label pouches | FedEx preprinted return airbill – warehouse |
| FedEx form 0215 | FedEx preprinted return airbill – stand |
| Toner cartridge (HP Laser Jet 4000) | Lab jackets (Petite, Lg., X-Lg.) |

9.3 Print Vessel Labels and Label Blood Processing Racks

Before each session, the technologist at workstation 3 prints all labels for all SPs assigned to a session. The correct bar-coded labels automatically print for each SP based on the SP’s age, sex, appointment type, and selection into one or more subsamples. Print pooled blood tube, blood processing, urine processing, pregnancy testing, VOC water processing, OGTT processing, and perchlorate water

processing labels for all SPs in the MEC session. The phlebotomist and the technologist assigned to shipping are responsible for labeling vessels and assembling the blood processing racks. The MEC physician prints the HPV labels.

Distribute labels

- Place urine processing, pregnancy testing, VOC water processing, and perchlorate water processing labels at workstation 2 in the laboratory.
- Save and recycle unused vessels.
- If the SP does not show up for the appointment, it is possible he or she will reschedule.
- Store the SP's vessels in a zip-closable bag until the end of the stand.
- If the SP has not shown up by the end of the stand, recycle the unused vessels.

Assemble blood-processing racks

The phlebotomist and the medical technologist assigned to the shipping workstation are responsible for labeling vessels and assembling the blood processing racks. Use extreme care in setting up the blood vessel racks and in labeling the vessels with the appropriate bar code label.

Label each vessel with the appropriate vessel label, according to the protocol. Place the label on the vessel, wrapping it around the vessel horizontally and making sure the label wraps onto itself. Place the label so the first digit of the vessel number is at the top of the vessel. Set the vessels in the cube racks in priority order.

Use the following materials to set up and label blood racks:

- Plastic rack
- Processing template

- Store vessels of the following sizes:
 - 2.0-mL vessel
 - 5.0-mL vessel
 - 14.0-mL tube
 - 50-mL conical tube
- Bar-coded SP ID labels each containing the unique 6-digit SP ID number concatenated with the vessel ID

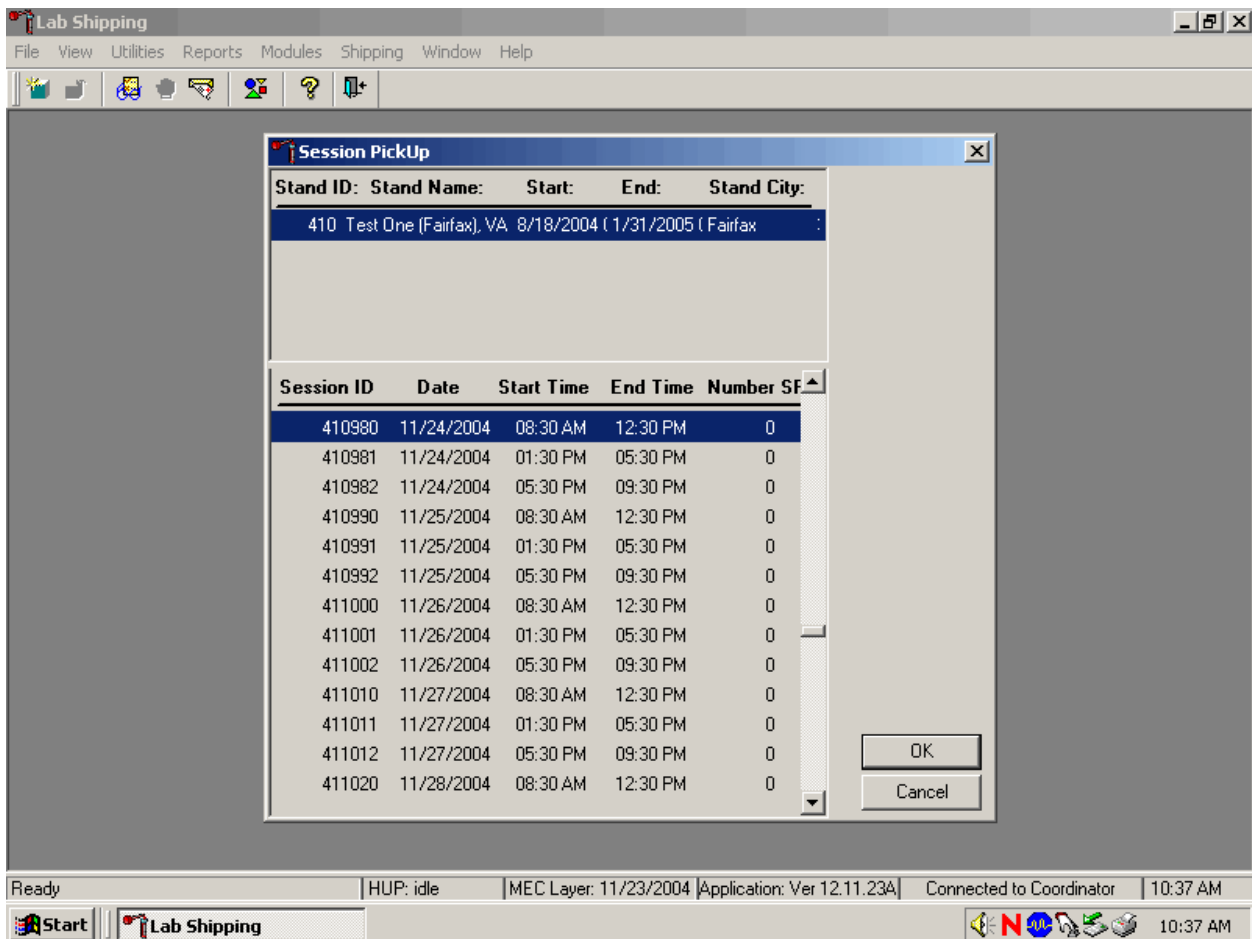
Prepare one blood processing rack for each SP. The set up of the rack depends on the subject's age, sex, appointment type, and inclusion in selected subsamples. When possible, prepare the racks at least 1 day before the SP arrives for the MEC examination.

- Place the OGTT labels at workstation 1 at the start of each session.
- Place the pre-labeled blood processing racks in the laboratory at the start of each session.

9.3.1 Print Vessel Labels Using the Print Labels Module

Open the Laboratory application. Log onto the computer terminal. If the laboratory is conducting a MEC session, the heads-up display will default to the current session. If the MEC is not conducting a session, then use the Set Session utility to access a different session.

If the MEC is not conducting a session, then the Session PickUp list displays. Select the correct session from the pick list.



The Session PickUp window displays if the MEC is not conducting a session. The current stand is displayed in the top section of the window. To select or highlight the correct MEC session, use the mouse to direct the mouse arrow to the correct session, date, and time and right click. Alternatively, to select or highlight a session, use the up and down keys to move up and down the list until the correct

session is highlighted and left click. Use the lower vertical scroll bar to view all sessions. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

After selecting a session from the Session PickUp list and selecting OK, the laboratory heads-up screen displays. If the staff is conducting a MEC session, the laboratory application defaults to the current MEC session.

Stand:410 Session:410331 09/20/2004 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

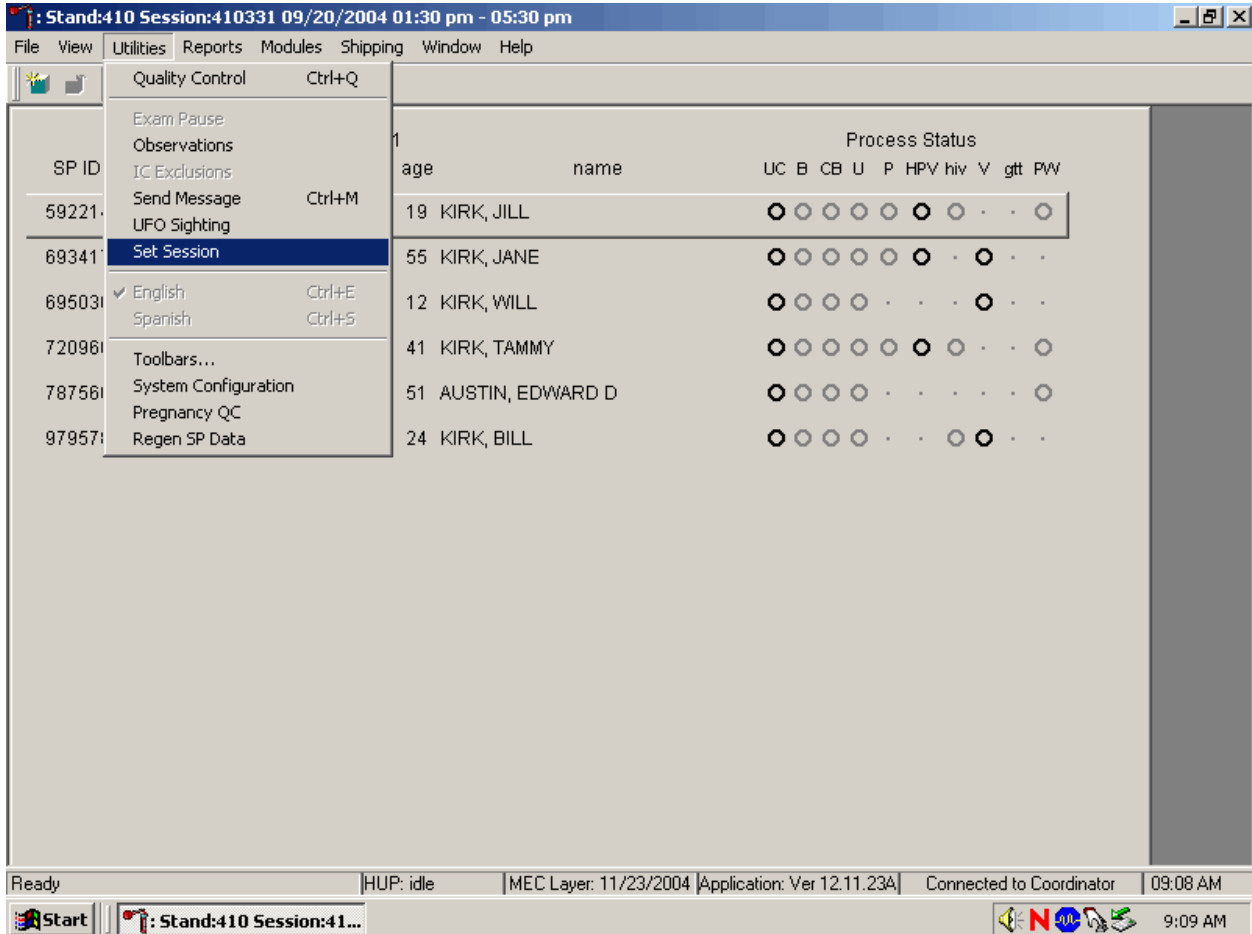
Appointments for Session: 410331

| SP ID | Sample ID | status | type | gender | age | name | Process Status | | | | | | | | | | | | |
|--------|-----------|--------|------|--------|-----|------------------|----------------|---|----|---|---|-----|-----|---|-----|----|---|---|---|
| | | | | | | | UC | B | CB | U | P | HPV | hiv | V | gtt | PW | | | |
| 592214 | 592214 | SC | P | F | 19 | KIRK, JILL | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 693417 | 693417 | SC | P | F | 55 | KIRK, JANE | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695036 | 695036 | SC | P | M | 12 | KIRK, WILL | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 720960 | 720960 | SC | P | F | 41 | KIRK, TAMMY | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 787560 | 787560 | SC | P | M | 51 | AUSTIN, EDWARD D | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 979578 | 979578 | SC | P | M | 24 | KIRK, BILL | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Ready | HUP: idle | MEC Layer: 11/23/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 09:08 AM

Start | Stand:410 Session:41... | 9:08 AM

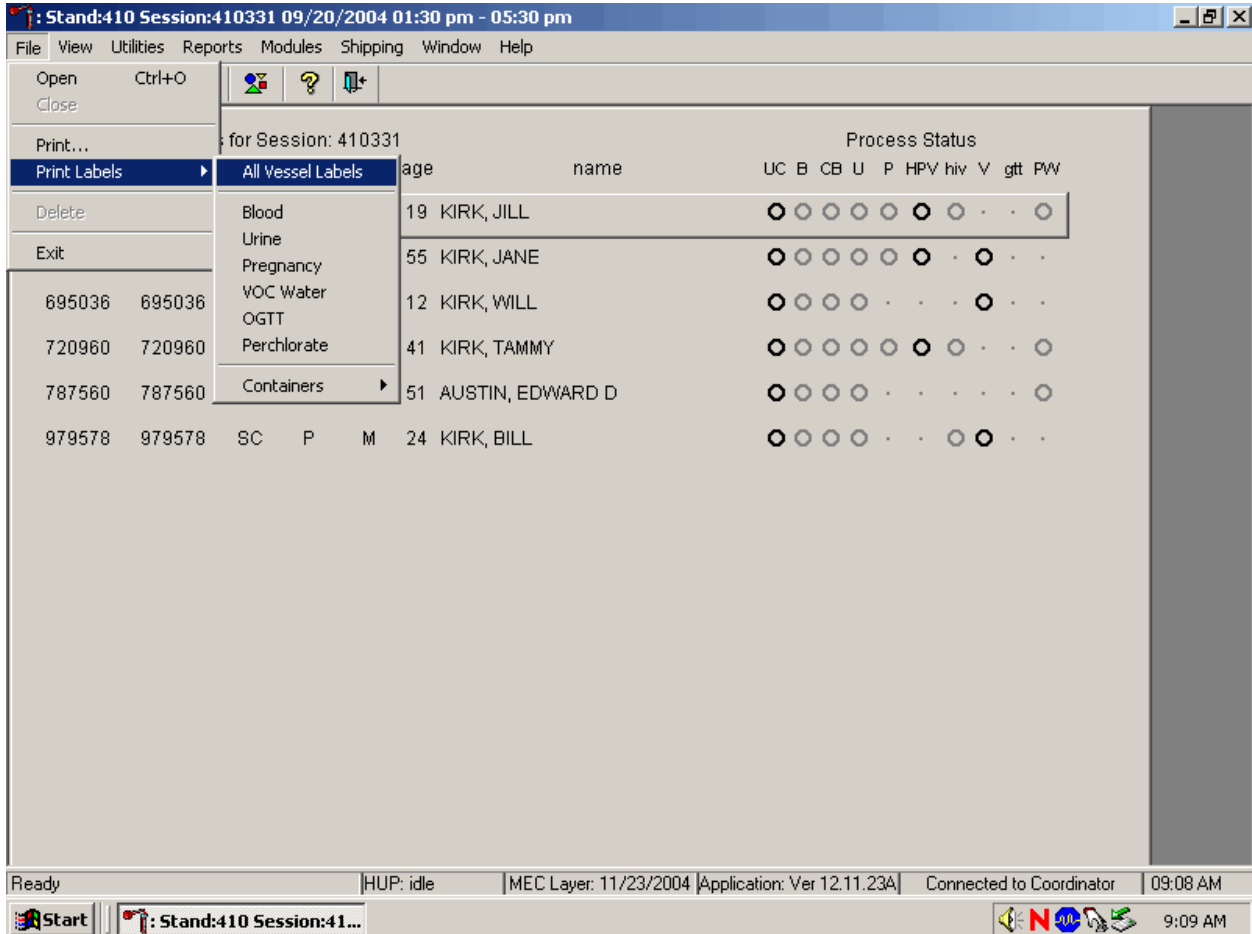
Use the Set Session utility to access a different MEC session when the staff is conducting a MEC session.



To access a different MEC session when the staff is conducting a MEC session, use the mouse to direct the mouse arrow to the {Utilities} module in the top menu bar, drag the mouse arrow to {Set Session}, and left click or type [ALT] [U/u], [N/n].

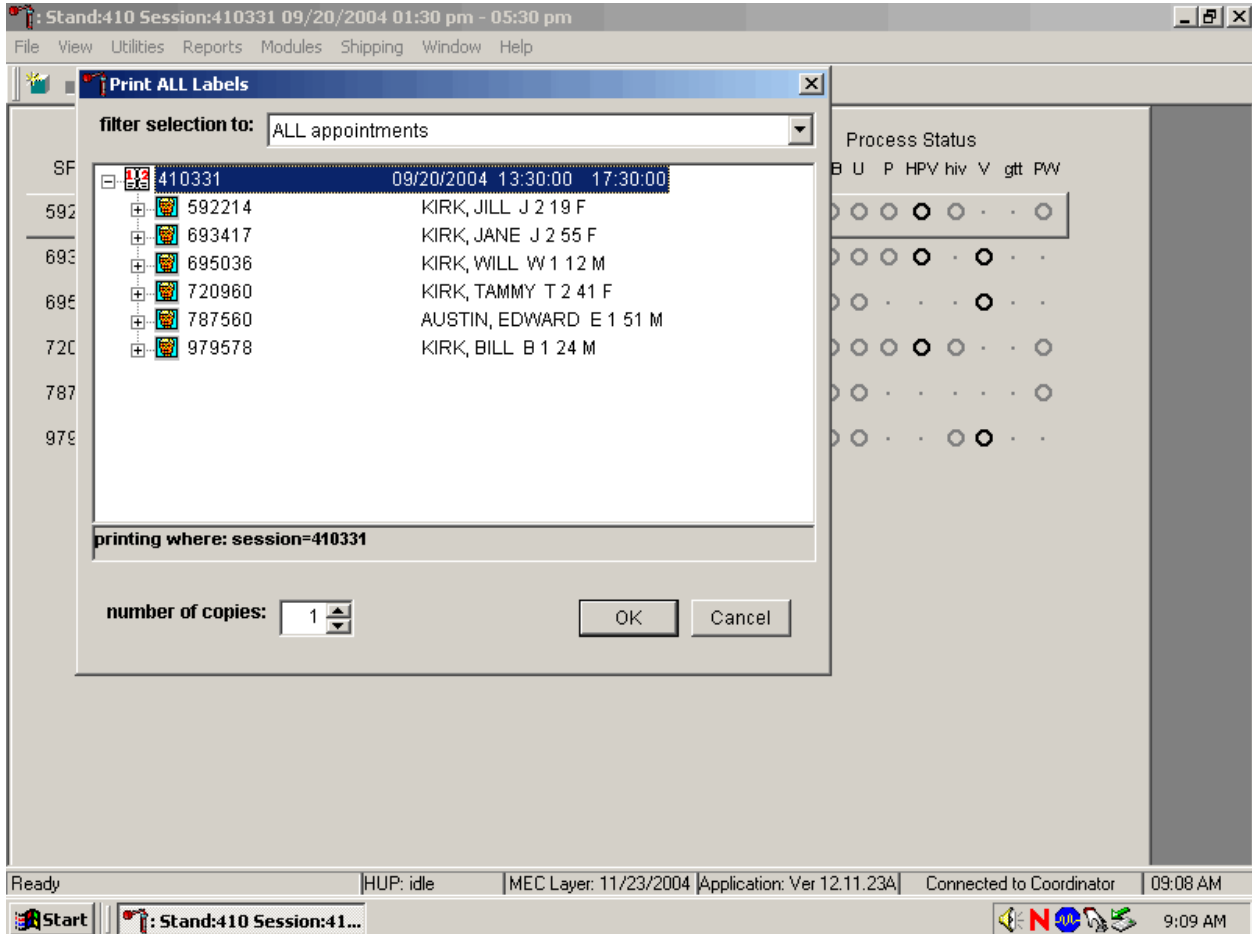
Print vessel labels using a variety of options. It is possible to print labels for all modules (blood, urine, pregnancy, VOC water, OGTT and perchlorate) or for individual modules. It is also possible to print labels for all SPs in a session, an individual SP, or print labels for ALL appointments, appointments NOT previously printed, or appointments previously printed.

Print vessel labels for all modules.



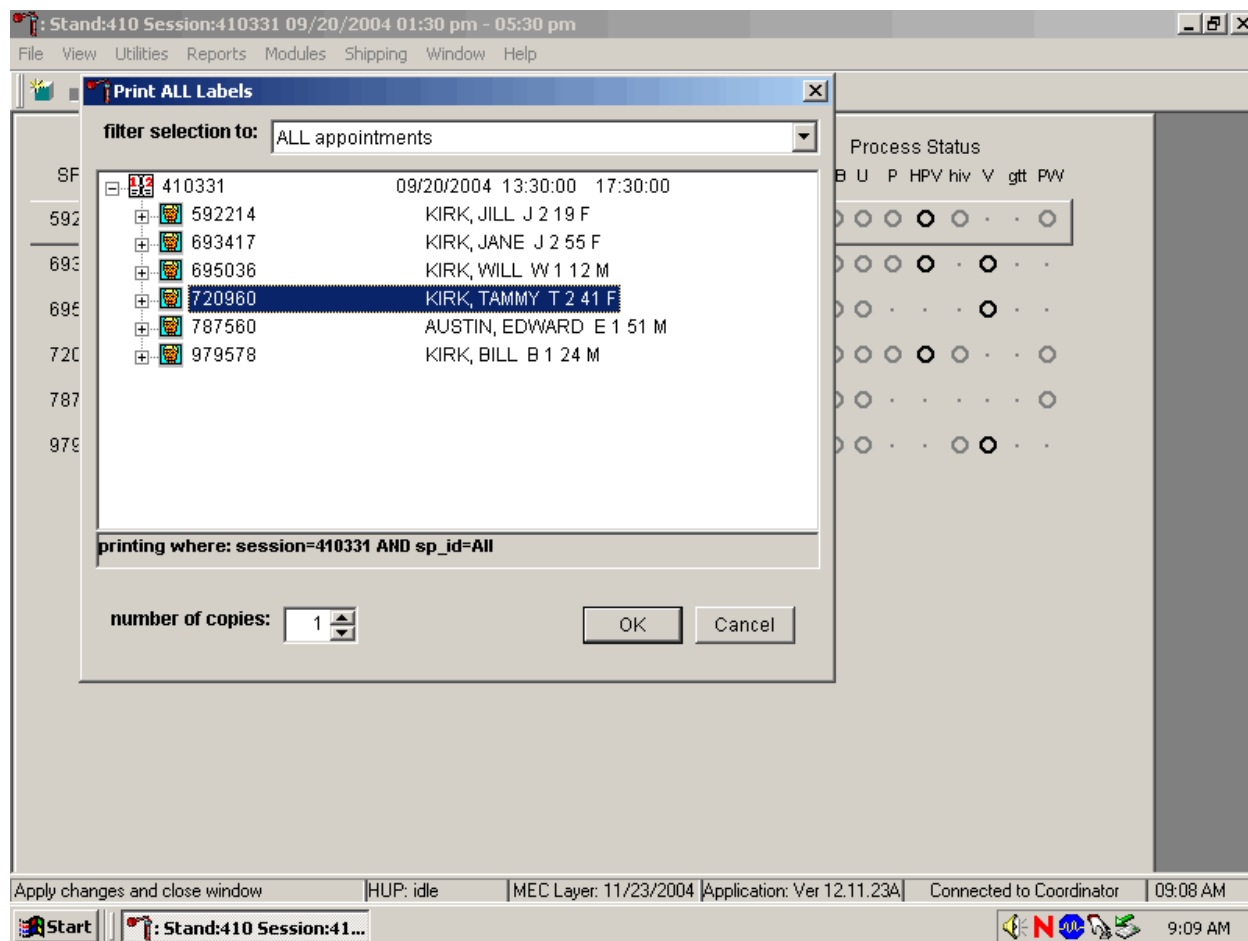
To print vessel labels for all modules, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Print Labels}, then to {All Vessel Labels} and left click, or type [Alt] [F/f], [L/l], [A/a]. Selecting {All Vessel Labels} prints a complete set of blood processing, urine processing, pregnancy testing, VOC water processing, OGTT processing, and perchlorate processing labels.

The Print ALL Labels window displays. Use the Print ALL Labels window to print vessel labels for all modules for all SPs in a MEC session.



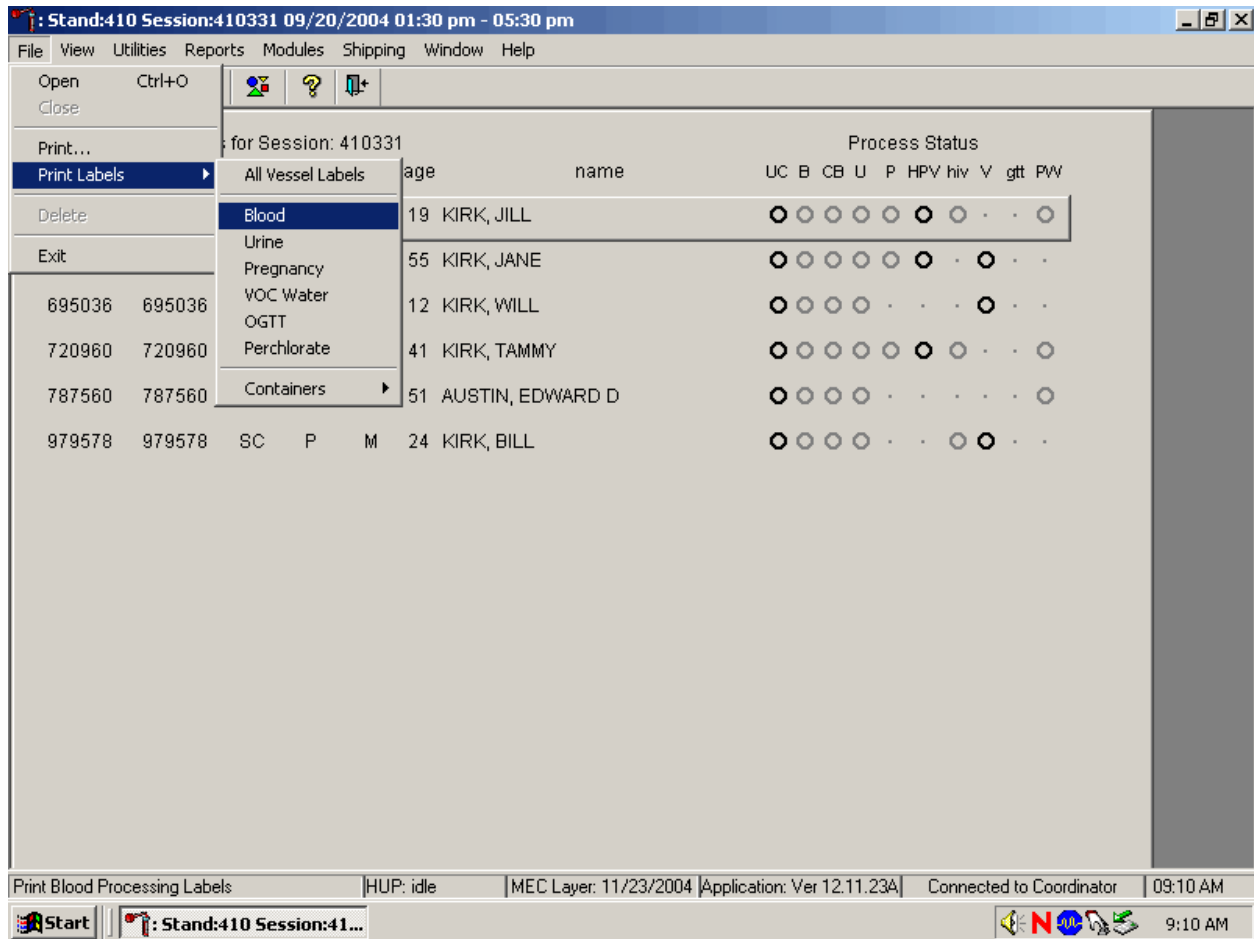
To print vessel labels for all modules for all SPs in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print vessel labels for all modules for one SP in a MEC session.



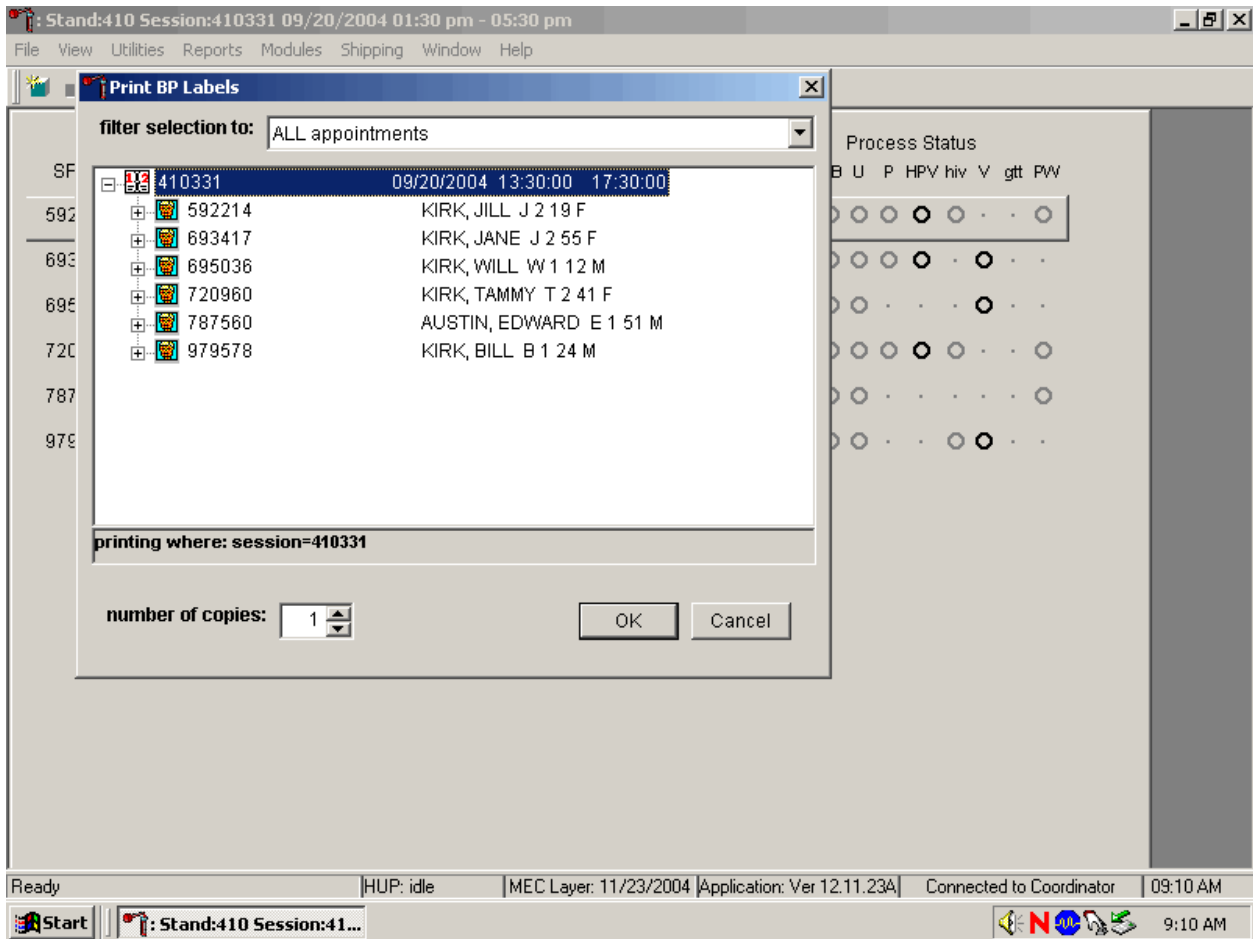
To print vessel labels for all modules for one SP in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print vessel labels for one specific module for all SPs in a MEC session.



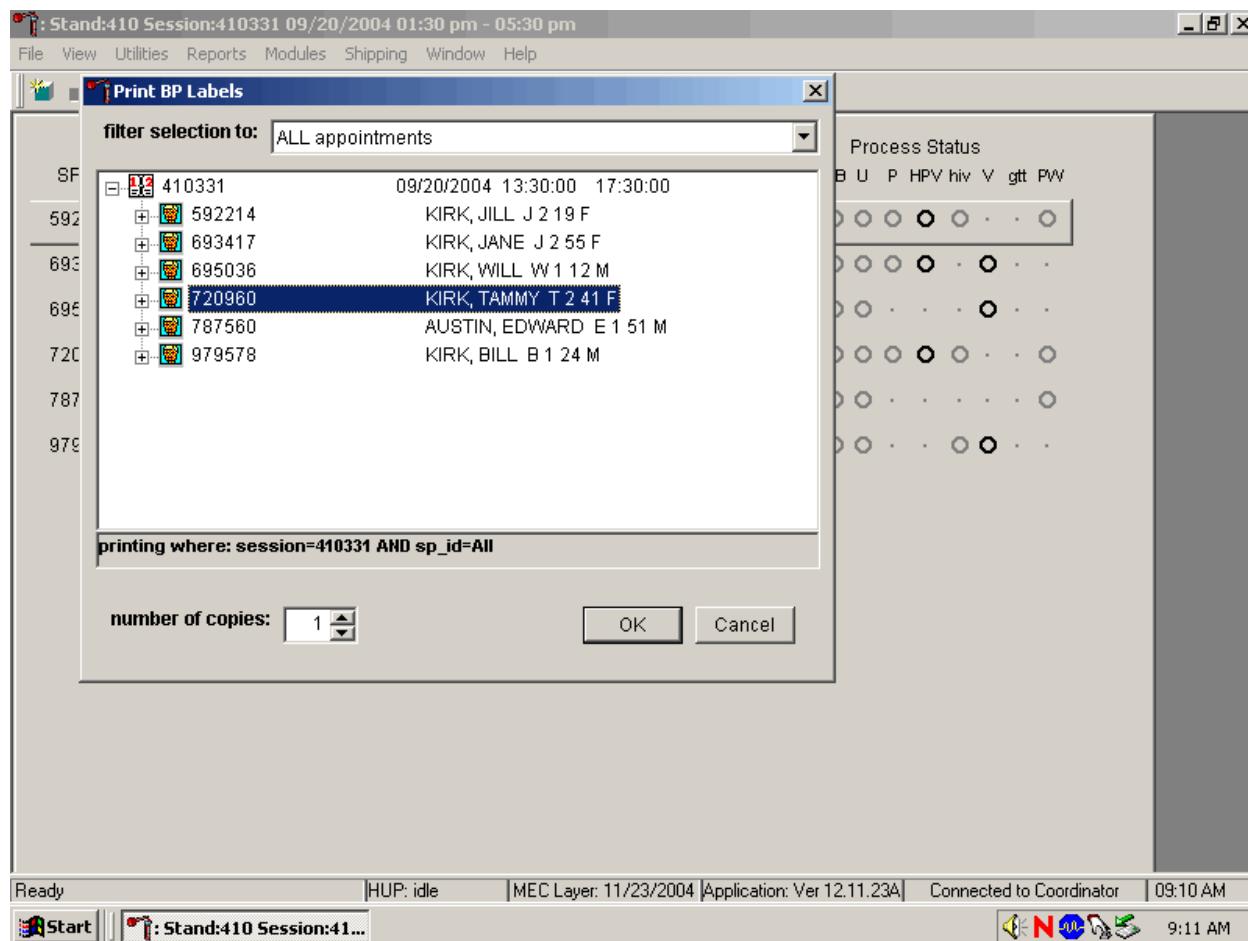
To print vessel labels for one specific module for all SPs in a MEC session, use the mouse to direct the mouse arrow {File} in the top menu bar, drag the mouse arrow to {Print Labels}, then to the specific module and left click or type [Alt] [F/f], [L/l], and the first letter of the specific module.

The Print {Module} Labels window displays.



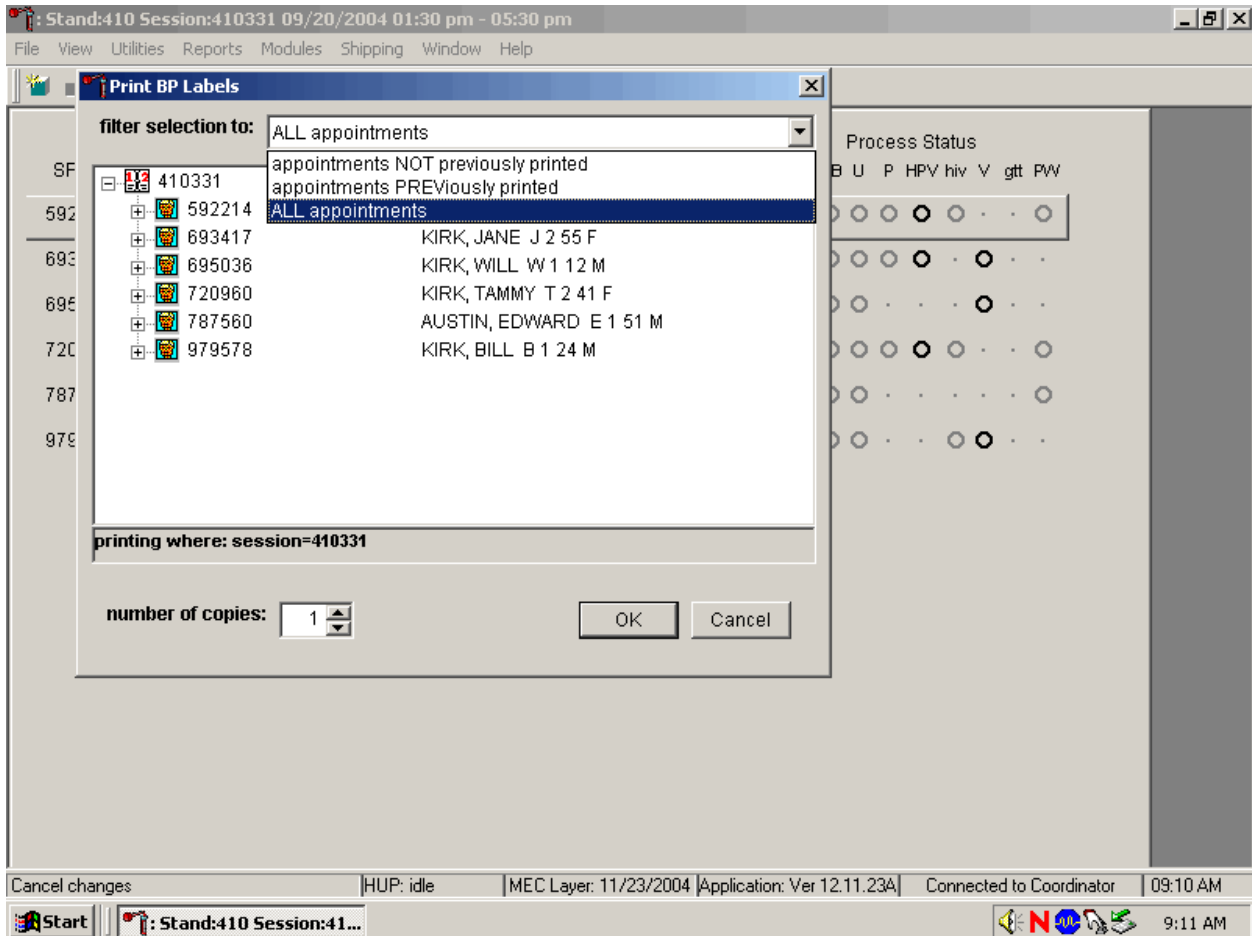
To print vessel labels for one module for all SPs in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print vessel labels for one specific module for one SP in a MEC session.



To print vessel labels for one specific module for one SP in a MEC session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

It is also possible to print labels for specific SPs using criteria such as “ALL appointments,” “appointments NOT previously printed,” or “appointments PREVIOUSly printed” by using a filter.

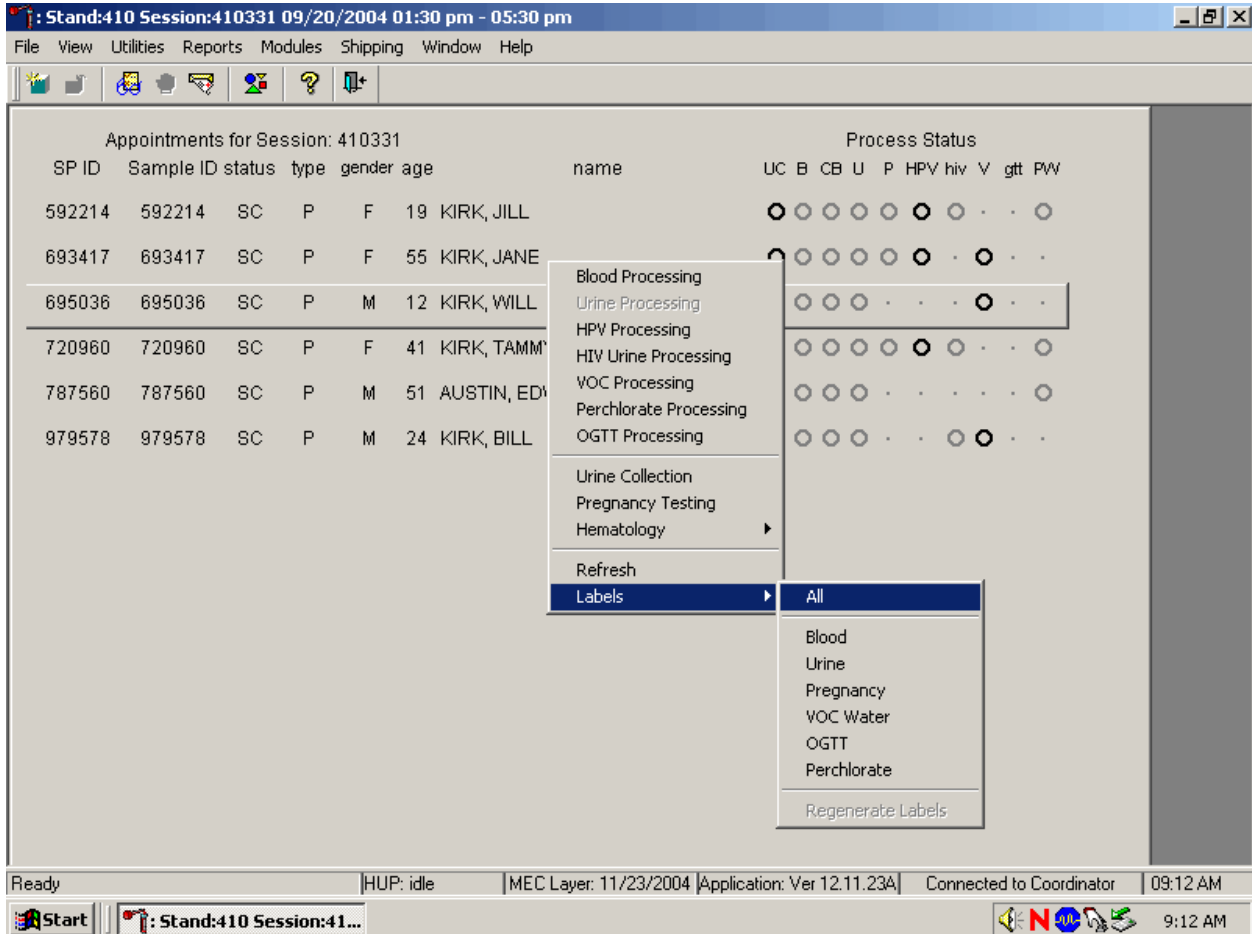


The default filter selection is “ALL appointments.” To select or change a filter, use the mouse to direct the mouse arrow to the drop-down list on the “Filter Selection to:” box and drag the mouse arrow to “Appointments NOT previously printed,” “Appointments PREVIOUSly printed,” or “All appointments” and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up/down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

9.3.2 Print Vessel Labels Using the Heads-up Display

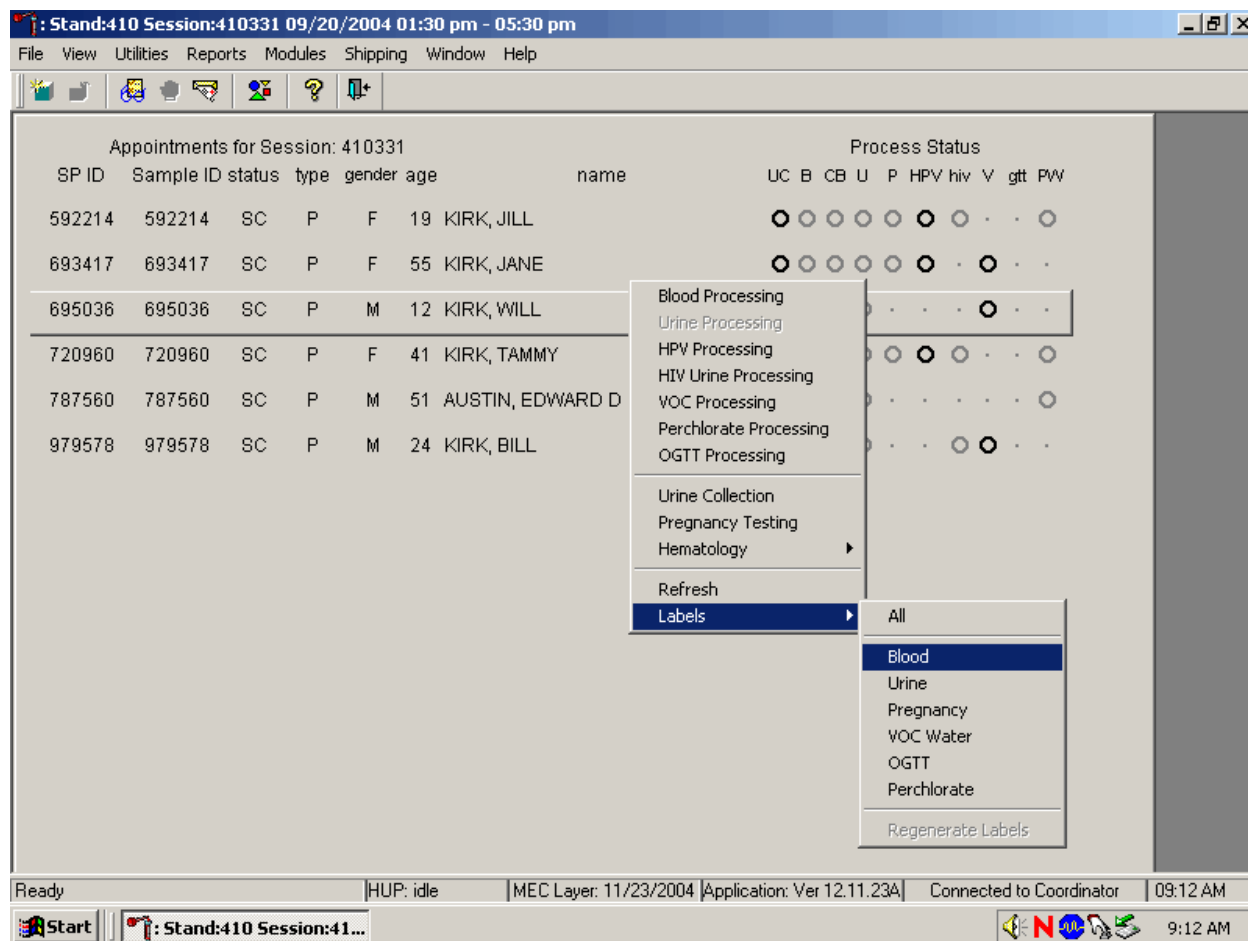
Print labels for a particular SP using the heads-up display. Print labels for all modules or for a specific module.

Print vessel labels for all modules for one SP.



To print labels for all modules for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then to {All} and left click or use the mouse to direct the mouse arrow to the correct SP, right click and type [L/I], [A/a]. Labels print in the label/ship area.

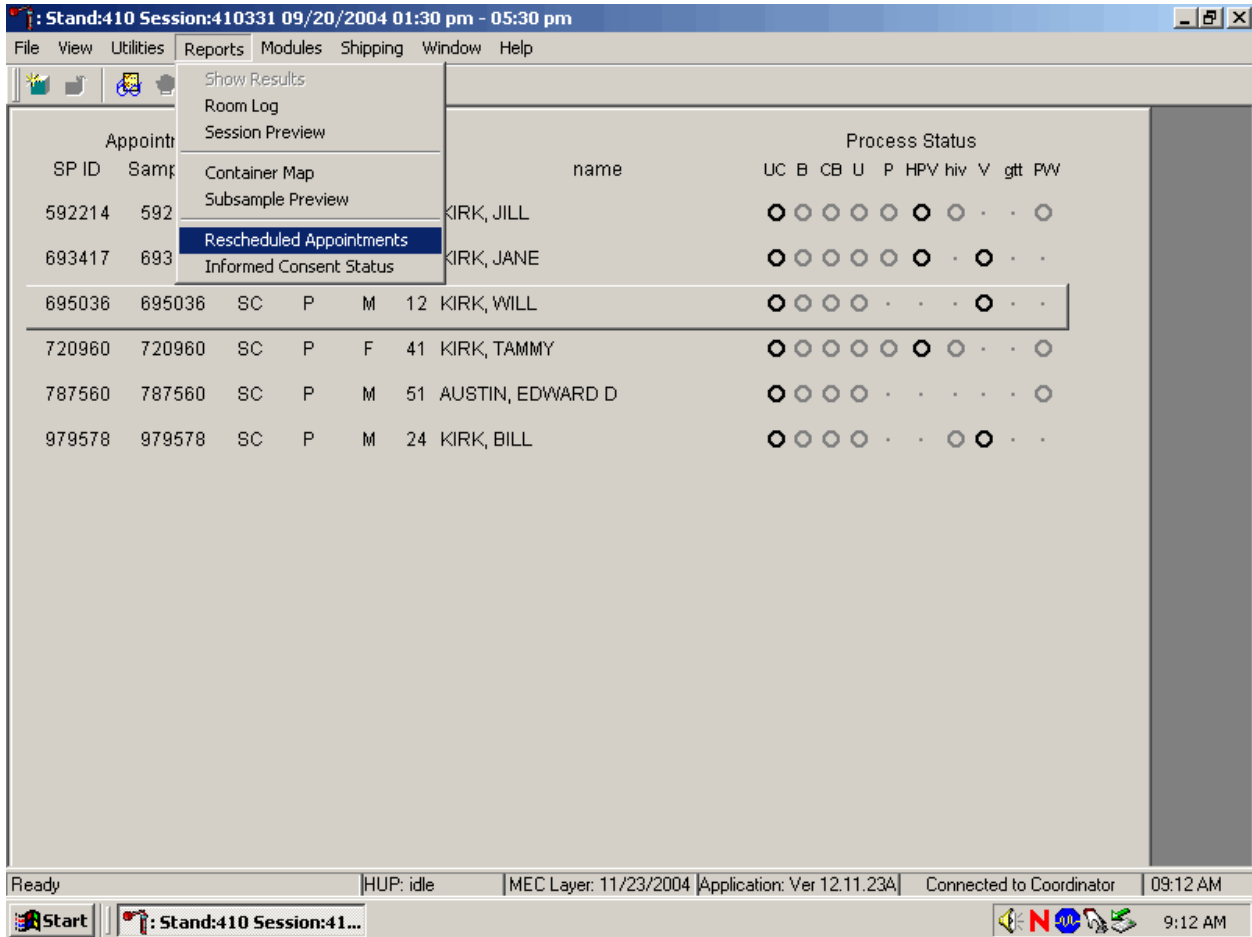
Print labels for one specific module for one SP in a MEC session using the heads-up display.



To print additional vessel labels for a particular SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then drag the arrow to {Blood}, {Urine}, {Pregnancy}, {VOC Water}, {OGTT}, or {Perchlorate} and right click. Alternatively, to print additional labels, use the mouse to direct the mouse arrow to the correct SP, right click, and type [L/l] and the appropriate letter of the module of interest. The labels print in the Label/Ship area.

9.3.3 Rescheduled Appointments Report

If the SP does not show up for a MEC exam, it is possible they will reschedule. Previously labeled vessels may be stored in individual zip closable bags. Do not store unused labels. At the beginning of each session, use the Rescheduled Appointments report to view a list of rescheduled SPs.



To access the Rescheduled Appointments report, use the mouse to direct the mouse arrow to {Reports} in the top menu bar, left click, drag the mouse arrow to {Rescheduled Appointments}, and left click or type [Alt] [R/r], [[R/r].

The Rescheduled Appointments report lists the rescheduled SPs.

Appointments for Session: 410331 Process Status

Rescheduled Appointments for Session 410331

| Sp Id | Last Name | First Name | MI |
|--------|-----------|------------|----|
| 787560 | AUSTIN | EDWARD | D |

Total Rescheduled: 1

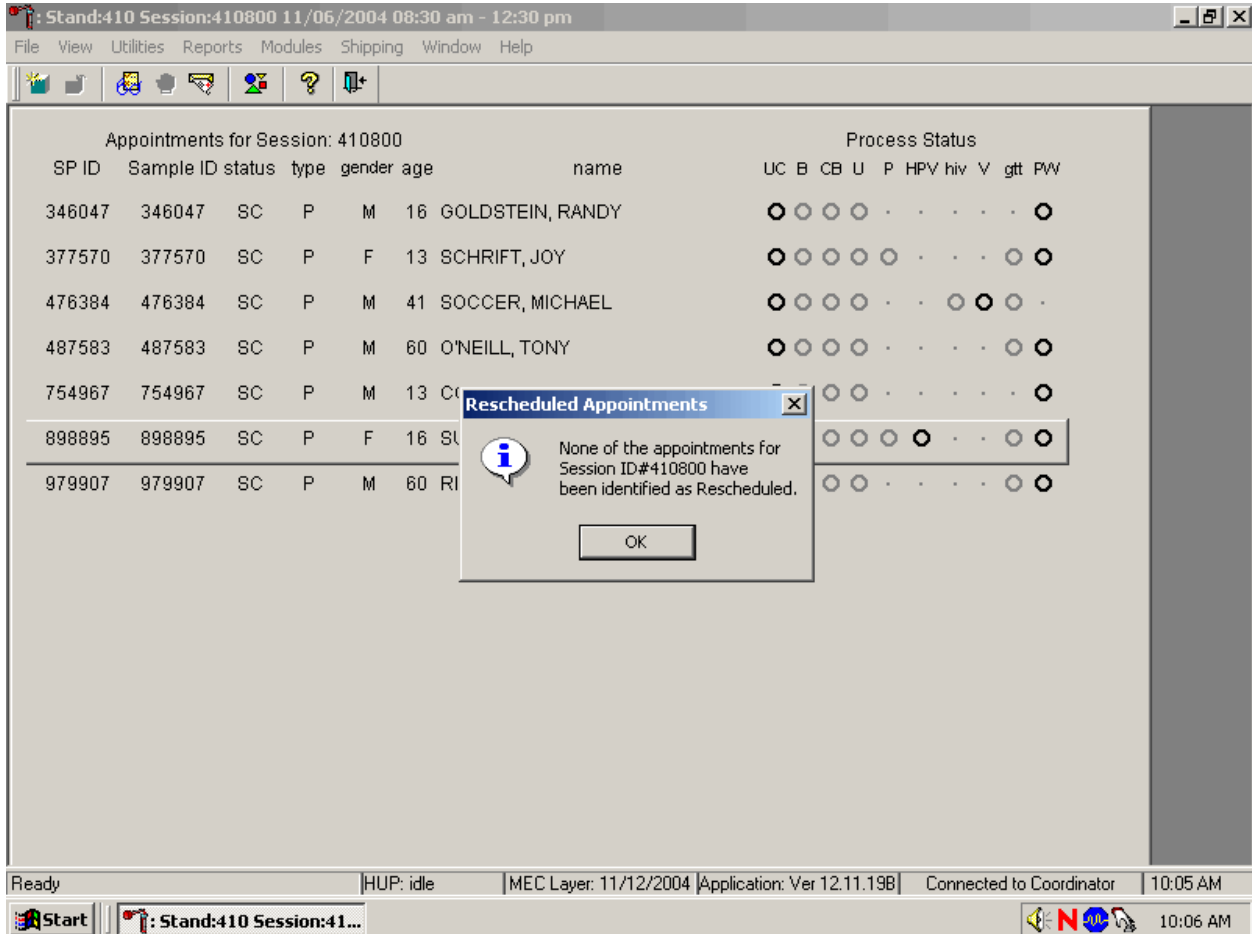
as of 24-Nov-2004 Page 1 of 1

Ready | HUP: idle | MEC Layer: 11/23/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 09:13 AM

Start | Stand:410 Session:41... | 9:13 AM

To close the report, use the mouse to direct the mouse arrow to the Close button and left click. To print the report, use the mouse to direct the mouse arrow to the Print button and left click.

The report may display a message text box indicating that no appointments have been rescheduled for the current session.



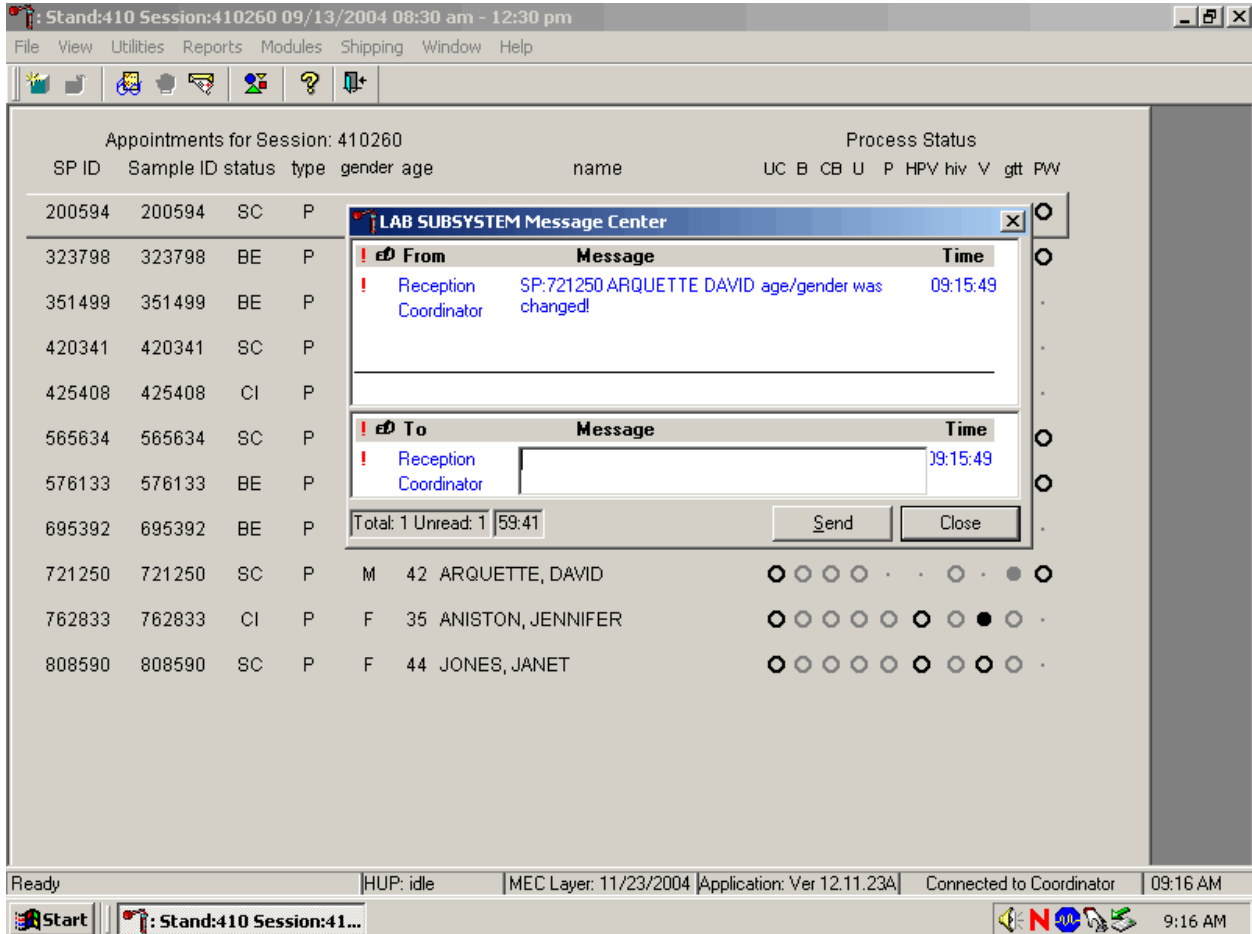
If no appointments have been rescheduled for the current session, the Rescheduled Appointments message text box displays the following message, “None of the appointments for Session IDXXXXXX have been identified as Rescheduled.” To remove the message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

9.4 Regeneration of Data

Processing protocols are SP specific and are based on the age and gender information obtained during the home interview. Protocols are also dependent on session times and appointment type. Labels are based on the SP's unique protocol. When a session is accessed for the first time, the laboratory record is generated. The application compares the profile for each SP when a session is subsequently opened by the coordinator.

If the age or gender information obtained during the home interview is incorrect, or the session time or appointment type changes, the processing protocol may be affected. If the incorrect information is corrected before labels are generated, no action is necessary. If the incorrect information is corrected after the labels have been printed and the SP's profile changes, the color of the SP's row on the heads-up display turns red. The SP's data must be regenerated to correct the protocol and the record in the database.

If the coordinator changes an SP's age and/or the gender, a message center text box displays on all three laboratory terminals.



Review the information. To send a response to the coordinator, type the text of the response into the lower Message text box, use the mouse to direct the mouse arrow to the Send button, and left click, or type [S/s]. To close the Message Center text box without responding to the message, use the mouse to direct the mouse arrow to the Close button and left click, type [C/c], or select [Enter].

Refresh the SP to initiate the regeneration process.

Stand:410 Session:411051 12/01/2004 01:30 pm - 05:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 411051

| SP ID | Sample ID | status | type | gender | age | | | | | | | | | | | | | | |
|--------|-----------|--------|------|--------|-----|------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 228032 | 228032 | CI | P | M | 16 | JAY, CHRISTOPHER | | | | | | | | | | | | | |
| 237466 | 237466 | SC | P | M | 35 | JAY, DAVID | | | | | | | | | | | | | |
| 252744 | 252744 | BE | P | F | 65 | JAY, DENISE | | | | | | | | | | | | | |
| 559019 | 559019 | SC | P | M | 72 | JAY, THOMAS | | | | | | | | | | | | | |
| 568910 | 568910 | BE | P | F | 14 | JAY, SAMANTHA | | | | | | | | | | | | | |
| 813081 | 813081 | BE | P | M | 15 | JAY, SAMUEL | | | | | | | | | | | | | |
| 827280 | 827280 | CI | P | F | 15 | JAY, MARINA | | | | | | | | | | | | | |
| 930129 | 930129 | BE | P | F | 22 | JAY, LAURIE | | | | | | | | | | | | | |

Process Status

B CB U P HPV hiv V gtt PW

- Blood Processing
- Urine Processing
- HPV Processing
- HIV Urine Processing
- VOC Processing
- Perchlorate Processing
- OGTT Processing
- Urine Collection
- Pregnancy Testing
- Hematology
- Refresh**
- Labels

recalculate this individual's profile | HUP: idle | MEC Layer: 11/12/2004 | Application: Ver 12.11.19B | Connected to Coordinator | 10:14 AM

Start | Stand:410 Session:41... | 10:14 AM

To refresh the SP, use the mouse to direct the mouse arrow to the SP's row on the heads-up display, right click, drag the mouse arrow to {Refresh}, and right click.

Regenerate the data for each MEC SP indicated in red on the heads-up display.

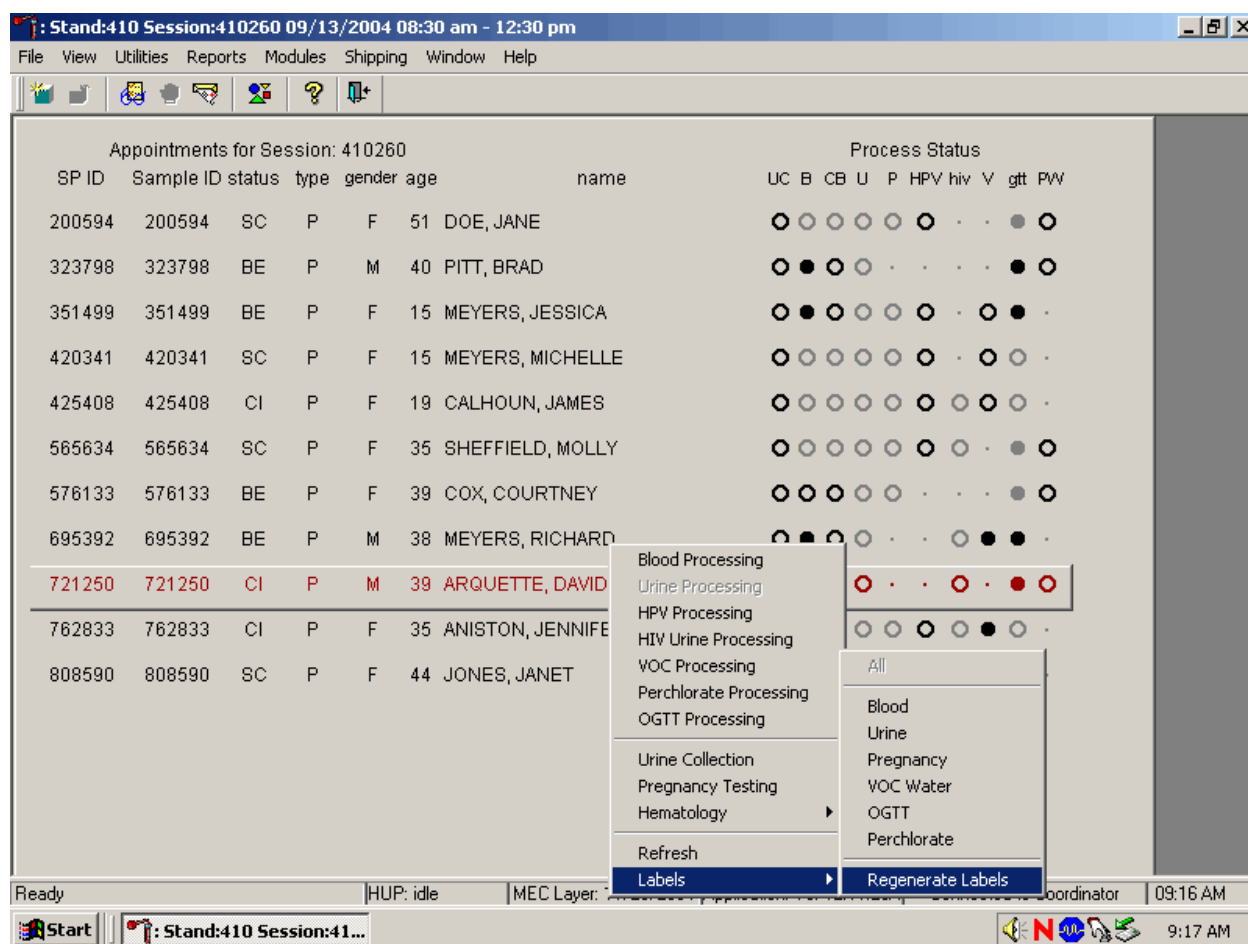
Appointments for Session: 410260

| SP ID | Sample ID | status | type | gender | age | name | Process Status | | | | | | | | | | | | | | |
|--------|-----------|--------|------|--------|-----|-------------------|----------------|---|----|---|---|-----|-----|---|-----|----|---|---|---|---|---|
| | | | | | | | UC | B | CB | U | P | HPV | hiv | V | glt | PW | | | | | |
| 200594 | 200594 | SC | P | F | 51 | DOE, JANE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 323798 | 323798 | BE | P | M | 40 | PITT, BRAD | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 351499 | 351499 | BE | P | F | 15 | MEYERS, JESSICA | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 420341 | 420341 | SC | P | F | 15 | MEYERS, MICHELLE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 425408 | 425408 | CI | P | F | 19 | CALHOUN, JAMES | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 565634 | 565634 | SC | P | F | 35 | SHEFFIELD, MOLLY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 576133 | 576133 | BE | P | F | 39 | COX, COURTNEY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695392 | 695392 | BE | P | M | 38 | MEYERS, RICHARD | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 721250 | 721250 | CI | P | M | 39 | ARQUETTE, DAVID | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 762833 | 762833 | CI | P | F | 35 | ANISTON, JENNIFER | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 808590 | 808590 | SC | P | F | 44 | JONES, JANET | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Ready | HUP: idle | MEC Layer: 11/23/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 09:16 AM

Do not process the SP's specimens if the line on the heads-up display is red.

Select the correct SP and regenerate the data.



To regenerate the data for the SP, drag the mouse arrow to the SP's row, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and left click. Alternatively, use the up and down keys to move up and down the list until the correct SP is selected or highlighted, right click, drag the mouse arrow to {Labels}, then to {Regenerate Labels}, and right click.

Respond to the question in the window.

Appointments for Session: 410260

| SP ID | Sample ID | status | type | gender | age | name | UC | B | CB | U | P | HPV | hiv | V | gtt | PW |
|--------|-----------|--------|------|--------|-----|-----------------|----------------------------------|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|----------------------------------|----------------------------------|----------------------------------|
| 200594 | 200594 | SC | P | F | 51 | DOE, JANE | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 323798 | 323798 | BE | P | M | 40 | PITT, BRAD | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> |
| 351499 | 351499 | BE | P | F | 15 | MEYERS, JESSICA | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 420341 | 420341 | SC | P | | | | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 425408 | 425408 | CI | P | | | | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 565634 | 565634 | SC | P | | | | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> |
| 576133 | 576133 | BE | P | | | | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> |
| 695392 | 695392 | BE | P | | | | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 721250 | 721250 | CI | P | | | | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input checked="" type="radio"/> |
| 762833 | 762833 | CI | P | | | | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 808590 | 808590 | SC | P | F | 44 | JONES, JANET | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Data Regen for Sample_ID 721250

Are you ready to print the following additional labels for their associated modules:

UP=>46
UC=>URXCOLL
PW=>103

* PLEASE NOTE * You are about to regenerate labels for an SP who did not have a complete set of labels printed originally. The new set of labels contains all labels in the new profile.

OK Cancel

Insert mec_exam_section 3 for module#8(CB) fr|HUP: regen | MEC Layer: 11/23/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 09:16 AM

Start | Stand:410 Session:41... | 9:17 AM

Review the question, follow the instructions, and respond to the question. To respond affirmatively to the message, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel the action, use the mouse to direct the mouse arrow to the Cancel button and left click.

New labels print for vessels that are in addition to the existing vessels. If an incomplete set of labels has been printed, then a complete set of all labels print.

Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Appointments for Session: 410260

| SP ID | Sample ID | status | type | gender | age | name | Process Status | | | | | | | | | |
|--------|-----------|--------|------|--------|-----|-------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| | | | | | | | UC | B | CB | U | P | HPV | hiv | V | gtt | PW |
| 200594 | 200594 | SC | P | F | 51 | DOE, JANE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 323798 | 323798 | BE | P | M | 40 | PITT, BRAD | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 351499 | 351499 | BE | P | F | 15 | MEYERS, JESSICA | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 420341 | 420341 | SC | P | F | 15 | MEYERS, MICHELLE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 425408 | 425408 | CI | P | F | 1 | | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 565634 | 565634 | SC | P | F | 3 | | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 576133 | 576133 | BE | P | F | 3 | | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695392 | 695392 | BE | P | M | 3 | | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 721250 | 721250 | CI | P | M | 3 | | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 762833 | 762833 | CI | P | F | 35 | ANISTON, JENNIFER | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 808590 | 808590 | SC | P | F | 44 | JONES, JANET | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Ready | HUP: regen | MEC Layer: 11/23/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 09:16 AM

Start | Stand:410 Session:41... | 9:17 AM

The informational message text box displays and states, “Please make sure you remove the following vessels from their associated modules:” Discard (destroy) the vessels and labels indicated in the message. To respond affirmatively to the message, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter].

Allow the heads-up screen to update.

| Appointments for Session: 410260 | | | | | | | Process Status | | | | | | | | | |
|----------------------------------|-----------|--------|------|--------|-----|-------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| SP ID | Sample ID | status | type | gender | age | name | UC | B | CB | U | P | HPV | hiv | V | glt | PW |
| 200594 | 200594 | SC | P | F | 51 | DOE, JANE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 323798 | 323798 | BE | P | M | 40 | PITT, BRAD | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 351499 | 351499 | BE | P | F | 15 | MEYERS, JESSICA | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 420341 | 420341 | SC | P | F | 15 | MEYERS, MICHELLE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 425408 | 425408 | CI | P | F | 19 | CALHOUN, JAMES | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 565634 | 565634 | SC | P | F | 35 | SHEFFIELD, MOLLY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 576133 | 576133 | BE | P | F | 39 | COX, COURTNEY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695392 | 695392 | BE | P | M | 38 | MEYERS, RICHARD | ○ | ● | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 721250 | 721250 | CI | P | M | 39 | ARQUETTE, DAVID | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 762833 | 762833 | CI | P | F | 35 | ANISTON, JENNIFER | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 808590 | 808590 | SC | P | F | 44 | JONES, JANET | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |


Ready | HUP: idle | MEC Layer: 11/23/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 09:18 AM


Allow the heads-up display to update before proceeding. After the screen updates, the color of the SP's row changes from red to black.

9.5 Create New Container Labels

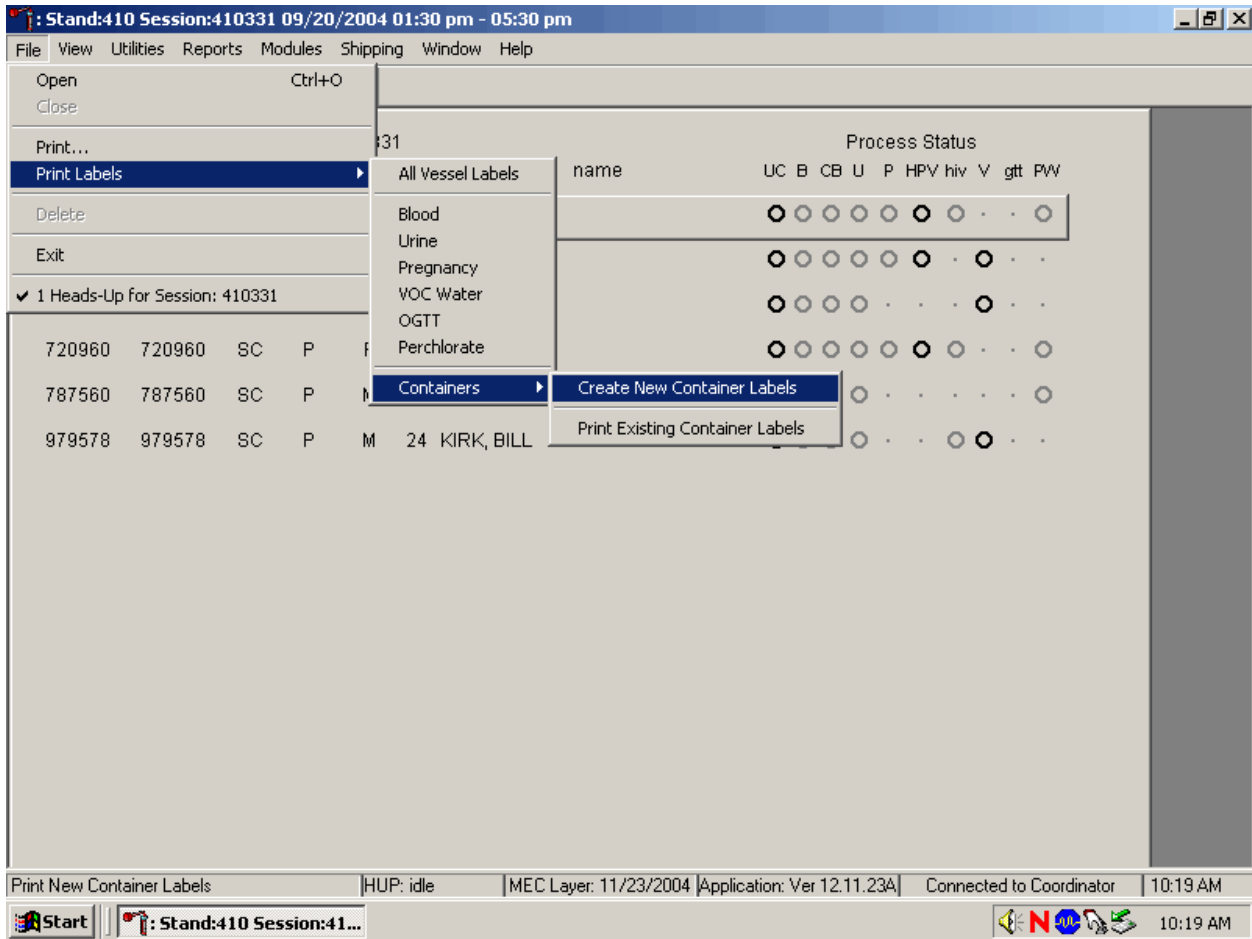
Store processed vessels and biological samples in boxes and bags (containers). Print and assign container labels using the {Create New Container Labels} module. Once a label has been created, the container is designated as “open” in the database; it is available for slot assignments as vessels are marked as filled.

At the beginning of each stand, print and assign one new container ID for each vessel using either the {Print} module or the {Shipping} module. Print additional labels as needed. Each stand is allocated a maximum of 999 labels. The actual container label will include the vessel name, vessel id, the size of the container (9x9 2-inch box, etc.), and the container number.

Chlam/GC (46)
5x5 3 inch box

410529

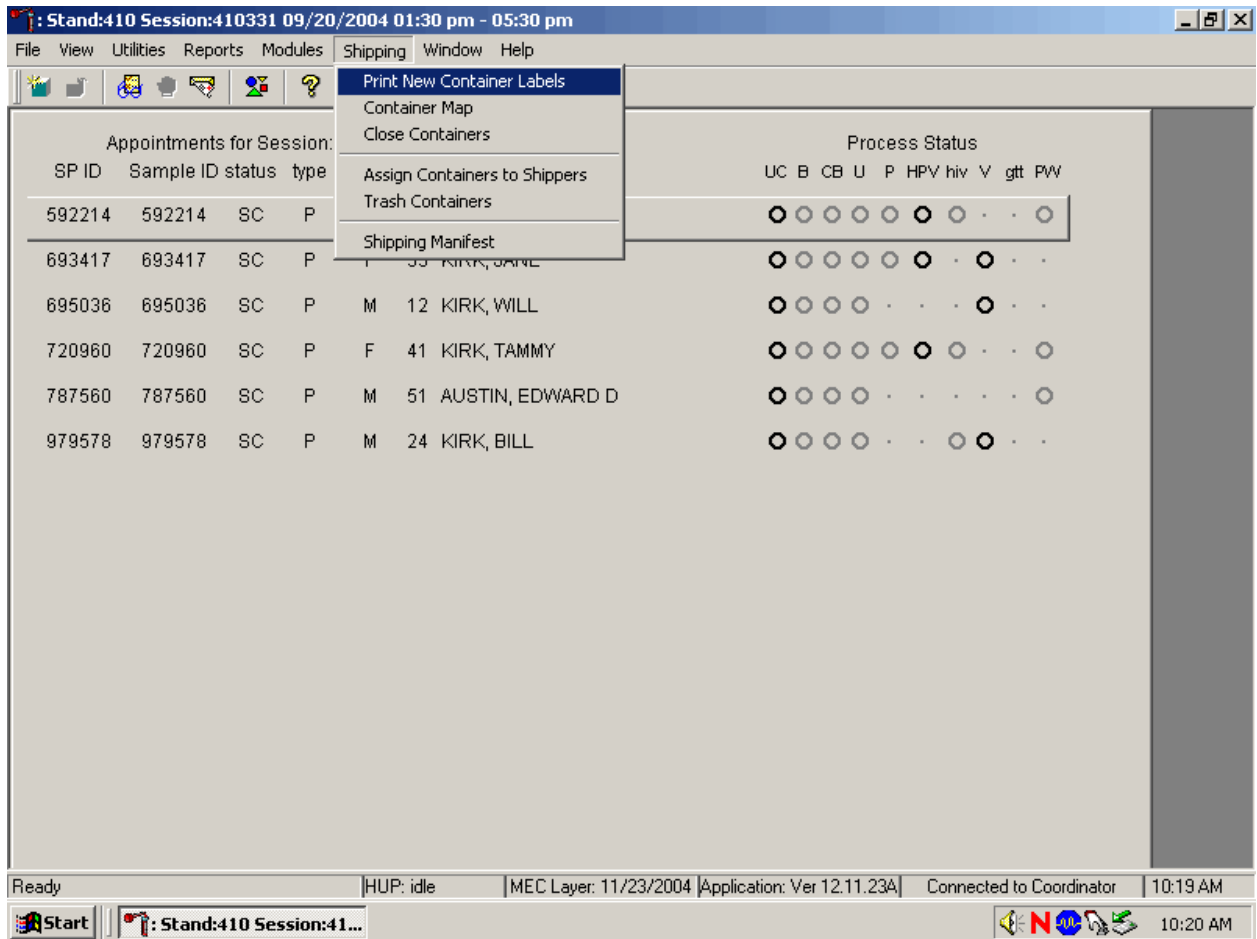
Prior Pest (48)
5x5 3 inch box

410530

Use one of the two locations within the laboratory application to print and assign new container ID numbers or labels. Print and assign new container ID numbers using the {Print Labels} module.



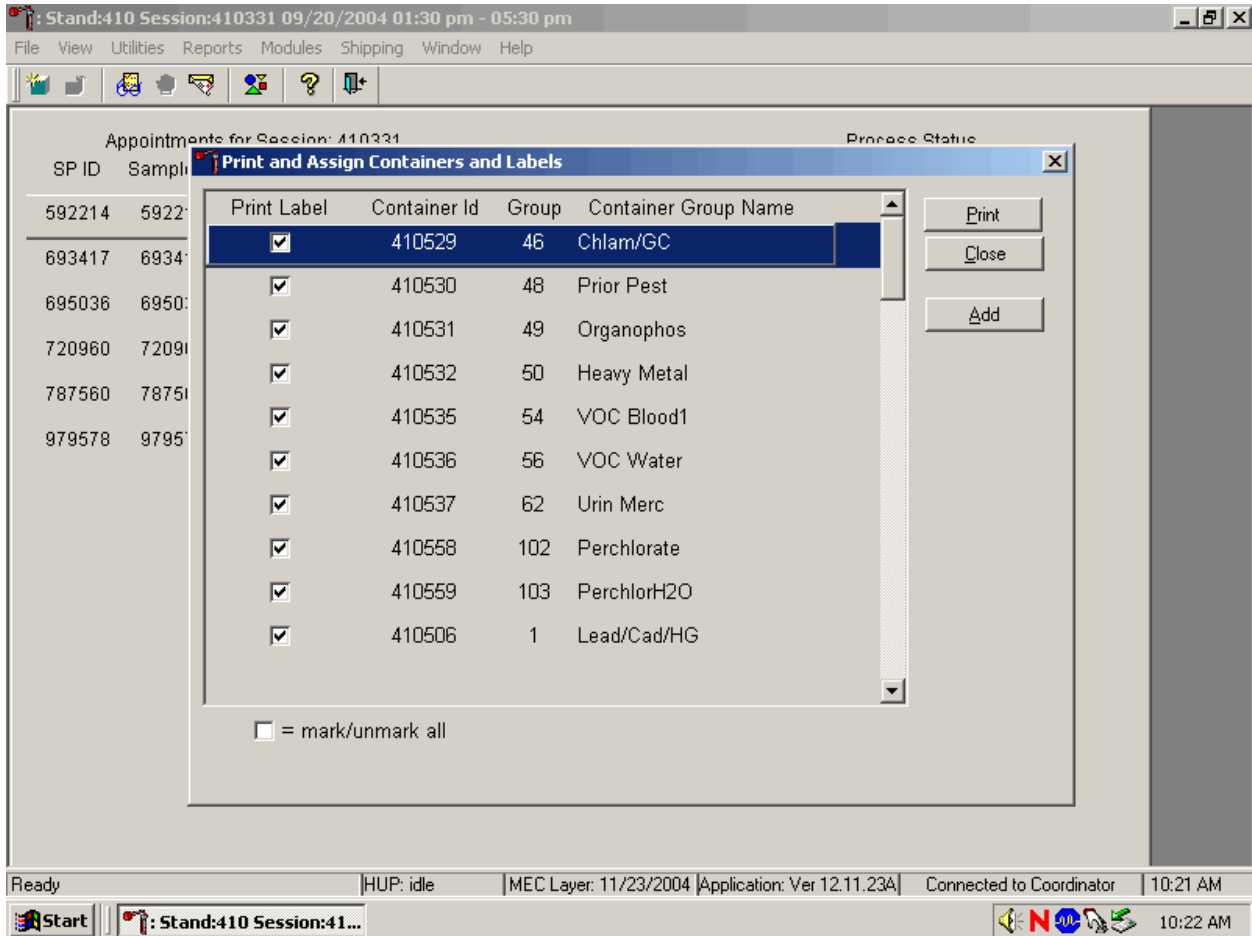
To print and assign new container ID numbers or labels using the {Print Labels} module, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, then drag the mouse arrow to {Print Labels}, {Containers}, {Create New Container Labels}, and left click or type [Alt] [F/f], [L/l], [C/c][C/c].

Print and assign new container ID numbers using the {Shipping} module.



To access the {Print New Container Labels} module, use the mouse to direct the mouse arrow to {Shipping} in the menu bar and left click, drag the mouse arrow to {Print New Container Labels}, and left click or type [Alt] [S/s], [P/p].

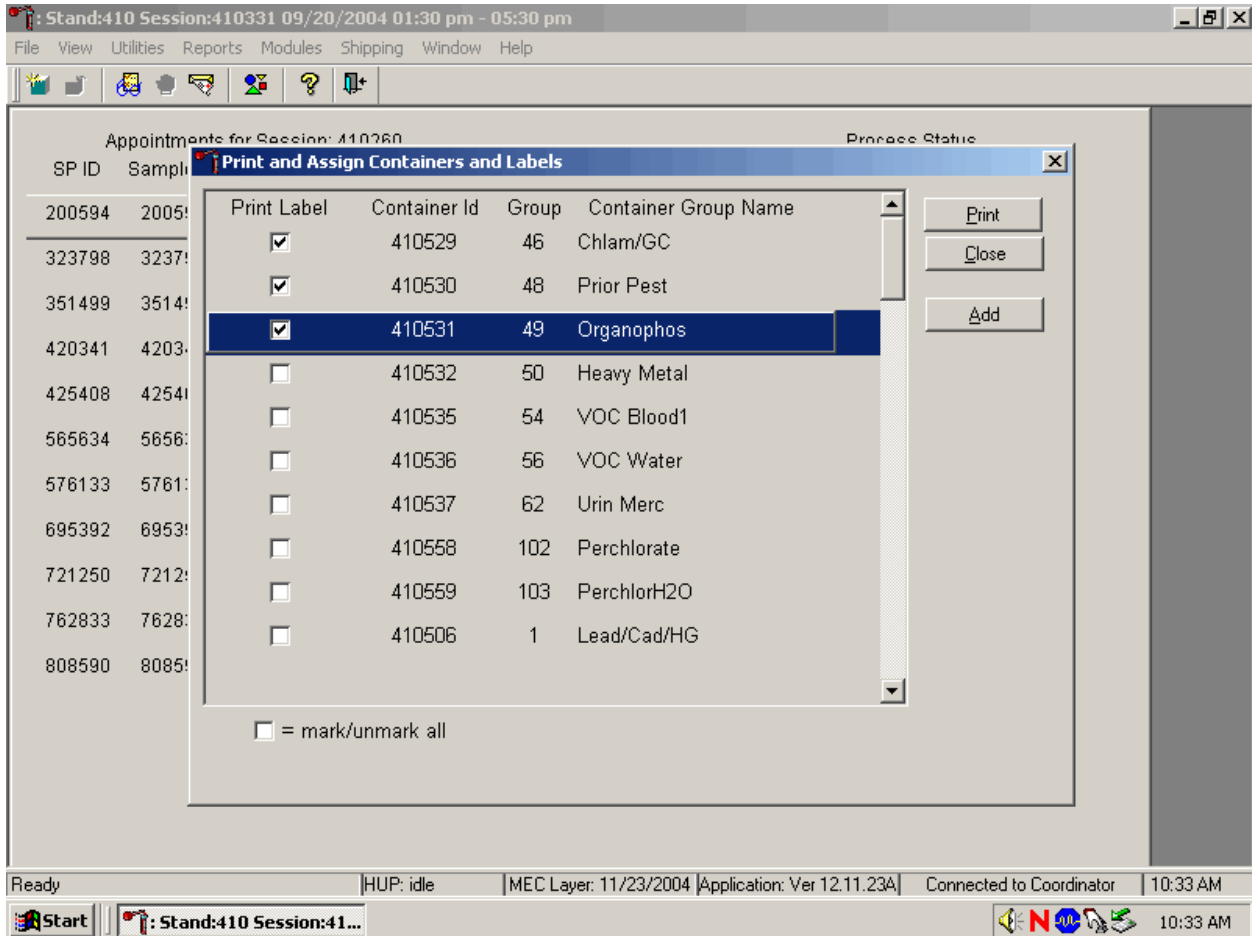
There are three instances when it is appropriate to use this module. At the start of each stand, create one new container label for each vessel ID or “group.” Use the same module to create a new label for a vessel after the last slot in an open container is filled. Use this module to print additional labels at any time.



The Print and Assign Containers and Labels window displays once the {Print New Container} module is accessed. The window includes check boxes to mark or identify specific groups, new Container Ids that are assigned to the Groups, the number of the Group, and the Container Group Name or vessel name. The Group and corresponding Container Group Name listed in this screen represent the Group where the container has been “closed” and a new label has not been created. This screen also includes a “mark/unmark all” check box and three buttons: Print, Close, and Add. Use the Print button to print the container labels, use the Close button to exit the module without printing any

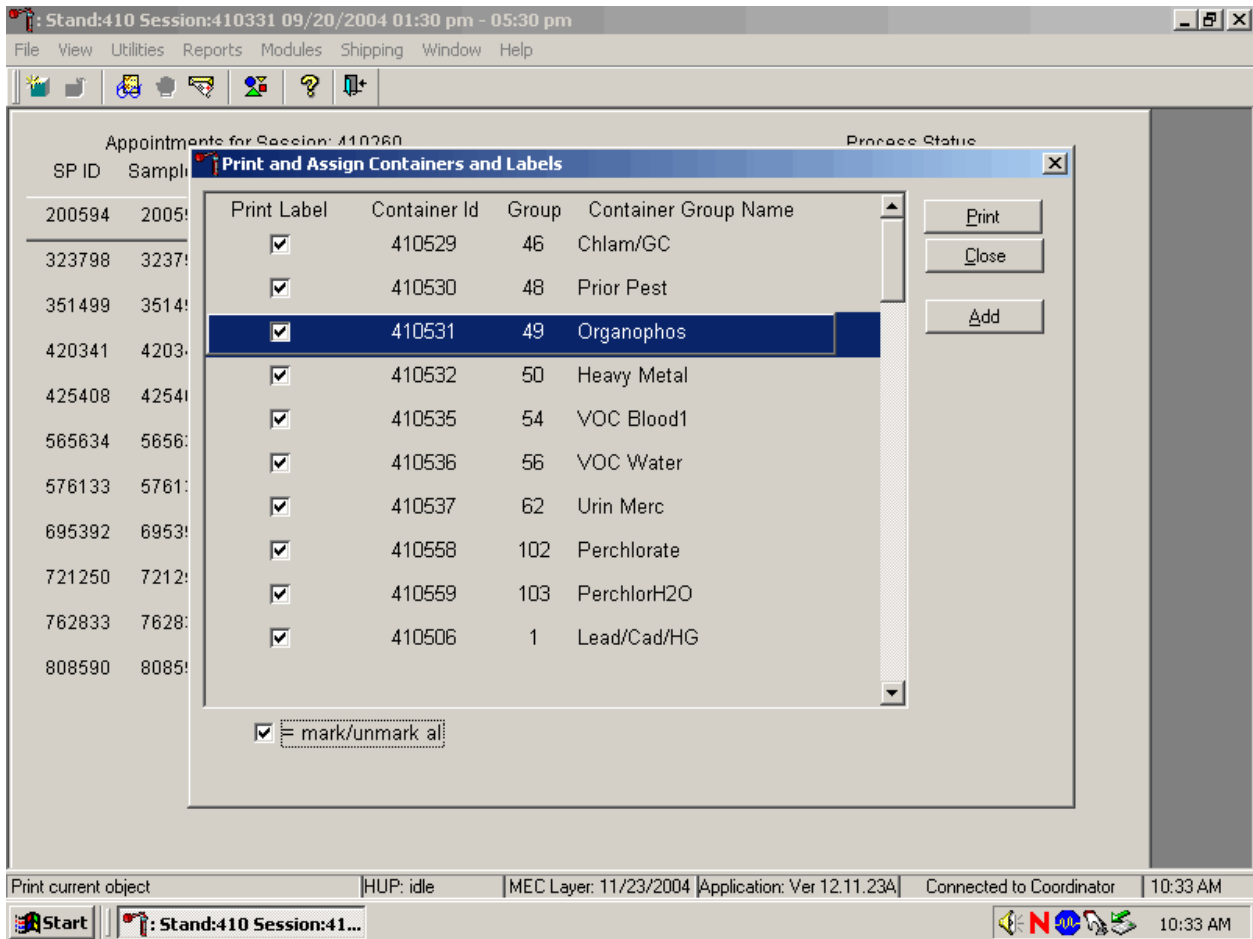
labels or assigning Container Ids to the Groups, and use the Add button to open another window that allows the user to add additional or multiple labels for any vessel.

Individually mark the Print Label check box to identify vessels that require labels.



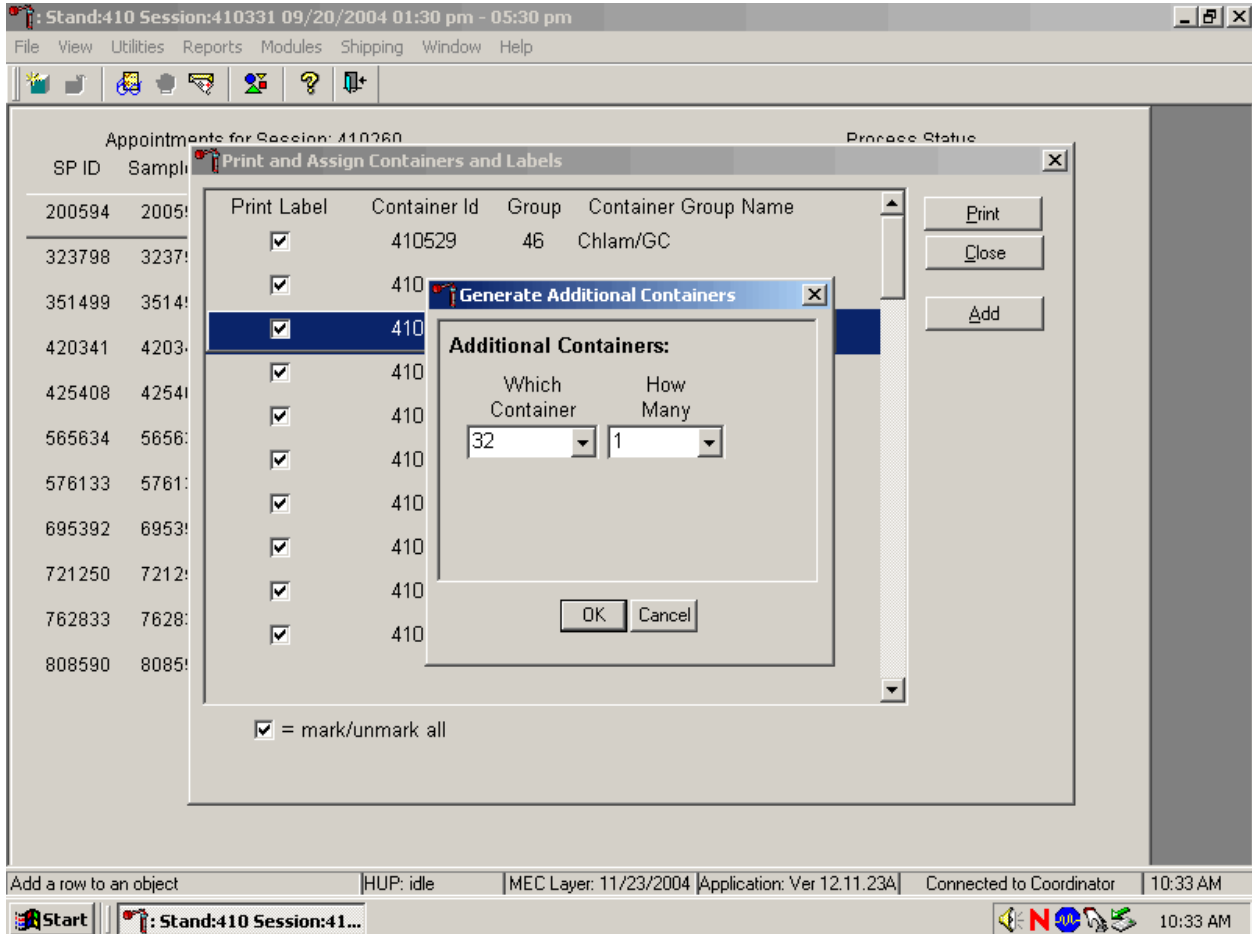
To begin the process of printing and assigning new Container Ids, mark the individual check boxes that correspond to the Group (vessel) of interest. To add a check mark to the Print Label check box, use the mouse to direct the mouse arrow to the Print Label check box and left click.

Collectively mark all the Print Label check boxes for all the Groups listed in the window.



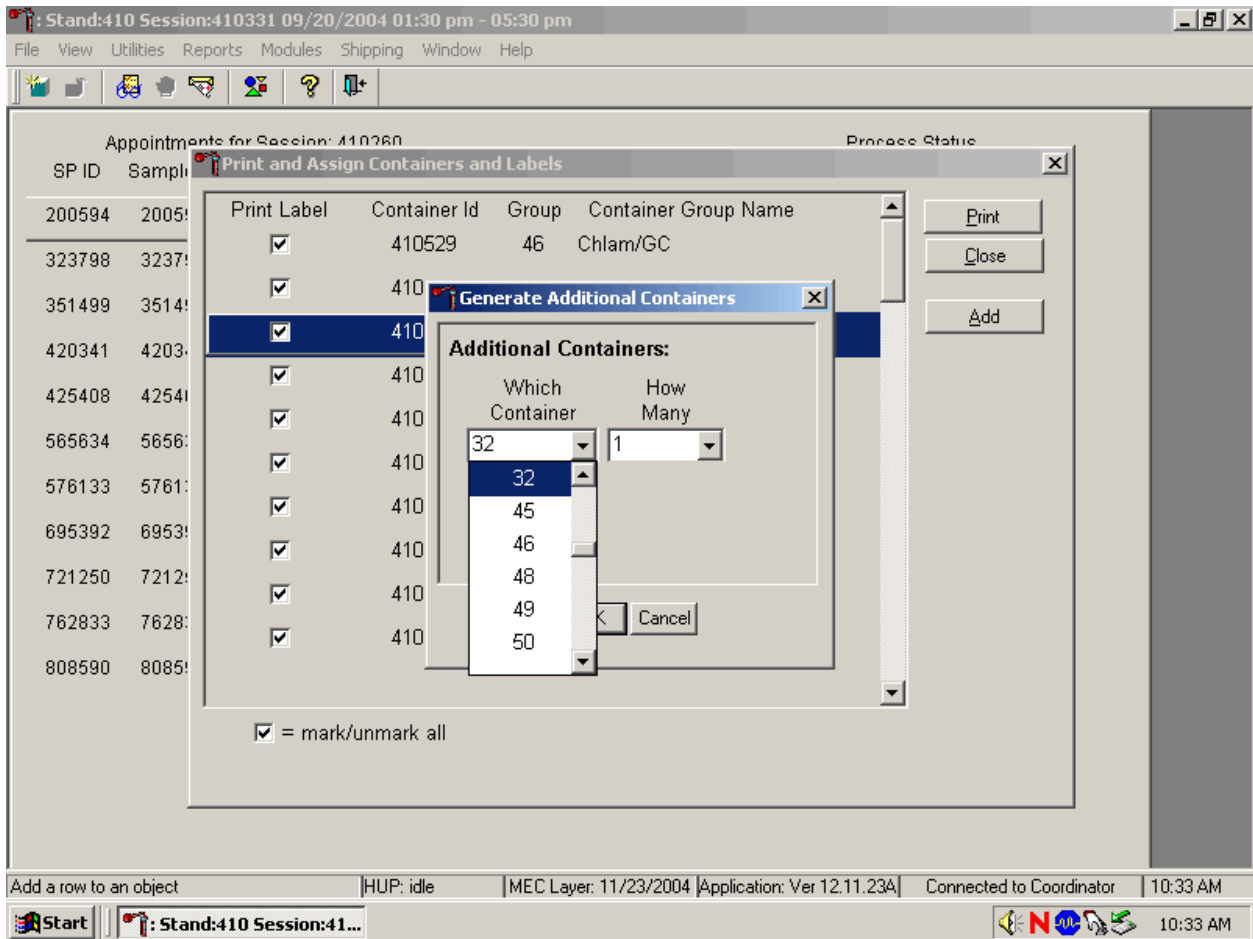
To collectively mark all the check boxes, use the mouse to direct the mouse arrow to the mark/unmark all check box and left click. To collectively unmark all the check boxes, use the mouse to direct the mouse arrow to the mark/unmark all check boxes and left click.

Access the Generate Additional Containers window to print additional labels for any Group at any time.



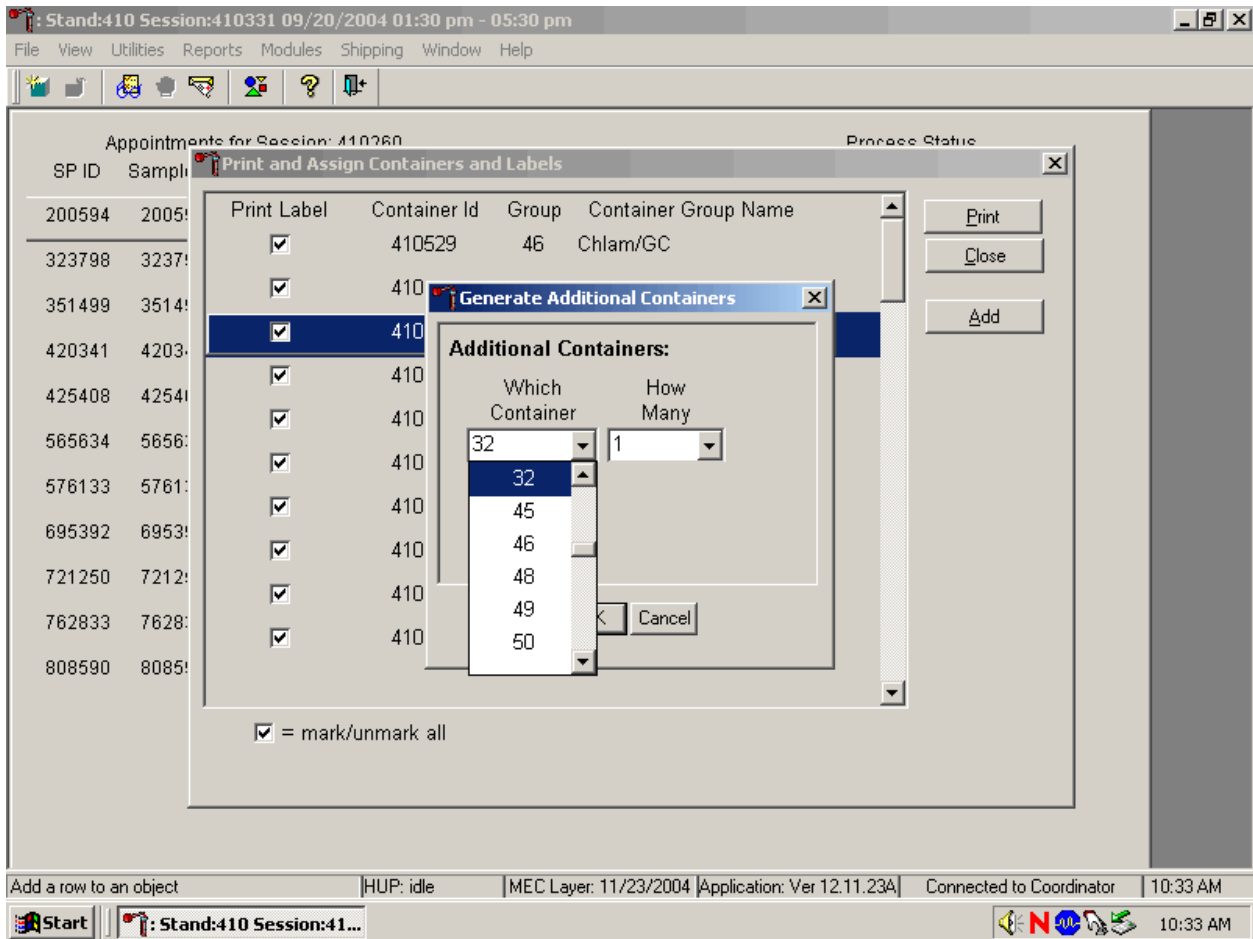
To access the Generate Additional Containers window, use the mouse to direct the mouse arrow to the Add button and left click, or type [Alt] [A].

The Generate Additional Containers window displays.



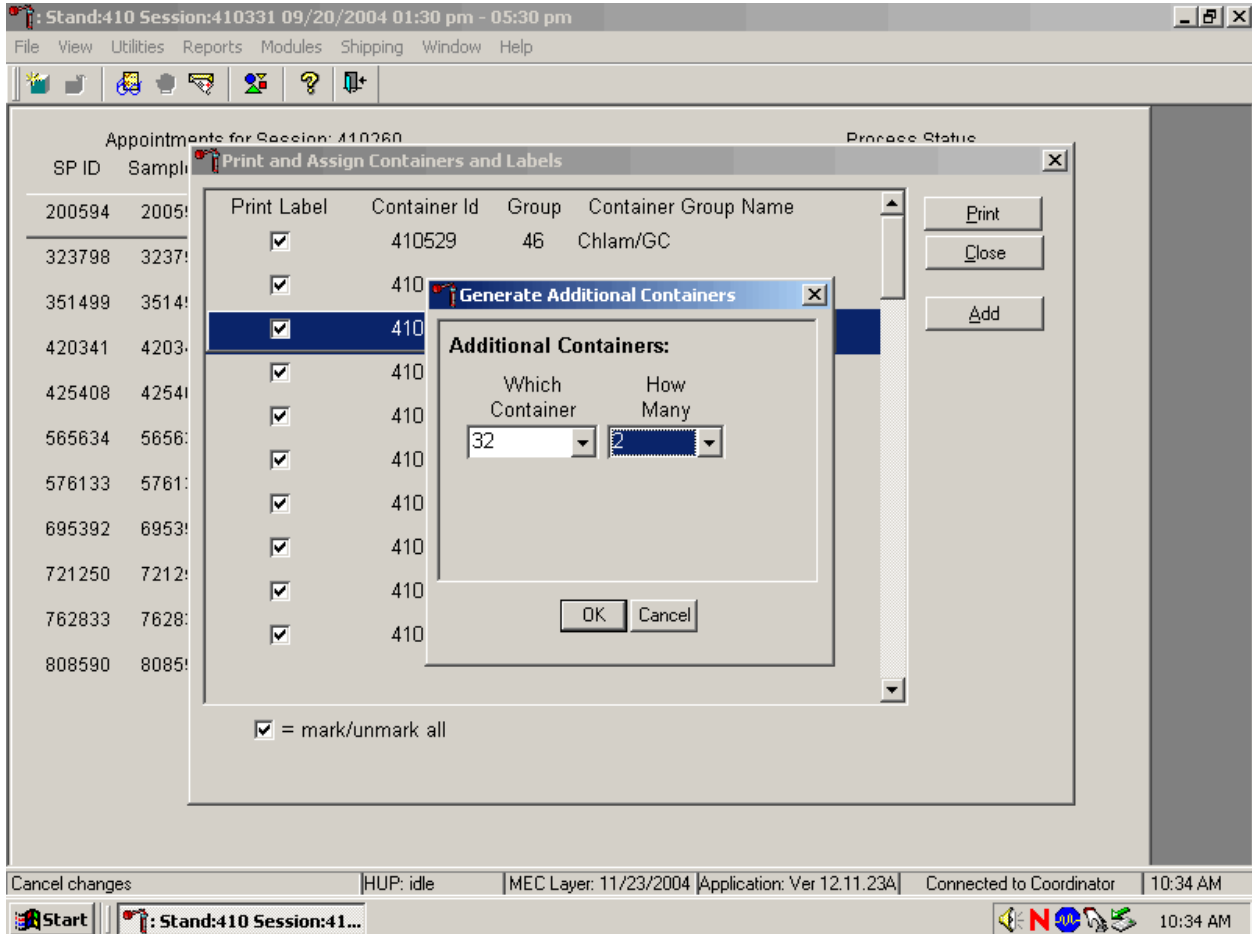
The Generate Additional Containers window includes two text boxes with drop-down lists: Which Container and How Many. The Which Container text box defaults to vessel 32. To select a vessel other than 32, use the mouse to direct the mouse arrow to the drop-down arrow and left click, drag the arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Select the number (1-5) of additional container labels.



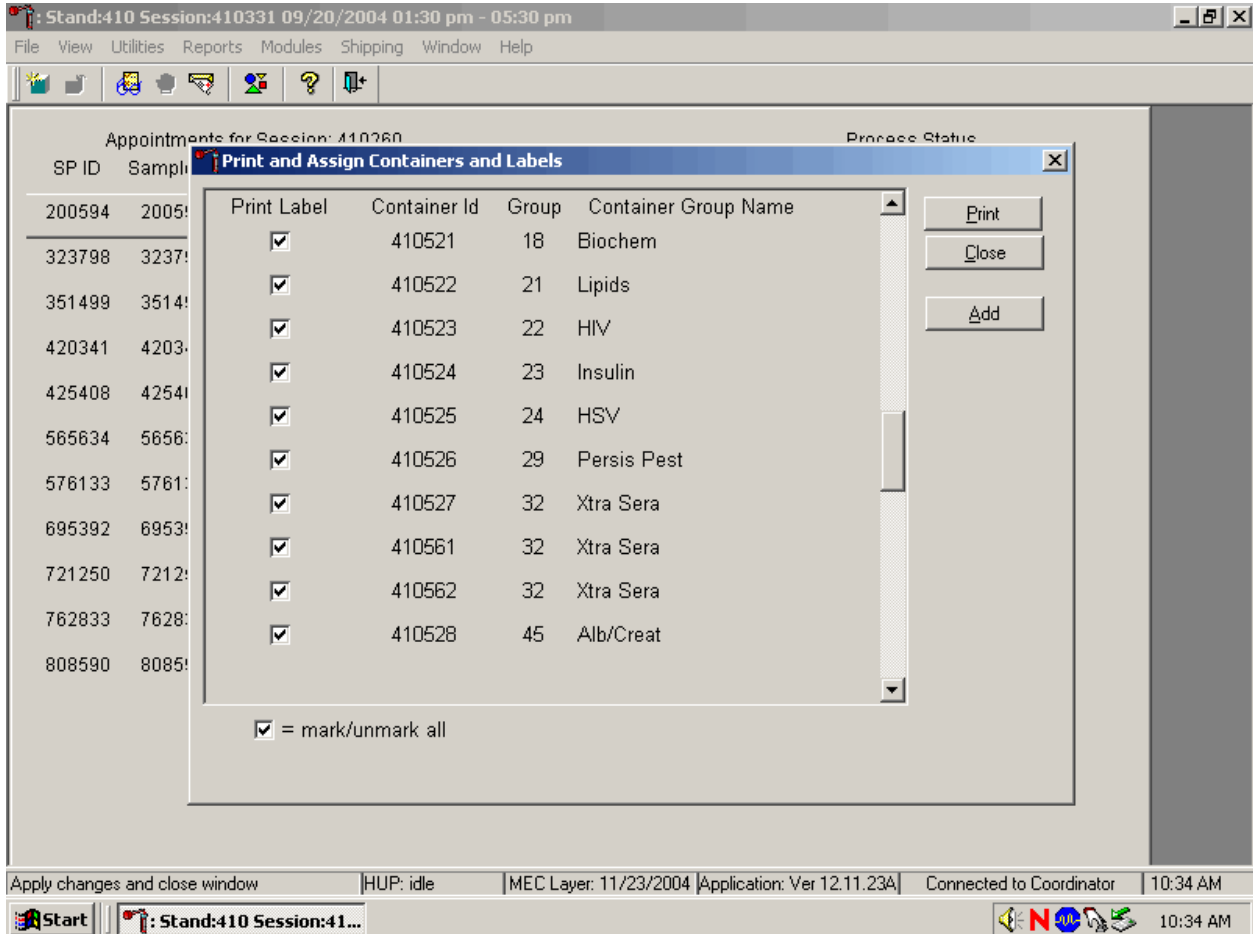
The How Many text box defaults to vessel 1. To select 2, 3, 4, or 5, use the mouse to direct the mouse arrow to the drop-down arrow and left click, then drag the arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Add these vessels to the Print and Assign Containers and Labels window or cancel the action.



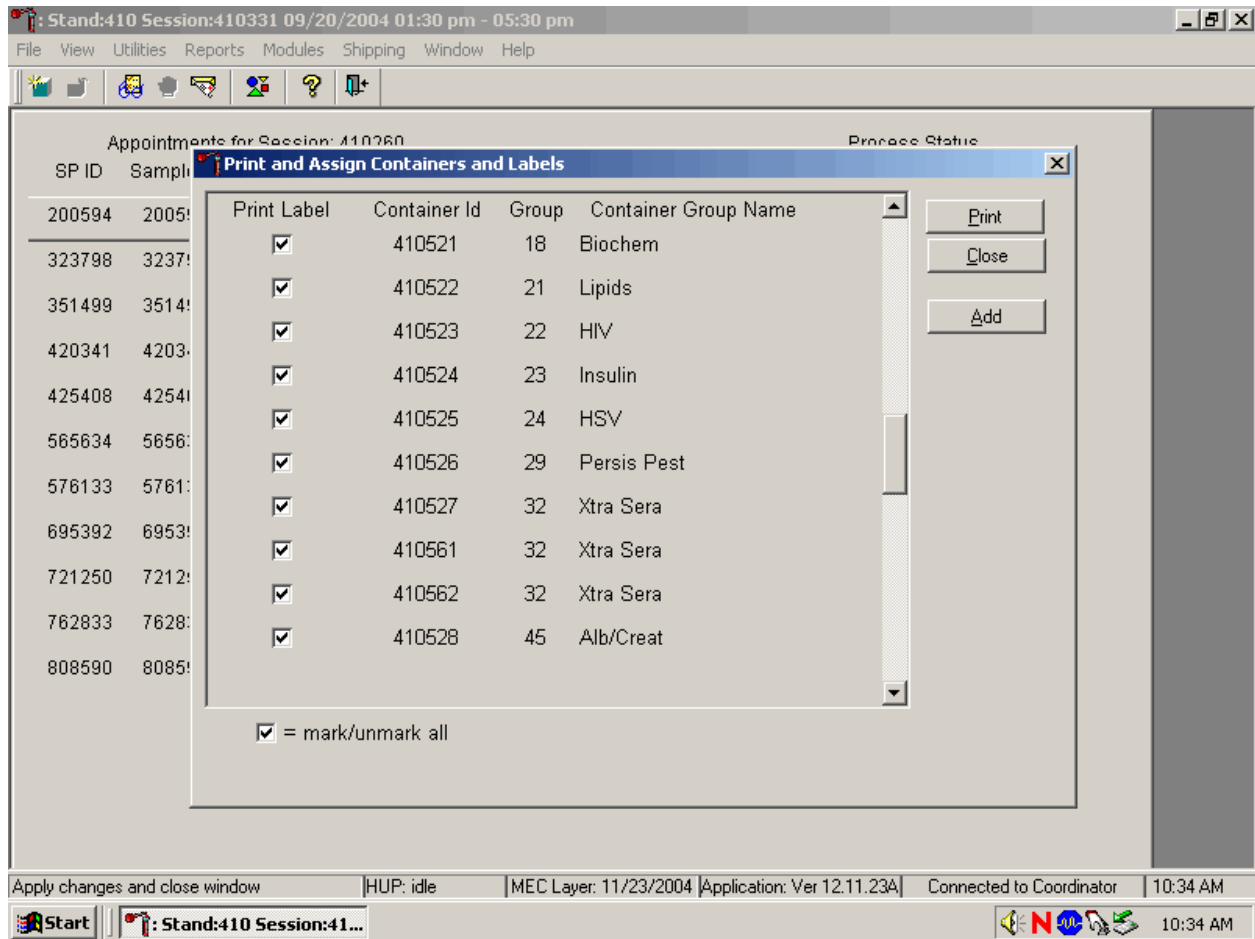
To accept the choices displayed in the Generate Additional Containers window, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter]. To close the window without creating a new container, use the mouse to direct the mouse arrow to the Cancel button and left click.

If the OK button is selected, then the containers are added to the Print and Assign Containers and Labels window.



Review the information on the screen.

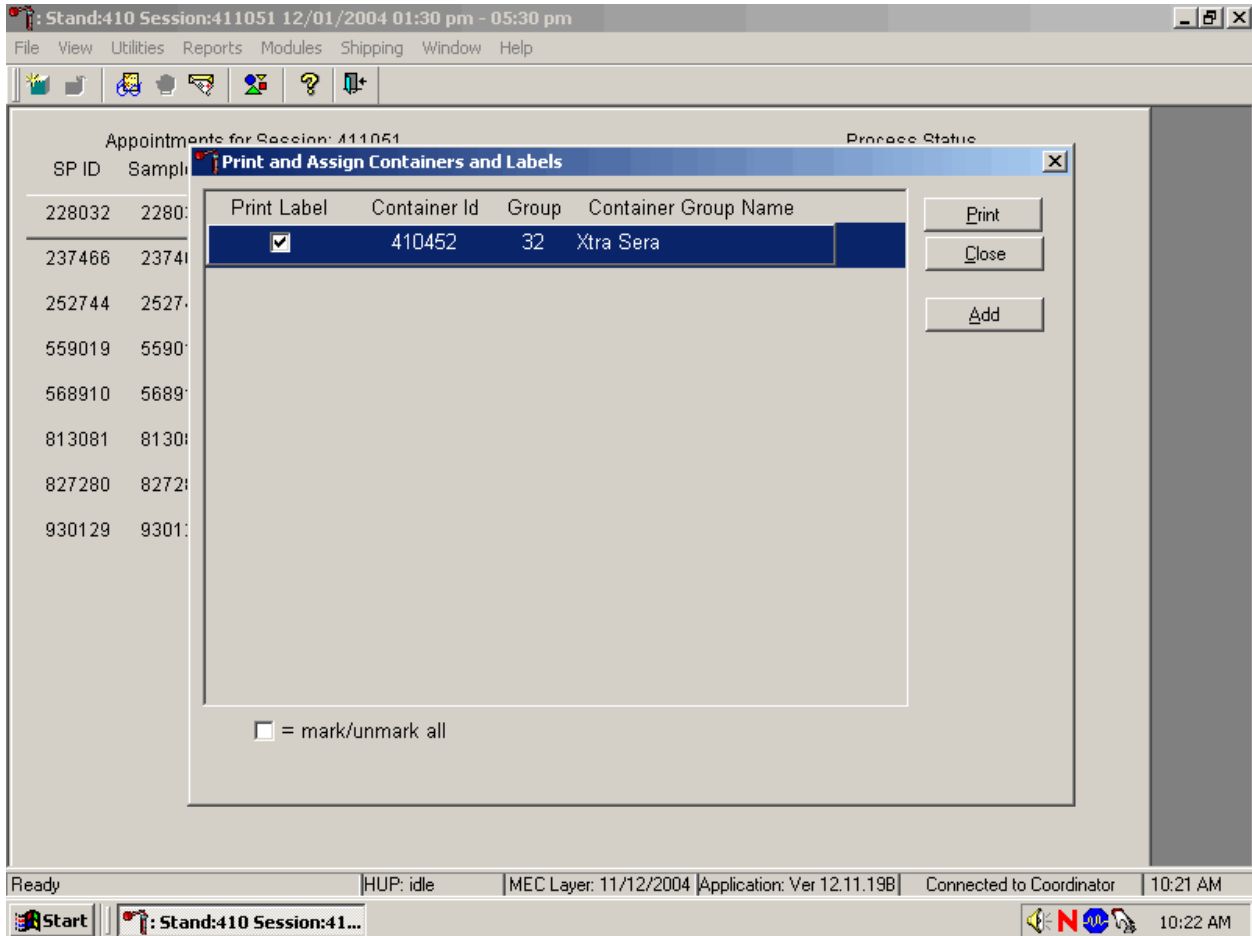
Complete the assignment process and print the labels.



After reviewing the screen, print the labels. To print the labels, use the mouse to direct the mouse arrow to the Print button and left click, or type [Alt] [P/p]. To exit the window without printing any labels, use the mouse to direct the mouse arrow to the Close button and left click, or type [Alt] [C/c].

Affix the container ID label(s) to the container(s) of the correct type.

When a container is full, the container will automatically “close” and the Print and Assign Containers and Labels window opens with that vessel displayed and the check mark prefilled. Alternatively, open a new container to replace the closed container by using the Print and Assign Containers and Labels window.

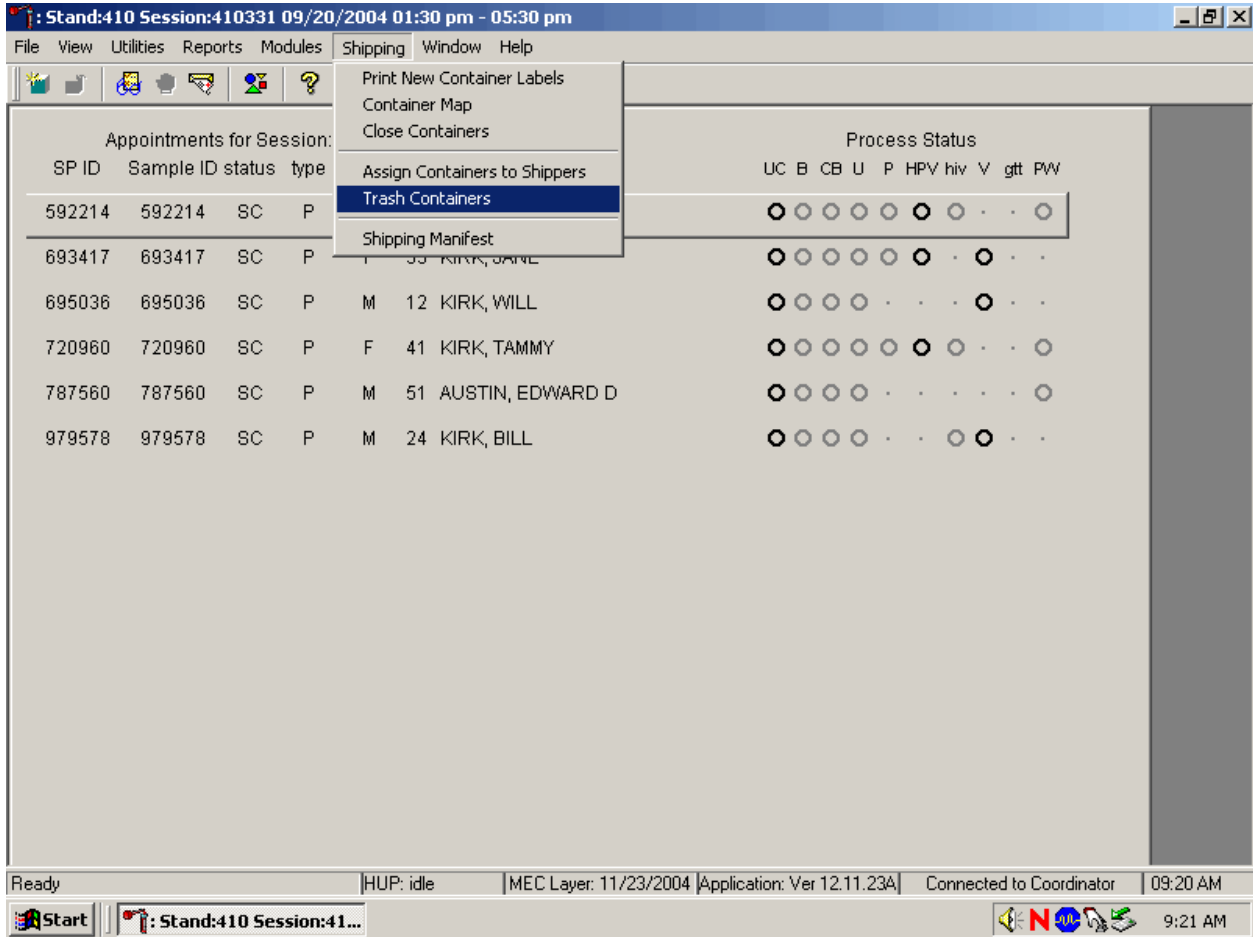


When a container is full, an opportunity to open a new container is automatically displayed on the “Print and Assign Container and Labels” window. Repeat the process of marking the check box and selecting the Print button.

9.6 Trash or Reprint Container Labels

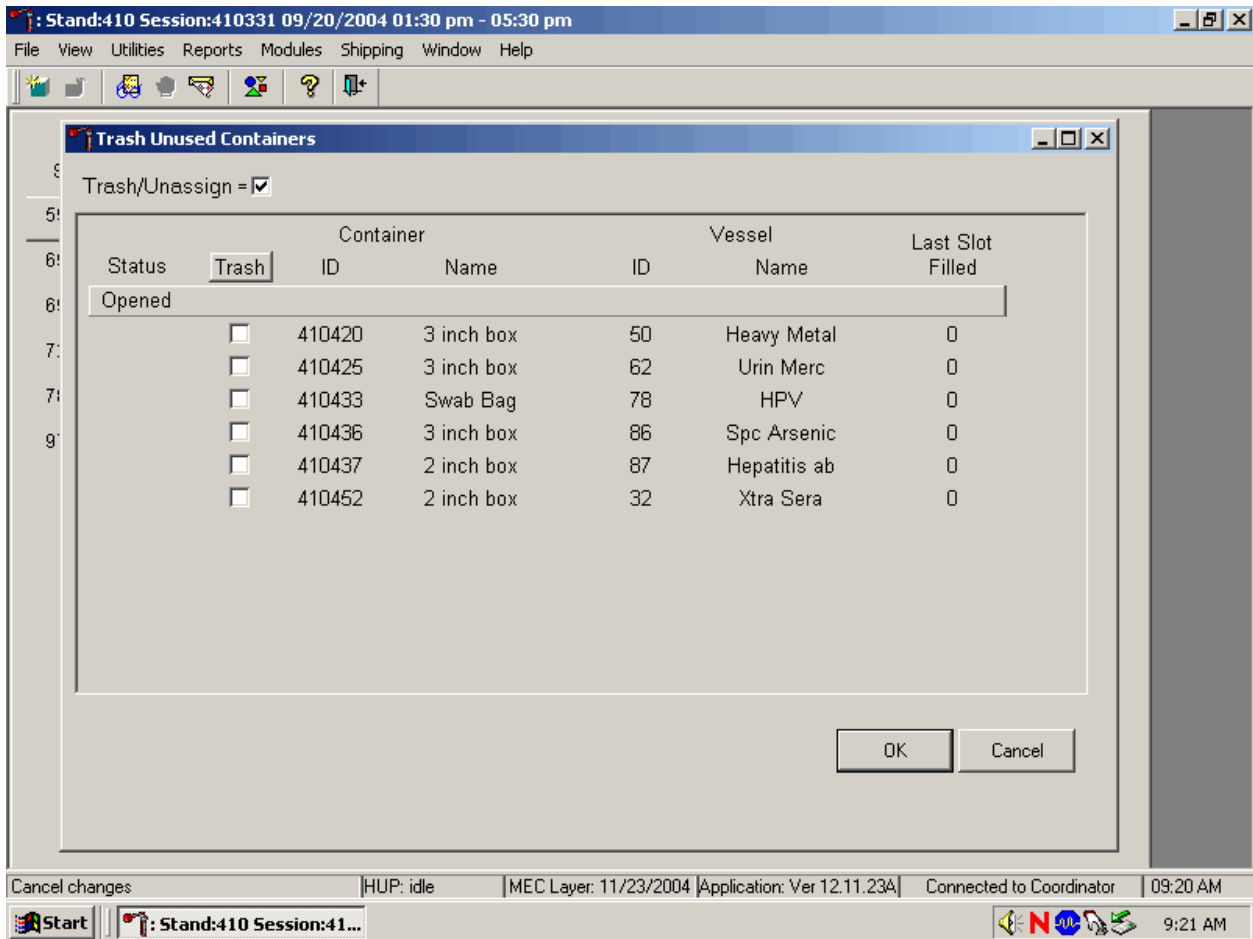
Each stand is allocated a maximum of 999 container IDs.

If unused container labels become lost or damaged, use the {Trash Container} module to delete the container IDs. Access the {Trash Containers} module.



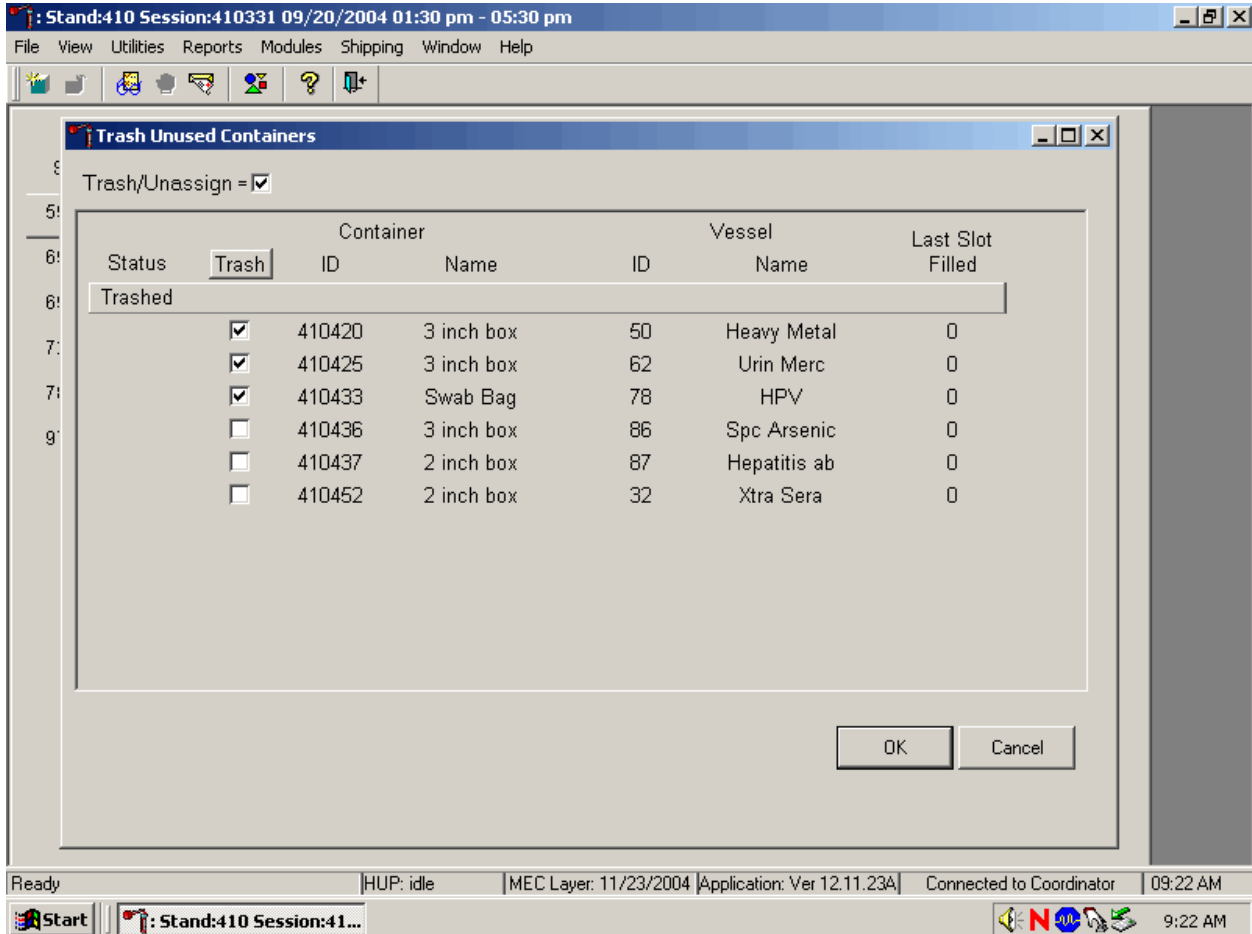
To access the {Trash Containers} module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the arrow to {Trash Containers}, and left click, or type [Alt] [S/s], [T/t].

The Trash Unused Containers window displays.



The status of each container ID is “Opened.” To individually mark the container IDs for deletion, use the mouse to direct the mouse arrow to the check boxes and individually left click on specific boxes or, to mark all outstanding container IDs for deletion, use the mouse to direct the mouse arrow to the Trash button and left click.

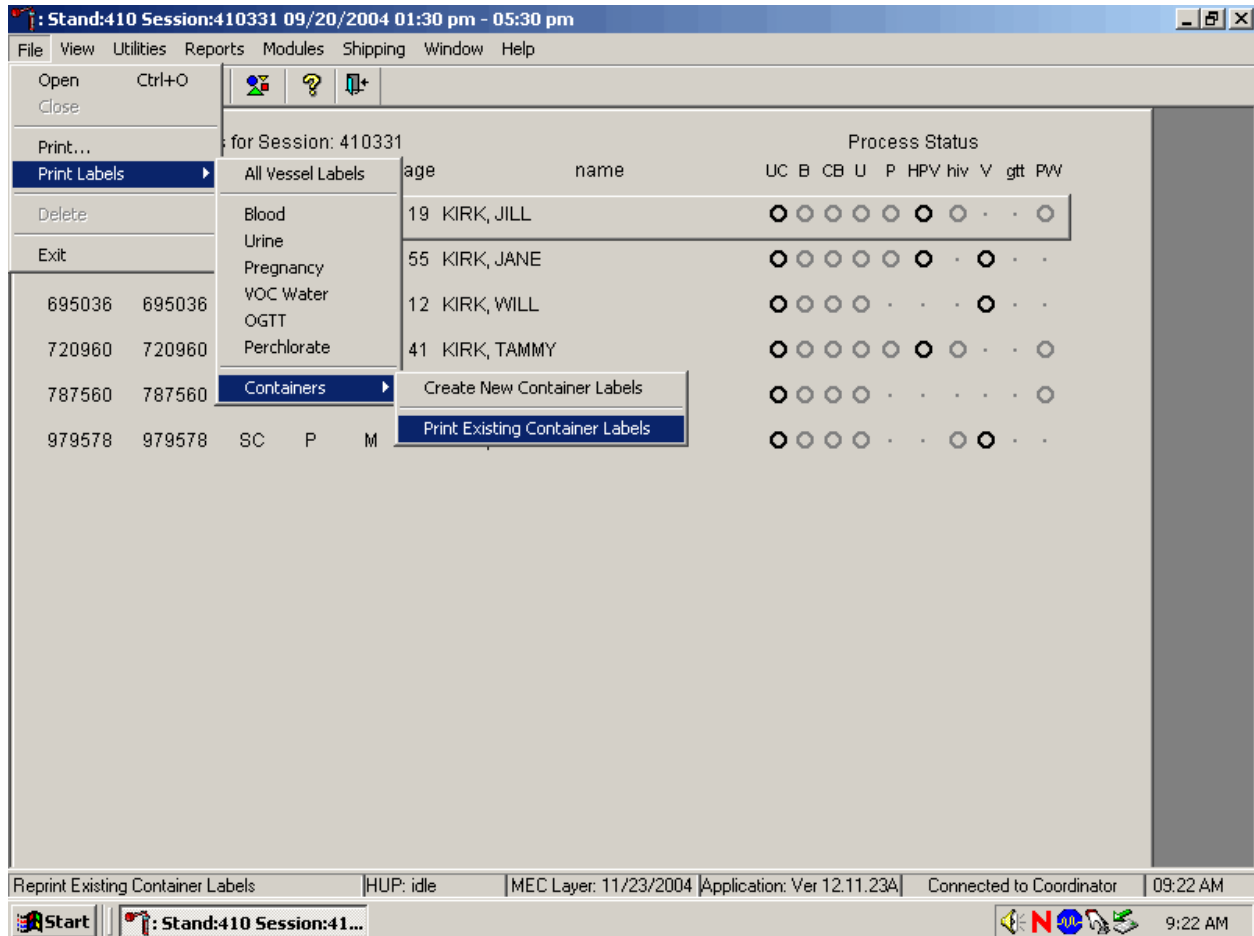
As the container IDs are marked for deletion, the status changes from “Opened” to “Trashed.”



To record these actions and execute the Trash Unused Containers function, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the {Trash Unused Containers} module without recording or executing the Trash Containers function, use the mouse to direct the mouse arrow to the Cancel button and left click.

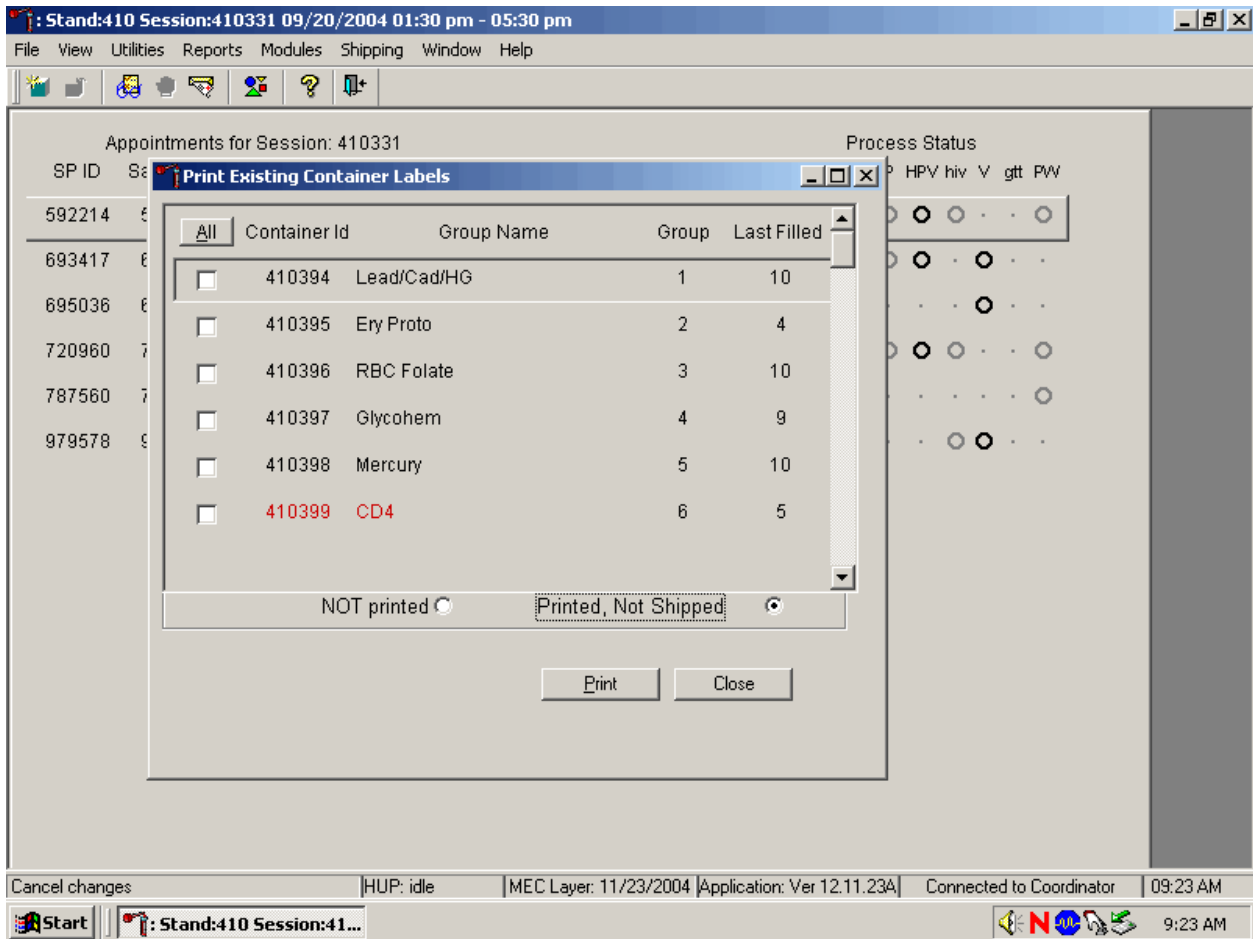
9.6.1 Reprint Container Labels for Existing Containers

Reprint labels for existing, not shipped containers.



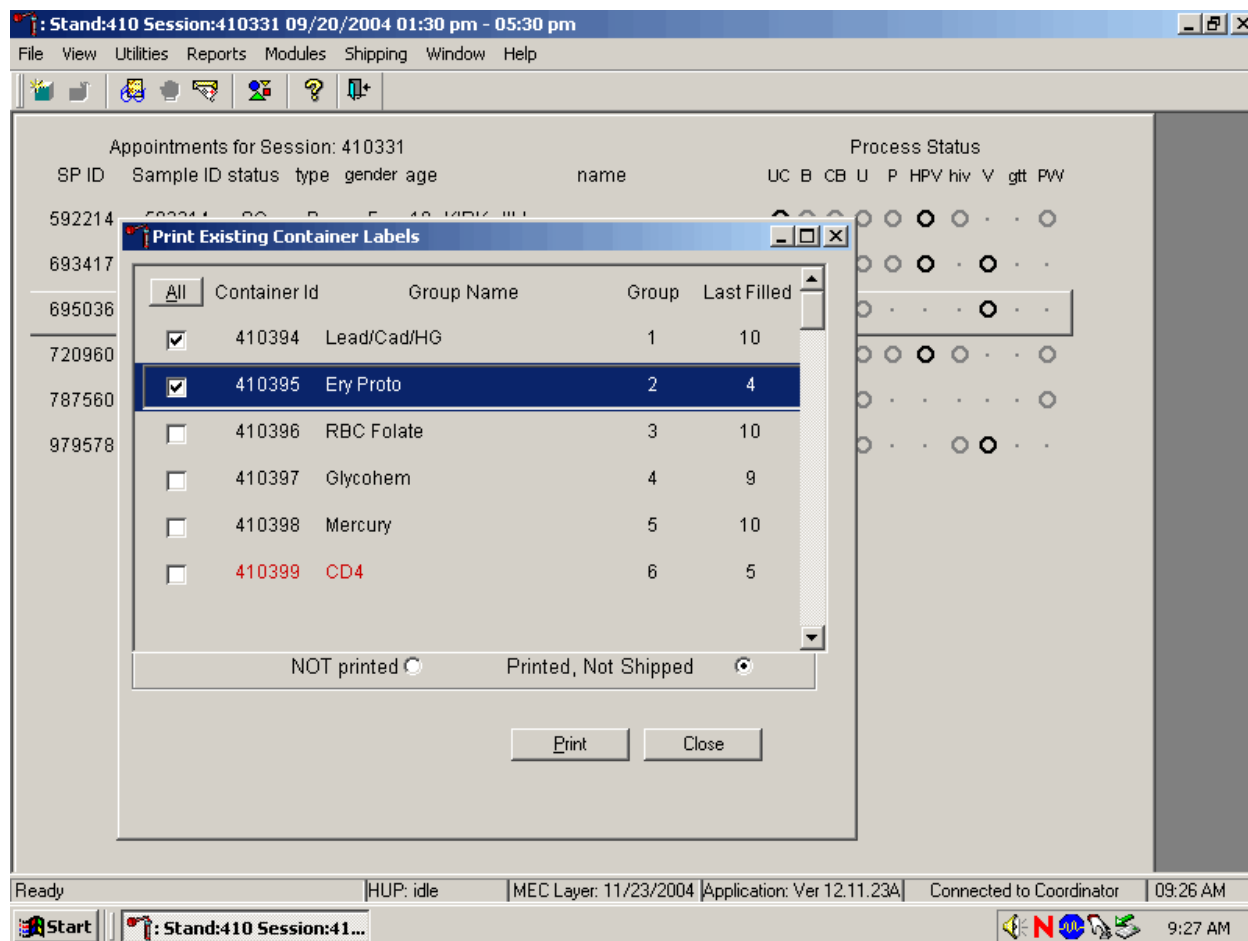
To reprint labels for an existing (not shipped) container, use the mouse to direct the mouse arrow to {File} in the top menu bar, left click, then drag the mouse arrow to {Print Labels}, {Containers}, {Print Existing Container Labels} and left click, or type [Alt] [F/f], [L/l], [C/c] [P/p].

A Print Existing Container Label screens displays.



The Print Existing Container Labels screen includes a check box associated with each open (not shipped) container, columns for container IDs (or labels), Group Name, Group number, Last Filled, an ALL selection button, radio buttons or filters for “Not printed” and “Printed, not Shipped,” and Print and Close buttons.

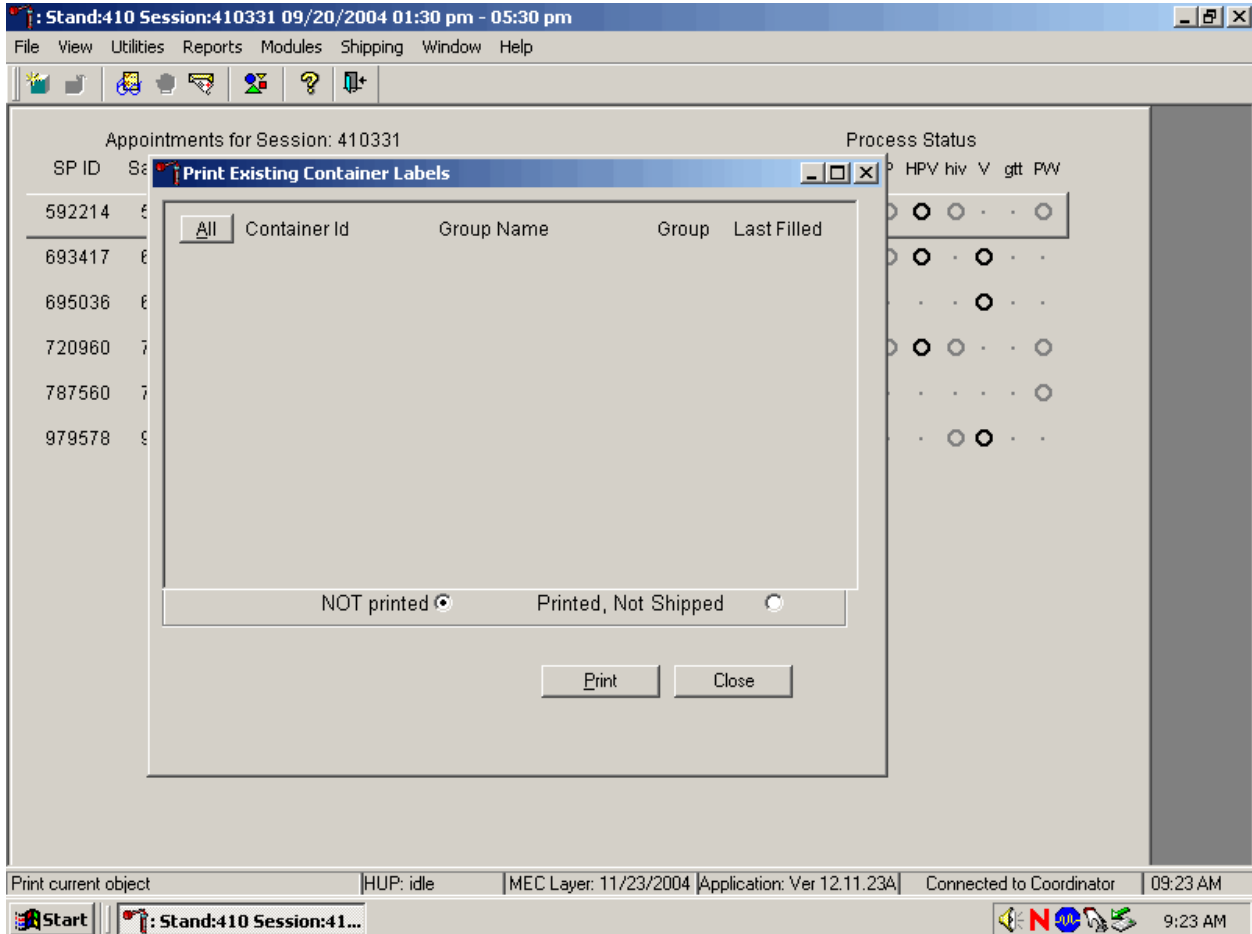
A list of container IDs displays if the radio button is set to Printed, Not Shipped.



To individually mark or identify a Container Id to be reprinted, use the mouse to direct the mouse arrow to an individual check box and left click. To mark all Container Ids to be reprinted, use the mouse to direct the mouse arrow to the All button and left click. Check marks fill in all the check boxes. To unmark all container IDs, use the mouse to direct the mouse arrow to the All button a second time and left click.

Select the Print button to print the labels. To select the Print button, use the mouse to direct the mouse arrow to the Print button and left click. To exit the screen without printing the labels, use the mouse to direct the mouse arrow to the Close button and left click.

The window will default to “NOT printed.” Select “Printed, not shipped” to display existing containers.



When the NOT Printed radio button is selected, the Print Existing Container Labels window displays all containers where the Container ID has been generated but the label has not been printed. These labels are in the queue waiting to be printed. To individually mark or identify a Container Id to be reprinted, use the mouse to direct the mouse arrow to an individual check box and left click. To mark all Container Ids to be reprinted, use the mouse to direct the mouse arrow to the All button and left click. Check marks fill in all the check boxes. To unmark all container IDs, use the mouse to direct the mouse arrow to the All button a second time and left click.

Select the Print button to print the labels. To select the Print button, use the mouse to direct the mouse arrow to the Print button and left click. To exit the screen without printing the labels, use the mouse to direct the mouse arrow to the Close button and left click.

9.7 Shipping Overview

The integrity of laboratory specimens is critical to NHANES. Storage temperatures have been established for each analyte in consultation with the National Center for Health Statistics (NCHS) and contract laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their ultimate receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient dry ice, refrigerant packs, and sending specimens by FedEx priority overnight.

Overnight delivery by FedEx can be delayed due to a weekend or holiday. This extraordinary circumstance usually occurs at the end of a stand or just before vacation. In any case, ship all specimens before vacations. The following actions are intended to mitigate unforeseen delay:

- Consider using medium shippers instead of small shippers for all laboratories east of the Mississippi when shipping from areas west of the Mississippi, and for all laboratories west of the Mississippi when shipping from areas east of the Mississippi. Substitute a larger shipper when shipping specimens in extreme summer heat or whenever professional judgment dictates added precautions.
- Use dry ice in blocks instead of pellets since blocks sublime at a slower rate.
- Increase the number of refrigerant packs from four to at least six per shipper.

The shipping technologist is primarily responsible for packing and shipping the specimens to various contract laboratories on a designated day. As necessary, other medical technologists assist in performing each of the steps listed below to complete the shipping procedures.

At the start of each stand, the laboratory staff creates address labels with the current MEC address to use on the Class 9 labels.

Shipping procedures:

- On the day before or the morning of a designated shipping day, create and print shipper labels (airbills) using FedEx Ship Manager.
- Prepare the Class 9 labels for shipments that use dry ice.
- On the morning of a shipping day, close all containers, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted “warning” labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.
- Pack the shippers with the containers, absorbent material, newsprint (padding), plastic bags, and a sufficient supply of dry ice or refrigerant packs as appropriate.
- Place the appropriate paper manifest and the preprinted FedEx return airbill in a 9 x 12 plastic bag and place the plastic bag on top of the Styrofoam shipper lid.
- Label each shipper with the appropriate FedEx label and warning labels.
- When the contract laboratory personnel receive the shippers, they unpack the specimens and return the shippers and refrigerant packs to either the field office (first 3-4 weeks of the stand) or the other concurrent stand (last 2 weeks of the stand).

9.8 Create Airbills using FedEx Ship Manager

Create airbills using the Ship Manager application at FedEx.com. Each physical stand location will be designated as a department under the Passkey system. The department is set up by home office staff. The name of the department shows up as the department designation in all of the screens within Ship Manager. The department designation is “stand###” where ### is the stand number. The default point of contact for the department will always be Barbara Lindstrom. The department address will be the address of the MEC for the stand the department represents. The main contact telephone number for the department is 301-738-8324. The FedEx account number that the department is assigned to use is 129015748. The service option for the department has been restricted to FedEx Priority Overnight. Each department is assigned a default reference number for each package shipped; this is the

project charge code for each stand. The User ID is designated “standxxx” where “xxx represents the stand number. The password is “labshipping.”

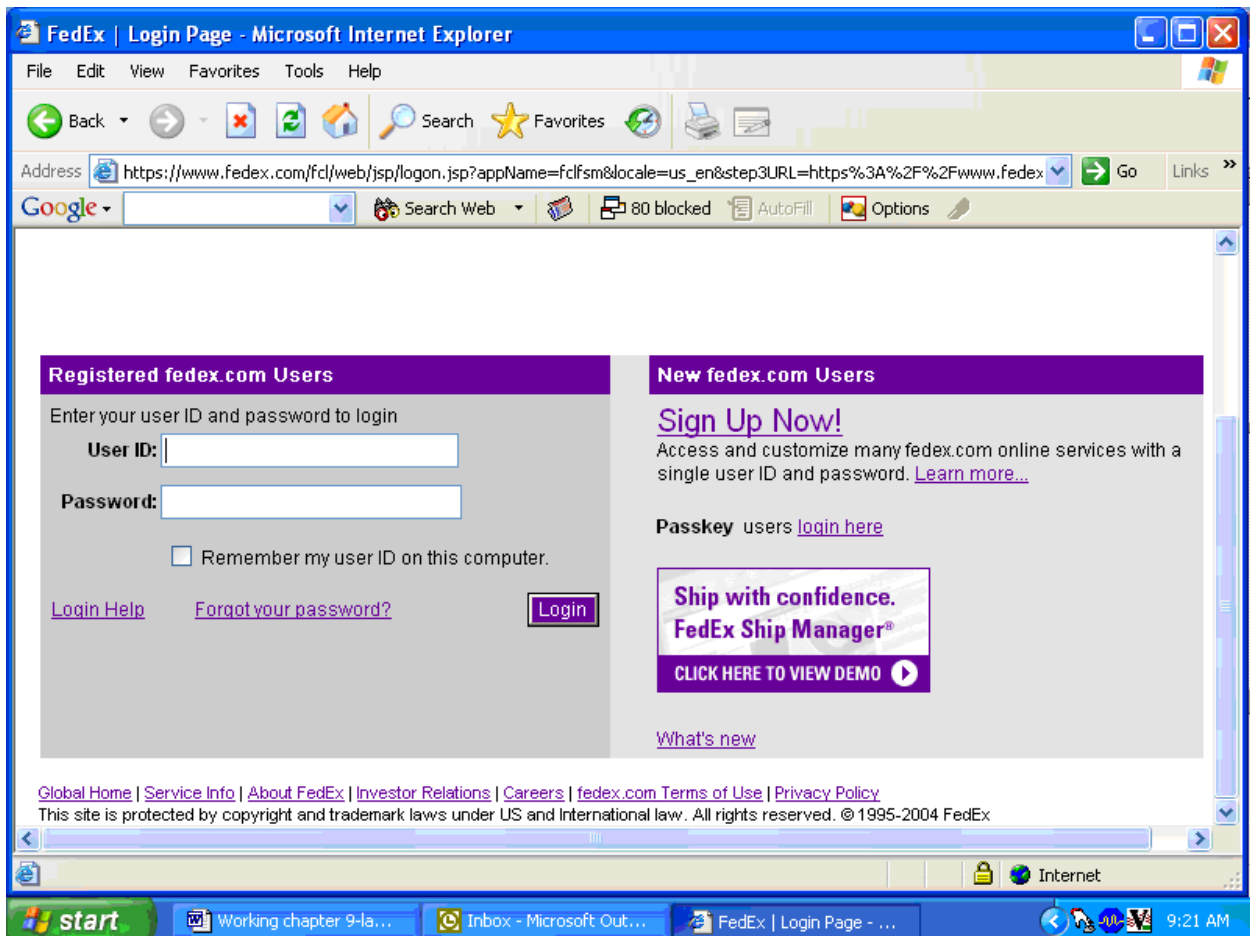
Access the FedEx web site using Explorer and logon to the application. Create one airbill for each shipment. Print the airbill, fold it in half, and insert it into a FedEx pouch. Attach the pouch to the shipper.

Use Internet Explorer to access the FedEx web site.



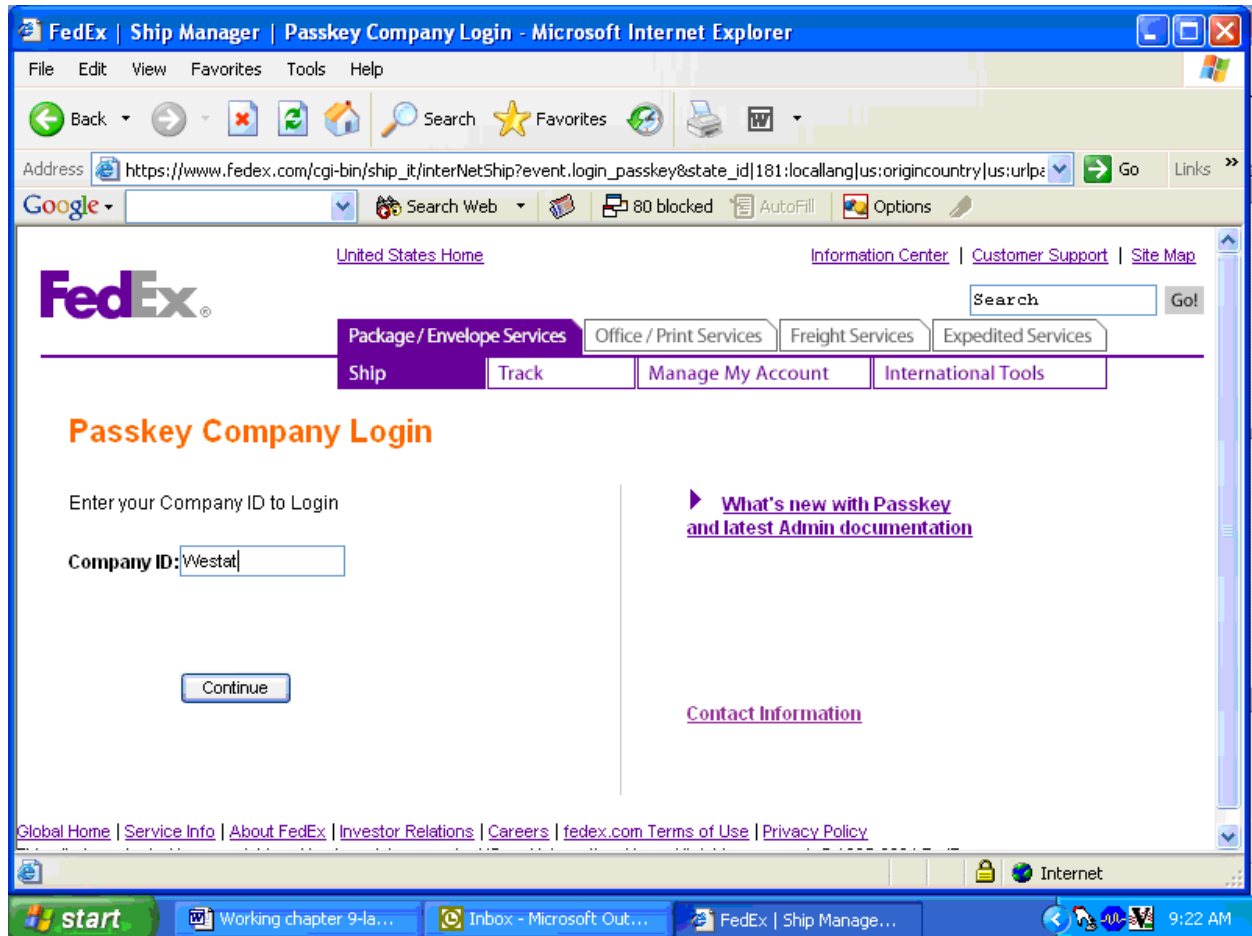
To access the Internet Explorer application, use the mouse to direct the mouse arrow to the Explorer icon on the desktop and double click.

Select FedEx from the Favorites menu. Select the “Passkey users login here” link located in the lower right-hand corner of the screen.



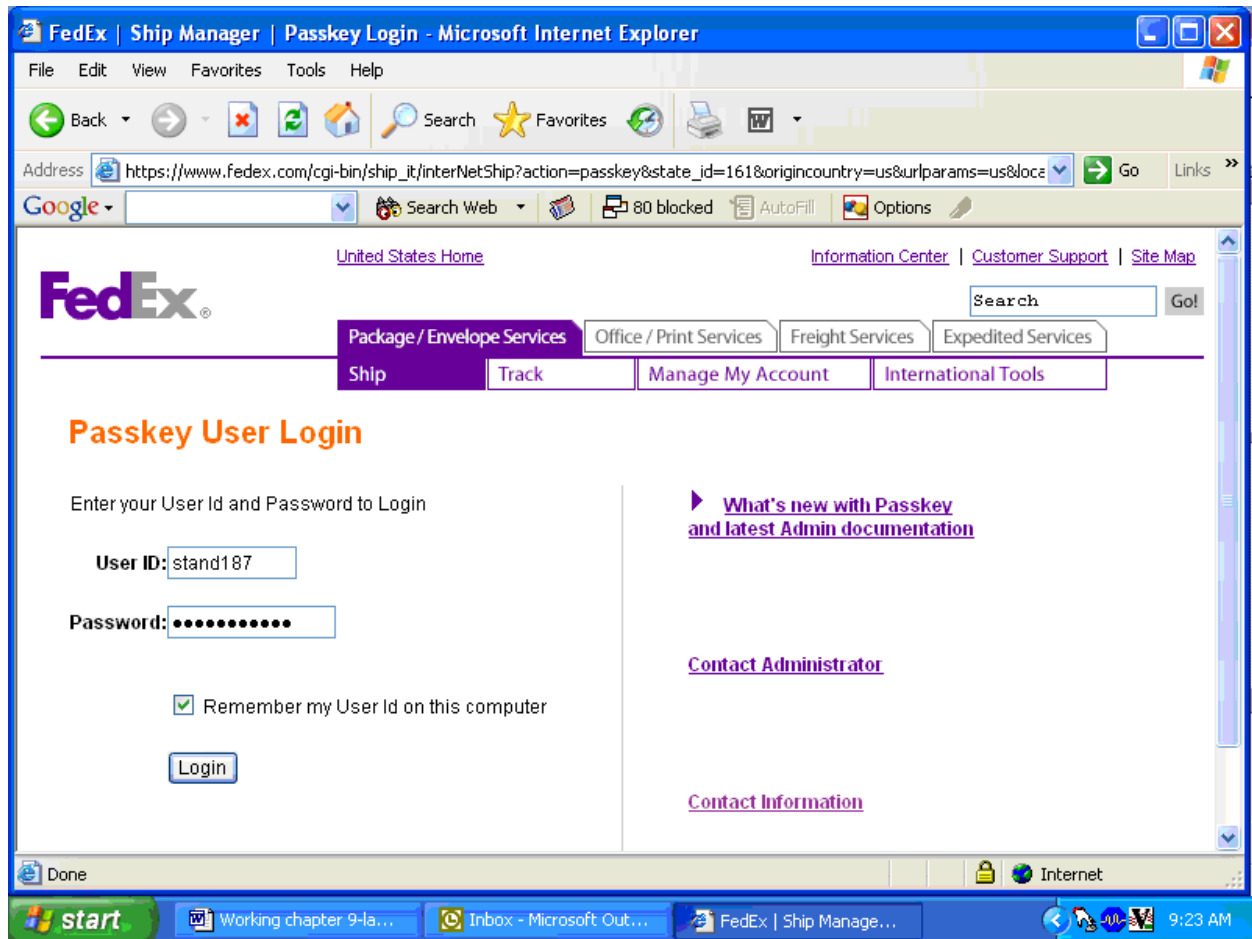
To select the Passkey users login here link, use the mouse to direct the mouse to the underlined link and left click.

Enter the Company ID in the text box.



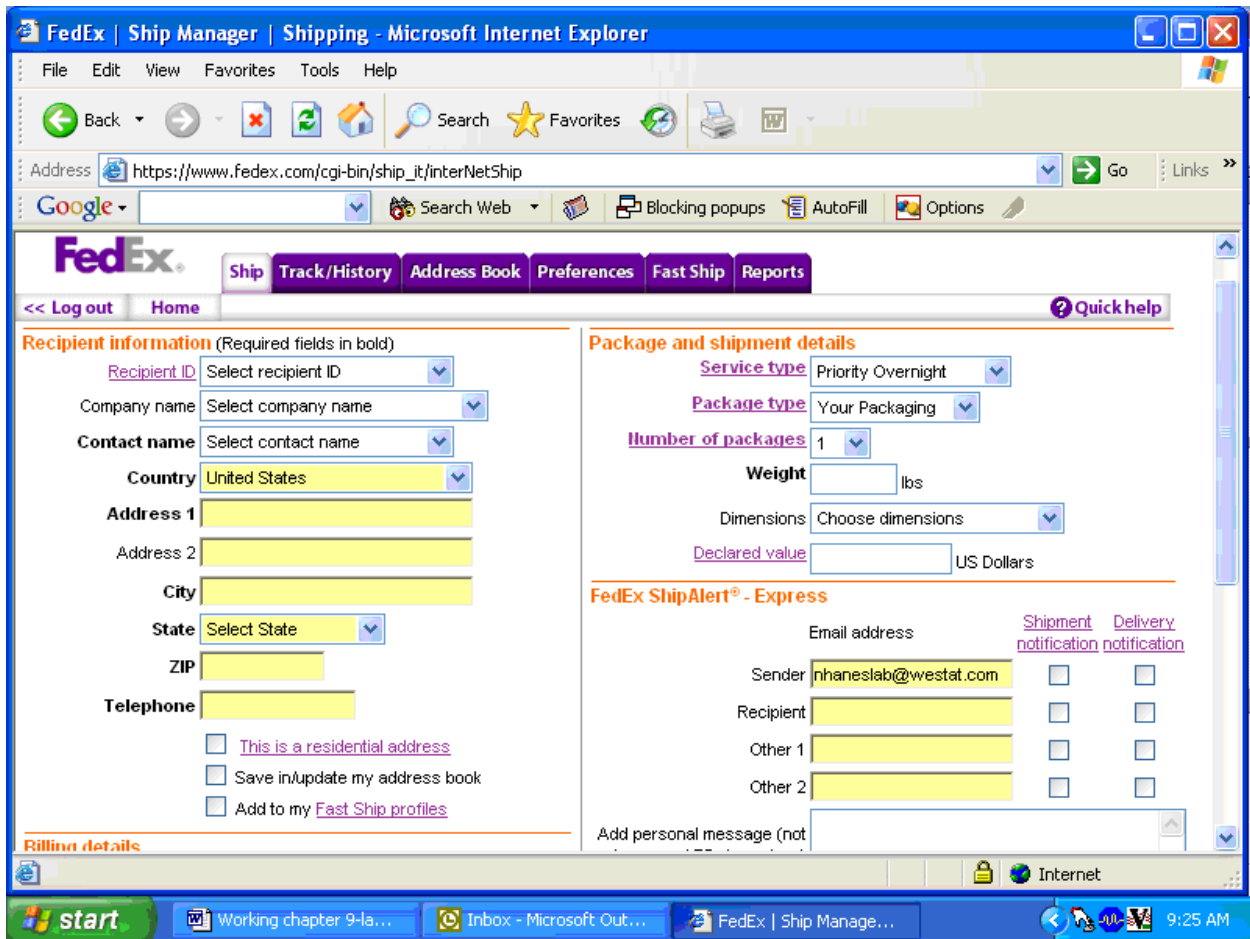
To enter the Company ID, use the mouse to direct the mouse arrow to the white text box and left click. Type “Westat” and then use the mouse to direct the mouse arrow to the Continue button and left click.

Enter the User ID and password.



To enter the User ID, use the mouse to direct the mouse arrow to the User ID text box and left click, then use the keyboard keys to type “standXXX” where XXX represents the stand number. To move to the Password text box, use the mouse to insert the cursor in the Password text box and left click or type [Enter]. Enter the Password by using the keyboard keys to type “labshipping.” Both text boxes are case sensitive. To move to the shipping window, use the mouse to direct the mouse arrow to the Login button and left click or select [Enter].

The Ship window displays.



This page contains all of the information necessary to create an airbill. The recipient information is contained in the Address Book.

The *Package and shipment details* and *Billing details* (located toward the bottom of the page) are preselected to default to the correct entries.

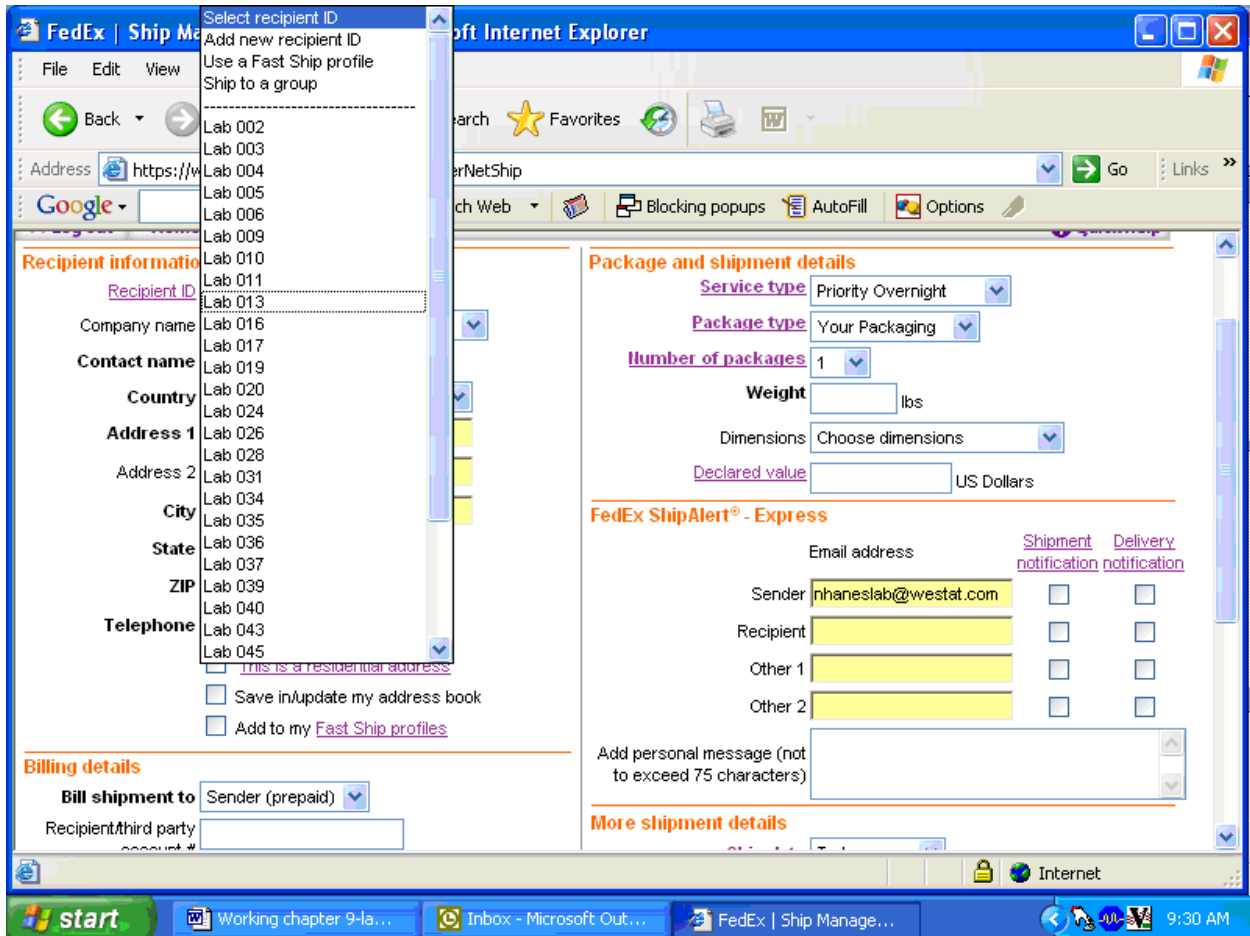
The screenshot shows a web form with two main sections: **Billing details** and **More shipment details**.
Billing details: Includes a dropdown for "Bill shipment to" (set to "Sender (prepaid)"), a text field for "Recipient/third party account #", and a "Your reference" field with the value "9851041015".
More shipment details: Includes a text area for "Add personal message (not to exceed 75 characters)", a dropdown for "Ship date" (set to "Today"), and a checkbox for "Create as Pending Shipment".
At the bottom, there are several buttons: "Clear fields", "Check recipient address", "Change sender address", "Get courtesy rate", "Go to options", and "Continue".

The *More shipment details* defaults the shipping date to today and the Go to options button links to the special services section where the dry ice option is located.

The *Recipient information* section of the airbill contains all of the information necessary for each recipient.

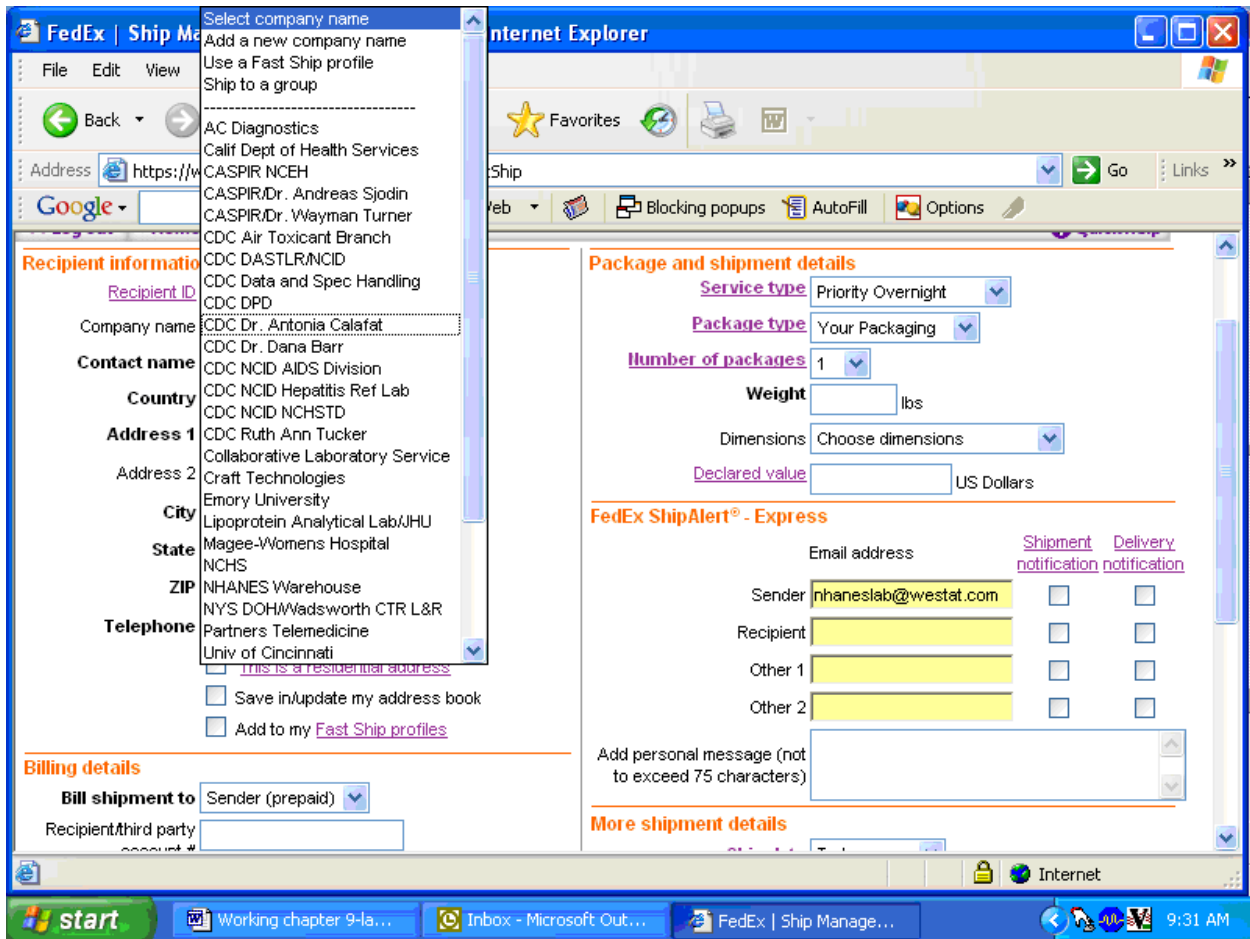
The screenshot shows the **Recipient information** section, which includes a note "(Required fields in bold)".
Recipient ID: Select recipient ID (dropdown)
Company name: Select company name (dropdown)
Contact name: Select contact name (dropdown)
Country: United States (dropdown)
Address 1: (text field)
Address 2: (text field)
City: (text field)
State: Select State (dropdown)
ZIP: (text field)
Telephone: (text field)
Below the form are three checkboxes:
 This is a residential address
 Save in/update my address book
 Add to my [Fast Ship profiles](#)

Select the entity to which the package is being shipped using one of three options. The *Recipient ID*, *Company name*, or *Contact name*.



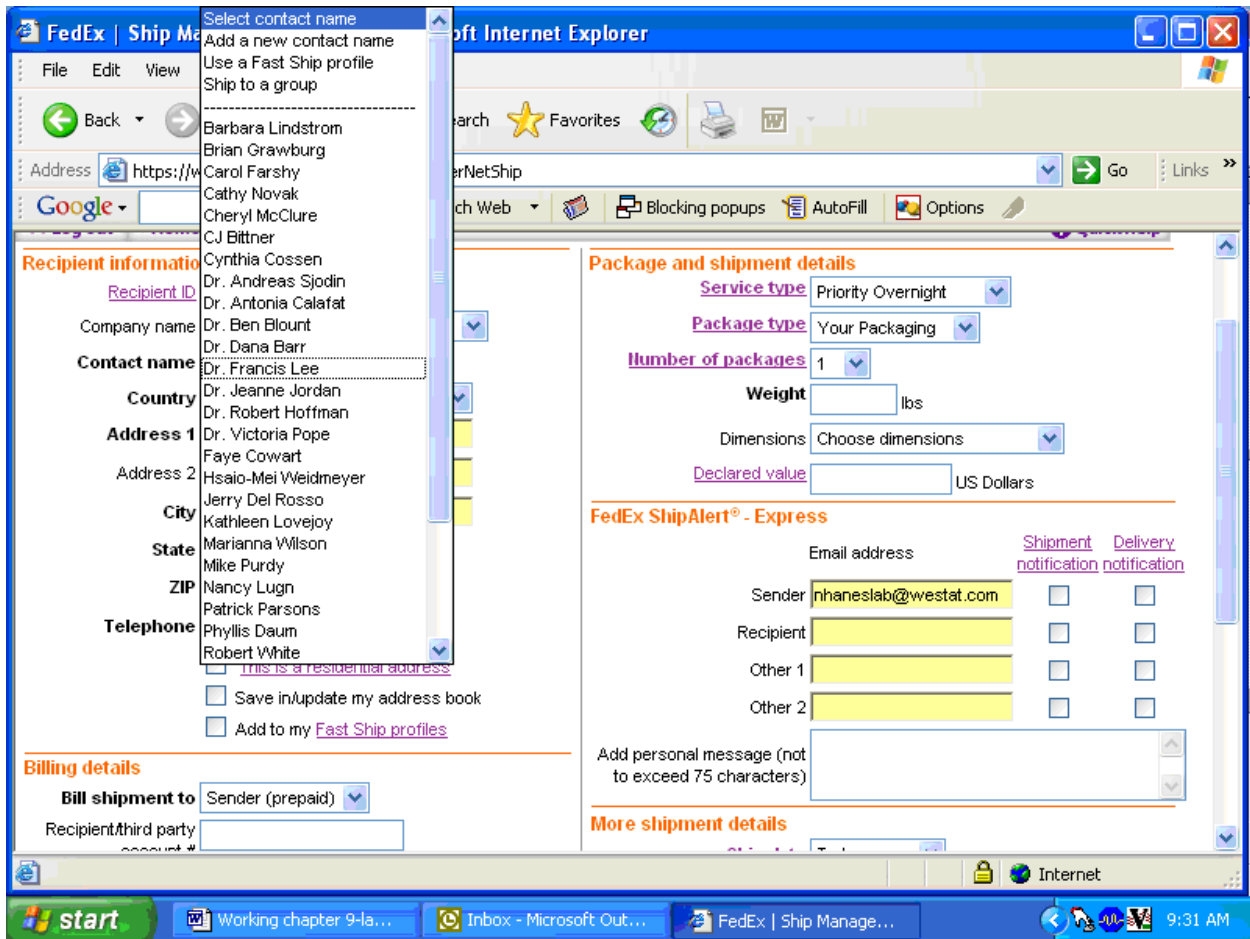
To select a recipient (or laboratory) by lab number, use the mouse to direct the mouse arrow to the down arrow on the right side of the Recipient ID text box and left click. Drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Select the entity to which the package is being shipped using the *Company name*.



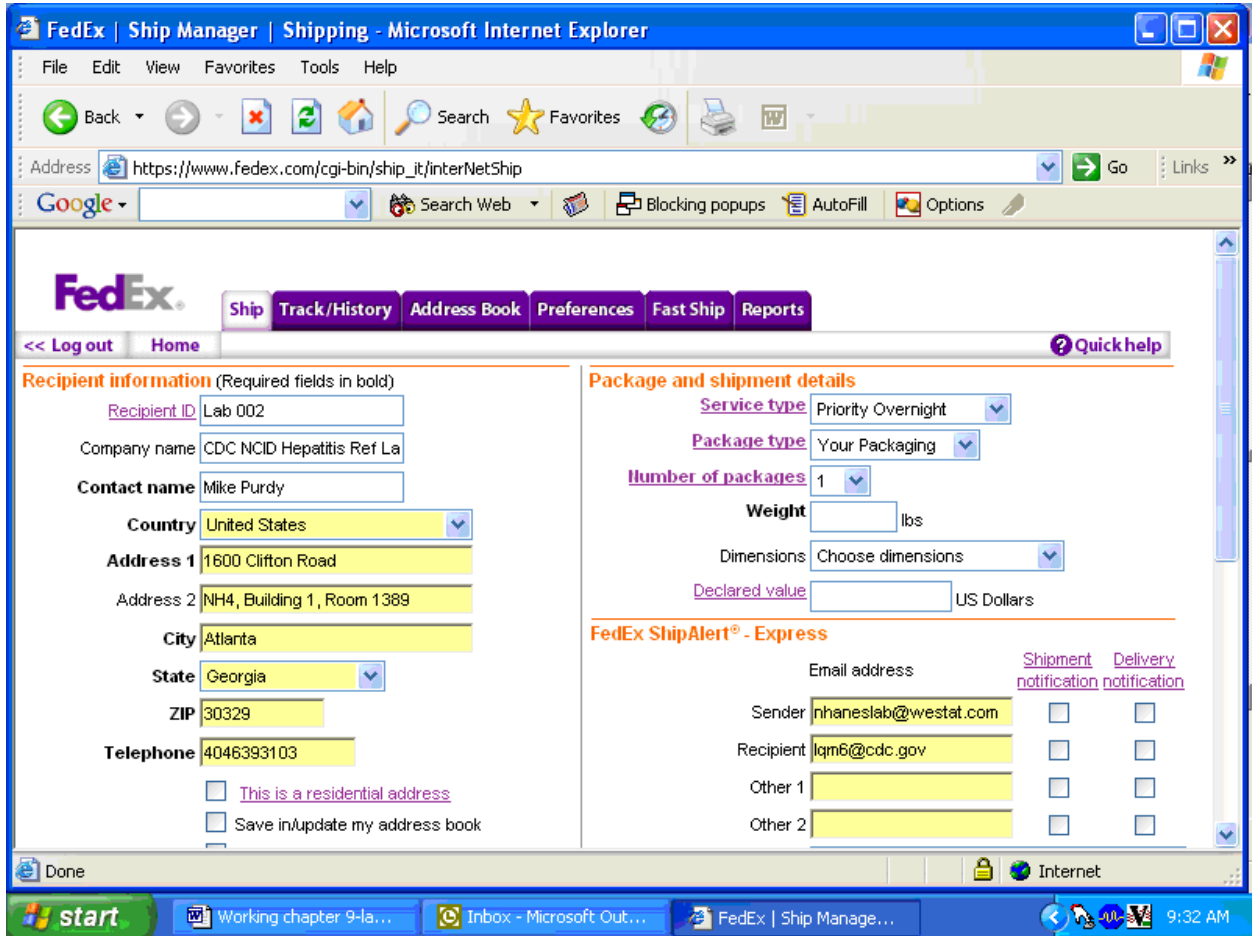
To select a company (or laboratory) by name, use the mouse to direct the mouse arrow to the down arrow on the right side of the *Company name* text box and left click. Drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all the choices.

Select the entity to which the package is being shipped using the *Contact name*.



To select a laboratory by contact name, use the mouse to direct the mouse arrow to the down arrow on the right side of the *Contact name* text box and left click. Drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all the choices.

After a *Recipient ID*, *Company name*, or *Contact name* has been selected, the remainder of the text field automatically fills in using information contained in the Address Book.



Review the information for accuracy. If it is incorrect, then contact the laboratory supervisor.

Review the default information contained in the *Package and shipment details* and *Billing details* sections of the airbill.

Package and shipment details

Service type Priority Overnight

Package type Your Packaging

Number of packages 1

Weight lbs

Dimensions Choose dimensions

Declared value US Dollars

Package and shipment details

- The Service type should default to Priority Overnight.
- The Package type should default to Your Packaging.
- The Number of packages should default to “1.”
- **Enter the weight of the package.** To enter the weight, use the mouse to direct the mouse arrow to the Weight text box and left click. Use the numbers in the keyboard to enter the correct weight in pounds. Use whole numbers.
- Do not change the default (choose dimensions) in the *Dimensions* text box or enter a declared value in the Declared value text box.

Billing Details

Billing details

Bill shipment to Sender (prepaid)

Recipient/third party account #

Your reference 9851041015

- The *Bill shipment to* should default to Sender (prepaid).
- Do not enter a number in the *Recipient/third party account number* text box.
- Your reference should default to the project number for the stand.

Complete the options in the More shipment details section.

The screenshot shows a web form with a section titled "More shipment details". Inside this section, there is a label "Ship date" followed by a dropdown menu. The dropdown menu is currently open, showing a list of dates: "Today", "Tomorrow", "Mon, Nov 29", "Tue, Nov 30", "Wed, Dec 1", "Thu, Dec 2", "Fri, Dec 3", and "Sat, Dec 4". The "Today" option is highlighted in blue. To the right of the dropdown menu, there is a label "Shipment" and a small blue button. Below the "More shipment details" section, there are two buttons: "Get courtesy rate" on the left and "Continue" on the right.

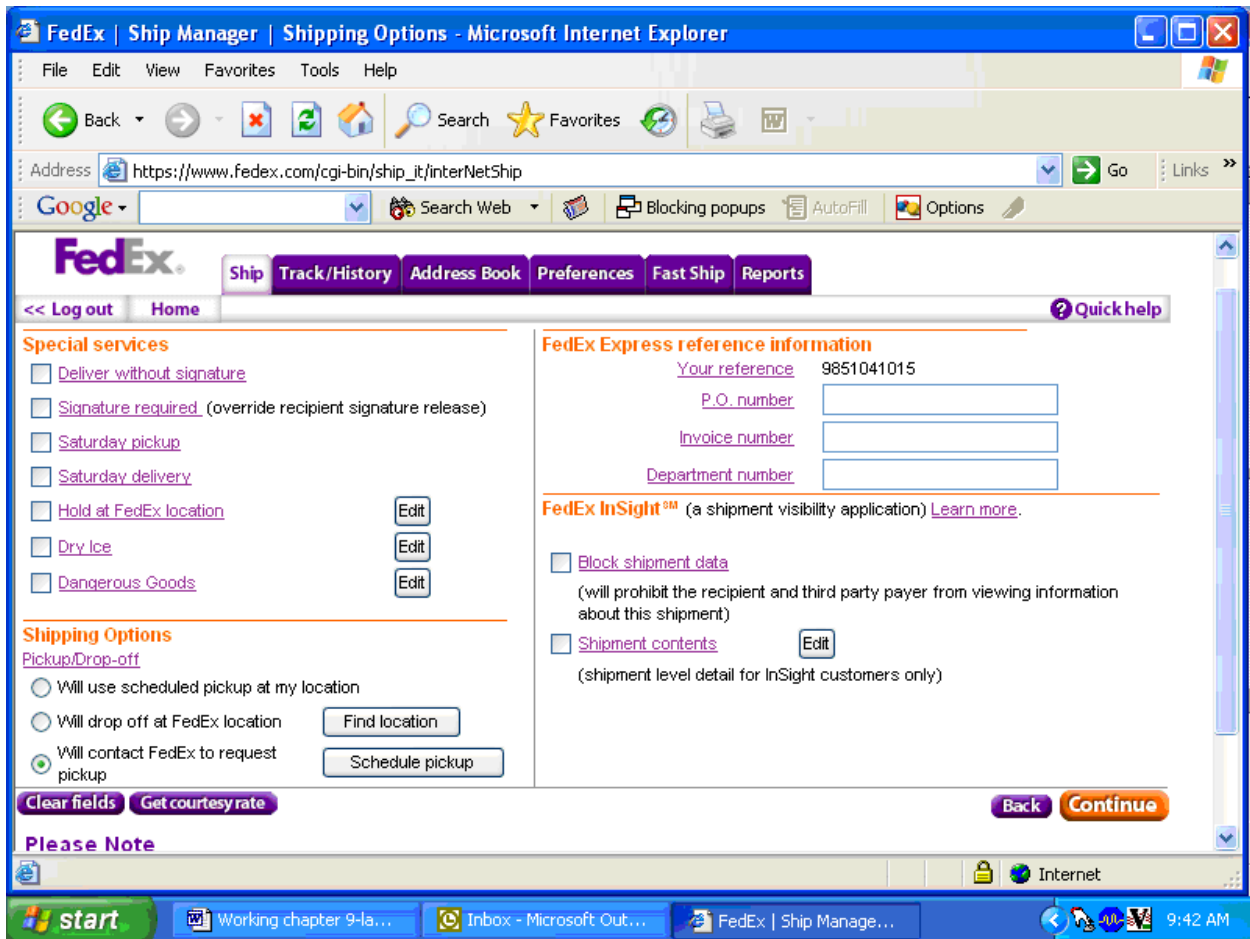
The Ship date will default to Today. To change the date to tomorrow or any of the next 6 days, use the mouse to direct the mouse arrow to the down arrow on the right side of the Ship date text box and left click. Drag the mouse arrow to the desired choice and left click.

For shipments containing dry ice, select the Go to options button.

The screenshot shows a web form with a section titled "More shipment details". In the center of this section, there is a button labeled "Go to options". Below the "More shipment details" section, there are two buttons: "Get courtesy rate" on the left and "Continue" on the right.

To select the Go to options button, use the mouse to direct the mouse arrow to the Go to options button and left click.

A second shipment options window displays.



The options window includes check boxes for special services, radio buttons for shipping options, text boxes for FedEx Express reference information, and check boxes for FedEx InSight™. Do not change any of the information in any of the sections except the Dry Ice option under *Special Services*.

Select the Dry Ice check box.

Special services

- [Deliver without signature](#)
- [Signature required](#) (override recipient signature release)
- [Saturday pickup](#)
- [Saturday delivery](#)
- [Hold at FedEx location](#)
- [Dry Ice](#)
- [Dangerous Goods](#)

To select the Dry Ice option, use the mouse to direct the mouse arrow to the Dry Ice check box and left click.

A second dry ice window displays. Enter the weight of the dry ice.

Dry Ice

Please enter weight of dry ice.

Weight 35 lbs

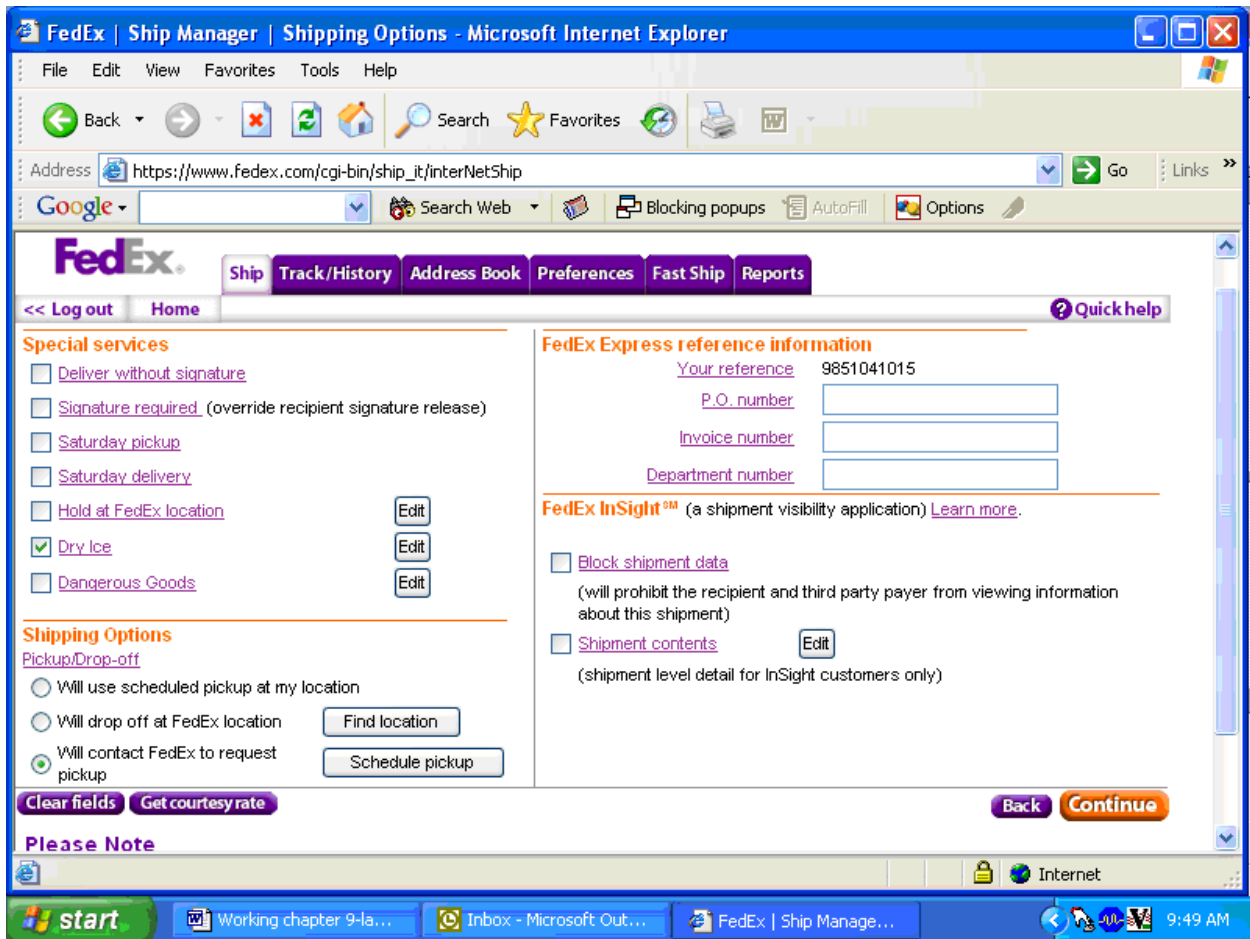
Weight of dry ice lbs

Dimensions x x in

Declared value US Dollars

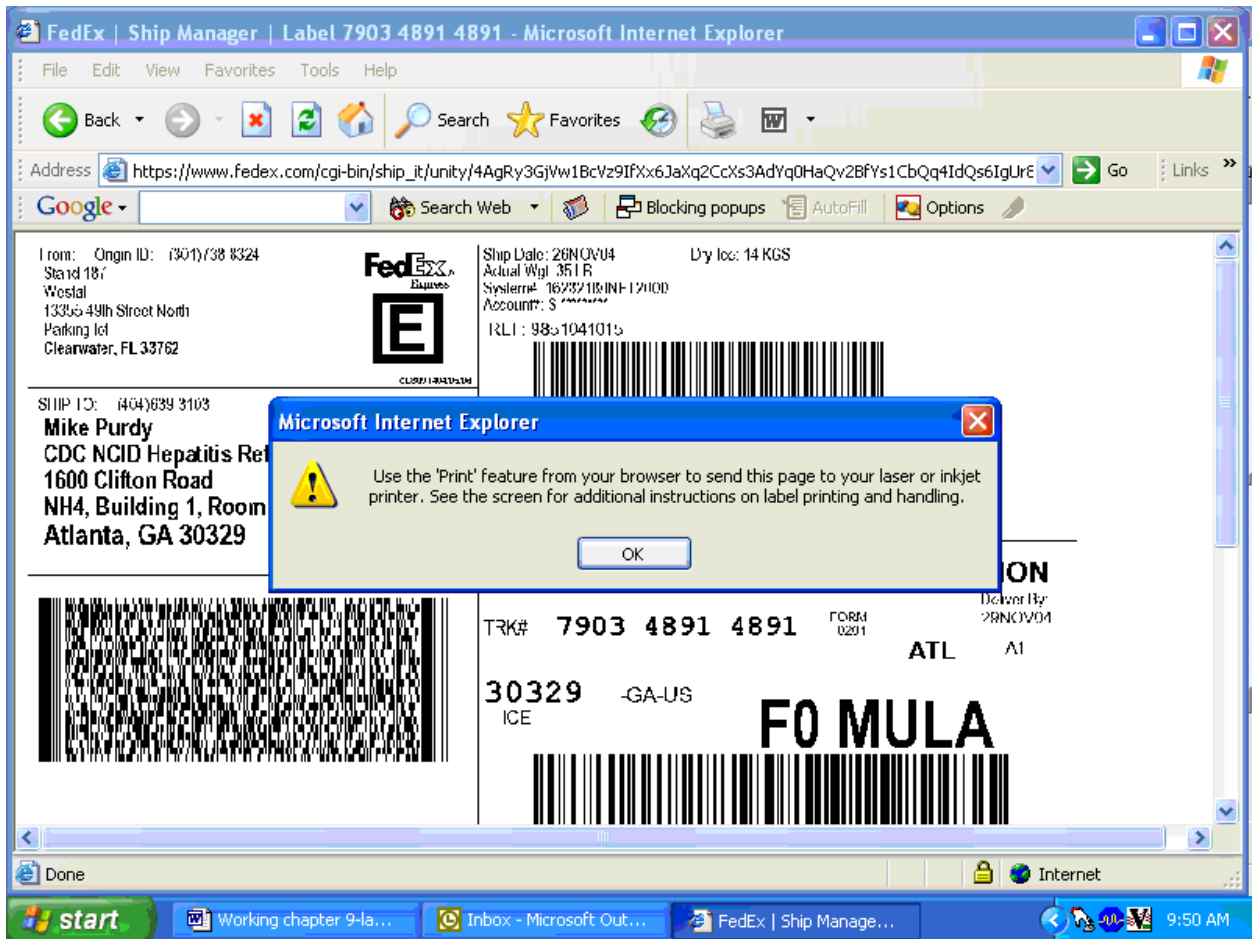
To enter the weight of the Dry Ice, use the mouse to the Weight of dry ice text box and left click. Type the weight, in pounds, into the text box using the keyboard keys. Use whole numbers. To exit this window and return to the special services window, use the mouse to direct the mouse arrow to the Cancel button and left click. To save the information and return to the special services window, use the mouse to direct the mouse arrow to the OK button and left click.

Continue to create the airbill.



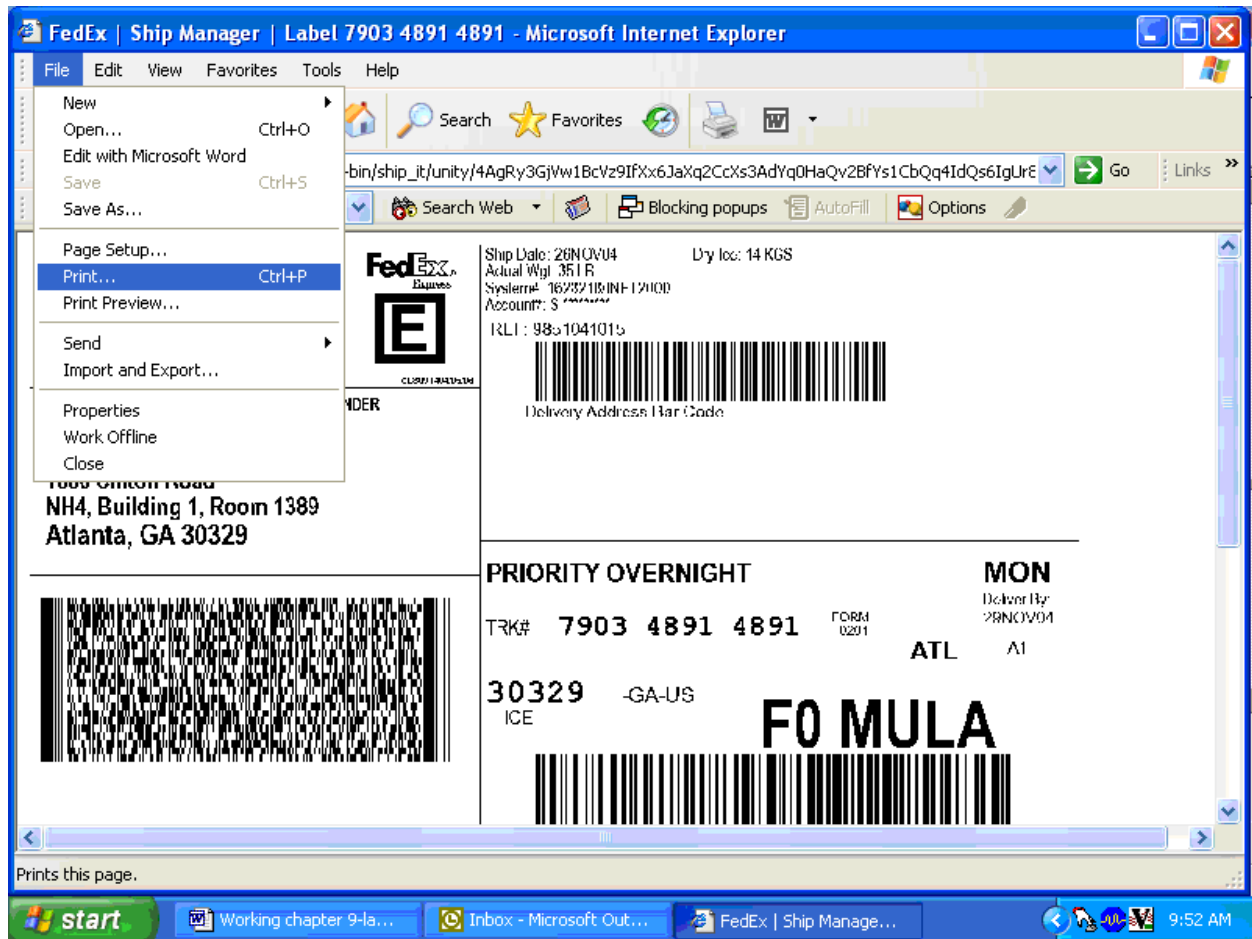
To edit the information in the dry ice window or to return to the dry ice window, use the mouse to direct the mouse arrow to the Edit Button to the right of the Dry Ice check box, and left click. To go back to the Recipient Information window, use the mouse to direct the mouse arrow to the Back button and left click. To clear the fields, use the mouse to direct the mouse arrow to the Clear Fields button and left click. To continue to create the airbill, use the mouse to direct the mouse arrow to the Continue button and left click. **Click the Continue button only once. Expect some delay due to transmission time. Do not click Stop or Reload; it may cause a duplicate shipment transaction to occur.**

Continue to create the airbill.



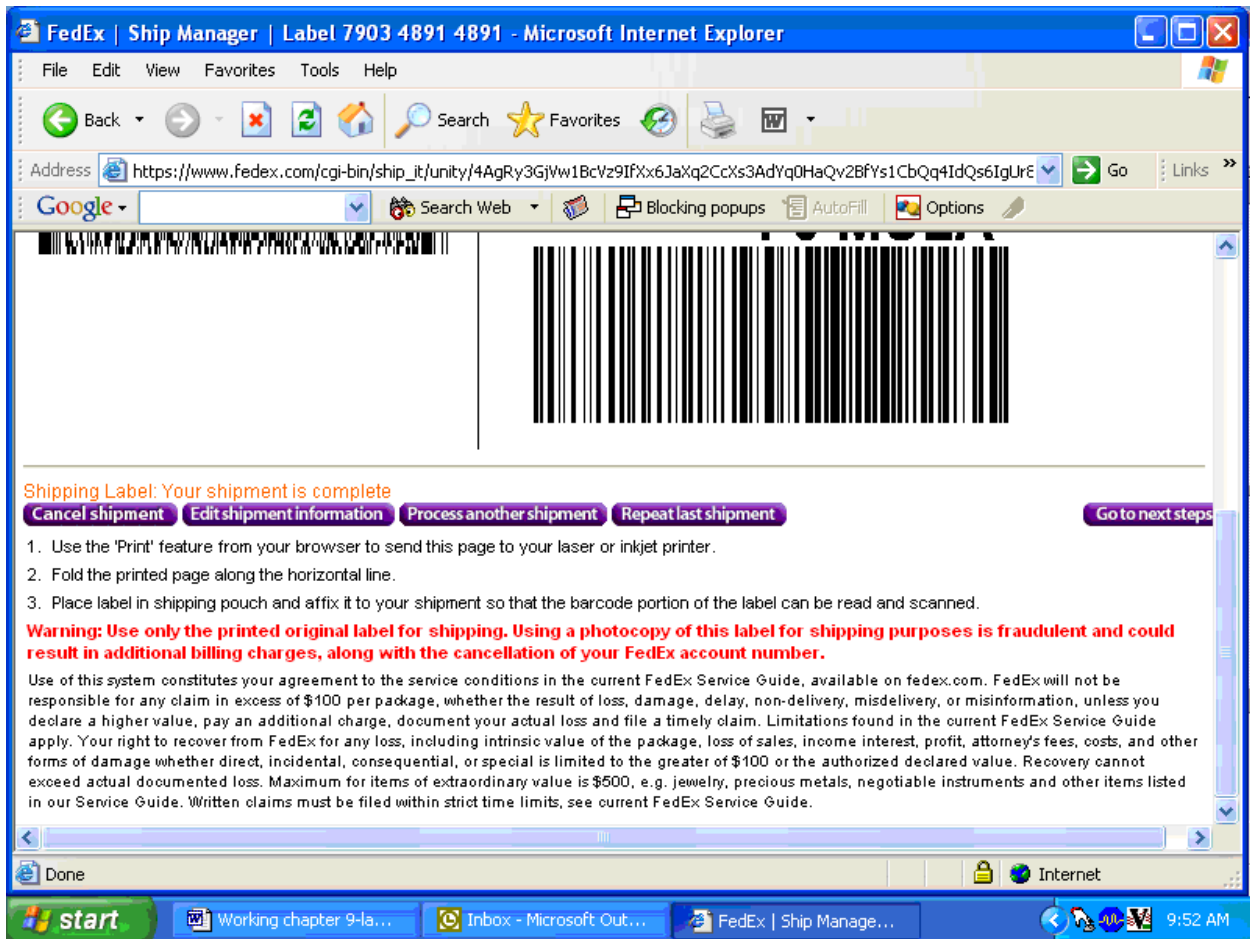
The airbill is created after the Continue button is selected. Click the Continue button only once. A pop-up window with an informational message displays. Follow the instructions contained in the pop-up window; “Use the ‘Print’ feature from your browser to send this page to your laser or inkjet printer. See the screen for additional instructions on label printing and handling.” To acknowledge the message, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter.]

Print the airbill.



To print the airbill, use the mouse to direct the mouse arrow to [File] in the top tile bar, drag the arrow to Print and left click, or type [Alt] [F] [P/p].

Scroll down to view the selections at the bottom of the window and follow the instructions.

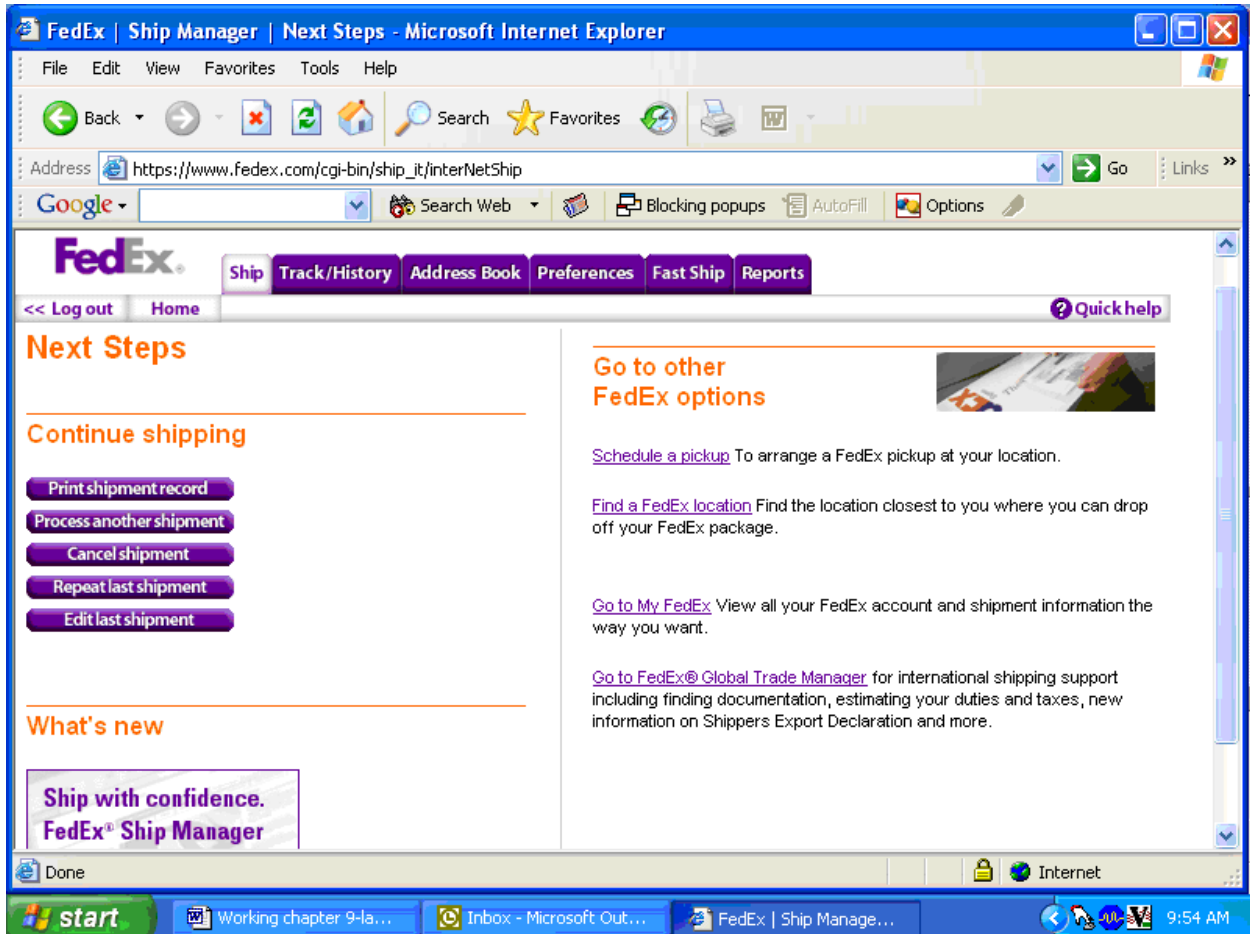


Select one of the buttons to proceed. The choices are as follows:

- Cancel shipment – Moves to the Track/History page where the sample can be marked and cancelled.
- Edit shipment information – Opens a window that instructs, “If you have already printed the label for this shipment, please discard it. If you have entered ‘Shipment Contents’ information, this information will not be saved and will need to be re-entered. To confirm that you want to edit this shipment, click the “Yes” button.”
- Process another shipment – Moves to the Recipient information page.
- Repeat last shipment – Opens a warning window that instructs, “You have chosen to repeat a shipment that includes one or more of the following: freight booking number, package dimensions or shipment contents. It will be necessary to reenter some information to complete the repeat shipment.”

- Go to next step – proceeds to the Next Steps page with the same choices.

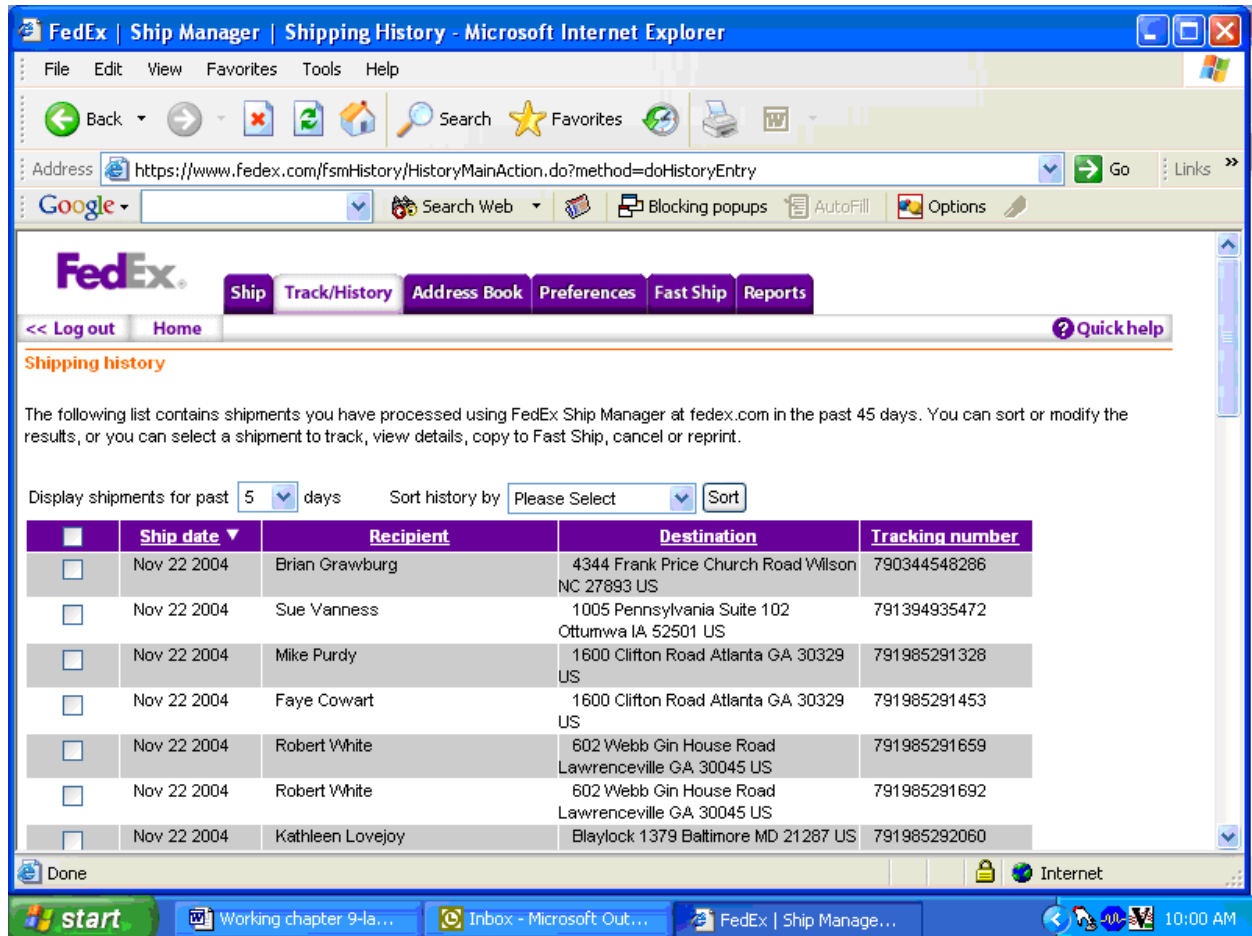
The Next Steps page displays if the Go to next step button is selected.



Complete the shipping process.

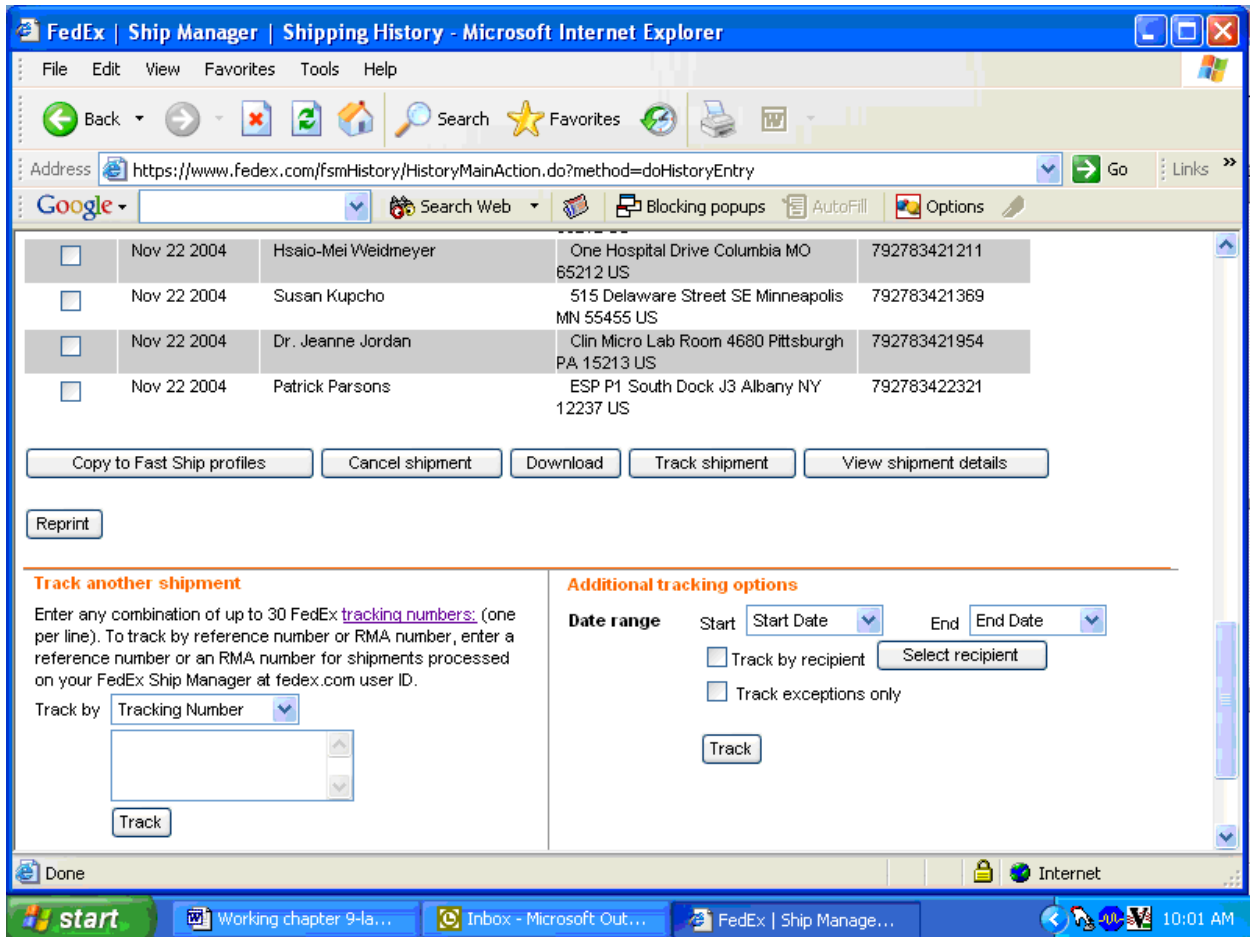
- Fold the printed page along the horizontal line.
- Place label in shipping pouch and affix it to your shipment so that the bar code portion of the label can be read and scanned.

Track a shipment, cancel a shipment, or view shipment histories using the Track/History file tab.



To access the Track/History window, use the mouse to direct the mouse arrow to the Track/History file tab at the top of the page and left click.

The Track/History window lists the shipments that have been processed using FedEx Ship Manager at FedEx.com in the past 45 days. Sort or modify the results, or select a shipment to track, view details, copy to Fast Ship, or cancel.

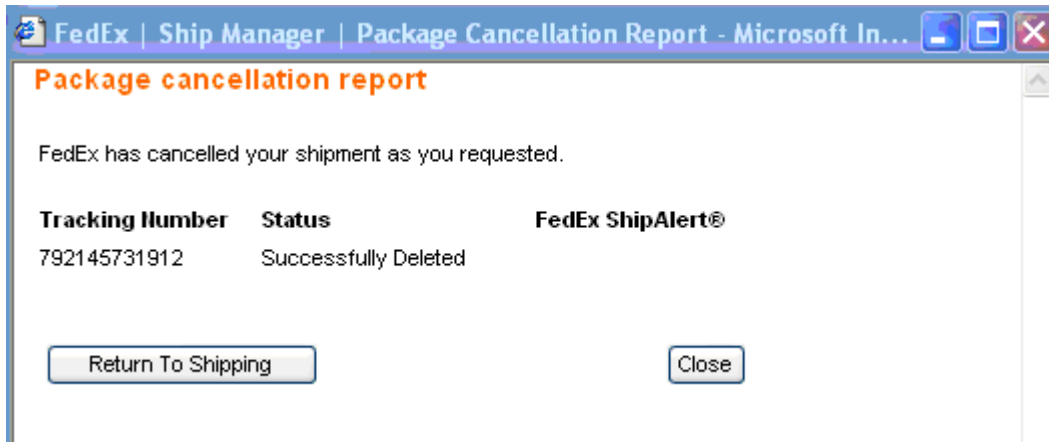


To mark one or more airbills, use the mouse to direct the mouse arrow to the check box and left click to insert a check mark. Then select one of the actions listed along the bottom of the window:

- Copy to Fast Ship profiles – not applicable
- Cancel shipment – Opens a Package Cancellation Report window
- Download – Not applicable
- Track shipment – Opens a Track Shipments, Summary Results window that displays the tracking information for one or more shipments. The details include the Tracking Number, Status Date/Time, Destination, and Service type.

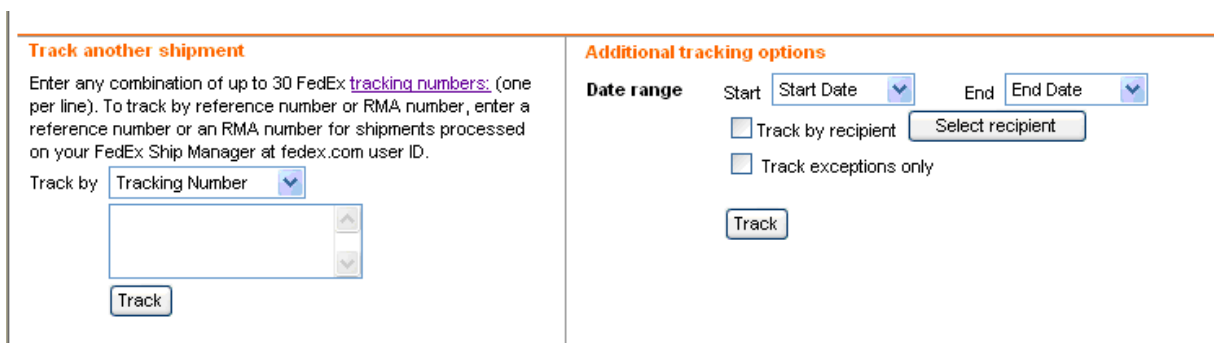
- View shipment details – Opens a window that displays the details for a shipment: Ship To, Tracking Number, Your Reference, Ship date, Service type, package type, Pick up/Drop off, Total Weight, Declared value, Courtesy Rate Quote, Special Services, and Shipment Type.

A shipment is cancelled as soon as the Cancel Shipment option is selected.



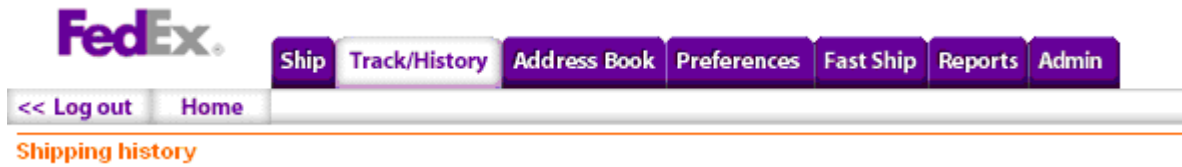
The Package cancellation report window confirms the status of the shipment. To return to the Recipient Information page, use the mouse to direct the mouse arrow to the Return to Shipping button and left click. To close the window and return to the Track/History window, use the mouse to direct the mouse arrow to the Close button and left click.

The bottom of the Track/History window includes a window to enter additional tracking numbers or additional tracking options.



Use the Additional tracking options to track using date filters, or check boxes to track by recipient or by exceptions only.

Log out of the application.

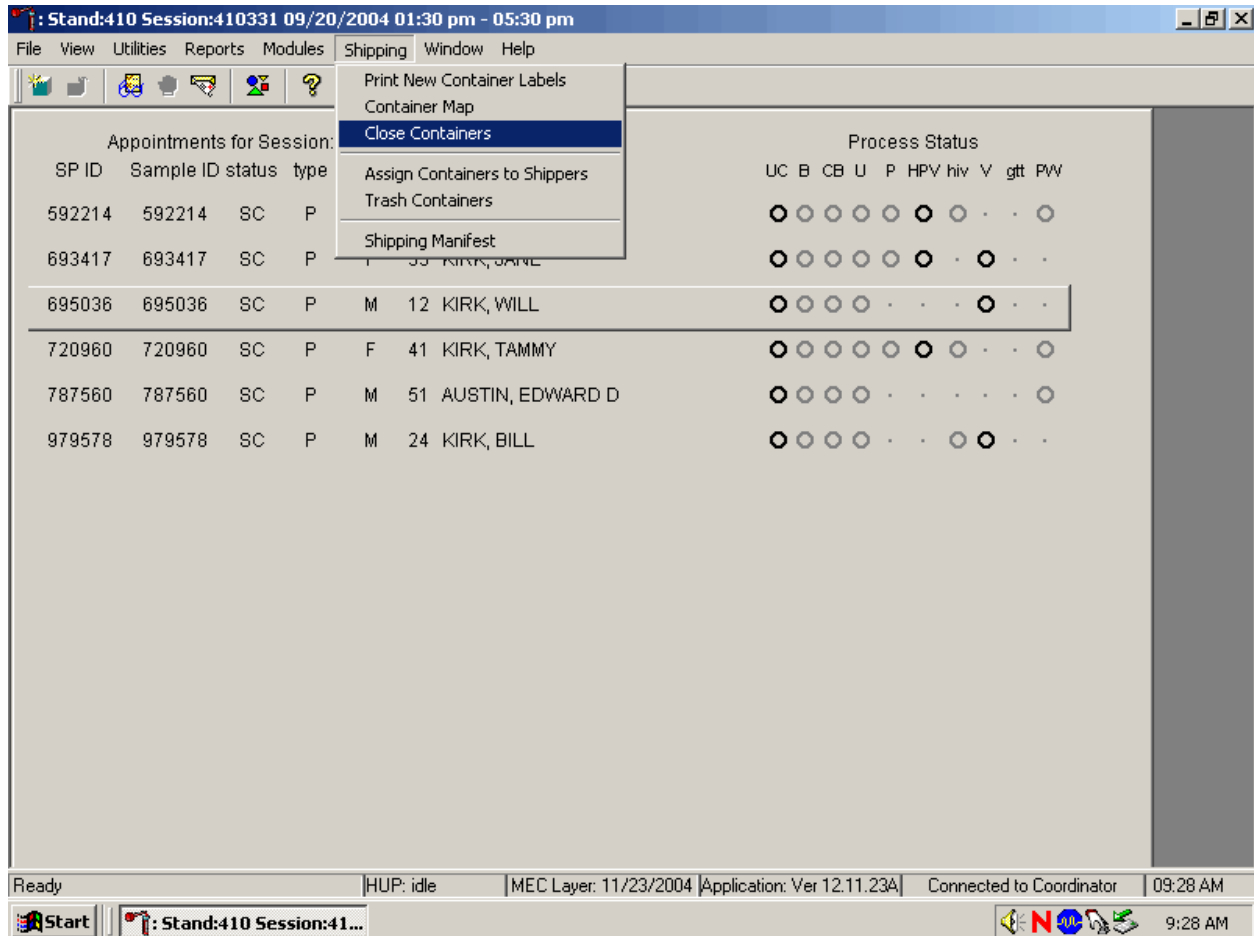


To log out of FedEx Ship Manager, use the mouse to direct the mouse arrow to the <<Log out header on the top left side of the window and left click.

9.9 Close Containers

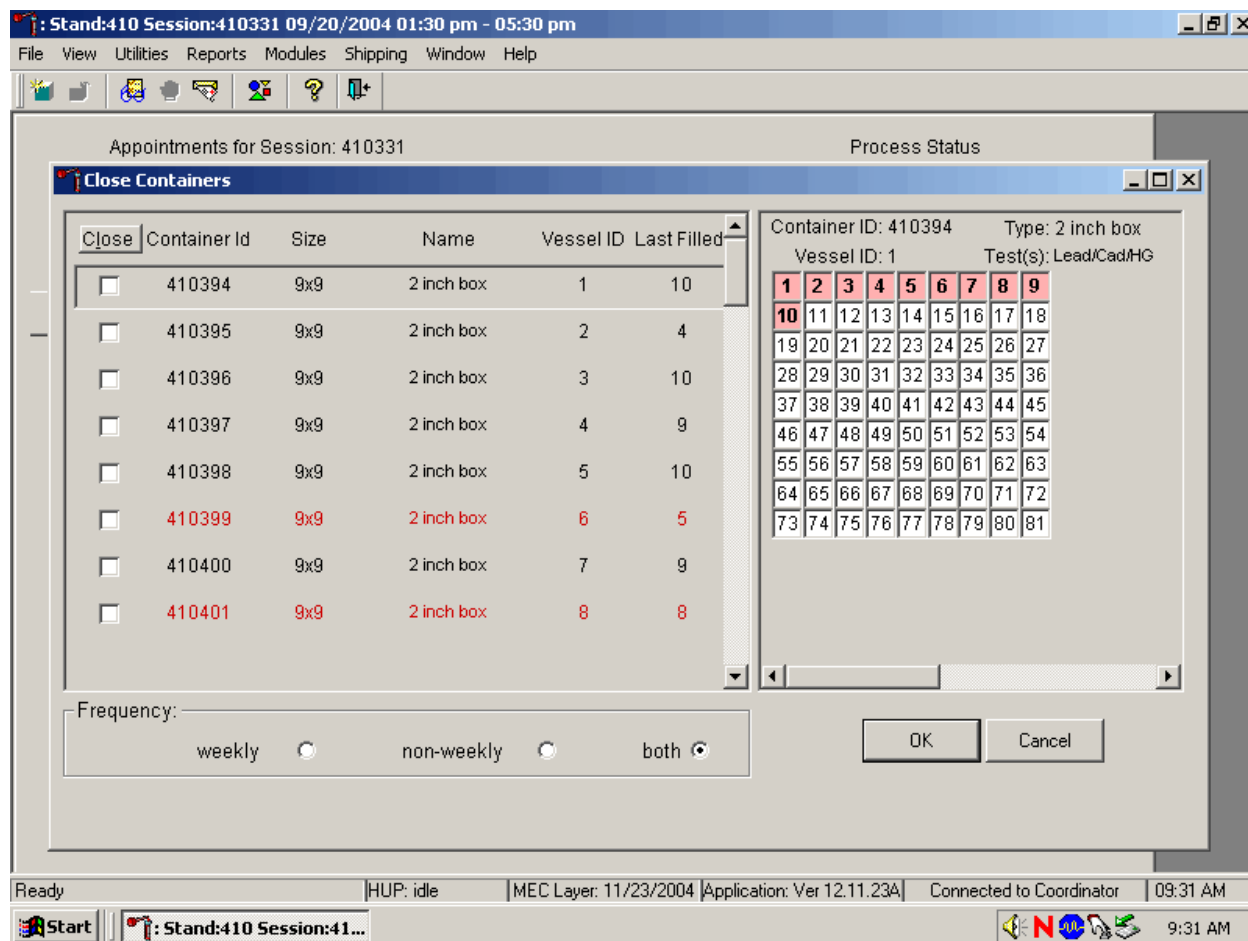
After a container is full, it is automatically closed. All open containers must be virtually and manually closed before shipping.

Access the {Close Containers} module.



To access the {Close Containers} module, use the mouse to direct the mouse arrow to {Shipping}, left click, drag the mouse arrow to {Close Containers}, and left click, or type [Alt] [S/s], [L/I].

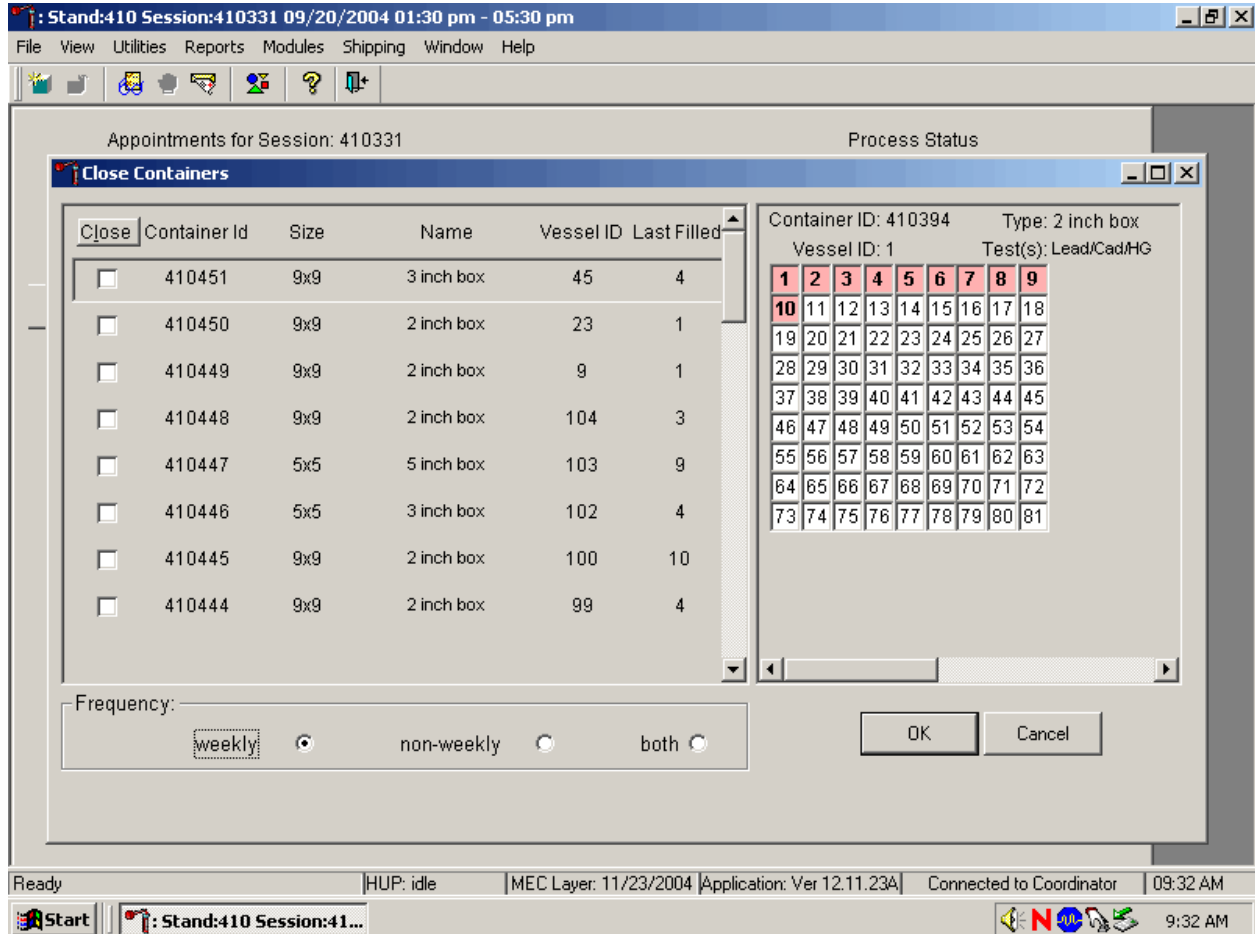
Individually close open containers or collectively close all open containers.



The left side of the Close Containers screen includes a check box for each open container and columns for the Container Id, Size, Name, Vessel ID, and number of the Last Filled slot. The container line in the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. Containers displayed in red indicate containers that can be shipped at the end of the stand or when they are full. The bottom of the screen includes three filters: weekly, non-weekly, and both.

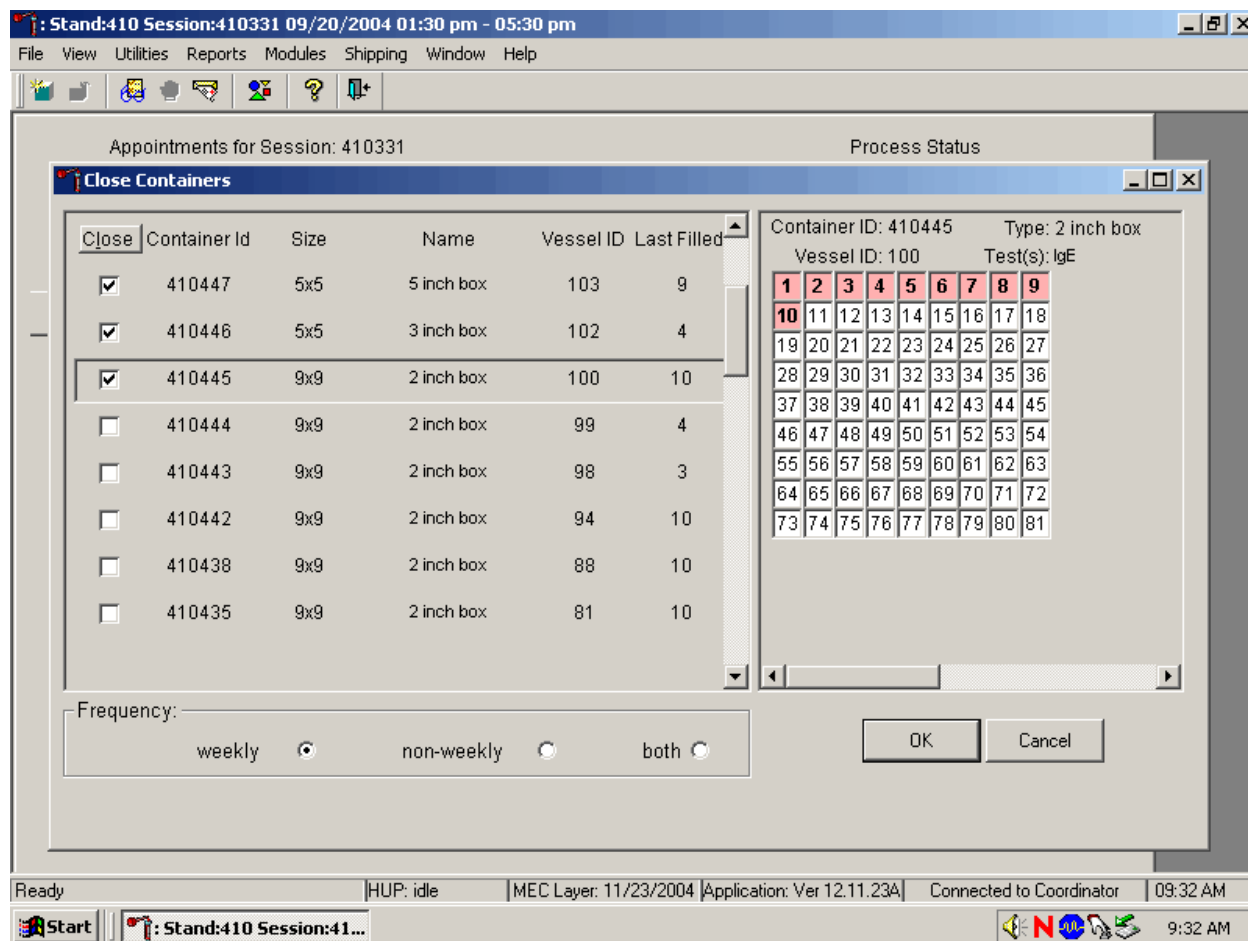
To move up and down the list, use the up and down keyboard arrows or use the mouse to direct the mouse arrow to any individual line. Use the vertical scroll bar to view all containers. To sort the lines by Container Id, Size, Name, Vessel ID or Last Filled, use the mouse to direct the mouse arrow to the column title and left click. The window will update and display the rows in the desired priority.

Use the filters to display containers that are shipped weekly, non-weekly, or both.



To select one of the three filters, use the mouse to direct the mouse arrow to the correct radio button and left click. The window updates to display those containers that meet the filter criteria.

Individually identify containers or select all containers.



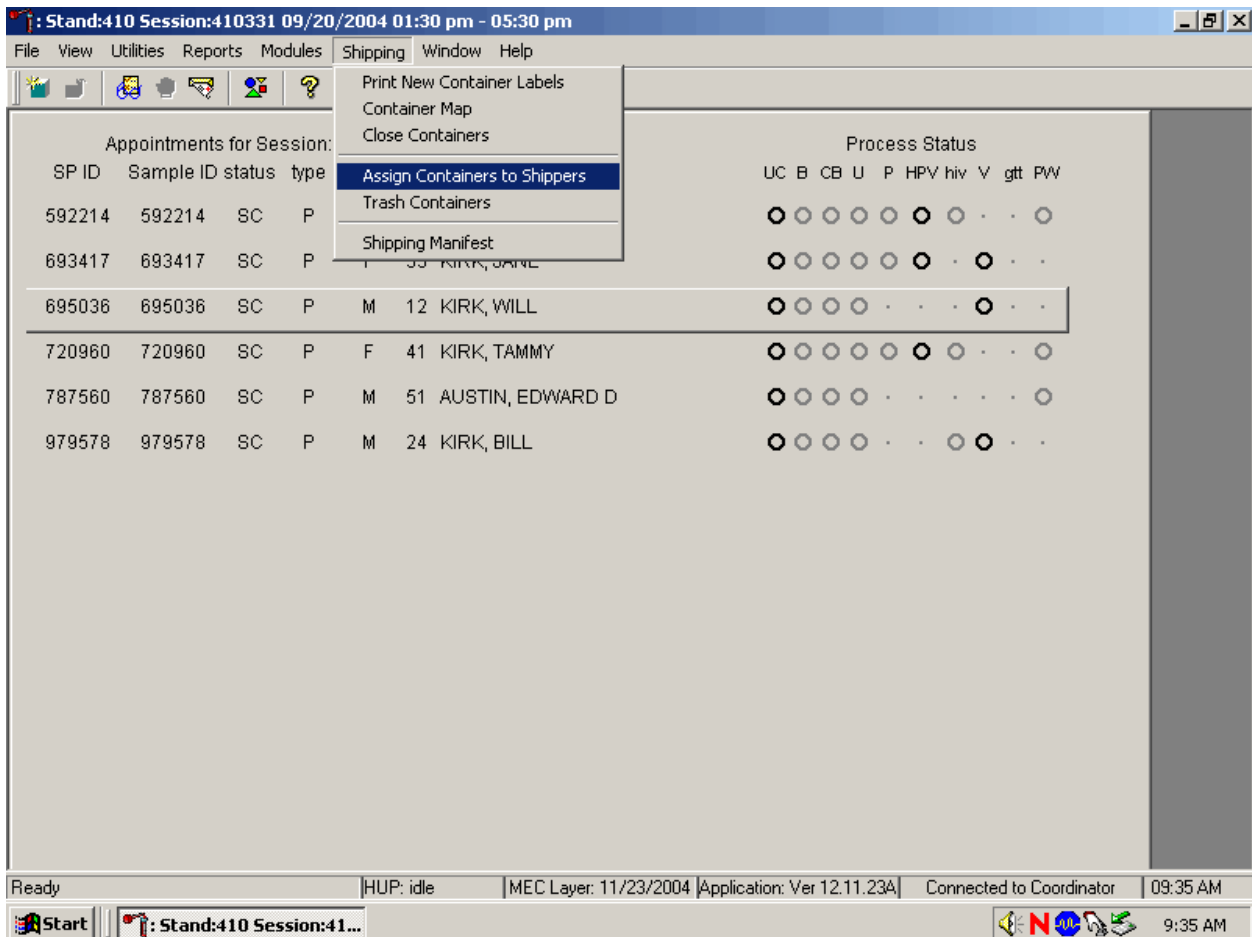
To mark individual containers, use the mouse to direct the mouse arrow to individual Close button check boxes and left click. To close all open containers, use the mouse to direct the mouse arrow to the Close button and left click. To remove the check marks, use the mouse to direct the mouse arrow to the Close button and left click a second time.

Verify the contents of each closed box by visually matching the contents of the box to the map. To record these actions, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the {Close Containers} module without recording these actions, use the mouse to direct the mouse arrow to the Cancel button and left click.

9.10 Assign Containers to Shippers

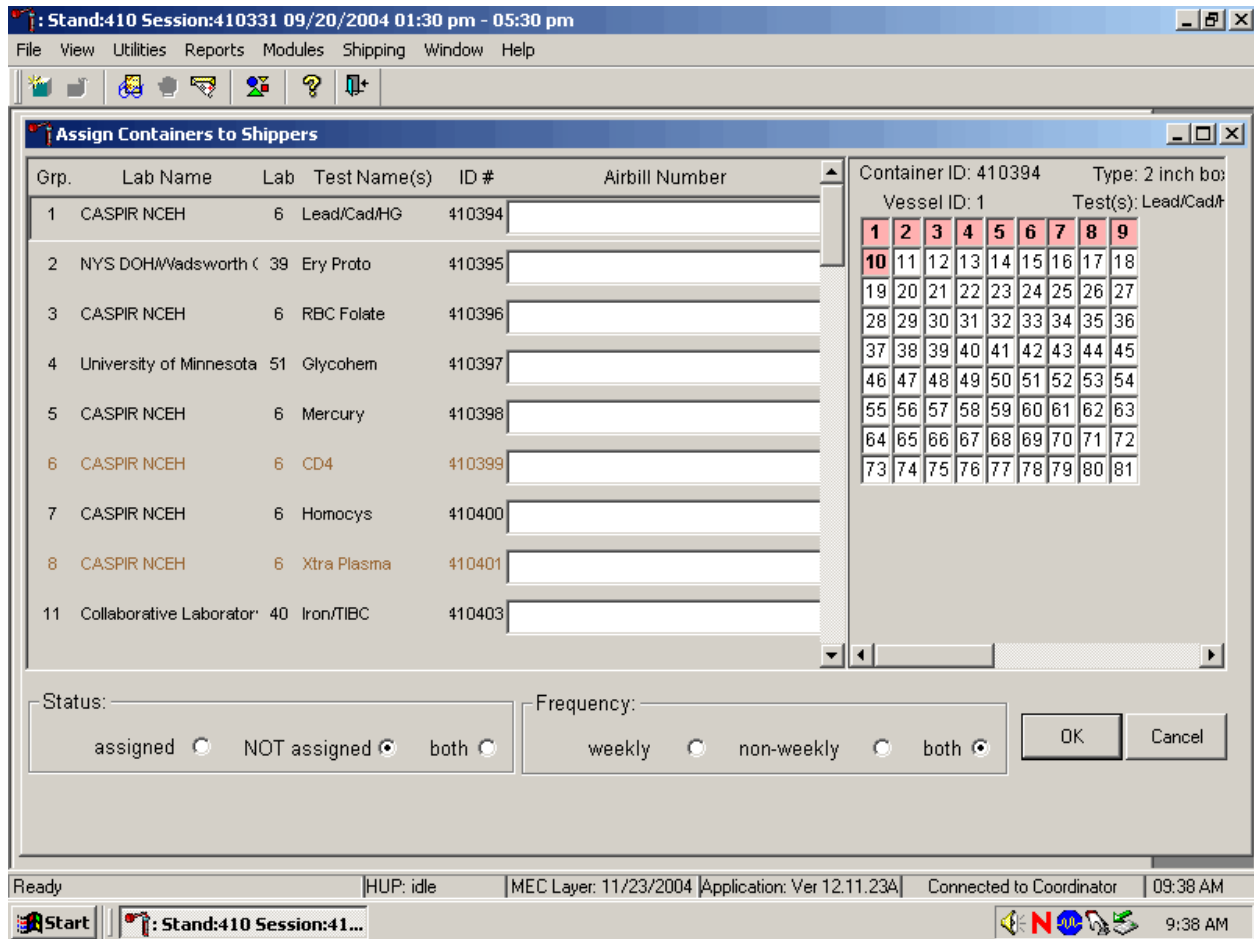
Assign closed containers to or associate closed containers with a specific airbill. To associate a specific closed container to the airbill for that laboratory, use the {Assign Container to Shippers} module.

Access the {Assign Containers to Shippers} module.



To access the {Assign Containers to Shippers} module, use the mouse to direct the mouse arrow to {Shipping} in the top menu bar, left click, drag the mouse arrow to {Assign Container to Shippers}, and left click or type [Alt] [S/s], [S/s].

The Assign Containers to Shippers window displays.



This left side of the screen includes columns for a group designation (which represents a number), Type of container, Lab designation, Test Name(s), Container ID number, and Airbill Number. The container line within the rectangular box is the active container. The right side of the screen displays the corresponding container map for the active container. The left side of the bottom of the window contains three “Status” filters (radio buttons): “assigned,” “NOT assigned,” and “both.” The right side of the bottom of the window contains three “Frequency” filters (radio buttons): “weekly,” “non-weekly,” and “both.” Use the column titles to sort the rows. To sort the rows, use the mouse to direct the mouse arrow to the desired column title and left click. The window updates based on the selection.

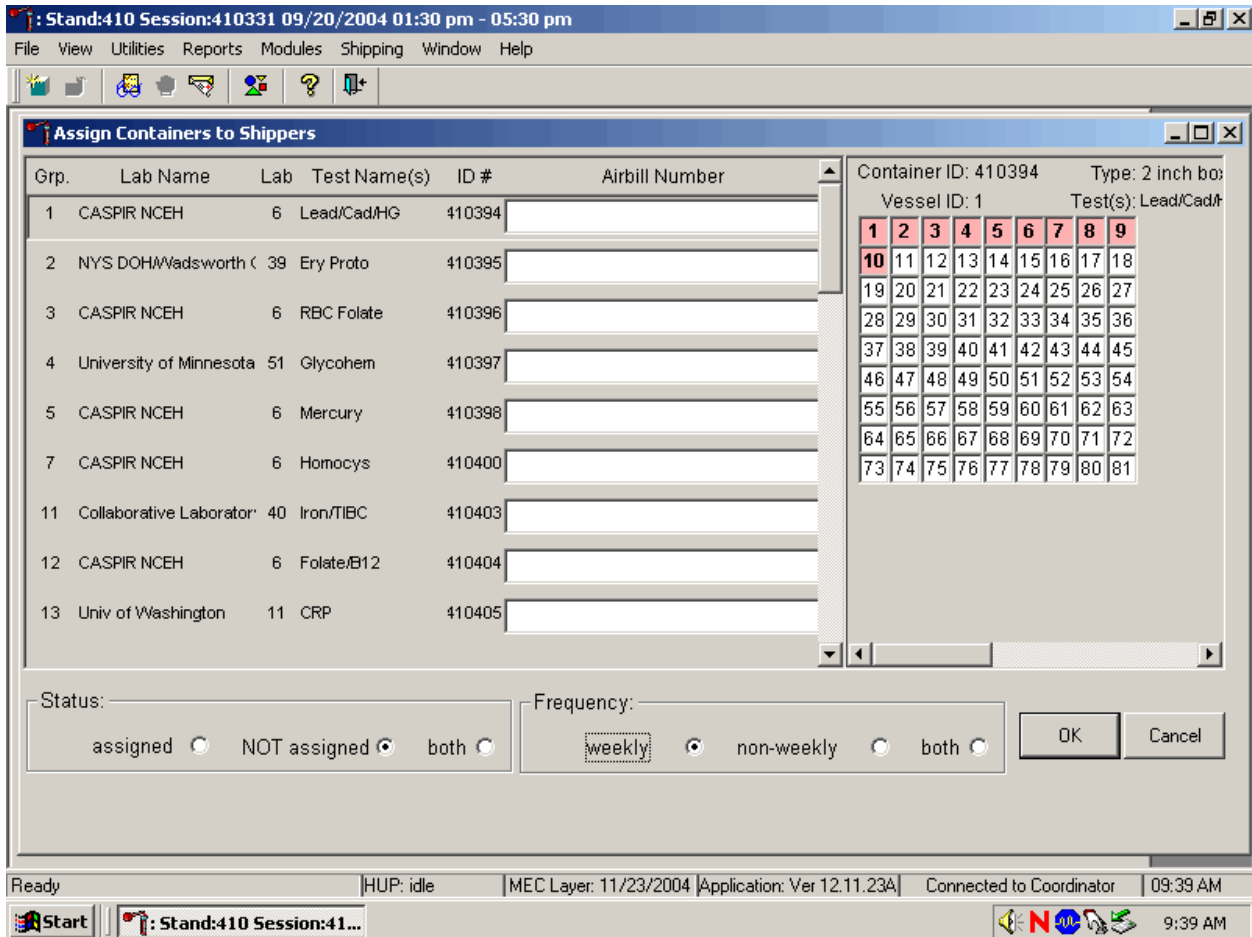
Enter an airbill number into each Airbill Number text box. There are three ways to enter the airbill number.

- Use the bar code gun to scan the bar code from the FedEx Ship Manager airbill. The bar code is located in the bottom of the top half of the folded airbill. It is the tallest bar code on the airbill. Hold the gun in the right hand, squeeze the trigger, and move the gun up and down to adjust the laser light so that it covers the width of the bar code. Once the gun successfully scans the bar code, an audible beep is emitted.
- Use the bar code gun to scan the bar code on the second page (Recipient's Copy) of the two-part Form ID 0215. This bar code is located on the lower left-hand side toward the bottom of the form. Hold the gun in the right hand, squeeze the trigger, and move the gun up and down to adjust the laser light so that it covers the width of the bar code. Once the gun successfully scans the bar code, an audible beep is emitted.
- Use the keyboard keys to type the airbill number from either the FedEx Ship Manager airbill or the FedEx airbill form 0215.

To assign a container to the corresponding airbill:

- Set the Status filter to: "NOT assigned";
- Set the Frequency to: weekly, non-weekly, or both, depending on the shipping situation; and
- Sort the laboratories by Lab number.

Set the Status and Frequency filters.



To select the Status filter, use the mouse to direct the mouse arrow to the assigned, NOT assigned, or both, radio button and left click. To select the shipping Frequency, use the mouse to direct the mouse arrow to weekly, non-weekly, or both, and left click.

Sort the rows by Lab number.

The screenshot shows a software application window titled "Assign Containers to Shippers". The window has a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main area contains a table with the following columns: Grp., Lab Name, Lab, Test Name(s), ID #, and Airbill Number. The table is sorted by Lab number, showing rows for various CDC and CASPIR labs. To the right of the table is a grid for container assignment, with a header row labeled 1-9 and a header column labeled 10-18. The grid is currently empty. Below the table and grid are controls for Status (assigned, NOT assigned, both) and Frequency (weekly, non-weekly, both). The window title bar shows "Stand:410 Session:410331 09/20/2004 01:30 pm - 05:30 pm". The taskbar at the bottom shows the Start button, the session title, and the system clock (9:40 AM).

| Grp. | Lab Name | Lab | Test Name(s) | ID # | Airbill Number |
|------|------------------------|-----|--------------|--------|----------------|
| 14 | CDC NCID Hepatitis Ref | 2 | Hep Profile | 410406 | |
| 22 | CDC NCID AIDS Division | 3 | HIV | 410411 | |
| 53 | CDC NCID AIDS Division | 3 | HIV Urine | 410422 | |
| 54 | CDC Air Toxicant Branc | 4 | VOC Blood1 | 410423 | |
| 56 | CDC Air Toxicant Branc | 4 | VOC Water | 410424 | |
| 102 | CDC Air Toxicant Branc | 4 | Perchlorate | 410446 | |
| 103 | CDC Air Toxicant Branc | 4 | PerchlorH2O | 410447 | |
| 46 | CDC NCID NCHSTD | 5 | Chlam/GC | 410417 | |
| 1 | CASPIR NCEH | 6 | Lead/Cad/HG | 410394 | |

Container ID: 410394 Type: 2 inch box
Vessel ID: 1 Test(s): Lead/Cad/HG

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|----|----|----|----|----|----|----|----|----|
| 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 |
| 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 |
| 46 | 47 | 48 | 49 | 50 | 51 | 52 | 53 | 54 |
| 55 | 56 | 57 | 58 | 59 | 60 | 61 | 62 | 63 |
| 64 | 65 | 66 | 67 | 68 | 69 | 70 | 71 | 72 |
| 73 | 74 | 75 | 76 | 77 | 78 | 79 | 80 | 81 |

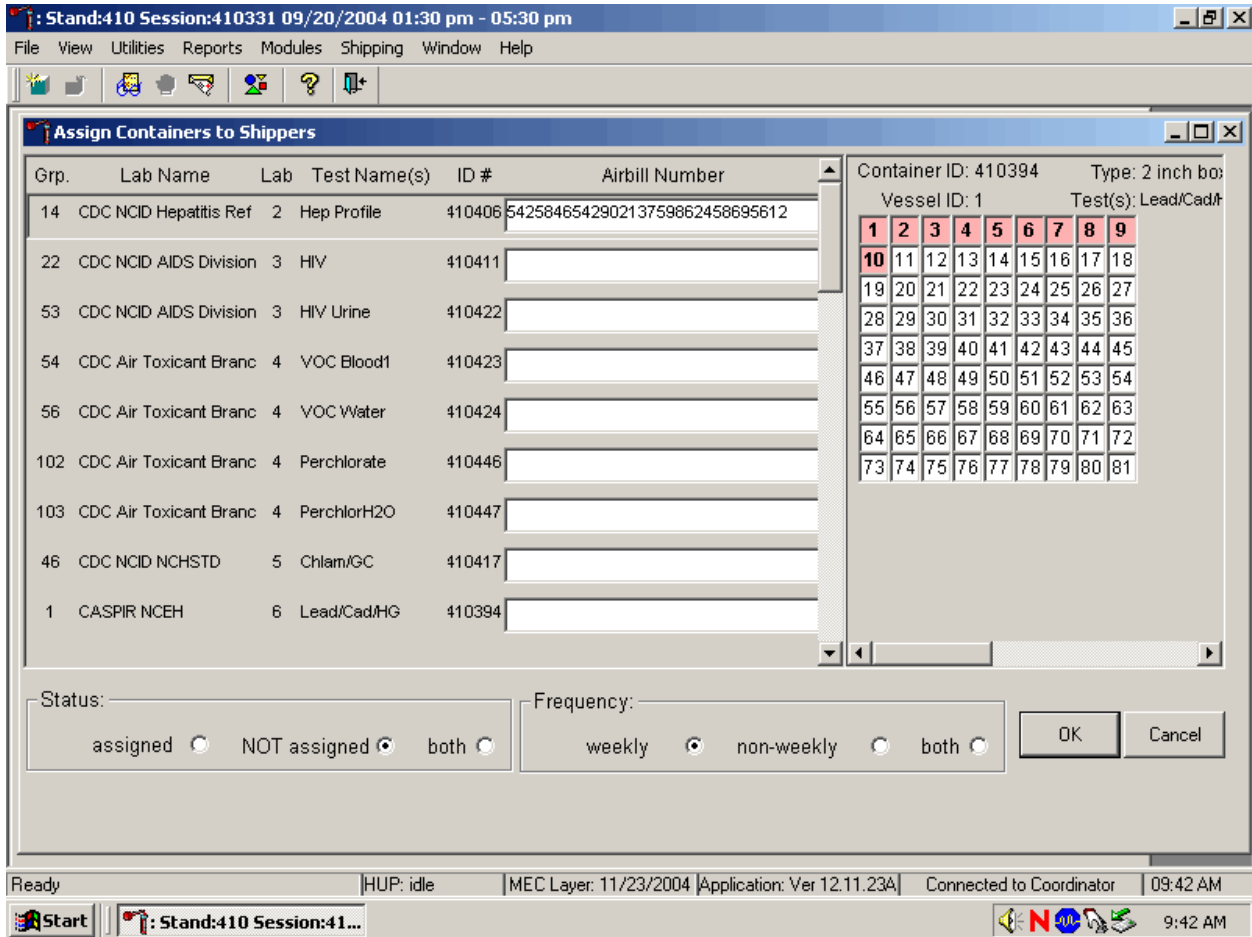
Status: assigned NOT assigned both
Frequency: weekly non-weekly both

Ready | HUP: idle | MEC Layer: 11/23/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 09:39 AM

Start | Stand:410 Session:41... | 9:40 AM

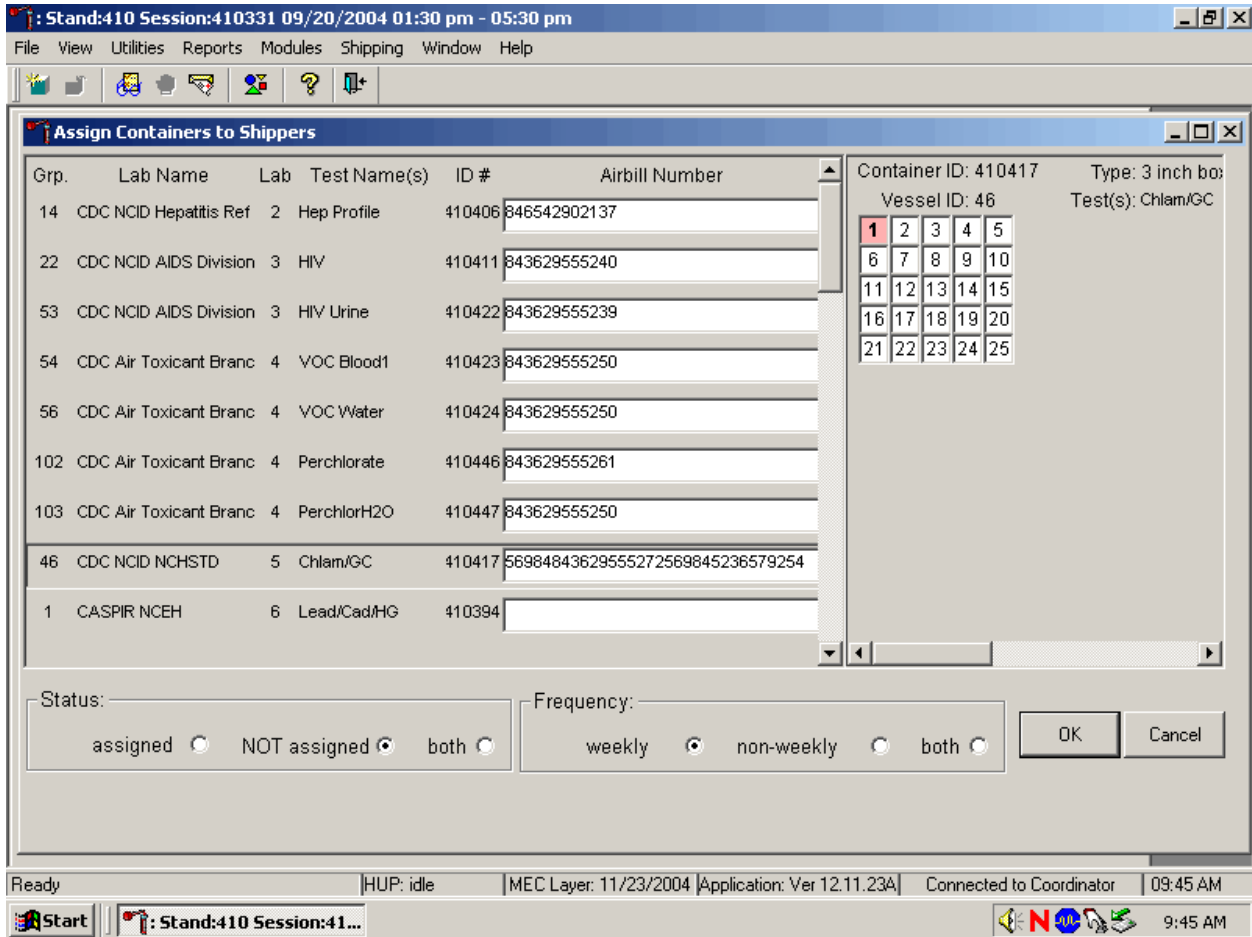
To sort the rows by lab number, use the mouse to direct the mouse arrow to the top header "Lab" and left click. All containers associated with a specific lab will be grouped together in ascending order.

Enter the airbill number into the Airbill Number text box.



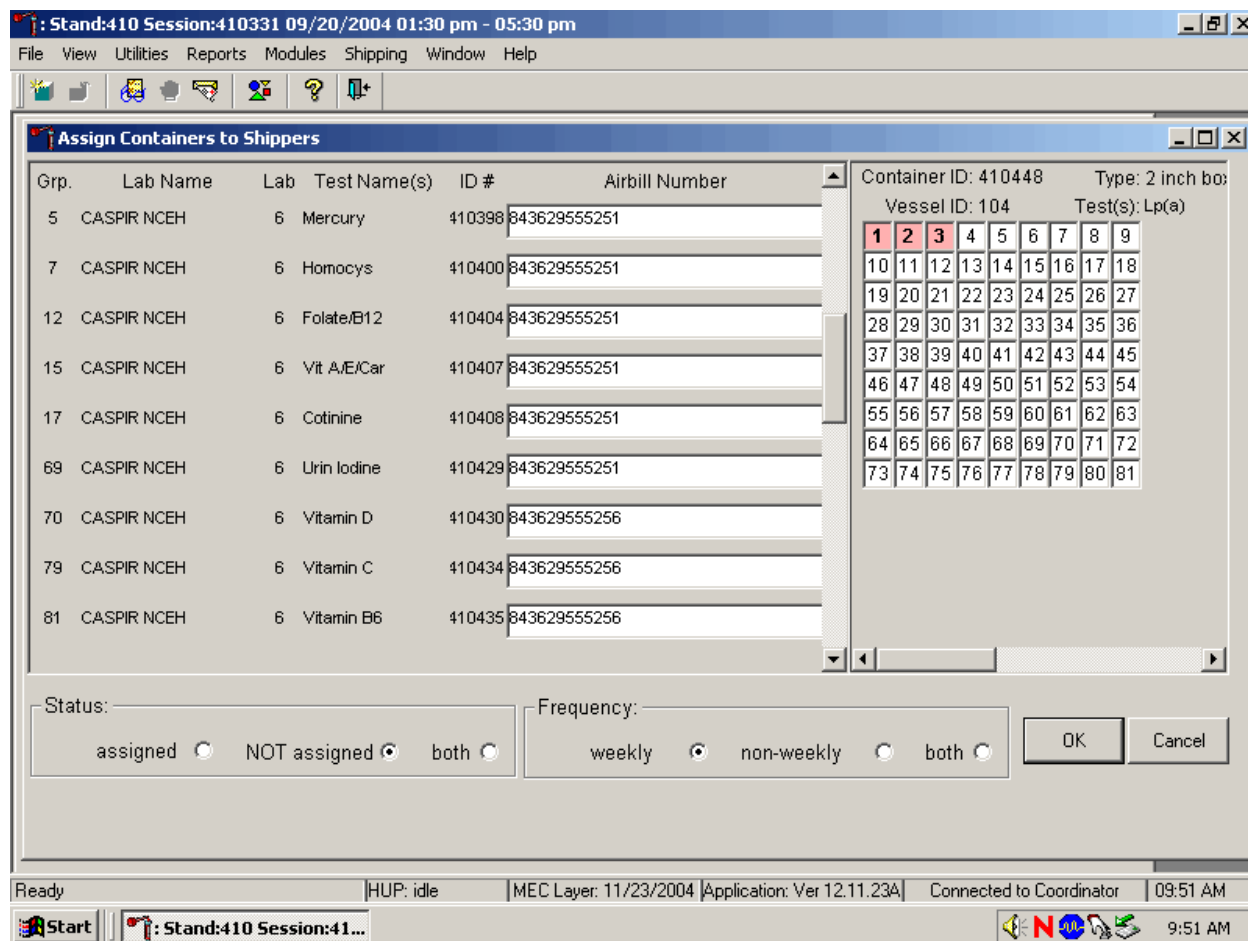
Place the cursor in the first Airbill Number text box. Use the bar code gun to scan the airbill number. The scanned number contains 20 extra digits. The actual 12-digit airbill number is embedded in the 32-digit scanned number. Select the [Tab] key to move to the next text box. Do not select the [Tab] key until the application has been allowed to enter the entire number into the text box. Once the [Tab] key is selected, the program edits the first airbill number to delete the extra numbers.

Continue the assignment process.



Continue scanning the bar codes and selecting the [Tab] key until all closed containers are assigned to airbills.

Complete the assignment process.

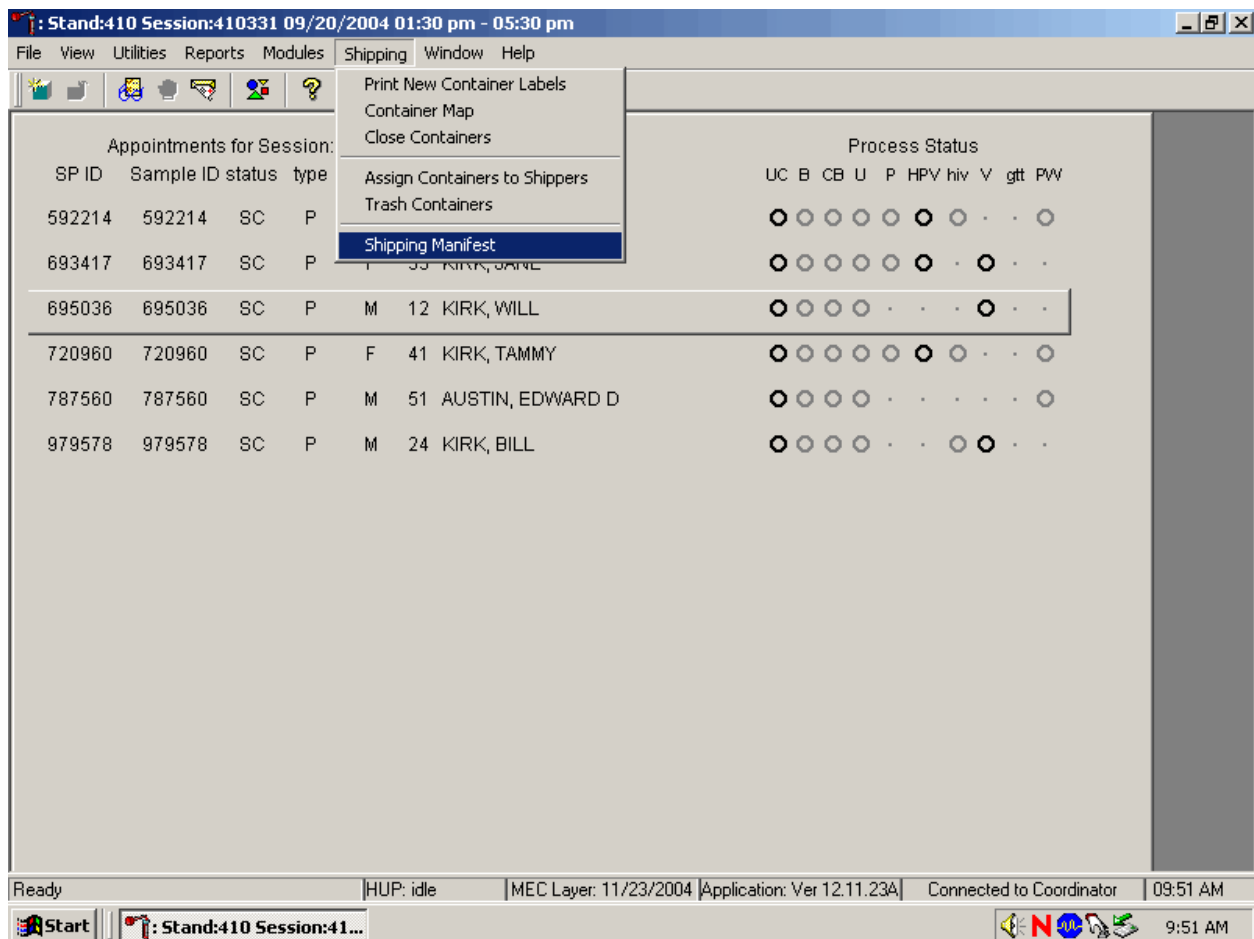


To record the assignment of containers to shippers, use the mouse to direct the mouse arrow to the OK button and left click. **This step is required to save the information.** To exit the {Assign Containers to Shippers} module without recording any assignments, use the mouse to direct the mouse arrow to the Cancel button and left click.

9.11 Create Shipping Manifests

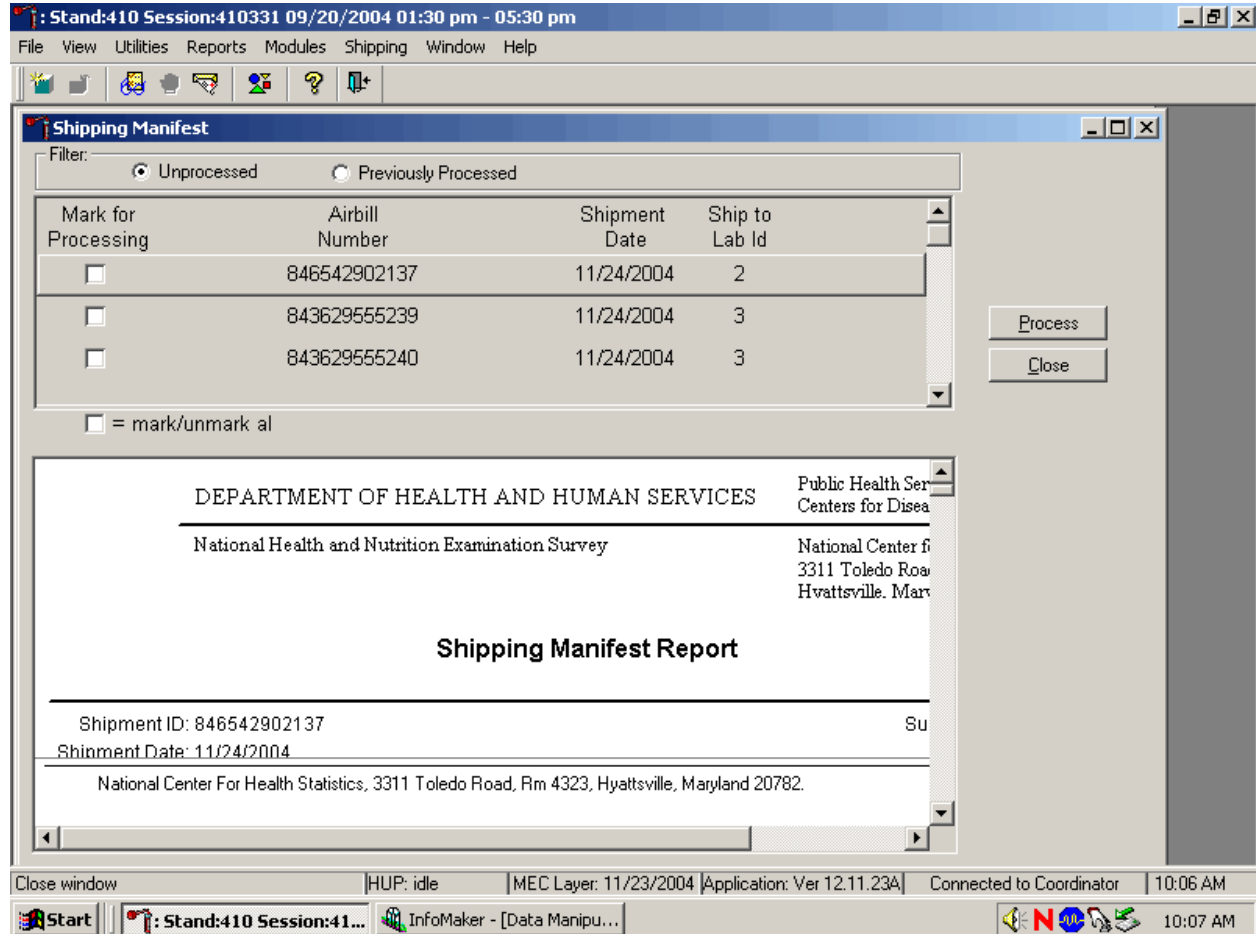
Each shipper must include a paper manifest, which lists the inventory of the specimens in the shipping boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed below to prepare the paper manifest and to send the electronic file.

Access the {Shipping Manifest} module.



To access the {Shipping Manifest} module, use the mouse to direct the mouse arrow to {Shipping} in the top menu bar, left click, drag the mouse arrow to {Shipping Manifest}, and left click or type [Alt] [R/r], [M/m].

A Shipping Manifest window displays either after the {Shipping Manifest} module is accessed or after a positive response is recorded to the IC Informed Consent Exclusion window.



The upper portion of the Shipping Manifest Report (Exhibit 9-3) contains two filters (Unprocessed and Previously Processed) and one row for each airbill assigned in the {Assign Container to Shipper} module. The row includes a processing check box, the Airbill Number, Shipment Date, and Ship to Lab ID, and one check box to mark or unmark all airbills.

The lower portion of the window includes the Shipment ID or airbill number, Shipment Date, Lab Name, Lab ID number, Address, Contact personnel, Survey Year, Container IDs associated with the shipment ID, container Size, container Type, Test(s) associated with the container, and a list by Slot ID of the Sample/Vessel ID, Astro ID, and Date Collected.

Exhibit 9-3. Shipping Manifest Report

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Health and Nutrition Examination Survey

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road, Rm 4323
Hyattsville, Maryland 20782

Shipping Manifest Report

410406

Shipment ID: 846542902137
Shipment Date: 11/24/2004

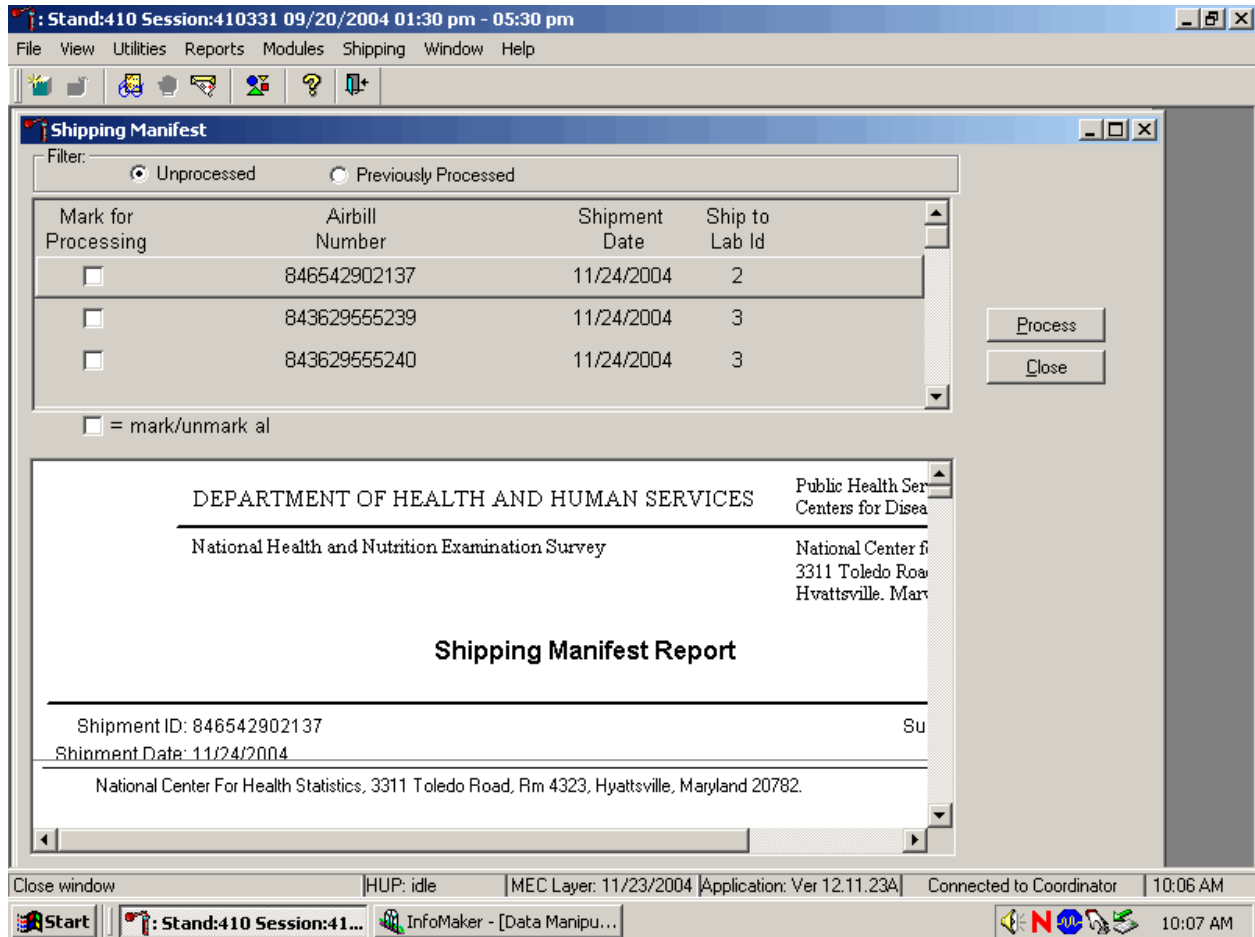
Survey Year: 2005

| | |
|---|---|
| Lab Name: CDC NCID Hepatitis Ref Lab | Lab ID: 2 |
| Address: Hepatitis Reference Laboratory 1600 Clifton Road NH4, Building 1, Room 1389 Atlanta, GA 30329 | Contact: Purdy, Mike Phone: (404) 639-3103 E-Mail: lqm6@cdc.gov |

| Container Id: 410406 | Size: 9x9 | Type: 2 inch box | Test(s): | Hep Profile |
|----------------------|------------------|------------------|----------------|-------------|
| Slot Id | Sample/Vessel Id | Astro Id | Date Collected | Age Group |
| 1 | 252744014 | 000OKVRV | 11/21/2004 | 2 |
| 2 | 930129014 | 000OKVWQ | 11/21/2004 | 2 |
| 3 | 351499014 | 000OKX17 | 11/23/2004 | 2 |
| 4 | 695392014 | 000OKX7O | 11/23/2004 | 2 |
| 5 | 112244014 | 000OKXBD | 11/24/2004 | 2 |
| 6 | 564077014 | 000OKXS1 | 11/24/2004 | 2 |
| 7 | 118671014 | 000OKXOI | 11/24/2004 | 2 |
| 8 | 725454014 | 000OKXK3 | 11/24/2004 | 2 |
| 9 | 978716014 | 000OKXNC | 11/24/2004 | 2 |
| 10 | 323798014 | 000OKWZX | 11/24/2004 | 2 |

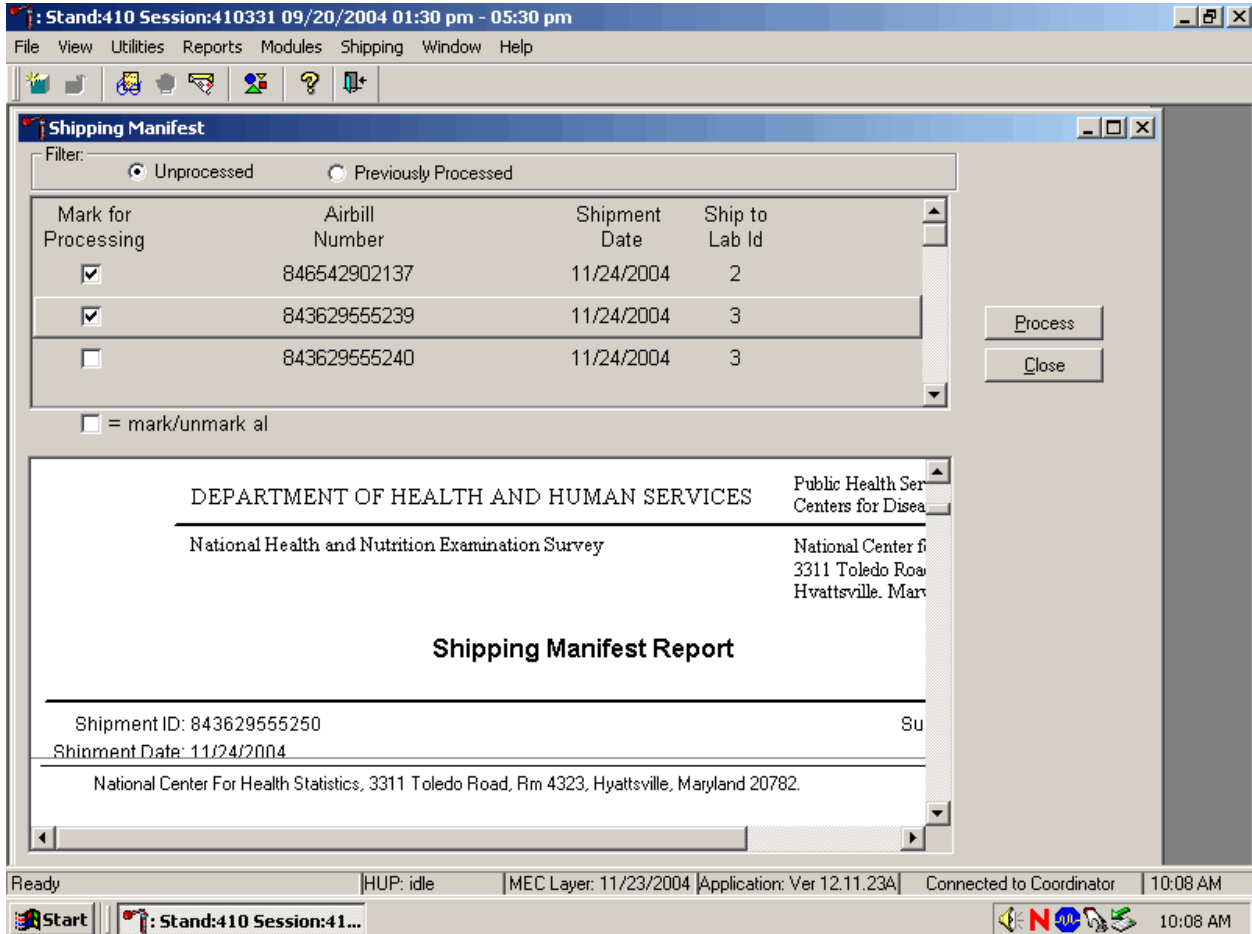
The right side of the window includes two buttons: Process and Close.

Select one of the process filters.



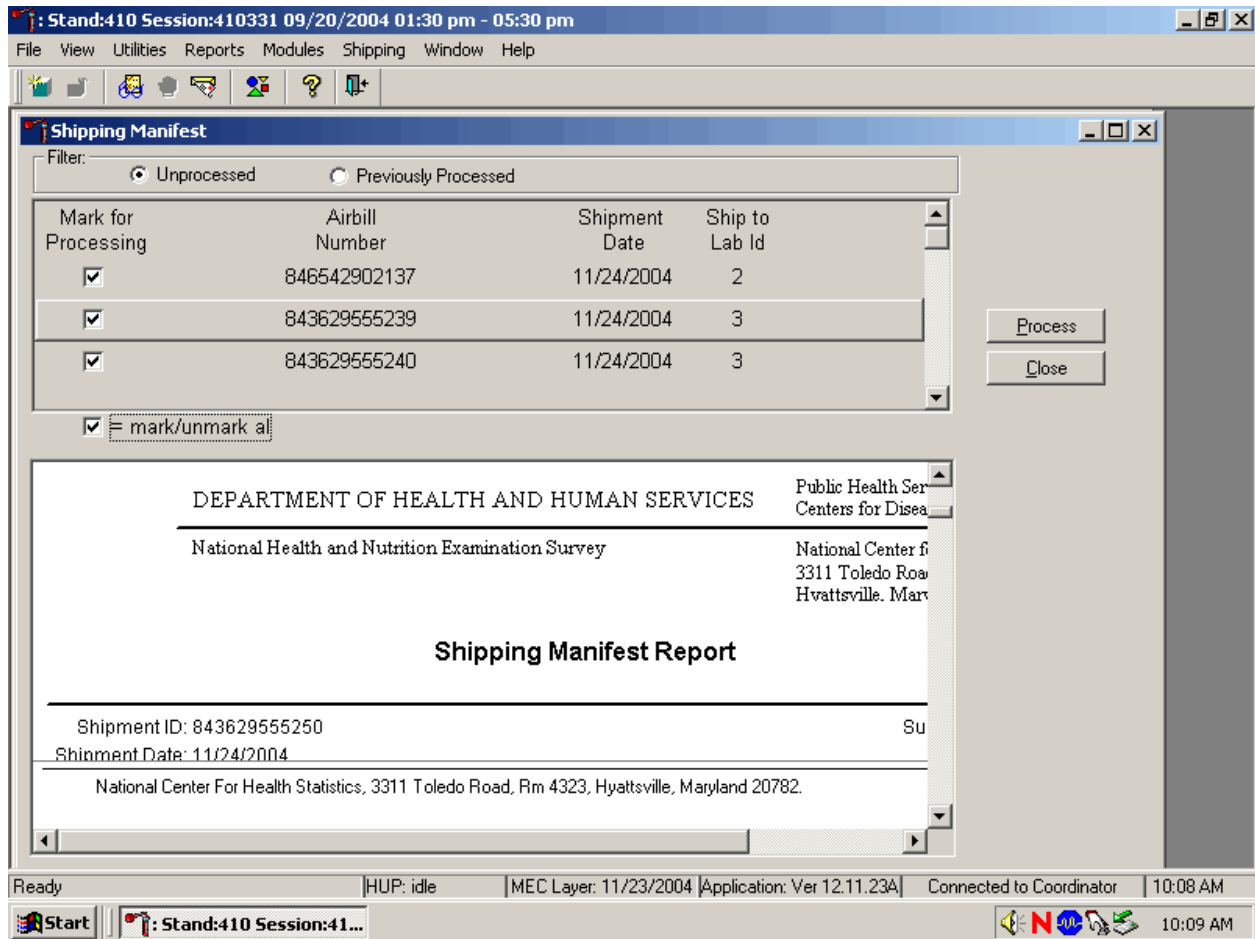
Set the filter to Unprocessed to print manifests and generate email files for shipments created but not previously processed using this module. Set the filter to Previously Processed to reprint an airbill or to recreate an electronic file for shipments previously processed using this module. To filter on Unprocessed airbills use the mouse to direct the mouse arrow to the Unprocessed radio button and left click. To filter on Previously Processed airbills, use the mouse to direct the mouse arrow to the previously Processed radio button and left click.

Select one or more manifests by placing a check mark in the Mark for Processing check boxes.



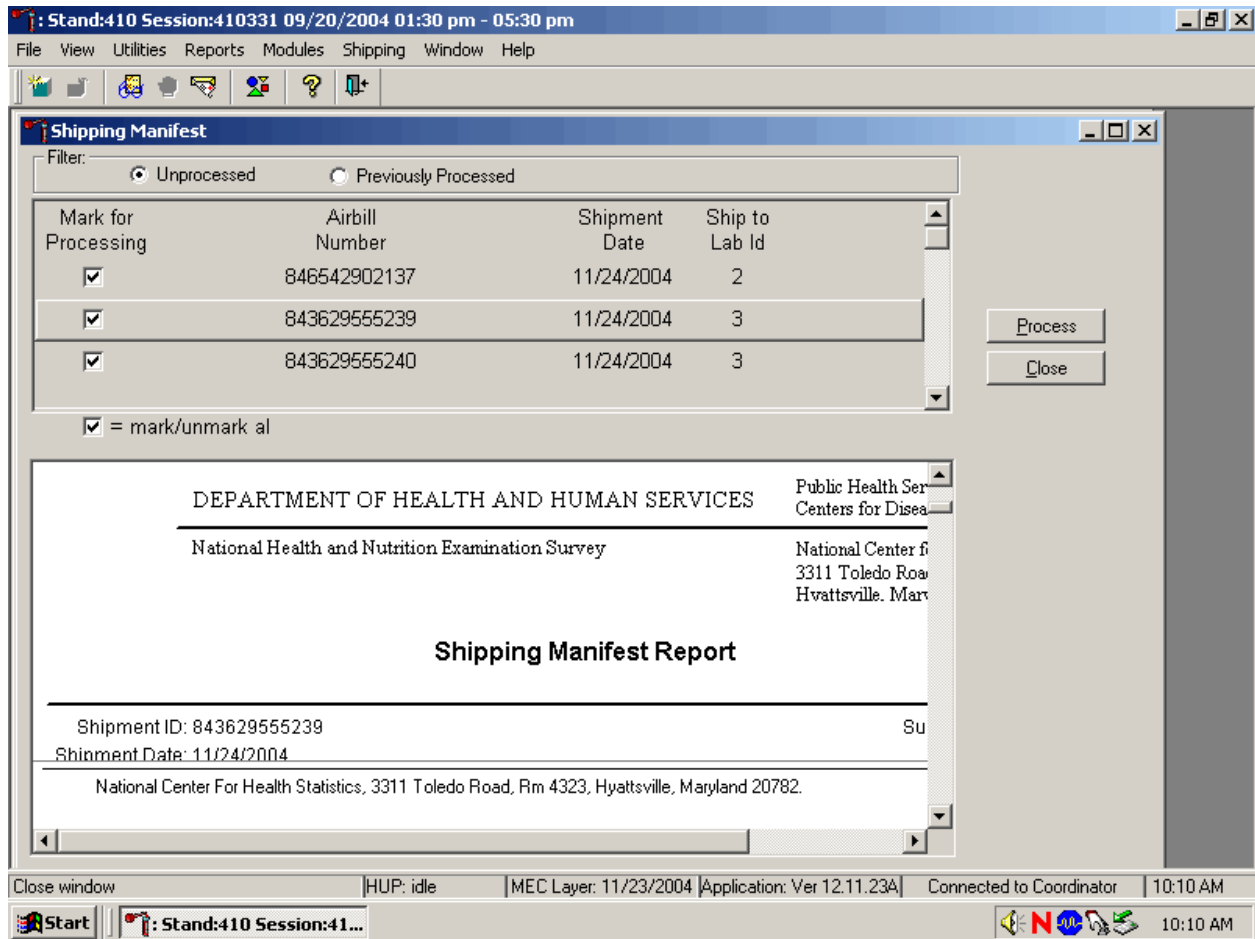
To select or mark one manifest for printing and email, use the mouse to direct the mouse arrow to the check box and left click. Repeat this process to include other airbills. Use the scroll bar to display all existing airbills. The lower portion of the window updates to display only marked airbills.

Collectively mark or unmark all the airbills.



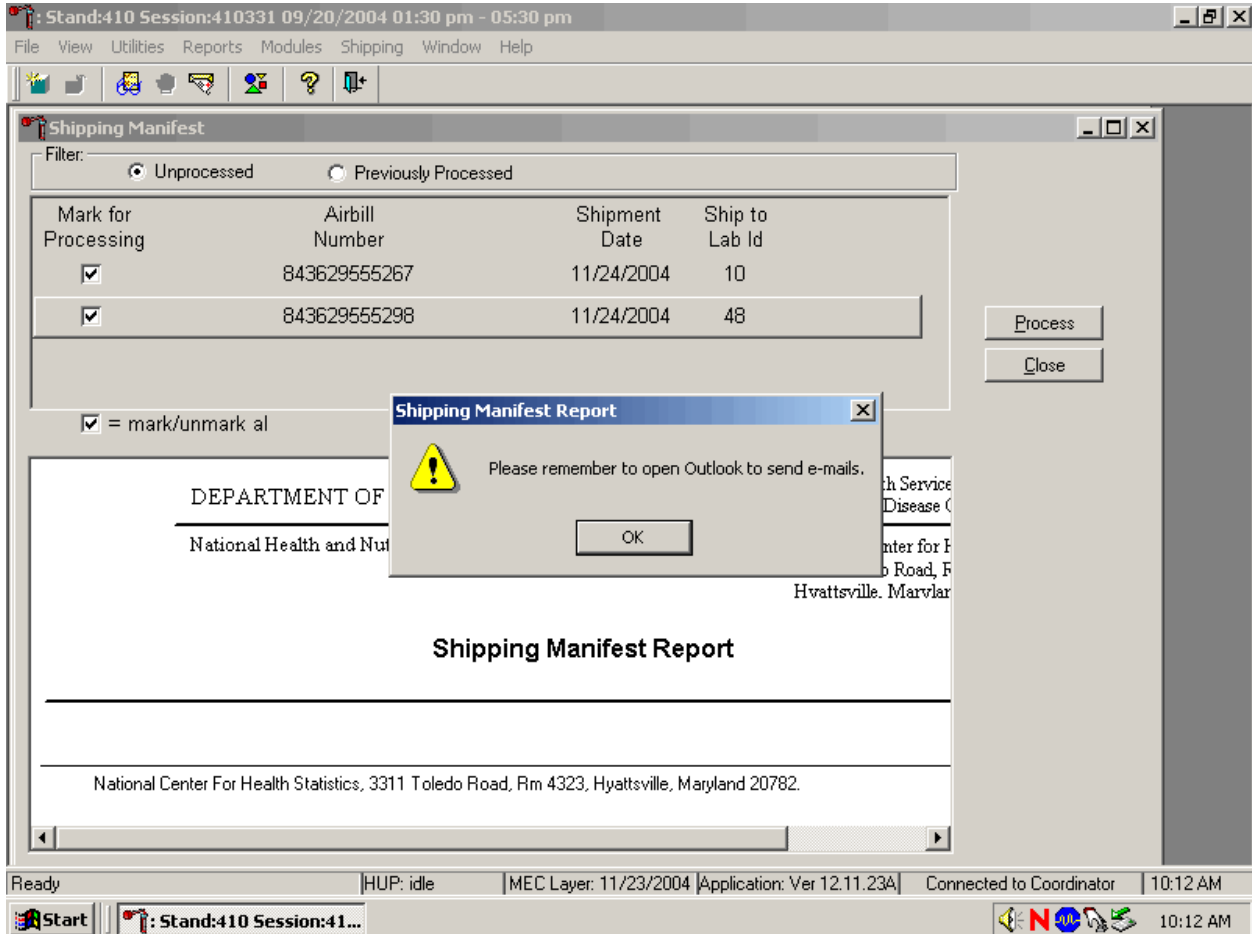
To collectively mark all the airbills, use the mouse to direct the mouse arrow to the mark/unmark all check box and left click. To collectively unmark all the airbills, use the mouse to direct the mouse arrow to the mark/unmark all check box and left click a second time. The lower portion of the screen will update to display the marked airbills.

Process the shipping manifests.



Selecting the Process button will generate and print the Shipping Manifest Report(s) and place a corresponding email in the Outlook send folder. To print the manifest and send the email file to Outlook, use the mouse to direct the mouse arrow to the Process button and left click, or type [Shift] [P/p]. To exit the module without printing the manifest or sending the electronic file, use the mouse to direct the mouse arrow to the Close button and left click, or type [Shift] [C/c.]

After the Process or Close button is selected, a Shipping Manifest Report message text box displays.



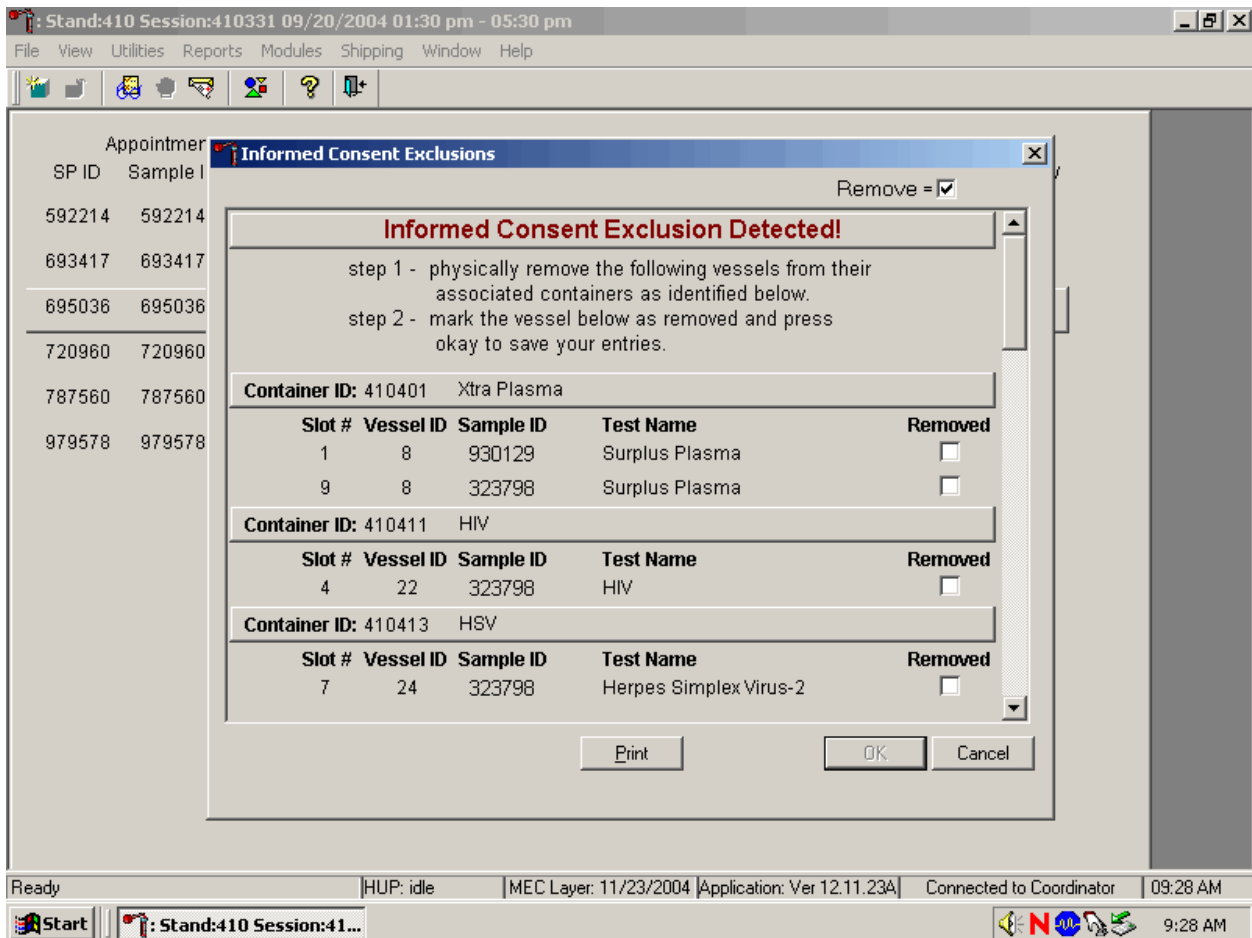
It is essential to open the Outlook email program to send the electronic files each time a manifest is created and a package is sent. It is the shipping technologist's responsibility to open the Outlook program immediately after shipping containers. Opening Outlook sends an email to each laboratory that receives a shipment. The email contains critical information and the contract laboratories rely on the electronic file contained in the email to prepare in advance for the shipment. Laboratories also use the airbill number in the email to track the shipment with FedEx. The data manager can explain the procedure to access and open Outlook. **Do not transmit or send the electronic files more than once.**

To acknowledge the reminder and to remove the message box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

9.12 Informed Consent Exclusions

The Informed Consent Exclusions window displays either when the {Close Container} or {Shipping Manifest} module is accessed. It displays when the following conditions have been met:

1. If SPs initially signed their consent form thereby agreeing to have their samples tested for HPV, PSA, and/or STD testing; and
2. They consent to have their vessels stored for future research; and
3. They subsequently revoke either consent; and
4. The associated vessels have already been processed.

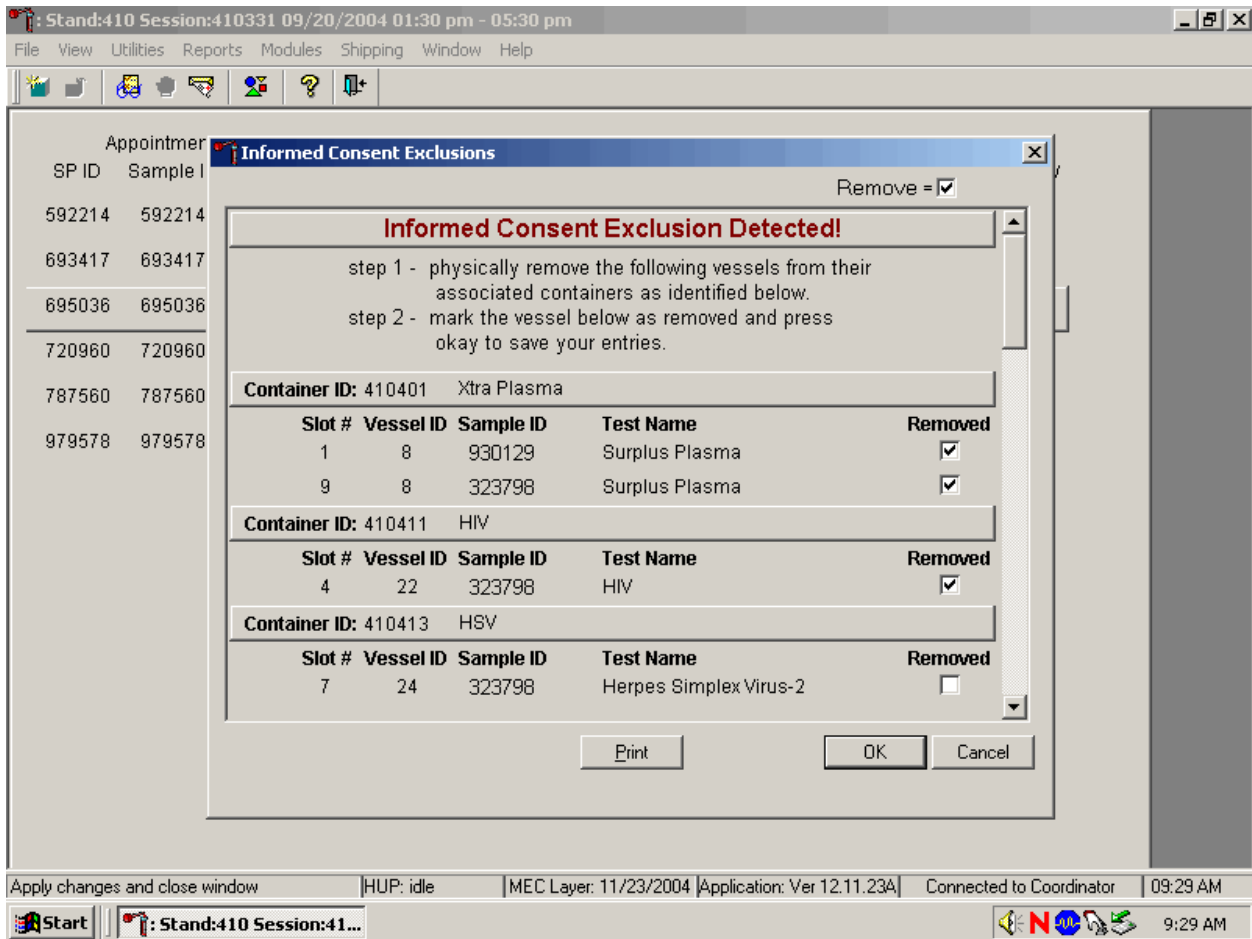


The window contains two steps that must be taken in order to resolve the inconsistencies. It includes the specific container ID and slot number within the container where the vessels are located, the

sample ID, and the test name. Each row represents a vessel that must be marked as removed by placing a check mark in the check box. A Print button on the bottom of the screen allows the list to be printed.

These vessels must be removed from the container and destroyed before the container is shipped. Follow the exact instructions indicated in the window – “Physically remove the following vessels from their associated containers as identified below.”

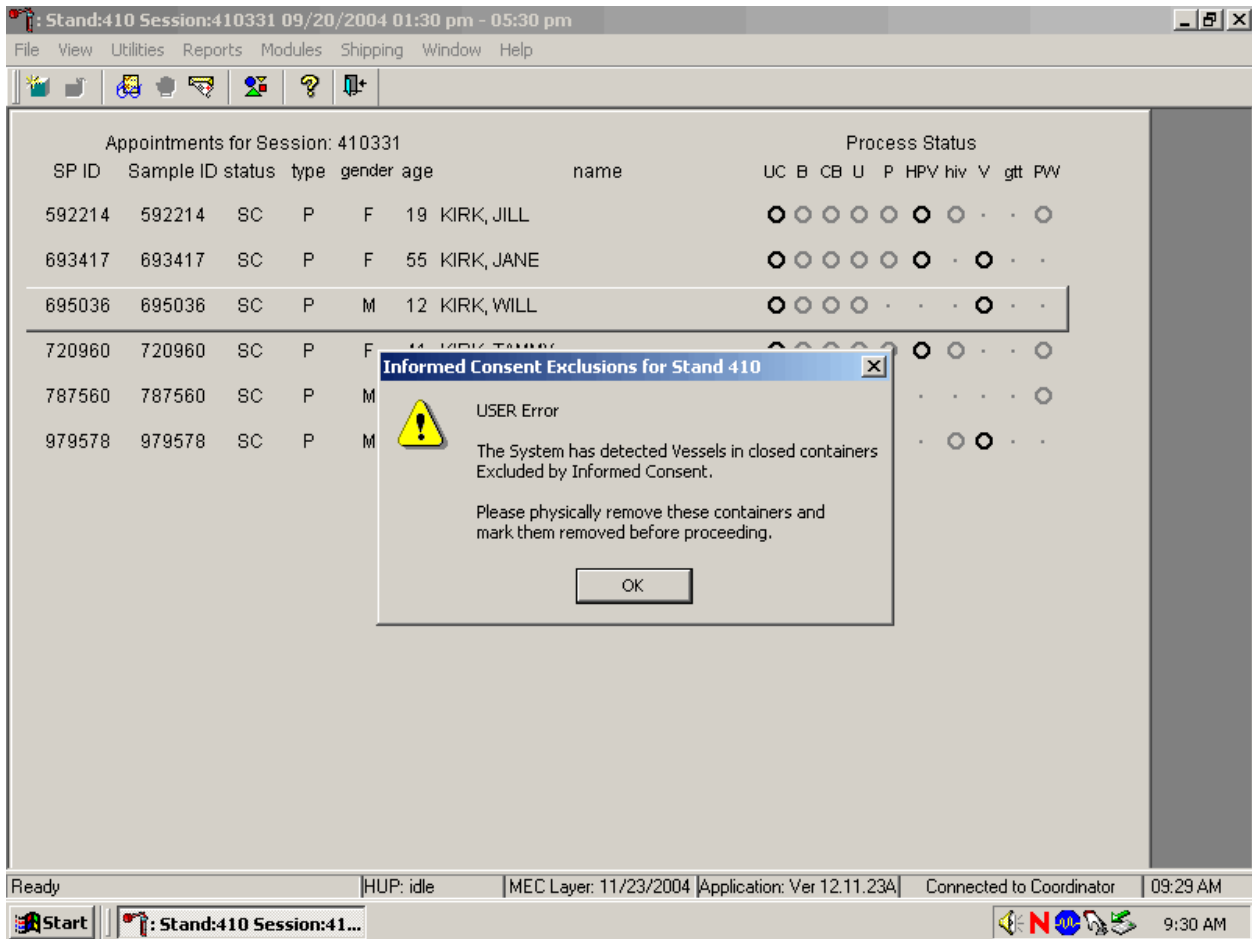
Affirm the actions taken to resolve these exclusions.



After following the exact instructions displayed in the window, record the actions taken to resolve the exclusions. To record these actions, use the mouse to direct the mouse arrow to the Removed check boxes and left click to insert a check mark. To record these actions in the database and to close the Informed Consent Exclusion window, use the mouse to direct the mouse arrow to the OK button and left

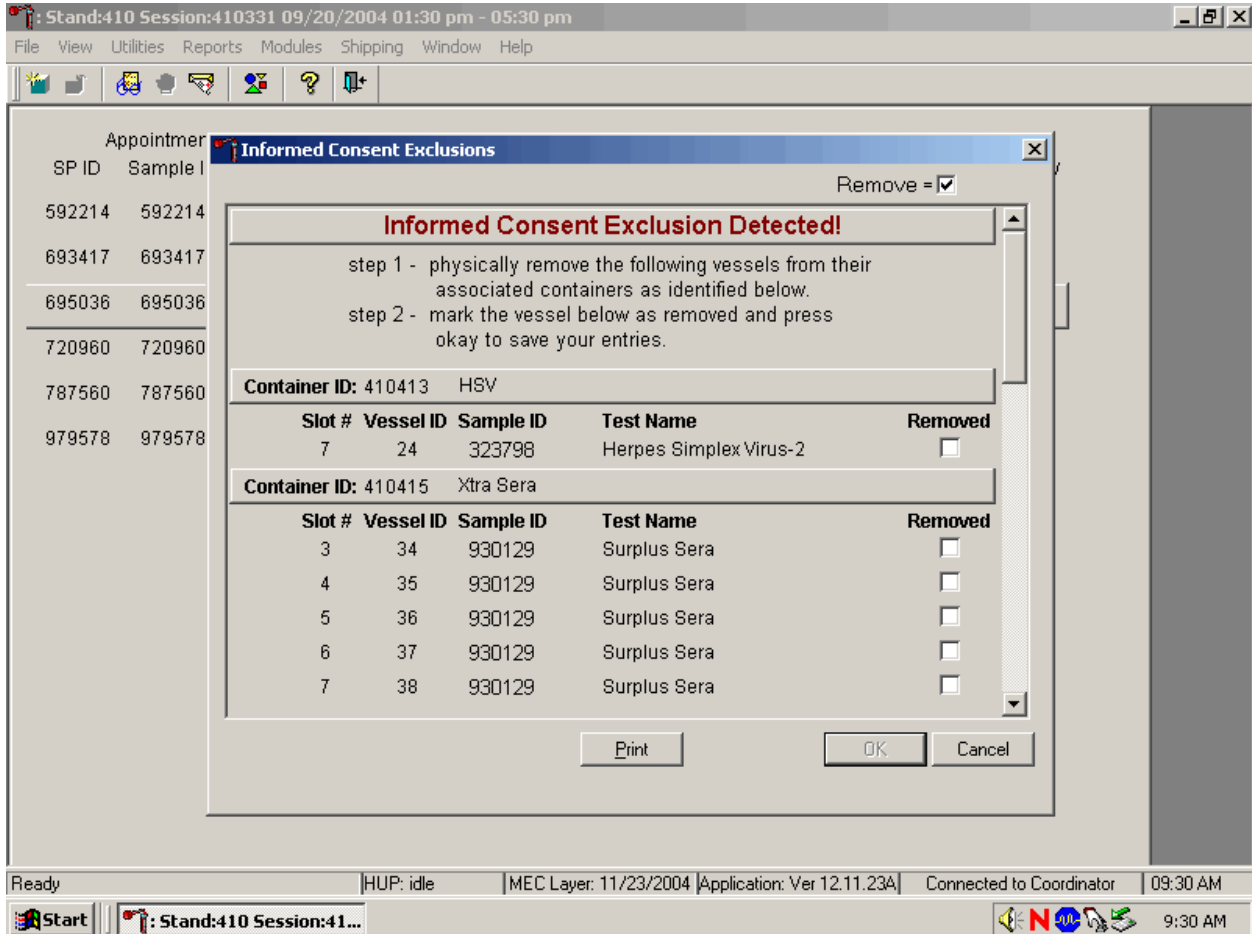
click, or select [Enter]. To remove the window and exit without saving the actions to the database, use the mouse to direct the mouse arrow to Cancel button and left click.

If all the vessels are not marked then an Informed Consent Exclusions of Stand XXX warning pop-up box displays.



The system tracks each vessel in the {Informed Consent Exclusion} module to ensure that every vessel is marked as removed. Follow the instructions in the pop-up box, “Please physically remove these containers, and mark them before proceeding.” To acknowledge the message, use the mouse to direct the mouse arrow to the OK button and left click, or type [Enter].

If all the vessels were not marked, then access the {Informed Consent Exclusion} module a second time.



Follow the exact instructions displayed in the window, and then record the actions taken to resolve the exclusions. To record these actions, use the mouse to direct the mouse arrow to the Removed check boxes and left click to insert a check mark. To record these actions in the database and to close the Informed Consent Exclusion window, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

9.13 Packing Procedure for the Shippers

Most of the shipments require dry ice to keep the specimens frozen during shipment. Some shipments require reusable refrigerant packs to keep specimens cold but not frozen. Store reusable refrigerant packs in the freezers. (Distribute the refrigerant packs across all freezers.) It is the chief medical technologist's responsibility to arrange for delivery of dry ice pellets or blocks for shipping specimens. Use sliced blocks whenever possible since these sublimate less than pellets. Well in advance of a scheduled shipment, the shipping technologist estimates how much dry ice to order for the shipment and informs the MEC manager. Store the dry ice in extra shipping containers. When handling dry ice, wear cryo gloves to avoid burning hands. Also, wear an eye shield when filling bags with ice chips or breaking blocks into chunks. Use the scale to ensure that each shipper has the required amount of dry ice. Exhibit 9-4 is a list of all contract laboratory addresses.

Federal regulations require packaging all blood, urine, and other liquid diagnostic specimens according to certain regulations and packaging procedures. A complete description of these regulations is contained in Appendix A.

Diagnostic specimens must be packed in good quality packaging, which must be strong enough to withstand the shocks and loading normally encountered during transport, including transshipment between transport units and warehouses as well as removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging must be constructed and closed to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity, or pressure.

The packaging must consist of three components:

- (a) a primary receptacle(s);
- (b) a secondary packaging; and
- (c) a rigid outer packaging.

Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not substantially impair the protection properties of the cushioning material or of the outer packaging.

Exhibit 9-4. Contract laboratory addresses

| Laboratory/destination specimen shipment address | Vessels/assays | Conditions | Contact name Telephone number |
|--|--|------------|--|
| CASPIR Attn: Robert White 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-339-5942 | 1 – Lead/Cad/HG 3 – RBC Folate 5 – Mercury 6 – CD4 7 – Homocys 88 – Acrylamide 8 – Xtra Plasma 81 – Vitamin B6 70 – Vitamin D 12 – Fol/B12 99 – Fer/TFR 17 – Cotinine 79 – Vitamin C 15 – Vit A/E/Car 32-40 – Xtra Serum 69 – Urn Iodine 86 – Speciated Arsenic 62 – Urn Merc 50 – Heavy Metal 52 – Extra urine | Frozen | Robert White 770-339-5942 |
| CASPIR/Dr. Andreas Sjodin Attn: Dr. Andreas Sjodin 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-4711 | 66 – PAH | Frozen | Dr. Andreas Sjodin 770-488-4711 |
| CASPIR/Dr. Christine Pfeiffer 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-7926 | 65 – Urn Phytoes | Frozen | Dr. Christine Pfeiffer 770 488-7926 |
| CASPIR/Dr. Wayman Turner Attn: Cheryl McClure 602 Webb Gin House Road Building C Lawrenceville, GA 30045-5427 770-488-7883 | 29 – Persis Pest 89 – Persis Pest2 92 – BFR1 93 – BFR3 | Frozen | Cheryl McClure 770-488-7883 |
| CDC Air Toxicant Branch Attn: Ben Blount 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341 770-488-7962 | 102 – Perchlorate | Frozen | Dr. Ben Blount 770-488-7962 |

Exhibit 9-4. Contract laboratory addresses (continued)

| Laboratory/destination specimen shipment address | Vessels/assays | Conditions | Contact name Telephone number |
|---|--|--------------|--|
| CDC Air Toxicant Branch Attn: Ben Blount 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341 770-488-7962 | 54 – VOC Blood 56 – VOC Water 103 – PerchlorH2O | Refrigerated | Dr. Ben Blount 770-488-7962 |
| CDC Dr. Antonia Calafat 4770 Buford Highway Building 17, Loading Dock Atlanta, Ga 30341-3724 770-488-7891 | 90 – Perfluor1 67 – Phthalates | Frozen | Dr. Antonia Calafat 770-488-7891 |
| CDC Dr. Dana Barr Attn: Dr. Dana Barr 4770 Buford Highway Building 17, Loading Dock Atlanta, GA 30341-3724 770-488-4598 | 91 – Srm Pest 48 – Prior Pest 49 – Organophos | Frozen | Dr. Dana Barr 770-488-4598 |
| CDC Kristi Singletary Meadows 1600 Clifton Rd NE MS G41 Building 7, Room 116 Atlanta, GA 30329 404-639-2183 | 77 – HPV Serum | Frozen | Kristi Singletary Meadows 404-639-2183 |
| CDC NCID AIDS Division Attn: Faye Cowart 1600 Clifton Road NE Building 17, Room 3126 MS D-12 Atlanta, GA 30329 404-639-0286 | 22 – HIV | Frozen | Faye Cowert 404-639-3174 |
| CDC NCID AIDS Division Attn: Faye Cowart 1600 Clifton Road NE Building 17, Room 3126 MS D-12 Atlanta, GA 30329 404-639-0286 | 53 – HIV Urine | Refrigerated | Faye Cowert 404-639-3174 |
| CDC NCID Hepatitis Ref Lab Attn: Dr. Wendi Kuhnert Code NH4 1600 Clifton Road NE Building 1, Room 1389 Atlanta, GA 30329 404-371-5451 | 14 – Hep profile 87 – Hepatitis ab | Frozen | Dr. Wendi Kuhnert 404-371-5451 |

Exhibit 9-4. Contract laboratory addresses (continued)

| Laboratory/destination specimen shipment address | Vessels/assays | Conditions | Contact name Telephone number |
|--|--|------------------|-----------------------------------|
| CDC NCID NCHSTD Attn: Carol Farshy 1600 Clifton Road NE MS D13 Atlanta, GA 30329 404-639-2870 | 46 – Chlam/GC | Frozen | Carol Farshy 404-639-2870 |
| CDC Ruth Ann Tucker 1600 Clifton Road NE MS G41 Building 7, Room 112 Atlanta, GA 30329 404-639-2183 | 78 – HPV | Room Temperature | Ruth Ann Tucker 404-639-2183 |
| Collaborative Laboratory Services Attn: Sue Vanness 1005 Pennsylvania Suite 102 Ottumwa, Iowa 52501 641 684-4621 | 11 – Iron/TIBC | Frozen | Attn: Sue Vanness 641 684-4621 |
| Collaborative Laboratory Services Attn: Sue Vanness 1005 Pennsylvania Suite 102 Ottumwa, Iowa 52501 641 684-4621 | 18 – Biochem | Refrigerated | Sue Vanness 641 684-4621 |
| Emory University Dr. Francis Lee 2015 Uppergate Dr. Room 560 Atlanta, GA 30322 404-727-4652 | 24 – HSV | Frozen | Dr. Francis Lee 404-616-6229 |
| Lipoprotein Analytical Lab/JHU Attn: Donna Virgil 600 North Wolfe Street Blaylock 1379 Baltimore, MD 21287 410-614-1030 | 21 – Lipids | Frozen | Donna Virgil 410-614-1145 |
| NHANES Diabetes Laboratory Jean Bucksa 420 Delaware St SE Mayo L275 Minneapolis, MN 55455 612-273-3645 | 9 – Glucose 98 – OGTT 23 – Insulin | Frozen | Jean Bucksa 612-273-3645 |

Exhibit 9-4. Contract laboratory addresses (continued)

| Laboratory/destination specimen shipment address | Vessels/assays | Conditions | Contact name Telephone number |
|---|-----------------------------------|--------------|---------------------------------------|
| NHANES Diabetes Laboratory Jean Bucksa 420 Delaware St SE Mayo L275 Minneapolis, MN 55455 612-273-3645 | 4 – Glycohem | Refrigerated | Jean Bucksa 612-273-3645 |
| NYS DOH/Wadsworth CTR L&R Attn: Patrick Parsons, PhD. ESP P1 South Dock J3 Albany, NY 12237 518-474-5475 | 2 – Ery Proto | Frozen | Patrick Parsons, PhD. 518-474-5475 |
| Univ of Minnesota Attn: Susan Kupcho 515 Delaware Street SE Room 13-219 – MOOS Tower Minneapolis, MN 55455 612-624-6153 | 45 – Alb/Creat | Frozen | Susan Kupcho 612-624-6153 |
| Univ of Washington Attn: Kathy Hutchinson Immunology NW 176, Box 357110 1959 NE Pacific Avenue Seattle, WA 98195 (206) 598-4181 | 13 – CRP 94 – PTH2 75 – PSA | Frozen | Kathy Hutchinson 206-548-4181 |
| TBD | 100/IgE | Frozen | |
| Univ of Washington – Michelle Mehan | 104/Lp(a) | Frozen | |

Packages must be prepared as follows:

650(a) For Liquids

- The primary receptacle(s) must be leakproof and must not contain more than 1 L;
- The secondary packaging must be leakproof;
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacle (so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging).
- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40°C to +55°C (-40°F to 130°F).
- The outer packaging must not contain more than 4 L.

Specific Requirements – refrigerated or frozen specimens: ice, dry ice, and liquid

nitrogen

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice (solid carbondioxide) has been dissipated. If ice is used, the packaging or overpack must be leakproof. If dry ice (solid carbon dioxide) is used, the outside packaging or overpack must be designed and constructed to permit the release of carbon dioxide gas to prevent a buildup of pressure that could rupture the packaging.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these regulations except for the following:

- (a) the name, address, and telephone number of a responsible person must be provided on the waybill or on the package;
- (b) The “Nature and Quantity of Goods” box of the air waybill must show the text “DIAGNOSTIC SPECIMENS” or “CLINICAL SPECIMENS” and UN 3373.

Packing Instruction 904 – Dry Ice

Dry ice (solid carbon dioxide), when offered for transport by air, must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a buildup of pressure that could rupture the packaging.

The net weight of dry ice must be marked on the outside of the package.

Arrangements between the shipper and operator(s) must be made for each shipment to ensure that ventilation and safety procedures are followed.

When a Shipper’s Declaration is not required, the following information as required by 8.2.3 for dry ice (solid carbon dioxide) must be contained in the “Nature and Quantity of Dangerous Goods” box on the air waybill:

- Proper shipping name (**Dry Ice** or **Carbon Dioxide, solid**);
- UN 1845;
- The number of packages; and
- The net weight of dry ice in each package.

The net weight of the dry ice must be marked on the outside of the package.

9.13.1 Pack Boxed Specimens

Store the blood and urine vessels in 2-, 3-, and 5-inch storage boxes. Separate the vessels with cardboard grids or foam inserts. Secure the top of the box to the bottom with a rubber band. Place the box in a pressure vessel, add one absorbent paper, and seal the pressure vessel.

Ship the vessels to the addresses listed in the Contract Laboratory addresses (see Exhibit 9-3).

9.13.2 Pack Medium Shipping Containers for Frozen Shipment

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the shipper on the scale and tare.
- Place a layer 3-inches thick or at least 15 pounds of chipped dry ice or dry ice slabs in the bottom of a medium Styrofoam shipper.
- Place a single layer of newsprint between the box and the dry ice.
- Place the sealed pressure vessels containing the boxes on top of the dry ice.
- Pack the sides with crumbled newsprint.
- Tare the scale.
- Place enough chipped dry ice or dry ice slabs on top so that the Styrofoam container is filled with dry ice to 1/4" below the rim or add a minimum of another 15 pounds of dry ice.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and return preprinted label on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume the medium shipper weighs approximately 35 pounds.
- Record the weight of the dry ice (30 pounds for a medium shipper) on the FedEx Class 9 label.

- Secure the shipper with tape.
- Attach the airbill.

9.13.3 Pack Small Shipping Containers for Frozen Shipment

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the shipper on the scale and tare.
- Place a layer 3-inches thick or at least 10 pounds of chipped dry ice or dry ice slabs in the bottom of a medium Styrofoam shipper.
- Place a single layer of newsprint between the box and the dry ice.
- Place the sealed pressure vessels containing the boxes on top of the dry ice.
- Pack the sides with crumbled newsprint.
- Tare the scale.
- Place enough chipped dry ice or dry ice slabs on top so that the Styrofoam container is filled with dry ice to 1/4" below the rim or add a minimum of another 10 pounds of dry ice.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place a plastic envelope containing the appropriate shipping manifest and return preprinted label on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume the medium shipper weighs approximately 25 pounds.
- Record the weight of the dry ice (20 pounds for a small shipper) on the FedEx Class 9 label.
- Secure the shipper with tape.
- Attach the airbill.

9.13.4 Pack Medium Shipping Container for Refrigerated Shipment

Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers.

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Seal the 9 x 12 zip closable plastic bag or the pressure vessel containing the boxes.
- Place at least two large frozen refrigerant packs in the bottom of a shipper.
- Place the sealed plastic bag containing the swabs or the pressure vessel containing the boxes on top of the refrigerant pack.
- Pack the sides with crumbled newsprint.
- Place two additional refrigerant packs on top of the container(s).
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place the appropriate shipping manifest and one return FedEx preprinted airbill into a 9 x 12 plastic bag and seal.
- Place the plastic envelope containing the appropriate shipping manifest and one FedEx preprinted airbill on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

9.13.5 Label Shippers

For all destinations, include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 4 weeks of the stand. Include a preprinted FedEx return airbill label with the address for the concurrent stand during the last 2 weeks of the stand.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

1. A “Keep Frozen” label and a FedEx Class 9 – Miscellaneous Dangerous Goods label on shippers containing dry ice.
2. A “Refrigerate” label on shippers containing refrigerant packs.
3. A DIAGNOSTIC SPECIMENS label on all shippers.
4. A UN 3373 label on all shippers. The marking must be applied adjacent to the words DIAGNOSTIC SPECIMENS.
5. All shippers with an “overpack” label.
6. Complete the section of the FedEx label that requests the weight of the contents of the shipper, and if applicable, the section that requests the weight of the dry ice contained in the shipper.
7. Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
8. Add one additional strip of tape across the FedEx pouch.

9.14 Container Protocol and Weekly Shipping List

Exhibit 9-5 illustrates the Container protocol and Exhibit 9-6 illustrates the FedEx weekly shipping list. Use the container protocol as an aid at the start of each stand when opening new containers. Use the weekly FedEx shipping list as an aid when creating airbills in FedEx Ship Manager.

Exhibit 9-5. Container protocol

NHANES 2004 CONTAINER PROTOCOL

| Vessel ID | Test ID/Name | Sample Type | Vessel Type | Vessel Storage | Storage Unit |
|-----------|-----------------|-------------|-------------|----------------------|------------------|
| 1 | Lead/Cad/HG | WB | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 2 | Ery Proto | WB | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 3 | RBC Folate | WB | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 4 | Glycohem | WB | 2-mL | 9 x 9 two inch box | Refrigerator # 1 |
| 5 | Mercury | WB | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 6 | CD4 | WB | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 7 | Homocys | Plasma | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 81 | Vitamin B6 | Plasma | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 8 | Xtra Plasma | Plasma | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 88 | Acrylamide | PC | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 9 | Glucose | Plasma | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 98 | OGTT | Plasma | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 100 | IgE | Serum | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 81 | Vitamin B6 | Serum | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 70 | Vitamin D | Serum | 2-mL | 9 x 9 two inch box | Freezer #1 |
| 12 | Fol/B12 | Serum | 2 mL | 9 x 9 two inch box | Freezer #1 |
| 13 | CRP | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 14 | Hep Profile | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 87 | Hepatitis ab | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 99 | Fer/TfR | Serum | 2-mL | 9 x 9 two inch box | Freezer #2 |
| 11 | Iron/TIBC | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 17 | Cotinine | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 21 | Lipids | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 104 | Lp(a) | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 94 | PTH2 | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 77 | HPV Serum | Serum | 2-mL | 9 x 9 two inch box | Freezer #2 |
| 79 | Vitamin C | Serum | 2 mL | 9 x 9 two inch box | Freezer #2 |
| 18 | Biochem | Serum | 2 mL | 9 x 9 two inch box | Refrigerator # 1 |
| 23 | Insulin | Serum | 2 mL | 9 x 9 two inch box | Freezer #3 |
| 22 | HIV | Serum | 2 mL | 9 x 9 two inch box | Freezer #3 |
| 24 | HSV | Serum | 2 mL | 9 x 9 two inch box | Freezer #3 |
| 75 | PSA | Serum | 2-mL | 9 x 9 two inch box | Freezer #3 |
| 15 | Vit A/E/Car | Serum | 2 mL | 9 x 9 two inch box | Freezer #3 |
| 32-40 | Xtra Sera | Serum | 2 mL | 9 x 9 two inch box | Freezer #3 |
| 29/89 | Persis Pest 1/2 | Serum | 5 mL | 9 x 9 three inch box | Freezer #3 |
| 90 | Perfluor 1 | Serum | 5 mL | 9 x 9 three inch box | Freezer #3 |
| 91 | Srm Pest | Serum | 5 mL | 9 x 9 three inch box | Freezer #3 |
| 92/93 | BFR 1/2 | Serum | 5 mL | 9 x 9 three inch box | Freezer #3 |
| 45 | Alb/Creat | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 46 | Chlam/GC | Urine | 14 mL | 5 x 5 three inch box | Freezer #4 |

Exhibit 9-5. Container protocol (continued)

| Vessel ID | Test ID/Name | Sample Type | Vessel Type | Vessel Storage | Storage Unit |
|-----------|--------------|--------------|------------------|----------------------------------|-----------------|
| 69 | Urn Iodine | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 86 | Spc Arsenic | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 48 | Prior Pest | Urine | 14 mL | 5 x 5 three inch box | Freezer #4 |
| 49 | Organophos | Urine | 14 mL | 5 x 5 three inch box | Freezer #4 |
| 62 | Urn Merc | Urine | 14 mL | 5 x 5 three inch box | Freezer #4 |
| 50 | Heavy Metal | Urine | 14 mL | 5 x 5 three inch box | Freezer #4 |
| 65 | Urn Phytoes | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 66 | PAH | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 67 | Phthalates | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 102 | Perchlorate | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 52 | Xtra Urine | Urine | 5 mL | 9 x 9 three inch box | Freezer #4 |
| 53 | HIV Urine | Urine | 5 mL | 9 x 9 three inch box | Refrigerator #1 |
| 54 | VOC Blood | WB | 5 mL gray | 5 x 5 five inch with foam insert | Refrigerator #2 |
| 56 | VOC Water | Water | 10 mL glass vial | 5 x 5 five inch with foam insert | Refrigerator #2 |
| 103 | PerchlorH2O | Water | 10 mL glass vial | 5 x 5 five inch with foam insert | Refrigerator #2 |
| 78 | HPV | Genital swab | Epicentre swab | 9 x 12 plastic bag | Workstation 2 |

Number of Boxes Per Week

| Number | Box type | Number | Box type |
|--------|----------------------|--------|-----------------------------------|
| 34 | 9 x 9 two inch box | 3 | 5 x 5 five inch box (foam insert) |
| 13 | 9 x 9 three inch box | 1 | 9 x 12 plastic bag |
| 5 | 5 x 5 three inch box | | |

Exhibit 9-6. FedEx weekly shipping list

NHANES 2005 FedEx Shipping List – Laboratory Name

| Lab # | Vessel ID | Vessels/Assays | Laboratory/Destination | Conditions | Dry Ice Pounds | Dry Ice Kg | Total Weight |
|-----------|-----------|-------------------------|--------------------------------------|---------------|----------------|------------|--------------|
| 6 | 1 | Lead/Cad/HG | CASPIR | Frozen | 30 | 14 | 35 |
| | 3 | RBC Folate | | Frozen | | | |
| | 5 | Mercury | | Frozen | | | |
| | 6 | CD4 | | Frozen | | | |
| | 7 | Homocys/MMA | | Frozen | | | |
| | 8 | Xtra Plasma | | Frozen | | | |
| | 88 | Acrylamide | | Frozen | | | |
| | 81 | Vitamin B6 | | Frozen | | | |
| | 70 | Vitamin D | | Frozen | | | |
| | 12 | Fol/B12 | | Frozen | | | |
| | 99 | Fer/TfR | | Frozen | | | |
| | 17 | Cotinine | | Frozen | | | |
| | 79 | Vitamin C | | Frozen | | | |
| | 15 | Vit A/E/Car | | Frozen | | | |
| | 32 | Xtra serum | | Frozen | | | |
| | 69 | Urn Iodine (UI) | | Frozen | | | |
| | 86 | Spc Arsenic (SA) | | Frozen | | | |
| | 62 | Urn Merc Heavy Metal | | Frozen | | | |
| | 50 | (HM) | | Frozen | | | |
| | 52 | Xtra Urine | | Frozen | | | |
| 31 | 66 | PAH (UA) | CASPIR/Dr. Andreas Sjodin | Frozen | 20 | 9 | 25 |
| 54 | 65 | Urn Phytoes (UY) | CASPIR/Dr. Christine Pfeiffer | Frozen | 20 | 9 | 25 |
| 28 | 29 | Persis Pest | CASPIR/Dr. Wayman Turner | Frozen | 30 | 14 | 35 |
| 28 | 89 | Persis Pest2 | CASPIR/Dr. Wayman Turner | Frozen | | | |
| 28 | 92 | BFR1 | CASPIR/Dr. Wayman Turner | Frozen | | | |
| 28 | 93 | BFR2 | CASPIR/Dr. Wayman Turner | Frozen | | | |
| 4 | 102 | Perchlorate | CDC Air Toxicant Branch | Frozen | 20 | 9 | 25 |
| 4 | 54 | VOC Blood | CDC Air Toxicant Branch | Refrigerated | | | 10 |
| 4 | 56 | VOC Water | CDC Air Toxicant Branch | Refrigerated | | | |
| 4 | 103 | PerchlorH20 | CDC Air Toxicant Branch | Refrigerated | | | |
| 24 | 90 | Perfluor1 | CDC Dr. Antonia Calafat | Frozen | 20 | 9 | 25 |
| 24 | 67 | Phthalates (UT) | CDC Dr. Antonia Calafat | Frozen | | | |
| 26 | 91 | Srm Pest | CDC Dr. Dana Barr | Frozen | 30 | 14 | 35 |
| 26 | 48 | Prior Pest (PP) | CDC Dr. Dana Barr | Frozen | | | |
| 26 | 49 | Organophos (OP) | CDC Dr. Dana Barr | Frozen | | | |
| 52 | 77 | HPV Serum | CDC Kristi Singletary Meadows | Frozen | 20 | 9 | 25 |
| 3 | 22 | HIV | CDC NCID AIDS Division | Frozen | 20 | 9 | 25 |
| 3 | 53 | HIV Urine | CDC NCID AIDS Division | Refrigerated | 20 | | 10 |
| 2 | 14 | Hep profile | CDC NCID Hepatitis Ref Lab | Frozen | 20 | 9 | 25 |
| 2 | 87 | Hepatitis ab | CDC NCID Hepatitis Ref Lab | Frozen | 20 | 9 | 25 |
| 5 | 46 | Chlam/GC | CDC NCID NCHSTD | Frozen | 20 | 9 | 25 |
| 37 | 78 | HPV | CDC Ruth Ann Tucker | Room Temp | | | 1 |
| 40 | 11 | Iron/TIBC | Collaborative Laboratory Services | Frozen | 20 | 9 | 25 |
| 40 | 18 | Biochem | Collaborative Laboratory Services | Refrigerated | | | 10 |

Exhibit 9-6. FedEx weekly shipping list (continued)

| Lab # | Vessel ID | Vessels/Assays | Laboratory/Destination | Conditions | Dry Ice Pounds | Dry Ice Kg | Total Weight |
|-------|-----------|--------------------|--------------------------------|--------------|----------------|------------|--------------------|
| 9 | 24 | HSV | Emory University | Frozen | 20 | 9 | 25 |
| 13 | 21 | Lipids | Lipoprotein Analytical Lab/JHU | Frozen | 20 | 9 | 25 |
| 51 | 9 | Glucose | NHANES Diabetes Laboratory | Frozen | 30 | 14 | 35 |
| 51 | 98 | OGTT | NHANES Diabetes Laboratory | Frozen | | | |
| 51 | 23 | Insulin | NHANES Diabetes Laboratory | Frozen | | | |
| 51 | 7 | Glycohem | NHANES Diabetes Laboratory | Refrigerated | | | 10 |
| 39 | 2 | Ery Proto | NYS DOH/Wadsworth CTR | Frozen | 20 | 9 | 25 |
| 53 | 104 | Lp(a) | U of Wash – Michelle Mehan | Frozen | 20 | 9 | 25 |
| 16 | 45 | Alb/Creat | Univ of Minnesota | Frozen | 20 | 9 | 25 |
| 11 | 13 | CRP | Univ of Washington | Frozen | 30 | 14 | 35 |
| 11 | 94 | PTH2 | Univ of Washington | Frozen | | | |
| 11 | 75 | PSA | Univ of Washington | Frozen | | | |
| | 100 | IgE | | Frozen | | | |
| | | STP-710 or STP-740 | STP-730 | STP-740 | | | 9 x 12 Plastic bag |

Bold/Black – Ship when full or at end of stand.

Shaded = Verify correct assignment of container to FedEx airbill

NHANES 2005 FedEx Shipping List – Laboratory Number

| Lab # | Vessel ID | Vessels/Assays | Laboratory/Destination | Conditions | Dry Ice Pounds | Dry Ice Kg | Total Weight |
|-------|-----------|--------------------|----------------------------|---------------|----------------|------------|--------------|
| 2 | 14 | Hep profile | CDC NCID Hepatitis Ref Lab | Frozen | 20 | 9 | 25 |
| 2 | 87 | Hepatitis ab | CDC NCID Hepatitis Ref Lab | Frozen | 20 | 9 | 25 |
| 3 | 22 | HIV | CDC NCID AIDS Division | Frozen | 20 | 9 | 25 |
| 3 | 53 | HIV Urine | CDC NCID AIDS Division | Refrigerated | 20 | | 10 |
| 4 | 102 | Perchlorate | CDC Air Toxicant Branch | Frozen | 20 | 9 | 25 |
| 4 | 54 | VOC Blood | CDC Air Toxicant Branch | Refrigerated | | | 10 |
| 4 | 56 | VOC Water | CDC Air Toxicant Branch | Refrigerated | | | |
| 4 | 103 | PerchlorH20 | CDC Air Toxicant Branch | Refrigerated | | | |
| 5 | 46 | Chlam/GC | CDC NCID NCHSTD | Frozen | 20 | 9 | 25 |
| 6 | 1 | Lead/Cad/HG | CASPIR | Frozen | 30 | 14 | 35 |
| | 3 | RBC Folate | | Frozen | | | |
| | 5 | Mercury | | Frozen | | | |
| | 6 | CD4 | | Frozen | | | |
| | 7 | Homocys/MMA | | Frozen | | | |
| | 8 | Xtra Plasma | | Frozen | | | |
| | 88 | Acrylamide | | Frozen | | | |
| | 81 | Vitamin B6 | | Frozen | | | |
| | 70 | Vitamin D | | Frozen | | | |
| | 12 | Fol/B12 | | Frozen | | | |
| | 99 | Fer/TfR | | Frozen | | | |
| | 17 | Cotinine | | Frozen | | | |
| | 79 | Vitamin C | | Frozen | | | |
| | 15 | Vit A/E/Car | | Frozen | | | |
| | 32 | Xtra serum | | Frozen | | | |

Exhibit 9-6. FedEx weekly shipping list (continued)

| Lab # | Vessel ID | Vessels/Assays | Laboratory/Destination | Conditions | Dry Ice Pounds | Dry Ice Kg | Total Weight |
|-----------|-----------|---------------------------|--------------------------------------|---------------|----------------|------------|--------------|
| | 69 | Urn Iodine (UI) | | Frozen | | | |
| | 86 | Spc Arsenic (SA) | | Frozen | | | |
| | 62 | Urn Merc Heavy Metal (HM) | | Frozen | | | |
| | 50 | | | Frozen | | | |
| | 52 | Xtra Urine | | Frozen | | | |
| 9 | 24 | HSV | Emory University | Frozen | 20 | 9 | 25 |
| 11 | 13 | CRP | Univ of Washington | Frozen | 30 | 14 | 35 |
| 11 | 94 | PTH2 | Univ of Washington | Frozen | | | |
| 11 | 75 | PSA | Univ of Washington | Frozen | | | |
| 13 | 21 | Lipids | Lipoprotein Analytical Lab/JHU | Frozen | 20 | 9 | 25 |
| 16 | 45 | Alb/Creat | Univ of Minnesota | Frozen | 20 | 9 | 25 |
| 24 | 90 | Perfluor1 | CDC Dr. Antonia Calafat | Frozen | 20 | 9 | 25 |
| 24 | 67 | Phthalates (UT) | CDC Dr. Antonia Calafat | Frozen | | | |
| 26 | 91 | Srm Pest | CDC Dr. Dana Barr | Frozen | 30 | 14 | 35 |
| 26 | 48 | Prior Pest (PP) | CDC Dr. Dana Barr | Frozen | | | |
| 26 | 49 | Organophos (OP) | CDC Dr. Dana Barr | Frozen | | | |
| 28 | 29 | Persis Pest | CASPIR/Dr. Wayman Turner | Frozen | 30 | 14 | 35 |
| 28 | 89 | Persis Pest2 | CASPIR/Dr. Wayman Turner | Frozen | | | |
| 28 | 92 | BFR1 | CASPIR/Dr. Wayman Turner | Frozen | | | |
| 28 | 93 | BFR2 | CASPIR/Dr. Wayman Turner | Frozen | | | |
| 31 | 66 | PAH (UA) | CASPIR/Dr. Andreas Sjodin | Frozen | 20 | 9 | 25 |
| 37 | 78 | HPV | CDC Ruth Ann Tucker | Room Temp | | | 1 |
| 39 | 2 | Ery Proto | NYS DOH/Wadsworth CTR | Frozen | 20 | 9 | 25 |
| 40 | 11 | Iron/TIBC | Collaborative Laboratory Services | Frozen | 20 | 9 | 25 |
| 40 | 18 | Biochem | Collaborative Laboratory Services | Refrigerated | | | 10 |
| 51 | 9 | Glucose | NHANES Diabetes Laboratory | Frozen | 30 | 14 | 35 |
| 51 | 98 | OGTT | NHANES Diabetes Laboratory | Frozen | | | |
| 51 | 23 | Insulin | NHANES Diabetes Laboratory | Frozen | | | |
| 51 | 7 | Glycohem | NHANES Diabetes Laboratory | Refrigerated | | | 10 |
| 52 | 77 | HPV Serum | CDC Kristi Singletary Meadows | Frozen | 20 | 9 | 25 |
| 53 | 104 | Lp(a) | U of Wash – Michelle Mehan | Frozen | 20 | 9 | 25 |
| 54 | 65 | Urn Phytoes (UY) | CASPIR/Dr. Christine Pfeiffer | Frozen | 20 | 9 | 25 |
| | 100 | IgE | | Frozen | | | |

STP-710 or STP-740

STP-730

STP-740

9 x 12 Plastic bag

Bold/Black – Ship when full or at end of stand.

Shaded – Verify correct assignment of container to FedEx airbill

10. HPV SWAB PROCESSING

10.1 Introduction

The purpose of collecting vaginal swabs is to obtain suitable biological specimens to test for human papillomavirus (HPV). Human papillomavirus infection is one of the most common sexually transmitted infections in the United States. Cervical infection with certain types of HPV is a major risk factor for cervical cancer in women. The “high-risk” types of HPV (e.g., HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) are associated with cervical cancer and the “low-risk” types (e.g., HPV 6, 11, 42, 43, 44) with genital warts. No national surveillance system exists to measure the full burden of HPV infection, and no reliable national population estimate of HPV exists. NHANES offers a unique opportunity to assess the prevalence of HPV infection in the general population.

Reducing the prevalence of HPV infection is a Developmental Healthy People 2010 objective: “Reducing the number of new HPV cases can help minimize the overall number of cases of high risk subtypes associated with cervical cancer in females.” Detection and typing of HPV DNA in vaginal swabs (in conjunction with testing of NHANES sera for HPV 16 antibody) will allow evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. HPV vaccine development is underway, and knowledge of the national prevalence of HPV infection will be critical for planning vaccination strategies in the United States. Studies have demonstrated that recovery of HPV from self-collected swabs is comparable to that from physician-collected cervical samples. The HPV Hybrid Capture® II DNA results will be reported to survey participants via the same reporting system as for STD/HIV testing. This system is a respondent-initiated toll-free phone call to NCHS. Results are given to persons tested after a password is provided to verify identity. The HPV-16 serology and the HPV DNA typology will not be reported.

Primary female SPs aged 14-59 collect the HPV swab. The physician prints the appropriate label. Each label includes the test name, 6-digit SP ID concatenated with the vessel ID, and the corresponding bar code. The physician counsels each eligible SP and introduces them to the vaginal collection technique using a prepared collection kit. The collection kit is designed for SPs aged 14-59 and it includes illustrated collection instructions and one Epicentre® Dacron swab with foam tip. The physician removes the appropriate swab from the collection kit and labels the Epicentre® Dacron swab with the foam tip with the label displaying the vessel ID #78, The physician then places the swab(s) back into the collection kit and gives the collection kit to the eligible SP.

The SP self-collects the appropriate swab in the mobile examination center (MEC) bathroom, places the swab back into its original container and places the swab back into the plastic bag. The SP hands the plastic bag containing the swab(s) to the assistant coordinator. The assistant coordinator delivers the plastic bag to the laboratory.

The laboratory staff verifies the SP ID and the vessel ID (#78) on the label of the Epicentre® Dacron swab with the foam tip, records the collection in the HPV module, and stores the swab at room temperature. The laboratory staff ships the specimens to the CDC laboratory weekly.

The laboratory staff also processes serum for vessel 77 (HPV Serum) on SPs aged 14-59 as part of a SP's blood processing profile. The vessels are stored at -20°C and shipped to the CDC (Kristi Singletary Meadows) laboratory weekly.

10.2 Supplies

The supplies needed for HPV processing and storage are listed in Exhibit 10-1.

Exhibit 10-1. Equipment and supplies – HPV processing and storage

| | |
|-----------------------|---------------------------------|
| Large padded envelope | Zip closable bag (9 x 12 clear) |
|-----------------------|---------------------------------|

10.3 Protocol

Exhibit 10-2 illustrates the SP's protocol for HPV processing. It is extremely important to follow the processing procedures outlined in these protocols and in this manual. Specimen loss or bias results will occur if the exact procedures are not followed.

Exhibit 10-2. HPV processing protocol

| ID | Test name | Ages | Sample | Sample type | Vessel type | Appointment type |
|----|-----------|---------------|--------|--------------|---------------------------|------------------|
| 78 | HPV | 14-59 females | 1 swab | Vaginal swab | Epicentre® Dacron swab | Primary only |

10.4 Labeling Vessels

The physician prints the vessel label. It is possible to reprint the label in lab using the Ad Hoc functionality.

10.5 HPV Protocol

Process the Epicentre® Dacron swab with the foam for HPV. Verify that the swab is labeled correctly and the label is legible.

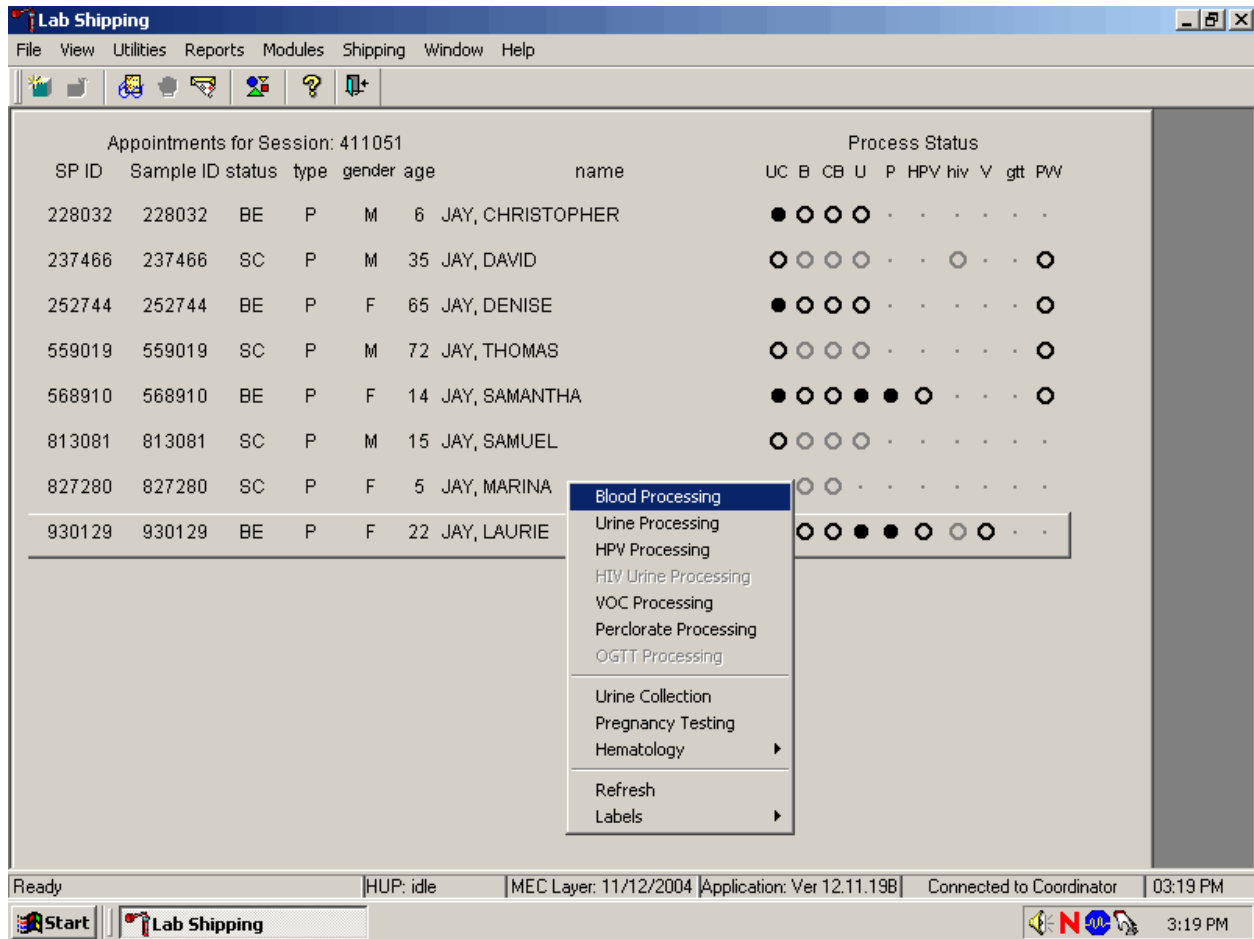
Access the HPV Processing module for all SPs.

- Vessel 78 – HPV
 - Verify that the tip of the Dacron swab in the clear plastic tube is foam and that the top of the tube is marked with a green dot. Verify that the SP ID on the label matches the SP ID on the processing screen. Record the processing results in the HPV module and store the swab at room temperature.

10.6 Record Processing Results

The protocol includes a serum vessel (HPV Serum #77) for primary SPs aged 14-59. The volume requirement is 0.5-mL of serum; the storage vessel is a 2-mL cryovial, and it is stored in a 2-inch box with a 9 x 9 grid. The vessel is processed after the PTH2 vessel (#94) and before the Vitamin C vessel (#79.) The serum vessel is displayed on the blood-processing screen in the correct priority and is recorded in the same manner as the other vessels. This vessel is frozen and shipped to CDC/Kristi Singletary Meadows weekly.

Select the correct SP and access the Blood Processing module.



To select an SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the Blood Processing module, drag the mouse arrow to {Blood Processing} and left click or left click and type [B/b].

Record processing results for vessel 77 (HPV Serum) in the Blood Processing module.

BP: 930129
B processing

Tech ID: 1126 Sample ID: 930129 Name: JAY, LAURIE Gender: F Age: 22
 SP ID: 930129 Appt Type: Primary Fasting Req: Afternoon - 0 Hour

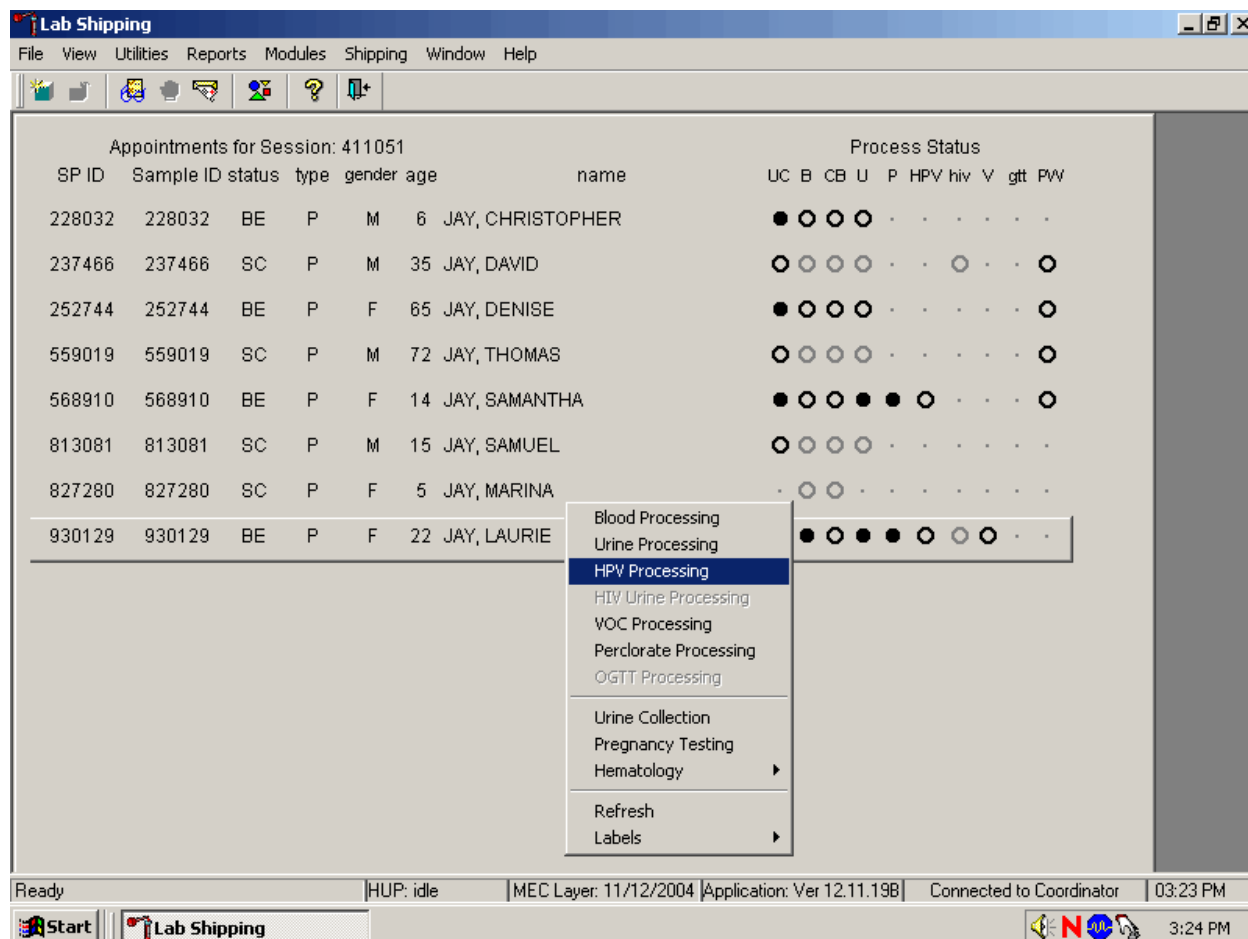
| Vessel ID | Test Name | Sample Volume | Vessel Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|-------------|---------------|----------------|--|----------|--------------|-------|
| 77 | HPV Serum | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 79 | Vitamin C | 0.1 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 18 | Biochem | 0.8 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 22 | HIV | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 24 | HSV | 0.2 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 15 | Vit A/E/Car | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 32 | Xtra Sera | 0.5 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

Buttons: Save, Phlebotomy, OK, Cancel

Status Bar: Ready | HUP: idle | MEC Layer: 11/12/2004 | Application: Ver 12.11.198 | Connected to Coordinator | 03:21 PM

Primary SPs aged 14-59 are eligible for the HPV serum test. Pool the serum and aliquot 0.5-mL into a prelabeled 2.0-mL cryovial. Mark the vessel as Filled –"Yes" or Filled –"No" using procedures described in Chapter 8. Store the vessels in a 2-inch tall container with a 9 x 9 grid. Pack the container in a small shipper, add sufficient dry ice, and ship weekly to CDC/Kristi Singletary Meadows. Use existing procedures described in Chapter 9 to pack, label, and ship the shipper.

Select the correct SP and access the HPV Processing module.



Use the scroll bar to view all SPs scheduled into the session. The active SP is contained in a rectangular box. Use the heads-up display to select the correct SP. Select a different SP if the active SP is not the correct SP.

To select a SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the HPV Processing module, drag the mouse arrow to {HPV Processing} and left click or right click and type [S/s]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, drag the mouse arrow to correct module and left click or type [S/s].

Document processing results.

The screenshot shows the 'Lab Shipping' application window. The main window is titled 'VS: 930129' and contains a sub-window for 'BV processing'. The patient information is as follows:

| | | | | |
|---------------|-------------------|--------------------|---------------------------------|---------|
| Tech ID: 1126 | Sample ID: 930129 | Name: JAY, LAURIE | Gender: F | Age: 22 |
| | SP ID: 930129 | Appt Type: Primary | Fasting Req: Afternoon - 0 Hour | |

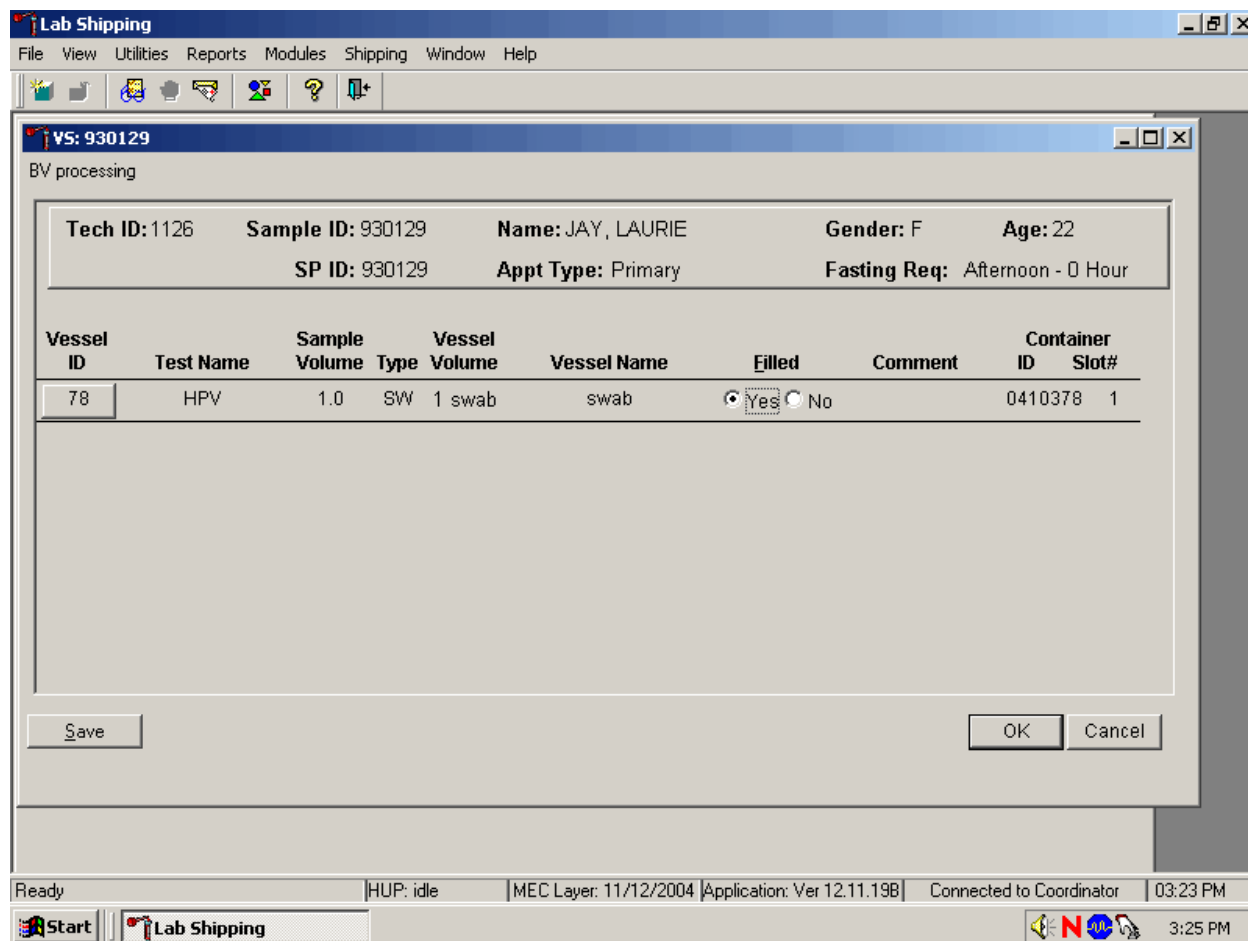
Below the patient information is a table with the following columns: Vessel ID, Test Name, Sample Volume, Sample Type, Vessel Volume, Vessel Name, Filled, Comment, Container ID, and Slot#. There is one data row for Vessel ID 78.

| Vessel ID | Test Name | Sample Volume | Sample Type | Vessel Volume | Vessel Name | Filled | Comment | Container ID | Slot# |
|-----------|-----------|---------------|-------------|---------------|-------------|--|---------|--------------|-------|
| 78 | HPV | 1.0 | SW | 1 swab | swab | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

At the bottom of the window are buttons for 'Save', 'OK', and 'Cancel'. The taskbar at the bottom shows the system tray with the time 3:25 PM and the date 11/12/2004.

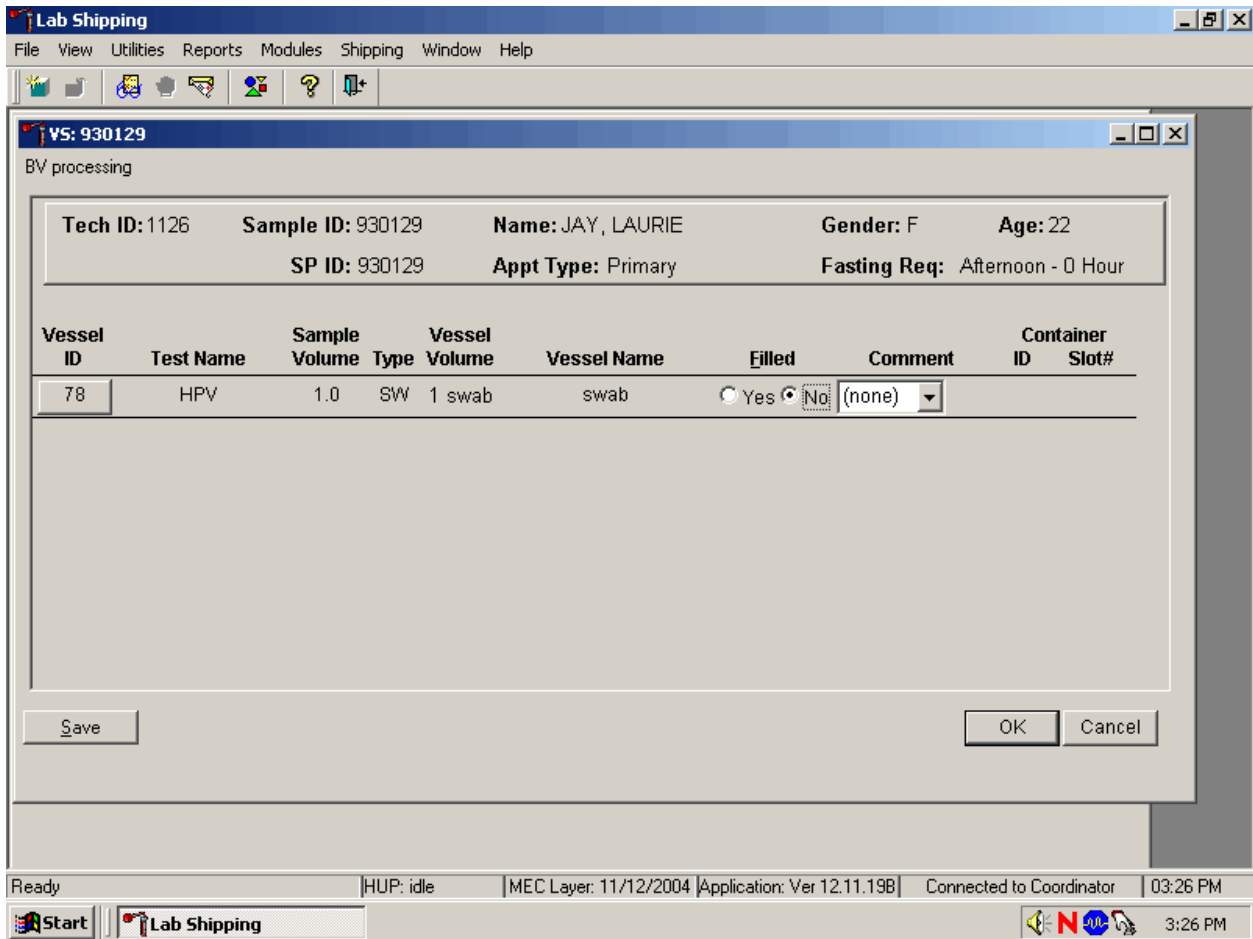
The HPV Processing window contains the following information for SPs: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, App (appointment) type, and Fasting_Req. There are columns that list the Vessel ID, Test Name, Sample Volume, Sample Type (SW = swab), Vessel Volume, Vessel Name, Filled (Yes or No) radio buttons, Comment drop-down box, and a Container ID and Container Slot# column. There is one row associated with vessel 78. Use radio buttons to record the processing results, Filled –"Yes" or Filled –"No," if necessary, attach a comment using the Comment drop-down box, and store the vessel in the assigned Container ID and Slot#.

Mark vessel 78 as Filled—"Yes" if the swab was collected.



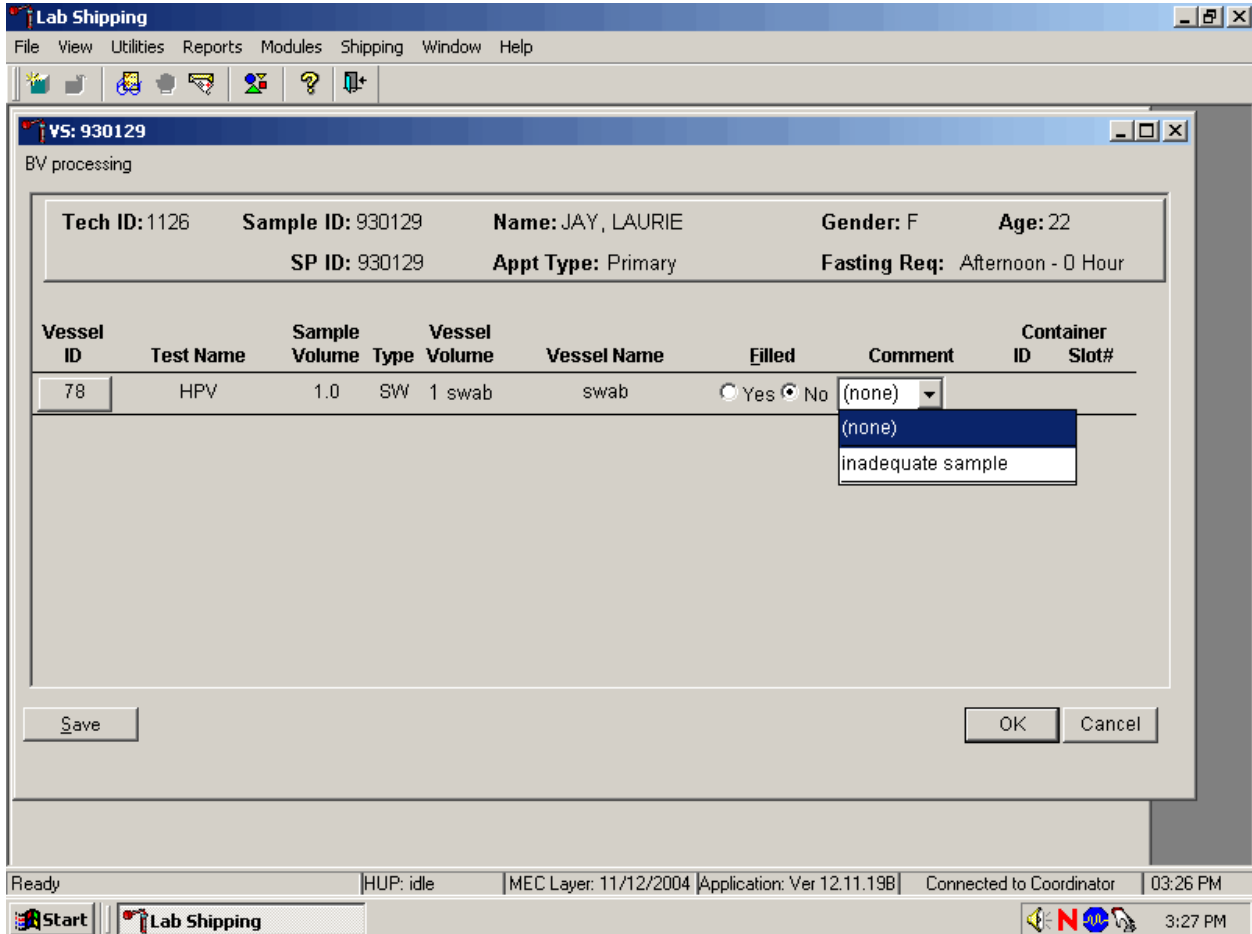
To mark vessel 78 as collected or Filled—"Yes" use the mouse to direct the mouse arrow to the "Yes" radio button and left click. As a vessel is marked as Filled—"Yes," it is automatically assigned to a slot in an existing (open) container.

Mark vessel 78 as Filled –"No" if the swab was not collected.



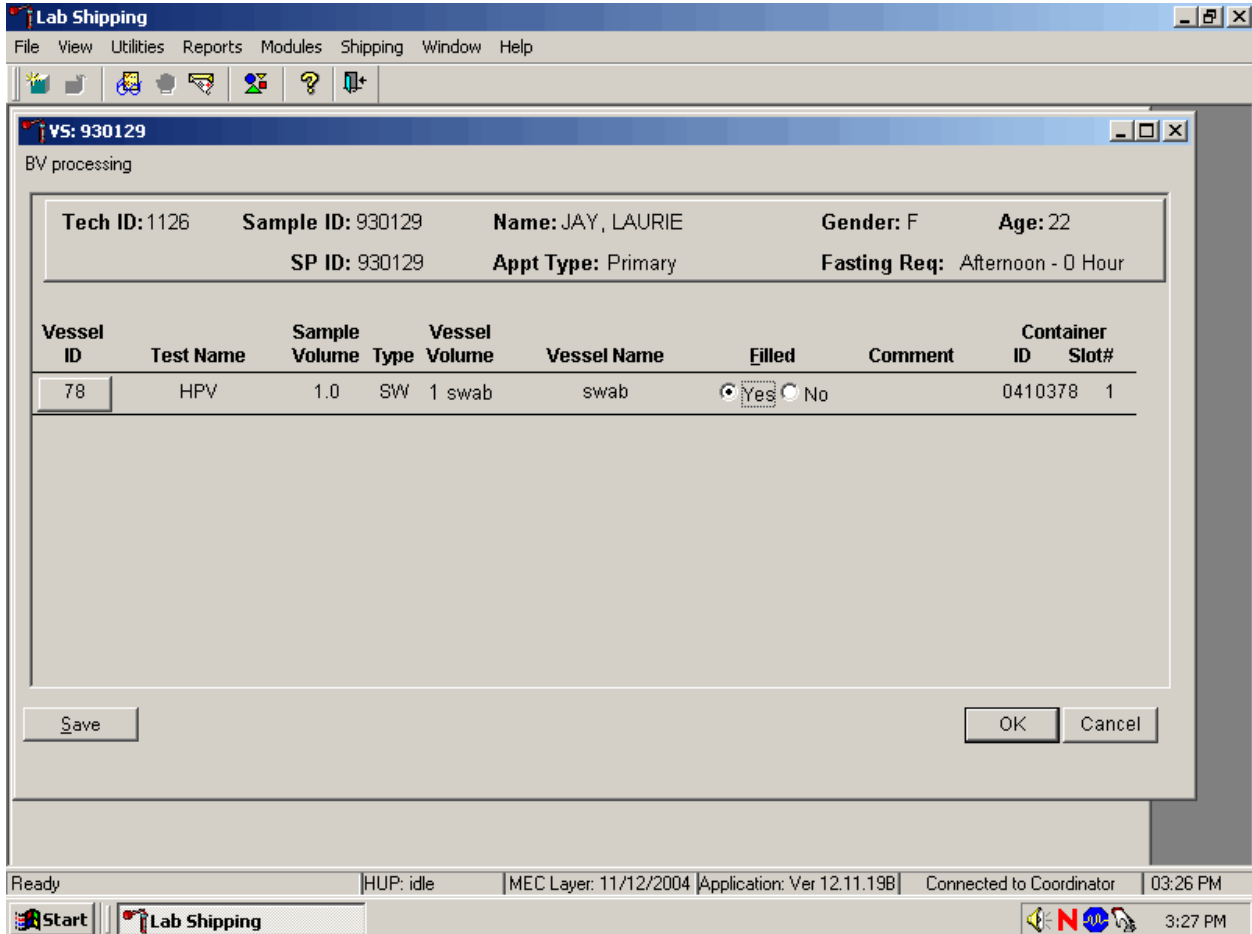
To mark vessel 78 as not collected or Filled –"No" use the mouse to direct the mouse arrow to the "No" radio button and left click.

Enter a quality control comment for vessel 78, when the swab is dry and the judgment is that the SP did not attempt to collect the sample(s).



To record an “inadequate sample” comment, use the mouse to direct the mouse arrow to the drop-down list, click to display the comment codes, drag the mouse arrow to “inadequate sample” and left click. Alternatively, to record the comment “inadequate sample,” [Tab] to advance to the Comment text box and type [I/I] and [Enter].

Store the Epicentre® Dacron swab in the assigned 9 x 12 plastic bag at room temperature; review the information in the HPV-Processing window, and save the data to the database.



Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [S/s]. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

The process status circle in the heads-up display fills in completely for SPs who vessel 78 recorded as collected or Filled –"Yes." Do not enter a result until the swab arrives in the laboratory. At the end of each session, review the results for each SP. Access each record and enter Filled –"No" result for all vessels for SPs for whom no swab was received.

10.7 Specimen Storage

Record the processing result for the Epicentre® Dacron swab and store the swab in a 9 x 12 plastic bag at room temperature. Store vessels in numbered storage containers according to vessel as indicated in Exhibit 10-3.

Store each vessel in the appropriate slot in the correct container immediately after processing. Check the slot assignment of containers associated with vessel 78 at the end of each session by accessing the Container Map report. Verify the contents of each container against the container map.

Exhibit 10-3. Storage protocol for HPV

| Shipping Location | Vessel | Condition | Vessel Storage |
|-------------------------------|--------------|------------------|--------------------|
| CDC/Kristi Singletary Meadows | 77 HPV Serum | Frozen | 9 x 9 2-inch box |
| CDC/Ruth Ann Tucker | 78 HPV | Room temperature | 9 x 12 plastic bag |

10.8 Shipping Procedures

Ship vessel 77 according to procedures described in Section 9.13. Ship vessel 78 in a padded envelope at room temperature. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 10-4, the Shipping protocol illustrates the specifications for the shipment of biological specimens to each contract laboratory.

Exhibit 10-4. Shipping protocol

| Laboratory | Vessel | Test Name | Vessel Storage | Shipping Frequency |
|-------------------------------|--------|-----------|------------------|--------------------|
| CDC/Kristi Singletary Meadows | 77 | HPV Serum | Frozen | Weekly |
| CDC/Ruth Ann Tucker | 78 | HPV | Room Temperature | Weekly |

10.8.1 Pack and Ship Vessel 78 at Room Temperature

Ship the container (9 x 12 plastic bag) for vessel 78 (HPV swab) at room temperature.

- Place the plastic bag containing the specimens into a large padded envelope.
- Place the appropriate shipping manifest into a 9 x 12 plastic bag and seal.
- Place a plastic envelope containing the appropriate shipping manifest into the padded envelope and seal.
- Assume that the package weighs 1 pound.
- Record the total weight of the envelope (1 pound) on the appropriate FedEx label.

10.8.2 Label Shippers

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Complete the section of the FedEx label that requests the weight of the contents of the shipper.
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Add one additional strip of tape across the FedEx pouch.

10.9 How to Deal With System Failure

If the computer system fails, record results on a preprinted HPV Processing worksheet (Exhibit 10-5). Complete a workstation 2 worksheet for each SP while processing the HPV specimens. Enter the results after the system is operational. Send the worksheets to the home office at the end of the stand.

Exhibit 10-5. HPV Processing worksheet

HPV PROCESSING

SP ID _____

| ID | Name | Ages Gender | Sample mL | Sample Type | pH | Filled ✓ | Slot # |
|----|------|---------------|-----------|---------------------------|----|-------------|--------|
| 78 | HPV | 14-59 females | 1 swab | Epicentre® Dacron Swab | | | |

11. PROTOCOL FOR VOLATILE ORGANIC COMPOUNDS (VOC/PERCHLORATE) STUDY AND PERCHLORATE COLLECTION AND PROCESSING

11.1 Overview

The purpose of the VOC study is to determine the prevalence of exposures to chemicals called Volatile Organic Compounds (VOCs). A one-half subsample of primary SPs aged 12+ years is randomly selected to participate in this study. This selection occurs when the SP ID is generated at the time the MEC appointment is made. This can occur in the home during the home interview or in the field office when the field office staff schedules the appointment with the SP.

The household interviewer introduces SPs aged 12+ to the VOC component. The interviewer application includes a reminder window that displays for SPs 12+ with the text, “VOC REMINDER - SP 12+ FOLLOW WATER COLLECTION KIT PROCEDURES AS APPROPRIATE.” The NHANES household interviewer collects a tap water sample from SPs aged 12+. The water sample is collected from the bathtub the SP uses or from an outside faucet (nonaerated). For a random half-sample of these SPs, the tap water will be examined, together with blood obtained from the SP during the MEC exam, to assess the SP’s exposure to numerous volatile organic compounds (VOCs). The remaining SPs 12+ will have their urine and water sample tested only for perchlorate. Household interviewers label the outside of the VOC/Perchlorate collection kit with a preprinted label containing the case ID, transport the sample to the field office, and refrigerate. The MEC manager transports the samples to the MEC lab.

When SPs come to the MEC for their exam, the phlebotomists collect one additional 10-mL tube of blood, and the MEC interviewers administer a questionnaire. The label for the blood tube prints on the Dymo printer in the phlebotomy room. The phlebotomist transfers the blood tube (vessel 54) to the MEC laboratory. The blood sample must be refrigerated within 15 minutes after completion of the venipuncture.

The medical technologists reconcile the VOC/perchlorate water vials using the laboratory application. They print and label the VOC water sample with a label containing the SP ID concatenated with the vessel ID (#56.) The samples that are not designated as vessel 56 are designated as vessel 103 – PerchlorH2O. This represents the other half subsample of the full sample collected on 12+. The technologists process, store, and ship the SP’s VOC blood tube (vessel 54), VOC water (vessel 56) vial

and PerchlorH20 (vessel 103) vials once a week via next day courier in insulated containers with enough ice packs to maintain their refrigerated temperature.

11.2 Supplies

The VOC/Perchlorate equipment and supplies are listed in Exhibit 11-1.

Exhibit 11-1. Equipment and supplies - VOC/Perchlorate

| | |
|--|--|
| 10-mL gray top Vacutainer ® blood tube | Water collection kit 10-mL vial Instructions Small zip closable bag |
| VOC questionnaire – English | Blue absorbent pad |
| VOC questionnaire – Spanish | #740 SafTPak pressure vessel |
| 5-inch box with 5 x 5 foam grid | Refrigerant gel pack |
| 9 x 12 plastic bag | Cardboard shipper |
| Packing tape | Absorbent pad |

The VOC/Perchlorate water vial is a 10-mL glass Wheaton glass vial that contains 125 µL quench buffer. Quench buffer is water with 1 M phosphate buffer and 0.1 M sodium thiosulfate.

At the start of each stand, the warehouse staff prepares and ships 325 water collection kits for the field office. The warehouse staff places the collection instruction document (see Exhibits 11-2 and 11-3 on p. 11-10) and one 10-mL glass water collection vessel into a zip closable bag. The field office staff store their collection kits in the field office. Do not discard any remaining water vials at the end of each stand; ship them back to the warehouse.

Blood Tube Preparation

CDC prescreens the gray-top tubes used for the VOC protocol for this study. The following is the procedure for preparing the 10-mL gray Vacutainer® VOC blood collection tubes and a statement of their purpose. Dr. David Ashley at the CDC provided this procedure.

Procedure for preparing the 10-mL gray Vacutainer® tubes:

- Because of the volatile organic compounds present in commercial Vacutainers® with rubber stoppers, it is necessary to decontaminate the tubes before blood collection. CDC laboratory personnel carry out this decontamination procedure. The vacuum is released and the glass tube with anticoagulant and the stopper are placed in a vacuum oven. These materials are then decontaminated under vacuum at 70° C for 2 weeks. The Vacutainers® are reassembled and tested for lack of contamination. A vacuum is reapplied to each Vacutainer® and they are sterilized in a Gamma-ray sterilizer to kill any microbiological organisms that may have entered the tubes.
- This procedure is necessary to acquiring a volatile organic compound measurement that is a true measure of an individual's internal dose level of VOCs.

Since the date on the Vacutainer® is a guarantee that the vacuum is reliable, this date has no reference to the current materials sent from CDC to NCHS. The laboratory at CDC will ensure that the Vacutainers® sent to the NHANES staff have been prepared on a date within the timeframe necessary for their use. Notify the technical supervisor if the tubes begin to lose their vacuum, but continue to use the tubes until replacements arrive.

11.3 Household Interviewer Responsibilities

The following information is from the Household Interviewers Manual.

11.3.1 Overview

The NHANES household interviewers will collect a tap water sample from SPs aged 12+. The water sample will be collected from the bathtub the SP uses or from an outside faucet (nonaerated). For a random half-sample of these SPs, the tap water will be examined together with blood obtained from the SP during the MEC exam to assess the SP's exposure to numerous volatile organic compounds (VOCs). The remaining SPs 12+ will have their urine and water sample tested only for perchlorate.

NHANES has been examining environmental chemical exposures for close to 30 years (1976 blood lead). Since 1999, NHANES has been studying about 150-200 environmental toxicants in blood, urine, and water samples of NHANES participants. Beginning in 2005, the numbers of environmental chemicals being studied will more than double to approximately 450. These data, collected for NCHS in collaboration with the National Center for Environment Health (NCEH), are the cornerstone

of the CDC publication, *The National Report on Human Exposure to Environmental Chemicals*. VOCs are one of the major classes of environmental exposure chemicals being studied by NHANES.

VOCs exist everywhere; however, chronic exposure to extremely high levels of certain VOCs can lead to cancer and neurocognitive dysfunction. NHANES VOC exposure assessment of blood will include examining chemicals of toxicological significance that are on priority toxicant or critical contaminant lists (e.g., chemicals used in solvents, the polymer industry, in soil fumigants, etc.). VOC exposure assessment of blood and water will include examining chemicals formed by water disinfection and fuel oxygenate ethers.

In addition to VOC exposures, urine and water samples will be used to measure perchlorate, a chemical used primarily in the production of solid fuel propellants for rockets and missiles but also used to produce everyday items such as matches, fireworks, and automotive airbags. Industries using perchlorate have dumped this substance so that there are large areas of contamination in many parts of the U.S. Perchlorate is currently found in tap water samples from 4 percent of communities nationwide. Long-term exposure to high levels of perchlorate can inhibit the thyroid gland and possibly compromise fetal brain development.

This chapter describes the procedures to be used in the VOC/perchlorate water collection component conducted by the household interviewers.

11.3.2 Additional Background Information

NCHS has developed the following “talking points” to describe the VOC/Perchlorate component.

| | |
|---------------------|---|
| <i>Component:</i> | Volatile Organic Compounds (VOCs) and perchlorate exposure assessment |
| <i>Examinees:</i> | Selected participants aged 12+ |
| <i>Examination:</i> | A water sample in the home A blood and urine sample on the MEC A questionnaire on the MEC |
| <i>Results:</i> | No reporting as of now |

In addition, use the following information to encourage SPs to participate.

- This component is part of an epidemiologic analysis of personal exposures to volatile organic compounds among a subset of participants in a statistically designed national survey.
- The NCEH is collaborating with NCHS on this component to collect environmental exposure data for a subset of the U.S. population, as part of a comprehensive nationally-based health study.

The primary aims of this component are:

1. To characterize the distribution of exposures to selected VOCs and perchlorate within the population;
2. To examine the relationship between exposures to the VOCs and socioeconomic, behavioral, demographic, and occupational characteristics; and
3. To investigate possible associations between exposures to VOCs and some selected indicators of health status, which are collected as part of the larger study.

The purpose of the VOC analysis will be to assess exposures to the group of VOCs being monitored, as well as exposures to particular VOCs, and to explore potential linkages between exposures and economic, behavioral, and other factors. A tap water sample is needed for the measurement of a subset of VOCs, which may be present in water. These include byproducts from disinfecting water (for example, chlorination) and oxygenates added to gasoline. The latter can sometimes contaminate ground water and end up in water supplies. An example is MTBE. For another subsample, perchlorate will be measured in the home water sample.

Associations of VOC and perchlorate exposures with potential health outcomes may not be possible to demonstrate because of the size of the sample. However, the opportunity exists to investigate health status markers among the data points collected as part of the larger study to elucidate any patterns, which are consistent with published studies of health outcomes.

11.3.3 Eligibility

Approximately 3,550 SPs per year will be eligible for the VOC/perchlorate component. The average number of water collections per stand will be 237. As noted earlier, half of the SPs 12+ will be in the perchlorate sample (urine and water) and the remaining half will be assessed for seven other chemicals in blood and water (disinfection byproducts and fuel oxygenates).

11.3.4 When to Collect the Water Sample

Generally, water collection should be conducted immediately following the SP interview. Interviewers will be prompted by CAPI to collect the SP water sample at the end of the SP questionnaire.

VOC REMINDER -SP 12+

FOLLOW WATER COLLECT KIT PROCEDURES AS APPROPRIATE.

601-01-0028-01-01 HPQ v. 4.00/3.60 VOC Reminder VOC001

Remarks Español Turn On Pad ▶

The screenshot shows a software interface with a large white box containing blue text. Below the box is a navigation bar with several buttons and labels. The buttons include 'Remarks', 'Español', 'Turn On Pad', and a right-pointing arrow. The labels include '601-01-0028-01-01', 'HPQ v. 4.00/3.60', 'VOC Reminder', and 'VOC001'.

Because water collection is so easy and short, we expect that few respondents will postpone or refuse this task. In the **rare** situations when water cannot be collected during the interview/appointment making visit, try to collect the sample when you need to complete another task in the household or the neighborhood. We want to avoid making trips to a household or neighborhood simply to collect a water sample.

11.3.5 Supplies

At the start of each stand, the home office warehouse will ship 325 water collection kits to the field office. Each kit contains everything an interviewer will need to complete the water collection for each SP. Each kit contains the following:

- 10-mL vial;
- Instructions (English and Spanish versions in all kits); and
- Small zip closable bag with identification label (name, date, time).

In addition each interviewer will receive a set of 10 household ID labels for every household in his or her assignment. These labels are attached to the Household Folder.

Whenever you are in the field you should always have 10 water collection kits and the assignment specific labels. This will ensure that you are fully prepared for any situation encountered on a given day. Inventory your water collection supplies on a regular basis so that you always have 10 complete kits on hand. Remember to pick up additional kits from your supervisor when you are running low.

11.3.6 Water Sample Collection Process

1. To assist you in introducing this component to the SP, we have provided a sample introduction in your Hand Card set. It is available in English and Spanish.

“The NHANES survey is studying a group of chemicals. These chemicals are in things that we use every day. For this test I will need to collect a tap water sample using a collection kit. This kit contains a glass water vial and instructions for collecting the water. I will collect, or ask you to collect, the water sample according to

the instructions. The small amount of liquid in the vial is not harmful to anyone in your household. I will take the water sample with me when I leave.”

2. Prior to collecting the water sample for an SP, enter the required information on the pink label (SP name and sample collection date and time) on the water collection kit and place the correct household ID label on the kit plastic bag (never the vial) as well. The latter label will have the stand, segment, and serial number appropriate to the case preprinted. However, you will need to enter the correct family and person number for each water sample. You can obtain these numbers by viewing the MEC appointment consent screen in the Consent Module or the case list in Interview Manager (see below).

The screenshot shows a software window titled "MEC Appt. Consent Module". At the top, it displays "Participant #: 601- 01-0001- 01- 01" and "Age: 28". Below this, there are input fields for the name "JOHN" and "DOE". The main section is a table with two columns: "Type of Consent" and "Consent Comment".

| Type of Consent | | Consent Comment |
|--|----|-----------------|
| MEC Consent/Assent Signed By SP? | No | |
| Future Research Consent Signed By SP or REF? | No | |
| Future Research Box Checked By SP? | No | |
| Genetic Research Box Checked By SP? | No | |

At the bottom of the window, there are buttons for "Help", "Previous Page", "Next Page", "Print", and "Close".

Interview Manager - Stand ID: 601 Emp ID: 50 - [Interviewer Case List]

File View Tools Help

List Displayed: Person Cases

All Cases View HH Count: 6

| Seg | Serial | Family | Person | Quex. Disposition | Address/Name |
|-----|--------|--------|--------|-------------------|---------------|
| 01 | 0001 | 01 | 01 | Not Worked | JOHN DOE |
| 01 | 0006 | 01 | 01 | Partially Worked | LOIS HOGAN |
| 01 | 0006 | 01 | 02 | Not Worked | RODNEY MILLER |
| 01 | 0006 | 01 | 03 | Not Worked | RACHAEL HOGAN |

Ready

Screener Relations Families Persons MEC Appts Dust

If there are more than 10 SPs in the household, write the complete Household ID number at the bottom of the pink label on the water collection kit bag.

3. Collect the water sample for each SP 12+, using the instructions in the water collection kit (Exhibits 11-2 and 11-3).

If the bathtub where the SP usually bathes is unavailable/nonfunctioning, etc., collect the sample from another bathtub in the home or from an outside faucet.

If the SP prefers to collect the water himself or herself, ask the SP to follow the instructions in the kit.

NOTE: It is critical that the water vial be filled to the top of the vial. Headspace introduces error into the water analysis and renders the samples nonanalyzable. However, they should not be filled to overflowing.

4. Complete the "WATER COLLECTED" column on the front cover of the case Household Folder for each SP water sample collected (see Exhibit 5-1).
5. Give the water sample(s) to your supervisor during your next visit to the field office. She or he will place an SP ID label on the plastic bag for all samples collected and then store the samples in the field office refrigerator until they are picked up by the MEC manager. Pick up by the MEC manager will occur about once per week.

Exhibit 11-2. Water collection instructions – English

Water Collection Instructions

Instructions for collecting tap water sample:

1. Collect the water sample from the bathtub or an outside faucet **ONLY**.
2. Turn on the cold water (all the way on).
3. Let the cold water run for 3 minutes (all the way on) and then decrease the flow to a trickle.
4. Take the black cap off the glass tube. (If the white liner in the cap falls out, put it back into the cap. The shiny side should be facing up.)
5. Carefully fill the glass tube with water until it is almost full.
6. Screw the black cap tightly on the tube.
7. Turn the tube upside down to make sure it does not leak. (If the tube does leak, then remove the cap and try tightening the cap again.)
8. Put the water vial back into the plastic bag.

Exhibit 11-3. Water collection instructions – Spanish

Instrucciones para recolectar la muestra de agua de la llave:

1. Tome la muestra de agua de la (bañadera/bañera/tina) o de una llave de afuera **SOLAMENTE**.
2. Abra la llave del agua fría (totalmente abierta).
3. Deje correr el agua fría por 3 minutos (totalmente abierta) y después disminuya el chorro de agua hasta que sea un goteo o un hilo agua.
4. Quite la tapa negra del tubo de vidrio. (Si la cubierta blanca de la tapa se sale, póngala nuevamente en el interior de la tapa. El lado brillante debe quedar a la vista.)
5. Cuidadosamente llene el tubo de vidrio con agua hasta que esté casi lleno.
6. Ponga la tapa negra bien apretada al tubo.
7. Dé vuelta el tubo al revés para asegurarse que no está goteando. (Si el tubo gotea, entonces saque la tapa y trate de ponerla bien apretada nuevamente).
8. Ponga el tubo de vidrio nuevamente dentro de la bolsa de plástico.

11.4 VOC MEC Exam

VOC data collection consists of the following: one 10-mL blood tube, a tap water sample, and answering the questionnaire questions.

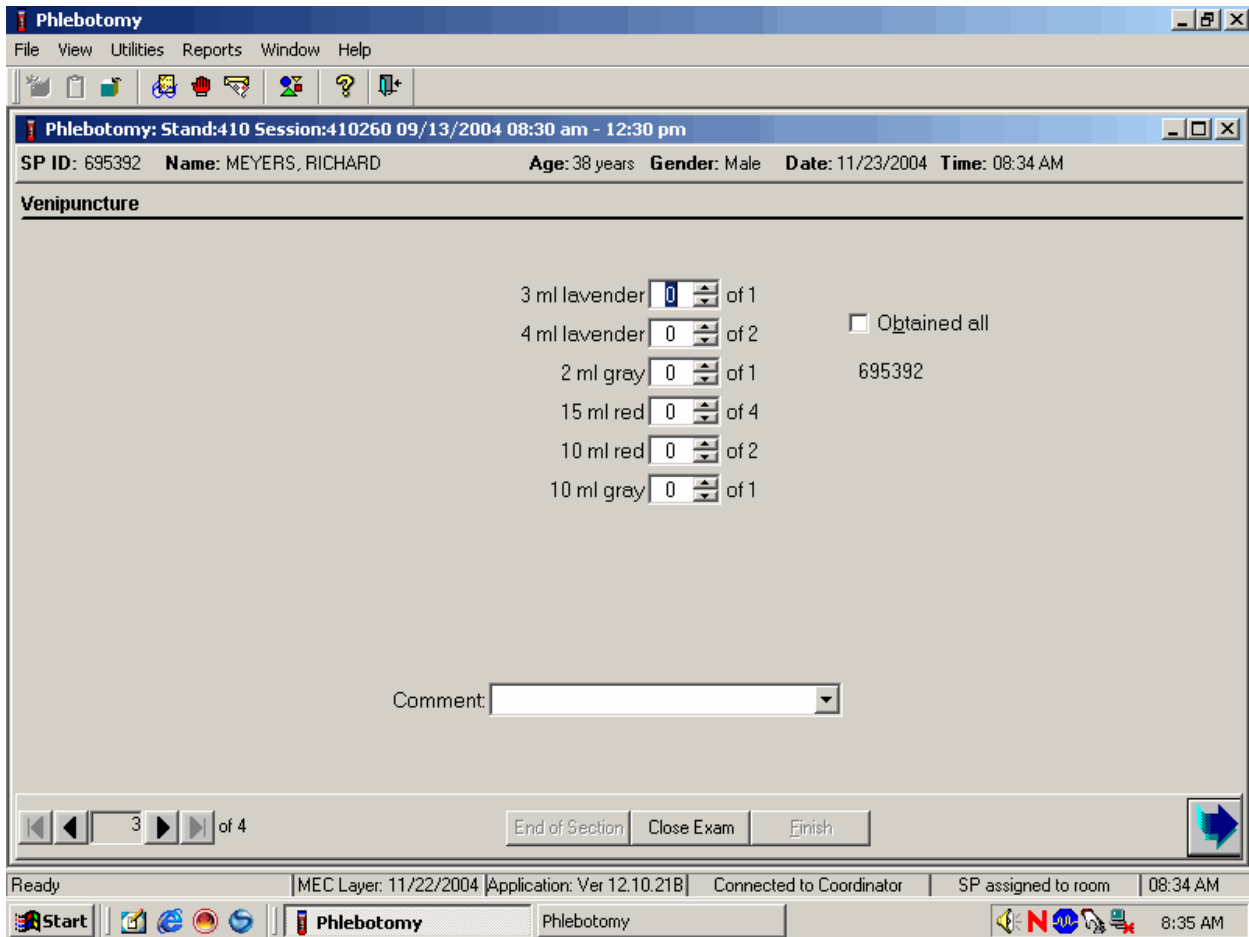
The coordinator assigns the SP to the phlebotomy room. In phlebotomy, the phlebotomist logs the SP into the application, and performs venipuncture to collect the protocol-dictated tubes, which includes the 10-mL gray top VOC blood tube. Labels print automatically for the blood tube.

The MEC manager transports VOC and perchlorate water samples from the field office to the MEC on a weekly basis. The laboratory staff print and label the sample, mark the vial as collected “Yes” or “No” in the VOC module, and store and ship the sample. (Perchlorate water, vessel 103, is processed using a separate module.)

The MEC interviewers administer a short questionnaire.

11.4.1 Complete the VOC Section of the Phlebotomy Exam

Access the Phlebotomy application. Log onto the application, open the Phlebotomy examination, log the SP into the component, verify the information, conduct the phlebotomy interview, administer the fasting questionnaire, and proceed to the Venipuncture protocol screen.



The window displays the appropriate venipuncture protocol for VOC SPs. Draw one 10-mL gray top tube as part of the venipuncture protocol using procedures described in Chapter 4. Thoroughly mix the 10-mL gray top tube immediately after drawing the tube and place the tube on the specimen rocker until the tubes are labeled and passed through to the window to the laboratory.

Immediately after completing the venipuncture, enter the results of the blood draw.

The screenshot shows the Phlebotomy software interface. The main window title is "Phlebotomy: Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". The patient information is: SP ID: 695392, Name: MEYERS, RICHARD, Age: 38 years, Gender: Male, Date: 11/23/2004, Time: 08:34 AM. The section is titled "Venipuncture".

| | | | |
|---------------|---|------|--|
| 3 ml lavender | 1 | of 1 | <input checked="" type="checkbox"/> Obtained all 695392 |
| 4 ml lavender | 2 | of 2 | |
| 2 ml gray | 1 | of 1 | |
| 15 ml red | 4 | of 4 | |
| 10 ml red | 2 | of 2 | |
| 10 ml gray | 1 | of 1 | |

Comment:

Navigation: 3 of 4, End of Section, Close Exam, Finish

System Status: Ready, MEC Layer: 11/22/2004, Application: Ver 12.10.21B, Connected to Coordinator, SP assigned to room, 08:34 AM

Label the blood tubes by placing the bar-coded label on the tube. Pass the blood through the window to the laboratory. Review the venipuncture status.

11.4.2 MEC Interview VOC Questionnaire

The MEC interviewers administer the CAPI VTQ section of the MEC interview examination. These specifications and directions are documented in the *MEC Interview Manual*.

The CAPI VTQ collects data about the SP's home, activities, amount of time spent in various locations and exposure to different chemicals over the past 76 hours. All VOC subsampled SPs are eligible for the VOC questionnaire.

11.5 VOC Water and Perchlorate Water Processing

The MEC manager transports the VOC and perchlorate water samples from the field office to the MEC at least weekly. Sort the samples numerically by the SP ID and store them in the MEC laboratory refrigerator. Samples will exist for every SP aged 12+ who was interviewed. They cannot be processed until the SP is MEC examined. Process these samples on a session-by-session basis and ship them weekly. Use the web-based VOC/Perchlorate Reconciliation report to reconcile the samples, at least weekly. Notify the field office staff of any discrepancy.

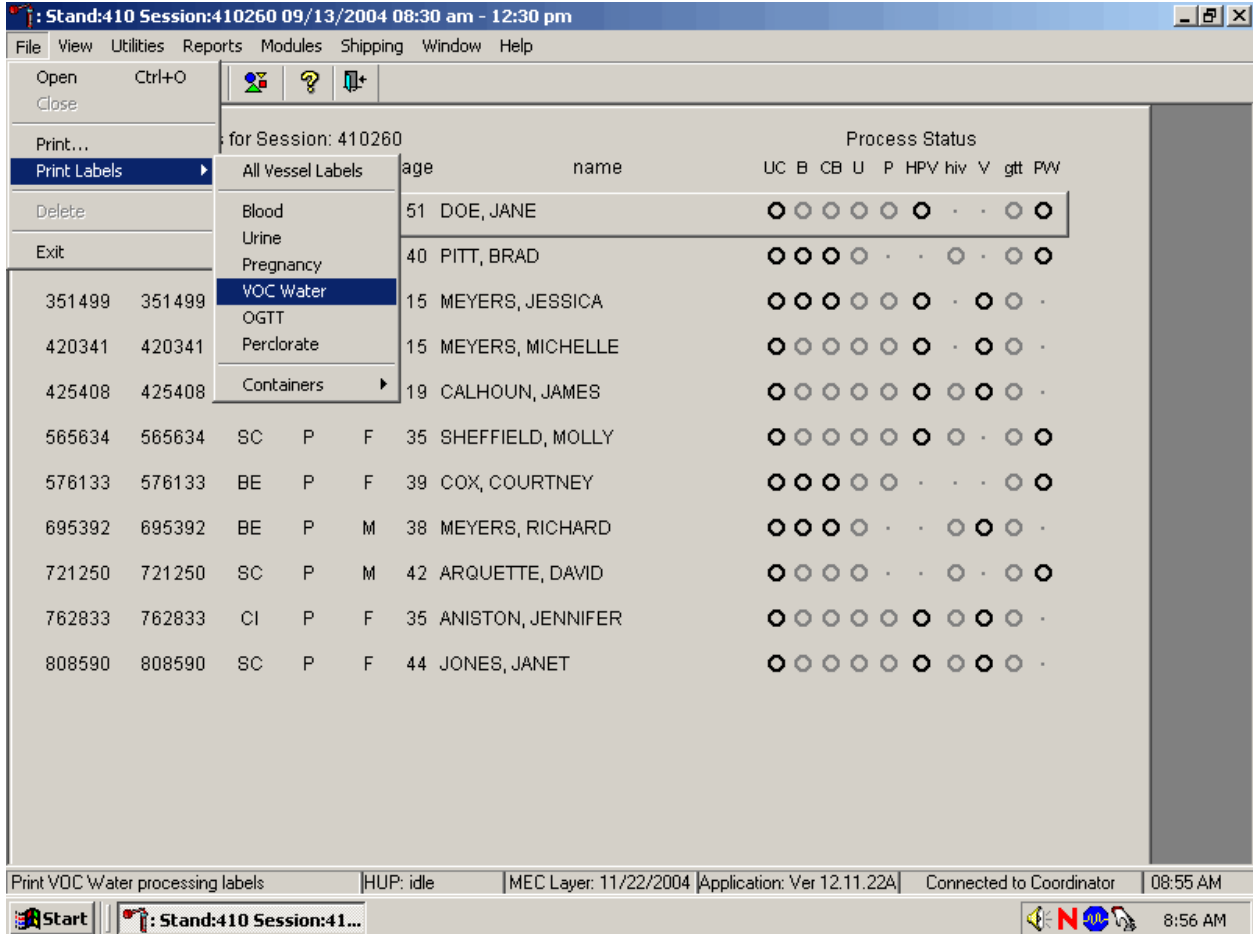
11.6 Processing VOC Specimens (Vessels) in the Laboratory

The VOC blood tube is labeled in phlebotomy; no further labeling is necessary. The tube is passed through to the lab immediately after collection. Ensure that the contents are thoroughly mixed; process the vial using the V module and refrigerate the vial within 15 minutes after the blood draw.

The household interviewers label the outside of the VOC/perchlorate water kit with a paper label containing the Household ID. They write the collection date and time on the pink label that is located on the outside of the water collection kit. Print a new laboratory label for every VOC water vial; the label must contain the standard 6-digit SP ID concatenated with the vessel ID (56.) The printing procedure is described in Section 11.7.

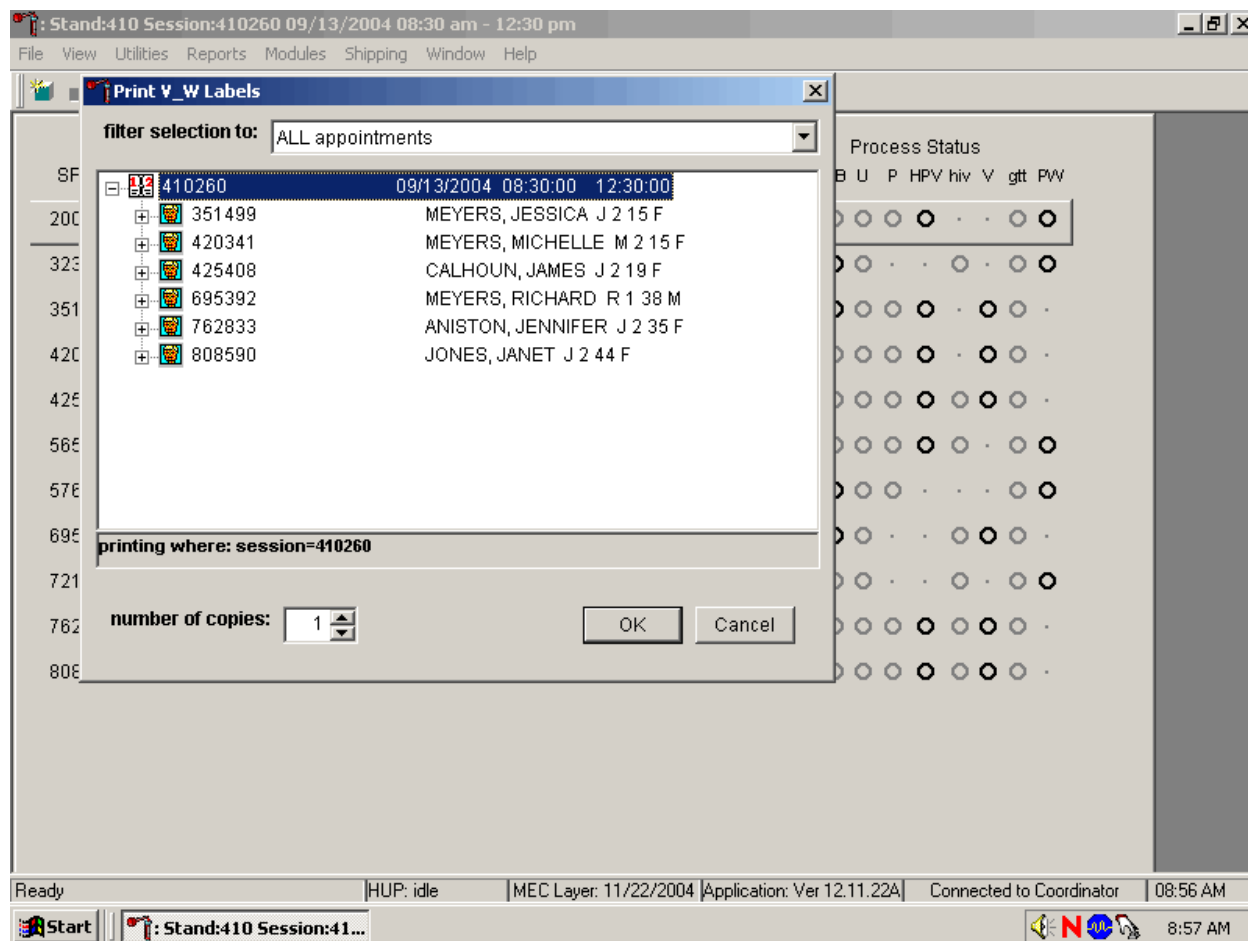
11.6.1 Print Labels for VOC Water Vials

Access the Print Labels module in the Laboratory application. Print vessel labels for the VOC Water vessels for specific SPs in a MEC session.



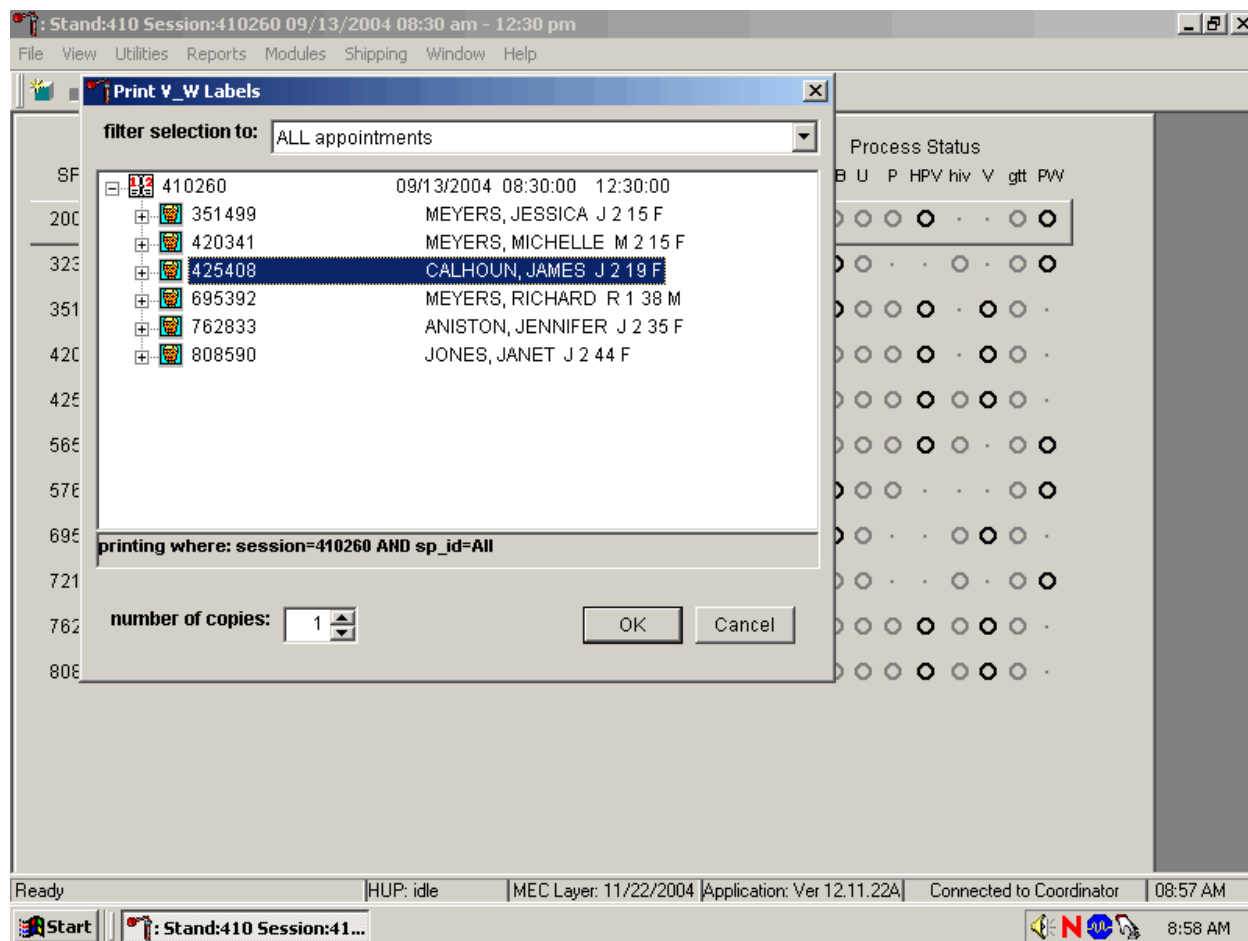
To print vessel labels for the VOC Water vessels, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Print Labels}, then to {VOC Water}, and left click or type [Alt] [F/f], [L/l], [W/w].

Print VOC Water vessel labels for **all** SPs in a MEC session.



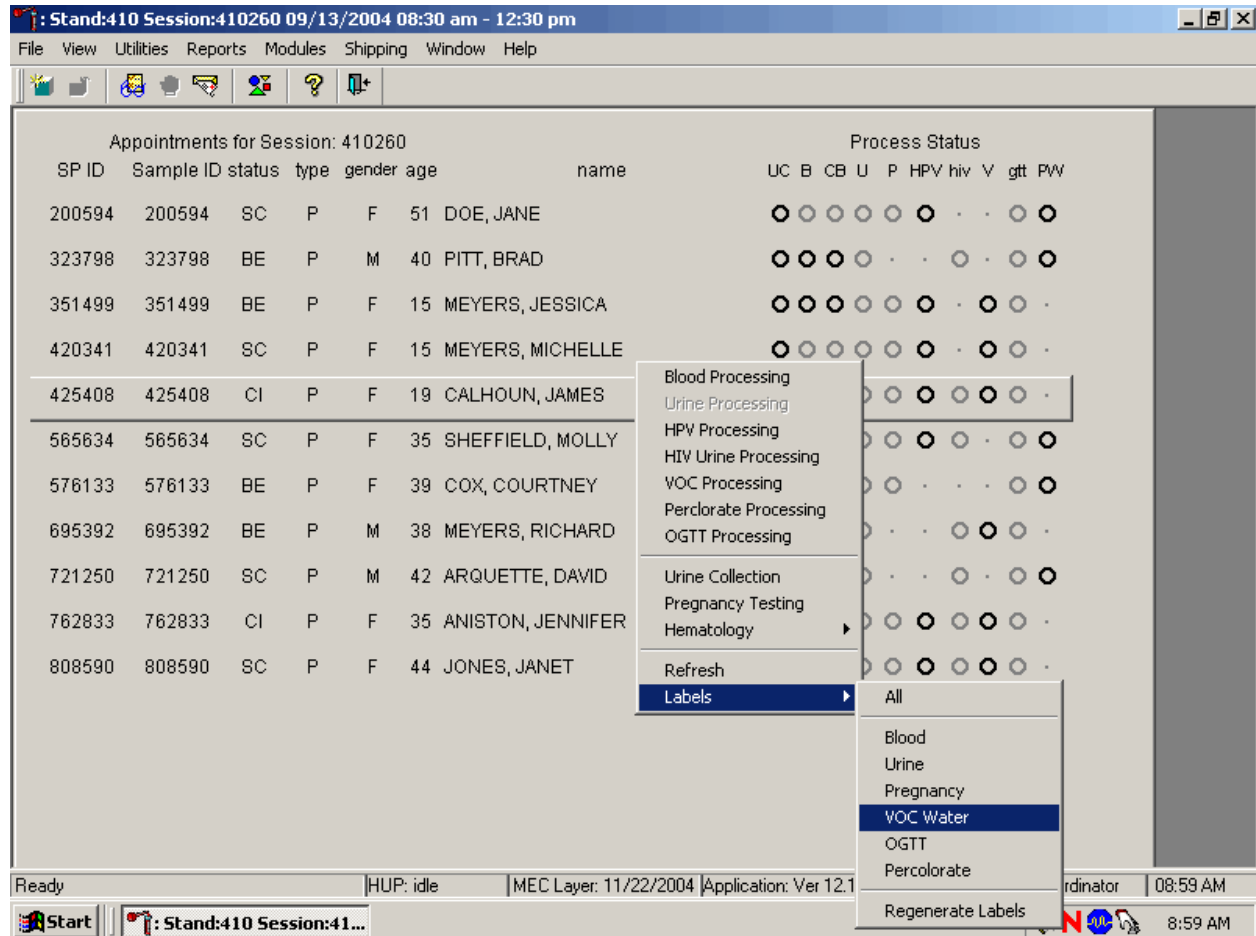
To print vessel labels for **one specific module** for **all** SPs, in a MEC or session, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled for the session are listed below the session number. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print VOC Water vessel labels for one SP in a MEC session.



To print vessel labels for **one specific module** for **one** SP, use the mouse to direct the mouse arrow to the session number or use the up and down arrows to move up and down the list and left click when the correct session is highlighted. All SPs scheduled into the session are listed below the session number. To select or highlight one SP, use the mouse to direct the mouse arrow to the line containing the SP and right click. Select the number of copies (number of sets of labels) by using the mouse to direct the mouse arrow to the up-down controls on the “number of copies” spin box to toggle the number up and down. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

Print labels for a particular MEC SP using the heads-up display. Print labels for one specific module for one SP in a MEC session using the heads-up display.



To print labels for one specific module for an SP using the heads-up display, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then {VOC Water} and right click. Alternatively, to print labels using the heads-up display, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, then drag the mouse arrow to {Labels} and then {VOC Water}, or left click or type [L/I] [W/w].

11.6.2 Process the VOC Blood and Water Vials

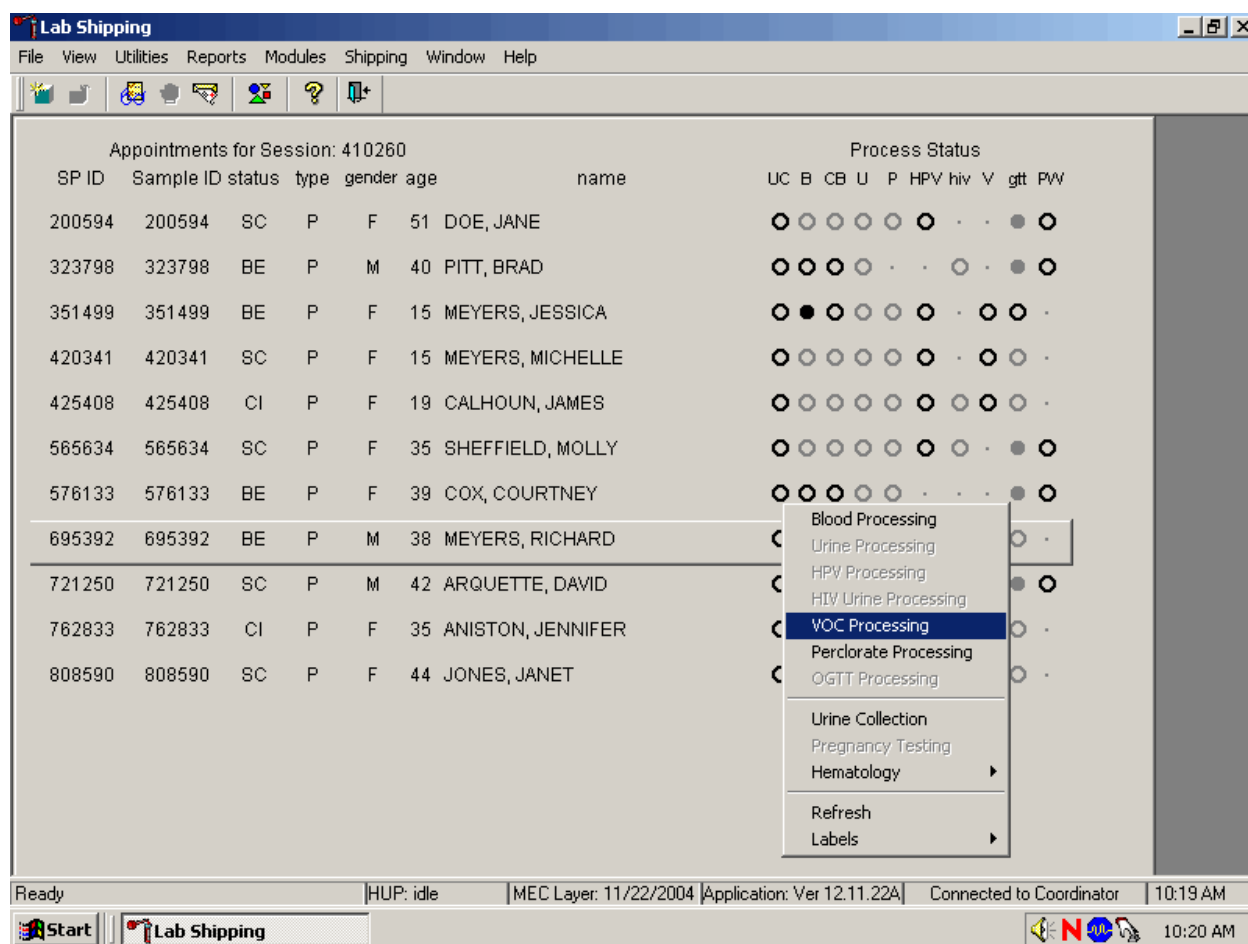
Open the Laboratory application, select the correct session, and review the heads-up display. Access the VOC Processing module and mark the vessels 54 and 56 as Filled–“Yes,” or Filled–“No.” Record the water collection date and time.

Exhibit 11-4 illustrates the VOC processing and storage protocol.

Exhibit 11-4. VOC processing and storage protocol

| Vessel No. | Assay | Age in years | Sample size mL | Collection type | Container |
|------------|-----------|--------------|----------------|-------------------|--|
| 54 | VOC Blood | 12+ | 10 | 10-mL Gray top | 5 x 5 5-inch box with foam insert |
| 56 | VOC Water | 12+ | 10 | 10-mL Glass | 5 x 5 5-inch box with foam insert |

Access the VOC Processing module.



To access the VOC Processing module, use the mouse to direct the mouse arrow to the correct SP and right click, drag the mouse arrow to {VOC Processing} and right click. Alternatively, to access the VOC Processing module, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, then drag the mouse arrow to {VOC Processing} and left click.

The VOC processing window displays.

The screenshot shows a software window titled "VOC: 695392" with a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main area is labeled "V processing" and contains the following information:

Tech ID: 1126 **Sample ID:** 695392 **Name:** MEYERS, RICHARD **Gender:** M **Age:** 38
SP ID: 695392 **Appt Type:** Primary **Fasting Req:** Morning - 9 Hour

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-----------|---------------|------|---------------|-------------|--|----------|--------------|-------|
| 54 | VOC Blood | 10.0 | VW | 10 ml | gray top | <input type="radio"/> Yes <input type="radio"/> No | | | |
| 56 | VOC Water | 10.0 | H2 | 10 ml | glass vial | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

Below the table is a "Collection Date and Time" field with the value "00/00/0000 00:00 AM". At the bottom of the window are "Save", "OK", and "Cancel" buttons.

The Windows taskbar at the bottom shows the system is "Ready", "HUP: idle", "MEC Layer: 11/22/2004", "Application: Ver 12.11.22A", "Connected to Coordinator", and the time is "09:01 AM".

The VOC processing window for an SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, Appt (appointment) Type, Fasting Req, columns for Vessel ID, Test Name, Sample Volume, Type (VW and H2), Vessel Volume, Vessel Name, Filled “Yes” and “No” radio buttons, Comments text box, and a Container ID/Slot # column. An additional calendar option used to record the water collection date and time is located in the vessel 56 row.

Mark each vessel as Filled–“Yes” or Filled–“No.”

The screenshot shows a software window titled "VOC: 695392" with the subtitle "V processing". The window contains the following information:

Tech ID: 1126 Sample ID: 695392 Name: MEYERS, RICHARD Gender: M Age: 38
 SP ID: 695392 Appt Type: Primary Fasting Req: Morning - 9 Hour

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-----------|---------------|------|---------------|-------------|---|----------|--------------|-------|
| 54 | VOC Blood | 10.0 | WW | 10 ml | gray top | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410423 | 2 |
| 56 | VOC Water | 10.0 | H2 | 10 ml | glass vial | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410424 | 3 |

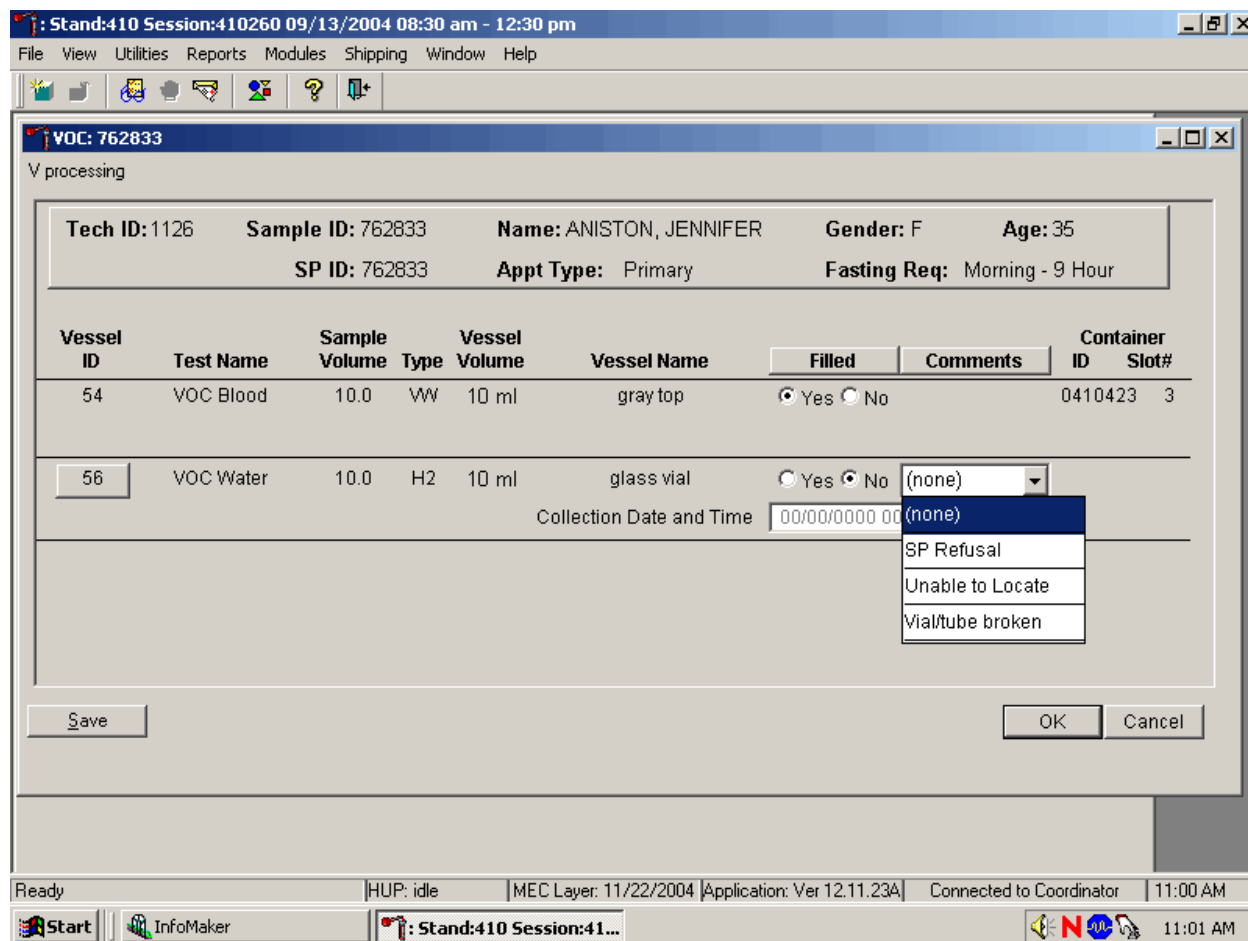
Collection Date and Time: 00/00/0000 00:00 AM

Buttons: Save, OK, Cancel

System tray information: Ready | HUP: idle | MEC Layer: 11/22/2004 | Application: Ver 12.11.22A | Connected to Coordinator | 09:04 AM

To individually mark **each** vessel as filled or not filled, use the mouse to direct the mouse arrow to the “Yes” or “No” radio button for a specific vessel ID (or test), and left click. As each vessel is marked as “Filled,” it is automatically assigned to a slot in an existing (open) container. There are no quality control comments available for vessels 54 and 56 if the vessels are marked as Filled “Yes.” There are no quality control comments available for vessel 54 if the vessel is marked as Filled–“No.”

Attach a comment to an individual Filled–“No” result for vessel 56.



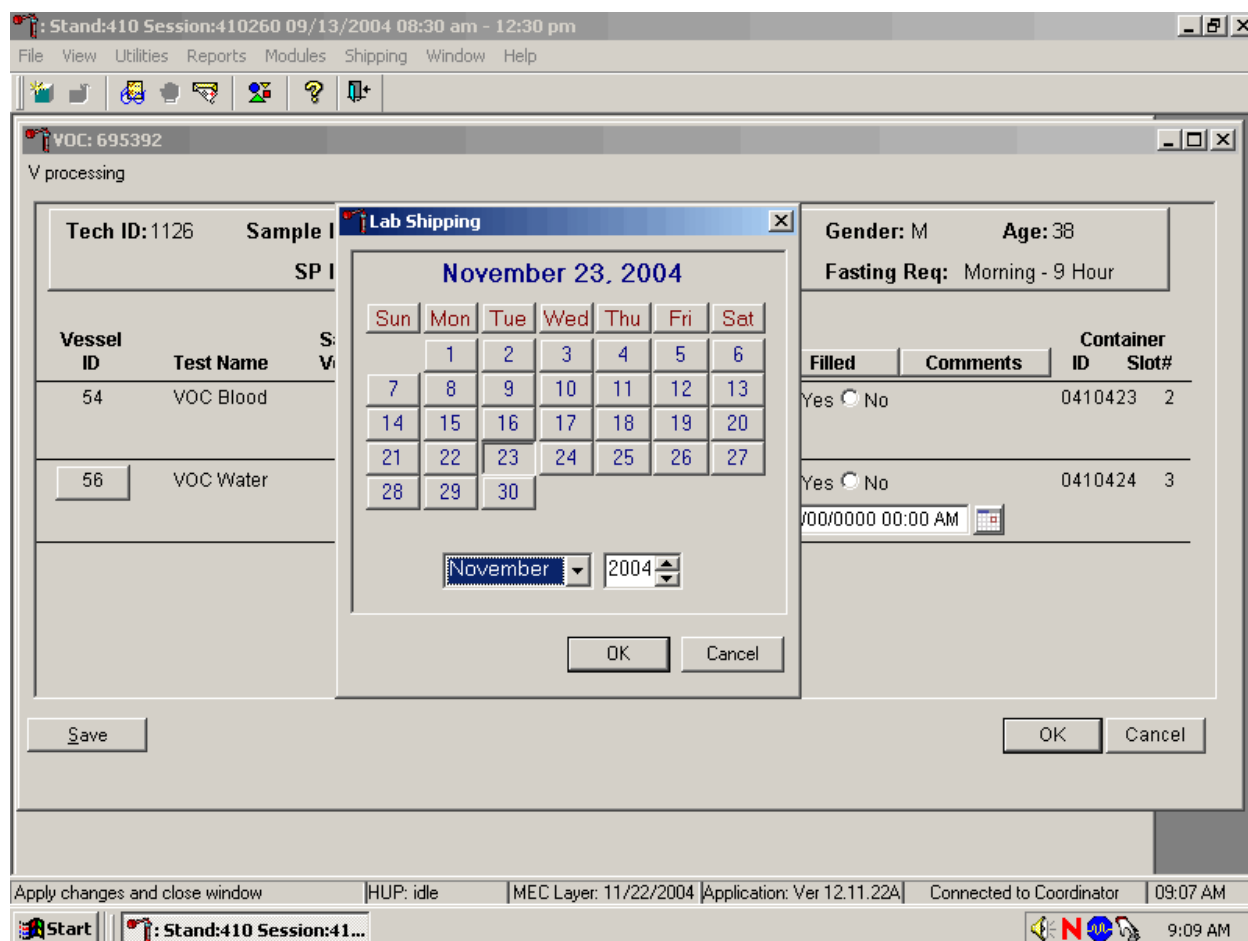
To attach a Filled–“No” comment to an individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments text box to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

All vessels marked as Filled–“No” require a comment or explanation. Enter comment codes to describe the reason that a vessel is marked as Filled–“No.”

| Comment for not filled vessels | Use when: |
|--------------------------------|---|
| SP refusal | This is an SP-initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses during the household interview, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam. |

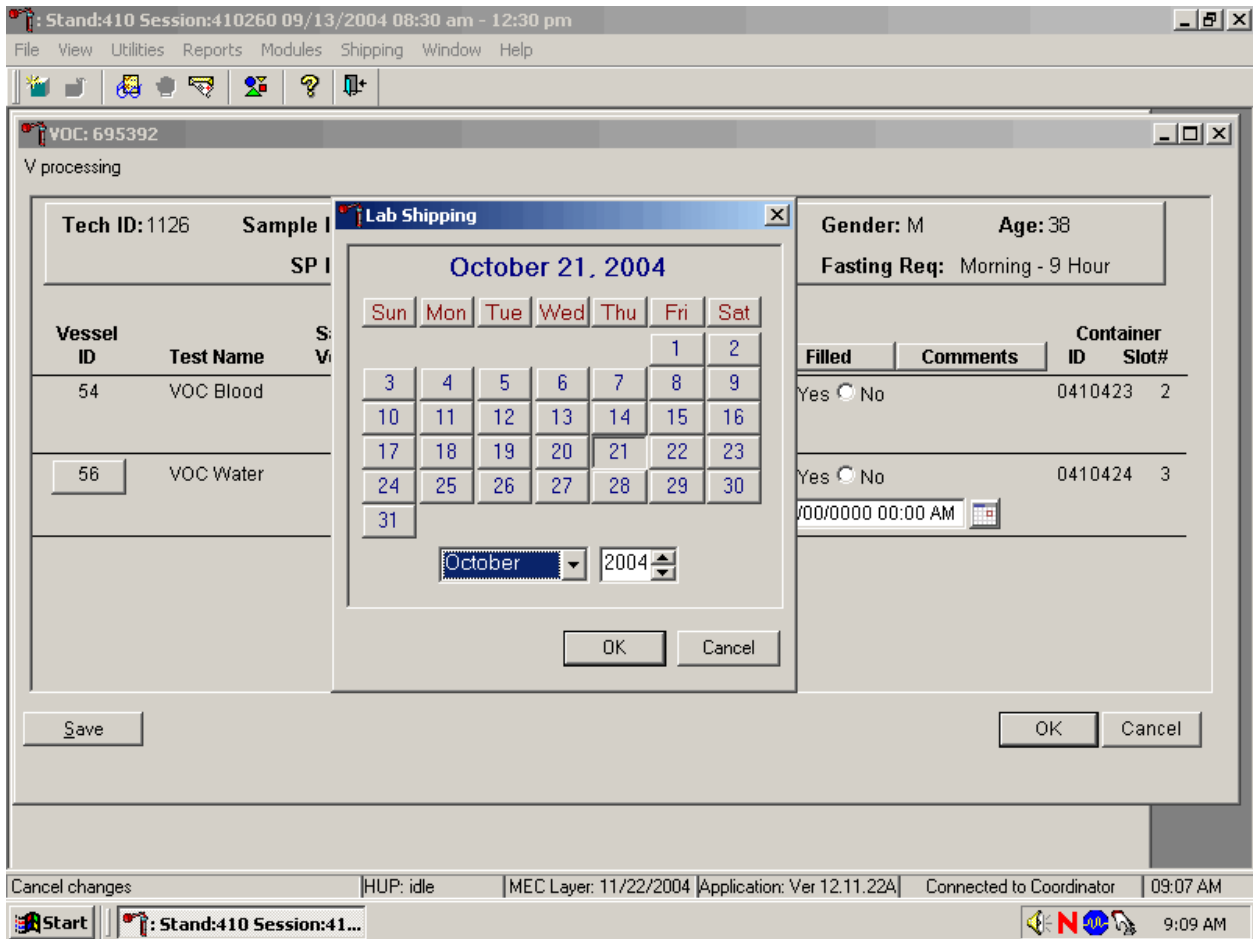
| Comment for not filled vessels | Use when: |
|--------------------------------|---|
| Unable to locate | Water collected during the household interview cannot be located. |
| Vial/tube broken | A tube breaks in the centrifuge, contents spill, or other technologist error. |

Record the water Collection Date and Time.



To enter the collection date and time (located on the pick label), use the mouse to direct the mouse arrow to the calendar icon located to the right of the Collection Date and Time text box and left click. The date will default to today's date.

Enter the collection date.



To select the correct month, use the mouse to direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary), and left click. To select the correct day, use the mouse to direct the mouse arrow to the correct day on the displayed month and left click. To correct the year, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To exit the calendar function, use the mouse to direct the mouse arrow to the Cancel button and left click.

Enter the collection time.

V processing

Tech ID: 1126 Sample ID: 695392 Name: MEYERS, RICHARD Gender: M Age: 38
SP ID: 695392 Appt Type: Primary Fasting Req: Morning - 9 Hour

| Vessel ID | Test Name | Sample Volume | Vessel Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-----------|---------------|-------------|---------------|-------------|---|----------|--------------|-------|
| 54 | VOC Blood | 10.0 | WW | 10 ml | gray top | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410423 | 2 |
| 56 | VOC Water | 10.0 | H2 | 10 ml | glass vial | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410424 | 3 |

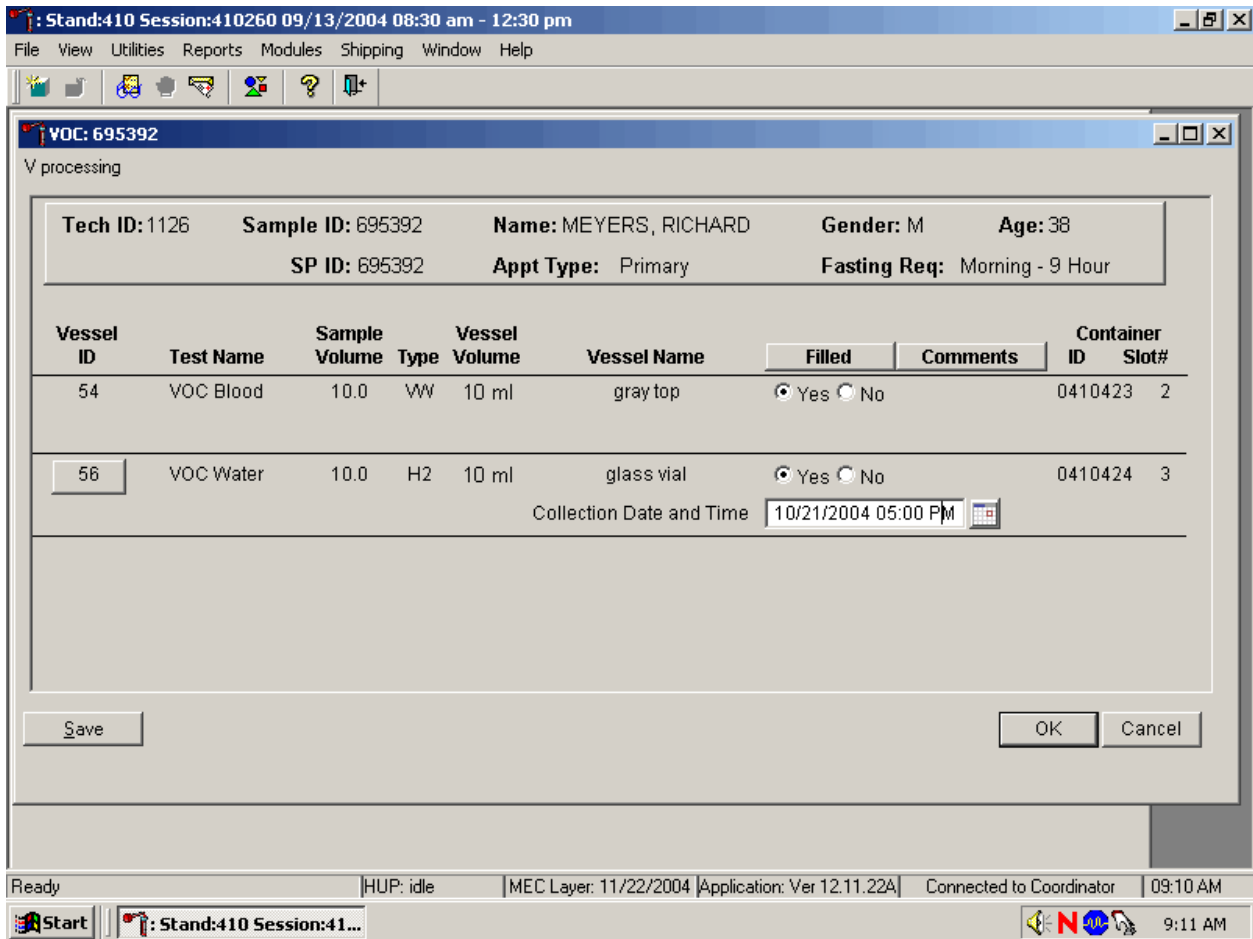
Collection Date and Time: 10/21/2004 12:00 AM

Buttons: Save, OK, Cancel

Taskbar: Stand:410 Session:41... 9:10 AM

Once the date is selected on the calendar and the OK button is selected, the calendar date is inserted into the text box and the time is highlighted in blue. The time will default to 12:00 AM. Enter the correct collection time by typing the numbers using the keyboard keys. Do not use 24 hour time (for example, 14:00 for 2:00 p.m.)

Review the information and save the data.



Store each vessel in the correct slot in the correct container. To record these actions or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To record these actions or to save these data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions and to exit the module, use the mouse to direct the mouse arrow to the Cancel button and left click.

Review the heads-up display. Verify that the heads-up display is updating correctly. Check the slot assignment of containers associated with vessels 54 and 56, at the end of each session. Verify the contents of each container against the container map.

11.7 Processing Perchlorate Water Specimens (Vessels) in the Laboratory

The household interviewers label the outside of the VOC/perchlorate water kit with a paper label containing the household ID. They write the collection date and time on the pink label that is located on the outside of the water collection kit. Print a new laboratory label for every perchlorate water vial; the label must contain the standard 6-digit SP ID concatenated with the vessel ID (103).

11.7.1 Print Labels for Perchlorate Water Vials

Access the Print Labels module in the Laboratory application. Print vessel labels for the Perchlorate vessels for specific SPs in a MEC session.

The screenshot shows a software window titled "Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm". The menu bar includes File, View, Utilities, Reports, Modules, Shipping, Window, and Help. The "Print Labels" menu is open, showing options: All Vessel Labels, Blood, Urine, Pregnancy, VOC Water, OGTT, Perchlorate (selected), and Containers. The main window displays a table of specimens with columns for age, name, and Process Status (UC, B, CB, U, P, HPV, hiv, V, gtt, PW). The row for "MEYERS, RICHARD" is highlighted.

| | | | | age | name | Process Status | | | | | | | | | |
|--------|--------|----|---|-----|----------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| | | | | | | UC | B | CB | U | P | HPV | hiv | V | gtt | PW |
| | | | | 51 | DOE, JANE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| | | | | 40 | PITT, BRAD | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 351499 | 351499 | | | 15 | MEYERS, JESSICA | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 420341 | 420341 | | | 15 | MEYERS, MICHELLE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 425408 | 425408 | | | 19 | CALHOUN, JAMES | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 565634 | 565634 | SC | P | F | 35 SHEFFIELD, MOLLY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 576133 | 576133 | BE | P | F | 39 COX, COURTNEY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695392 | 695392 | BE | P | M | 38 MEYERS, RICHARD | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ● | ○ | ○ |
| 721250 | 721250 | SC | P | M | 42 ARQUETTE, DAVID | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 762833 | 762833 | CI | P | F | 35 ANISTON, JENNIFER | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 808590 | 808590 | SC | P | F | 44 JONES, JANET | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Print Perchlorate processing labels | HUP: idle | MEC Layer: 11/22/2004 | Application: Ver 12.11.22A | Connected to Coordinator | 09:15 AM

To print vessel labels for the Perchlorate Processing modules, use the mouse to direct the mouse arrow to {File} in the top menu bar, drag the arrow to {Print Labels}, then to {Perchlorate}, and left click or type [Alt] [F/f], [L/l], [E/e]. Use procedures described in Section 11.7.1 to print Perchlorate vessel labels for **all** SPs in a MEC session or for a particular SP in a session. Alternatively, print labels for the perchlorate vessel for an SP using the heads-up display, which is also described in Section 11.7.1.

11.7.2 Process Perchlorate Water Vials

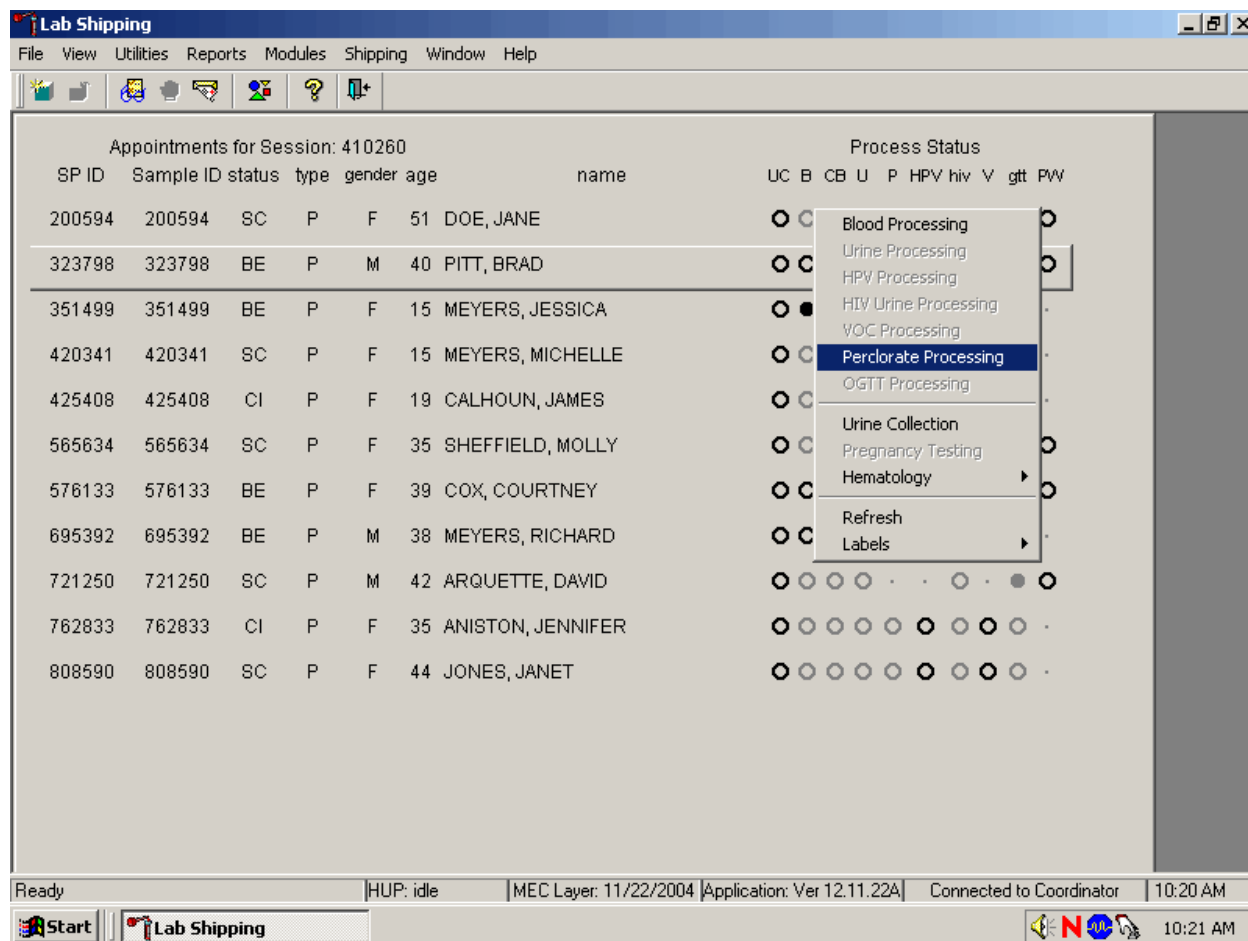
Open the Laboratory application, select the correct session, and review the heads-up display. Print labels for the perchlorate water vials then access the PW (Perchlorate water) processing module and mark the vessels as Filled–“Yes,” or Filled–“No.”

Exhibit 11-5 illustrates the perchlorate water processing and storage protocol.

Exhibit 11-5. Perchlorate water processing and storage protocol

| Vessel No. | Assay | Age in years | Sample size mL | Collection type | Container |
|------------|-------------|--------------|----------------|-------------------|--|
| 103 | PerchlorH2O | 12+ | 10 | 10-mL Gray top | 5 x 5 5-inch box with foam insert |

Access the Perchlorate Processing module.



To access the Perchlorate Processing module, use the mouse to direct the mouse arrow to the correct SP and right click, drag the mouse arrow to {Perchlorate Processing} and right click. Alternatively, to access the Perchlorate Processing module, use the up and down keys to move up and down the list until the correct SP is highlighted, right click, then drag the mouse arrow to {Perchlorate Processing} and left click.

The Perchlorate Processing window displays.

The screenshot shows a software window titled "Perchlorate" with a subtitle "PerchlorH2O Processing". The window has a menu bar (File, View, Utilities, Reports, Modules, Shipping, Window, Help) and a toolbar. The main content area is divided into two sections. The upper section contains summary information: Tech ID: 1126, Vessel ID: 103, Test Name: PerchlorH2O, Vessel Name: glass vial, Total Volume: 10 ml, and Sample Volume: 10.0. The lower section is a table with the following columns: Sample ID, Person Name, Gender, Age, Filled (Yes/No radio buttons), Comments (text box), and Container ID/Slot# (dropdown menu). The table lists five samples. At the bottom of the window are buttons for "Save", "OK", and "Cancel". The Windows taskbar at the bottom shows the system tray with "Ready", "HUP: idle", "MEC Layer: 11/22/2004", "Application: Ver 12.11.22A", "Connected to Coordinator", and "09:21 AM".

| Sample ID | Person Name | Gender | Age | Filled | Comments | Container ID/Slot# |
|-----------|------------------|--------|-----|--|----------|--------------------|
| 200594 | DOE, JANE | F | 51 | <input type="radio"/> Yes <input type="radio"/> No | (none) | |
| 323798 | PITT, BRAD | M | 40 | <input type="radio"/> Yes <input type="radio"/> No | (none) | |
| 565634 | SHEFFIELD, MOLLY | F | 35 | <input type="radio"/> Yes <input type="radio"/> No | (none) | |
| 576133 | COX, COURTNEY | F | 39 | <input type="radio"/> Yes <input type="radio"/> No | (none) | |
| 721250 | ARQUETTE, DAVID | M | 42 | <input type="radio"/> Yes <input type="radio"/> No | (none) | |

The upper section of the PerchlorH2O Processing window for an SP contains the following information: Tech ID, Sample ID, Test Name (PerchlorH2O), Total Volume (10 ml), Vessel ID (103), Vessel Name (glass vial), and Sample Volume (10.0.) The lower section of the window contains columns for Sample ID, Person Name (Last, First), Gender, Age, Filled “Yes” and “No” radio buttons, Comments text box, and a Container ID/Slot # column. Each SP is listed in a separate row but all eligible SPs are listed in the same window.

Mark each vessel as Filled–“Yes” or Filled–“No.”

PerchlorH2O Processing

Tech ID: 1126 Test Name: PerchlorH2O Total Volume: 10 ml
 Vessel ID: 103 Vessel Name: glass vial Sample Volume: 10.0

| Sample ID | Person Name | Gender | Age | Filled | Comments | Container ID | Slot# |
|-----------|------------------|--------|-----|---|----------|--------------|-------|
| 200594 | DOE, JANE | F | 51 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 9 |
| 323798 | PITT, BRAD | M | 40 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 6 |
| 565634 | SHEFFIELD, MOLLY | F | 35 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 7 |
| 576133 | COX, COURTNEY | F | 39 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 8 |
| 721250 | ARQUETTE, DAVID | M | 42 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 10 |

Buttons: Save, OK, Cancel

Apply changes and close window | HUP: idle | MEC Layer: 11/22/2004 | Application: Ver 12.11.23A | Connected to Coordinator | 11:05 AM

Start | InfoMaker | Stand:410 Session:41... | 11:06 AM

To individually mark **each** vessel as filled or not filled, use the mouse to direct the mouse arrow to the “Yes” or “No” radio button for a specific Sample ID and left click. As each vessel is marked as “Filled,” it is automatically assigned to a slot in an existing (open) container. There are no quality control comments available for vessel 103 if the vessel is marked as Filled–“Yes.”

Attach a comment to an individual Filled–“No” result for vessel 103.

Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Perchlorate
PerchlorH2O Processing

Tech ID: 1126 Test Name: PerchlorH2O Total Volume: 10 ml
 Vessel ID: 103 Vessel Name: glass vial Sample Volume: 10.0

| Sample ID | Person Name | Gender | Age | Filled | Comments | Container ID | Slot# |
|-----------|------------------|--------|-----|---|----------|--------------|-------|
| 200594 | DOE, JANE | F | 51 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 9 |
| 323798 | PITT, BRAD | M | 40 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 6 |
| 565634 | SHEFFIELD, MOLLY | F | 35 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 7 |
| 576133 | COX, COURTNEY | F | 39 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 8 |
| 721250 | ARQUETTE, DAVID | M | 42 | <input type="radio"/> Yes <input checked="" type="radio"/> No | (none) | | |

Save Cancel

Ready HUP: idle MEC Layer: 11/22/2004 Application: Ver 12.11.23A Connected to Coordinator 11:05 AM

Start InfoMaker Stand:410 Session:41... 11:06 AM

To attach a Filled–“No” comment to an individual vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments text box to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

All vessels marked as Filled–“No” require a comment or explanation. Enter comment codes to describe the reason that a vessel is marked as Filled–“No.”

| Comment for not filled vessels | Use when: |
|--------------------------------|---|
| SP refusal | This is an SP-initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses during the household interview, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam. |
| Unable to locate | Water collected during the household interview cannot be located. |
| Vial/tube broken | A tube breaks in the centrifuge, contents spill, or other technologist error. |

Review the information and save the data.

Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

Perchlorate
PerchlorH2O Processing

Tech ID: 1126 **Test Name:** PerchlorH2O **Total Volume:** 10 ml
Vessel ID: 103 **Vessel Name:** glass vial **Sample Volume:** 10.0

| Sample ID | Person Name | Gender | Age | Filled | Comments | Container ID | Slot# |
|-----------|------------------|--------|-----|---|------------|--------------|-------|
| 200594 | DOE, JANE | F | 51 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 9 |
| 323798 | PITT, BRAD | M | 40 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 6 |
| 565634 | SHEFFIELD, MOLLY | F | 35 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 7 |
| 576133 | COX, COURTNEY | F | 39 | <input checked="" type="radio"/> Yes <input type="radio"/> No | | 0410447 | 8 |
| 721250 | ARQUETTE, DAVID | M | 42 | <input type="radio"/> Yes <input checked="" type="radio"/> No | SP Refusal | | |

Save OK Cancel

Ready HUP: idle MEC Layer: 11/22/2004 Application: Ver 12.11.23A Connected to Coordinator 11:06 AM

Start InfoMaker Stand:410 Session:41... 11:07 AM

Store each vessel in the correct slot in the correct container. To record these actions or to save these data to the database, use the mouse to direct the mouse arrow to the Save button and left click or type [Shift] [S/s]. To record these actions or to save these data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions and to exit the module, use the mouse to direct the mouse arrow to the Cancel button and left click.

11.8 Shipping VOC/Perchlorate Specimens

Ship VOC blood and water vessels and the perchlorate water vessels to one contract laboratory (Exhibit 11-6) in a double-sided Styrofoam shipper or hard-sided cooler using wet refrigerant packs. Include a copy of a shipping manifest, which contains a list of the items contained in the shipment and certain demographic information with each shipment. Exhibit 11-7, the VOC/perchlorate shipping protocol, illustrates the specifications for the shipment of biological specimens to the contract laboratory.

Exhibit 11-6. Contract laboratory addresses

| Laboratory/destination specimen shipment address | Vessels/assays | Conditions | Contact Person(s) Telephone number |
|---|---|--------------|------------------------------------|
| CDC/Air Toxicant Branch 4770 Buford Highway NE Building 17, Loading Dock Atlanta, GA 30341 | 54/VOCBlood 56/VOCWater 103/PerchlorH2O | Refrigerated | Dr. Ben Blount 770-488-7962 |

Exhibit 11-7. VOC/perchlorate shipping protocol

| Location | Vessels | Conditions | Vessel storage | Shipping frequency |
|-------------------------|-----------------|--------------|---|--------------------|
| CDC/Air Toxicant Branch | 54/VOCBlood | Refrigerated | 5 x 5 5-inch box with foam insert | Weekly |
| CDC/Air Toxicant Branch | 56/VOCWater | Refrigerated | 5 x 5 5-inch box with foam insert | Weekly |
| CDC/Air Toxicant Branch | 103/PerchlorH2O | Refrigerated | 5 x 5 5-inch box with foam insert | Weekly |

The integrity of laboratory specimens, including the VOC and perchlorate vessels, is critical to NHANES. Storage temperatures have been established for each analyte in consultation with NCHS and contact laboratories. It is critical to maintain these established conditions throughout specimen storage and shipping and until their ultimate receipt by the contract laboratories. Maintain these conditions by using documented procedures, which include using sufficient refrigerant packs, and sending specimens FedEx priority overnight.

The shipping technologist is primarily responsible for packing and shipping the specimens to all laboratories on a designated day. As necessary, other medical technologists, the phlebotomist, and the medical technologist assist in performing each of the steps listed below to complete the shipping procedures.

- On the day before a designated shipping day, create and print shipper labels (airbills) using FedEx Ship software.
- On the morning of a shipping day, close all containers following the protocol listed in Exhibit 11-8. Also, import FedEx airbill numbers into the shipping module, assign containers to a shipper, print the paper shipping manifest for each shipper, email the electronic file, and open all new containers.
- Assemble the paper shipping manifest, prepared FedEx label, FedEx preprinted return airbills, and assorted “warning” labels for each shipper. Clip all materials together until ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.
- Pack the containers for vessels 54 and 56 in the VOC shipper in the following order:
 - Cold packs at -20°C
 - Padding
 - Container for vessel 56 (VOC Water)
 - Container for vessel 103 (PerchlorH2O)
 - Container for vessel 54 (VOC Blood tube)
 - Padding
- Place the appropriate paper manifest and the FedEx return airbill in a 9 x 12 plastic bag and place the plastic bag on the Styrofoam lid of shipper and place the lid on the shipper.
- Label each shipper with the appropriate FedEx label and warning labels.

Exhibit 11-8. Container protocol

| Vessel ID | Test ID/Name | Sample type | Vessel type | Vessel storage | Storage unit |
|-----------|--------------|-------------|---------------------|--------------------------------------|-----------------|
| 54 | VOC Blood | WB | 10-mL Gray top | 5 x 5 5-inch box (Foam insert) | Refrigerator #2 |
| 56 | VOC Water | Water | 10-mL glass vial | 5 x 5 5-inch box (Foam insert) | Refrigerator #2 |
| 103 | PerchlorH2O | Water | 10-mL glass vial | 5 x 5 5-inch box (Foam insert) | Refrigerator #2 |

When the contract laboratory personnel receive the shippers and/or hard-sided coolers, they unpack the specimens and return the shippers, coolers, and refrigerant packs to either the field office (first 3-4 weeks of the stand) or the NHANES warehouse (last 2 weeks of the stand).

Follow the instructions in Chapter 9, Section 9.8, to create one airbill for CDC/Air Toxicant Branch. Follow instructions in Section 9.9 to close containers for vessels 54, 56, and 103. Follow instructions in Section 9.10 to assign the airbills to the shippers. Vessels 54, 56, and 103 are assigned to the same shipper.

Each shipper must include a paper manifest, which lists the inventory of the specimens in the storage boxes. In addition, each laboratory receives an identical electronic file. Follow the steps listed in Chapter 9, Section 9.11, to prepare the paper manifest and to send the electronic file.

11.8.1 Pack Medium Shipping Container for Refrigerated VOC/Perchlorate Shipment

Some shipments require a coolant to keep the specimens cold but not frozen during shipment. For these shipments, use reusable refrigerant packs. Add enough frozen refrigerant packs to the shipper to keep specimens cold for at least 48-72 hours. Keep approximately 30 refrigerant packs in the freezers at all times, replacing as necessary. Pack all refrigerated containers in Styrofoam shippers.

Pack the specimen storage boxes tightly in the Styrofoam container to prevent movement.

- Place the container associated with vessel 54 into a pressure vessel (STP-740) and seal.
- Place the container associated with vessel 56 (VOC Water) in a 9 x 12 plastic bag.
- Place the container associated with vessel 103 (PerchlorH20) in a 9 x 12 plastic bag.
- Place at least two large frozen refrigerant packs in the bottom of a shipper. (Place enough cold packs to cover the bottom of the shipper; lay them flat, not on their edges.)
- Cover the cold packs with a blue insulation pad.
- Place the container associated with vessel 56 (VOC Water) on top of the insulating material. The water samples are not as temperature sensitive as the blood samples.
- Place the container associated with vessel 103 (PerchlorH20) on top of the containers associated with vessel 56.
- Place the sealed pressure vessel containing the blood samples (vessel 54) on top of the container associated with vessel 103.
- Add another layer of insulated material.
- Pack the sides with crumbled newsprint.
- Place the Styrofoam lid on top of the Styrofoam bottom.
- Place the appropriate shipping manifest and one return FedEx preprinted airbill into a 9 x 12 plastic bag and seal.
- Place the plastic envelope containing the appropriate shipping manifest and one FedEx preprinted airbill on top of the Styrofoam lid.
- Weigh the shipper on the scale or assume that the package weighs 10 pounds.
- Record the total weight of the shipper (10 pounds) on the appropriate FedEx label.

11.9 Label Shippers

For all destinations, include a preprinted FedEx return airbill. Include a preprinted FedEx return airbill label with the current field office address for the first 4 weeks of the stand. Include a preprinted FedEx return airbill label with the address for the concurrent stand during the last 2 weeks of the stand.

All shippers must contain a FedEx bar-coded label and appropriate orientation and warning labels. Label all shippers with the appropriate warning labels as follows:

- Label shippers containing refrigerant packs with a “Refrigerate” label.
- Label shippers containing whole blood, serum, plasma, or urine with a “Biohazard” label.
- Complete the section of the FedEx label that requests the weight of the contents of the shipper, and if applicable, the section that requests the weight of the dry ice contained in the shipper.
- Place the FedEx label with the appropriate contract laboratory address in a plastic FedEx pouch and attach the window to the cardboard lid of the shipper.
- Add one additional strip of tape across the FedEx pouch.

11.10 The MEC Environment

Maintaining a stable interior environment is critical to many laboratory analytes and processes. Environmental contamination of specimens can result if specimens are exposed to outdoor air and/or contaminants. For this reason, the windows in the MEC should generally be kept closed. This is especially important when actively processing specimens in the laboratory. Confine smoking outside the MEC to areas where there are no air intake vents and there is no possibility of second-hand smoke entering the interior of the MEC. Adjust thermostats to maintain a comfortable MEC environment; opening and closing windows to adjust the temperature inside the MEC is not an alternative.

Exceptions to this policy are allowed under certain circumstances. Windows and/or bay doors can be opened when:

- An SP is uncomfortable and requires brief exposure to fresh air.
- The blood processing technologist is not processing specimens and the laboratory has dry ice inside the MEC.
- The MEC is not in session and the medical technologist is shipping specimens with dry ice.
- The blood processing technologist is not processing specimens and opening the laboratory bay door is required to provide access to the FedEx courier.

- The blood processing technologist is not processing specimens and opening the laboratory bay door is required to dispose of biohazardous trash.
- Performing setup and teardown activities. (This is done before any laboratory processing has occurred at the beginning of a stand and after all laboratory processing is complete at the end of a stand.)

12. ORAL GLUCOSE TOLERANCE TEST (OGTT)

12.1 Introduction

Because of the increasing occurrence of diabetes in younger ages, NHANES is adding this component to the examination protocol to reassess the prevalence of diabetes and impaired glucose tolerance (IGT) in the U.S. population.

Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and over 1 million new cases of diabetes are diagnosed each year. Diabetes is the leading cause of kidney failure, nontraumatic lower extremity amputation, and blindness in working-age adults, and an estimated \$135 billion was spent on direct and indirect medical costs for diabetes in 2002. Alarming, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.

Persons with IGT – 15.6 percent of the U.S. population – are at high risk for developing diabetes. In addition, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined on the basis of an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hour value of 140-199 mg/dl are considered to have IGT.

Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT. Furthermore, NHANES III data indicate a tremendous opportunity for the prevention of diabetes—over 12 million persons aged 45-74 have prediabetes (defined as overweight persons with either IGT or impaired fasting glucose metabolism). These data also indicate that over 50 percent of persons with prediabetes are detected only by IGT findings. As risk factors for diabetes, IGT, and prediabetes increase (e.g., physical inactivity, obesity, and aging), the prevalence of these conditions is also likely to increase.

The inclusion of OGTTs on NHANES will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the

Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts such as DHHS's STEPS program and efforts by the National Diabetes Education Program.

A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast. After the venipuncture, participants are asked to drink a calibrated dose (generally 75 milligrams) of Trutol® and to have a second venipuncture 2 hours (plus or minus 15 minutes) after drinking the Trutol.

There are minimal risks associated with this procedure. The package label for Trutol lists the following rare but known adverse reactions: nausea, vomiting, abdominal bloating, and headache. In addition, there is a rare incidence of hypoglycemia. The risks associated with venipuncture include excessive bleeding, fainting/feeling lightheaded, hematoma, infection, and multiple punctures to identify veins. Participants eligible for OGTT will have to endure the discomfort of a second venipuncture; however, they will benefit by the report of findings that will inform them if they have impaired glucose tolerance.

The results from the OGTT will be reported to parents of participants 12-17 years and directly to participants 18 years and older in the Final Report of Findings. If the 2-hour blood glucose values are equal to or greater than 140 mg/dL, (i.e., glucose levels consistent with impaired glucose tolerance or diabetes mellitus), an early report will be sent.

12.2 Field Office Responsibilities

The field office is responsible for instructing SPs to fast and for introducing the OGTT during the household interview by using an informational flyer (Exhibit 12-1). There is no change to the existing fasting remuneration.

Oral Glucose Tolerance Test, aged 12 years and older

Why are we asking participants to have an Oral Glucose Tolerance test (OGTT)?

We are asking teenagers and adults who are examined in the morning exam session to have an OGTT so we can learn more about how many people in the United States have diabetes.

Why is the study of diabetes in teenagers important?

Doctors and other health workers have seen an increase of type 2 diabetes in teenagers and adults over the past 20 years. This is an important problem since it can lead to many health problems such as heart disease, poor circulation, and blindness.

What is diabetes?

Diabetes mellitus is a group of diseases that cause high blood sugar levels. Type 1 diabetes was called insulin-dependent diabetes or juvenile diabetes and develops when the body's immune systems destroy the cells that make the hormone insulin that controls blood sugar levels. Type 2 diabetes was previously called non-insulin diabetes or adult-onset diabetes. Type 2 diabetes happens when the cells in our body do not use insulin right. In the past it was seen mostly in old people, overweight people, and people who were inactive. Today, type 2 diabetes is seen more and more in children and teenagers.

What will participants have to do to have the OGTT test?

Participants aged 12 years and older who are examined in the morning will be asked not to eat or drink anything (EXCEPT WATER) 9 hours before coming to the exam center. They will have their blood drawn for laboratory tests that include a fasting glucose test. They will then drink a special sugar drink. After 2 hours they will have more blood drawn to see how their body handled the sugar they drank.

What will this test tell participants about their health?

This test measures how the body handles sugar. We will be able to tell if a person is at risk for diabetes or already has it. The person or his or her parents will be told if the test shows a blood sugar problem.

Consent:

Page 3 of the consent brochure has been modified as follows:

Safety of Tests

We chose the tests and measurements because they are safe. Some of the exams or procedures may cause you slight discomfort. Examples are collecting a blood sample or fasting for 9 hours. For the blood sample, a person will have a small amount of blood drawn from a vein in his or her arm with a needle. Participants 12 years and older with a morning appointment will be asked to drink a sugar solution and have blood taken a second time. Although rare, the sugar solution can cause nausea, vomiting, bloating, or headache. We will not ask you to have any test or procedure that is wrong for you because of a health problem or condition.

12.3 MEC Overview

Diabetics taking insulin who are assigned to morning sessions are asked to fast for 9 hours so these SPs will be assigned to phlebotomy as the highest priority. They are not eligible for the GTT.

Female SPs aged 12-15 must complete the physician examination before being assigned to phlebotomy.

SPs aged 12 and older assigned to the morning session who have fasted for 9 hours are eligible for the GTT. It is generally important to assign SPs aged 12 and older to phlebotomy as soon as possible at the start of a session, but it is especially important during a morning session. It is also important to assess the fasting status of SPs aged 12 and older assigned to a morning session because they are not eligible for the GT examination if they have not met their 9-hour fast requirement. The coordinator gives each SP a hard copy verification form as part of the check-in process. For SPs aged 12 and older who are examined during a morning session, it includes the question, “Did you eat or drink anything, other than plain water, after 11:30 last night?” The SP records “Yes” or “No” in a checkbox and the coordinator enters this information into the coordinator application. The coordinator application then highlights (hot pink) the names of SPs who responded “Yes.” The coordinator must queue these SPs after those who have met their fast, although judgment is always required when managing MEC flow.

If the 9-hour fast is not met but it will be met, and 1 hour and 40 minutes remains in the session, then the phlebotomist will draw all the tubes, including the 2-mL gray top for glucose. The SP will continue with other exams until the fast is met. Once the fast is met, the SP will be assigned to the GT component so that he or she can drink the Trutol and have the second blood drawn 1 hour and 40 minutes later. The phlebotomist must take care not to give the SP juice and crackers at the conclusion of the first blood draw.

The coordinator will use the “GT” component in the coordinator application to assign and track SPs. After the initial phlebotomy examination, the SP will be assigned to phlebotomy or the CV fitness room for the first section of the GT component. If the SP is not excluded, then he or she will be instructed to drink a calibrated dose (generally 10 oz.) of a glucose solution (Trutol) immediately after the first venipuncture has been completed. The SP must drink the entire dose within 10 minutes. The phlebotomist, MEC interviewers, health technologists, the medical technologist assigned to workstation 3, or the MEC manager, will monitor the time it takes for the SP to consume the Trutol using the first of two

sections in the OGTT application. After the SP has consumed the solution, he or she will continue with the other MEC exams.

The SP is eligible to return to phlebotomy for a second blood draw 2 hours, -20 or +15 minutes, after he or she finished consuming the Trutol. (He or she must maintain the fast until the second blood draw is completed.) The coordinator will track the reassignment using the GT component in the coordinator application. After 100 minutes has elapsed since the SP finished drinking the solution, the coordinator will reassign the SP to the phlebotomy room for the second section of the GT component to have a second venipuncture performed. The phlebotomist will draw one additional 2-mL gray top tube for the OGTT test and any tubes that were not drawn during the first venipuncture. The second venipuncture must be complete 135 minutes after the SP finishes drinking the Trutol.

Most SPs will drink the Trutol solution in the CV fitness room. Some SPs may stay in the phlebotomy room to drink the Trutol, but this will generally occur only during lightly booked sessions. The coordinator must exercise judgment to determine the best location for the SP to consume the Trutol solution. Judgment should be guided by the goal to complete all MEC exams for an SP, balance the phlebotomist's workload, and assign the SP to the GT component as soon as possible after the initial venipuncture is complete.

It is critical that the SP drink the entire calibrated dose in 10 minutes as soon as possible after the first venipuncture is complete because he or she must wait at least 100 minutes before being eligible for the second blood draw. SPs must maintain their fast until the second blood draw is complete. Therefore, the entire MEC staff must be aware that the SP must continue the fast and must be sensitive to the discomfort caused by the Trutol and the effect of being around other SPs who may be eating or drinking juice. The SP may drink water. If an SP breaks his or her fast, then he or she is not eligible for the second blood draw but must be reassigned to OGTT in the phlebotomy room to complete the examination.

As noted earlier, drinking 10 oz. of Trutol may have some unpleasant side effects. These side effects may include nausea, vomiting, abdominal bloating, and/or headache. To enhance the palatability, chill enough of each flavor to accommodate all SPs scheduled into the session. Chill the solution in the refrigerators in the CV fitness and phlebotomy rooms. Protect from light, do not freeze, and discard any remaining solution. After the second blood draw, the phlebotomist will ask the SP if he or she is allergic to peanuts. If not, offer the SP peanut butter crackers and juice.

A paper label prints on the Dymo printer in the CV fitness and phlebotomy rooms. The label displays the time at which the SP is eligible for the second blood draw. Place this label on the upper right hand side of the SP's paper top. All MEC staff members are responsible for monitoring the time on this label and ensuring that the SP is taken to the coordinator in time to be reassigned to phlebotomy for the second blood draw.

The MEC lab staff will process this OGTT vessel (#98) per the glucose protocol. They will use the "gtt" module that is similar to the urine collection module to record the vessel as filled "Yes" or "No." All SPs are listed in the same window in this module. The lab staff ships the samples weekly to the contract laboratory.

12.3.1 Coordinator Responsibilities

The coordinator uses the hard-copy verification form and the check-in screen to determine and record an SP's initial fasting compliance.

A GT component tracks assignment to the GT component and the time between the consumption of the solution and reassignment of the SP to phlebotomy for the second venipuncture (2 hours, -20 and +15 minutes, after the SP finishes drinking the solution.) The earliest reassignment time is 1 hour 40 minutes or 100 minutes. The coordinator can drag the mouse arrow over the yellow GT progress bar to view the time remaining until the reassignment to phlebotomy.

A new priority has been created for GTT SPs aged 16+ so that they are assigned to phlebotomy first, GTT second so they can drink the Trutol, and reassigned to GTT in phlebotomy for the second blood draw. Female SPs aged 12-15 must complete the physician examination before they are eligible for phlebotomy. A series of pop-up messages assist the coordinator and the phlebotomist in assigning and tracking SPs through the three activities.

It is the coordinator's responsibility to monitor the MEC flow, including tracking the assignment of staff and SPs, to ensure that every eligible SP completes the GT component. SPs who have successfully consumed the Trutol, but who are not assigned to phlebotomy in time for the second blood draw, will automatically be coded as "SP return time expired."

12.3.2 MEC Staff Responsibilities

The MEC phlebotomist completes the initial blood collection procedure, which consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw. The phlebotomist also collects one additional blood tube on SPs selected for the VOC special study.

The OGTT application has been created to (1) calculate and display the amount of Trutol that an SP should drink (calibrated dose); (2) monitor the time it takes for an SP to consume the Trutol solution; and (3) record the second venipuncture results. This application has been installed in the phlebotomy and CV fitness rooms. The phlebotomist, MEC interviewers, health technologists, the medical technologist assigned to workstation 3, and the MEC manager, are responsible for using the first section of this application to dispense the correct amount of Trutol for the weight of the SP and monitor the time it takes for the SP to drink the Trutol. After 100-135 minutes have elapsed since the SP consumed the Trutol, the phlebotomist is responsible for drawing a second 2-mL gray top tube and for using the second section of the OGTT application to record the results of the second blood draw.

After the first venipuncture is complete, the phlebotomist will either administer the Trutol solution or escort the SP to the coordinator to have the MEC interviewers, health technologists, the medical technologist assigned to workstation 3, and the MEC manager, monitor the SP. When the SP is reassigned to phlebotomy for the second blood draw, the phlebotomist will draw one 2-mL gray top tube and any tubes that were missed during the first venipuncture.

12.4 Equipment and Supplies

The equipment and supplies used in the OGTT are listed in Exhibit 12-2. The average number of examined SPs aged 12 and older is 232 per stand.

At the start and end of each stand, the phlebotomist will take a complete inventory using procedures described in Chapter 11, Section 11.3. The OGTT supplies are included in the phlebotomy start and end of stand inventory sheets.

Exhibit 12-2. Equipment and supplies – OGTT

| OGTT | Par level |
|---------------------------------|--|
| Trutol | |
| Orange (part number 401223) | 12 cases of 12 |
| Lemon-Lime (part number 401421) | 8 cases of 12 |
| Cola (part number 401025) | 5 cases of 12 |
| Peanut butter crackers | 4 packages of 80 |
| 2-mL gray top Vacutainer tube | 3 trays of 100 |
| Plastic drinking straws | 3 boxes of 100 |
| Dymo labels | 7 rolls of 500 (for use in phlebotomy and CV fitness room) |
| Small graduated medicine cups | 1 sleeve |

12.5 Gaining Cooperation

The coordinator will introduce the SP to the OGTT examination and briefly explain the examination process. The coordinator can answer any general questions the SP has about venipuncture or the OGTT. However, the entire MEC staff must be prepared to answer all the questions the SP poses about the OGTT procedure and must convince the SP of the importance of participating in the OGTT component of the examination.

Prepare to answer questions about the rationale for the OGTT component, the discomfort involved and the side effects, and the composition of the Trutol. It is essential to create a pleasant atmosphere and maintain a pleasant attitude. To address SPs' concerns effectively, know the following information about the procedures used for the study:

Rationale

- Although the SP has provided much useful information in the household and individual interviews, the successful completion of the OGTT component of NHANES is critical to the success of the pilot. This information is contained in the introduction to this chapter. Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and over 1 million new cases of diabetes are diagnosed each year. It is the leading cause of kidney failure, non-traumatic lower extremity amputation, and blindness in working-age adults, and an estimated \$135 billion was spent on direct and indirect medical costs for diabetes in

2002. Alarming, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.

- Persons with impaired glucose tolerance (IGT) – 15.6 percent of the U.S. population – are at high risk for developing diabetes. In addition, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined based on an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hour value of 140-199 mg/dl are considered to have IGT. Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT. Furthermore, NHANES III data indicate a tremendous opportunity for the prevention of diabetes - over 12 million persons aged 45-74 have prediabetes (defined as overweight persons with either IGT or impaired fasting glucose metabolism). These data also indicated that over 50 percent of persons with prediabetes are only detected by IGT findings. As risk factors for diabetes, IGT, and prediabetes increase (e.g., physical inactivity, obesity, and aging), the prevalence of these conditions is likely to increase.
- The inclusion of OGTTs on NHANES will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts, such as DHHS's STEPS program and efforts by the National Diabetes Education Program.

Discomfort and Side Effects

- Venipuncture causes only minimal discomfort. A certified, experienced phlebotomist performs venipunctures. A variety of blood collection needles are available so that the most appropriate size can be selected for each SP.
- Side effects of drinking the Trutol can include nausea, vomiting, abdominal bloating, and/or headache. To enhance the palatability, chill before serving. Protect from light, do not freeze, and discard any remaining solution.

Composition of the Trutol

Ten ounces of Trutol contains 75 grams of dextrose and 300 calories. The following items contain approximately the same amount of sugar:

- 2 cans of Pepsi or Coke (66 grams)
10 ounces of Coke or Pepsi has 33 grams of sugar and 121 calories
- 3/4 cup of raisins (86 grams)
1 cup contains 115 grams of sugar and 435 calories
- 1 cup of dried apricots (80 grams)
1 cup contains 80 grams of sugar and 310 calories
- A small McDonalds sundae (61 grams)
A 6.4-ounce McDonald's hot caramel sundae contains 61 grams of sugar and 360 calories
- A small McDonalds M&M McFlurry (90 grams)
A 12-ounce (small) McDonalds M&M McFlurry contains 90 grams of sugar and 630 calories
- A small McDonalds vanilla shake (67 grams)
A 12-ounce (small) McDonald's vanilla shake contains 67 grams of sugar and 430 calories
- A small Dairy Queen Misty slush (56 grams)
A small Dairy Queen Misty slush contains 56 grams of sugar and 454 calories

Creating a Pleasant Atmosphere and Positive Attitude

Gaining the cooperation of an SP is easier if the atmosphere in the examination room is pleasant and makes the SP feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere in the examination room.

- Maintain a clean and uncluttered work area.
- Be aware of body image; a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a smile.
- Speak face to face with the subject and maintain eye contact. Staring at other areas in the room may cause the SP some uneasiness since it implies that he or she is not important. It also implies disinterest.
- Avoid nervous behaviors such as squirming and tapping that can be distracting. The SP may begin to feel nervous, hurried, and anxious because of such behaviors.

12.6 Exclusion Criteria

There are seven exclusion criteria. Female SPs aged 12-15 are asked a shared exclusion pregnancy question during the physician examination. The phlebotomist will ask SPs aged 16-59 the shared exclusion pregnancy question if the question has not already been asked elsewhere in the MEC. Hemophilia and chemotherapy safety exclusion questions are asked and fasting status is assessed in phlebotomy as a prelude to the initial venipuncture examination. If the SP refuses one or more of the blood tubes, then he or she is excluded. The other two exclusion criteria are listed in the first screen of the first section of the OGTT examination.

Persons will be **excluded** from this component if they:

- Report that they are taking oral medications for diabetes (asked during the household interview or in OGTT);
- Report that they are taking insulin (asked during the household interview or in OGTT);
- Report that they are pregnant (shared exclusion question);
- Report that they have hemophilia (asked in phlebotomy);

- Report that they have received cancer chemotherapy in the last 3 weeks (asked in phlebotomy);
- Report that they have not fasted at least 9 hours (as determined by the fasting questionnaire in phlebotomy); and
- Refuse one or more blood tubes in phlebotomy during the initial venipuncture.

12.7 The Coordinator Application

The coordinator application assigns SPs according to priorities, monitoring the time that an SP is eligible to return to phlebotomy for the second blood draw and for sending the appropriate messages to itself and any relevant applications. The coordinator application has a timer that runs every minute to check that an SP is eligible for either the first or the second section of the OGTT examination and if the time to return has expired. The component priority has been modified so that the names of diabetics taking insulin are displayed in red on the coordinator screen; assign these SPs to phlebotomy first. The names of SPs aged 12 and older who have **not** met the 9-hour fast as indicated during the verification form/check-in process are indicated in hot pink on the coordinator's display. Female SPs aged 12-15 must complete the physician examination before they are eligible for phlebotomy and subsequent GT examination.

SPs who have successfully consumed the Trutol are reassigned to phlebotomy for the second blood draw. A pop-up message alerts the coordinator that an SP is due to return to phlebotomy. If an SP wants to exit the MEC before the required 1 hour and 40 minutes has elapsed, then reassign him or her to phlebotomy immediately so that the second blood draw can be conducted (provided no primary exams would be missed.) SPs who have successfully consumed the Trutol but who are not assigned to phlebotomy in time for the second blood draw will automatically be coded as "SP return time expired." If there is less than 1 hour and 40 minutes left in the session and the SP has not been assigned to phlebotomy yet, he or she is no longer eligible for GT. The coordinator application will automatically code the SP as not done and attach the comment code, "Less than 1 hour 40 minutes remaining."

12.7.1 Coordinator Progress Bar Colors

The GT component is included in the list of examinations and the OGTT component has been added to the phlebotomy and CV fitness rooms.

Coordinator Console
 File Reports Utilities Window Help

Coordinator Console Stand:410 Session:410180 05-Sep-2004 08:30 am - 12:30 pm

| SP Name | Status | Rof | G | Aqe | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | |
| Webster, Kyle | 2 | M | 13 | | | | | | | | | | | | | | |
| Webster, Gregory | 2 | M | 14 | | | | | | | | | | | | | | |
| Cullen, Carolyn | 2 | F | 15 | | | | | | | | | | | | | | |
| Cullen, Stanley | 2 | M | 17 | | | | | | | | | | | | | | |
| Cullen, Kitty | 2 | F | 17 | | | | | | | | | | | | | | |
| Patton, Todd | 2 | M | 18 | | | | | | | | | | | | | | |
| Patton, Susanna | 2 | F | 19 | | | | | | | | | | | | | | |

| | | | |
|---|--|---|---|
| Open Audiometry | Open Oral Health | Open Body Measures | Open Body Composition |
| Open Cournoyer J. M. Johnston J. M. Lindstrom B. E. Newell B. E. Laboratory | Available Edwards P. Z. Phleb | Busy OGTT | Open Lbl/Shp |
| Open Ophthalmology | Available Gutierrez L. M. Dietary 2 | Available Kube G. E. Dietary 1 | Open Doss S. J. Guerrero-Ponce C. McWilliams J. T. Pinkerton R. L. Staff Area |
| Open CV Fitness | Open OGTT | Open Vision | Open Webster, Charlie Coordinator |
| | | | Available Urbina P. Physician |

| Technician | Skill |
|-----------------|-------------------|
| Aranz-Lomas | Asst. Coordinato |
| Velazquez N | Asst. Coordinato |
| Lopez J. S. | Clerk |
| Gutierrez L. I. | Dietary Interview |
| Kube G. E. | Dietary Interview |
| Doss S. J. | Health Tech |
| Guerrero-Pon | Health Tech |
| McWilliams. | Health Tech |
| Pinkerton R. | Health Tech |
| Trumbore R. | Health Tech |
| Cournoyer J. | Lab Tech |
| Johnston J. I. | Lab Tech |
| Lindstrom B. | Lab Tech |
| Newell B. E. | Lab Tech |
| Araujo E. | MEC Interviewe |
| Ortega M. | MEC Interviewe |
| O'Dea D. D. | MEC Manager |
| Edwards P. Z. | Phlebotomist |
| Urbina P. | Physician |

Ready | 08:36 AM

The progress bar colors represent the following conditions:

| Color | Corresponds to: |
|--------|---|
| White | <p>Unblocked</p> <ol style="list-style-type: none"> 1. The SP is eligible for the component. |
| Teal | <p>Blocked if they are:</p> <ol style="list-style-type: none"> 1. On insulin –”safety exclusion.” 2. Taking oral medications for diabetes – “safety exclusion.” 3. Have hemophilia, as determined in phlebotomy – “safety exclusion.” 4. Received cancer chemotherapy in the past 4 weeks, as determined in phlebotomy – “safety exclusion.” 5. Pregnant, as reported in the shared exclusion question – “SP pregnant.” 6. Have not fasted at least 9 hours and will not meet their fast in time to complete the exam – “Fast less than 9 hours.” <p>If an SP refuses one or more of the blood tubes during the initial venipuncture, he or she is “Blocked: Not done (SP Refused Blood Draw).”</p> |
| Yellow | <p>Waiting</p> <ol style="list-style-type: none"> 1. SP is waiting for 9-hour fast to be met in order to be assigned to the phlebotomy or CV fitness rooms for the Trutol administration section of the OGTT examination. “Eligible for the OGTT Trutol administration for the next Xh and XXm.” 2. SP is waiting for the required 1 hour and 40 minute time restriction to expire so that he or she can return to the phlebotomy room for the second blood draw section of the OGTT examination. “Xh and XXm until eligible for OGTT blood draw.” |
| Green | <p>Eligible</p> <ol style="list-style-type: none"> 1. SP has completed phlebotomy and is eligible for the first section of the OGTT examination (Trutol administration). 2. SP can be reassigned to the phlebotomy room for the second section of the OGTT examination (blood draw). |
| Blue | <p>Complete</p> <ol style="list-style-type: none"> 1. Completed OGTT examination. |

12.7.2 Coordinator Priorities and Verification Form

New priorities have been established so that insulin-dependent diabetics must be assigned to phlebotomy ahead of all other eligible SPs. The names of these SPs are indicated in red on the coordinator's display. Female SPs aged 12-15 are not eligible for phlebotomy until they complete the physician examination since the shared exclusion pregnancy question is asked during the physician examination for these SPs.

When an SP arrives at the MEC, he or she is given a hard-copy verification form (Exhibit 12-3) If the SP is 12 years or older and is scheduled into a morning session, then the verification form includes a question to assess fasting status. If the SP is less than 12 years or is scheduled into an afternoon or evening session, the form does not include this question (Exhibit 12-4).



WELCOME / BIENVENIDO

National Health and Nutrition Examination Survey *Encuesta Nacional de Examen de Salud y Nutrición*

Your participation is important to us. Please check all of the information shown below to ensure it is accurate. If you find mistakes, please tell the Coordinator or write the correct information on this form and return it to the Coordinator.

Su participación es importante para nosotros. Por favor revise toda la información que se muestra abajo para asegurarse de que es precisa. Si encuentra errores, por favor dígaselo al Coordinador o escriba la información correcta en este formulario y devuélvase.

| | | |
|----------------------|-----------------------|---------------------------|
| Name: | JENNIFER ANISTON | |
| Nombre: | | _____ |
| Date of Birth: | 9/14/1968 | |
| Fecha de Nacimiento: | | _____ |
| Gender: | Female | |
| Sexo: | | _____ |
| Consents Required: | Exam SP Consent (12+) | Research SP Consent (18+) |

Check this box if the above information is correct
Marque esta casilla si la información de arriba es correcta

Did you eat, or drink anything other than plain water, after 11:30 last night?

¿Comió o bebió algo que no haya sido agua sola, después de las 11:30 de anoche?

Yes

Check one box

No

Marque una casilla

Thank you!

¡Gracias!

Jennifer Aniston, 762833, October 01, 2004.

NCHS National Center For Health Statistics, 3311 Toledo Road, Rm 4323, Hyattsville, Maryland 20782.



WELCOME / BIENVENIDO

National Health and Nutrition Examination Survey *Encuesta Nacional de Examen de Salud y Nutrición*

Your participation is important to us. Please check all of the information shown below to ensure it is accurate. If you find mistakes, please tell the Coordinator or write the correct information on this form and return it to the Coordinator.

Su participación es importante para nosotros. Por favor revise toda la información que se muestra abajo para asegurarse de que es precisa. Si encuentra errores, por favor dígaselo al Coordinador o escriba la información correcta en este formulario y devuélvase.

| | | |
|----------------------|-----------------------|---------------------------|
| Name: | JEN CALHOUN | _____ |
| Nombre: | | _____ |
| Date of Birth: | 1/2/1954 | _____ |
| Fecha de Nacimiento: | | _____ |
| Gender: | Female | _____ |
| Sexo: | | _____ |
| Consents Required: | Exam SP Consent (12+) | Research SP Consent (18+) |

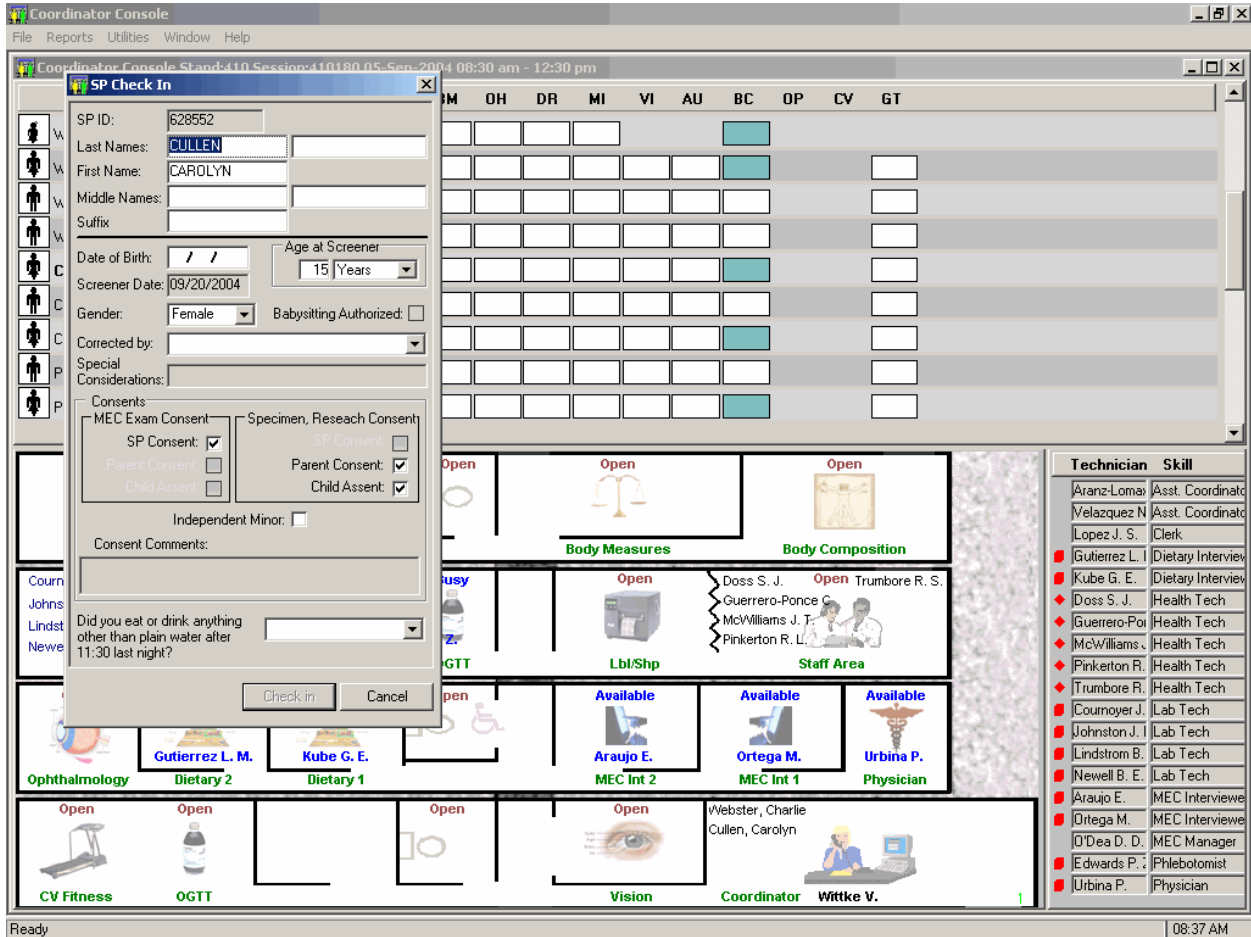
Check this box if the above information is correct
Marque esta casilla si la información de arriba es correcta

Thank you!
¡Gracias!

Jen Calhoun, 318374, September 29, 2004.

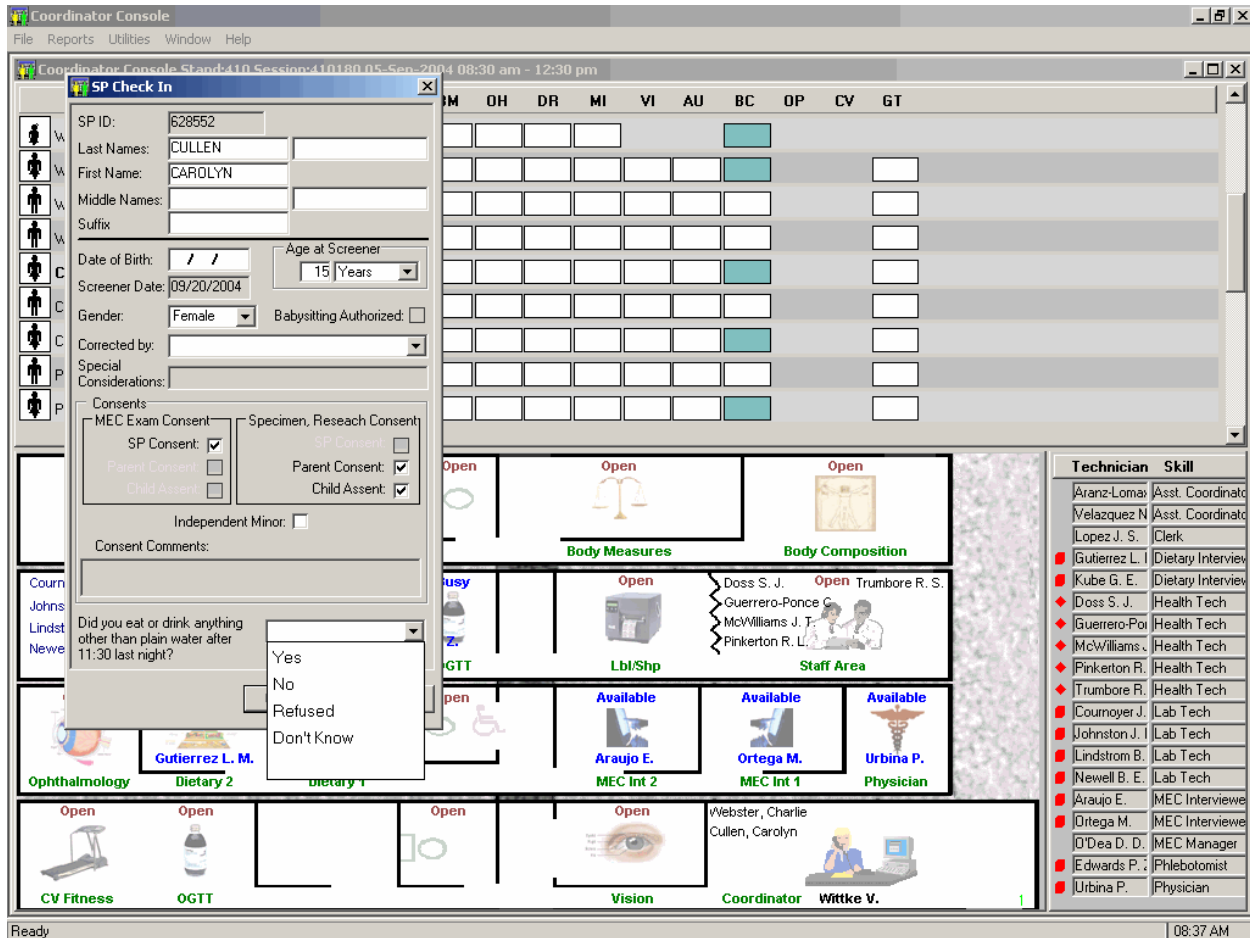
 National Center For Health Statistics, 3311 Toledo Road, Rm 4323, Hyattsville, Maryland 20782.

Access the SP Check In screen as part of the routine check-in process. For SPs aged 12 and older who are assigned to a morning session, the verification form includes the fasting question, "Did you eat or drink anything other than plain water after 11:30 last night?" The SP marks one of two checkboxes: "Yes" or "No." The coordinator enters this information into the check-in screen. SPs who respond "Yes" have not met their fast and their names are displayed in hot pink. Assign SPs whose names are not hot pink to phlebotomy as their first priority.



If the SP has not met the fast, the name displays in hot pink on the coordinator screen.

Review the verification form and enter the SP's response to the fasting question. It is displayed at the bottom of the SP Check In screen.

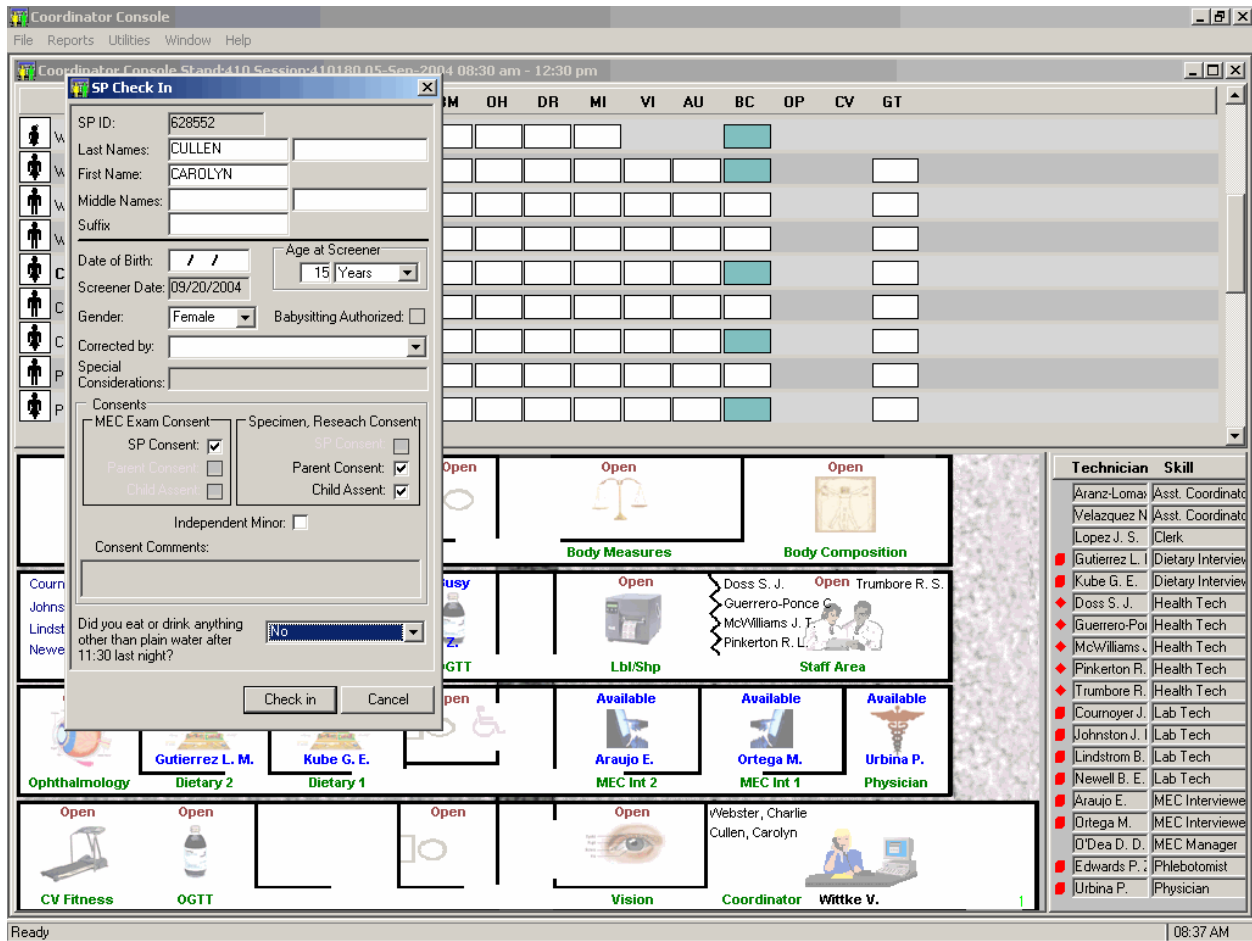


The response options are “Yes,” “No,” “Refused,” and “Don’t know.”

If the SP responds:

- “No,” then he or she **has met** the 9-hour fast. Assign phlebotomy and GTT as the first priority.
- “Refused” or “Don’t know,” then the actual fasting time is unknown. Prioritize these SPs for phlebotomy after SPs who responded “No.”
- “Yes,” then he or she has not met the fast or the actual fasting time is unknown. The name is indicated in hot pink on the coordinator display. Assign these SPs to phlebotomy after all other SPs.

After a response has been recorded, continue to check the SP into the session.



To continue the check-in process, use the mouse to direct the mouse arrow to the Check In button and left click or select [Enter]. To cancel the check-in process, use the mouse to direct the mouse arrow to the Cancel button and left click. The check-in process cannot continue until a response has been recorded.

12.7.3 Phlebotomy Exclusion Criteria

There are seven exclusion criteria. Shared exclusion pregnancy questions are asked during the physician examination for female SPs aged 12-15. The questions are displayed and asked in phlebotomy and body composition for SPs aged 16-59. Hemophilia and chemotherapy safety exclusion questions are asked and fasting status is assessed in phlebotomy as a prelude to the initial venipuncture examination. If the SP has not met the 9-hour fast, and will not meet the fast with 1 hour and 40 minutes remaining in the session, then he or she is excluded. If the SP refuses one or more of the initial venipuncture blood tubes, he or she is excluded from the GTT. (The other two exclusion criteria, taking insulin or oral medications for diabetes, are listed in the first screen of the first section of the OGTT examination.)

Shared Exclusion Pregnancy Question

Female SPs aged 12-59 are blocked from GT until the SP provides an answer to the shared exclusion question, “Are you currently pregnant?” and “How many weeks?” (if applicable.) Female SPs aged 12-15 are asked these questions in the physician examination. Female SPs aged 16-59 are asked these questions during the MEC examination in the first examination where shared exclusions are asked. Each question is asked only once, even when the question is relevant for more than one component. If the shared exclusion pregnancy questions were answered during the body composition examination, the answers appear in the text boxes and the questions are disabled for the phlebotomy examination, as well as any other component where the questions are relevant. (The shared exclusion question is, SEQ060 “Are you currently pregnant?” The responses are, 1=Yes, 2=No, 3=Don’t know.) The coordinator application uses the answer to this question to exclude from the GT examination SPs who report that they are currently pregnant. SPs are excluded from phlebotomy until the questions are asked in physician for SPs aged 12-15.

The responses given during any component cannot be changed after the answer is recorded and the screen advanced.

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar is a header bar with the text "Phlebotomy: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm". A status bar below the header displays "SP ID: 141854 Name: PATTON, SUSANNA Age: 19 years Gender: Female Date: 10/26/2004 Time: 08:53 AM". The main area is titled "Phlebotomy Interview" and contains the following questions and input fields:

- Are you currently pregnant?
- How many weeks?
- Do you have hemophilia?
- Have you received cancer chemotherapy in the past four weeks?

At the bottom of the main area, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom of the window shows "Ready", "MEC Layer: 10/18/2004", "Application: Ver 12.10.21B", "Connected to Coordinator", "SP assigned to room", and "08:53 AM".

If the response to the question “Are you currently pregnant?” is “Yes,” the SP is excluded from GT due to pregnancy status.

If the response to the pregnancy question is “Yes,” then the phlebotomist asks, “How many weeks?”

The screenshot shows a software window titled "Phlebotomy" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar displays "Phlebotomy: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm". A patient information bar shows "SP ID: 141854 Name: PATTON, SUSANNA Age: 19 years Gender: Female Date: 10/26/2004 Time: 08:53 AM". The main area is titled "Phlebotomy Interview" and contains the following questions and answers:

- Are you currently pregnant? Yes
- How many weeks? 40
- Do you have hemophilia? No
- Have you received cancer chemotherapy in the past four weeks? No

At the bottom, there are navigation buttons (back, forward, 1 of 4), "End of Section", "Close Exam", and "Finish" buttons. The system tray at the very bottom shows "Ready", "MEC Layer: 10/18/2004", "Application: Ver 12.10.21B", "Connected to Coordinator", "SP assigned to room", and "08:53 AM".

The phlebotomist records the SP’s response to “How many weeks?”

If the answer to the shared exclusion pregnancy question is “Yes,” then the SP is excluded from the GT component. The GT component is blocked and the status defaults to “Not Done” with the comment “SP pregnant.” To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The current status and reason will display.

| SP Name | Status | Ref | G | Age | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | |
| Webster, Kyle | 2 | M | 13 | | | | | | | | | | | | | | |
| Webster, Gregory | 2 | M | 14 | | | | | | | | | | | | | | |
| Cullen, Carolyn | 2 | F | 15 | | | | | | | | | | | | | | |
| Cullen, Stanley | 2 | M | 17 | | | | | | | | | | | | | | |
| Cullen, Kitty | 2 | F | 17 | | | | | | | | | | | | | | |
| Patton, Todd | 2 | M | 18 | | | | | | | | | | | | | | |
| Patton, Susanna | 2 | F | 19 | | | | | | | | | | | | | | |

Blocked: Not done (SP pregnant)

If the response to the question “Are you currently pregnant?” is “No” or “Don’t Know,” the SP is **not excluded** from the GTT.

Only SPs who responded “No” to the hemophilia and chemotherapy questions in phlebotomy are eligible for the GT examination.

The screenshot displays the 'Coordinator Console' interface. At the top, a menu bar includes 'File', 'Reports', 'Utilities', 'Window', and 'Help'. The main window title is 'Coordinator Console Stand:410 Session:410180 05-Sep-2004 08:30 am - 12:30 pm'. Below this is a table of Standard Patients (SPs) with columns for Name, Status, Role, Gender, Age, and various medical history checkboxes (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, CV, GT). A 'Message Center' window is open, showing a message from 'Phlebotomy' stating 'SP WEBSTER, KYLE (816331) was excluded from DGT(48)' at 09:04:35. Below the list is a grid of icons representing different medical specialties and their status (e.g., 'Open', 'Busy', 'Available'). A 'Technician Skill' list on the right side shows various roles and skills assigned to technicians.

| SP Name | Status | Ref | G | Age | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT | |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|--|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | | |
| Webster, Kyle | 2 | M | 1 | | | | | | | | | | | | | | | |
| Webster, Gregory | 2 | M | 1 | | | | | | | | | | | | | | | |
| Cullen, Carolyn | 2 | F | 11 | | | | | | | | | | | | | | | |
| Cullen, Stanley | 2 | M | 1 | | | | | | | | | | | | | | | |
| Cullen, Kitty | 2 | F | 1 | | | | | | | | | | | | | | | |
| Patton, Todd | 2 | M | 11 | | | | | | | | | | | | | | | |
| Patton, Susanna | 2 | F | 11 | | | | | | | | | | | | | | | |

SPs who respond to these questions with a response other than “No” are blocked from GT and are coded as safety exclusion. To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The current status and reason will display.

Only SPs who have fasted for 9 hours are eligible for the GT examination. During the phlebotomy examination, the fasting time is calculated. It is based on the date and time that the SP reports that he or she ate or drank anything other than plain water. If the 9-hour fast is not met, but it will be met, and 1 hour and 40 minutes remains in the session, then the phlebotomist will draw all the tubes, including the 2-mL gray top for glucose. The SP will continue with other exams until the fast is met.

The screenshot displays the 'Coordinator Console' interface. At the top, a table lists SPs with columns: SP Name, Status, Rof, G, Age, LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, CV, GT. A 'Message Center' window is open, showing messages from 'Reception Coordinator' regarding a return to NADINE WEBSTER. Below the table is a grid of icons representing different exam stations (Audiometry, Oral Health, Body Measures, Body Composition, Laboratory, Phleb, OGTT, Lbl/Shp, Staff Area, Ophthalmology, Dietary 2, Dietary 1, MEC Int 2, MEC Int 1, Physician, CV Fitness, OGTT, Vision, Coordinator). On the right, a 'Technician Skill' list shows various roles and their associated skills. The bottom status bar indicates 'Ready' and the time '09:06 AM'.

Once the fast is met, the progress bar will turn green, indicating that the SP should be assigned to the GT component in order to drink the Trutol and have the second blood drawn 1 hour and 40 minutes later. The phlebotomist must take care not to give the SP juice and crackers at the conclusion of the first blood draw.

If the fast cannot be met during the session and 1 hour and 40 minutes does not remain in the session, then the coordinator application automatically blocks the GT component and attaches the comment code “fast less than 9 hours.”

The screenshot displays the Coordinator Console interface. At the top, a table lists staff members with columns for SP Name, Status, Ref, G, Age, and various service categories (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, CV, GT). A 'Message Center' window is open, showing messages from Phlebotomy. Below the table is a grid of service icons with status indicators. On the right, a 'Technician Skill' list is visible. At the bottom, a status bar indicates a block: 'Blocked: Not done (Fast less than 9 hours)'.

To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The current status and reason will display.

If an SP refuses one or more blood collection tubes during the phlebotomy examination, then he or she is blocked from the GT component. A pop-up box will display on both the coordinator and phlebotomy monitors.

The screenshot displays the 'Coordinator Console' interface. At the top, a menu bar includes 'File', 'Reports', 'Utilities', 'Window', and 'Help'. Below the menu, a status bar shows 'Coordinator Console Stand:410 Session:410180 05-Sep-2004 08:30 am - 12:30 pm'. The main area features a table with columns for 'SP Name', 'Status', 'Ref', 'G', 'Age', and various test components (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, CV, GT). A 'Message Center' pop-up window is open, showing a message from 'Phlebotomy' to 'SP PATTON, BEN (515414)' stating 'SP PATTON, BEN (515414) was excluded from DGT(4B)'. Below the table, a grid of icons represents different services like Audiometry, Oral Health, Body Measures, etc. On the right, a 'Technician Skill' list shows various roles and their associated skills. A status bar at the bottom indicates 'Ready' and the time '09:11 AM'.

To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The current status and reason will display.

12.7.4 Less than 1 Hour and 40 Minute Blocking

If an eligible SP has not been assigned to GT and 1 hour and 40 minutes remains in the session, then the SP's GT exam will automatically be blocked.

| SP Name | Status | Ref | G | Age | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| Cullen, Moriah | 2 | F | 32 | | | | | | | | | | | | | | |
| Patton, Ben | 2 | M | 34 | | | | | | | | | | | | | | |
| Patton, Trish | 2 | F | 36 | | | | | | | | | | | | | | |
| Mitchell, Grant | 2 | M | 36 | | | | | | | | | | | | | | Blocked: Not done (Less than 1 hour 40 min left in session) |
| Mitchell, Chad | 2 | M | 45 | | | | | | | | | | | | | | |
| Mitchell, Laurie | 2 | F | 46 | | | | | | | | | | | | | | |
| Patton, Jeannie | 2 | F | 55 | | | | | | | | | | | | | | |
| Mitchell, Brian | 2 | M | 58 | | | | | | | | | | | | | | |
| Caudle, Gwen | 2 | F | 60 | | | | | | | | | | | | | | |

If less than 1 hour and 40 minutes remains in the session and an SP has not been assigned to the GT component, then the GT will be blocked for that SP. The coordinator application will automatically code the component as “Blocked: Not Done (Less than 1 hour 40 minutes left in session).” The comment code will automatically be added to all SPs who have not been assigned to GT by 10:50 AM.

Continue to review the coordinator screen and assign SPs to the GT component as soon as possible after their current examination is complete.

12.7.5 Return Time Expired Blocking

If an eligible SP has completed the first section (Trutol administration) section of the GT component and more than 2 hours and 15 minutes has elapsed, then the SP's GT exam will automatically be Blocked: Partial (Return Time Expired).

| SP Name | Status | Rof | G | Aqe | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | █ | | | | | | | | | | █ |
| Webster, Kyle | 2 | M | 13 | | | | █ | | | | | | | | | | █ |
| Webster, Gregory | 2 | M | 14 | | | | | | | | | | | | | | █ |
| Cullen, Carolyn | 2 | F | 15 | | | | █ | | | | | | | | | | █ |
| Cullen, Stanley | 2 | M | 17 | | | | | | | | | | | | | | █ |
| Cullen, Kitty | 2 | F | 17 | | | | █ | | | | | | | | | | █ |
| Patton, Todd | 2 | M | 18 | | | | █ | | | | | | | | | | █ |
| Patton, Susanna | 2 | F | 19 | | | | █ | | | | | | | | | | █ |

Blocked: Partial (Return Time Expired)

| Technician | Skill |
|-----------------|-------------------|
| Aranz-Lomas | Asst. Coordinator |
| Velazquez N | Asst. Coordinator |
| Lopez J. S. | Clerk |
| Gutierrez L. I. | Dietary Interview |
| Kube G. E. | Dietary Interview |
| Doss S. J. | Health Tech |
| Guerrero-Poi | Health Tech |
| McWilliams | Health Tech |
| Pinkerton R. | Health Tech |
| Trumbore R. | Health Tech |
| Cournoyer J. | Lab Tech |
| Johnston J. I. | Lab Tech |
| Lindstrom B. | Lab Tech |
| Newell B. E. | Lab Tech |
| Araujo E. | MEC Interview |
| Ortega M. | MEC Interview |
| O'Dea D. D. | MEC Manager |
| Edwards P. J. | Phlebotomist |
| Urbina P. | Physician |

Continue to review the coordinator screen and assign SPs to the blood draw section of the GT component as soon as possible after 1 hour and 40 minutes has expired.

12.7.6 Coordinator Messaging

The progress bar turns green when the SP has completed phlebotomy and is ready for the first section of the OGTT examination (Trutol administration) or the SP is eligible to return to phlebotomy for the second section of the OGTT examination (blood draw).

| SP Name | Status | Ref | G | Age | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | Eligible for OGTT Trutol administration for the next 0h 55m |
| Webster, Kyle | 2 | M | 13 | | | | | | | | | | | | | | |
| Webster, Gregory | 2 | M | 14 | | | | | | | | | | | | | | |
| Cullen, Carolyn | 2 | F | 15 | | | | | | | | | | | | | | |
| Cullen, Stanley | 2 | M | 17 | | | | | | | | | | | | | | |
| Cullen, Kitty | 2 | F | 17 | | | | | | | | | | | | | | |
| Patton, Todd | 2 | M | 18 | | | | | | | | | | | | | | |
| Patton, Susanna | 2 | F | 19 | | | | | | | | | | | | | | |

To view the timer, use the mouse to direct the mouse arrow to the progress bar and hold the arrow over the progress bar until the text containing the timer appears.

The progress bar turns yellow to indicate that the SP is waiting to go to CV fitness or phlebotomy for the first section of the OGTT examination or to phlebotomy for the second section of the OGTT examination.

| SP Name | Status | Ref | G | Age | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | |
| Webster, Kyle | 2 | M | 13 | | | | | | | | | | | | | | |
| Webster, Gregory | 2 | M | 14 | | | | | | | | | | | | | | |
| Cullen, Carolyn | 2 | F | 15 | | | | | | | | | | | | | | |
| Cullen, Stanley | 2 | M | 17 | | | | | | | | | | | | | | 0h 27m until eligible for OGTT blood draw |
| Cullen, Kitty | 2 | F | 17 | | | | | | | | | | | | | | |
| Patton, Todd | 2 | M | 18 | | | | | | | | | | | | | | |
| Patton, Susanna | 2 | F | 19 | | | | | | | | | | | | | | |

To view the timer, use the mouse to direct the mouse arrow to the progress bar and hold the arrow over the progress bar until the text containing the timer appears.

A pop-up message indicating that an SP is eligible to continue with either the first section (Trutol administration) or second section (second blood draw) of the OGTT component displays. The message also indicates when 1 hour and 40 minutes has elapsed since the SP finished drinking the Trutol solution.

Coordinator Console
 File Reports Utilities Window Help

Coordinator Console Stand:410 Session:410180 05-Sep-2004 08:30 am - 12:30 pm

| SP Name | Status | Ref | G | Aqe | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|-----------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Cullen, Carolyn | 2 | F | 15 | | | | | | | | | | | | | | |
| Cullen, Stanley | 2 | M | 17 | | | | | | | | | | | | | | |
| Cullen, Kitty | 2 | F | 1 | | | | | | | | | | | | | | |
| Patton, Todd | 2 | M | 11 | | | | | | | | | | | | | | |
| Patton, Susanna | 2 | F | 11 | | | | | | | | | | | | | | |
| Cullen, Moriah | 2 | F | 3 | | | | | | | | | | | | | | |
| Patton, Ben | 2 | M | 3 | | | | | | | | | | | | | | |
| Patton, Trish | 2 | F | 3 | | | | | | | | | | | | | | |
| Mitchell, Grant | 2 | M | 3 | | | | | | | | | | | | | | |

Message Center

From: Reception Coordinator
Message: TRISH PATTON (SPID 671247) is eligible to continue to OGTT.
Time: 09:19:15

To: Reception Coordinator
Time: 09:19:15

Total: 1 Unread: 1 0:34 [Send] [Close]

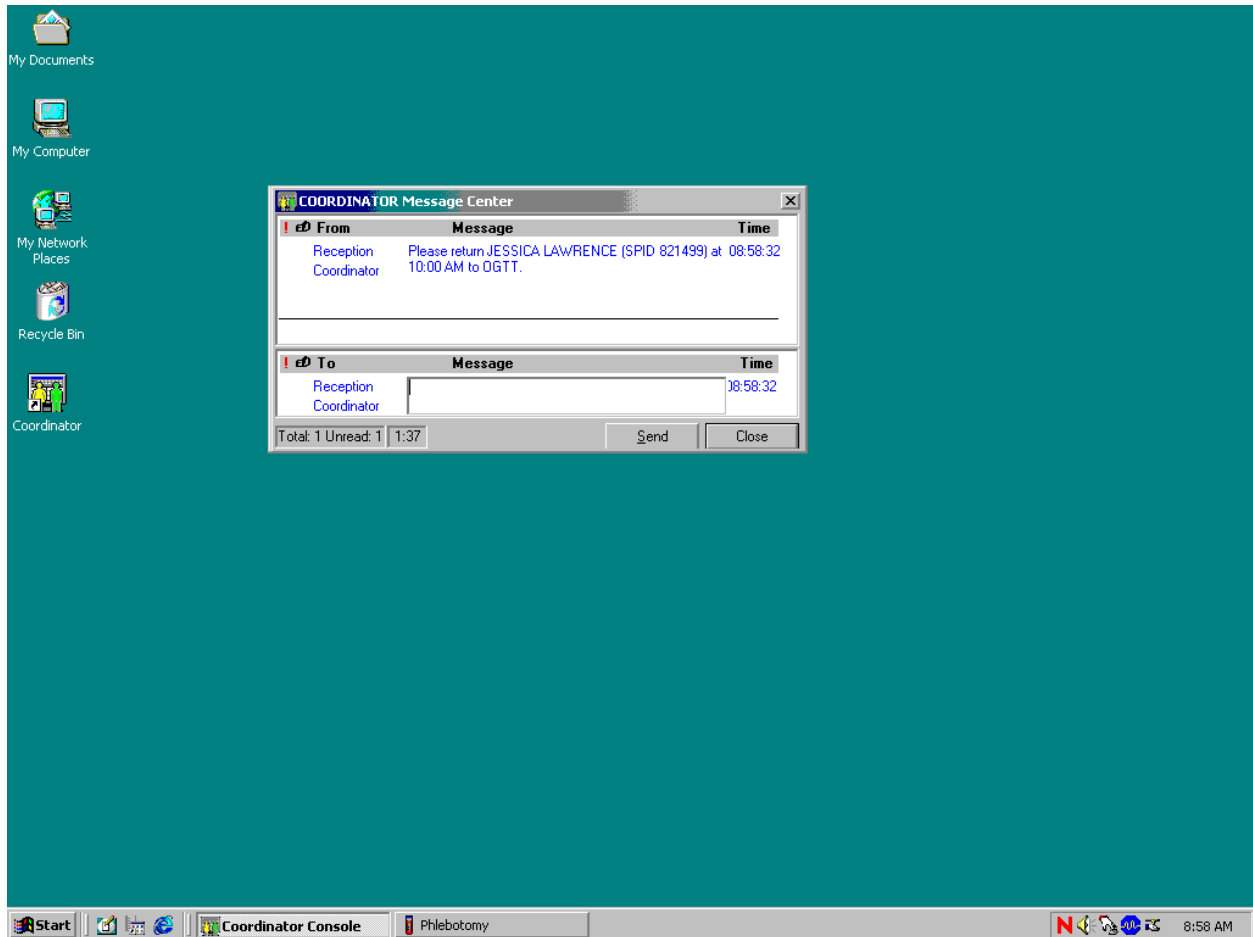
Eligible for OGTT Trutol administration for the next 1h 29m

Technician Skill

| Technician | Skill |
|-----------------|-------------------|
| Aranz-Lomas | Asst. Coordinator |
| Velazquez N | Asst. Coordinator |
| Lopez J. S. | Clerk |
| Gutierrez L. I. | Dietary Interview |
| Kube G. E. | Dietary Interview |
| Doss S. J. | Health Tech |
| Guerrero-Po | Health Tech |
| McWilliams | Health Tech |
| Pinkerton R. | Health Tech |
| Trumbore R. | Health Tech |
| Cournoyer J. | Lab Tech |
| Johnston J. I. | Lab Tech |
| Lindstrom B. | Lab Tech |
| Newell B. E. | Lab Tech |
| Araujo E. | MEC Interview |
| Ortega M. | MEC Interview |
| O'Dea D. D. | MEC Manager |
| Edwards P. J. | Phlebotomist |
| Urbina P. | Physician |

To close or remove the coordinator Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

If the SP will meet the fast during the session and 1 hour and 40 minutes remains in the session then the SP is eligible to continue with the exams until the fast is met. A pop-up box displays indicating the time at which the SP is eligible to begin the OGTT examination.



To close or remove the coordinator Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

Once the fast has been met, the progress bar turns green indicating that the SP is eligible to be assigned to the GT component.

The screenshot displays the 'Coordinator Console' application window. At the top, there is a menu bar with 'File', 'Reports', 'Utilities', 'Window', and 'Help'. Below the menu bar, the window title is 'Coordinator Console Stand:200 Session:200690 18-Jun-2001 08:30 am - 12:30 pm'. The main area is divided into several sections:

- Staff Roster:** A table with columns for 'SP Name', 'Status', 'Ref', 'G', 'Age', and various service codes (LB, MD, PH, BM, OH, DR, MI, VI, LE, AU, BA, BC, CV, DE, GT, OP). The 'GT' column shows a green bar for Eramia, Bruce, indicating eligibility.
- COORDINATOR Message Center:** A pop-up window showing a message from 'Reception Coordinator' to 'BRUCE EYRAMYA (SPID 248274)' stating he is eligible to continue to OGTT. The message was received at 09:15:15.
- Technician Skill Grid:** A grid of icons representing different services and technicians. Each icon is labeled with a status (e.g., 'Open', 'Available', 'Busy') and a technician name. Services include Audiometry, Oral Health, Body Measures, Dermatology, Body Composition, Laboratory, Phleb, OGTT, Lbl/Shp, Staff Area, LED, Dietary 2, Dietary 1, MEC Int 2, MEC Int 1, CV Fitness, Balance, Vision, Coordinator, and Wittke V.
- Technician Skill List:** A list on the right side of the grid showing technician names and their skills. For example, Aranz-Lomas is an Asst. Coordinator, and Taylor O. is a Dentist.

At the bottom of the window, the status bar shows 'Ready' and the time '09:15 AM'.

To close or remove the coordinator Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

12.7.7 Assigning an Examiner and SP to the OGTT Component

Assign unblocked SPs aged 12 and older to the phlebotomy component and then immediately assign eligible SPs to OGTT after phlebotomy is complete. Generally, assign an SP to the CV Fitness OGTT workstation. Assign an SP to the OGTT phlebotomy workstation only if the session is lightly booked and the phlebotomist's workload will accommodate all exams, without fail.

The screenshot shows the 'Coordinator Console' interface. At the top, there is a menu bar with 'File', 'Reports', 'Utilities', 'Window', and 'Help'. Below the menu bar is a title bar with the text 'Coordinator Console Stand:410 Session:410180 05-Sep-2004 08:30 am - 12:30 pm'. The main area contains a table with columns for 'SP Name', 'Status', 'Ref', 'G', 'Age', 'LB', 'MD', 'PH', 'BM', 'OH', 'DR', 'MI', 'VI', 'AU', 'BC', 'OP', 'CV', and 'GT'. The table lists several staff members, including Jackie Webster, Nadine Webster, Kyle Webster, Gregory Webster, Carolyn Cullen, Stanley Cullen, Kitty Cullen, Todd Patton, and Susanna Patton. Below the table, there are several icons representing different components: Audiometry, Oral Health, Body Measures, Body Composition, Laboratory, Phleb, OGTT, Lbl/Shp, Staff Area, Ophthalmology, Dietary 2, Dietary 1, MEC Int 2, MEC Int 1, Physician, CV Fitness, Vision, and Coordinator. A 'Technician Skill' list is visible on the right side of the interface.

| SP Name | Status | Ref | G | Age | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | |
| Webster, Kyle | 2 | M | 13 | | | | | | | | | | | | | | |
| Webster, Gregory | 2 | M | 14 | | | | | | | | | | | | | | |
| Cullen, Carolyn | 2 | F | 15 | | | | | | | | | | | | | | |
| Cullen, Stanley | 2 | M | 17 | | | | | | | | | | | | | | |
| Cullen, Kitty | 2 | F | 17 | | | | | | | | | | | | | | |
| Patton, Todd | 2 | M | 18 | | | | | | | | | | | | | | |
| Patton, Susanna | 2 | F | 19 | | | | | | | | | | | | | | |

Use the PH and GT progress bar colors and the timing description to manage the SPs. To view the timing description, use the mouse to direct the mouse arrow to the progress bar. The timing text will display.

Assign an SP to OGTT.

| SP Name | Status | Rof | G | Aqe | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | |
| Webster, Kyle | 2 | M | 1 | | | | | | | | | | | | | | |
| Webster, Gregory | | | | | | | | | | | | | | | | | |
| Cullen, Carolyn | | | | | | | | | | | | | | | | | |
| Cullen, Stanley | | | | | | | | | | | | | | | | | |
| Cullen, Kitty | | | | | | | | | | | | | | | | | |
| Patton, Todd | | | | | | | | | | | | | | | | | |
| Patton, Susanna | | | | | | | | | | | | | | | | | |

| Technician | Skill |
|-----------------|-------------------|
| Aranz-Lomas | Asst. Coordinato |
| Melazquez N | Asst. Coordinato |
| Lopez J. S. | Clerk |
| Gutierrez L. I. | Dietary Interview |
| Kube G. E. | Dietary Interview |
| Doss S. J. | Health Tech |
| Guerrero-Poi | Health Tech |
| McWilliams | Health Tech |
| Pinkerton R. | Health Tech |
| Trumbore R. | Health Tech |
| Cournoyer J. | Lab Tech |
| Johnston J. I. | Lab Tech |
| Lindstrom B. | Lab Tech |
| Newell B. E. | Lab Tech |
| Araujo E. | MEC Interviewe |
| Ortega M. | MEC Interviewe |
| O'Dea D. D. | MEC Manager |
| Edwards P. J. | Phlebotomist |
| Urbina P. | Physician |

To assign an SP to the GT component in the CV Fitness room (after the phlebotomy examination is complete), use the mouse to direct the mouse arrow to the highlighted OGTT selection on the flying box and double click.

To assign the SP to the OGTT component in the phlebotomy room, drag the phlebotomist name to the bathroom, and then drag the name back to OGTT.

The screenshot shows the 'Coordinator Console' software interface. At the top, there is a menu bar with 'File', 'Reports', 'Utilities', 'Window', and 'Help'. Below the menu bar, the window title is 'Coordinator Console Stand:410 Session:410180 05-Sep-2004 08:30 am - 12:30 pm'. The main area is a staff roster table with columns for 'SP Name', 'Status', 'Ref', 'G', 'Age', 'LB', 'MD', 'PH', 'BM', 'OH', 'DR', 'MI', 'VI', 'AU', 'BC', 'OP', 'CV', and 'GT'. A context menu is open over the 'Patton, Todd' row, listing 'Phlebotomy', 'OGTT', 'Dietary', 'Body Composition', 'CHITA Mec Interv', 'Audiometry', 'Oral Health', 'Vision', and 'Reception area'. Below the roster is a room layout grid with icons and labels for various services: 'Audiometry', 'Oral Health', 'Body Measures', 'Body Composition', 'Laboratory', 'Phleb', 'OGTT', 'Lbl/Shp', 'Staff Area', 'Ophthalmology', 'Dietary 2', 'Dietary 1', 'MEC Int 2', 'MEC Int 1', 'Physician', 'CV Fitness', and 'OGTT'. A 'Technician Skill' list is visible on the right side of the interface.

| SP Name | Status | Ref | G | Age | LB | MD | PH | BM | OH | DR | MI | VI | AU | BC | OP | CV | GT |
|------------------|--------|-----|----|-----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Webster, Jackie | 2 | F | 11 | | | | | | | | | | | | | | |
| Webster, Nadine | 2 | F | 13 | | | | | | | | | | | | | | |
| Webster, Kyle | 2 | M | 13 | | | | | | | | | | | | | | |
| Webster, Gregory | | | | | | | | | | | | | | | | | |
| Cullen, Carolyn | | | | | | | | | | | | | | | | | |
| Cullen, Stanley | | | | | | | | | | | | | | | | | |
| Cullen, Kitty | | | | | | | | | | | | | | | | | |
| Patton, Todd | | | | | | | | | | | | | | | | | |
| Patton, Susanna | | | | | | | | | | | | | | | | | |

After the phlebotomist is assigned to the OGTT side of the phlebotomy room, it is then possible to assign the SP to the OGTT component.

12.8 OGTT Application

Introduce the OGTT component as the “next component” in the SP’s exam profile. The OGTT application consists of two sections and five total screens. The first section contains the safety exclusion questions and monitors the time it takes the SP to drink the Trutol. This application is active in the phlebotomy and CV fitness rooms. This section is used by the phlebotomist, MEC interviewers, health technologists, the medical technologist assigned to workstation 3, and the MEC manager. The second section is used by the phlebotomist to record the results of the second blood collection.

The first Trutol Administration Information section includes three screens. The first Exclusion Question screen, p. 12-44, includes the two exclusion questions and a ‘Length of Fast’ read-only text box. The second Trutol Administer Information screen, p. 12-53, contains instructions, a ‘Length of Fast’ read-only text box, a ‘Your weight is’ text box, an ‘Amount to drink’ calculation (in oz. and mL), a ‘Please drink this solution within 10 minutes’ script, a 10:00 timer, Start button, Start and Stop read-only text boxes, a timer Reset button and an ‘Amount of solution the SP drank’ text box. The Trutol Administer Information section status screen, p. 12-61, displays after the first screen if the SP is excluded or after the second screen if the SP is not excluded.

The second blood draw section contains two screens. The first blood draw screen includes the second 2-mL gray top tube in the upper section and any tubes that were not drawn during the first venipuncture in the lower section. The second screen is the blood draw section status screen.

12.8.1 OGTT Application - Section One (Exclusion Questions and Trutol Administration)

The first section of the OGTT application is used by the phlebotomist, MEC interviewers, health technologists, the medical technologist assigned to workstation 3, and the MEC manager to screen for safety exclusions and to administer and monitor the time it takes the SP to drink the Trutol solution.

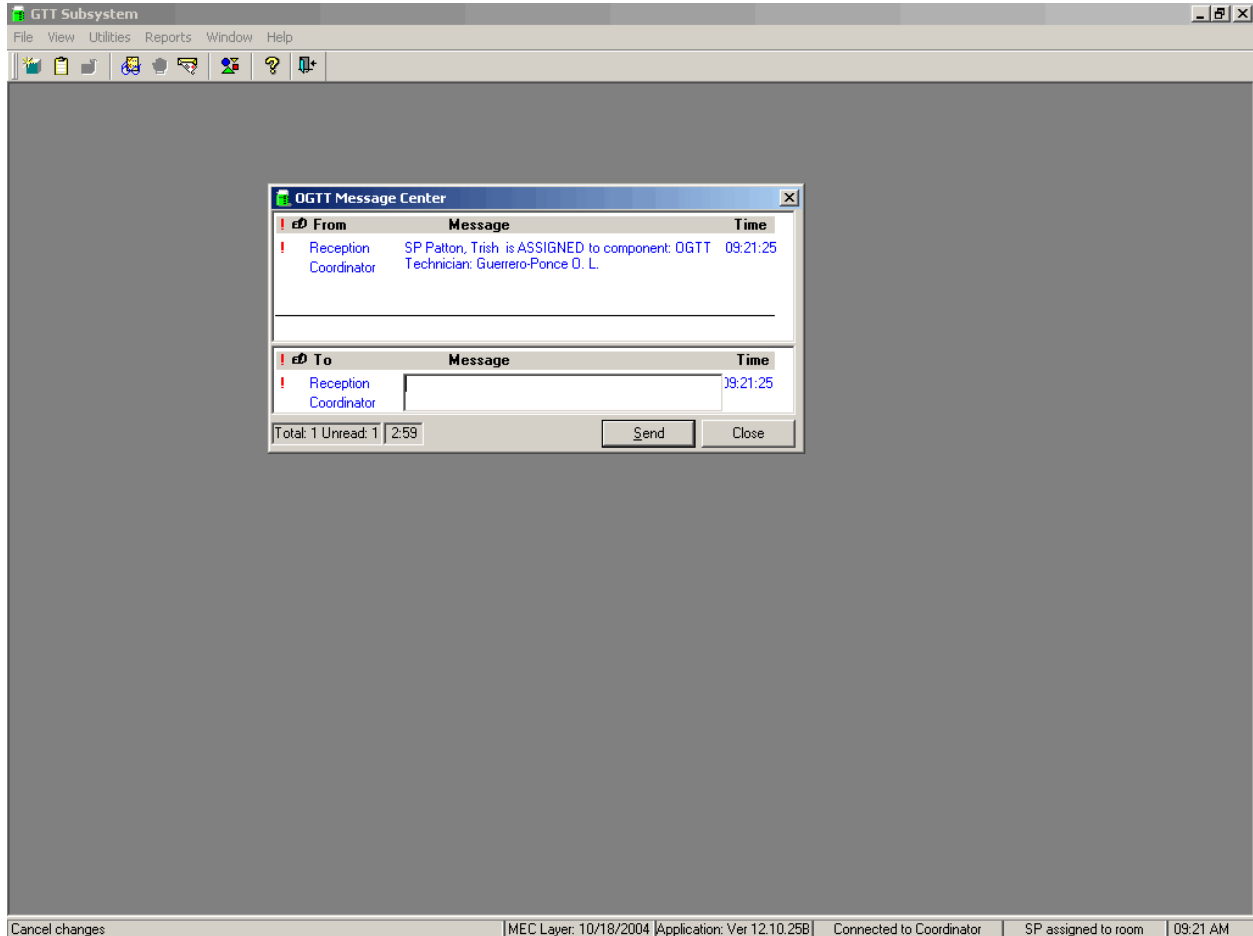
Two safety exclusion questions are asked in the Trutol administration section of the OGTT application. The first question asks the SP if he or she is taking insulin, and the second question asks if he or she is taking oral medications for diabetes. The insulin question is asked during the household interview. The oral medications question may be asked during the household interview, but in the event

that it is not, then it is asked in the OGTT examination. Only a “yes” response to either question will exclude the SP from the OGTT examination.

SPs who weigh less than 94 pounds must have a calibrated dose of Trutol. If the SP has been weighed in body measures, then the weight is pulled into the Trutol Administration screen and displayed in the “Your weight is” text box. If the SP has not been weighed in body measures, then the self-reported weight will be pulled into the Trutol Administration screen and displayed in the text box. (The self-reported weight is WGQ020 “How much do you weigh without clothes or shoes?”) If the self-reported weight is less than 100 pounds, then weigh the SP on the CV fitness scale.

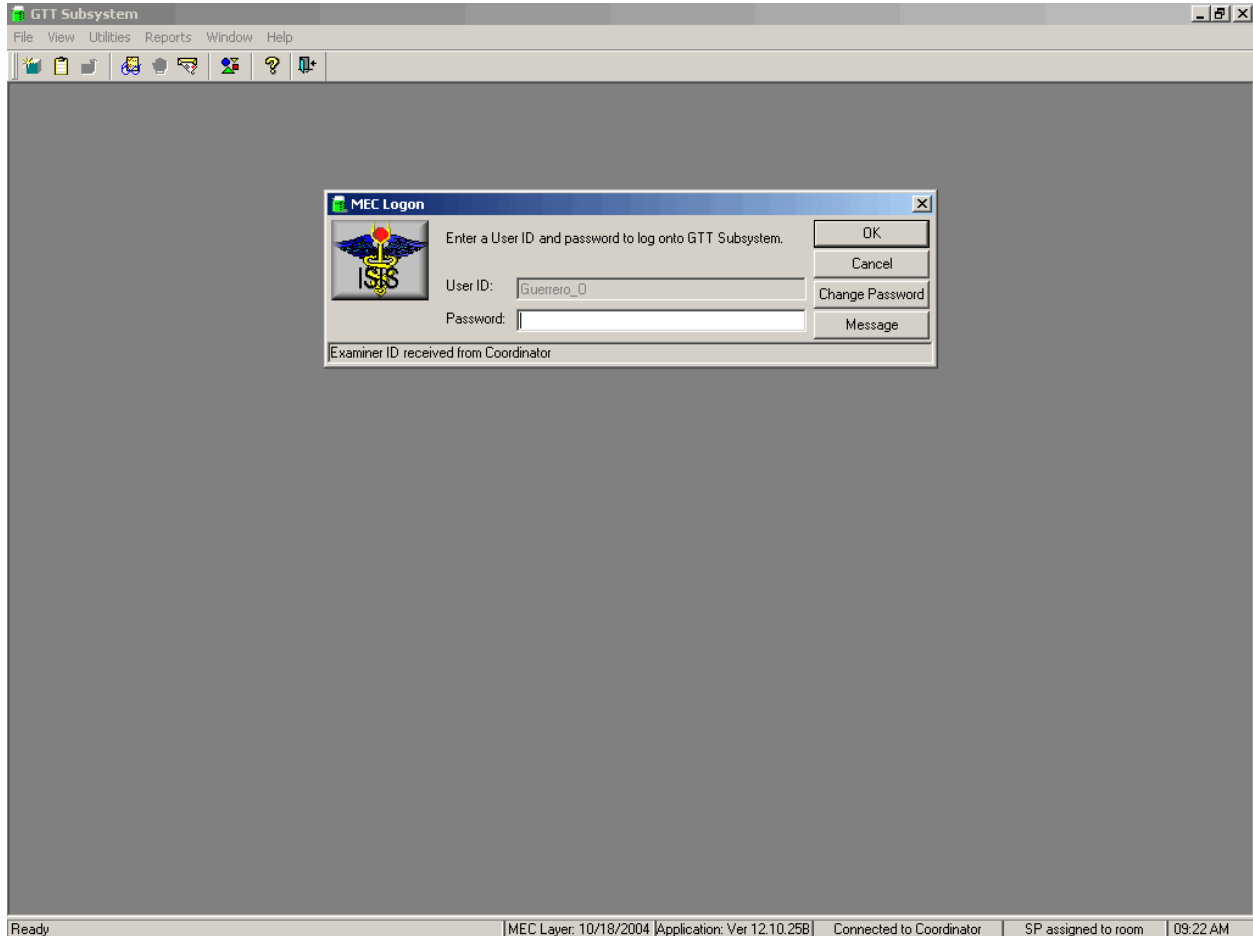
The SP must meet the 9-hour fast requirement before he or she is eligible for the OGTT. The fasting time is based on information given during the fasting interview that was administered before the first venipuncture in phlebotomy.

The Message Center window displays once an examiner and SP are assigned to the OGTT component.



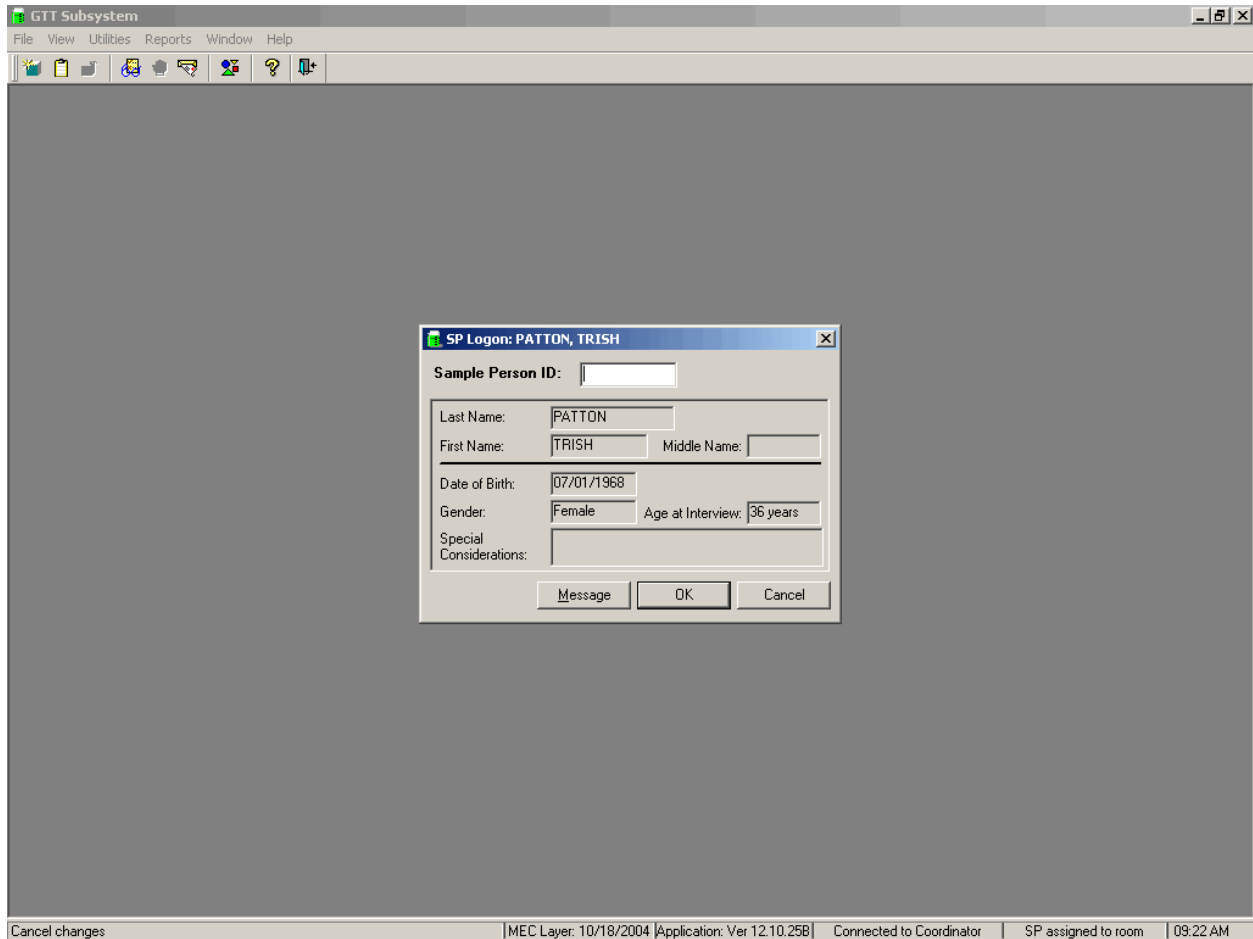
A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the OGTT component. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the Send button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the Close button and left click, or select [Enter].

The logon screen, shown below, appears after the coordinator assigns the examiner to the component and the assigned examiner accesses the OGTT application.



The MEC Logon window displays. The User ID (Last Name_First Initial) will automatically appear and cannot be changed. Type last name, underscore, first initial in the User ID space, and [Tab] or [Enter]. Enter the password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the OK button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the Cancel button, and left click. Examiner logoff is automatic at the end of the session.

Open the OGTT exam. To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o]. Log the SP into the exam component.



The SP Logon window displays for the SP assigned to the component. To log the SP into the component, either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box, or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the OK button, and left click. To cancel the logon process and to remove the window, use the mouse to direct the mouse arrow to the Cancel button, and left click.

Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

The Exclusion Question screen displays.

GGT Subsystem

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 756670 Name: MITCHELL, CHAD Age: 45 years Gender: Male Date: 10/26/2004 Time: 09:32 AM

Exclusion Question

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)

Length of Fast **24 hours 02 minutes**

1 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 09:31 AM

The Exclusion Question screen lists the two safety exclusion questions and displays the Length of Fast timer. If the data for the first two questions was captured during the household interview, then the response is displayed in the text box and the text box is grayed out. The length of fast is initially captured by the fasting questionnaire screen in the phlebotomy application. The Length of Fast timer continues to update until this section is complete.

Use the following Q x Qs to guide the SP through the exclusion question interview.

Q1: Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.) Yes, No, Refused, Don't know

| | |
|---|--|
| <p>Q1: This question asks if the SP if he or she is taking insulin, which is an exclusion criterion for this procedure.</p> | <p>Explain that SPs who are taking insulin are excluded due to safety concerns.</p> <p>Insulin is a hormone and therefore, a protein. Insulin is secreted by groups of cells within the pancreas called islet cells. The pancreas is an organ that sits behind the stomach and has many functions in addition to insulin production. The pancreas also produces digestive enzymes and other hormones. Carbohydrates (or sugars) are absorbed from the intestines into the bloodstream after a meal. Insulin is then secreted by the pancreas in response to this detected increase in blood sugar. Most cells of the body have insulin receptors, which bind the insulin, which is in the circulation. When a cell has insulin attached to its surface, the cell activates other receptors designed to absorb glucose (sugar) from the blood stream into the inside of the cell.</p> <p>Diabetes is a disease in which the body either fails to produce any insulin (type 1, also called insulin-dependent or juvenile-onset), or the insulin that it does produce is unable to adequately trigger the conversion of food into energy (type 2, also called non-insulin-dependent or adult-onset).</p> <p>SPs are asked to respond to DIQ050, “[Is SP/Are you] now taking insulin” during the household interview. The response choices are, 1=yes, 2=no, 7=refused, 9=don't know.</p> <p>If the SP answers, “yes,” the SP is excluded from the OGTT.</p> |
|---|--|

| | |
|--|---|
| | <p>If the SP answers, “refused” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>If the SP answers “no,” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>If the SP answers “don’t know,” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].</p> <p>If the answer is “No,” “Refused,” or “Don’t Know,” then continue to the next question.</p> |
|--|---|

Q2: Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.) Yes, no, refused, don’t know

| | |
|--|--|
| <p>Q2: This question asks whether the SP is currently taking diabetic pills to lower his or her blood sugar, which is an exclusion criterion for this procedure.</p> | <p>Explain that SPs who are taking pills to lower blood sugar are excluded due to safety concerns.</p> <p>People take pills or capsules to lower the level of glucose in the blood. The pills work for some people with type 2 diabetes if their pancreas still makes some insulin. They can help the body in several ways, such as causing the cells in the pancreas to release more insulin.</p> |
|--|--|

A great deal of research toward the development of more effective ways of treating the disease has led to the development of orally active agents, including the [sulfonylureas](#) and the [biguanides](#). These oral agents have been widely received and are primarily used for the treatment of non-insulin-dependent type of diabetes.

Types of these pills for sale in the United States are:

[Sulfonylureas](#) (many varieties)

Biguanides: [metformin](#) (Glucophage)

Alpha-glucosidase inhibitors: [acarbose](#) (Precose); miglitol (Glyset)

Thiazolidinediones (or “glitazones”): [rosiglitazone](#) (Avandia); [pioglitazone](#) (Actos)

Meglitinides: [repaglinide](#) (Prandin); nateglinide (Starlix)

Sulfonylureas

Generic Name: Tolbutamide (*Trade Name*: Orinase)

Generic Name: Acetohexamide (*Trade Name*: Dymelor)

Generic Name: Tolazamide (*Trade Name*: Tolinase)

Generic Name: Chlorpropamide (*Trade Name*: Diabinese)

Generic Name: Glipizide (*Trade Name*: Glucotrol, Glucotrol XL)

Generic Name: Glyburide (*Trade Name*: Diabeta, Micronase, Glynase)

Generic Name: Glimpiride (*Trade Name*: Amaryl)

Metformin

Pioglitazone

Rosiglitazone (Avandia)

Repaglinide (Prandin)

SPs may be asked DIQ070 “{Is SP/Are you} now taking diabetic pills to lower {his/her}/your} blood sugar? These are sometimes called oral agents or oral hypoglycemic agents” as part of the household interview. However, because this is dependent on a positive response to a previous question, most SPs will not be asked this question before they get to the OGTT component. The response choices are, 1=yes, 2=no, 7=refused, 9=don’t know.

If the SP answers “yes,” the SP is excluded from the OGTT.

If the SP answers “refused,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.

If the SP answers “no,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.

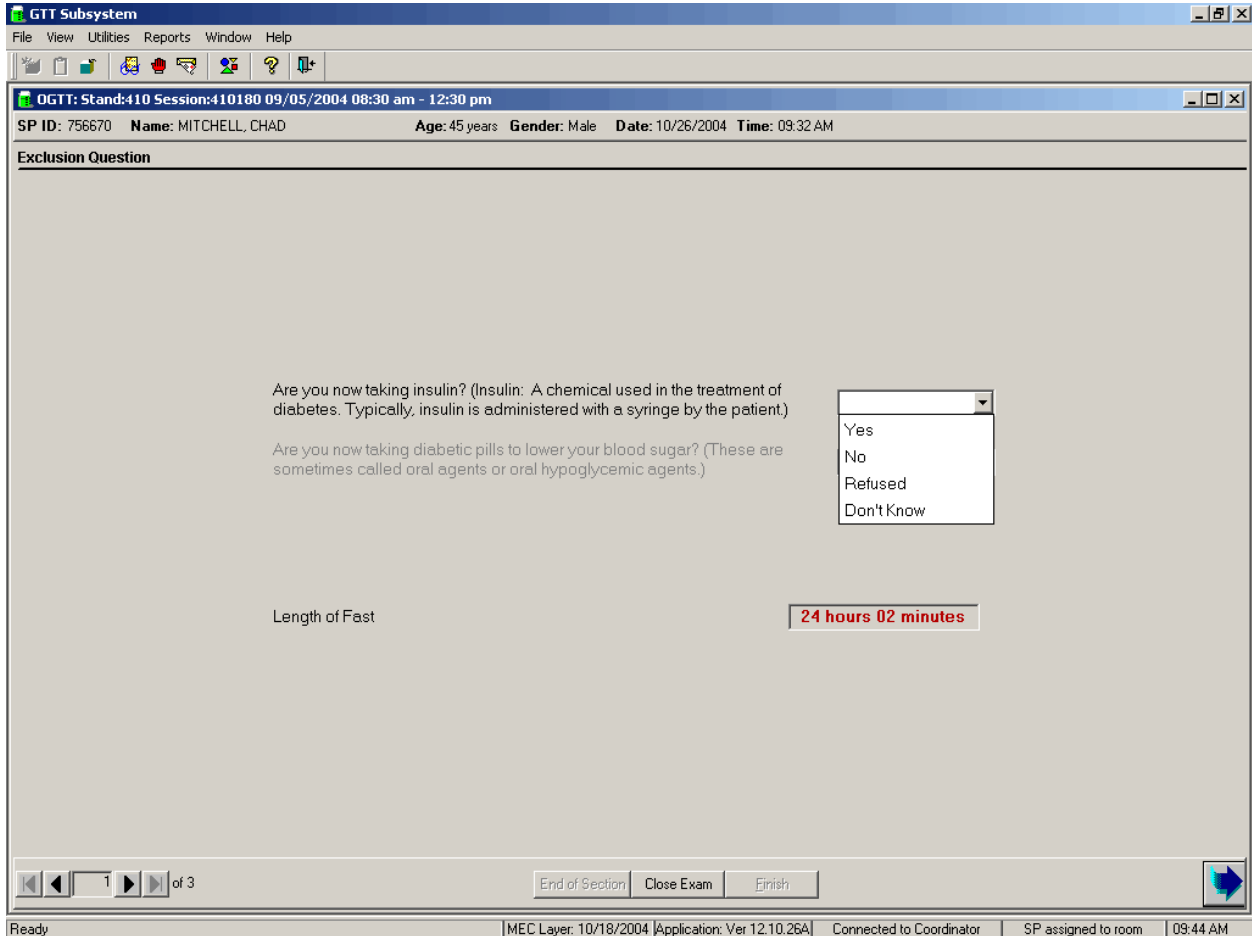
If the SP answers “don’t know,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.

Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].

If the answer is “No,” “Refused,” or “Don’t Know,” then continue to the next screen.

12.8.1.1 Recording Responses to the Exclusion Questions

If the text box is not grayed out, then ask the first exclusion question, “Are you now taking insulin?” Record the exact response.



Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter]. If the answer is “No,” Refused,” or Don’t know,” ask the next question.

If the SP has not been excluded, continue the exclusion question interview by asking the second question displayed on the screen, “Are you now taking diabetic pills to lower your blood sugar?”

The screenshot shows a software window titled "GTT Subsystem" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar, a status bar displays "OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm". The main content area is titled "Exclusion Question" and contains the following text and controls:

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)

Length of Fast

At the bottom of the window, there is a navigation bar with a left arrow, a right arrow, and the text "1 of 3". To the right of this are three buttons: "End of Section", "Close Exam", and "Finish". A blue arrow icon is located in the bottom right corner of the main content area.

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 09:45 AM

Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click. If the answer is “No,” Refused,” or Don’t know,” continue to the next slide.

Review the length of fast; this is informational only. The coordinator could not assign the SP to the GT component unless the SP's fast was at least 9 hours.

GTT Subsystem

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 756670 Name: MITCHELL, CHAD Age: 45 years Gender: Male Date: 10/26/2004 Time: 09:32 AM

Exclusion Question

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)

Length of Fast

1 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 09:45 AM

To progress to the Trutol Administer Information screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

Review the section status.

The screenshot shows a software window titled "GTT Subsystem" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main content area is titled "OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm" and displays patient information: "SP ID: 756670 Name: MITCHELL, CHAD Age: 45 years Gender: Male Date: 10/26/2004 Time: 09:32 AM". Below this is a section titled "Trutol Administer Information". A central form contains a "Status" section with three radio buttons: "Complete", "Partial", and "Not Done" (which is selected). Below the status section is a "Comments" dropdown menu with "safety exclusion" selected, and an "Other text" input field. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the very bottom shows "Ready", "MEC Layer: 10/18/2004", "Application: Ver 12.10.26A", "Connected to Coordinator", "SP assigned to room", and "09:46 AM".

SPs excluded due to a “Yes,” response to either of the two exclusion questions are automatically coded by the application as “safety exclusion.” Escort the SP back to the coordinator or to the next component as directed by the Message Center.

12.8.1.2 Trutol Administer Information

If the SP is not excluded, then the Trutol Administration Information screen displays. Review the length of fast; this is informational only.

GTT Subsystem

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 578999 Name: WEBSTER, NADINE Age: 13 years Gender: Female Date: 10/26/2004 Time: 09:55 AM

Trutol Administer Information

Length of Fast

Your weight is LBs

Amount to drink is 8.0 oz (235 ml), remove 2.0 oz.

Please drink this solution within 10 minutes.

Start

Timer

Start

Stop

Total

Amount of solution the SP drank

2 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 09:55 AM

The Trutol Administer Information screen contains a ‘Length of Fast’ timer, a ‘Your weight is’ text box, an ‘Amount to drink’ calculation, a script (“Please drink this solution within 10 minutes.”) to recite to the SP, a 10:00 timer to record the Start, Stop, Total elapse time, and a text box to record the ‘Amount of the solution’ (Trutol) that the SP consumed.

If the SP has been weighed in body measures, then the weight is pulled into the Trutol Administration screen and displayed in the “Your weight is” text box. If the SP has not been weighed in body measures, then the self-reported weight will be pulled into the Trutol Administration screen and displayed in the text box. (The self-reported weight is WGQ020 “How much do you weigh without clothes or shoes?”)

If the self-reported weight is less than 100 pounds, then weigh the SP on the CV fitness scale. SPs who weigh less than 94 pounds must have a calibrated dose of Trutol. Enter the weight into the ‘Your weight is’ text box and select [TAB]. The application will calculate the amount of Trutol to remove from the Trutol bottle. Use a small medicine cup to measure the correct amount to remove and then discard the excess Trutol.

Exhibit 12-5. Trutol Calibrated Dosage Chart

| Body Weight | | 75g Concentration | | Remove | |
|-------------|-------|-------------------|-----|--------|-----|
| lb. | kg | oz. | mL | oz. | mL |
| 94+ | 42.7+ | 10.0 | 295 | 0 | 0 |
| 90-93 | 40.9 | 9.5 | 283 | 0.5 | 12 |
| 85-89 | 38.6 | 9.0 | 267 | 1.0 | 28 |
| 80-84 | 36.4 | 8.5 | 251 | 1.5 | 44 |
| 75-79 | 34.1 | 8.0 | 235 | 2.0 | 60 |
| 70-74 | 31.8 | 7.4 | 220 | 2.6 | 75 |
| 65-69 | 29.5 | 6.9 | 204 | 3.1 | 91 |
| 60-64 | 27.3 | 6.4 | 188 | 3.6 | 107 |

If the SP consumes the entire dose of Trutol, then the examiner must place a Dymo label on the outside of the SP’s top. The time displayed is the earliest time at which the SP is eligible for the GTT blood draw. The SP is eligible for the second blood draw 1 hour and 40 minutes after the time he or she consumed the Trutol, but the second blood draw must occur within 2 hours and 15 minutes after consuming the Trutol. The entire MEC staff should monitor the SP and the time displayed on the top. Encourage the SP to continue his or her fast.

Taking an SP's Weight

Follow these steps to take the SP's weight:

1. Make sure the scale weighs in pounds by checking the switch on the underside of the digital display.
2. Place the scale on the floor.
3. Switch on the scale by pressing the ON button; 888.8 will appear on the digital display.
4. Have the SP remove his or her shoes and any heavy outer clothing such as sweaters, jackets, etc.
5. As soon as the display switches to 0.0, have the SP step on the scale with his or her feet positioned in the center.
6. Ask the SP to stand straight and remain still.
7. Wait about 4 seconds for the weight to display on the digital readout.
8. Record the weight in pounds in the "Your weight is" text box.
9. Ask the SP to step off the scale. The scale switches off automatically after 30 seconds.

Enter the weight into the “Your weight is” text box and select [TAB]. The application will calculate and display the calibrated dose of Trutol.

The screenshot shows the 'GTT Subsystem' application window. The title bar reads 'GTT Subsystem'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window content is titled 'OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm'. Below this, patient information is displayed: 'SP ID: 578999 Name: WEBSTER, NADINE Age: 13 years Gender: Female Date: 10/26/2004 Time: 09:55 AM'. The section is titled 'Trutol Administer Information'. The interface includes the following fields and controls:

- 'Length of Fast' field with the value '09 hours 10 minutes'.
- 'Your weight is' field with the value '75.0' and 'LBs' unit.
- Instructional text: 'Amount to drink is 8.0 oz (235 ml), remove 2.0 oz. Please drink this solution within 10 minutes.'
- 'Timer' field with the value '10:00'.
- 'Start', 'Stop', and 'Total' fields, each with an empty input box.
- 'Amount of solution the SP drank' dropdown menu with 'None' selected.
- 'Start' and 'Reset' buttons.
- Navigation buttons at the bottom: 'End of Section', 'Close Exam', and 'Finish'.
- Status bar at the bottom: 'Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 09:55 AM'.

Ask the SP to indicate a preference for one of the three flavors. Choose the flavor that matches the preference of the soft drink flavor that he or she prefers. Follow the instructions; remove the correct amount of Trutol from the bottle before handing the bottle to the SP. Use a small medicine cup to measure the correct amount to remove and discard the excess Trutol. Hand the SP a cold bottle of Trutol (containing the calibrated dose) and a straw. SPs MUST consume the entire calibrated dose of the Trutol within 10 minutes.

Recite the script “Please drink this solution within 10 minutes” and start the timer. The timer counts down from 10:00 minutes.

The screenshot shows the 'GTT Subsystem' application window. The title bar reads 'GTT Subsystem'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window content is titled 'OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm'. Below this, patient information is displayed: 'SP ID: 578999 Name: WEBSTER, NADINE Age: 13 years Gender: Female Date: 10/26/2004 Time: 09:55 AM'. A section titled 'Trutol Administer Information' contains the following fields and controls:

- 'Length of Fast' is set to '09 hours 10 minutes'.
- 'Your weight is' is set to '75.0' LBS.
- Instructions: 'Amount to drink is 8.0 oz (235 ml), remove 2.0 oz. Please drink this solution within 10 minutes.'
- 'Timer' is set to '10:00'.
- 'Start', 'Stop', and 'Total' are empty text input fields.
- 'Amount of solution the SP drank' is set to 'None' in a dropdown menu.
- 'Start' and 'Reset' buttons are present.

At the bottom of the window, there is a navigation bar with 'End of Section', 'Close Exam', and 'Finish' buttons, and a status bar showing 'Ready', 'MEC Layer: 10/18/2004', 'Application: Ver 12.10.26A', 'Connected to Coordinator', 'SP assigned to room', and '09:55 AM'.

To start the timer, use the mouse to direct the mouse arrow to the start button and left click or type [Alt] [S/s].

When the SP has finished drinking the entire calibrated dose of Trutol, or cannot continue drinking the Trutol, then select the Stop button.

The screenshot shows a software window titled "GTT Subsystem" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main window displays patient information: "OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm", "SP ID: 578999", "Name: WEBSTER, NADINE", "Age: 13 years", "Gender: Female", "Date: 10/26/2004", and "Time: 09:55 AM". Below this is a section titled "Trutol Administer Information".

Key fields and controls include:

- Length of Fast:** 09 hours 10 minutes
- Your weight is:** 75.0 LBS
- Amount to drink:** 8.0 oz (235 ml), remove 2.0 oz.
- Instruction:** Please drink this solution within 10 minutes.
- Timer:** 09:43
- Start:** 09:56:59
- Stop:** [Empty text box]
- Total:** [Empty text box]
- Amount of solution the SP drank:** [Dropdown menu]
- Buttons:** Stop, Reset

At the bottom, there is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, and a status bar showing "Ready", "MEC Layer: 10/18/2004", "Application: Ver 12.10.26A", "Connected to Coordinator", "SP assigned to room", and "09:57 AM".

To stop the timer, use the mouse to direct the mouse arrow to the Stop button, and left click or type [Alt] [S/s].

It is possible to restart the timer.

The screenshot shows the 'GTT Subsystem' application window. The title bar reads 'GTT Subsystem'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window title is 'OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm'. Below this, patient information is displayed: 'SP ID: 578999 Name: WEBSTER, NADINE Age: 13 years Gender: Female Date: 10/26/2004 Time: 09:55 AM'. A section titled 'Trutrol Administer Information' contains the following fields and controls:

- Length of Fast:
- Your weight is: LBs
- Amount to drink is 8.0 oz (235 ml), remove 2.0 oz.
- Please drink this solution within 10 minutes.
- Buttons: Done, Reset
- Timer:
- Start:
- Stop:
- Total:
- Amount of solution the SP drank:

At the bottom of the window, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. The status bar at the very bottom shows 'Ready', 'MEC Layer: 10/18/2004', 'Application: Ver 12.10.26A', 'Connected to Coordinator', 'SP assigned to room', and '09:57 AM'.

To restart the timer, use the mouse to direct the mouse arrow to the Reset button and left click. The Start, Stop, and Total fields will be cleared and the Start button will be enabled.

Record the amount of Trutol that the SP consumed.

The screenshot shows the 'GTT Subsystem' application window. The title bar reads 'GTT Subsystem'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window title is 'OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm'. Below this, patient information is displayed: 'SP ID: 578999 Name: WEBSTER, NADINE Age: 13 years Gender: Female Date: 10/26/2004 Time: 09:55 AM'. The section is titled 'Trutol Administer Information'. The form contains the following fields and controls:

- 'Length of Fast' is set to '09 hours 10 minutes'.
- 'Your weight is' is set to '75.0 LBS'.
- Instructions: 'Amount to drink is 8.0 oz (235 ml), remove 2.0 oz. Please drink this solution within 10 minutes.' with 'Done' and 'Reset' buttons.
- 'Timer' is set to '08:42'.
- 'Start' is '09:58:22'.
- 'Stop' is '09:59:40'.
- 'Total' is '00:01:18'.
- 'Amount of solution the SP drank' is a drop-down menu with options: 'All', 'Some', and 'None'.

At the bottom of the window, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. A status bar at the very bottom shows 'Ready', 'MEC Layer: 10/18/2004', 'Application: Ver 12.10.26A', 'Connected to Coordinator', 'SP assigned to room', and '09:59 AM'.

The choices for the amount of solution that the SP consumed are “All,” “Some,” or “None.” To record the amount, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “All,” “Some,” or “None” and left click. To progress to the section status screen, use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click.

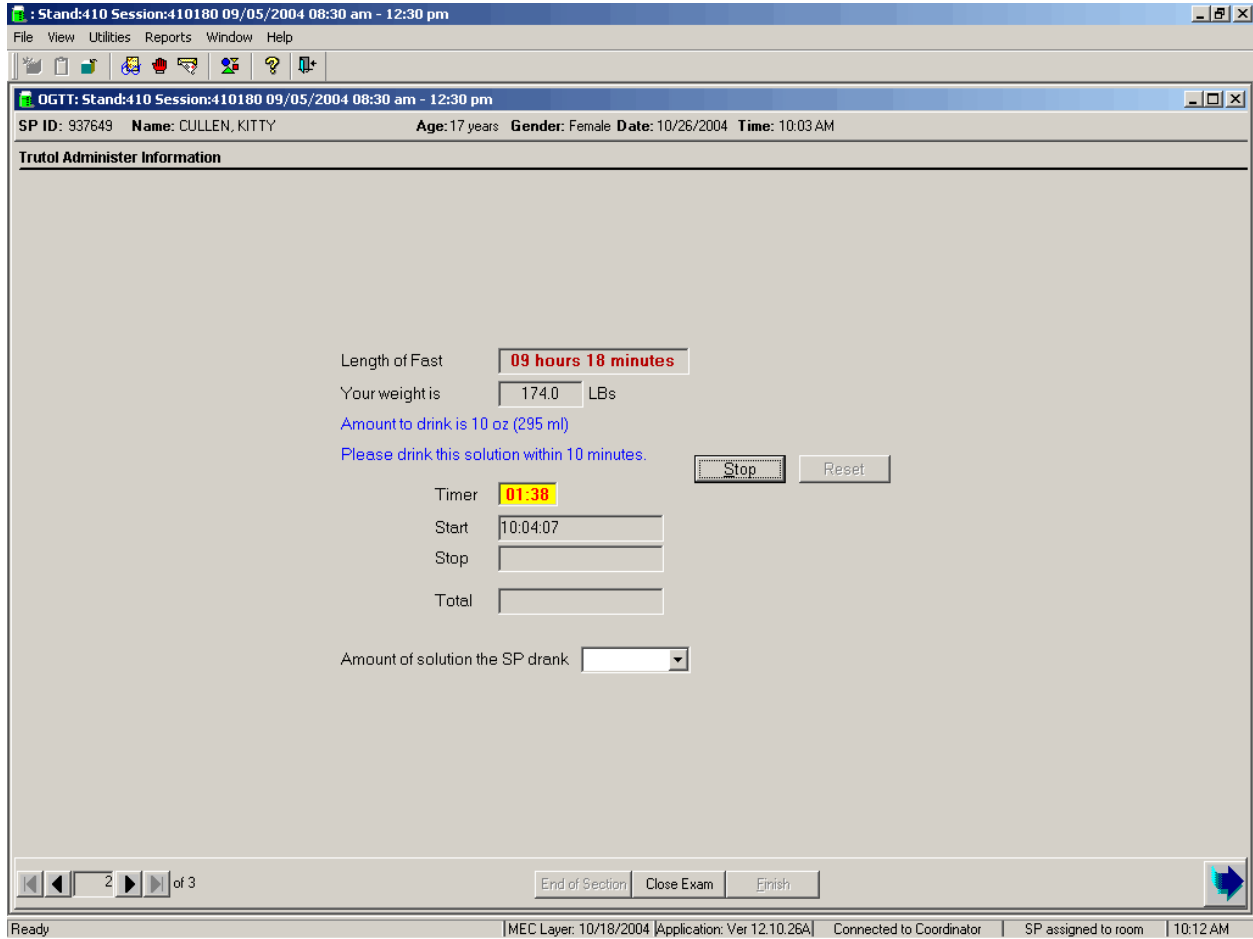
Verify the Trutol Administer Information section status.

The screenshot displays the 'GTT Subsystem' application window. At the top, the menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. The main content area is titled 'OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm'. Below this, a header bar contains the following information: 'SP ID: 578999', 'Name: WEBSTER, NADINE', 'Age: 13 years', 'Gender: Female', 'Date: 10/26/2004', and 'Time: 09:55 AM'. The main section is titled 'Trutol Administer Information'. In the center of this section is a form with the following elements: a 'Status' label, three radio buttons labeled 'Complete', 'Partial', and 'Not Done' (with 'Complete' selected), a 'Comments' dropdown menu, and an 'Other text' text input field. At the bottom of the window, there is a navigation bar with a page indicator '3 of 3', buttons for 'End of Section', 'Close Exam', and 'Finish', and a right-pointing arrow button. The status bar at the very bottom shows 'Ready', 'MEC Layer: 10/18/2004', 'Application: Ver 12.10.26A', 'Connected to Coordinator', 'SP assigned to room', and '09:59 AM'.

If the SP drank all of the Trutol solution, then the section status is complete. To complete the examination, use the mouse to direct the mouse arrow to the Finish button or type [Enter].

NOTE: Place the Dymo label with the return time on the outside of the SP's top.

The timer counts down from 10:00 minutes. When the timer reaches 1:40, the background turns yellow and the numbers change to red.



Monitor the timer display. Coach or encourage the SP to drink the solution before the 10 minutes expire.

If the total time is greater than 10 minutes, then the timer will automatically stop at 00:00 and insert 00:10:00 in the Total field.

: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 937649 Name: CULLEN, KITTY Age: 17 years Gender: Female Date: 10/26/2004 Time: 10:03 AM

Trutol Administer Information

Length of Fast

Your weight is LBS

Amount to drink is 10 oz (295 ml)

Please drink this solution within 10 minutes.

Timer

Start

Stop

Total

Amount of solution the SP drank

2 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 10:14 AM

Record the amount of solution the SP drank and proceed to the section status screen. If the SP drank “some” or “none” of the Trutol solution, then the section status is Not Done.

Review the comment in the section status screen.

The screenshot shows a software window titled "Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm". The interface includes a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu is a header section for "OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm" containing patient details: "SP ID: 937649", "Name: CULLEN, KITTY", "Age: 17 years", "Gender: Female", "Date: 10/26/2004", and "Time: 10:03 AM".

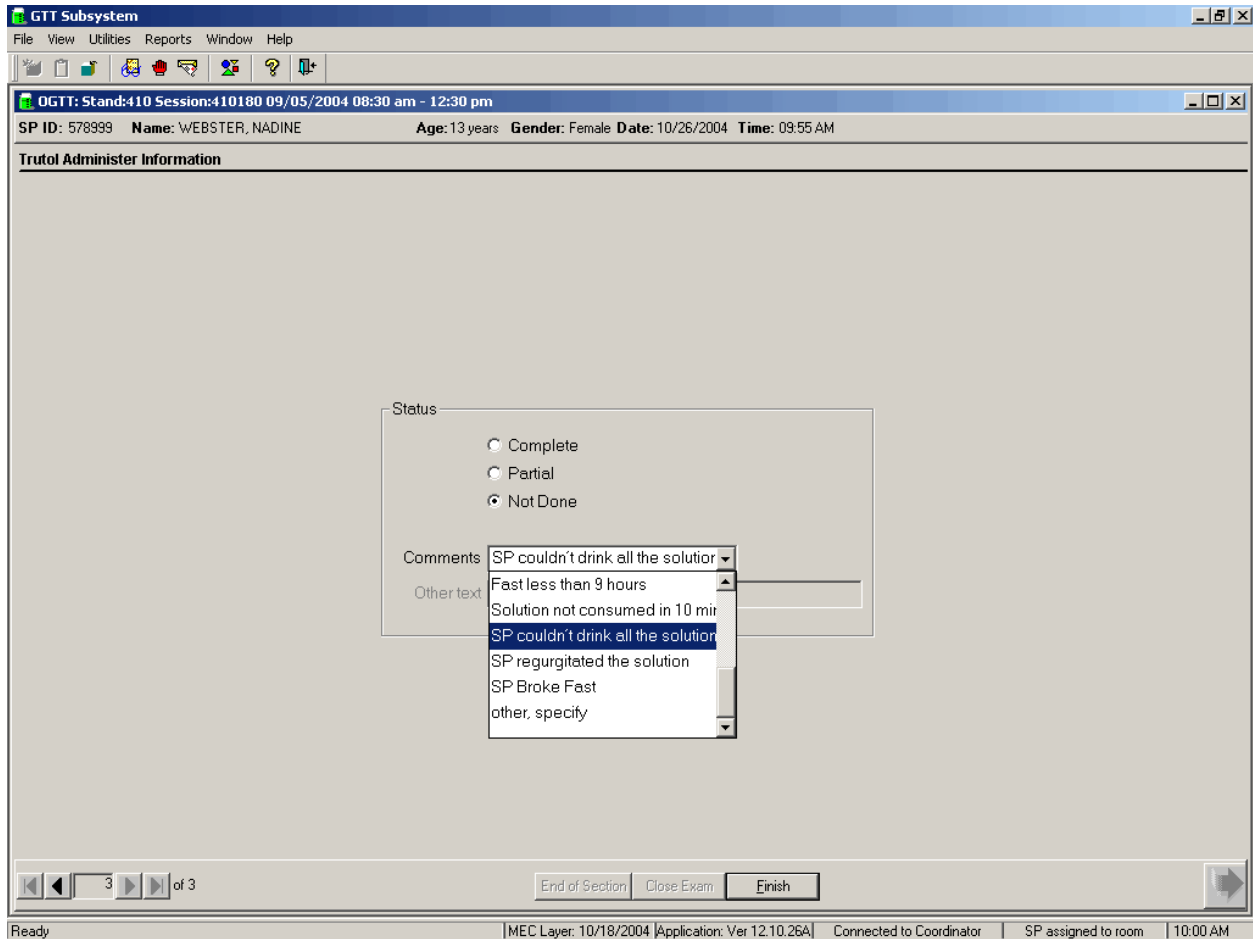
The main area is titled "Trutol Administer Information" and contains a form with the following fields:

- Status:** Three radio buttons are present: "Complete" (unselected), "Partial" (unselected), and "Not Done" (selected).
- Comments:** A dropdown menu with the text "Solution not consumed in 10 mi".
- Other text:** An empty text input field.

At the bottom of the window, there is a navigation bar with a "3 of 3" indicator, buttons for "End of Section", "Close Exam", and "Finish", and a right-pointing arrow. The system tray at the very bottom shows "Ready", "MEC Layer: 10/18/2004", "Application: Ver 12.10.26A", "Connected to Coordinator", "SP assigned to room", and "10:14 AM".

If the total time is 00:10:00, then the comment will default to “Solution not consumed in 10 minutes.”

If the SP drank “some” or “none” of the Trutol solution, then the section status is Not Done. Choose and enter the appropriate comment code when the Trutol Administer Information section status is Not Done.



To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code. To complete the examination, use the mouse to direct the mouse arrow to the Finish button or type [Enter].

| Comment Code | Use when: |
|-----------------------------------|---|
| Safety exclusion | Not applicable This is reserved for positive responses to the insulin, oral diabetic medications, hemophilia and chemotherapy exclusion questions, and positive pregnancy tests. It is automatically coded by the application. The coordinator may code exams using this comment. |
| SP refusal | The SP refuses to drink the Trutol. This is SP initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam. |
| No time | Not applicable |
| Physical limitation | Not applicable |
| Communication problem | Not applicable |
| Equipment failure | Not applicable |
| SP ill/emergency | Use this comment to code not done or partial when the SP faints or is about to faint or the SP becomes ill or an emergency occurs and the test cannot be performed on the SP. |
| Interrupted | Not applicable |
| SP did not drink all the solution | Use this code when the SP cannot consume all of the calibrated dose of the Trutol. |
| Time exceeded 10 minutes | Use this code when the timer expires before the SP has consumed the entire calibrated dose of the Trutol. |
| SP regurgitated the solution | Use this code when the SP becomes ill and regurgitates the Trutol. |
| SP broke fast | Use this code if the SP eats anything or drinks anything other than plain water after consuming the Trutol but before completing the second blood draw. |
| Other, specify | If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field. |

12.8.2 OGTT Application – Section Two (Blood Draw)

If an SP consumed the entire calibrated dose of the Trutol solution in 10 minutes and 1 hour and 40 minutes has elapsed, then he or she is eligible to return to phlebotomy to have (1) one additional 2-mL gray top drawn and (2) any tubes that were not drawn during the initial venipuncture examination drawn.

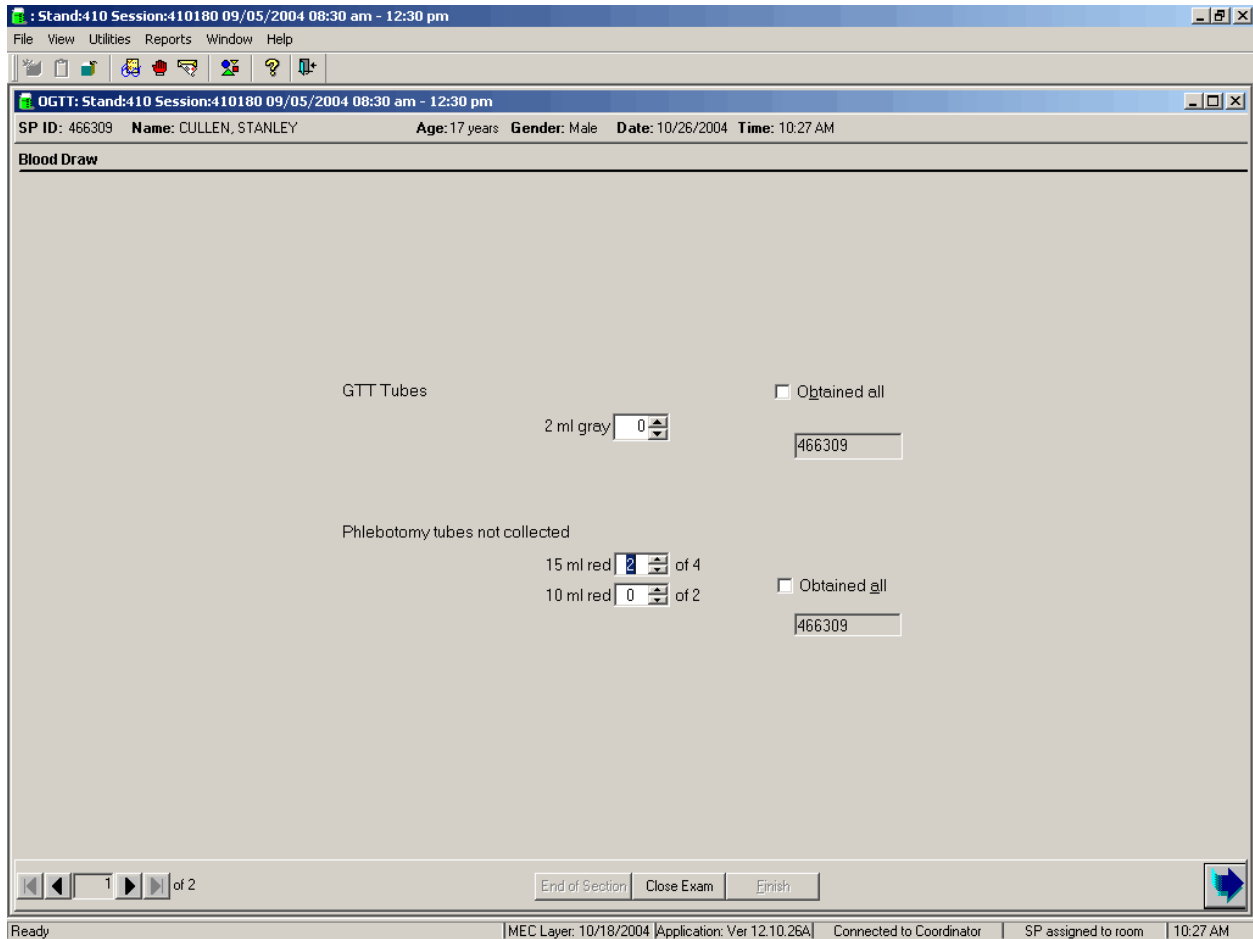
A pop-up message window will alert the coordinator and the phlebotomist when an SP is eligible to return to phlebotomy for the second blood draw.

The screenshot displays the 'Coordinator Console' application window. At the top, a menu bar includes 'File', 'Reports', 'Utilities', 'Window', and 'Help'. Below the menu bar, the window title is 'Coordinator Console Stand:410 Session:410180 05-Sep-2004 08:30 am - 12:30 pm'. A table lists staff members with columns for 'SP Name', 'Status', 'Rof', 'G', 'Age', 'LB', 'MD', 'PH', 'BM', 'OH', 'DR', 'MI', 'VI', 'AU', 'BC', 'OP', 'CV', and 'GT'. A 'Message Center' pop-up window is open, showing a message from 'Reception Coordinator' to 'Cullen, Stanley' at 10:27:15, stating 'STANLEY CULLEN (SPID 466309) is eligible to continue to OGTT.'. Below the message center, a grid of technician skill areas is visible, including 'Audiometry', 'Oral Health', 'Body Measures', 'Body Composition', 'Laboratory', 'Phleb', 'OGTT', 'Lbl/Shp', 'Staff Area', 'Ophthalmology', 'Dietary 2', 'Dietary 1', 'MEC Int 2', 'MEC Int 1', 'Physician', 'CV Fitness', 'OGTT', 'Vision', 'Coordinator', and 'Wittke v.'. On the right side, a 'Technician Skill' list shows names and their corresponding skills, such as 'Aranz-Lomas Asst. Coordinato', 'Velazquez N Asst. Coordinato', and 'Lopez J. S. Clerk'. The bottom status bar shows 'Ready' and the time '10:27 AM'.

To close or remove the Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

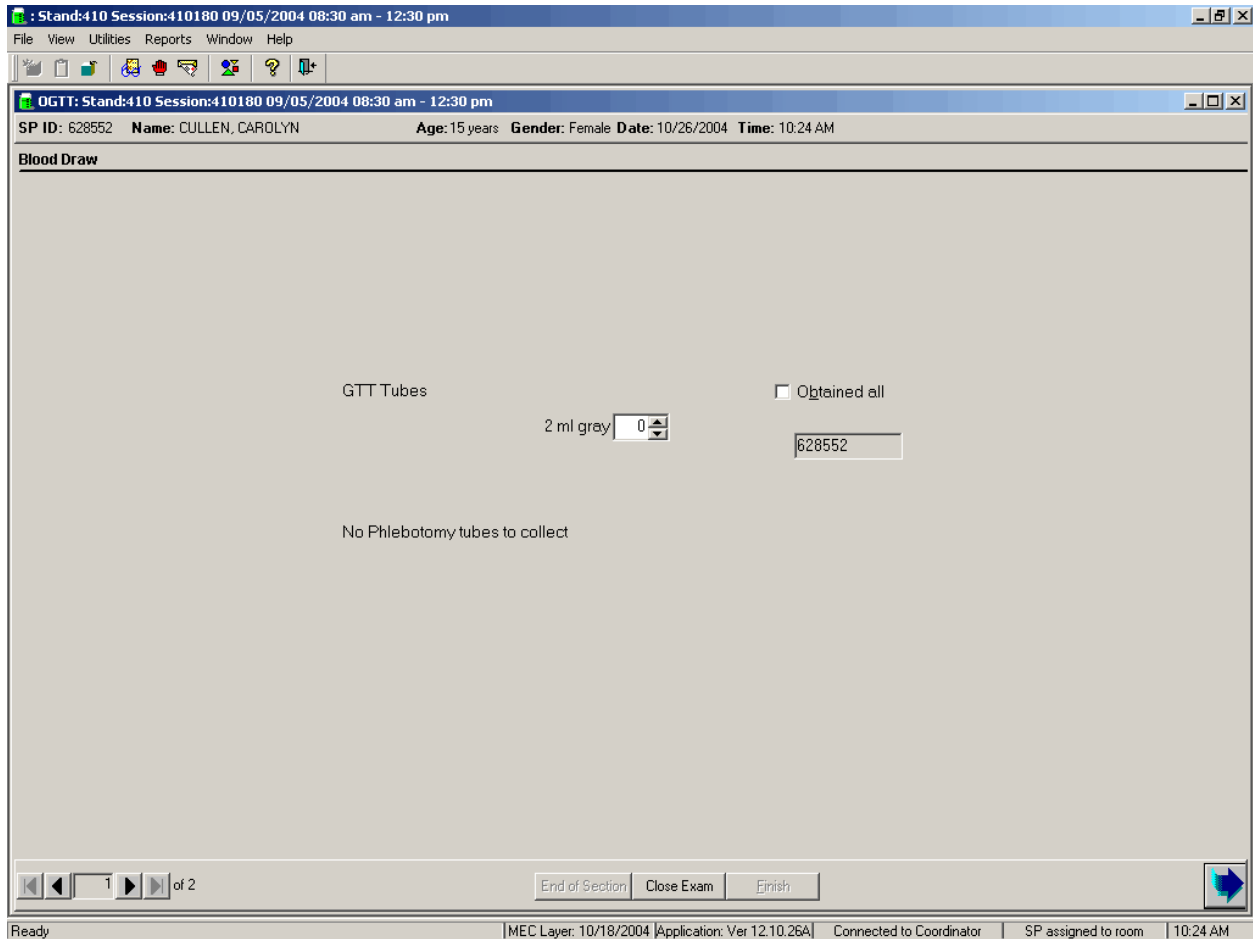
Logon to the OGTT application and log the SP into the component.

The blood draw screen is divided into two sections.



The upper section is identical to the venipuncture screen in the phlebotomy examination except that it contains only one 2-mL gray top tube. The bottom half of the screen lists any tubes that were not drawn during the initial venipuncture examination. The sections function exactly like the venipuncture screen in the phlebotomy examination.

If all of the blood tubes were drawn during the phlebotomy examination, then only the first half of the blood draw screen will contain the 2-mL gray top tube. The lower section of the blood draw screen will indicate that there are “No phlebotomy tubes to collect.”



Draw the additional 2-mL gray top tube and then any tubes that were missed during the phlebotomy examination first. Draw all tubes according to the protocol described in Chapter 4 of the *Laboratory Procedures Manual*.

Labels will print for all the tubes marked as collected, including the second 2-mL gray top tube. The label for the second 2-mL gray top tube contains a bar code with the SP ID concatenated with the vessel ID (# 98) and includes the test name “OGTT.”

Immediately after completing the venipuncture, enter the results of the blood draw and any comments about the venipuncture.

The screenshot shows a software window titled "OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm". The window contains a form for recording blood draw results. At the top, it displays patient information: "SP ID: 466309 Name: CULLEN, STANLEY Age: 17 years Gender: Male Date: 10/26/2004 Time: 10:27 AM". Below this, the section is titled "Blood Draw".

The form is divided into two main sections:

- GTT Tubes:** This section includes a label "GTT Tubes" and a checkbox labeled "Obtained all" which is currently unchecked. Below this, there is a spin box for "2 ml grey" tubes, currently set to "0". To the right of the spin box is a text input field containing the number "466309".
- Phlebotomy tubes not collected:** This section includes a label "Phlebotomy tubes not collected" and a checkbox labeled "Obtained all" which is currently checked. Below this, there are two spin boxes: "15 ml red" set to "4 of 4" and "10 ml red" set to "2 of 2". To the right of these spin boxes is another text input field containing the number "466309".

At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish". A status bar at the very bottom of the screen displays: "Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 10:28 AM".

To record all tubes as filled or obtained, use the mouse to direct the mouse arrow to the “Obtained all” check box and left click, or type [Alt] [B/b]. This records a check mark in the box and marks all tubes as obtained. To mark individual tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number of each tube up or down or type the correct number using the numeric keys.

Verify the Blood Draw section status.

: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 628552 Name: CULLEN, CAROLYN Age: 15 years Gender: Female Date: 10/26/2004 Time: 10:24 AM

Blood Draw Section Status

Status

Complete
 Partial
 Not Done

Comments

Other text

2 of 2

End of Section Close Exam Finish

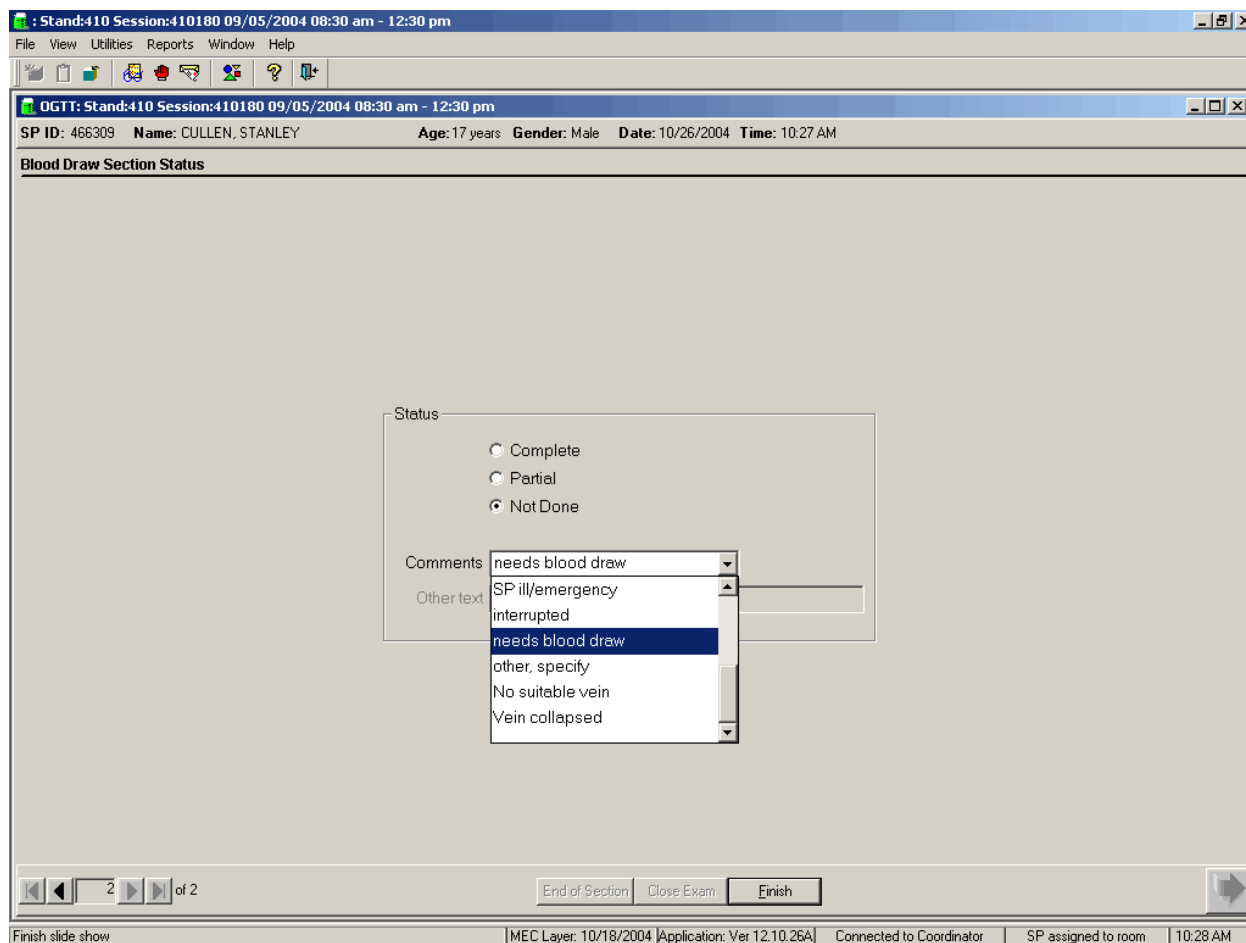
Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 10:25 AM

The blood draw section status is complete if the second 2-mL gray top tube is collected.

If any blood tubes were not drawn during the initial phlebotomy examination and they were drawn during the blood draw section of the OGTT examination, then the phlebotomy section status will automatically update to reflect the additional tubes drawn during the OGTT examination.

Remove the Dymo label from the SP's gown and ask the SP if he or she is allergic to peanuts. If not, then offer the SP peanut butter crackers and juice. If the SP is allergic to peanuts or does not know, then offer the standard crackers and juice.

Use comment codes to explain Not Done status codes.



The blood draw section status is Not Done if the second 2-mL gray top tube is not collected. **Once the tube is marked as not obtained, the comment will default to “needs blood draw.”** Correct the comment by selecting the most appropriate comment code. To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

| Comment Code | Use when: |
|------------------------------------|---|
| Safety exclusion | Not applicable This is reserved for positive responses to the hemophilia and chemotherapy exclusion questions and it is automatically coded by the application. The coordinator may code exams using this comment. |
| SP refusal | The SP refuses to have his or her blood collected. This is an SP-initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam. Use this comment to code partial exams when the SP refuses after one tube has been drawn, or the blood flow stops after one tube but before all tubes have been successfully drawn. |
| No time | Not applicable |
| Physical limitation | Not applicable |
| Communication problem | Not applicable |
| Equipment failure | Not applicable |
| SP ill/emergency | Use this comment to code not done or partial when the SP faints or is about to faint or the SP becomes ill or an emergency occurs and the test cannot be performed on the SP. |
| Interrupted | Not applicable |
| Error (technician/software/supply) | Use this comment to code partial and not done exams when there are phlebotomist errors, or software or supply issues. |
| Other, specify | If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field. |
| No suitable vein | Use this comment to code exams as not done (no tubes drawn) when the SP does not have an accessible vein, any arms available, casts on both arms, there is a rash over the entire area, or the blood draw was started but there was no blood in the tubing. |
| Vein collapsed | Use this comment to code exams as partial when one or more tubes are successfully drawn but blood flow stops before all tubes are drawn or when the veins collapse. |

When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click to exit or select [Enter] when this blue arrow is highlighted.

12.9 Laboratory

The vessel for OGTT is #98 (Exhibit 12-6). Use the gtt processing module to record the blood processing results. Labels for the OGTT vessel print for all SPs after the last blood processing set of labels. Keep the OGTT labels together and place them in the lab with the blood processing racks. Do not label the vessels in advance; label each vessel as it is processed.

Exhibit 12-6. Primary SP's OGTT processing protocol

| ID | Test name | Ages | Sample (mL) | Sample type | Collection type | Vessel type | Remarks |
|----|-----------|------|-------------|-------------|-----------------|-------------|------------------|
| 98 | OGTT | 12+ | 0.5 | Plasma | Gray | 2-mL | Morning SPs only |

12.9.1 Process the 2-mL Gray Top Tube for OGTT

Centrifuge and separate the plasma from the 2-mL gray top tube as soon as possible. Process the specimen even if the contents of the gray tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 2-mL gray tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 98 (OGTT.)

Vessel 98

- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 98 (OGTT) on primary into a 2-mL vessel.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Close all vessels secured to prevent leakage and evaporation.
- Record results using the gtt module as described in Section 8.7.3.
- Store all specimens immediately as outlined in Section 8.10.

12.9.2 Record the Results of Specimen Processing

Open and log onto the Laboratory application. Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status. Record blood processing results for vessel 98 using the 'gtt' module.

Stand:410 Session:410260 09/13/2004 08:30 am - 12:30 pm

File View Utilities Reports Modules Shipping Window Help

| Appointments for Session: 410260 | | | | | | | Process Status | | | | | | | | | |
|----------------------------------|-----------|--------|------|--------|-----|-------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| SP ID | Sample ID | status | type | gender | age | name | UC | B | CB | U | P | HPV | hiv | V | gtt | PW |
| 200594 | 200594 | SC | P | F | 51 | DOE, JANE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 323798 | 323798 | BE | P | M | 40 | PITT, BRAD | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 351499 | 351499 | BE | P | F | 15 | MEYERS, JESSICA | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 420341 | 420341 | SC | P | F | 15 | MEYERS, MICHELLE | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 425408 | 425408 | CI | P | F | 19 | CALHOUN, JAMES | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 565634 | 565634 | SC | P | F | 35 | SHEFFIELD, MOLLY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 576133 | 576133 | BE | P | F | 39 | COX, COURTNEY | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 695392 | 695392 | BE | P | M | 38 | MEYERS, RICHARD | ○ | ○ | ○ | ○ | ○ | ○ | ● | ○ | ○ | ○ |
| 721250 | 721250 | SC | P | M | 42 | ARQUETTE, DAVID | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 762833 | 762833 | CI | P | F | 35 | ANISTON, JENNIFER | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| 808590 | 808590 | SC | P | F | 44 | JONES, JANET | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

Ready | HUP: idle | MEC Layer: 11/22/2004 | Application: Ver 12.11.22A | Connected to Coordinator | 10:02 AM

Start | Stand:410 Session:41... | 10:03 AM

The 'gtt' module is grayed out until at least one SP has the second 2-mL gray top tube drawn. Once one SP has the second 2-mL gray top tube drawn, the processing circle for that SP turns black.

Select the correct SP and access the OGTT processing module. To access the OGTT module, use the mouse to direct the mouse arrow to the SP on the heads-up display, left click, drag the mouse arrow to OGTT Processing, and right click. Record the vessel 98 processing results in the OGTT processing window. All SPs are included in the same window but are listed separately by rows.

The screenshot shows the 'Lab Shipping' application window with the 'OGTT' (Glucose Tolerance Test) processing module open. The window title is 'OGTT' and the subtitle is 'Glucose Tolerance Test'. The main area contains a summary of test parameters and a table of samples.

Test Summary:

- Tech ID: 1126
- Vessel ID: 98
- Test Name: OGTT
- Vessel Name: Nalge Cryovial
- Total Volume: 2 ml
- Sample Volume: 0.5

Sample List:

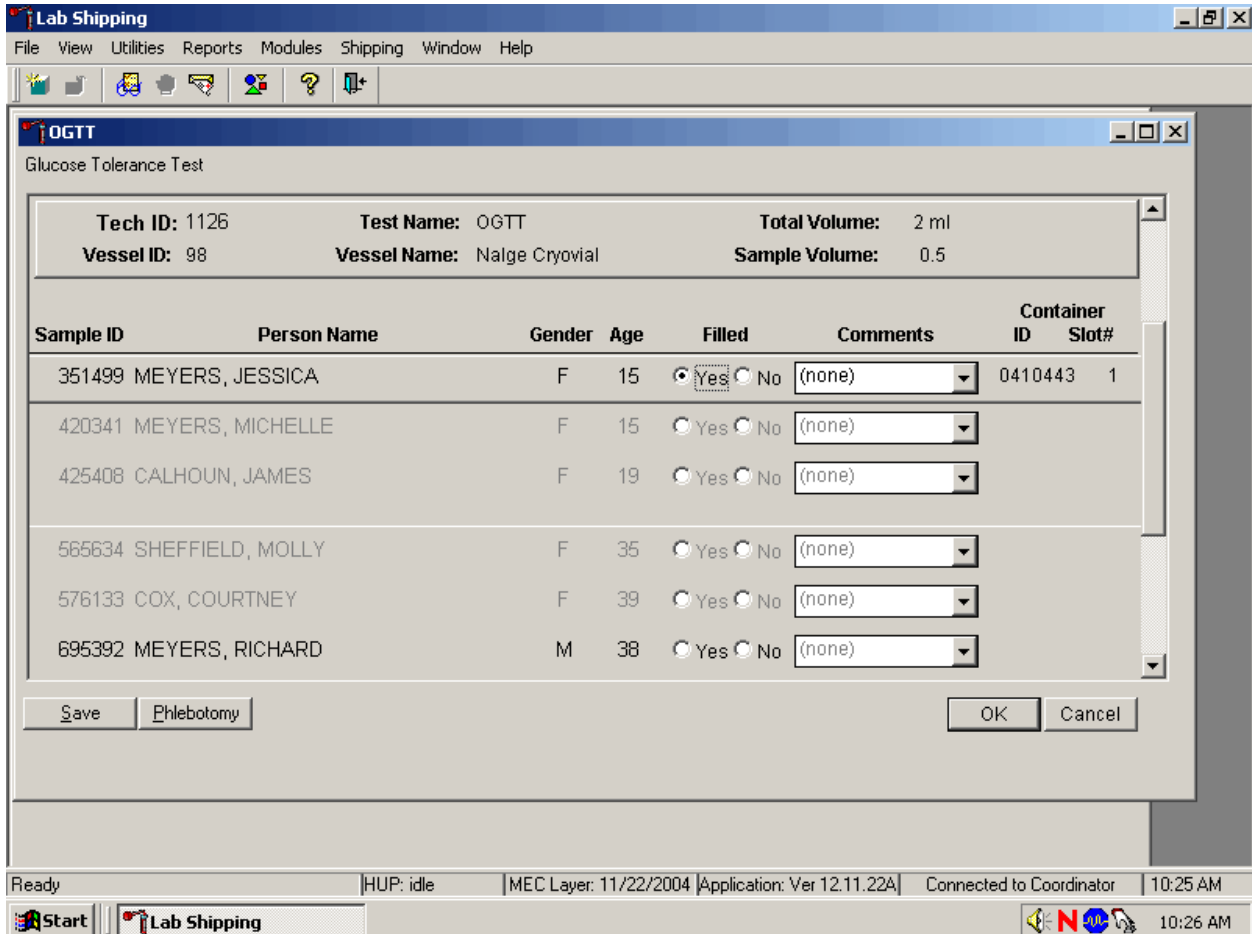
| Sample ID | Person Name | Gender | Age | Filled | Comments | Container ID | Slot# |
|-----------|------------------|--------|-----|--|----------|--------------|-------|
| 351499 | MEYERS, JESSICA | F | 15 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 420341 | MEYERS, MICHELLE | F | 15 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 425408 | CALHOUN, JAMES | F | 19 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 565634 | SHEFFIELD, MOLLY | F | 35 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 576133 | COX, COURTNEY | F | 39 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |
| 695392 | MEYERS, RICHARD | M | 38 | <input type="radio"/> Yes <input type="radio"/> No | (none) | | |

At the bottom of the window, there are buttons for 'Save', 'Phlebotomy', 'OK', and 'Cancel'. The system tray at the bottom shows the time as 10:23 AM and the application version as 12.11.22A.

The OGTT processing window lists the vessel requirements across the top. SPs are listed separately in rows. The upper section of the Glucose Tolerance Test window contains the following information: Tech ID, Vessel ID (98), Test Name (OGTT), Total Volume (2 ml), Vessel Name (Nalge cryovial), and Sample Volume (0.5.) The lower section of the window contains columns for Sample ID, Person Name (Last, First), Gender, Age, Filled Yes and No radio buttons, Comments text box, and a Container ID/Slot # column N. Use the Phlebotomy button to view the SP's original venipuncture protocol and updated results. Use the Save button to save the results to the database. Use the OK button to

save the results to the database and close the module. Use the Cancel button to close the window without saving any data to the database.

Record blood processing results for each SP. Individually mark each vessel as Filled–“Yes.”

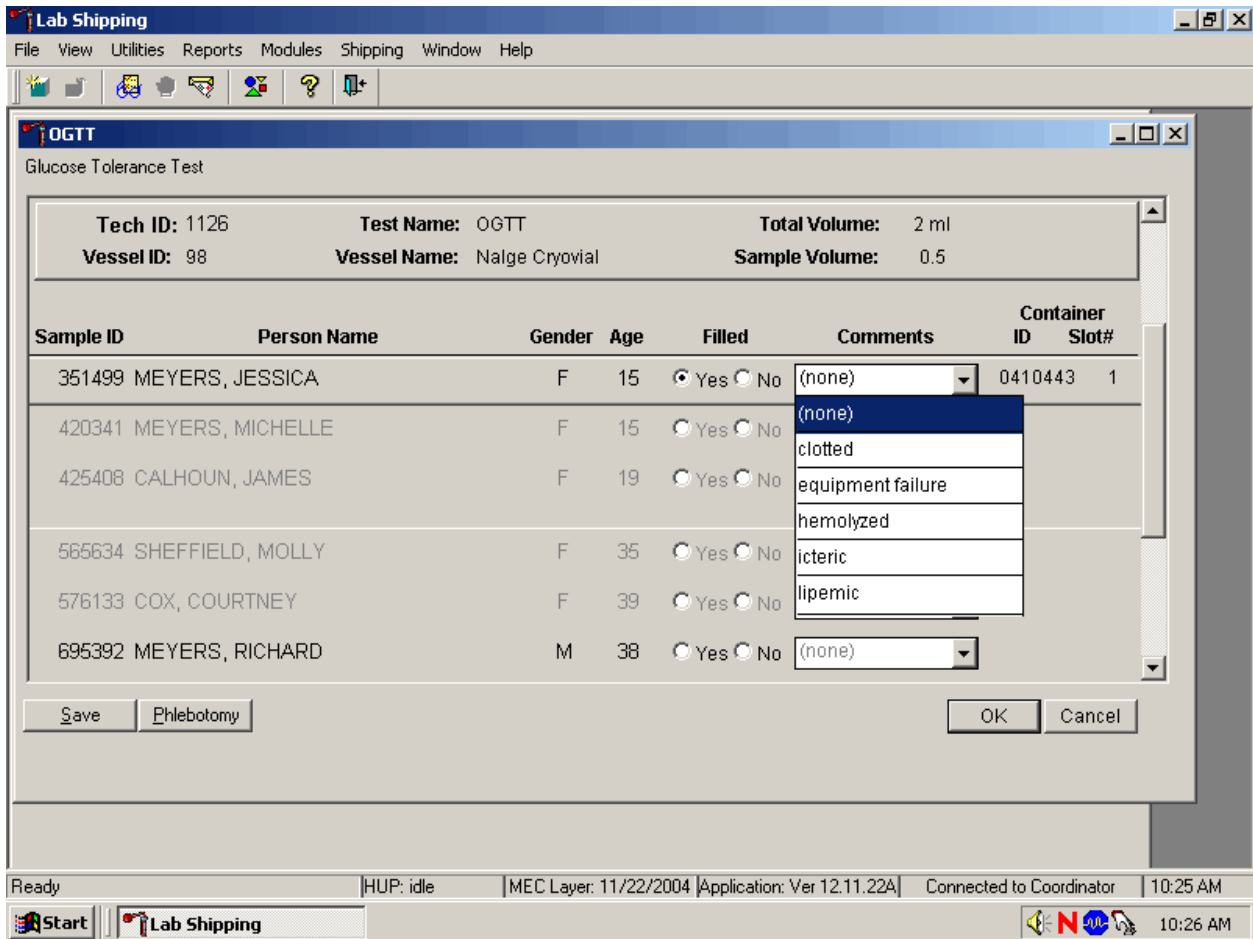


Only SPs who have had the second 2-mL gray top tubes marked as collected in the OGTT application are eligible to be processed. Once the tube is collected, the row turns from gray to black, indicating that the SP is ready to be marked as processed. To mark an individual vessel as collected or Filled–“Yes” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As each vessel is marked as Filled–“Yes,” it is automatically assigned to a slot in an existing (open) container.

Quality comment codes are available to describe the quality of the specimen.

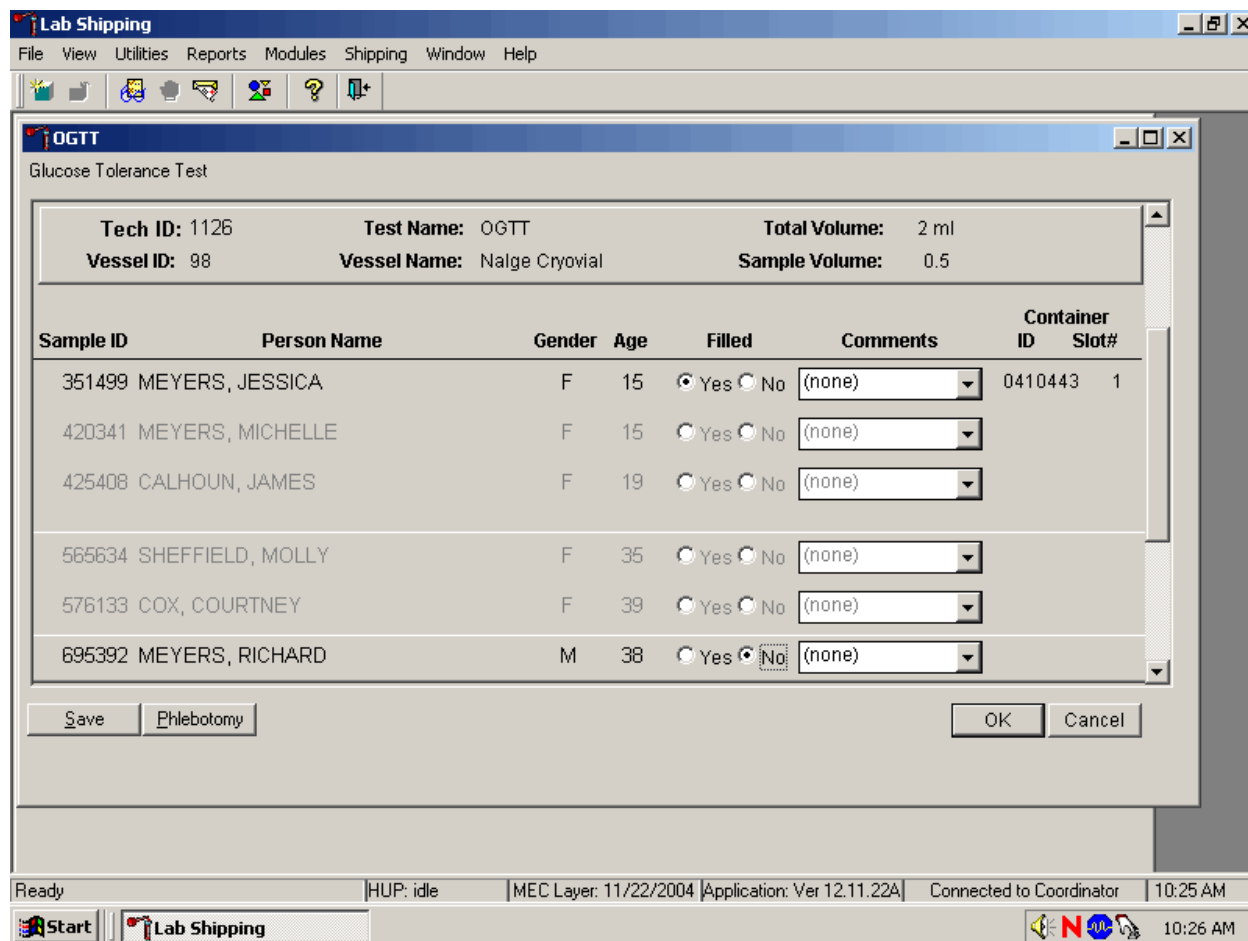
| Comment for filled vessels | Use when: |
|----------------------------|---|
| clotted | The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting. |
| equipment failure | Pipettes are malfunctioning. |
| hemolyzed | There is red appearance to the serum or plasma. Hemolysis refers to the abnormal lysis of erythrocytes. Hemolysis can occur before venipuncture (<i>in vivo</i> hemolysis) or during the analytic procedure (<i>in vitro</i> hemolysis). If <i>in vivo</i> , hemolysis will give plasma a red color. Use when describing visible hemolysis, which occurs when the concentration of hemoglobin exceeds 200 mg/L. |
| icteric | There is visible orange color to the serum or plasma. Icteric refers to orange color imparted to a sample because of the presence of bilirubin. Bilirubin present in serum results in visible “jaundice” color when the concentration of bilirubin is above 430 umol/L. |
| lipemic | There is turbid appearance to the serum or plasma. Lipemia refers to the presence of lipid particles (usually very low-density lipoprotein) in a sample, which gives the sample a turbid appearance. Plasma appears visibly lactescent or lipemic when the concentration of triglycerides exceeds 4.6 mmol/L. |

Attach a comment to an individual filled vessel.



To attach a quality control comment to a filled vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (c, e, h, i, l).

Record blood processing results for each SP. Individually mark each vessel as Filled–“No.”

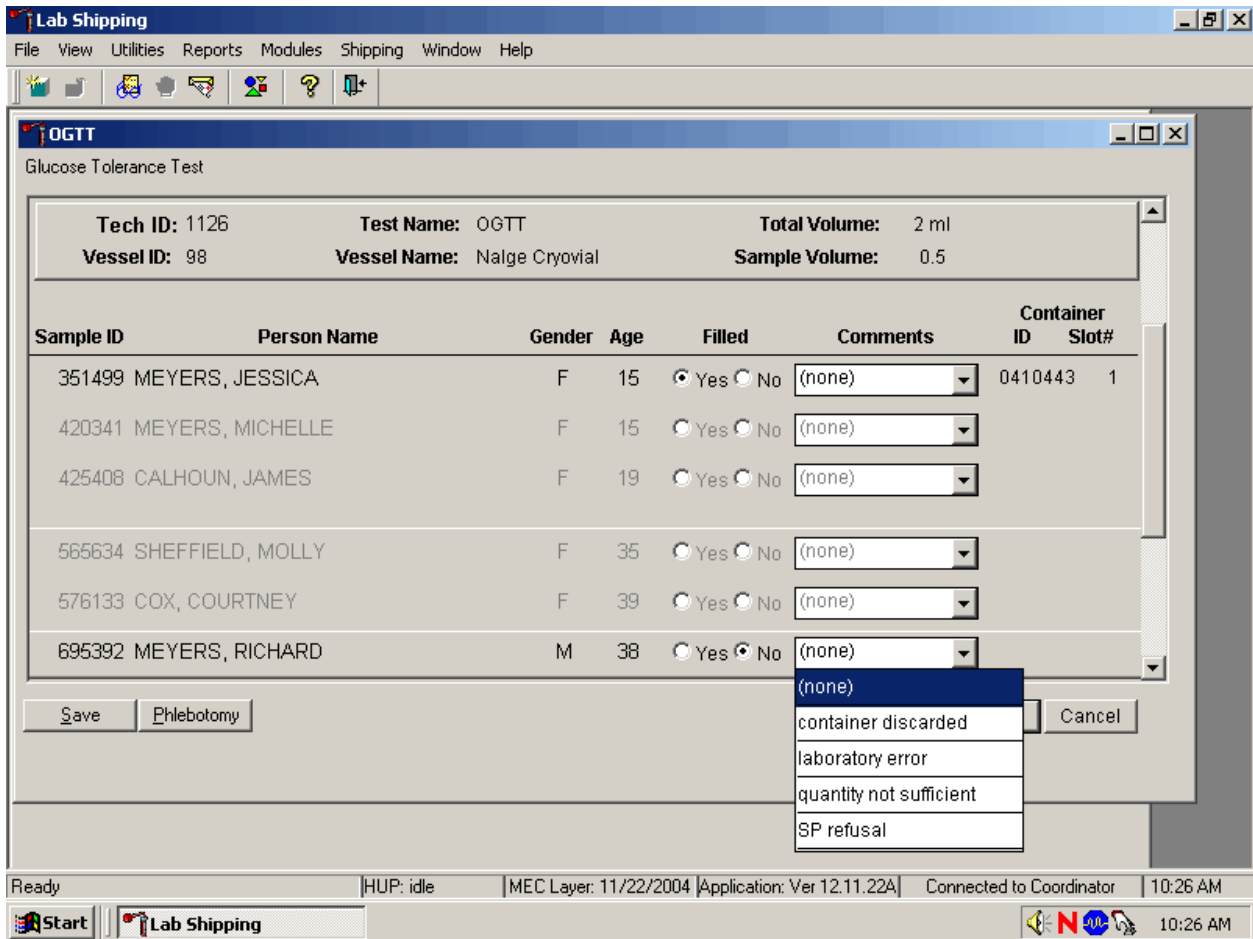


To mark vessel 98 as not collected or Filled–“No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. Vessels marked as “No” require a comment.

Enter comment codes to describe the reasons why a vessel is marked as Filled–“No,” or why the protocol is incomplete.

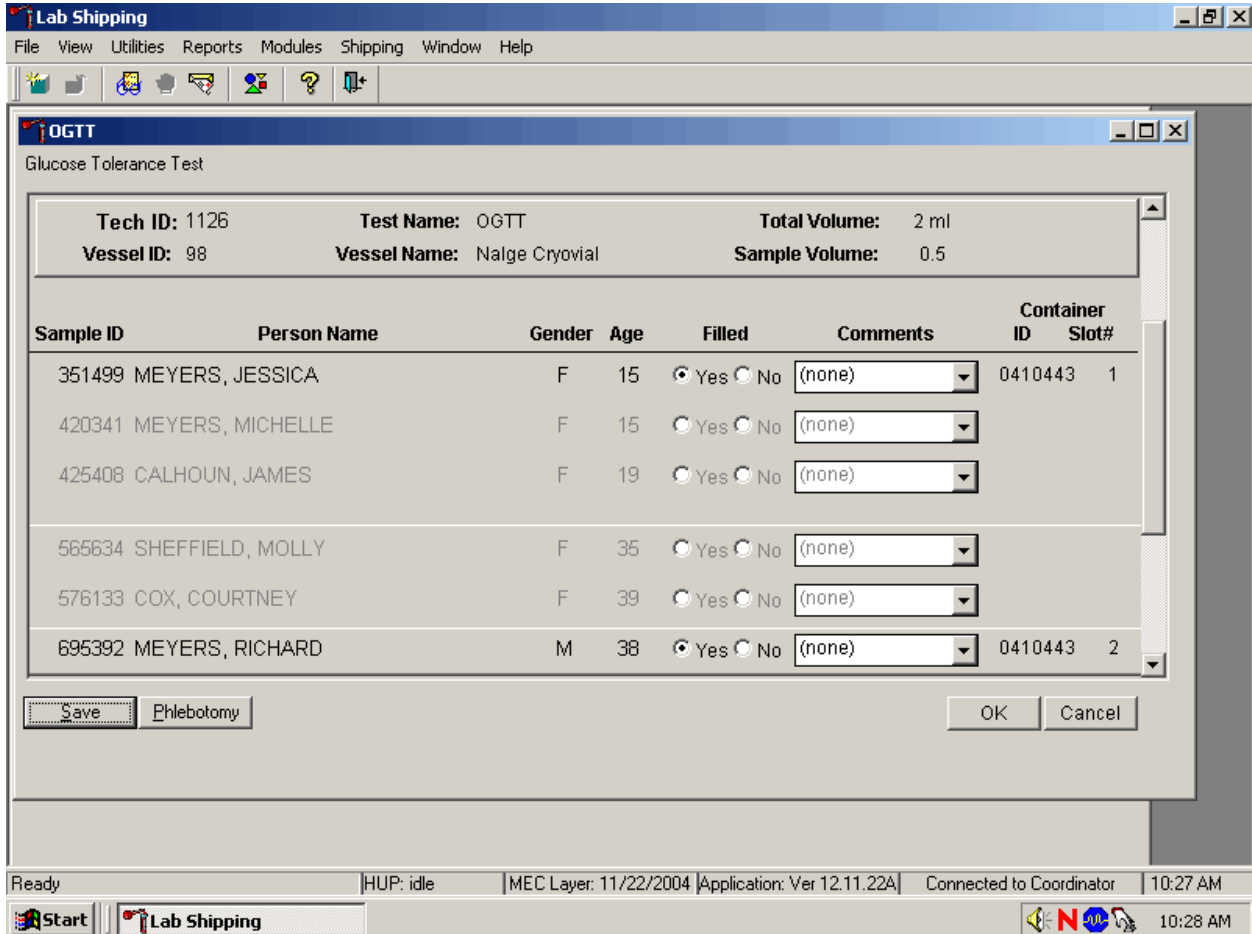
| Comment for not filled vessels | Use when: |
|--------------------------------|---|
| container discarded | Do not use this comment. |
| laboratory error | A tube breaks in the centrifuge, contents spill, or other technologist error. |
| quantity not sufficient | Quantity of blood is not sufficient to complete the protocol. |
| SP refusal | The SP refused the blood draw. |

Attach a comment to an individual Filled–“No” vessel.



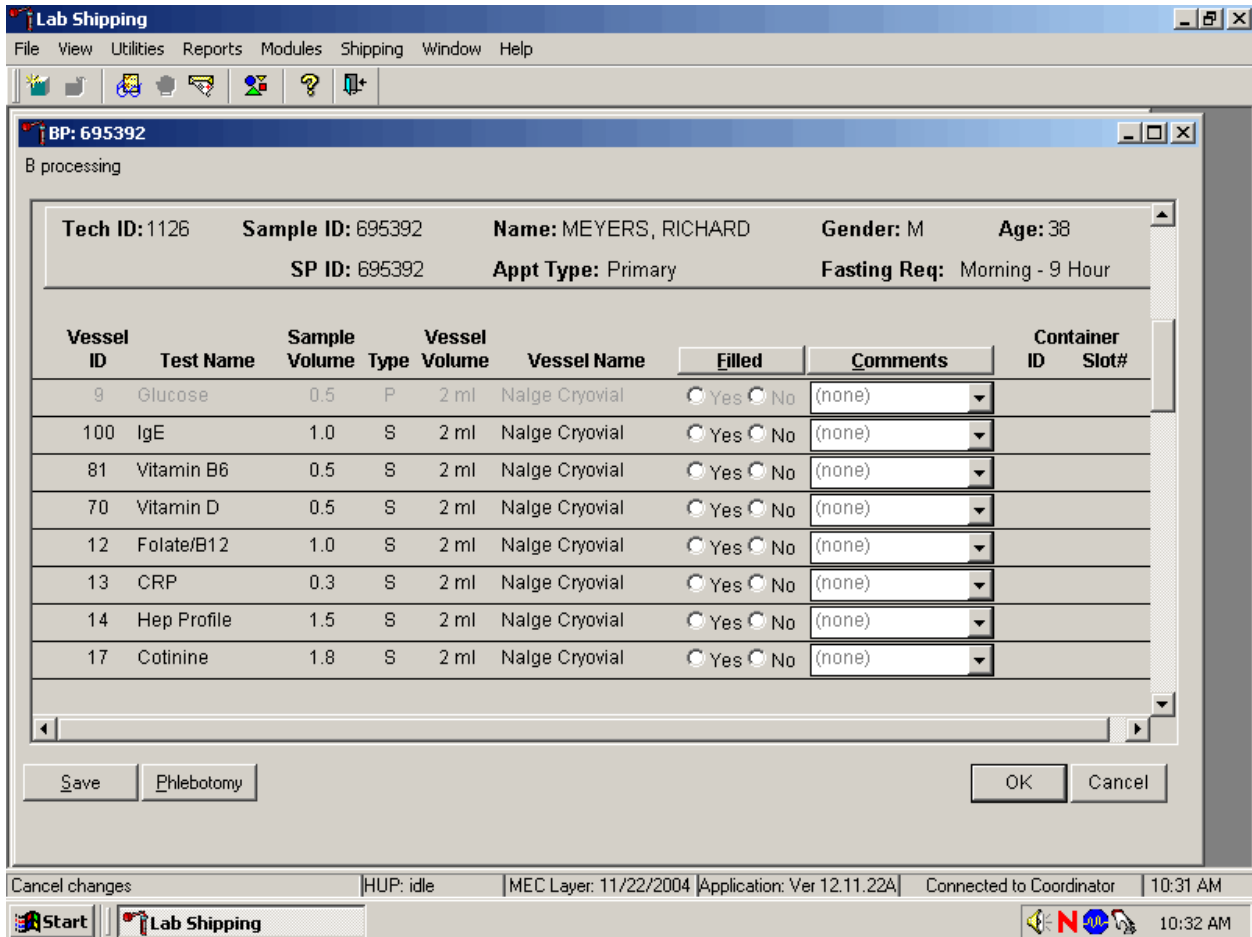
To attach a Filled–“No” comment to a vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

Continue to enter results as vessels are processed. Review the information in the OGTT processing window and save the data to the database.



Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button, and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button, and left click.

It is not possible to mark vessels 9 (glucose) and 23 (insulin) in the blood processing module after the second 2-mL gray top tube has been marked as collected in phlebotomy. They are grayed out on the blood processing window.



Process the blood from the first venipuncture as soon as possible. Contact the system programmer if the blood tubes for vessels 9 and 23 were drawn before the second 2-mL gray top tube was marked as collected in phlebotomy.

During the OGTT blood draw (two hours after the initial venipuncture and after the SP has consumed the Trutol), the phlebotomist will draw any tubes that were missed during the first venipuncture. Add the “Post OGTT draw” comment to any blood vessel processed or filled from blood collected during the OGTT blood draw.

The screenshot shows the 'Lab Shipping' application window. The main window title is 'BP: 695392' and the status is 'B processing'. The patient information is as follows:

- Tech ID: 1126
- Sample ID: 695392
- Name: MEYERS, RICHARD
- Gender: M
- Age: 38
- SP ID: 695392
- Appt Type: Primary
- Fasting Req: Morning - 9 Hour

Below the patient information is a table of blood vessels with the following columns: Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Filled (Yes/No), Comments, Container ID, and Slot#.

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|----------------|--------------|-------|
| 94 | PTH 2 | 1.0 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | Post OGTT draw | 0410442 | 4 |
| 77 | HPV Serum | 0.5 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | Post OGTT draw | 0410432 | 3 |
| 79 | Vitamin C | 0.1 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | Post OGTT draw | 0410434 | 4 |
| 18 | Biochem | 0.8 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | Post OGTT draw | 0410409 | 4 |
| 23 | Insulin | 1.0 | S | 2 ml | Nalge Cryovial | <input type="radio"/> Yes <input checked="" type="radio"/> No | (none) | | |
| 22 | HIV | 0.5 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | Post OGTT draw | 0410411 | 1 |
| 24 | HSV | 0.2 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | Post OGTT draw | 0410413 | 2 |
| 15 | Vit A/E/Car | 0.5 | S | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | Post OGTT draw | 0410407 | 3 |

At the bottom of the window, there are buttons for 'Save', 'Phlebotomy', 'OK', and 'Cancel'. The taskbar at the bottom shows the system is 'Ready', 'HUP: idle', 'MEC Layer: 11/22/2004', 'Application: Ver 12.11.22A', 'Connected to Coordinator', and the time is '10:33 AM'.

To attach a quality control comment to an individual filled vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (c, e, h, I, l, p.)

To collectively assign the same comment to all vessels, use the mouse to direct the mouse arrow to the Comments button on the top of the radio buttons, left click, drag the arrow to {Filled Comments}, drag the mouse arrow to the correct choice, and left click. Alternatively, to assign the same comment to all filled vessels type [Shift] [C/c], and the first letter of the correct choice (i, l, e, c, h, p.)

12.9.3 Vessel 98 Storage Protocol

Fill the vessels, enter the OGTT processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Exhibit 12-7.

Exhibit 12-7. Storage protocol for GTT

| Shipping Location | Vessels | Conditions | Vessel Storage |
|----------------------------|---------|------------|--------------------|
| NHANES Diabetes Laboratory | 98 OGT | Frozen | 9 x 9 two inch box |

12.9.4 Vessel 98 Shipping Protocol

Ship the OGTT container weekly on dry ice to the NHANES Diabetes Laboratory Exhibit 12-8 describes the shipping protocol.

Exhibit 12-8. GTT shipping protocol

| Location | Vessels | Conditions | Vessel storage | Shipping frequency |
|--------------------------------------|---------|------------|--------------------|--------------------|
| Blood | | | | |
| NHANES Diabetes Laboratory Vessel 98 | OGTT | Frozen | 9 x 9 two inch box | Weekly |

Pack the container in the same shipper as vessels 9 and 23. Close the container using procedures described in Section 9.9 of the *Laboratory Procedures Manual*. Assign the closed container(s) to or associate closed containers with the same airbill that was created for the frozen shipper being sent to the NHANES Diabetes Lab. Exhibit 12-9 includes the contract laboratory address. Use procedures described in Section 9.10 of the *Laboratory Procedures Manual*. Follow the steps listed in Section 9.11 to create the shipping manifest and to send the electronic file. Pack and label the shipper using procedures described in Section 9.13 of the *Laboratory Procedures Manual*.

Exhibit 12-9. Contract laboratory addresses

| Laboratory/destination specimen shipment address | Vessels/assays | Conditions | Contact name Telephone number |
|--|---------------------------------------|------------|-------------------------------|
| NHANES Diabetes Laboratory Jean Bucksa Fairview-University Medical Center 420 Delaware St SE Mayo L275 Minneapolis, MN 55455 | 9/Glucose 23/Insul/Cpep 98/OGTT | Frozen | Jean Bucksa (612) 273-3645 |

12.10 Performing the OGTT on SPs Who do not Speak English

When the MEC staff must conduct the OGTT procedure with an SP who does not speak English and the staff member does not speak the language of the SP, a translator who does speak the language of the SP assists the phlebotomist.

The translator stays with the phlebotomist and the SP **for the entire procedure**. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the examination.

12.10.1 Convert Screen Text to English or Spanish

Convert exam screen text from English to Spanish or from Spanish to English at any time before, during, or after an exam.

To view the exam screen text in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S/s]. To return exam screen text to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E/e].

| | |
|--------------------------|--|
| English <i>Ctrl+E</i> | Toggle option to set exam language to English. |
| Spanish <i>Ctrl+S</i> | Toggle option to set exam language to Spanish. |

The following eight screenshots document the English and official Spanish translations for the phlebotomy and OGTT components:

- Phlebotomy Interview English;
- Phlebotomy Interview Spanish;
- Fasting Questionnaire English;
- Fasting Questionnaire Spanish;
- Exclusion Questions English;
- Exclusion Questions Spanish;
- Trutol Administration English; and
- Trutol Administration Spanish.

Phlebotomy Interview English

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 515414 Name: PATTON, BEN Age: 34 years Gender: Male Date: 10/26/2004 Time: 09:09 AM

Phlebotomy Interview

Do you have hemophilia?

Have you received cancer chemotherapy in the past four weeks?

1 of 4 End of Section Close Exam Finish

Start Phlebotomy GTT Subsystem 9:09 AM

Phlebotomy Interview Spanish

Phlebotomy [Window Control Icons]

File View Utilities Reports Window Help

[Icons]

Phlebotomy: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm [Window Control Icons]

SP ID: 515414 Name: PATTON, BEN Age: 34 years Gender: Male Date: 10/26/2004 Time: 09:09 AM

Phlebotomy Interview

¿Tiene hemofilia?

¿Ha recibido tratamiento de quimioterapia para el cáncer en las

[Navigation Icons] 1 of 4 [End of Section] [Close Exam] [Finish] [Next Icon]

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.21B | Connected to Coordinator | SP assigned to room | 09:09 AM

Fasting Questionnaire English

Phlebotomy [Window Icons]

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm [Window Icons]

SP ID: 515414 Name: PATTON, BEN Age: 34 years Gender: Male Date: 10/26/2004 Time: 09:09 AM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? [Do not include soda de dieta, café sin azúcar ni leche o té con sacarina o 'Equal'] [:] [] [//]

Have you had any of the following since

Coffee or tea with cream or sugar? [Include milk or non-dairy productos lácteos.] [] [:] [] [//]

Alcohol, such as beer, wine, or liquor? [] [:] [] [//]

Gum, breath mints, lozenges or cough drops, or other cough or cold medicina para la tos o el resfriado? [] [:] [] [//]

Antacids, laxatives, or anti-diarrheals? [] [:] [] [//]

Dietary supplements such as vitamins and minerals? [Include [Incluya multivitaminas y suplementos nutritivos individuales.] [] [:] [] [//]

Fasting Hours Minutes

[Navigation Icons] 2 of 4 [End of Section] [Close Exam] [Finish] [Next Icon]

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.21B | Connected to Coordinator | SP assigned to room | 09:10 AM

Fasting Questionnaire Spanish

Phlebotomy [Window Icons]

File View Utilities Reports Window Help

[Icons]

Phlebotomy: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm [Window Icons]

SP ID: 515414 Name: PATTON, BEN Age: 34 years Gender: Male Date: 10/26/2004 Time: 09:09 AM

Fasting Questionnaire

¿Cuándo fue la última vez que comió o bebió algo que no haya sido agua sola? [No incluya soda de dieta, café sin azúcar ni leche o té con sacarina o 'Equal'] [: [] [//]

Ha tomado o comido algo de lo siguiente ¿desde

¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.] [] [: [] [//]

¿Alcohol, tal como cerveza, vino o licor? [] [: [] [//]

¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado? [] [: [] [//]

¿Antiácidos, laxantes, o antidiarreicos? [] [: [] [//]

¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.] [] [: [] [//]

Fasting Hours Minutes

[Navigation Icons] 2 of 4 [End of Section] [Close Exam] [Finish] [Next Icon]

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.21B | Connected to Coordinator | SP assigned to room | 09:10 AM

Exclusion Questions English

GTT Subsystem [Window Control Icons]

File View Utilities Reports Window Help

[Icons]

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm [Window Control Icons]

SP ID: 671247 **Name:** PATTON, TRISH **Age:** 36 years **Gender:** Female **Date:** 10/26/2004 **Time:** 09:23 AM

Exclusion Question

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)

Length of Fast 12 hours 23 minutes

[Navigation Icons] 1 of 3 [End of Section] [Close Exam] [Finish] [Next Question Icon]

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.25B | Connected to Coordinator | SP assigned to room | 09:24 AM

Exclusion Questions Spanish

GTT Subsystem

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 671247 Name: PATTON, TRISH Age: 36 years Gender: Female Date: 10/26/2004 Time: 09:23 AM

Exclusion Question

¿Está usted ahora tomando insulina? (Insulina: Producto químico que se usa para el tratamiento de la diabetes. Típicamente, el paciente mismo se administra la insulina con una jeringa.)

¿Está usted ahora tomando píldoras para la diabetes para reducir el nivel de azúcar en la sangre? (A veces estos son llamados agentes orales o agentes orales hipoglucémicos.)

Length of Fast **12 hours 23 minutes**

1 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.25B | Connected to Coordinator | SP assigned to room | 09:23 AM

Trutol Administration English

Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 900970 Name: MITCHELL, LAURIE Age: 46 years Gender: Female Date: 10/26/2004 Time: 10:21 AM

Trutol Administer Information

Length of Fast

Your weight is LBs

Amount to drink is

Please drink this solution within 10 minutes.

Timer

Start

Stop

Total

Amount of solution the SP drank

2 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 10:21 AM

Trutol Administration Spanish

Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 900970 Name: MITCHELL, LAURIE Age: 46 years Gender: Female Date: 10/26/2004 Time: 10:21 AM

Trutol Administer Information

Length of Fast

weight LBs

Amount to drink is

Por favor tómesese esta solución dentro de 10

Timer

Start

Stop

Total

Amount of solution the SP drank

2 of 3

End of Section Close Exam Finish

Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 10:22 AM

13. QUALITY CONTROL AND QUALITY ASSURANCE – POLICIES AND PROCEDURES

National Health and Nutritional Examination Survey 2005
National Center for Health Statistics
Centers for Disease Control and Prevention
Public Health Service
Department of Health and Human Services

Current revision: 01/06/2005

Approval: _____ Date: _____

Onno W. VanAssendelft, M.D., Ph.D.
Clinical Consultant, NCHS

Approval: _____ Date: _____

Brenda Lewis, MPH, MT (ASCP)
Laboratory Director, NCHS

Approval: _____ Date: _____

Barbara Lindstrom, MSPH, MT (ASCP)
Technical Supervisor, Westat

Abbreviations

NCHS - National Center for Health Statistics
CDC - Centers for Disease Control and Prevention
NHANES - National Health and Nutrition Examination Survey
MEC - mobile examination center
LPM - NHANES Laboratory Procedures Manual
U.S. - United States
CBC - complete blood count
IRB - institutional review board
QC - quality control
QA - quality assurance
IQAP- Interlaboratory Quality Assurance Program
PT - proficiency testing
CLIA - Clinical Laboratory Improvement Amendments of 1988
HCFA - Health Care Financing Administration
ISIS - Integrated Survey and Information System
PC - personal computer
LAN - local area network

This policies and procedure quality control and quality assurance chapter is an adjunct to the Westat Policies Manual.

13.1 Safety

13.1.1 Introduction

NCHS and Westat maintain an ongoing Health and Safety Committee that acts in cooperation with the CDC Office of Health and Safety to assure safe working conditions for technologists in the NHANES mobile examination center (MEC). Safety precautions for all methods are documented in the Biosafety appendix in the *NHANES Laboratory Procedures Manual, 2005*. This manual is readily available to all laboratory staff. In addition to annual safety training, the NCHS Biomedical Engineer performs safety inspections at the beginning of each location. The technical supervisor assures that the primary laboratory analyst reads and is familiar with safety precautions.

13.2 Specimen Submission and Handling

13.2.1 Introduction

The goal of specimen submission and handling is to optimize the accurate and reliable measurement of analytes of interest. Each analytical procedure used in NHANES is documented in the *NHANES Laboratory Procedures Manual (LPM)*. Each method in the LPM specifies the procedure to be used for preparation of the sample person, specimen collection, labeling, processing, and preservation, and conditions for specimen transport that are appropriate for that method. The methods may refer to the NHANES blood collection protocol, or urine collection protocol, noting any special requirements specific to the particular method. These protocols are a starting point due to the special contamination requirements needed for collection of specimens analyzed for metals.

13.2.2 Identification of Specimens

Personal identifiers (e.g., names) are not included on test specimens. NHANES uses a random internal specimen ID number to identify and track individual samples. The Integrated Survey and Information System (ISIS) system at Westat and the National Center for Health Statistics (NCHS) maintains information that links the specimen ID number to the sample person's name.

13.2.3 Questions on Specimen Submission and Handling

The chief medical technologist addresses questions concerning specimen collection including handling and testing.

13.3 Test Requisition

13.3.1 Introduction

Under a congressional mandate (Section 306 of the Public Health Service Act 42 U.S.C.242k) since 1960, NCHS has collected data on the health of the people of the United States through interviews and extensive physical examinations. Seven surveys using health examination procedures have been completed since 1960. As in previous NHANES programs, the survey's primary purpose is to produce descriptive statistics that can be used to measure and monitor the health and nutritional status of the civilian, noninstitutional U.S. population. Data collection for this survey involves about 7,000 sample persons per year, of whom about 5,000 per year are expected to be examined. Data collection begins in January 2005 and continues for about 8 years at 15 different locations (stands) per year.

NHANES performs a complete blood count on sample persons 1 year and older. A record of the test result report is maintained for a period of 7 years by Westat, the primary NHANES contractor and by NCHS for an indefinite period.

13.3.2 Laboratory Tests

“Panic” or abnormally high CBC results are reported to the sample person. The report includes laboratory tests that will be performed. The NCHS medical officer or MEC physician involved in the measurement may also confer with the sample person to obtain any other pertinent information, which might facilitate the laboratory measurement process.

13.3.3 Human Subjects Review

The NCHS IRB as defined by the CDC institutional review board (IRB) criteria shall perform all laboratory analyses conducted on human specimens, which are part of a “survey,” only after approval of the survey.

13.4 Test Records

13.4.1 Introduction

The purpose of test records is to ensure correct and reliable identification of sample person specimens and to report accurate test results. The laboratory test record system is distinguished from the test report that is provided to the sample person.

13.4.2 Components of Test Records

Test records include:

- Person performing the test (may be identified by initials);
- Printed or electronically stored output from instrumentation that the technical supervisor judges as necessary to document the analytical result;
- Date of specimen analysis;
- Date and time specimen was collected by the laboratory; and

- Condition of specimens that did not meet criteria for acceptable specimens (e.g., hemolyzed or insufficient quantity for test).

Test records are maintained for at minimum of 7 years. Records may be bound in laboratory notebooks, in loose-leaf form, or stored electronically.

13.5 Test Report

13.5.1 Introduction

The laboratory report is provided promptly to the sample person. This occurs as soon as the quality control has been reviewed and approved. The laboratory maintains confidentiality of the sample person results since it identifies samples only by a specimen ID number. Westat and NCHS maintain the link between the specimen ID number and the identity of the sample person.

13.5.2 Review, Approval, and Release of Test Results

Upon completion of laboratory testing, results are reviewed by laboratory staff responsible for review of the quality control results to assure the measurement process was in-control for each of the sample person's analyses.

For NHANES surveys, the initial evaluation of quality control (QC) results is accomplished electronically by comparing the QC results to QC limits stored in a relational database. The laboratory staff performing the CBC reviews these QC performance results and ensures that only acceptable sample persons' (SPs') data are reported.

Review and approval of the results by the MEC physician are documented. Review by the MEC physician includes an evaluation of the consistency of sample person results with information that may be available on the sample person (e.g., age, sex). All SPs' samples are run in duplicate whenever possible. If inconsistent results are noted, and an adequate sample is available, the test is repeated a third time. If inconsistent results are again noted, the sample is run a fourth time. If the amount of sample is inadequate for repeat, then the sample person is informed verbally and in writing of the inconsistent result.

The paper hard copy of the results with the NCHS medical officer's signature is filed by Westat and kept with the test record for 7 years. The NCHS medical officer signs all laboratory reports before release.

Laboratory reports are released only to the authorized sample person. Each method includes a description of actions taken such as when results are markedly elevated or are "panic values." The sample person is contacted immediately by the MEC physician with such results.

In addition to the written laboratory report, the data may be transmitted electronically in a suitable format; for example, a SAS data set or an ASCII file by email to the Westat home office and to NCHS.

13.5.3 List of Methods and Method Details

NHANES maintains a *Laboratory Procedures Manual* (LPM) which includes detailed descriptions of each analytical procedure including analytical sensitivity, specificity, and accuracy, interfering substances, and other information.

13.5.4 Format of the Test Report

The test report includes:

- The name and address of NCHS;
- The test result;
- Units of measurement;
- Reference range for each analyte, if available;
- The condition of specimens not meeting the laboratory's criteria for acceptability; and
- Signature of the NHANES medical officer.

The laboratory report consists of:

- 1st page: a cover letter; and
- 2nd page: an analysis summary table.

A corrected laboratory report has the same format, except the words “corrected laboratory results” replace the words “laboratory results” in the letter and title of the pages. In addition, in the text of the cover letter, the date of the previous laboratory report is noted.

13.5.5 Format for Laboratory Report Cover Letter

An example of the Laboratory Report cover letter (report of findings) is available upon request.

13.5.6 Format for Listing of Laboratory Results

An example of the laboratory results is available upon request.

13.6 Quality Control

13.6.1 Introduction

Most quantitative analytical procedures involve several operations, or steps, and each operation is subject to some inaccuracy or imprecision or to the possibility of a mistake. The immediate aim of quality control is to ensure that the analytical values produced by a clinical laboratory are sufficiently reliable for their intended purpose. A broader objective is to ensure that all laboratories produce analytical values that meet acceptable standards of precision and accuracy.

Quality control in laboratory medicine is the study of those errors that are the responsibility of the laboratory, and the procedures used to recognize and minimize them. An alternate term, “quality assurance,” represents the techniques available to ensure with a specified degree of confidence that the

result reported by the laboratory is correct. Both “precision control” (the agreement between replicate measurements) and “accuracy control” (the agreement between the mean estimate of a quantity and its true value) are evaluated to establish this degree of confidence.

A quality control program also monitors laboratory performance to detect excessive random or systematic error. Factors contributing to random error are those that affect the reproducibility of the measurement. These include instability of the instrumentation, variations in the temperature, and variations in reagents and calibrators, handling techniques such as pipetting, mixing, and timing, and operators. Terms used to describe random error include precision, imprecision, reproducibility, and repeatability. Systematic error describes the error that is consistently low or high. Factors that contribute to systematic error are independent of the analyte concentration. Examples of these factors include interfering substances or incorrect assignment of the amount of substance in the calibrator.

A good quality control program includes both internal (intralaboratory) and external (interlaboratory) surveillance and monitors the following five parameters:

- **Clerical Error:** This includes properly documented acknowledgment of transmittal and receipt of specimens (for example, “logging in”), proper labeling of all specimens, correct assignment of laboratory values to the proper SP ID number, and maintenance of proper records for all specimens for future reference.
- **Techniques:** This includes continued assurance that all personnel performing an assay understand the principles underlying a particular assay and are cognizant of the proper technique for that assay; that all personnel use the same technique for a particular assay; that there is ready access to a current technique manual; and that periodic review is undertaken to ensure use of the most current and reliable techniques.
- **Reagents and Materials:** This includes confirmation of commercial standards and controls before they reach the bench; proper labeling of reagents, particularly those prepared in the laboratory; ensuring all reagents in use are not outdated; having an adequate supply of current reliable reagents; proper calibration of equipment, such as pipettes; and proper washing of glassware.
- **Bench Performance:** This includes the use of controls and standards for each assay performed, a technique based on sound statistical principles which allows the technologist performing the assay to detect error outside of previously determined limits before reporting data; documentation of daily bench performance for detection of less obvious error (particularly those which tend to accumulate over time, so-called “drift”); and established procedures to be followed wherever error is found to exceed previously determined limits.

- **Instrumentation:** This includes periodic preventive maintenance of all instruments in use in the laboratory and documentation that each instrument is maintaining a previously determined level of each performance at each check.

In this context, QC procedures monitor and evaluate the quality of the analytical testing process of each method to ensure the accuracy and reliability of test results. Thus, QC procedures referenced here refer to the analytical phase of testing and not to the preanalytic or postanalytic phases. Quality assurance (QA) addresses all three phases of measurement: preanalytic, analytic, and post-analytic. QC is therefore viewed here as one part of the overall QA process.

13.6.2 Method Specific QC Procedures

Specific QC procedures exist for each analytical laboratory procedure in the Laboratory Procedures Manual. The following are some general aspects of QC procedures.

13.6.3 QC Definitions

Internal (“Bench”) Quality Control

For purposes of this document, internal quality control is the evaluation of analytical performance that includes QC bench samples for which the analyst knows the expected measurement result. Internal commercial quality control materials contain predetermined amounts of analyte in the matrix, qualify under Clinical Laboratory Improvement Amendments (CLIA) as “calibration materials,” and may be used as a “calibration verification” as defined by CLIA.

- **External (“Blind”) Quality Control** – For purposes of this document, external quality control is the evaluation of analytical performance that includes QC samples for which the analyst does *not* know the expected measurement result. The analyst is “blind” to the expected measurement result. Examples include proficiency testing samples.
- **Interlaboratory Quality Assurance Program (IQAP)** – For purposes of this document, NHANES participates in Beckman Coulter’s® IQAP program. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance.

- **Proficiency Testing** – For purposes of this document, proficiency testing is one method of external quality control in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 3 months).
- **Analytical Run (sometimes referred to just as a run)** – An analytical run is a set of samples analyzed in a time within which the measurement system is considered to have stable accuracy and precision. The time for a run may not exceed 24 hours. An analytical run usually consists of both quality control specimens and sample person specimens.
- **Calibration** – Defined by CLIA as “the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.”
- **Calibration Material** – Defined by CLIA as “a solution which has a known amount of analyte weighed in or has a value determined by repetitive testing using a reference or definitive test method.” Many standards are therefore calibration materials.
- **Calibration Verification** – Defined by CLIA as “the assaying of calibration materials in the same manner as sample person samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for sample person test results.”
- **QC Requirements of Each Analytical Run** – Analysis of sample person samples is organized into analytical runs. The minimum QC requirement for an analytical run, which is analyzing sample person specimens, is that the run includes four internal (“bench”) QC specimens.

13.6.4 Overview of the Relationship between Internal QC, Proficiency Testing, and External QC

A Beckman Coulter® technical representative performs instrument setup, verification, and performs and verifies QC checks according to their procedure at the beginning of each stand. Medical technologists perform instrument calibration.

Most laboratory quality control programs include running internal (“bench”) QC with each analytical run to ensure each analytical run is in-control. The laboratory participates in proficiency testing programs administered by an outside scientific group to be sure on a periodic basis that accuracy and precision are within acceptable limits. The IQAP compares NHANES 5C cell control results to other laboratories. These QC systems are used within NHANES. The linearity of the instrument is evaluated at least once a year.

In addition to these systems, NHANES uses calibration materials at the beginning of each stand to standardize the three Beckman Coulter® MAXM instruments and to provide additional objective evaluation of the quality of specimen analysis. S-CAL is a calibration material as defined by CLIA (i.e., “a solution, which has a known amount of analyte, weighed in or has a value determined by repetitive testing using a reference or definitive test method”) that is useful for monitoring method performance.

13.6.5 Internal (“Bench”) QC

The goal of internal QC is to provide a rapid feedback to the analyst on the performance of the measurement process to be sure analytical results and factors affecting analytical results are within acceptable limits. At least three internal QC specimens (5C® Cell Control) are included in each analytical run. The QC material used as internal QC specimen has levels of the analyte, which are useful for monitoring method performance.

The 5C® Cell Control is a hematology reference control used to monitor the performance of instruments with complete CBC and VCS differential technology. The 5C® Cell Control consists of human blood so repeated measurements to monitor daily performance of the instrument system are possible. The 5C® Cell Control Tri-Pack contains three levels—normal, abnormal I, and abnormal II. When used with Beckman Coulter’s® blood diluent, Isoton III, they serve as a check on the accuracy of dilution, WBC counts, RBC counts, platelet counts, hemoglobin determinations, and differential counts.

The technologists run all three levels at the beginning of each session to monitor the precision of the instrument following procedures described in Chapter 7, Section X.B.

Standard Levy-Jennings QC charts are maintained for this internal QC specimen. A separate QC chart is to be maintained for each QC material used for this internal QC specimen. Standard criteria for run rejection based on statistical probabilities are used to declare a run either in-control or out-of-control. No results for a given analyte are reported from an analytical run that has been declared out-of-control for that analyte as assessed by internal (“bench”) QC. Rejection criteria are described in each method procedure in the LPM. Quality control results and remedial actions for out-of-control conditions are documented in a QC logbook.

In addition, a latex control (Latron®) is used to monitor the volume, conductivity, and light scatter (VCS) of the diff mode only. This control is run at the beginning of each day.

The Latron® control is a ready-to-use suspension of latex particles used to monitor differential parameters on the Beckman Coulter® MAXM. These particles pass through the flow cell and produce characteristic electrical signals. It measures these signals as volume, conductivity, and light scatter. The technologist runs the Latron® control immediately following the Latron® primer.

13.6.6 Interlaboratory Quality Assurance Program (IQAP)

All MAXM instruments participate in Beckman Coulter's® Interlaboratory Quality Assurance Program (IQAP.) The Beckman Coulter® Data Management System saves results of 5C® cell controls in files. Technologists transfer the files to a disk and then send the disk to Beckman Coulter®, who compares the results to other laboratories. Beckman Coulter® issues a report that contains a statistical analysis to evaluate performance. The technologists perform this procedure on the last day of each month, at the end of each stand, or when a control lot expires using procedures described in Chapter 7, Section X.D.

13.6.7 Proficiency Testing

Participation in the College of American Pathologist (CAP) proficiency-testing (PT) program is part of the comprehensive quality control program. Each MEC submits results for CAP specimens for evaluation. CAP compares the results to established values and issues a report.

The laboratory will satisfactorily participate in the HCFA-approved PT program for each method used to analyze human samples. Performance in the PT program, along with documentation of remedial action taken for unacceptable performance, is documented in a QC logbook that is available for review.

CAP samples are sent three times a year for hematology. Each shipment includes five 2.5-mL whole blood specimens. Duplicate Beckman Coulter® CBC determinations are performed on each whole blood sample using procedures described in Chapter 7, Section X. PT samples are handled and

analyzed in a manner identical to SP samples. Results are recorded on the CAP forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS.

CAP samples are sent three times a year for qualitative serum and urine hCG. Each serum shipment includes five lyophilized sera specimens and each urine shipment contains five liquid specimens. PT samples are handled and analyzed in a manner identical to SP samples. Results are recorded on the CAP forms and sent to the address specified by CAP Surveys Program Support with a copy to NCHS at the following address:

Brenda Lewis, MPH
National Center for Health Statistics
3311 Toledo Road
6525 Belcrest Road
Hyattsville, MD 20782

13.6.8 Calibration Verification

Calibration verification is defined by CLIA as “the assaying of calibration materials in the same manner as sample person specimens to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory’s reportable range for sample person test results.” Thus, calibration verification assures that the accuracy of the measurement process across the reportable range is maintained over time. For methods approved by FDA, calibration verification is performed according to the manufacturer’s specification and at the frequency recommended by the manufacturer.

Note that the calibration materials must bracket the reportable range; that is, results should not be reported as a numerical value unless they are within the reportable range. If a result is higher than the upper end of the reportable range and the method permits sample dilution, the sample may be diluted to bring it within the reportable range. If dilution has been necessary, the reported value will exceed the upper end of the reportable range. Each analytical procedure specifies acceptable limits for results of analyses of the calibration materials based on the method precision of these materials.

The reliability of analytical values obtained when using a procedure often depends on the quality of the standards and the calibration procedure. The College of American Pathologists (CAP) suggests that automated instruments be calibrated using multiple analytical whole blood specimens or a certified, stabilized whole-blood type preparation. The International Committee for Standardization of

Hematology (ICSH) by its definition requires that a calibrator “be based on or traceable to a reference preparation or material.”

Beckman Coulter® provides the S-CAL® calibrator to meet these requirements. The MAXM uses the S-CAL® kit that requires a calibrator to convert electronic measurements of each sample into accurate results expressed in clinical terms. S-CAL® calibrates the WBC, RBC, Hgb, MCV, Plt, and MPV parameters. It is a stabilized human-blood preparation. S-CAL® is an acceptable alternative to whole blood calibration. Hct, MCH, MCHC, RDW, and the DIFF parameters do not require calibration.

Calibration is a procedure to standardize the instrument by determining its deviation from calibration references and to apply any necessary correction factors. The calibration procedure uses replicate measurements of S-CAL® calibrator. The S-CAL® divides the average result into the calibrator Assigned Value to give an Adjustment Factor. Then, it obtains and adjusts an instrument reading according to the Adjustment Factor.

S-CAL® is used to calibrate the Beckman Coulter® MAXM at the beginning of each stand (once every 6-8 weeks), after replacing any component dealing with dilution preparation, if the Beckman Coulter® representative suggests it, controls demonstrate unusual trends or are outside limits, or when the temperature varies by more than 10°F (5.5°C) from the room temperature during the last calibration.

Instructions for the performance of calibration procedures using S-CAL® calibration are in Section VII of Chapter 7.

13.6.9 X_B Analysis

X_B analysis is a QC method that monitors instrument performance by tracking the MCV, MCH, and MCHC parameters of SPs' samples. These indices are very stable and show little variance between patient samples. This method displays the moving average of SP's samples and compares it to established target values. Target values are MCV = 88.5 (fL), MCH = 29.5 (pg), and MCHC = 33.5 (g/dL or g/100 mL). This method of quality control requires many samples in order to provide valid trends. Coulter indicated that because our population is small and we run samples in duplicate, the abnormal data are overweighted so they do not recommend using this method.

13.6.10 Linearity

The linearity controls verify the reportable range of Beckman Coulter® hematology systems. Linearity is performed at installation, at least yearly, and whenever experiencing an altitude change of 1 mile or more between locations using either Beckman Coulter® Lin-C™ or CAP LN9 survey material.

Beckman Coulter® Lin-C™ linearity controls are human blood components from which repeated measurements verify the reportable range of Beckman Coulter® hematology systems that use both Isoton® III diluent and Lyse S® III diff lytic reagent. Controls contain one each of Ultra Low Range, Low Range, Mid Range, and High Range, and Ultra High Range. Lin-C™ verifies ranges for the following parameters: WBC, RBC, Hgb, and Plt. Beckman Coulter® Lin-C™.

CAP Hematology Calibration Verification/Linearity Survey (LN9) materials are shipped twice per year and consist of 18 3.0-mL liquid specimens. The medical technologist follows all CAP instructions in preparing and running the materials before performing the test. They fill out the CAP result form, make a copy for the logbook, send results to CAP, and send the copy back to the home office at the end of the stand.

13.6.11 Quality Control Records

Records of all quality control results are maintained for at least 7 years. A QC logbook is maintained which documents quality control results, out-of-control conditions, and remedial actions taken to correct out-of-control conditions. The QC logbook also includes copies of results for Proficiency Testing.

13.7 Test Methods, Equipment, Reagents, Supplies, and Facilities

13.7.1 Introduction

Analytical procedures use equipment, reagents, materials, and supplies that are appropriate for achieving acceptable accuracy, precision, analytical sensitivity, and analytical specificity from the method. The documentation of individual analytical procedures included in the *Laboratory Procedures*

Manual (LPM) specifies acceptable equipment, reagents, materials, and supplies. If special requirements concerning water quality, temperature, humidity, electrical power, or other conditions are required for acceptable method performance, then these are described for each procedure in the LPM. Special procedures to monitor these requirements are also included in the documentation of the individual procedure. A lack of requirements in the documentation of the analytical procedure means that the expected day-to-day variation in any of these parameters is acceptable for proper method performance.

Documentation of problems with conditions required (e.g., water quality) for acceptable method performance is maintained in the logbook of the primary instrument used in the analysis. This documentation includes remedial action.

13.7.2 Labeling of Reagents, Solutions, Supplies

Reagents, solutions, and other supplies are labeled to indicate the identity of contents, the concentration (if significant), the recommended storage requirements, the preparation and expiration date, and any other pertinent information required for proper use. Reagent, solutions, and other supplies are not used when they have exceeded their expiration date.

If a method uses a manufacturer's kit, components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

Beckman Coulter® reagents are monitored and documented in the Beckman Coulter® Data Management System and are additionally located on the daily instrument startup result sheet. A copy of all startup results is filed in the quality control notebook and sent back to the home office at the end of each stand. The technologist documents any unusual occurrence in the automated Unusual Occurrence Log or repair of the Beckman Coulter® MAXM in the automated Equipment Tracking System.

Logs are maintained for reagents other than the Beckman Coulter® reagents. The technologist documents reagent use by entering the reagent's name, date made, date put into use, expiration date, and tech ID in the automated Supply Use Control Log. The technical supervisor reviews the Supply Use Control Log at the end of each stand.

13.7.3 Facilities

Laboratories are arranged to ensure that adequate space, ventilation, and utilities are available for all phases of testing: preanalytic, analytic, and postanalytic.

13.8 Analytical Procedure Manual

13.8.1 Introduction

All procedures performed in the laboratory on human specimens are documented in the LPM. A copy of the LPM is maintained at the Westat home office and NCHS. The individual procedure is also available at or nearby the bench site where the procedure is performed.

13.8.2 Contents of the Analytical Procedure Documentation

Each analytical procedure includes, when applicable:

- Requirements for specimen collection and processing including criteria for specimen rejection;
- Step-by-step performance of the procedure including test calculations and interpretation of results;
- Preparation of reagents, calibrators, controls, solutions, and other materials used in testing;
- Calibration and calibration verification procedures;
- The reportable range for sample person test results;
- Quality control procedures;
- Remedial action to be taken when calibration or control results are outside acceptable limits;
- Limitation in methods, including interfering substances;
- Reference range (normal values);

- Life-threatening or “panic values;”
- Pertinent literature references;
- Specimen storage criteria;
- Protocol for reporting panic values;
- Course of action if test system becomes inoperable; and
- Safety considerations for performing the method;

13.8.3 Approval and Record Maintenance

Each procedure is reviewed, approved, signed, and dated by the clinical consultant and technical supervisor and laboratory director of NHANES. Procedures are reapproved, signed, and dated if the director changes. Each change in a procedure is approved, signed, and dated by the current director. The procedure includes the dates of initial use and discontinuance, if discontinued. The procedure documentation is maintained for 7 years after discontinuance of the method.

13.8.4 Method Performance Specifications

Method performance specifications for each analytical method are established or verified:

- Accuracy – accuracy of each analytical method will be determined by analysis of calibrators and yearly linearity checks as described in the section of the LPM on quality control.
- Precision – precision of each analytical method is determined by analysis of QC reference materials as described in the section of this manual on quality control.
- Analytical specificity – analytical specificity is determined for each method including effects of potential interfering substances. This may be verified by testing the effect of potential interfering substances in method development, by analyzing reference materials, by comparing results on split samples with a method considered more definitive, and/or by analyzing a sample of persons (n>20) and examining the measurement output searching for interference. The appropriate procedures for verifying analytical specificity will vary by analytical method. Substances that interfere with the analysis in the reportable range are listed in the method procedure.

- Reportable range of test results – the reportable range of test results is described in the documentation of the analytical procedure.
- Reference range (normal range) – if available, the reference range of test results is described in the documentation of the analytical procedure and on the test report.
- Other pertinent performance specifications – other performance specifications that are required for adequate method performance are specified in the documentation of the analytical procedure.

13.9 Equipment Maintenance and Function Checks

13.9.1 Introduction

Laboratory equipment is checked regularly to ensure acceptable performance. Maintenance (including preventive maintenance) and function checks are documented in the Laboratory and Phlebotomy Quality Control modules in the Integrated Survey and Information System (ISIS). The frequency of maintenance and function checks follows manufacturers' recommendations, when available. Manufacturers' recommendations are included in the manuals that are located in notebooks in the laboratory.

Each analytical procedure outlines the equipment maintenance and function checks for proper method performance and acceptable results from the checks. These checks must be made at the interval specified in the documentation of the procedure. Failure of a function check is documented in the automated Unusual Occurrence Log.

13.9.2 Eppendorf Pipette Calibration

The Eppendorf Research pro electronic pipettes are calibrated once per year. Pipettes are sent to the manufacturer and calibration certificates are kept on file at the home office.

13.9.3 Temperature Monitoring

Temperature recordings are required for storage and preservation of reagents and sample material (analytical specimens), as well as quality control and reference materials.

Beckman Coulter® and Vacutainer have recommended the following storage conditions for reagents and tubes. Quality control temperature ranges have been established based on these recommendations.

| Reagent | Manufacturer's recommended storage conditions | Established range |
|--|---|----------------------|
| Coulter® reagents Isoton Coulter Clenz Scatter Pack Lyse-S III | 2-25°C (36-77°F) | 17-25°C (63-77°F) |
| S-Cal at room temperature | 16-32°C (60-90°F) | 17-25°C (63 to 77°F) |
| S-Cal at refrigerated temperature | 2-8°C (35-46°F) | 2-8°C (36 to 46°F) |
| Latron | 2-30°C (36-86°F) | 17-25°C (63 to 77°F) |
| 5C Cell Control | 2-8°C (36-46°F) | 2-8°C (36 to 46°F) |
| Vacutainers | Not greater than 77°F | 17-25°C (63 to 77°F) |

The following ranges have been established for monitoring instrument quality control.

| Instrument | Manufacturer's instrument range or limit | Established range |
|--|--|-----------------------------|
| Beckman centrifuge (refrigerated) | -5 to +25°C (23-77°F) | 2-8°C (35 to 46°F) |
| Beckman centrifuge (room temperature) | -5 to +25°C (23-77°F) | 17-25°C (62 to 77°F) |
| Revco freezer | -30°C (-22°F) Limit | -26 to -34°C (-15 to -29°F) |
| Jewett freezer | -20°C (-4°F) Limit | -18 to -23°C (0 to -10°F) |
| Jewett refrigerator | 2-5°C (35 to 41°F) | 2-8°C (35 to 46°F) |

| Instrument | Manufacturer's instrument range or limit | Established range |
|-------------------------|--|--------------------|
| LFBSC | 0.450 | 0.350 to 0.550 |
| Phlebotomy refrigerator | None | 2-8°C (35 to 46°F) |

Two thermometers monitor ambient temperature in the laboratory and one thermometer monitors ambient temperature in the phlebotomy room. The allowable temperature range for these rooms is 17-25°C (63 to 77°F).

The acceptable temperature range for refrigerators used for storage of CLIA-regulated specimens and reagents is 2-8°C and is checked and recorded daily. If temperatures are recorded automatically on a continuous monitoring system graph, the individual's initials are captured.

Freezer temperatures are monitored daily by visual inspection of either a thermometer or graphs and recorded. All freezers are monitored automatically by built-in visual systems (with thermographic or digital reading). The range of allowable temperature for the -20°C Jewett model is -18 to -23°C. The range of allowable temperature for the -30°C Revco model is -26 to -34°C. If the range is exceeded, the technologist contacts the MEC manager.

A separate automated continuous Sensaphone system monitors the room temperature and the internal temperature of the laboratory refrigerators and freezers. When the system detects a significant increase in the temperature, it begins calling designated staff. The MEC managers and data managers have been identified as those individuals responsible for responding to the call by typing in a response code. The temperature increase could be confined to one freezer or refrigerator, to multiple units, or all units. The temperature increase could be due to any number of circumstances such as a loss of power because a circuit breaker tripped, a compressor malfunctioned, or a system failed. The MEC manager or data manager implements corrective actions that are warranted to prevent loss of biological specimens.

Freezers and refrigerators are regularly monitored for excessive ice deposit, inoperative cooling fans, and frayed or worn electrical power connections. Problems are reported to the MEC manager.

13.10 Calibration and Calibration Verification

13.10.1 Introduction

Calibration and calibration verification are specified in the documentation of the CBC analytical procedure.

13.10.2 Comparison of Methods Performed on Multiple Instruments or at Multiple Sites

At least once every 6 to 8 weeks, each of the three instruments is calibrated with S-Cal.

13.11 Remedial Actions

13.11.1 Introduction

Remedial actions are taken and documented when:

- Test systems perform outside acceptable performance specifications. Remedial action is documented in the appropriate QC manual.
- Results of control materials and calibration materials fail to meet quality control criteria. Remedial action is noted in the appropriate QC logbook.
- The laboratory cannot report sample person test results within its established period. If the reporting of data will exceed the agreed upon time frame, the MEC and final Report of Findings indicate that test results are not available.
- Errors in the reported SP test results are detected. When errors are detected in the reporting of sample person results, the MEC physician notifies the sample person by phone, followed by the issuance of a corrected report within a time period suitable to the sample person, but not to exceed 1 week. The corrected report clearly shows the corrected results in the title. Exact duplicates of the original as well as the corrected report are maintained for 7 years.

13.12 Integrated Survey Information System (ISIS)

13.12.1 Introduction

One of the purposes of the ISIS is to store sample person results for retrieval in a period acceptable for the intended use of the data. Sample person test results are stored in a database. The ISIS consists of the PC databases used for storing sample person results. This form for the ISIS facilitates the interfacing of varied and complex instrumentation used in many of the analytical procedures. The MEC LAN hardware serves as the hardware for the ISIS. The identification of the sample person result will be by specimen ID number, and the result is accessible by this number.

The minimum amount of data stored for each analytical result is the specimen ID number, the analyte name, and the measured result. If the specimen ID does not provide sufficient information to relate the measured result to the QC data for the run, then the run number and run date must also be stored. The specimen ID, run date, and run number should be sufficient information to relate the measured result to the quality control information for that run. Access to the ISIS database is password protected so that only the persons authorized by the Westat and NCHS may access the data.

13.12.2 Integrated Survey and Information System Data Down Times

Each laboratory method is able to run and temporarily store results even if the MEC LAN is inoperable.

13.12.3 Maintenance of LAN Hardware

After failure of a LAN component, ISIS should be able to be repaired or replaced within a day by a functioning component. LAN hardware is readily available. PC components and the infrequent problems with this hardware are readily correctable in this period. Westat participates in the standard service contract arranged for NHANES for service of failing or failed computer equipment.

13.12.4 Backup Schedule of Integrated Survey and Information System Data

ISIS data stored on LAN hard disk drives are backed up to tape once each weekday (Monday through Friday). If ISIS data are stored on local PC or minicomputer hard drives, they are archived to a second hard disk, tape, optical diskette, or CD-ROM at least once a week.

13.13 Communications and Complaints

13.13.1 Introduction

Good communication between the laboratory and persons reviewing laboratory analyses is essential for proper use of laboratory results. NHANES encourages collaborative relationships between technologists and physicians utilizing laboratory data. This collaborative interaction is the primary mechanism by which NHANES evaluates the effectiveness of laboratory protocols and other laboratory communications. If the laboratory has a persistent problem with meeting laboratory criteria (e.g., inadequate amount of specimen), the MEC manager, technical supervisor, or laboratory director will discuss the problem with the person in a collaborative spirit.

Similarly, complaints of laboratory performance are carefully considered. Usually, these complaints are fixed with minor adjustment or explanation. Each member of laboratory staff is responsive to complaints that have merit and relate to her or his responsibilities. Nontrivial complaints are reported to supervisors who will decide appropriate actions, including investigation and remedial action. The technical supervisor maintains documentation of nontrivial complaints concerning laboratory performance that are reported to her or him.

13.14 Quality Promotion

13.14.1 Introduction

High quality laboratory results are generated when all phases of the measurement process (i.e., preanalytic, analytic, and postanalytic) are conducted properly. Factors that promote high quality results include:

- Competent, well-trained, and motivated laboratory staff;

- Quality laboratory facilities;
- Well-maintained, high quality laboratory equipment;
- High quality laboratory analytical methods; and
- Clear commitment of management to quality laboratory results.

NHANES is committed to supporting each one of these factors in order to enhance quality.

13.15 Quality Assurance Program

13.15.1 Introduction

The goal of the NHANES Quality Assurance Program (QAP) is to monitor and evaluate the overall quality of the testing process including preanalytic, analytic, and postanalytic phases.

The initial database and reporting system design included the following requirements:

- All data are released in a timely manner relative to its intended use. All CBC results are provided to the SP in a preliminary Report of Findings when the SP checks out of the MEC. If the results are not available by the time the SP checks out of the MEC, they are reviewed by the MEC physician as soon as they are available, and the SP is notified by telephone of any abnormal results. A hard copy of the CBC results is included in the final Report of Findings sent to the SP 6-12 weeks after the MEC examination. In the case where no blood was drawn, the preliminary or final Report of Findings states, "Not enough blood drawn to test." In the case where no results were transmitted, the preliminary or final Report of Findings states, "Not Done."
- The preliminary and final Report of Findings are ISIS-generated and are based on results in the database; they are not predefined reports stored in the system. The format for the English and Spanish preliminary and final Report of Findings is tested annually to determine if the generic format is legible.
- The preliminary and final Report of Findings format includes reference ranges, units of measure, or notation for inadequate specimen. Sample preliminary and final English and Spanish Report of Findings are printed and the format is tested annually.
- NCHS is responsible for sending the final Report of Findings to each survey participant. Mailing labels are printed, the mailing label is matched to the final Report of Findings, and the final Report of Findings is inserted into the envelope. NCHS monitors communications from SPs who report that they have received the incorrect Report of Findings.

- All results are generated based on results stored in the database. The ISIS system prohibits the MEC technologist from changing data in the database after the SP has checked out of the MEC or if the MEC Report of Findings has been printed. All subsequent copies of results should match the original results. If any result is ever changed in the database, a back-end editing request system form is submitted, tracked, and maintained by ISIS.
- A comprehensive security system guards against unauthorized access. A complete description of this system is maintained by and is available through NCHS.

The basic mechanism for the QAP is the quality audit. The quality audit is conducted by the NHANES technical supervisor or laboratory director, who maintains documentation of the results of the quality audits, including remedial actions taken to address conditions that merited corrective action.

13.15.2 Quality Audit: Sample Person Test Management

The quality audit for sample person test management is conducted at least yearly and consists of:

- A survey of the laboratory staff, and of the analytical procedures used in NHANES. The survey includes requests for information on:
 - Any changes which need to be made in sample person preparation, specimen collection, labeling, preservation, and transportation
 - Any changes which need to be made in completeness and relevance of sample person information obtained at the time the specimen is acquired, and the use and appropriateness of specimen rejection criteria based on their experience and interactions with persons requesting the tests
 - Laboratory-reporting errors encountered since the last survey
 - Whether the performance of the Integrated Survey and Information System (ISIS) is adequate for their measurement systems
 - Nontrivial complaints from outside the laboratory about performance of the lab

The technical supervisor and laboratory director assess the results of the audit and, in consultation with Beckman Coulter®, implement corrective actions that are warranted.

13.15.3 Quality Audit: Quality Control

Quality control addresses the analytic phase of measurement. The purpose of the internal (“bench”) quality audit is to ensure that the QC analyses were performed and appropriate actions were taken when out-of-control conditions occurred. The quality audit of quality control shall be conducted at least yearly by the technical supervisor and laboratory director and shall consist of:

- A review of a random 10 percent sample of 5C Cell and Latron control results. The review evaluates whether appropriate corrective action was performed and documented for out-of-control conditions.
- An analysis of the proficiency testing results. The analysis and review will assess PT performance and, if unsatisfactory, whether the deficiencies have been adequately addressed. The technical supervisor and laboratory director compare results to determine the correlation coefficient. This correlation must be greater than 0.95 or the laboratory director may give written approval that the methods are sufficiently similar for the intended use of the data.
- The review of documents that demonstrate that at least once every 6 to 8 weeks S-Cal calibrator was run on three instruments.

The technical supervisor and laboratory director assess the results of the audit and, in consultation with Beckman Coulter®, implement corrective actions that are warranted.

13.15.4 Quality Audit: Personnel

Well-trained and competent personnel are essential components of good laboratory performance. The quality audit of personnel is conducted at least yearly by the technical supervisor and laboratory director and shall consist of:

- A review of the 5C Cell and Latron control (“bench”) results or IQAP QC results for 10 percent of the total control runs covering a period of not less than 1 year. The internal (“bench”) QC reflects the performance of persons performing the method. If out-of-control conditions occur with a frequency more than twice the expected statistical probability (e.g., 95% control limits would normally be exceeded by 5% of the analytical runs), the technical supervisor and laboratory director will assess whether the unacceptable performance is due to the performance of the person in question or other factors (e.g., failing equipment). If the personnel performance is the cause, the technical supervisor and laboratory director determine and implement appropriate remedial action (e.g., training).

- A review of all remedial action since the last audit to assess the effectiveness of the action. Acceptable performance of the method by the person involved for 1 month after remedial action is acceptable evidence of the effectiveness of remedial action.
- The technical supervisor and laboratory director audit the documentation of personnel training and evaluation to check whether the analyst has been appropriately evaluated in the last year (or 6 months if in first year performing a new method). The evaluation criteria are described in the Personnel Training and Evaluation section of the LPM (Chapter 10, Section 10.16).

The technical supervisor maintains documentation of the results of the audit.

13.15.5 Quality Assurance Review with Staff

The technical supervisor and laboratory director prepare a report of the results of quality audits within 3 weeks of the completion of the audit. The technical supervisor and laboratory director review pertinent information with appropriate staff to ensure effective remedial actions are taken. The technical supervisor and laboratory director also notify staff members who have been involved in the audit if performance was acceptable and no remedial action is needed. At least once every 6 months, the technical supervisor and laboratory director review the results of quality audits.

13.16 Personnel Training and Evaluation

The technical supervisor assures that persons performing laboratory tests receive appropriate training. The performance of persons performing laboratory tests is evaluated every 6 months for the first year testing is performed and annually thereafter. The evaluation shall consist of:

- Direct observation of test performance including sample person preparation (if applicable), specimen handling, specimen processing, and testing;
- Direct observation of the recording and reporting of test results;
- Review of QC results, IQAP, PT, and linearity results and preventive maintenance records;
- Direct observation of performance of instrument maintenance and function checks;

- Assessment of testing performance using blind QC materials; and
- Assessment of problem-solving skills.

The technical supervisor maintains documentation of the evaluations for at least 7 years. If remedial action is warranted, the technical supervisor shall discuss the results of a personnel evaluation with the person evaluated and implement appropriate action (e.g., training).

14. OPERATIONAL ISSUES

14.1 Start of Stand Activities

The Westat warehouse manager sends supplies for all stands, schedules shipments so that they arrive on or before setup day, and ships supplies requiring refrigeration so that they arrive the day before set up. Store laboratory supplies in the laboratory cabinets or in MEC trailer compartments.

The advance arrangement staff may assist in completing some setup activities. On setup day, the phlebotomists and medical technologists work together to complete all activities. These tasks include assisting in unpacking the warehouse pallets and boxes, sorting the laboratory supplies by storage location, completing an inventory of all existing and new supplies, organizing and storing all inventoried supplies in MEC cabinets or trailer compartments, and setting up each work area by stocking the area with appropriate supplies. Medical technologists and phlebotomists perform maintenance on and test the functionality of all instruments and equipment. Notify the MEC manager if additional supplies are required and document all instrument and equipment malfunctions in the automated Unusual Field Occurrence utility. Record all lot numbers and expiration dates for consumables (phlebotomy and lab) in the Supply Use Control Log, which is located in the respective QC module.

Mark and store miscellaneous hardware in a safe location in the laboratory until the end of stand. Hardware includes wood blocks with Velcro, refrigerator and freezer bottle caps, temperature-recording pen protectors, restraining straps, wood boards, and carpeted counter supports and straps for the Beckman Coulter® MAXM instrument and printer.

Phlebotomy Room

- Phlebotomist's responsibilities include the following tasks:
 - Inventory consumables and nonconsumables.
 - Check the sink for hot and cold running water and proper drainage.
 - Remove the wood door and drawer blocks from the refrigerator and store for reuse at the end of the stand.

- Turn on the refrigerator in phlebotomy and the CV fitness/OGTT room.
- Verify the refrigerator's operation.
- Check the function of the telephone intercom.
- Clean the refrigerators.
- Clean all work surfaces and storage areas.
- Stock and organize supplies.
- Record all lot numbers and expiration dates in the automated Supply Use Control Log.
- Check the computer operations.

Laboratory

- Medical technologists' responsibilities include the following tasks:
 - Inventory consumables and nonconsumables.
 - Check the sink and eyewash for cold running water and proper drainage.
 - Check telephone operation.
 - Check the wall thermometers for damage.
 - Remove the wood door blocks from the refrigerators and freezers and store.
 - Replace the freezer and refrigerator temperature probe solid bottle caps with the caps with holes and save solid caps for reuse at the end of the stand.
 - Place the temperature probes back into the bottles.
 - Plug in the refrigerators and freezers.
 - Verify freezer and refrigerator operation.
 - Reconnect the batteries inside the temperature-recording units.
 - Change temperature-recording charts, check pen ink, and save the black pen protector for use at the end of the stand.
 - Check light, blowers, and magnehelic pressure gauge reading in the LFBSC.

- Release the Beckman Coulter restraining straps, remove the wood board, detach the bolted carpeted counter supports and store the straps, wood board, and counter supports until the end of the stand.
- Remove the restraining strap on the Beckman Coulter® printer and store the straps until the end of the stand.
- Contact Beckman Coulter® at 1-800-526-7694 to schedule instrument verification by a service technician. Provide the current address and instrument system ID.
- Perform all Beckman Coulter® beginning of stand operations as described in Chapter 7, Section VIII.F. This includes installing and priming all new reagents, performing a start-up procedure, and reviewing and verifying the system setup.
- Calibrate the Beckman Coulter® MAXM. Complete the calibration before performing routine CBCs on SPs.
- Refrigerate the serum and urine pregnancy controls, and Beckman Coulter® Latron and 5C Cell controls as soon as they arrive.
- Clean all work surfaces and storage areas.
- Stock and organize supplies.
- Clean the interior and exterior of refrigerators, freezers, centrifuges, and LFBSC.
- Perform centrifuge maintenance.
- Open and label all new containers using the laboratory application.
- Mentally step through labeling, blood processing, urine processing, pregnancy testing, complete blood count, and specimen storage to make sure all the necessary equipment is functioning and all supplies are available in the phlebotomy/laboratory area.
- Document all readings and activities in the Laboratory QC module.
- Call FedEx to check availability (1-800-463-3339).
- NCHS biomedical engineer (annual) responsibilities include the following tasks:
 - Determine the rpm of the centrifuges using a strobe or tachometer.
 - Perform a timer check.

- Verify that both centrifuges are operating at 4-8°C.
- Enter the results in the Laboratory QC module.

14.2 End of Stand Activities

For security reasons, lock all needles in the cabinet each day after examinations are complete. Turn off the centrifuges. Sign off from all computer terminals.

At the end of a stand, shut down all equipment and inventory all supplies. On teardown day, the phlebotomist and medical technologists work together to complete all activities. Carefully wrap all breakable supplies in preparation for the move. Lock all cabinets and drawers or secure with Velcro straps. Safely discard all biohazardous waste.

Packing Phlebotomy Room

- Phlebotomist's responsibilities include the following tasks:
 - Inventory consumables and nonconsumables.
 - Turn off and clean the refrigerators in the phlebotomy and CV fitness/OGTT rooms.
 - Place wood blocks with Velcro strips on the refrigerator doors to prevent the doors from closing or moving. Be careful not to damage the rubber gasket on the door.
 - Pack all juice and crackers in labeled plastic boxes and store them inside the MEC.
 - Remove all loose supplies (clock, telephone handset, etc.) and equipment from the counter tops; pack loose supplies in boxes and label "Phlebotomy Room." If possible, place the boxes in the cupboards above the counter, under the bench, or in the corners on the floor in phlebotomy. If these areas are full, place the boxes in the designated compartments under the trailers. Do not store Vacutainer® tubes in these trailer compartments.
 - Lock the wall arm boards.
 - Bolt the room door in the open position.

- Close all cabinets and lock them or secure with Velcro strips.
- Place a dowel through the drawer handles or secure with a stretch cord.
- Lock all needles in the cupboards or in compartments under the MEC.
- Lay the phlebotomy cart on its side on the floor.

Packing the Laboratory

- Medical technologists' responsibilities include the following tasks:
 - Inventory consumables and nonconsumables.
 - Perform the Beckman Coulter® end of stand procedures as described in Chapter 7.
 - Review, print, and clear the error file.
 - Download the IQAP files.
 - Print DMS database.
 - Print Latron and 5C Cell control cum statistics (files) and graphs.
 - Perform daily shut down.
 - Bleach the apertures and flow cell.
 - Bleach, rinse, and drain reagent lines.
 - Turn off the power.
 - Rinse exterior of the BSV.
 - Wash exterior of the instrument.
 - Dispose of all opened reagents.
 - Check the expiration dates on the Beckman Coulter® Latron, Beckman Coulter® 5C Cell control, pregnancy test kit, and pregnancy controls. If unopened and they will not expire before the beginning of the next stand, pack them in a shipper with refrigerant packs, print a label using FedEx Ship, and ship back to the warehouse.
 - Unplug the refrigerators and freezers.

- Clean refrigerators and freezers.
- Disinfect and clean the pipettes.
- Replace the freezer and refrigerator temperature probe bottle caps (with holes), with the bottle caps without holes, and save the caps with holes for reuse at the start of the next stand.
- Place wood blocks with Velcro strips on each refrigerator and freezer door to prevent the door from closing or moving. Be careful not to damage the rubber gasket on the door.
- Remove the temperature recording charts and send to the home office. Store the pen arm in the "Change chart" (#3) position. Replace the black pen tip protectors.
- Disconnect the batteries inside the temperature-recording units.
- Unplug the LFBSC.
- Close and lock centrifuge lids and turn off centrifuges.
- Pack all tube rockers securely in boxes or in drawers.
- Remove all small supplies from the counters and LFBSC and pack in boxes or cabinets.
- Close all cupboards and secure with Velcro strips.
- Remove the fire extinguisher from the wall and lay inside the laboratory sink.
- Clean all counters, the LFBSC, and equipment with 1:100 bleach solution.
- Place chairs upside down or lay them down on the floor.
- Attach Beckman Coulter's bolted carpeted supports to the counter. Secure the Beckman Coulter® by laying the wood board across the top of the instrument and tightening the straps. Place foam blocks behind the instrument to cushion it during transit. Place a strap around the bottom front of the instrument. (Do not apply too much pressure.)
- Secure the Beckman Coulter® printer by strapping it to the printer shelf.

Sending Laboratory Files and Supplies

At the end of each stand, use FedEx Ship to create a label to send the following hard copy documentation to the technical supervisor at the home office:

- Temperature recording charts
- Beckman Coulter® Start Up printouts
- Beckman Coulter® Latron and 5C Cell Control printouts
- Calibration printouts
- Linearity printouts
- Latex CBC/Diff cumulative statistic and graph printouts
- Beckman Coulter® database printout
- Error file printout
- Proficiency testing copies (hematology and serum hCG)
- Dry ice receipts (at the discretion of the MEC manager)
- Biohazard receipts (at the discretion of the MEC manager)

At the end of each stand use FedEx Ship to create a label to send the following supplies to the warehouse supervisor:

- Unopened pregnancy test kits
- Unopened pregnancy urine controls – refrigerated
- Pregnancy serum controls – refrigerated
- Unopened Coulter® 5C Cell and Latron controls – refrigerated

Pack supplies using procedures described in Chapter 9.

14.3 Inventory Procedures and Supplies

At the start and end of each stand, take a complete inventory. The warehouse uses this inventory to stock the MEC for the next stand.

14.3.1 General Inventory Procedures

- Since item units can change, verify the units each time you record a count. Examples of units are pack, each, bag, box, case, roll, tray, bottle, pair, and pouch.
- Do not redefine or reiterate the Unit of Measure.
- Do not write any notes, comments, etc. on the End of Stand Inventory Count Sheet. If you have any comments or concerns, attach a note to the inventory sheet.
- Remember to use items with older expiration dates first. Rotate items by first using items you have in the rooms, then items in the belly compartment. Place items you just received in the back of the stock, unless you need them immediately. Only restock your rooms with items that were just shipped to the stand when you are out of that item in your room. Many items such as gloves, alcohol prep pads, and electrodes, deteriorate over time.
- Do not purchase items listed on the inventory sheets. The warehouse stocks every item listed on the inventory sheets; purchasing items locally creates chaos with the Inventory Management System. Contact the warehouse manager before replacing items listed on the inventory with items purchased locally.
- Do not borrow items from other components. Usage is tracked by component. The “Counted By” tech ID is entered into the database to track inconsistencies and trends. Everyone is accountable for his or her component counts.

14.3.2 End of Stand Inventory Procedures

The End of Stand Inventory Count Sheet (EOSCS) includes the stand number, Site ID (MEC number), a “Counted By:” line, and Exam Supply columns for item number, general item description, Unit designation, and a Count box. The MEC manager prints these EOSCSs for every component. The MEC staff is responsible for accurately counting (inventorying) exam supplies and entering this number into the Count box. The MEC staff gives the completed sheets back to the MEC manager who sends them

to the warehouse manager. The warehouse manager enters the item counts into the Inventory Management System.

- Print only one name in the “Counted By” field. This is the person responsible for taking and verifying the inventory count.
- Place a number in each “Count” box.
- Do not count partial units; record whole numbers only in the “Count” field.
- Record a number in each count box; do not leave a count box blank.
- If the par for an item is more than one (1) and the box or container is open, do not count that container.
- If the par for an item is only one (1) unit and it is more than half empty, record a zero (0) as the count unit. Can the next stand get by without needing more? If not, record a zero (0) as the count unit.
- All active lot numbers and expiration dates are listed on the count sheets if they are applicable for that item. If you see a lot number and expiration date, you must put a number (even if it is zero) in this Count field.

14.3.3 Start of Stand Inventory Procedures

The Start of Stand Pull Sheets (SOSPS) include the stand number, Site ID (MEC number), and Exam Supply columns for item number, general item description, Previous EOS Count number, Par level, Unit designation, and a Ship to Stand box. The warehouse manager uses this report to bring each item back to par level. For example, if the Previous EOS Count (captured by the IMS) is four and the Par level is five, the Ship to Stand Count box will contain the number one. The Warehouse Manager prints and packs one SOSPS for each component. The MEC staff is responsible for accurately reconciling the supplies and numbers in the SOSPS. The MEC staff gives the completed sheets back to the MEC manager who sends them to the warehouse manager. The warehouse manager reviews each sheet and sends additional supplies to the field if necessary.

- Reconcile the inventory for each item.
- Verify the Previous EOS Count for each item.
- Verify that the start of stand shipment contains the exact number of each item listed in the Ship to Stand box.

- If the counts are correct, place a check mark by each reconciled item.
- If there is a discrepancy, write the physical count on hand to the right of the Ship to Stand box.

14.3.4 Consumables vs. Nonconsumables

Inventory items are divided into two categories—consumable and nonconsumable. Take an inventory of both types of items at the end of each stand. The definition for a consumable item is anything that is typically consumed during an examination. Whereas some items may be used (consumed) in case of emergency, these are still considered nonconsumables since they are not typically consumed during the course of an exam.

14.3.5 Shipping Excess Inventory Back to the Warehouse

When shipping excess inventory back to the warehouse, please use the “Transfer Inventory to Warehouse Manifest” which is found on the IntraWeb and can be printed by the MEC manager or data manager. This form looks similar to the “End of Stand Count Sheets.” Print your name in the “Count By” field and indicate next to each item how many units are being shipped back to the warehouse. This information is entered into the Inventory Management System by the warehouse manager and is used to adjust the Stand inventory and usage information as well as increase the warehouse inventory counts.

14.3.6 Tracking of Expired and Broken Inventory

Complete the “Delete Expired/Broken Inventory Report” whenever inventory has expired and must be destroyed or has broken and is no longer usable. This report is found on the IntraWeb and should be completed and forwarded to the warehouse manager so that the expired or broken inventory can be removed from the stand inventory.

The chief medical technologist and the phlebotomist are responsible for notifying the MEC manager if additional supplies are needed during the stand. However, each technologist and phlebotomist

is responsible for identifying any potential shortage of supplies at each workstation. Contact the warehouse manager directly at 301-330-7092.

The equipment and supplies associated with the MEC laboratory are listed in Exhibit 14-1, Equipment and supplies.

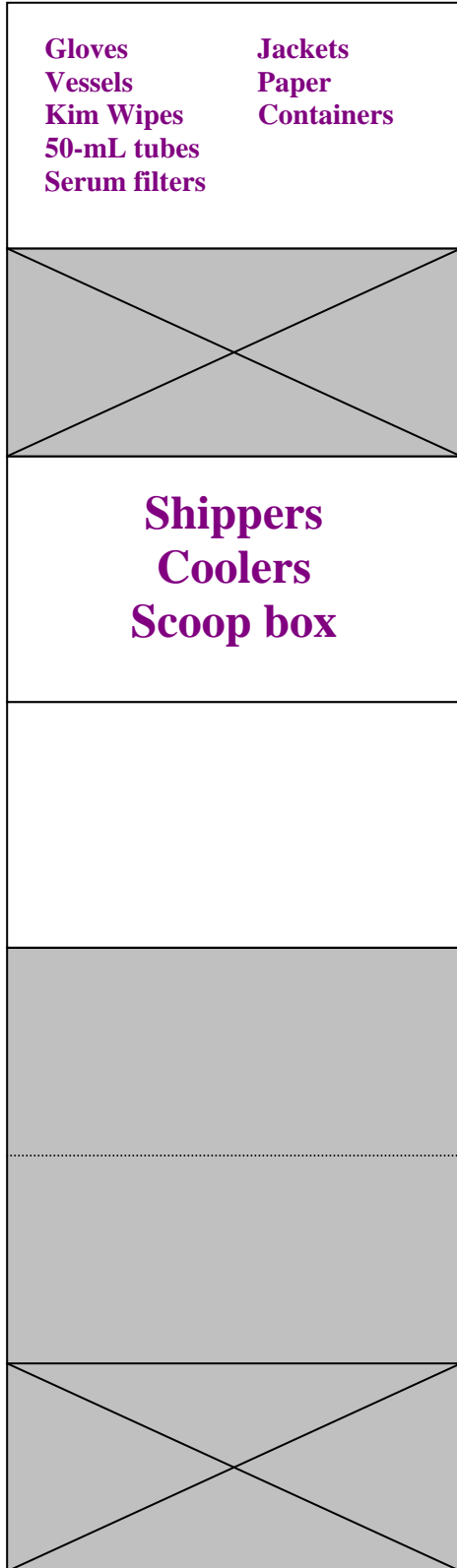
Exhibit 14-1. Equipment and supplies

| | |
|---------------------------------------|---|
| -20 Jewett freezers UCF5BH | Two Jewett refrigerators UC5B |
| -30 Revco Freezer ULT 430A18 | Five Jewett temperature monitoring units 8ER-1B |
| Two Beckman Coulter GS 6R centrifuges | Laminar flow biological safety cabinet |
| One refrigerator (CV Fitness) | One Revco refrigerator (phlebotomy) |
| Two Thermolyne Vari-Mix M48700 (lab) | One Thermolyne Speci-Mix (phlebotomy) |
| Two Maxi-Mixer (lab) | One Thermolyne Speci-Mix (lab) |
| Two solar wall thermometers (lab) | One solar wall thermometer (phlebotomy) |
| | Thermometer (centrifuge calibration) |
| Temperature charts | Temperature chart pens |

Store supplies in the trailer compartments as indicated in the trailer maps (Figure 14-1).

Figure 14-1. MEC trailer compartment maps

Trailer 1



Trailer 4



14.4 Dry Run

After setting up the phlebotomy and laboratory rooms at each new stand, the staff conducts a “dry run” session using volunteers to verify data and specimen collection and processing procedures. One purpose of the dry run session is to help identify any problem areas, particularly with equipment, and to resolve the problems before the stand begins. Another purpose is to provide the contract laboratories with blind split samples for quality control determinations. Two distinct IDs are assigned to each volunteer—the original SP ID and a second unique Sample ID. Document the results of the dry run session in a manner identical to an actual session except enter results twice, first using the SP ID, and second using the Sample ID.

Procedures

- Collect the amount of blood specified in the Dry Run Venipuncture Protocol (see Exhibit 14-2). This amount is less than the blood required from a routine examinee.
- Prepare split samples for each volunteer.
 - Collect 8-mL of urine and process as specified in Dry Run Urine Processing Protocol (see Exhibit 14-3).
 - Process the blood as directed in the Dry Run Blood Processing Protocols (see Exhibits 14-4, 14-5, and 14-6).
 - Ship these split samples to contract laboratories for analysis with the first routine shipment.

14.4.1 Phlebotomy Protocol and Procedures

The dry run venipuncture protocol is dependent on the last digit in the SP ID. If the last digit is an odd number, the volunteer’s protocol includes two 3-mL lavender, two 2-mL gray, two 3-mL red, and four 10-mL red top tubes. If the last digit is an even number, then the volunteer’s protocol includes four 3-mL lavender, two 2-mL gray, and four 10-mL red top tubes.

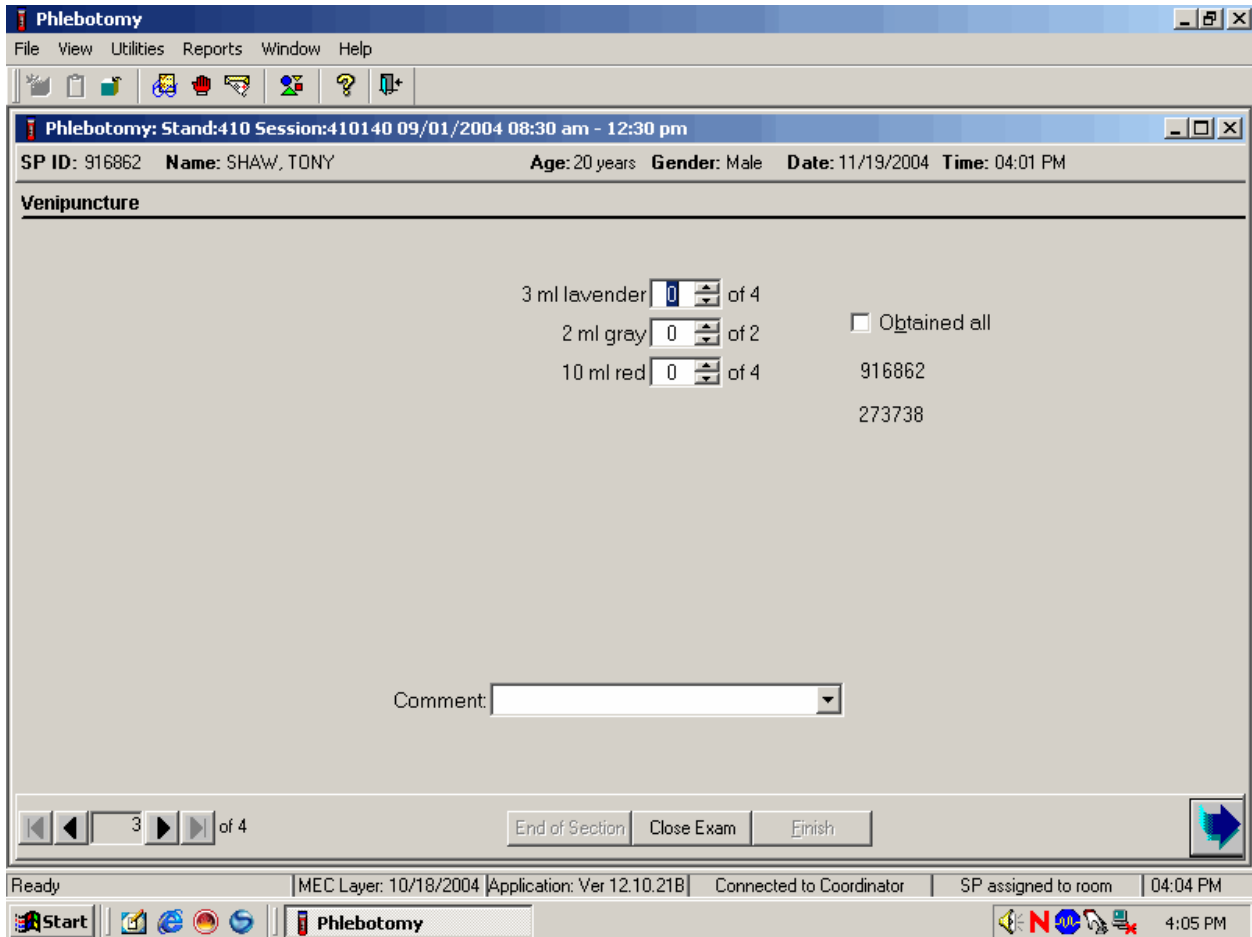
Exhibit 14-2. Dry run venipuncture protocol

| Tube type (in priority order) | Last digit in SP ID = Odd | Last digit in SP ID = Even |
|-------------------------------|------------------------------|-------------------------------|
| 3-mL Lavender | 2 | 4 |
| 2-mL Gray | 2 | 2 |
| 3-mL Red | 2 | |
| 10-mL Red | 4 | 4 |

On dry run day the phlebotomist refers to the following instructions to conduct the phlebotomy procedures:

- Access the phlebotomy application; open the exam and wand the dry run volunteer into the component.
- Conduct the phlebotomy interview and administer the fasting questionnaire as described in Chapter 4.
- Perform the venipuncture using procedures described in Chapter 4.

The last digit in the SP ID determines the dry run volunteer’s venipuncture protocol. The correct venipuncture automatically displays. Note that there are two IDs—an SP ID (916862), and a Sample ID (273738). Both the SP ID and the Sample ID display under the “Obtained all” check box.



Enter the venipuncture results using procedures described in Chapter 4. Enter any reasons for a tube not being drawn according to protocol, and any comments about the venipuncture. Refer to Chapter 4 for specific instructions.

Label the Vacutainer® tubes for each volunteer; label half of the tubes with the SP ID and the other half with the Sample ID. If only one tube is drawn, discard the tube. If less than four of the 10-mL red tubes are successfully drawn, label the first tube with the original SP ID and the second one with the Sample ID. If an odd number of tubes are drawn, discard the odd tube.

For dry run volunteers with the SP ID and Sample ID ending in an even number:

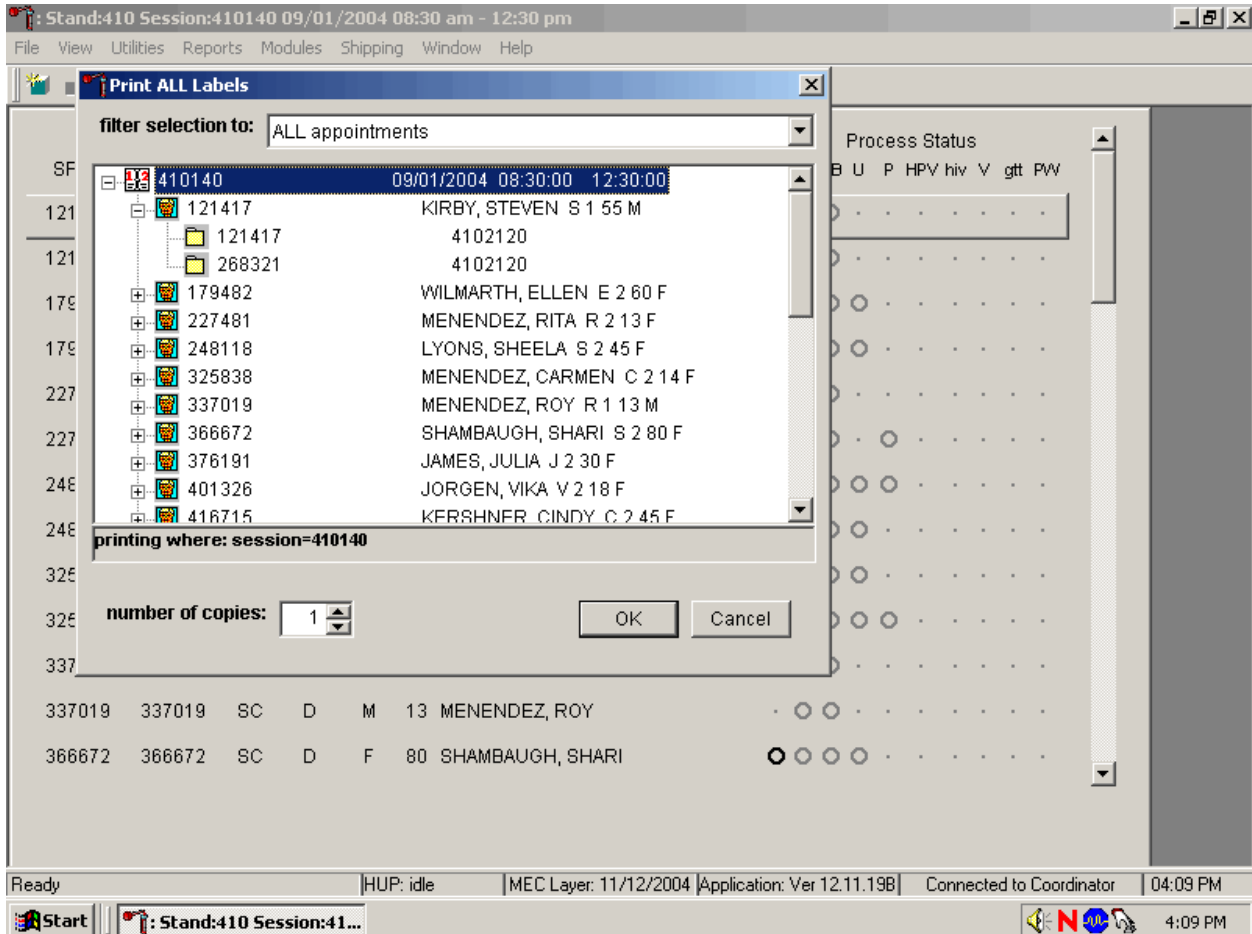
- Place the labels with the original SP ID on two of the four 3-mL lavender tubes and place the labels with the Sample ID on the other two 3-mL EDTA lavender tubes.
- Place the label with the original SP ID on one tube of the pair of 2-mL gray tubes and place the label with the Sample ID on the other 2-mL gray tube.
- Place the labels with the original SP ID on two of the four 10-mL red tubes and place the labels with the Sample ID on the other two 10-mL red tubes.

For dry run volunteers with the SP ID and Sample ID ending in an odd number:

- Place the label with the original SP ID on one tube of the pair of 3-mL lavender tubes and place the label with the Sample ID on the other 3-mL lavender tube.
- Follow the same procedure for the pair of 2-mL gray tubes.
- Follow this same procedure for the pair of 3-mL red tubes.
- Place the labels with the original SP ID on two of the four 10-mL red tubes and place the labels with the Sample ID on the other two 10-mL red tubes.

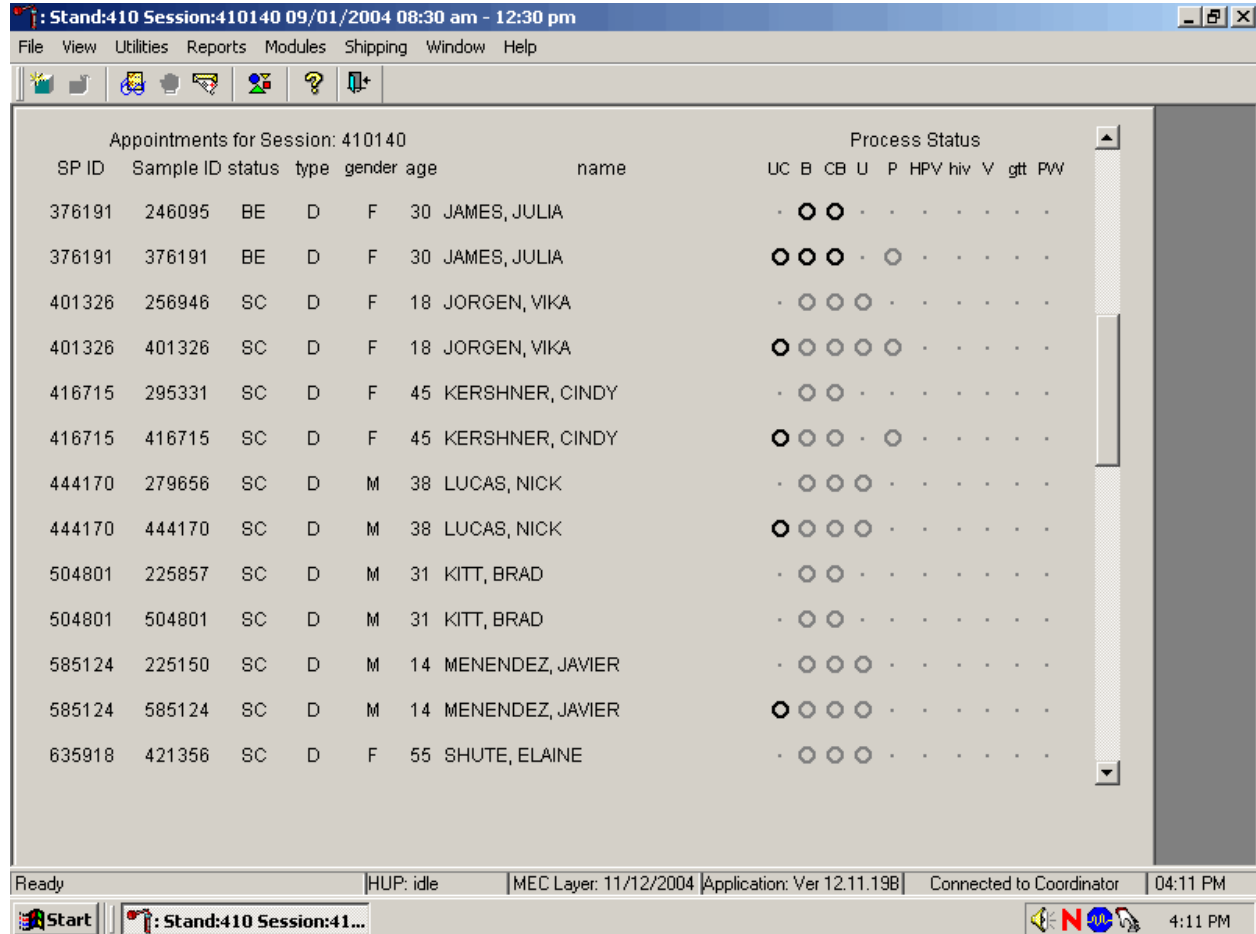
14.4.2 Printing Labels, Urine Processing and Pregnancy Testing

Access the laboratory application and logon using the MEC Logon window. Two distinct IDs are assigned to each volunteer—the original SP ID and a second unique Sample ID.



The Print All Labels pick list demonstrates that for each dry run volunteer, there are two entries, the original SP ID and the Sample ID. There are two sets of urine and blood processing vessel labels and one pregnancy label (if eligible) for each dry run volunteer. The correct vessel labels automatically print based on the protocol. Print labels using procedures described in Chapter 9. Place urine and pregnancy labels at workstation 2. Each volunteer has two unique blood processing racks—one with labels containing the SP ID and the second with labels containing the Sample ID. Assemble and label the blood processing racks for each dry run volunteer using procedures described in Chapter 9.

Review the laboratory heads-up display. Use the heads-up display to view the modules for which the dry run volunteer is eligible and the current process status.

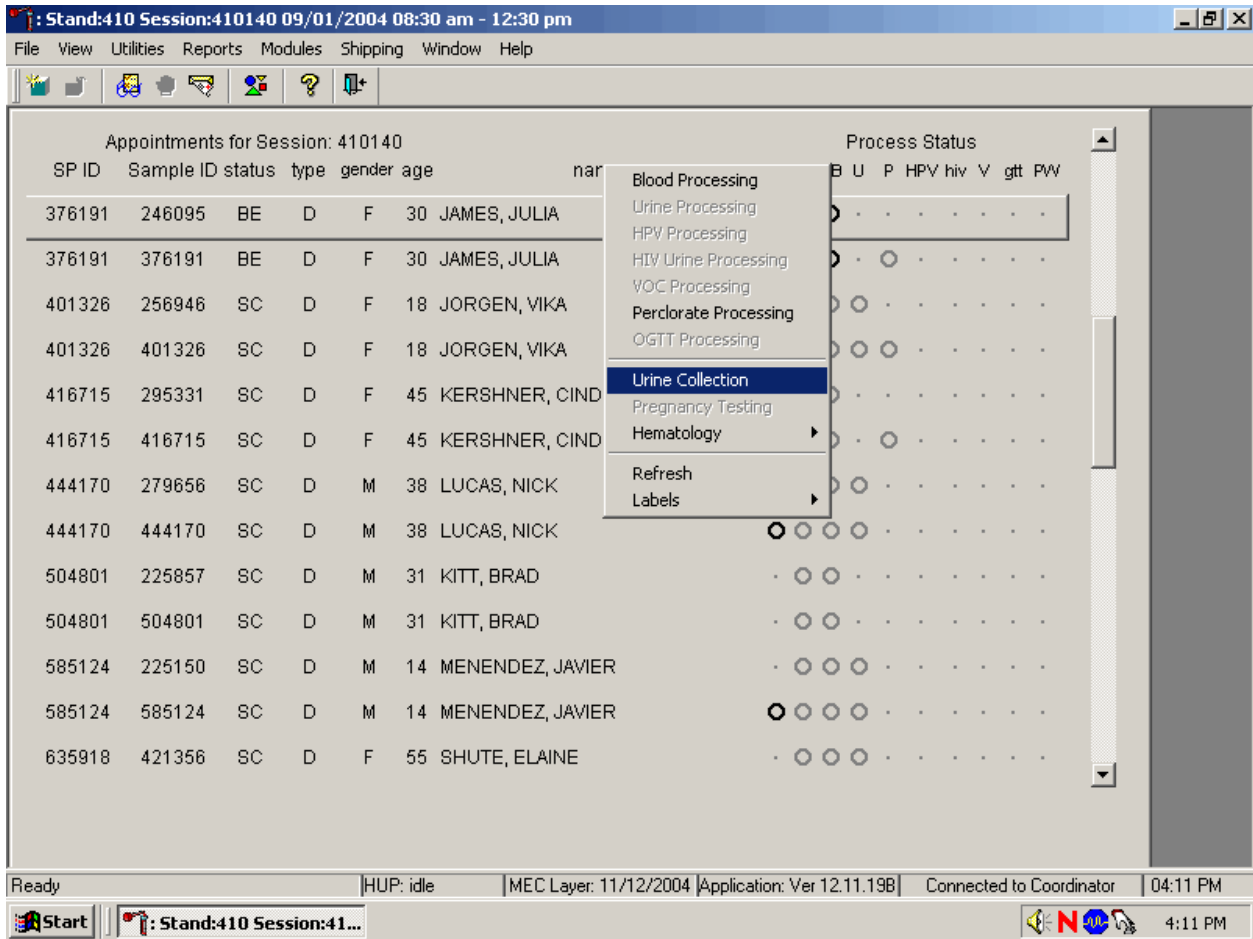


| Appointments for Session: 410140 | | | | | | | Process Status | | | | | | | | | |
|----------------------------------|-----------|--------|------|--------|-----|------------------|----------------|---|----|---|---|-----|-----|---|-----|----|
| SP ID | Sample ID | status | type | gender | age | name | UC | B | CB | U | P | HPV | hiv | V | gtt | PW |
| 376191 | 246095 | BE | D | F | 30 | JAMES, JULIA | . | ● | ● | . | . | . | . | . | . | . |
| 376191 | 376191 | BE | D | F | 30 | JAMES, JULIA | ● | ● | ● | . | ● | . | . | . | . | . |
| 401326 | 256946 | SC | D | F | 18 | JORGEN, VIKA | . | ● | ● | ● | . | . | . | . | . | . |
| 401326 | 401326 | SC | D | F | 18 | JORGEN, VIKA | ● | ● | ● | ● | . | . | . | . | . | . |
| 416715 | 295331 | SC | D | F | 45 | KERSHNER, CINDY | . | ● | ● | . | . | . | . | . | . | . |
| 416715 | 416715 | SC | D | F | 45 | KERSHNER, CINDY | ● | ● | ● | . | ● | . | . | . | . | . |
| 444170 | 279656 | SC | D | M | 38 | LUCAS, NICK | . | ● | ● | ● | . | . | . | . | . | . |
| 444170 | 444170 | SC | D | M | 38 | LUCAS, NICK | ● | ● | ● | ● | . | . | . | . | . | . |
| 504801 | 225857 | SC | D | M | 31 | KITT, BRAD | . | ● | ● | . | . | . | . | . | . | . |
| 504801 | 504801 | SC | D | M | 31 | KITT, BRAD | . | ● | ● | . | . | . | . | . | . | . |
| 585124 | 225150 | SC | D | M | 14 | MENENDEZ, JAVIER | . | ● | ● | ● | . | . | . | . | . | . |
| 585124 | 585124 | SC | D | M | 14 | MENENDEZ, JAVIER | ● | ● | ● | . | . | . | . | . | . | . |
| 635918 | 421356 | SC | D | F | 55 | SHUTE, ELAINE | . | ● | ● | ● | . | . | . | . | . | . |

The heads-up display lists each dry run volunteer twice. Note the difference between the SP ID and the Sample ID and the types of tests for which the dry run volunteer is eligible. Dry run volunteers with an SP ID and Sample ID ending in an even digit are eligible for urine collection and processing, CBC, blood processing, and the pregnancy test (if female.) Dry run volunteers with an SP ID and Sample ID ending in an odd digit are eligible for CBC, blood processing, and the pregnancy test (if female.) The urine and blood protocols constitute a limited subset of the primary SP's test protocol. Each test has the same age and gender restrictions as a primary SP. Dry run volunteers are never eligible for any of the subsamples, including VOC and perchlorate water. Notice that one urine collection result and one pregnancy test are required for each dry run volunteer whose SP ID and Sample ID end in an even digit.

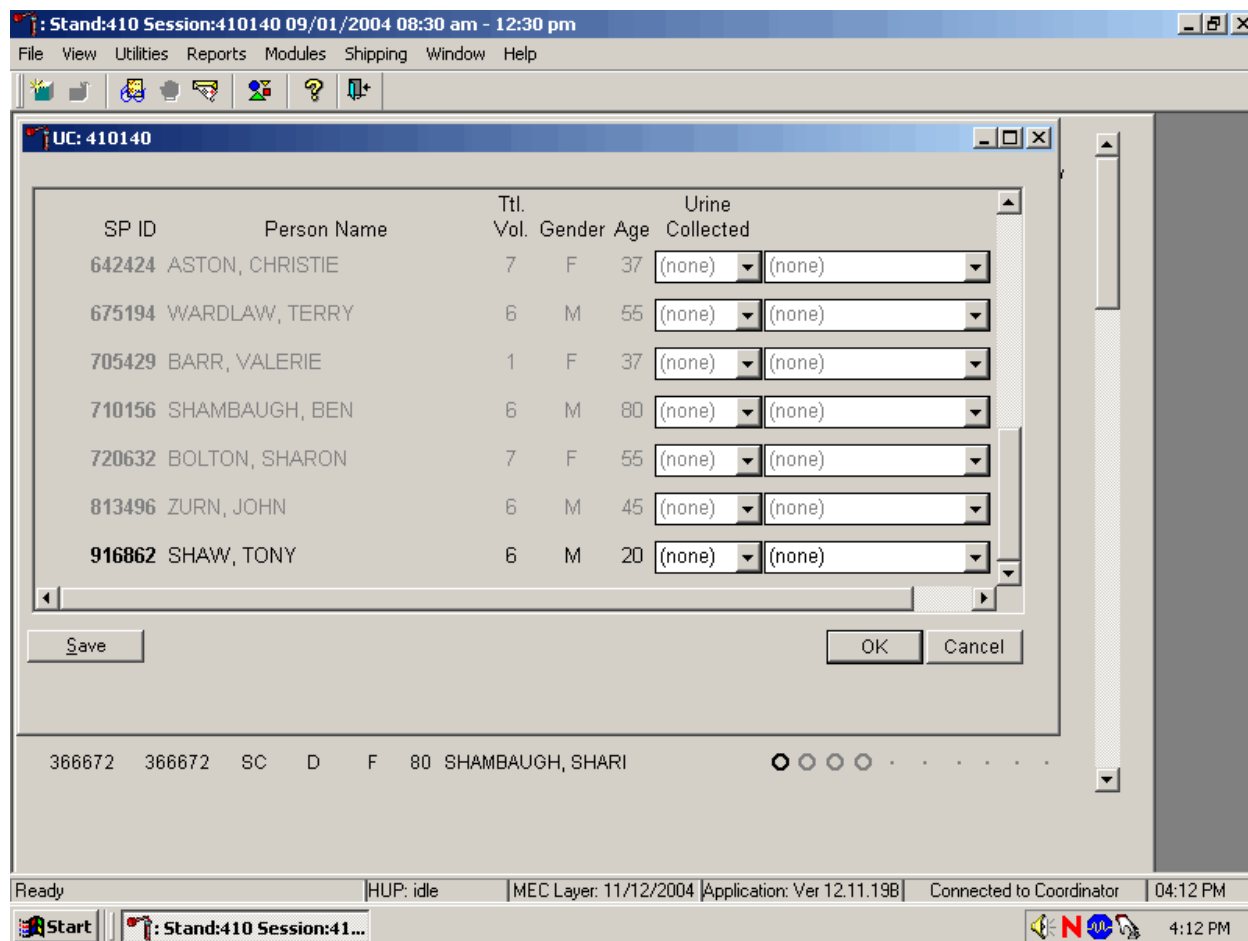
Collect approximately 8-mL urine from all dry run volunteers. The MEC coordinator instructs each volunteer to void at the same time that the volunteer changes clothes or ideally, within 45 minutes after arrival at the MEC. After collection, the coordinator or local assistant transports the initial specimen to the laboratory. Dry run volunteers with a SP ID ending in an odd digit do not require any urine at this time, since they are not eligible for any tests. Discard urine if it is not required.

Document the urine collection in the laboratory application.



To select the correct dry run volunteer's record, locate the record in the heads-up display that contains the urine collection circle. To access the urine collection module, use the up and down keys to move up and down the list until the correct record is highlighted or drag the mouse arrow to the correct volunteer and right click. Continue by dragging the mouse arrow to {Urine Collection} then left click or type [C/c].

The urine collection window displays.



The urine collection window contains columns for the SP ID, Person Name (last, first), Ttl Vol. (total volume required to complete the protocol), Gender, Age, and Urine Collection and Comments result fields. Only dry run volunteers who have checked into the MEC session are available for processing. This result field for checked-in volunteers is indicated in black while the result text box for volunteers who have not checked into the MEC session is gray. Use the scroll bar to view all volunteers scheduled into the session.

Evaluate the sufficiency of the quantity of urine received in the laboratory. Use the gradations on the urine collection cup to estimate the amount of urine received. Record the urine collection result for each volunteer by typing [Y/y] for “Yes,” [N/n] for “No” [Y/y] a second time for “Yes/QNS.” Alternatively to record the collection result, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to “Yes,” “No,” or “Yes/QNS” and left click. A “Yes/QNS” result notifies the coordinator, who then asks the dry run volunteer to provide an additional urine specimen. Refrigerate all insufficient urine samples. If additional urine is obtained, pool the urine, mix, and process.

Do not enter a result until urine arrives in the laboratory. At the end of each session, review the results for each dry run volunteer. Enter “No” in the result field for all volunteers who have not produced a urine sample. Record a result other than “(none)” for all records. Record a comment for all insufficient urine collections.

Save each result after entering it in the Urine Collected result field. To save a result to the database without exiting the module or removing the window, use the mouse to direct the arrow to the Save button and left click or press [Enter] when it is highlighted. To save a result to the database and exit the module and to remove the window, use the mouse to direct the mouse arrow to the OK button and left click. To exit the module and remove the window without saving any information to the database, use the mouse to direct the mouse arrow to the Cancel button and left click. To exit the module or close the window after saving results to the database and without recording any further actions, use the mouse to direct the mouse arrow to the X in the upper right hand corner of the module and left click.

Use the urine processing labels printed in advance to label the SP's urine vessels. The urine processing protocol is displayed in Exhibit 14-3. Dry run volunteers with a SP ID and Sample ID ending in an odd digit are not eligible for any urine vessels. Dry run volunteers with a SP ID and Sample ID ending in an even digit are eligible for one vessel – 45. There are two sets of labels for each dry run volunteers whose SP ID and Sample ID end in an even digit. Label one set of vessels with the first set of labels (SP ID) and the second set of vessels with the second set of labels (Sample ID).

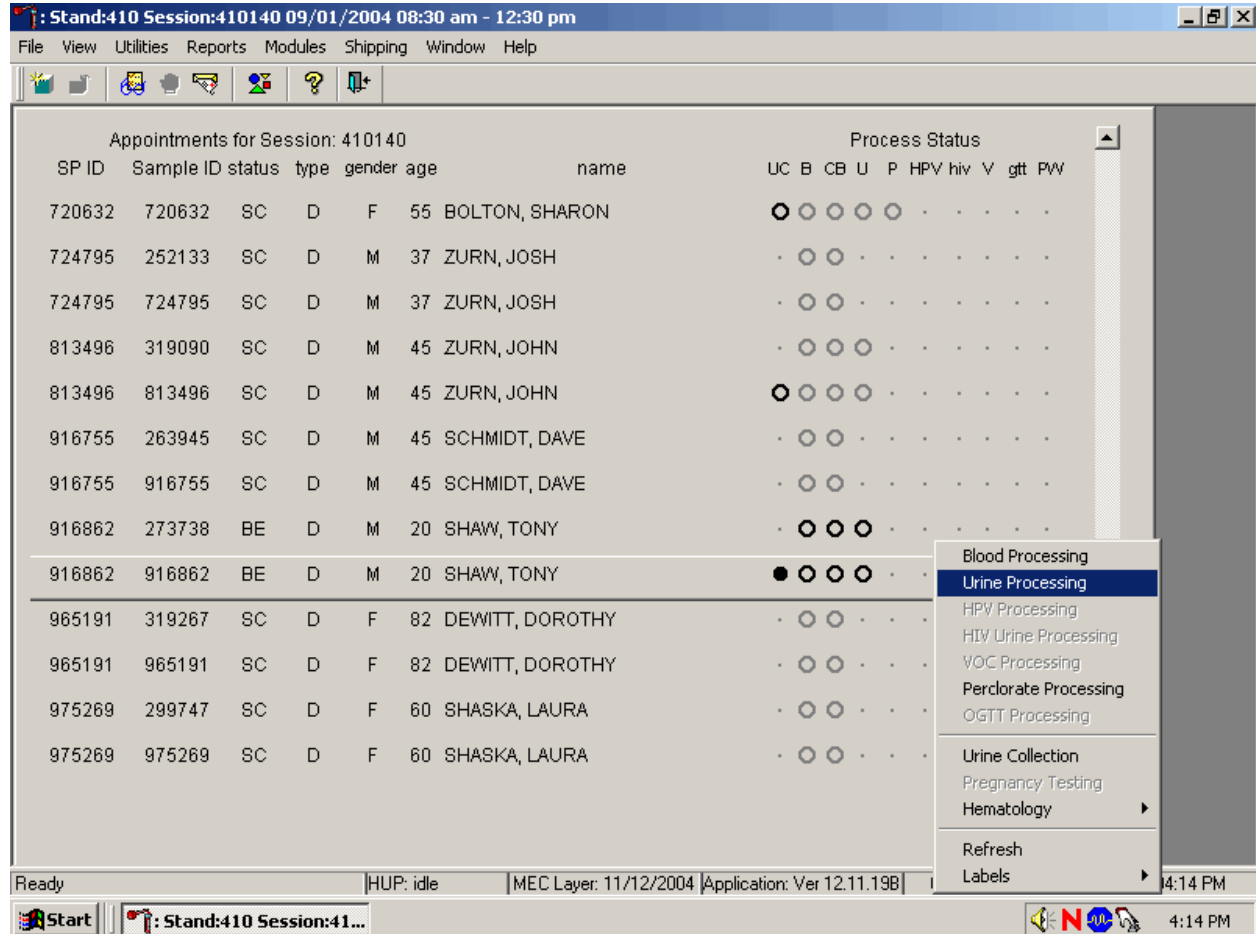
Exhibit 14-3. Dry run urine processing protocol

| ID | Assay | Odd Digit | Even Digit | Sample size mL | Vessel |
|----|-----------|-----------|------------|----------------|---------------|
| 45 | Alb/Creat | | 6 | 3 | 5-mL Cryovial |

Procedures for Dry Run Volunteers

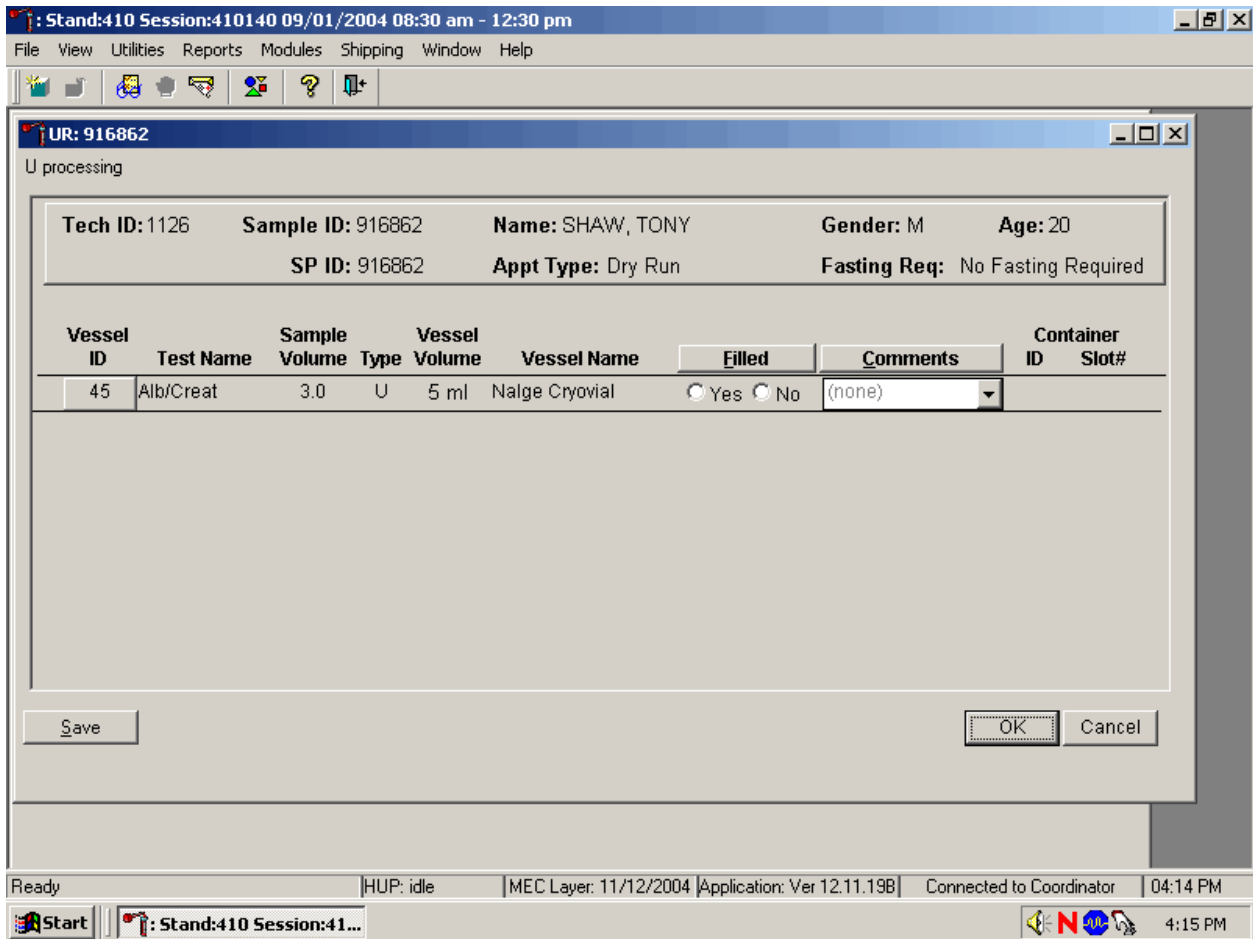
- Label one 5-mL cryovial for the first test - #45. Label one tube with the volunteer's original SP ID. Label the other tube with the volunteer's Sample ID.
- Pour 3-mL urine into the vessels.
- Enter the results of urine processing for the original SP ID and again for the Sample ID.

After filling the urine specimen vessels for each dry run volunteer, use the Urine Processing module to enter the urine processing results.



To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct volunteer, right click, drag the mouse arrow to {Urine Processing} and right click or right click and type [U/u]. Alternatively to access the Urine Processing module, use the up and down keys to move up and down the list until the correct volunteer is highlighted, right click, drag the mouse arrow to {Urine Processing}, and right click or right click and type [U/u].

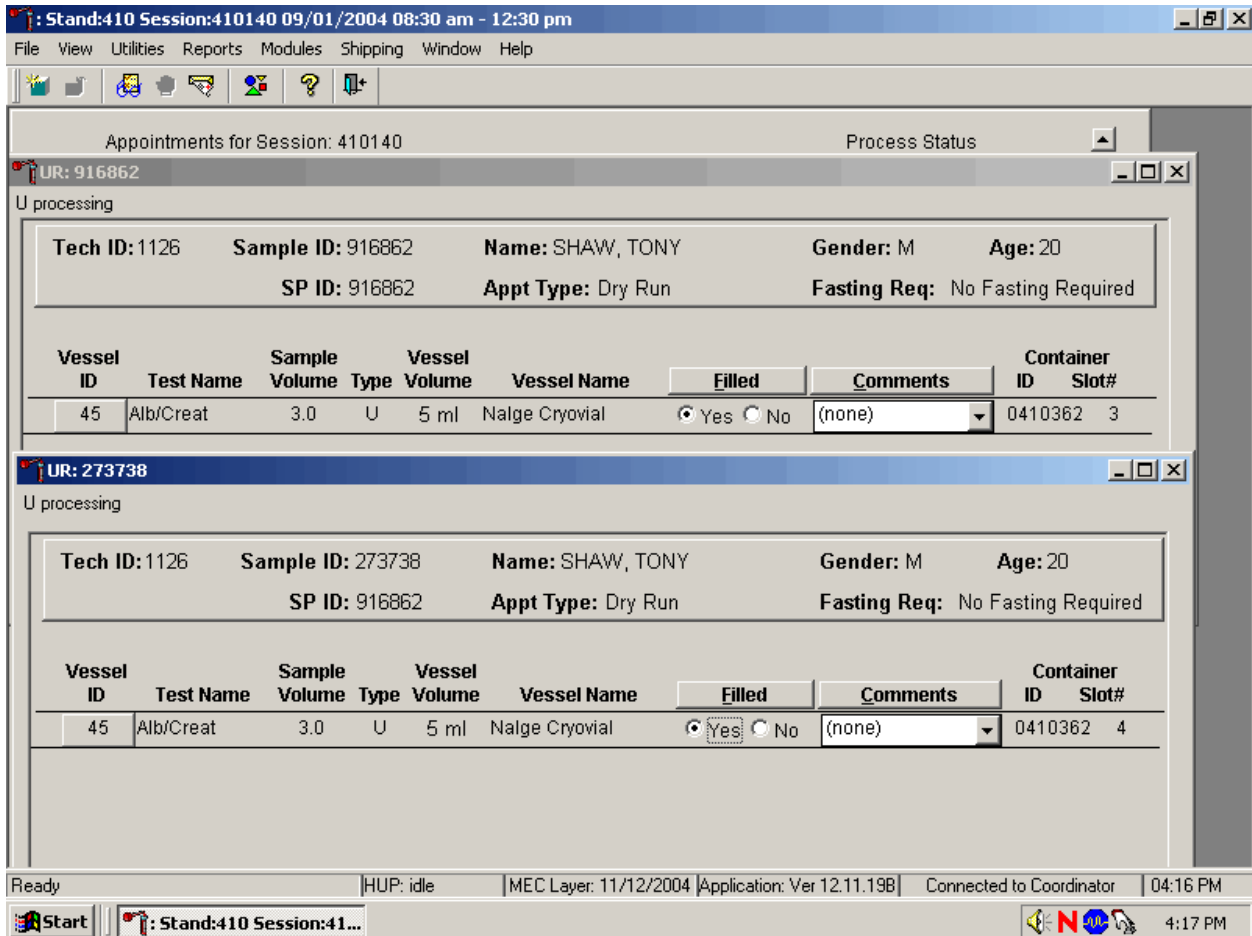
The volunteer's urine processing screen displays.



To mark an individual urine vessel as collected or Filled – “Yes,” use the mouse to direct the mouse arrow to the “Yes” radio button and left click. As each vessel is marked as Filled – “Yes,” it is automatically assigned to a slot in an existing (open) container. To mark an individual urine vessel as not collected or Filled – “No,” use the mouse to direct the mouse arrow to the “No” radio button and left click. As each vessel is marked as Filled “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column. To collectively mark all vessels as Filled – “Yes,” use the mouse to direct the mouse arrow to the Filled button above the radio buttons, left click, and drag the arrow to {Fill All} and left click or type [Shift] [F/f]. To mark all vessels as Filled – “No,” use the mouse to direct the mouse arrow to the Filled button above the radio buttons, left click, drag the mouse arrow to {Not Filled All} and left click or type [Shift] [F/f], [N/n]. Use the quality comment code to indicate if blood is present. Store each filled vessel in the assigned slot in the assigned container. To record this action or to

save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button and left click.

Access the Sample ID record on the heads-up display and record the processing results.



Remember to process vessels in pairs and if the quantity of urine is insufficient to fill both vessels; do not record either vessel as filled.

Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink. Flush the sink with water. Discard urine cup in the biohazard trash.

The urine-processing technologist performs the pregnancy test on female dry run volunteers aged 8-59 years and documents the results following the procedures in Chapter 6.

14.4.3 Hematology

The technologist at workstation 2 runs two CBCs, in duplicate, for each dry run volunteer after the blood processing technologist processes whole blood from the 3-mL lavender tubes according to the whole blood processing protocol (see Exhibit 14-4). Run the first CBC in duplicate on the first 3-mL lavender tube with the original SP ID on the tube. Evaluate results, and save the data using procedures described in Chapter 7.

Run the second CBC in duplicate on the second 3-mL lavender tube using the Sample ID. Evaluate results, and save the data using procedures described in Chapter 7.

14.4.4 Blood Processing and Storage

Print blood-processing labels using procedures described in Chapter 9. There are two sets of labels for each dry run volunteer; one set of labels contains the SP ID and the second set of labels contains the Sample ID. Prepare two blood processing racks (one with the SP ID labels and one with the Sample ID labels) using the blood-processing template for ages 12+.

Treat each set of venipuncture tubes and prelabeled blood processing racks as two independent and separate dry run volunteers. Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID, then process the second set of venipuncture tubes and blood processing vessels using the Sample ID.

For volunteer's whose SP ID and Sample ID ends in an even or an odd digit, process one of the 3-mL lavender top tubes for Lead/Cad/HG, Ery Proto, RBC Folate, Glycohem, and Mercury using the procedures described in Chapter 8. Match the first 3-mL lavender tube with the SP ID to the corresponding blood processing rack. Match the second 3-mL lavender tube with the sample ID to the corresponding blood processing rack. Reserve the remaining whole blood in the 3-mL lavender tubes for the CBC.

Exhibit 14-4. Dry run processing protocol – whole blood

| ID | Test name | Groups | Sample (mL) | Sample type | Collection type | Vessel type |
|----|-------------------------------|--------|-------------|-------------|-----------------|-------------|
| 1 | Lead/Cad/HG | Both | 0.3 | Whole Blood | 3-mL lavender | 2-mL |
| 2 | Ery Proto (age 12-49 females) | Odd | 0.4 | Whole Blood | 3-mL lavender | 2-mL |
| 3 | RBC Folate | Even | 0.1 | Whole Blood | 3-mL lavender | 2-mL |
| 4 | Glycohem | Odd | 0.4 | Whole Blood | 3-mL lavender | 2-mL |
| 5 | Mercury | Even | 0.5 | Whole Blood | 3-mL lavender | 2-mL |

When the SP ID ends in an even digit, process the plasma in each of the other two 3-mL lavender top tubes for Homocys/MMA as described in Chapter 8. When the SP ID ends in an even or an odd digit, process each of the 2-mL gray top tubes for Glucose using the same procedures described in Chapter 8. Process plasma for the dry run volunteers using the dry run processing protocol – plasma (Exhibit 14-5).

Exhibit 14-5. Dry run processing protocol - plasma

| ID | Test Name | Groups | Sample (mL) | Sample Type | Collection Type | Vessel Type |
|----|-------------|--------|-------------|-------------|-----------------|-------------|
| 7 | Homocys/MMA | Even | 1.0 | Plasma | 3-mL lavender | 2-mL |
| 9 | Glucose | Both | 0.5 | Plasma | 2-mL Gray | 2-mL |

Process pooled serum for the dry run volunteers using the Dry run blood processing protocol – serum (Exhibit 14-6).

Exhibit 14-6. Dry run blood processing protocol - serum

| ID | Test Name | Groups | Sample (mL) | Sample Type | Collection Type | Vessel Type |
|-----|---------------------------|--------|-------------|-------------|-----------------|-------------|
| 100 | IgE | Odd | 1.0 | Serum | 10-mL/3-mL Red | 2-mL |
| 81 | Vitamin B6 | Odd | 0.5 | Serum | 10-mL/3-mL Red | 2-mL |
| 70 | Vitamin D | Odd | 0.5 | Serum | 10-mL/3-mL Red | 2-mL |
| 12 | Folate/B12 | Odd | 1.0 | Serum | 10-mL/3-mL Red | 2-mL |
| 13 | CRP | Even | 0.3 | Serum | 10-mL Red | 2-mL |
| 14 | Hep profile | Even | 1.5 | Serum | 10-mL Red | 2-mL |
| 99 | Fer/TfR (12-49 females) | Odd | 0.5 | Serum | 10-mL/3-mL Red | 2-mL |
| 11 | Iron/TIBC (12-59 females) | Even | 1.0 | Serum | 10-mL Red | 2-mL |
| 17 | Cotinine | Even | 1.8 | Serum | 10-mL Red | 2-mL |
| 21 | Lipids | Both | 1.0 | Serum | 10-mL/3-mL Red | 2-mL |
| 104 | Lp(a) | Both | 0.5 | Serum | 10-mL/3-mL Red | 2-mL |
| 94 | PTH2 | Odd | 1.0 | Serum | 10-mL/3-mL Red | 2-mL |
| 79 | Vitamin C | Odd | 0.1 | Serum | 10-mL/3-mL Red | 2-mL |
| 18 | Biochem | Both | 0.8 | Serum | 10-mL/3-mL Red | 2-mL |
| 23 | Insulin | Odd | 0.2 | Serum | 10-mL/3-mL Red | 2-mL |
| 16 | Vit A/E/Car | Even | 0.5 | Serum | 10-mL Red | 2-mL |

- Fill each vessel as described in the blood processing protocol.
- Process the complete first set of venipuncture tubes and blood processing vessels on the dry run volunteer using the original SP ID. Continue to use the labeled vessels in the prepared rack.
- Process the second set of venipuncture tubes and blood processing vessels using the Sample ID. Continue to use the labeled vessels in the prepared rack.
- Use the same techniques for spinning and separating the blood as described in Chapter 8.
- Check the vessel labels before filling the vessel making sure that each vessel has the correct SP ID or Sample ID.

Match the two processing racks to each other. Record the blood processing results.

BP: 273738

B processing

Tech ID: 1126 Sample ID: 273738 Name: SHAW, TONY Gender: M Age: 20
 SP ID: 916862 Appt Type: Dry Run Fasting Req: No Fasting Required

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|----------|--------------|-------|
| 1 | Lead/Cad/HG | 0.3 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410340 | 3 |
| 3 | RBC Folate | 0.1 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410342 | 3 |
| 5 | Mercury | 0.5 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410344 | 3 |
| 7 | Homocys | 1.0 | P | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410346 | 3 |
| 9 | Glucose | 0.5 | P | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410348 | 2 |

BP: 916862

B processing

Tech ID: 1126 Sample ID: 916862 Name: SHAW, TONY Gender: M Age: 20
 SP ID: 916862 Appt Type: Dry Run Fasting Req: No Fasting Required

| Vessel ID | Test Name | Sample Volume | Type | Vessel Volume | Vessel Name | Filled | Comments | Container ID | Slot# |
|-----------|-------------|---------------|------|---------------|----------------|---|----------|--------------|-------|
| 1 | Lead/Cad/HG | 0.3 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410340 | 2 |
| 3 | RBC Folate | 0.1 | W | 2 ml | Nalge Cryovial | <input checked="" type="radio"/> Yes <input type="radio"/> No | (none) | 0410342 | 2 |

Cancel changes HUP: idle MEC Layer: 11/12/2004 Application: Ver 12.11.19B Connected to Coordinator 04:20 PM

Start Stand:410 Session:41... 4:21 PM

Enter results for those vessels where both vessels are filled for the whole blood, plasma, and serum protocol. Enter the results of blood processing using the correct Sample ID and SP ID numbers and procedures described in Chapter 8, Section 8.8. Store the blood vessels in a manner identical to blood vessels processed during a regular session.

14.4.5 Shipping Dry Run Specimens

Ship the split sample blood and urine vessels with samples from the regular sessions following procedures described in Chapter 9.

14.5 Centrifuges – Equipment Maintenance

Technologists are responsible for inspecting the centrifuges at the beginning of each stand, and inspecting and cleaning the centrifuges at the end of each stand and whenever necessary. Clean the interior of the chamber with a mild soap, as time permits. Rinse thoroughly and dry completely.

1. Inspect the rotor yolk and buckets.
 - Inspect for rough spots or pitting, white powder deposits or heavy discoloration. If any of these signs are evident, do not use the rotor. Use the second centrifuge and notify the NCHS engineer. Check the condition of the O-ring in the tie-down nut; replace it if it is worn or damaged.
2. Clean the rotor.
 - Use mild detergent, diluted 10 to 1 with water and a soft brush to clean the rotor yolk and tie-down nut. Thoroughly rinse the cleaned rotor and components with water and air-dry upside down. When the rotor is dry, lubricate the bucket sockets and pins by saturating a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk. Before reinstalling the rotor, lightly lubricate the drive hole of the rotor with Anti-Seize to prevent the rotor from sticking, as follows:
 1. Apply the lubricant onto a swab.
 2. Draw the coated swab through a paper towel to remove excess lubricant.
 3. Lightly coat the inside of the drive hole with the lubricant remaining on the swab.
3. Clean the buckets.
 - Remove the O-ring.
 - Clean the bucket and O-ring with a mild detergent diluted 10 to 1 with water, then rinse thoroughly, and dry completely.
 - Coat the O-ring with a light film of silicone vacuum grease. Place the O-ring on the ledge inside the bucket.
 - Once a week and after every cleaning, lubricate contact areas between the buckets and the pins on the rotor. Saturate a lintless tissue with Tri-Flow oil and wipe it on each bucket socket and pin. Also, put a drop of Tri-Flow oil between the pin and rotor yolk.

4. Inspect and clean Aerosolve canisters.
 - Inspect the O-ring for nicks, abrasions, or other damage. Coat the O-ring with a light film of silicone vacuum grease before installing. Place the O-ring in the groove.
 - Inspect the canister and lid threads and bottom of canister for heavy crazing or cracks.
 - Inspect the tube racks for heavy scratches or cracks and inspect the rubber cushions for damage or for imbedded glass from broken tubes.
 - Clean the canisters, lids, and racks with a mild detergent, diluted 10 to 1 with water, and a soft brush. Thoroughly rinse the cleaned components with water and air-dry upside down. Coat the O-ring with a light film of silicone vacuum grease before reinstalling it into the groove.

The NCHS biomedical engineer certifies both centrifuges annually. The NCHS engineer determines the rpm of the instruments using a strobe light or a tachometer. The engineer records multiple readings for each centrifuge. The Beckman GS-6R centrifuge should exceed 3,750 rpm to ensure adequate centrifugal force development. The engineer checks each centrifuge timer against a stopwatch and records the values in the Laboratory QC module – NCHS QC.

Document beginning and end of stand cleaning procedures in the Laboratory QC module.

14.6 Refrigerators and Freezers – Equipment Maintenance

The freezers require proper ventilation in order to operate efficiently and the air around the freezers must be free to circulate. Vents in the counters allow the heat from the freezers to rise and dissipate. Keep the vents open and do not obstruct the airflow. Do not store anything between the freezers or between the counter supports and the freezer.

Quality control procedures for the refrigerators and freezers include cleaning them at the beginning and end of the stand and whenever necessary. Continuously monitor the temperatures of refrigerators and freezers on a daily basis and record the results in the Laboratory QC module. Additionally, monitor temperatures using the automated recording instrument procedure that follows. Before putting a new chart on the recording device, date the chart and record the assigned instrument number.

- Change the tempscribe chart weekly.
- Save and send the used charts to the home office at the end of each stand.
- Document these activities in the Laboratory QC module.
- Change recording pens when necessary.
- Document any necessary unscheduled maintenance in the Unusual Occurrence Log.

Cleaning

Wear rubber gloves when cleaning. Use warm soapy water and avoid the use of abrasive cleansers. After cleaning the unit, disinfect the interior and exterior by cleaning with a 1:10 solution of bleach and water.

14.7 Use of the Temperature Recording Instrument

The Jewett Instrument is a microprocessor-based, AC operated temperature recording device, which automatically monitors the interior temperature of the refrigerator and freezers. The device continuously graphs this record on a circular paper chart so that 7 days of temperature data can be inspected easily. When this recorder functions under normal conditions and receives proper care, it renders lasting accurate service.

The NHANES engineer is responsible for mounting, installing, and calibrating the recorder as specified in the manufacturer's Operating Manual. The results of the recorder should be monitored at the beginning of each day. Replace charts on a weekly basis, and replace batteries and pens, as needed.

To monitor the results of the recorder, look at the chart for each refrigerator and freezer at the beginning of each day, read the temperature indicated on the chart, and record it in the Laboratory QC module. Record the highest temperature shown on the chart since the last reading.

The acceptable temperature range for refrigerators used for storage of CLIA-regulated specimens and reagents is 2-8°C and is checked and recorded daily.

Freezer temperatures are monitored daily by visual inspection of either a thermometer or graphs and recorded. All freezers are monitored automatically by built-in visual systems (with thermographic or digital reading). The range of allowable temperature for the -20 Jewett model is -18 to -23°C. The range of allowable temperature for the -30 Revco model is -26 to -34°C. If the range is exceeded, the technologist contacts the MEC manager.

Maintenance of the Jewett Temperature Recorder involves chart installation on a weekly basis, replacement of the cartridge pen, and replacement of the batteries as needed (approximately once a year).

To install the new chart:

1. Press and hold the Change Chart push button switch for 1 second until the pen begins to move to the left of the chart.
2. To remove the chart, unscrew the knob at the center of the chart.
3. Position the new chart so that the correct timeline coincides with the timeline groove on the chart plate, then replace the knob and screw tightly against the chart.
4. Again, push the Change Chart push button switch for 1 second until the pen begins to move back onto the chart.
5. Check to make sure the pen is marking on the paper. If not, lightly adjust the pen arm to establish contact with the paper.

The Jewett temperature recorder uses a standard cartridge pen that requires no filling. It consists of a self-contained ink reservoir with a porous plastic stylus that snaps around the outer edge of the pen. Use the two screws at the top of the pen arm to adjust the length to ensure that the pen tracks the timeline on the chart. Check the length after each pen replacement and adjust accordingly if required. If the stylus does not touch the chart, make adjustments by slightly bending the pen arm in the center. Do not use more pressure than is necessary to create a fine line.

NOTE: As the ink supply runs out, the ink color becomes lighter. Replace the pen when this occurs.

If AC power fails, the LED changes to a flashing green to alert the user of the power failure. The 9-Volt battery allows the recorder to sense and record temperatures for a minimum of 12 hours.

Occasionally, a recorder may malfunction. Contact technical service at 800-879-7767. The manufacturer offers the following troubleshooting guide:

| LED status | Chart rotation | Pen location | Battery status | AC power status | Cause | Repair |
|----------------|----------------|--------------|----------------|-----------------|---------------------------|--|
| Green | OK | OK | OK | OK | Normal | None required |
| Flashing Green | OK | OK | Low | Off | AC failure or low battery | Check power source and transformer – Replace battery if necessary. |
| Green | OK | Inner hub | OK | OK | Probe failure | Check connection on board – Replace probe |

14.8 Use of the Class II Type A Biological Safety Cabinet

The Class II Laminar Flow Biological Safety Cabinet (LFBSC), with proper technique, provides an effective partial containment system for safe manipulation of moderate- and high-risk microorganisms. The vertical laminar airflow barrier prevents contaminated air from entering or escaping from the open-front work chamber, protecting the cabinet contents and the technologist. A high-efficiency filter system decontaminates both the incoming air and the exhaust.

Installation, Certification, and Maintenance

The NCHS biomedical engineer arranges for a certified engineer to perform the required annual certification that includes replacement of HEPA filters as necessary.

The basic concept of the LFBSC is to take air through a blower system, pressurize a plenum, and force air through a filter. Built-in supply and exhaust blowers come with separate HEPA filters. The recirculating airflow pattern directs a portion of the HEPA filtered air straight down over the central work area driving the airborne contaminants into the surrounding grills, allowing a pollution free environment for particular specifications. If a filter is defective, the filtration system no longer filters and becomes a vacuum cleaner, taking in gross contamination and exploding it through the defective filter onto and around the critical work area. The filter of the LFBSC is a permanent part of the disposable plenum. A magnehelic gauge is calibrated in “inches of water gauge” pressure (w.g.). The gauge indicates when the

supply HEPA filter is clogged. As the filter loads with particulate matter, the amount of pressure registered on the gauge will increase. The initial pressure reading is approximately 0.4 w.g. \pm 0.05 w.g. depending on the altitude from sea level. Check and record the reading on the gauge every day. If the gauge registers an increase in pressure of more than 0.1 w.g., notify the NCHS engineer. The NCHS engineer will arrange to have the airflow pressure and the HEPA filter system checked. If the HEPA filter is no longer effective, the engineer or MEC manager discards the entire filter and plenum and substitutes a new replacement unit.

Clean the LFBSC at the beginning and end of each stand. Lift the front glass and wash both the interior and exterior glass. Remove all contents from the interior of the cabinet. Remove and wash the front grill. Lift the cover to the table and wash the base underneath. Put table cover and grill back into cabinet. Lock front glass into place. Document these activities in the Laboratory QC module. Take and record the pressure reading in the Laboratory QC module at the beginning of stand and at the start of each session.

Document all unscheduled maintenance for the LFBSC in the automated Unusual Field Occurrence utility.

14.9 Ambient Air Temperature

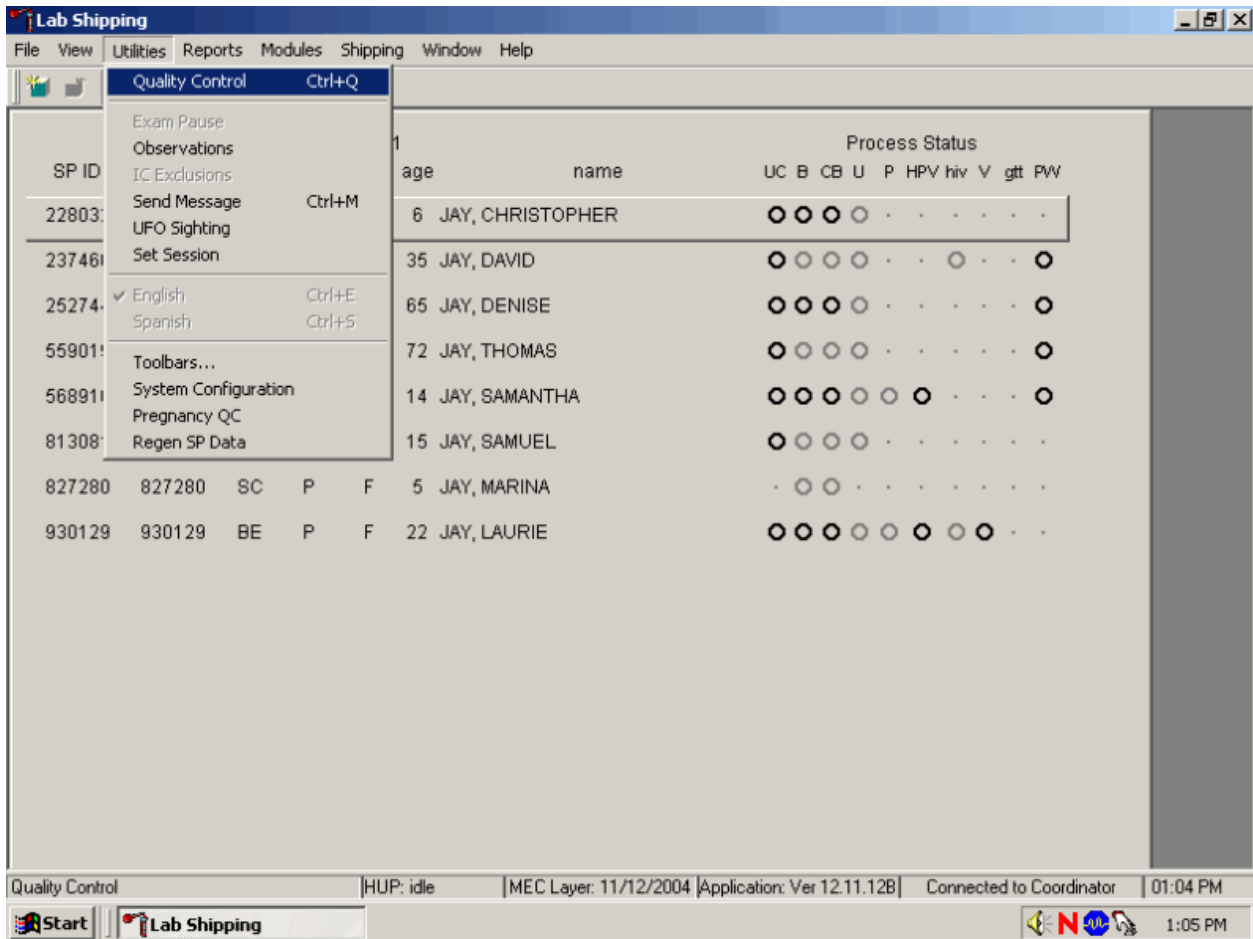
Two thermometers monitor ambient temperature in the laboratory. Quality control procedures for ambient air temperatures involve checking these thermometers for damage, monitoring the temperature each session, and documenting any unusual occurrences. Check the two wall thermometers for damage at the beginning of each stand. Notify the MEC manager of any damage.

The allowable ambient temperature range for the laboratory is 17° to 25°C (63° to 77°F).
NOTE: If the room temperature is out of allowable range since the last reading, document this in the automated Unusual Field Occurrence utility and inform the MEC manager immediately.

14.10 Laboratory Quality Control Module

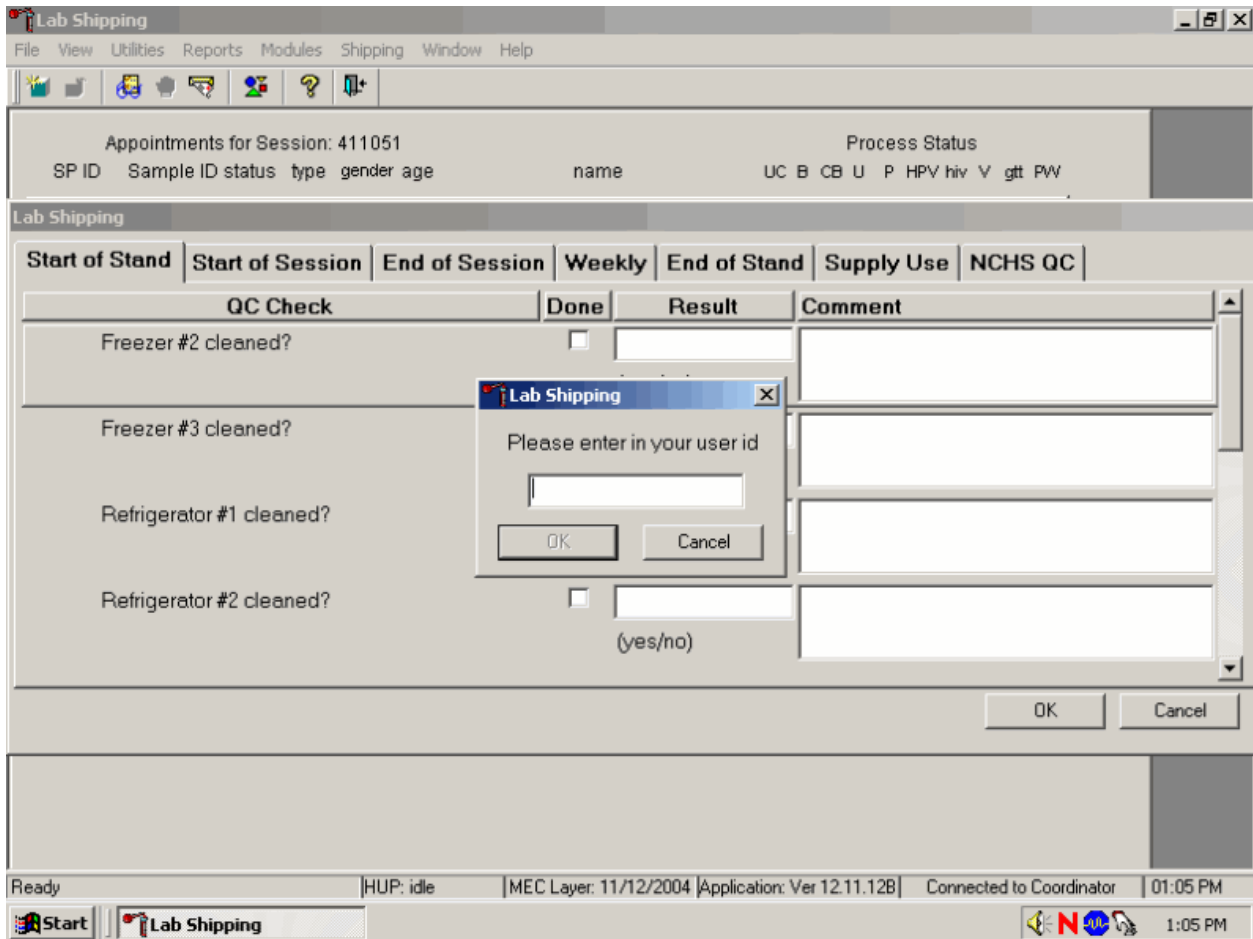
Document all instrument quality control activities in the Laboratory QC module.

Access the Laboratory QC module.



To access the QC module, use the mouse to direct the mouse arrow to {Utilities}, drag the arrow to {Quality Control}, and left click or type [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

Enter the required user ID.



Enter user ID as last name_first initial. Type in the user ID and use the mouse to direct the mouse arrow to the OK button and left click or select [Enter.]. To exit without entering a user ID, use the mouse to direct the mouse arrow to the Cancel button and left click.

Enter quality control activities and readings.

The screenshot shows the 'Lab Shipping' application window. At the top, it displays 'Appointments for Session: 411051' and 'Process Status'. Below this is a table with columns: SP ID, Sample ID, status, type, gender, age, name, UC, B, CB, U, P, HPV, hiv, V, gtt, PW. The main section is titled 'Lab Shipping' and contains a tabbed interface with options: Start of Stand, Start of Session, End of Session, Weekly, End of Stand, Supply Use, and NCHS QC. The 'Weekly' tab is selected, showing a table for 'QC Check' with columns: Done, Result, and Comment. The table lists four activities: Freezer #2 cleaned?, Freezer #3 cleaned?, Refrigerator #1 cleaned?, and Refrigerator #2 cleaned?. Each activity has an unchecked checkbox in the 'Done' column, an empty text box in the 'Result' column (with '(yes/no)' below it), and an empty text box in the 'Comment' column. At the bottom right of the window are 'OK' and 'Cancel' buttons. The status bar at the bottom shows 'Apply changes and close window', 'HUP: idle', 'MEC Layer: 11/12/2004', 'Application: Ver 12.11.12B', 'Connected to Coordinator', and '01:05 PM'. The Windows taskbar at the very bottom shows the Start button, the 'Lab Shipping' taskbar icon, and the system tray with the time '1:05 PM'.

| QC Check | Done | Result | Comment |
|--------------------------|--------------------------|----------------------------------|----------------------|
| Freezer #2 cleaned? | <input type="checkbox"/> | <input type="text"/> (yes/no) | <input type="text"/> |
| Freezer #3 cleaned? | <input type="checkbox"/> | <input type="text"/> (yes/no) | <input type="text"/> |
| Refrigerator #1 cleaned? | <input type="checkbox"/> | <input type="text"/> (yes/no) | <input type="text"/> |
| Refrigerator #2 cleaned? | <input type="checkbox"/> | <input type="text"/> (yes/no) | <input type="text"/> |

Select the correct activity (Start of Stand, Start of Session, End of Session, Weekly, End of Stand, Supply Use, or NCHS QC) by using the mouse to direct the mouse arrow to the correct heading on the top of the file and left click. At each stand, perform and record weekly activities on the same weekday as set up.

Mark activities as done and enter the result.

The screenshot shows the 'Lab Shipping' application window. At the top, there is a menu bar with 'File', 'View', 'Utilities', 'Reports', 'Modules', 'Shipping', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. The main area displays 'Appointments for Session: 411051' and a 'Process Status' section with fields for 'UC', 'B', 'CB', 'U', 'P', 'HPV', 'hiv', 'V', 'glt', and 'PW'. Below this is a 'Lab Shipping' section with a table. The table has columns for 'QC Check', 'Done', 'Result', and 'Comment'. The rows list 'Pregnancy Test Kit (ICON 25)', 'Sure-Vue Serum Control', 'Sure-Vue Urine Control', and 'Triple Display Timer'. Each row has a checkbox in the 'Done' column and a text box in the 'Result' column. At the bottom right of the table area are 'OK' and 'Cancel' buttons. The status bar at the bottom shows 'Apply changes and close window', 'HUP: idle', 'MEC Layer: 11/12/2004', 'Application: Ver 12.11.12B', 'Connected to Coordinator', and '01:05 PM'. The Windows taskbar at the very bottom shows the 'Start' button, the 'Lab Shipping' taskbar icon, and the system tray with the time '1:06 PM'.

| QC Check | Done | Result | Comment |
|------------------------------|--------------------------|--------|---------|
| Pregnancy Test Kit (ICON 25) | <input type="checkbox"/> | | |
| Sure-Vue Serum Control | <input type="checkbox"/> | | |
| Sure-Vue Urine Control | <input type="checkbox"/> | | |
| Triple Display Timer | <input type="checkbox"/> | | |

To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the done column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box.

Enter the response or reading in the Result text box.

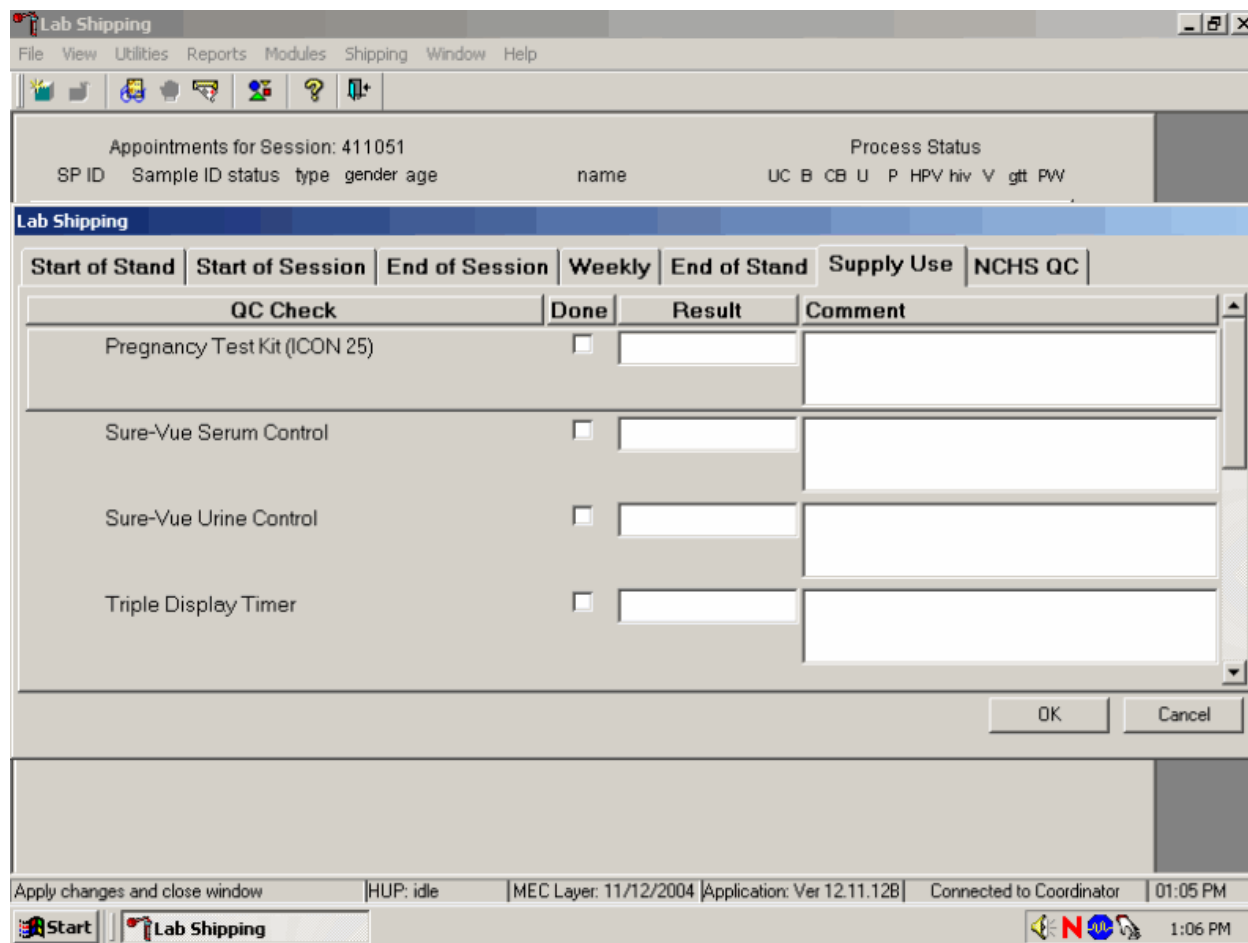
The screenshot shows the 'Lab Shipping' application window. At the top, it displays 'Appointments for Session: 411051' and 'Process Status'. Below this is a table with columns: SP ID, Sample ID, status, type, gender, age, name, UC, B, CB, U, P, HPV, hiv, V, gtt, PW. The main section is titled 'Lab Shipping' and contains a table with columns: Start of Stand, Start of Session, End of Session, Weekly, End of Stand, Supply Use, NCHS QC. Below this is a 'QC Check' table with columns: QC Check, Done, Result, and Comment.

| QC Check | Done | Result | Comment |
|--------------------------|-------------------------------------|----------------------------------|---|
| LFBSC cleaned? | <input checked="" type="checkbox"/> | Yes (yes/no) | |
| Magnahelic gauge reading | <input checked="" type="checkbox"/> | 0.450 (w.g.) | |
| Freezer #4 cleaned? | <input checked="" type="checkbox"/> | No (yes/no) | Freezer inoperative - notified MEC Manager and Chief Medical Technologist |
| Freezer #1 cleaned? | <input type="checkbox"/> | <input type="text"/> (yes/no) | |

At the bottom of the window, there are 'OK' and 'Cancel' buttons. The status bar at the very bottom shows: 'Apply changes and close window | HUP: idle | MEC Layer: 11/12/2004 | Application: Ver 12.11.12B | Connected to Coordinator | 01:05 PM'. The taskbar at the bottom right shows the system clock as 1:07 PM.

Enter “Yes” or “No” for text responses, whole numbers for rpm measurements, minutes, and seconds for timer readings, three decimals for w.g., and whole negative and positive numbers for thermometer readings in the Result text box. Select [Tab] or [Enter] to move to the Comment text box. Type any actions associated with an unexpected result in the Comment text box. Select [Tab] to move to the next line.

Enter the lot numbers and expiration dates in the Supply Use activity. This activity lists every inventory item associated with the component. Record the pregnancy test kit and the serum and urine pregnancy control lot numbers and expiration dates even though these are captured in the Pregnancy QC module.



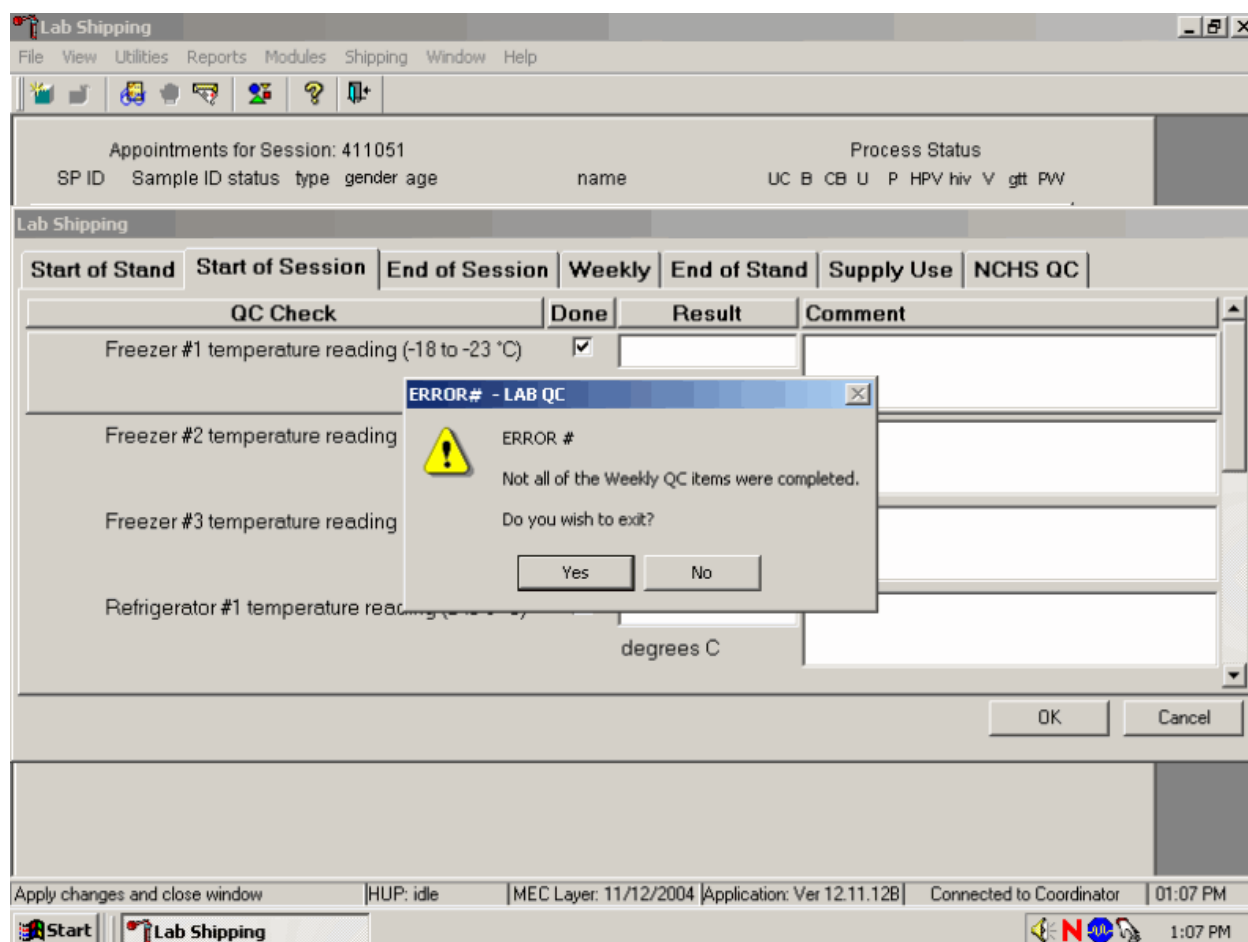
Mark each check box and record the lot and expiration date of each item in the Comments text box at the start of the stand and whenever a new lot is put into use. To record an activity as complete or done, use the mouse to direct the mouse arrow to the check box in the done column and left click to insert a check mark. Select [Tab] or [Enter] to move to the Result text box. Do not enter the response or reading in the Result text box. Select [Tab] or [Enter] to move to the Comment text box.

- For the ascorbic acid and MPA, record the stand week (Week 1, Week 2, etc), add a comma, and record the date the reagent was reconstituted using the MM/DD/YY format.
- For the timers and thermometers, record the calibration date (12/02), add a comma, and record the expiration date using the MM/DD/YYYY format.
- For items with lot numbers, record the lot number, add a comma, and record the expiration date using the MM/DD/YY format.

There is no frequency requirement for this activity within the QC application. Update the information each time a new lot is put into use

To save the results to the database, use the mouse to direct the mouse arrow to the OK button and left click; to exit the QC module without saving the results, use the mouse to direct the mouse arrow to the Cancel button and left click. Once results are saved to the database, they cannot be changed, except for the information contained in the Supply Use Comments text box.

A warning message text box displays if required QC is incomplete.



A warning message text box displays when an attempt is made to access a laboratory module if the required QC activities have not been performed or if some activities are incomplete. Respond to the message text box. To exit the QC module, use the mouse to direct the mouse arrow to the Yes button and left click or type [Y/y] or select [Enter]. To remain in the QC module, use the mouse to direct the mouse arrow to the No button and left click or type [N/n]. Continue to perform the required QC activities and record the results.

A red check mark on the top of the file header indicates that all QC activities associated with that requirement were successfully recorded and saved to the database.

14.11 Unusual Field Occurrence (UFO)

Document any unusual occurrence using the Unusual Field Occurrence utility. The hard copy Unusual Occurrence Log (see Exhibit 14-7) is available as a back up. Record the date, Tech ID number, an explanation of the incident, and the steps to resolve the incident. Be sure to record the model and the serial number of the instrument. Refer to the *UFO User Guide* for complete instructions.

Exhibit 14-7. Hard copy Unusual Occurrence Log

**NHANES
Unusual Occurrence Log**

Stand Number _____

Beginning Stand Date _____

Technologist Name and ID

Date

Time

Comments or Issue

Action Taken

Resolution

Reviewed by _____

Date reviewed _____

Enter information into the appropriate line(s):

- Stand Number;
- Beginning Stand Date;
- Technologist Name and ID;
- Date;
- Time;
- Comments or Issue;
- Action Taken; and
- Resolution.

NOTE: Do not enter any text in the Reviewed by or Date reviewed lines.

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

14.12 Hard Copy Supply Use Control Log

Document the lot number and expiration dates for all Vacutainer® tubes, needles, and reagents in the Supply Use Control activity of the Quality Control module. This hard copy Supply Use Control Log (Exhibit 14-8) is available as a backup.

Enter information into the appropriate column(s):

- Reagent or Supply Name;
- Beginning Stand Date;
- Lot Number;

- Date in Use;
- Expiration Date; and
- Technologist ID.

Print these results and file in the QC notebook. Send to the home office at the end of each stand. The data manager can answer any questions about accessing, saving, and printing this document.

14.13 Eppendorf Pipette Care, Sterilization, Maintenance, and Calibration

The MEC laboratory has four Eppendorf Research pro electronic pipettes: one 5-100 μ L, two 50-1000 μ L, and one 100-5000 μ L. The lab also uses 100 μ L and 1000 μ L Biopur pipette tips and 5-mL bulk pipette tips. Charge the pipettes in the 4-stand charger.

- Do not clean the display or any of the labeling using acetone or aggressive solutions.
- Do not allow any liquid to enter the device.
- Authorized service personnel may carry out repairs only.
- Use original spare parts and accessories (battery, pipette tips) only.

Care

Wipe the outside of the pipette with a moist cloth. The use of water with wetting agent is also permitted.

WARNING: DO NOT ALLOW ANY LIQUID TO ENTER THE PIPETTE.

Rinse (with distilled water) and dry only the lower part of the pipette. The pipette may be wiped clean with 60 percent isopropanol.

Disassemble the lower half of the Research pro if the pipette is very contaminated or if very aggressive chemicals are dispensed. Rinse the individual parts in distilled water and then dry the parts. Lightly lubricate the piston using silicone grease.

After opening the pipette, check that position of the piston and execute a motor reset. Trigger the motor reset by holding down the Reset key until **R** appears in the display.

Sterilization

Disassemble only the lower half of the pipette. The individual parts of the lower part must be disassembled further into separate pieces. Please review the diagrams on page 27 of the Research Pro Instruction Manual before attempting to disassemble any pipette.

To loosen the lower part of the pipette (for all pipettes except the 5,000 μL):

- Hold down the ejector and pull off the ejector sleeve. Force may be required.
- Unscrew the lower part using the key. During disassembly, do not damage the piston.
- Unscrew the piston. If necessary, first loosen the piston at the upper end using flat-nose pliers. The piston is moved to the lowest position.

To loosen the lower part of the 5,000 μL pipette:

- Hold down the ejector and pull off the ejector sleeve. Force may be required.
- Unscrew the cylinder. The piston is held in place magnetically. During reassemble, do not damage the piston.
- Pull the piston out of the upper part.

Assemble in reverse order. Engage the magnetic coupling of the 5,000 μ L piston as shown in the diagram on page 27 of the Instruction Manual. Check that the dispensing function of the pipette is working correctly.

Maintenance and Calibration

Apart from general care and occasional discharging (when the battery symbol starts flashing) and recharging of the pipette, no special maintenance is necessary if the pipette is used correctly. The lower part of the pipette may be replaced. Part B: "Ordering information/service parts," describes the process for replacing the seals in the lower part.

The pipettes are calibrated at least once per year, when the staff is on their break in June/July or December. When instructed, send the pipettes to the warehouse. The warehouse manager will contact the service department at Brinkmann Instruments at 800-645-3050, Ext 404 to schedule the calibration; send the pipettes to Brinkmann, and then back to the field.

A complete list of troubleshooting information is included on pages 28 and 29 of the Instruction Manual.

14.14 Power Loss and Laboratory Operations

Three scenarios may occur if power is lost to the MEC. Scenario 1 occurs when power is lost during an exam session and there is no backup generator. Scenario 2 occurs when power is lost when the MEC is not conducting a session. Scenario 3 occurs when power is lost but there is a backup generator available. Procedures to address each scenario are described in detail.

14.14.1 Scenario 1 - Power Loss during Exam Session with No Backup Generator

If a power loss occurs during a MEC session, action must be taken to either continue processing the blood or preserve the integrity of the processed specimens. The phlebotomist should not draw blood during a power loss because of safety concerns due to insufficient light.

Centrifuges

- **Overview** - There are two centrifuges in each MEC: one centrifuge is operated at ambient temperature and the second is operated at refrigerated (2-6°C) temperature. All blood tubes can be spun in the refrigerated centrifuge but the lavender tube for vessel 7 must be spun in the refrigerated centrifuge. The plasma from vessel 7 must be off the cells within 30 minutes or the lavender blood tube must be kept refrigerated.
- While power is generally required to open or unlock the centrifuge door, an emergency access procedure will allow the technologists to open the door to retrieve the blood tubes if a power failure occurs.
- **Consequences** – All blood tubes can remain in the locked centrifuge for up to 4 hours except for the lavender blood tube for vessel 7. If the plasma from this tube is not separated and frozen within 30 minutes, the data from this vial are lost.
- **Actions**
 1. It is not possible to routinely spin all tubes in one centrifuge; if a power loss is anticipated, spin all tubes in the refrigerated centrifuge.
 2. Use the emergency access procedure to retrieve the blood tubes from the centrifuge. Aliquot the serum and plasma into the vessels if the serum or plasma has sufficiently separated from the cells.
 - Move the secondary latch lever to UNLOCK position.
 - Insert a 5-mm (3/16 in.) or smaller screwdriver into the override key slot in the front panel (See Figure 4-1 on page 4-4 of the Operations Manual).
 - Turn the screwdriver clockwise until you hear a “click” or until the door pops open.

Laminar flow hood

- **Overview** - The technologists require the laminar flow hood to process the blood for two reasons: (1) the hood provides an uncontaminated or clean environment for processing environmental blood specimens; (2) the hood is required to provide a full-face shield in case of an accidental blood splash. In addition, the outlet in the hood provides power to the electronic pipettes. The electronic pipette is required to perform an accurate dilution for vessel 3 (RBC Folate.)
- **Consequences** – The environmental specimens may become contaminated. The pipette will lose battery power after ~60 minutes.

- **Actions**

1. Complete an Unusual Occurrence Log to document the SP IDs of the samples processed without a fully functioning hood. This information is subsequently recorded in an annual summary for NCHS.
2. Attach the comment “equipment failure” to vessels 1, 5, and 29.
3. Use the backup full-face shields when processing blood.
4. Process vessel 3 immediately so specimens are not lost due to battery failure.

Freezers and refrigerators

- **Overview** – There are four freezers and two refrigerators in each MEC lab. The freezers are located under the counter that holds the two large centrifuges and they are numbered 1 to 4 from left to right. Refrigerator #1 is located to the right of the laminar flow hood and refrigerator #2 is located to the right of the Coulter MAXM. There is one wall-mounted Jewett temperature-recording unit for each freezer and refrigerator. These units are blue and they contain a round paper chart with a red pen tracing. Each unit is marked with a label that matches the corresponding freezer or refrigerator. Refrigerant gel packs are distributed and stored in the freezers. Most specimens are stored in various plastic vials and the vials are placed in cardboard boxes with grids; the cardboard boxes are then stored in the freezers and refrigerators. In addition, some blood tubes (vessels 54 and 55), swabs (vessels 73 and 76), the VOC water (vessel 56), and the Coulter and pregnancy controls are stored in the refrigerator.
- **Consequences** – Specimen integrity is affected if frozen specimens thaw or if refrigerated specimens reach ambient temperature. Some analytes are more sensitive than other analytes. The temperature-monitoring chart provides a constant readout of the actual temperature. A full freezer takes approximately 3 hours to rise from -20°C to -10°C; a 1/2 filled freezer takes 2 hours and 25 minutes to rise to -10°C; and a 1/4 filled freezer takes 1 hour and 45 minutes to rise to -10°C. Once the temperature reaches -10°C the staff has approximately 30 minutes before the specimens thaw.
- **Actions**
 1. Do not open the freezer or refrigerator doors, if possible.
 2. Refrigerators - After 30 minutes or when the temperature recording chart reading reaches 7°C, add 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator. Do not add dry ice to the refrigerators; this will cause the refrigerator to explode.

3. Freezers – Contact the local dry ice company and order 200 pounds of dry ice. Obtain four large ice chests or coolers; each cooler should hold the boxes from one freezer and 50 pounds of dry ice. Within 2 hours or when the temperature recording chart reading reaches -10°C , move the containers (boxes) to the ice chests and add 50 pounds of dry ice to each ice chest. Alternatively, move the containers to Styrofoam shippers and distribute the dry ice across the shippers. Do not add dry ice to the freezers; this will cause the freezer to explode.

Coulter MAXM

- **Overview** - The Coulter consists of the MAXM, the monitor, hard drive, and printer. The MAXM will not function without the hard drive and monitor. The blood components for the CBC (complete blood count) are stable for a maximum of 24 hours when stored at room temperature.
- **Consequences** – None.
- **Actions** – None.

NOTE: The data manager should disable the Sensaphone system before a scheduled power loss.

14.14.2 Scenario 2- Power Loss when the MEC is Not Conducting Exams

If the power loss occurs when the MEC is not conducting a session, the freezers and refrigerators require action to protect the integrity of the specimens. The lab staff can continue to ship if all the ISIS processes are complete. If the ISIS processes are not complete, the lab staff can still pack the shippers and complete the ISIS process once power is restored.

Freezers and refrigerators

- **Overview** – All three MECs now have the Sensaphone system installed. The Sensaphone system monitors the room temperature and the internal temperature of the refrigerators and freezers in the MEC laboratory. When the system detects a significant increase in the temperatures, it begins calling designed staff. The MEC managers and data managers have been identified as those individuals responsible for responding to the call by typing in the response code. The temperature increase could be confined to one freezer or refrigerator, to multiple units, or all units. The temperature increase could be due to any number of circumstances such as a loss of

power because a circuit breaker tripped, or due to a compressor malfunction or failure. Whoever enters the code must act to prevent loss of biological specimens. The Sensaphone temperature trigger was established to allow 30 minutes of travel time. After 30 minutes, frozen specimens may begin to thaw.

- **Consequences** – Same as scenario #1.

- **Actions**

1. Examine each recording unit chart to verify which unit(s) is/are affected. The red pen line on the affected freezer or refrigerator chart should show a distinct movement toward the center of the graph.
2. Refrigerators - If one refrigerator has been affected, move all the specimens to the other refrigerator. If both refrigerators have been affected, keep the specimens cold by adding 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator. Do not add dry ice to the refrigerators; this will cause the refrigerator to explode.
3. Freezers – If only one freezer has been affected, move all the specimens from the affected unit to an unaffected unit. If more than one freezer has been affected and there is sufficient space in the unaffected freezers to accommodate the specimens, move the specimens to the other unaffected freezers. If there is insufficient space to accommodate the frozen specimens in the unaffected units or if all four freezers are affected, try to reach the chief medical technologist or any of staff medical technologists to assist. Contact the local dry ice company and order 200 pounds of dry ice. Obtain four large ice chests or coolers; each cooler should hold the boxes from one freezer and 50 pounds of dry ice. Within 2 hours or when the temperature recording chart reading reaches -10°C , move the containers (boxes) to the ice chests and add 50 pounds of dry ice to each ice chest. Alternatively, move the containers to Styrofoam shippers and distribute the dry ice across the shippers. Do not add dry ice to the freezers; this will cause the freezer to explode.
4. Leave a note on the unit indicating the new location of the specimens.
5. Unplug the affected unit. Each plug is bound to an extension cord or is labeled and assigned to a corresponding wall outlet.

14.14.3 Scenario 3- Power Loss with a Backup Generator

If the power loss occurs when the MEC is conducting a session and there is a backup generator available, continue to monitor the temperature of the freezers and refrigerators and assess the situation with the MEC manager. If the temperature approached the established thresholds:

- Retrieve the generator from the trailer belly compartment;
- Retrieve the power strip;
- Plug the freezers into the power strip;
- Start the generator; and
- If both refrigerators have been affected, keep the specimens cold by adding 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator.

If a power loss occurs and the MEC is not conducting a session, the freezers and refrigerators require action to protect the integrity of the specimens. The Sensaphone system alerts the MEC and data managers that the temperature of the freezers and/or refrigerators has exceeded established thresholds. The MEC or data managers must respond to the call, travel to the MEC immediately, and do the following:

- Retrieve the generator from the trailer belly compartment;
- Retrieve the power strip;
- Plug the freezers into the power strip;
- Start the generator; and
- If both refrigerators have been affected, keep the specimens cold by adding 12 frozen gel packs (stored in the bottom of each freezer) to the center of each refrigerator. Alternatively, add 25 pounds of ice cubes or blocks to each refrigerator.

Appendix A

International Air Transport Association (IATA)
Dangerous Goods Regulations
January 2005

APPENDIX A

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) DANGEROUS GOODS REGULATIONS

A.1 General Provisions

Dangerous goods can be transported safely by air transport provided certain principles are strictly followed. The International Air Transport Association (IATA) publishes dangerous goods regulations. NHANES shipments fall under these regulations because diagnostic specimens (UN 3373) are packed in dry ice, which is classified as dangerous goods, and shipped via Federal Express, which uses air transport.

Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety, or to property, when transported by air and which are classified as to the type of hazard. The IATA Dangerous Goods Regulations are applicable to all shippers and agents that offer consignments of dangerous goods to airlines. A shipper must comply fully with these regulations when offering a consignment of dangerous goods to IATA member airlines, and to airlines participating in IATA interline agreements for cargo. Before offering any package for air transport, the shipper must comply with the following responsibilities (1.3.2).*

- A shipper must provide such information to his employees as will enable them to carry out their responsibilities with regard to the transport of dangerous goods by air.
- The shipper must ensure that the articles or substances are not prohibited for transport by air.
- The articles or substances must be properly identified, classified, packed, marked, labeled, and documented in accordance with IATA regulations.
- Before a consignment of dangerous goods is offered for air transport, all relevant persons involved in its preparation must have received training to enable them to carry out their responsibilities.

The successful application of regulations concerning the transport of dangerous goods and the achievement of their objectives are greatly dependent on the appreciation of all individuals concerning

* Notations in parentheses throughout this appendix represent the appropriate section in the *IATA Dangerous Goods Regulations*.

the tasks involved and on a detailed understanding of the regulations. Initial and recurrent training programs achieve this for all persons concerned in the transport of dangerous goods. Training must be provided or verified upon the employment of a person in a position involving the transport of dangerous goods by air (1.5.0.2). Recurrent training must take place within 24 months of previous training to ensure knowledge is current (1.5.0.3). A test must be undertaken following dangerous goods training to verify understanding of the regulation. A certificate must be issued confirming successful completion of the test (1.5.0.4).

Training requirements (1.5) include:

- General familiarization aimed at providing familiarity with IATA general provisions (1.5.2.2);
- Function specific training in the requirements applicable to the function for which that person is responsible; and
- Safety training to cover the hazards presented by dangerous goods, safe handling, and emergency response procedures.

A record of training must be maintained, which must include the following (1.5.4):

- The individual's name;
- The most recent training completion date;
- A description, copy, or reference to training materials used to meet the training requirement;
- The name and address of the organization providing the training; and
- A copy of the certification issued when the individual was trained, which shows a test has been completed satisfactorily.

Training Curricula (table 1.5A)

Aspects of transport of dangerous goods by air which packers should be familiar, as a minimum include:

- General philosophy
- Limitations

- General requirements for shippers
- Classifications
- List of dangerous goods
- General packing requirements
- Packing instructions
- Labeling and marking
- Shipper's Declaration and other relevant documentation
- Recognition of Undeclared Dangerous Goods
- Provisions for passengers and crew
- Emergency procedures

A.2 Limitations

Some dangerous goods are too dangerous to be carried by aircraft, others may be carried on cargo aircraft only, and some are acceptable on both cargo and passenger aircraft. A number of limitations are placed on dangerous goods, which are permitted to be transported by air. These limitations are established by these Regulations (2.0).

The following goods are permitted on aircraft as checked baggage only and with the approval of the operator(s) (2.3.2).

- Dry Ice – Carbon Dioxide, solid (dry ice) in quantities not exceeding 2 kg (4.4 lbs) per person when used to pack perishables not subject to these Regulations, provided the checked baggage (package) permits release of carbon dioxide gas (2.3.2.1).

A.3 Classifications

Dangerous goods are defined as those goods which meet the criteria of one or more of the nine UN hazard classes and, where applicable, to one of the three UN packing groups according to provisions of IATA regulations. The nine classes relate to the *type of hazard*, whereas the packing groups

relate to the *degree of danger* within the class (3.0.1). The nine classes are: Class 1 Explosives; Class 2 Gases; Class 3 Flammable Liquids; Class 4 Flammable Solids, Substances Liable to Spontaneous Combustion, Substances Which, in Contact with Water, Emit Flammable Gases; Class 5 Oxidizing Substances and Organic Peroxide; Class 6 Toxic and Infectious Substances; Class 7 Radioactive Material; Class 8 Corrosives; and Class 9 Miscellaneous Dangerous Goods.

Dangerous goods are assigned to the relevant packing group according to the degree of hazard that they present (3.0.3). The three packing groups are: Packing Group 1 – high danger; Packing Group 2 – medium danger; and Packing Group 3 – low danger.

A.3.1 Class 6.2 – Infectious Substances (3.6.2)

Division 6.2 defines infectious substances as substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals. (3.6.2.1).

Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373, as appropriate. (3.6.2.2.1) The proper shipping name for UN 2814 is *Infectious substance, affecting humans*. The proper shipping name for UN 2900 is *Infectious substance, affecting animals*. The proper name of UN 3373 is *Diagnostic specimens* or *Clinical specimens*. (3.6.2.2.1)

Human or animal material including, but not limited to, excreta, secreta, blood and its components, for purposes such as research, diagnosis, investigational activities, disease treatment or prevention, are governed by UN 3373 and Special Provision A141. (3.6.2.2.3)

A.3.2 Class 9 – Miscellaneous Dangerous Goods

Class 9 defines miscellaneous dangerous goods as substances and articles, which, during air transport, present a danger not covered by other classes (3.9.1.1). Included in this class is solid carbon dioxide, or dry ice. Dry ice is regulated by packing instruction 904.

A.3.3 List of Dangerous Goods

Diagnostic specimens and clinical specimens are classified as UN number 3373 and are classified as Class 6.2 dangerous goods. The relevant packing instruction is 650. (Pg 165) A special provision directs that this entry applies to human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, and body parts being transported for purpose such as research, diagnosis, investigational activities, disease treatment or prevention. (4.4 A141 Pg 304).

Dry ice is classified as UN number 1845 and is classified as Class 9 dangerous goods. Shipping packaging must be labeled with a Miscellaneous Class 9 label (pg. 149). Dry ice is included within Packing Group III, which is classified as a minor danger. A maximum net quantity per package is 200 kg or 441 lb. The relevant packing instruction is 904. (Pg 149) A special provision directs that packing tests are not considered necessary (4.4 A48 Pg 298).

A.4 General Packing Provisions

The shipper is responsible for all aspects of the packing of dangerous goods in compliance with these Regulations. (5.0.1.1) For packing purposes, Packing Group numbers I, II, or III are assigned to dangerous goods in Classes 3, 4, 5, 6, 8 and 9 according to the relative degree of danger presented by the article or substance. (5.2.2.1)

- Packing Group I – Substances presenting high danger
- Packing Group II – Substances presenting medium danger
- Packing Group III – Substances presenting low danger

Dry ice is reassigned to packing group III. Dry ice (solid carbon dioxide) is produced by expanding liquid carbon dioxide to vapor and “snow” in presses that compact the product into blocks. Dry ice is used primarily for cooling and can cause severe burns (its temperature is about -79° C) to skin in case of direct contact. When dry ice (solid carbon dioxide converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent buildup of pressure due to release of carbon dioxide gas.

Dangerous goods must be packed in good quality packaging, which must be strong enough to withstand the shocks and loadings normally encountered in transport. Packages must be constructed, and closed as to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration or by changes in temperature, humidity, or pressure (resulting from altitude, for example) (5.0.2.4.1).

New, remanufactured, reused, or reconditioned packaging must be manufactured and tested under a program of quality assurance to ensure that such packaging meets requirements (5.0.2.5).

Packaging for which retention of liquid is a basic function, must be capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95 kPa for liquids in packing group III, Class 3, or Division 6.1 (5.0.2.9).

Packaging used for solids, which may become liquid at temperatures likely to be encountered during air transport, must also be capable of containing that substance in the liquid state (5.0.2.10).

Inner packaging – cushioning material: Inner packaging must be packed, secured, or cushioned in an outer packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into outer packaging and so as to control their movement (5.0.2.12.1).

A.4.1 Packing Instruction 650 - Diagnostic Specimens (Pg 454-455)

Diagnostic specimens must be packed in good quality packaging, which must be strong enough to withstand the shocks and loading normally encountered during transport, including transshipment between transport units and warehouses as well as removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging must be constructed and closed to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity, or pressure.

The packaging must consist of three components:

- (a) a primary receptacle(s);
- (b) a secondary packaging; and
- (c) a rigid outer packaging.

Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into secondary packaging. Secondary packaging must be secured in outer packaging with suitable cushioning material. Any leakage of the contents must not substantially impair the protection properties of the cushioning material or of the outer packaging.

Packages must be prepared as follows:

650(a) For Liquids

- The primary receptacle(s) must be leak proof and must not contain more than 1 L.
- The secondary packaging must be leakproof.
- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.
- Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity to absorb the entire contents of the primary receptacle (so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging).
- The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40°C to +55°C (-40°F to 130°F).
- The outer packaging must not contain more than 4 L.

650(b) for Solids

- The primary receptacles must be siftproof and must not exceed the outer packaging weight limit.
- The secondary packaging must be siftproof.

- If multiple fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated to prevent contact between them.
- The outer packaging must not contain more than 4 kg.
- If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent material, must be used.

Package Testing

- Each completed package must be capable of successfully passing the following drop tests described in 6.6.1 except that the height of the drop must not be less than 1.2 m.
 - Samples must be subjected to free-fall drops onto a ridged, nonresilient, flat, horizontal surface from a height of 9 m (30 ft)
 - Where the samples are in the shape of a box, five must be dropped in sequence:
 1. Flat onto the base;
 2. Flat onto the top;
 3. Flat onto the longest side;
 4. Flat onto the shortest side; and
 5. Onto a corner.
 - Following the appropriate drop sequence, there must be no leakage from the primary receptacles(s), which must remain protected by absorbent material in the secondary packaging.
 - The samples must be subjected to a water spray that simulated exposure to rainfall of approximately 5 cm per hour for at least 1 hour. It must then be subjected to the drop test.
 - The samples must be conditioned in an atmosphere of -18°C (0°F) or less for a period of at least 24 hours and within 15 minutes of removal from that atmosphere be subjected to the drop test (6.6.1.3). Where the samples contain dry ice, the conditioning period may be reduced to 4 hours.
 - Where packaging is intended to contain dry ice (solid carbon dioxide), an additional test must be carried out. One sample must be stored so that all the dry ice dissipates and then it is subjected to the drop test.

For Liquids and Solids

- An itemized list of contents must be enclosed between the secondary packaging and the outer packaging
- Packages must have one side with dimensions of not less than 100 mm x 100 mm (4 in x 4 in) or packages must be in an overpack that has one side with dimensions of not less than 100 mm x 100 mm (4 in x 4 in).
- For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of contrasting color and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm (2 in), the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high and must be marked on the outer package adjacent to the diamond shaped mark.



Unless all package markings are clearly visible, the following conditions apply when packages are placed in an overpack:

- The overpack must be marked with the work "Overpack;" and
- The package markings must be reproduced on the outside of the overpack.

Specific Requirements – refrigerated or frozen specimens: ice, dry ice and liquid nitrogen

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice (solid carbon dioxide) has been dissipated. If ice is used, the packaging or overpack must be leak-proof. If dry ice (solid carbon dioxide) is used, the outside packaging or overpack must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packaging.

- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.
- Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these regulations except for the following:
 - (a) The name, address and telephone number of a responsible person must be provided on the waybill or on the package;
 - (b) The classification must be in accordance to 3.6.2 (see Section A.3.1);
 - (c) The incident reporting requirements in 9.6.1 must be met; and
 - (d) The inspection for damage or leakage requirements in 9.4.1 and 9.4.2.

9.6.1 – An operator must report dangerous goods accidents or incidents to the appropriate authorities of the State of the operator and the State in which the accident or incident occurred, in accordance with the reporting requirements of those appropriate authorities.

9.4.1 and 9.4.2 – Packages and overpacks containing dangerous goods must be inspected for signs of damage or leakage upon unloading from the aircraft or unit load device. If evidence of damage or leakage is found, the position where the dangerous goods or unit load was stowed on the aircraft must be inspected for damage or contamination and any hazardous contamination removed. The special responsibilities of operators regarding infectious substances are detailed in 9.4.2. (9.4.1)

- The “Nature and Quantity of Goods” box of the air waybill must show the text “DIAGNOSTIC SPECIMENS” or “CLINICAL SPECIMENS” and UN 3373.
- A Shipper’s Declaration for Dangerous Goods is not required.
- Clear instructions on filing and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package to enable the package to be correctly prepared for transport.

A.4.2 Packing Instruction 904 - Dry Ice (Pg 502)

This instruction applies to UN 1845 on passenger and cargo aircraft. The General Packaging Requirements of 5.0.2 must be met.

Dry ice (solid carbon dioxide), when offered for transport by air, must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.

The net weight of dry ice must be marked on the outside of the package.

Arrangements between the shipper and operator(s) must be made for each shipment to ensure that ventilation and safety procedures are followed.

When a Shipper's Declaration is not required, the following information as required by 8.2.3 for dry ice (solid carbon dioxide) must be contained in the "Nature and Quantity of Dangerous Goods" box on the air waybill:

- Proper shipping name (**Dry Ice** or **Carbon Dioxide, solid**);
- UN 1845;
- The number of packages; and
- The net weight of dry ice in each package.

The net weight of the dry ice must be marked on the outside of the package.

A.5 Packing Specifications and Performance Tests

Performance tests are designed to ensure that there will be no loss of contents under normal transport conditions. The severity of the tests on a packaging is dependent on the intended contents, taking account of the degree of danger; that is, packing group, relative density (specific gravity), and vapor pressure (for liquids) (6.3.0.2).

The design type of each packaging must be tested as provided in accordance with procedures established by IATA regulation (6.3.1). Tests must be successfully performed on each packaging type before such packaging is used (6.3.1.1.1).

A.6 Marking and Labeling

All markings must be so placed on packages or overpacks that they are not covered or obscured by any part of or attachment to the packaging or any other label or marking. (7.1.3.1)

All markings must be:

- Durable and printed or otherwise marked on, or affixed to, the external surface of the package or overpack;
- Readily visible and legible;
- Able to withstand open weather exposure without a substantial reduction in effectiveness; and
- Displayed on a background of contrasting color (7.1.3.2).

Unless all markings representative of all dangerous goods in the overpack are clearly visible, the overpack must be marked with the word “Overpack.” (7.1.4)

Each package must be marked durably and legible on the outside with each of the following:

- The word “Overpack;”
- The proper shipping name of the contents and the corresponding UN numbers (7.1.5.1a) (diagnostic specimens is UN 3373 and dry ice is UN 1845);
- The full name and address of the shipper and the consignee (7.1.5.1b);
- The NET Quantity of dry ice contained in each package or overpack must be shown. The quantity must be marked on each package or overpack adjacent to the UN number and Proper Shipping Name (7.1.5.1d);
- The name and telephone number of a responsible person (7.1.5.1e); and
- For packages containing UN 3373: - “Diagnostic Specimens;” “DIAGNOSTIC SPECIMENS” or “CLINICAL SPECIMENS.” (7.1.5.1g)

Empty Packaging

- Other than Class 7, a packaging which previously contained dangerous goods must be marked as required for those dangerous goods unless steps such as cleaning, purging

of vapors, or refilling with a nondangerous substance are taken to nullify any hazard. (7.1.5.6)

There are two types of labels: hazard labels (in the shape of a square set at 45°) which are required for most dangerous goods in all classes and handling labels (in various rectangular shapes), which are required, wither alone or in addition to hazard labels for some dangerous goods (7.2.2.2).

A primary hazard label is specified for each listed article and substance and a secondary hazard label or labels for each article and substance having subsidiary risks (7.2.3.1). For Class 9 materials, the package must bear the class 9, “Miscellaneous Dangerous Goods” label as required for all dry ice shipments (7.2.3.10).

All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label (7.2.6.1a). Each label must be affixed on a background of contrasting color or must have a dotted or solid line outer border (7.2.6.1b). The label must not be folded or affixed in such a manner that different parts of the label appear on different faces of the package (7.2.6.1c). The package must be of such a size that there is adequate space to affix all required labels (7.2.6.1e).

Labels must be located on the same surface of the package near the proper shipping name marking if the package dimensions are adequate (7.2.6.2.1).

A.7 Documentation

An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). A “Shipper’s Declaration for Dangerous Goods” is not required for shipments containing diagnostic specimens or dry ice (Pg 455 and 502).

If a Shipper’s Declaration is not required for dangerous goods, the Nature and Quantity of Goods” box of the Air Waybill must show in sequence (8.2.3):

- Proper Shipping Name;
- Class or Division number:

- UN or ID number;
- Subsidiary risk, if any;
- Number of packages; and
- Net quantity per package.

For dry ice, it is not necessary to show the packing group and packing instruction number on the air waybill.

A.8 References

1. *IATA Dangerous Goods Regulations*, 46th Edition, effective January 1, 2004, ISBN 92-9195-318-0
2. *FedEx Service Guide Vol. 1*, effective June 1, 2000.

A.9 IATA Regulations Examination

Name _____

Date _____

1. IATA is the acronym for: _____

2. Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety or to property, when transported by air and which are classified as to the type of hazard. (T or F)

3. What are the four responsibilities the shipper must comply with before offering any package for air transport?

- _____
- _____
- _____
- _____

4. List the three training requirements:

- _____
- _____
- _____

5. How many UN hazard classes are there? _____

6. What are the three classifications of infectious substances?

- _____
- _____
- _____

7. To what UN hazard class do diagnostic specimens belong? _____

8. To what UN hazard class does dry ice belong? _____
9. What is the dry ice UN number? _____
10. To what packing group does dry ice belong? _____
11. Solid carbon dioxide or dry ice is produced by expanding liquid carbon dioxide to vapor and “snow” in presses that compact the product into blocks. Dry ice is used primarily for cooling and can cause severe burns (its temperature is about -79°C) to skin in case of direct contact. When dry ice (solid carbon dioxide) converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent buildup of pressure due to release of carbon dioxide gas.
(T or F)
12. List the four types of packaging that must be tested to ensure that packaging meets requirements:
- _____
 - _____
 - _____
 - _____
13. Diagnostic specimens must be packed in good quality packaging, which must be strong enough to withstand the shocks and loading normally encountered during transport, including transshipment between transport units and warehouses as well as removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging must be constructed and closed to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity, or pressure.
What packing instruction regulates diagnostic specimens? _____
14. List the three packaging components:
- _____
 - _____
 - _____

15. Properly prepared shipments containing liquids must meet the following 6 conditions:
- _____
 - _____
 - _____
 - _____
 - _____
 - _____
16. An itemized list of contents must be placed between the secondary packaging and the outer packaging. (T or F)
17. Each package and the “Nature and Quantity of Goods” box of the air waybill must show the text “DIAGNOSTIC SPECIMENS” or “CLINICAL SPECIMENS” and UN 3373. (T or F)
18. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or overpack. Interior supports must be provided to secure secondary packagings in the original position after all the ice or dry ice has dissipated. (T or F)
19. The weight of dry ice is required on the outside of the packaging. (T or F)
20. The performance tests are designed to ensure that there will be _____ under normal transport conditions.
21. All markings must be:
- _____
 - _____
 - _____
 - _____
22. For Class 9 goods (dry ice), the package is required to bear the dangerous goods label. (T or F)
23. All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label. (T or F)
24. An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). (T or F)

A.10 IATA Regulations Examination (Answer Key)

Name _____

Date _____

1. IATA is the acronym for the International Air Transport Association
2. Dangerous goods are articles or substances that are capable of posing a significant risk to health, safety or to property, when transported by air and which are classified as to the type of hazard.
(T or F) True
3. What are the four responsibilities the shipper must comply with before offering any package for air transport?
 - Information to employees as will enable them to carry out their responsibilities.
 - Ensure that articles or substances are not prohibited for transport by air.
 - Articles must be properly identified, classified, packed, marked, labeled, and documented.
 - All persons involved in preparing consignment must have received training.
4. List the three training requirements:
 - General familiarization aimed at providing familiarity with IATA general provisions;
 - Function specific training in the requirements applicable to the function for which that person is responsible; and
 - Safety training to cover the hazards presented by dangerous goods, safe handling, and emergency response procedures.
5. How many UN hazard classes are there? 9 (nine)
6. What are the three classifications of infectious substances?
 - UN 2814 Infectious substance, affecting humans
 - UN 2900 Infectious substance, affecting animals
 - UN 3373 Diagnostic specimens or clinical specimens
7. To what UN hazard class do diagnostic specimens belong? Class 6.2

8. To what UN hazard class does dry ice belong? Class 9
9. What is the dry ice UN number? UN 1845
10. To what packing group does dry ice belong? Packing group 3
11. Solid carbon dioxide or dry ice is produced by expanding liquid carbon dioxide to vapor and “snow” in presses that compact the product into blocks. Dry ice is used primarily for cooling and can cause severe burns (its temperature is about -79°C) to skin in case of direct contact. When dry ice (solid carbon dioxide) converts (sublimates) directly to gaseous carbon dioxide, it takes heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas as it displaces air. Packages containing dry ice must be designed and constructed to prevent buildup of pressure due to release of carbon dioxide gas.
(T or F) True
12. List the four types of packaging that must be tested to ensure that packaging meets requirements:
- New
 - Remanufactured
 - Reused
 - Reconditioned
13. Diagnostic specimens must be packed in good quality packaging, which must be strong enough to withstand the shocks and loading normally encountered during transport, including transshipment between transport units and warehouses as well as removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging must be constructed and closed to prevent any loss of contents when prepared for transport, which might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity, or pressure.
What packing instruction regulates diagnostic specimens? Packing instruction 650
14. List the three packaging components.
- Primary receptacle
 - A secondary packaging
 - A rigid outer packaging
15. Properly prepared shipments containing liquids must meet the following 6 conditions:
- The primary receptacle must be leakproof
 - The secondary packaging must be leakproof

- Fragile receptacles must be individually wrapped or separated to prevent contact
 - Absorbent material must be placed between primary receptacle and secondary packaging
 - Primary receptacle or secondary packaging must be capable of withstanding an internal pressure producing a pressure differential of not less than 95 kPa in the range of -40°C to +55°C
 - The outer package must not contain more than 4 L
16. An itemized list of contents must be placed between the secondary packaging and the outer packaging. (T or F) True
17. Each package and the “Nature and Quantity of Goods” box of the air waybill must show the text “DIAGNOSTIC SPECIMENS” or “CLINICAL SPECIMENS” and UN 3373. (T or F) True
18. When used, ice or dry ice must be placed outside the secondary packaging or in the outer packaging or overpack. Interior supports must be provided to secure secondary packagings in the original position after all the ice or dry ice has dissipated. (T or F) True
19. The weight of dry ice is required on the outside of the packaging. (T or F) True
20. The performance tests are designed to ensure that there will be no loss of contents under normal transport conditions.
21. All markings must be:
- Durable and printed or otherwise marked on, or affixed to, the external surface of the package or overpack
 - Readily visible and legible
 - Able to withstand open weather exposure without a substantial reduction in effectiveness
 - Displayed on a background of contrasting color
22. For Class 9 goods (dry ice), the package is required to bear the Class 9 “Miscellaneous” dangerous goods label. (T or F) True
23. All labels must be securely affixed or printed on the packaging so that they are readily visible and legible and not obscured by any part of the packaging or by any other label. (T or F) True
24. An “air waybill” must be completed for each consignment of dangerous goods (8.0.1). (T or F) True

46th Edition International Air Transport Association.

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International Air Transport Association (IATA) Dangerous Goods Regulations

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Appendix B

Biosafety

APPENDIX B. BIOSAFETY

B. POLICY FOR MANAGEMENT OF EXPOSURE TO BLOODBORNE PATHOGENS

Exposure Control Plan for NHANES Training and Examinations

B.1 Introduction

The policy presented in this section is intended to serve as the written policy for the NHANES mobile examination center staff training and main study period. It is based on the OSHA Regulations for exposure to bloodborne pathogens as published in the *Federal Register* (29CFR 1910.1030), the Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis (MMWR, June 29, 2001), the CDC recommendations, Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC) (December 1997) and the revised Occupational Exposure to Bloodborne Pathogens: Needlestick and Other Sharps injuries; Final Rule.

This manual describes the procedures required to treat and document blood exposure injuries to MEC staff. Universal precautions are the foundation of standard operating procedures and emergency procedures throughout the exam center. MEC staff, the home office staff, and NCHS monitor compliance with these precautions and the pertinent OSHA regulations.

OSHA's rule applies to all persons occupationally exposed to blood or other potentially infectious materials. Blood means human blood, blood products, or blood components. On NHANES, the only body fluids that are collected are blood, vaginal swabs, and urine. Urine is not considered infectious unless the specimens are visibly contaminated with blood or are known to contain an infectious agent.

The Occupational Safety and Health Administration revised the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act. This Act directs OSHA to (1) revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; (2) require that Exposure Control Plans reflect how employers implement new developments in control technology; (3) require employers to solicit input

from employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and (4) require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps.

B.2 Exposure Determination

B.2.1 MEC Employees by Group

Exposure determination is based on the definition of occupational exposure without regard to personal protective clothing and equipment. Job classifications within the work environment are reviewed for exposure and two groups of exposures are identified: Category I job classifications in which all the employees have occupational exposure, and Category II classifications in which some of the employees have occupational exposure. Where all employees have occupational exposure, it is not necessary to list specific work tasks. Where only some employees have occupational exposure, procedures causing occupational exposure must be listed.

Occupational exposure for NHANES staff is categorized as follows:

Category I Exposures

- Phlebotomist
- Medical technologist

Category II Exposures

- Physician
- MEC manager

The physician may risk exposure in the event of an emergency in the MEC. The physician is expected to respond to any emergency and perform appropriate procedures, but this does not include the initiation of IV fluids. The MEC manager is responsible for insuring that biohazardous waste is removed and thus may occasionally handle bagged biohazardous waste. The MEC manager is also expected to respond to emergencies and thus may risk exposure if the emergency involves a laceration.

B.3 Methods of Compliance

B.3.1 Control for Category I and Category II Exposures

Risks posed by bloodborne pathogens may be reduced through vaccination, engineering controls, employee work practices, personal protective equipment, and housekeeping procedures. Bloodborne pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Because some infectious diseases can be communicable through contact with SPs and blood, all Category I and Category II staff members are advised to:

- Obtain the hepatitis B vaccine if recommended by Westat for their category of exposure; and
- Use universal precautions (see Section B.3.2) when there is a potential for exposure to blood or body fluids.

B.3.2 General - Universal Precautions

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. Universal precautions are observed to prevent contact with blood or other potentially infectious materials. Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. Universal precautions are applied to procedures involving all sample persons.

B.3.3 Engineering and Work Practice Controls

Engineering and work practice controls are the primary methods used to prevent occupational transmission of HBV, HIV, and other bloodborne pathogens. Sharps disposal containers, self-sheathing needles, and biological safety cabinets are examples of engineering controls used in the NHANES.

Biological safety cabinets are similar in appearance to laboratory fume hoods and protect employees from exposure to airborne biohazards by providing an enclosed, mechanically ventilated space for them to work. A laminar flow biological safety cabinet is located in the laboratory in every MEC.

Sharps containers are liquid-tight, puncture-resistant vessels used to minimize the hazards posed by discarded needles, broken glass, scalpels, and other contaminated sharp objects. Light plastic bottles such as those that hold consumer products are unacceptable because the walls are easily penetrated by sharps. Metal, heavy-gauge plastic or laminated multi-ply cardboard containers are a much better choice.

Engineering controls isolate or remove the bloodborne pathogen hazard from the workplace. Work Practice Controls are controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique). These include procedures for processing and handling blood and blood products, waste disposal, and personal hygiene.

Category I

Specific procedures for preventing exposures in Category I staff are as follows:

- All materials intended for reuse are inspected and decontaminated on a regular basis and are cleaned and decontaminated immediately upon visible contamination.
- Sinks that can be used for hand washing are provided in the bathrooms in trailers 1 and 4 and in the hallways in trailers 1 and 2, in the laboratory, phlebotomy room, and staff lounge in trailer 3, and in the dental exam room in trailer 4. The laboratory and dental sinks include an electronic eye on/off mechanism.

- All MEC exam staff are instructed to wash hands with soap and water after removing gloves or upon accidental skin contact with blood or body fluids, and between each SP exam.
- Employees are instructed to wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.
- Sharps should be handled with extreme care and discarded into the needle disposal containers provided in the MEC. Staff members are instructed that contaminated needles and other contaminated sharps shall not be bent, recapped, or removed. Shearing or breaking of contaminated needles is prohibited. They are required to use the shielding mechanism. Contaminated sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires. Use of the safety shielding mechanism is mandatory.
- Discarded needles and other waste sharps must be placed in an "approved" sharps container. Care must also be taken when mounting a sharps container on the walls and cabinets to make sure the container is accessible to everyone. Immediately or as soon as possible after use, contaminated reusable sharps are placed in puncture resistant and leakproof containers until properly reprocessed. These containers are identified as containing potentially infectious materials and are not allowed to overfill.
- Employees are instructed not to eat, drink, smoke, handle contact lenses, or apply cosmetics or lip balm in the exam rooms.
- No food or drinks are kept in refrigerators, freezers, shelves, cabinets, or work surfaces in the examination rooms. An employee lounge with a refrigerator is provided for personal food storage.
- Procedures involving blood or other potentially infectious materials are performed in such a manner as to minimize splashing, spraying, spattering, or aerosolizing. For example, the splattering of blood or serum that occurs when rubber stoppers are pulled out of specimen tubes is minimized by covering the stopper with gauze before removing it and performing this procedure under the biosafety hood.
- Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.
- Equipment should be checked and decontaminated before servicing and shipping. Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
- Work surfaces and or equipment contaminated with blood or body fluids are washed with detergent and disinfected with a 1:10 or 1:100 dilution of bleach at the end of every examination session, as described in the examiner manuals.

- Protective coverings used to cover equipment and environmental surfaces are removed and replaced as soon as feasible when overtly contaminated with blood or body fluids during the exam session.
- Broken glassware is never picked up by hand, but swept up with a brush and dustpan. To minimize aerosol formation, broken glass is not dropped into a disposal container but gently placed in the container.

Category II

Although the MEC is not set up to treat or manage medical problems, medical emergencies may occur. If the staff must administer CPR, it is recommended that all staff observe the following procedures to prevent exposures:

- Wear gloves and a lab coat when performing emergency procedures. Disposable impervious lab jackets are available in the lab if needed.
- Use the disposable resuscitation masks found in designated areas.
- Follow the instructions of the MEC physician, who will direct the emergency response.
- Decontaminate and/or dispose of all emergency medical supplies.
- Change any protective equipment contaminated with blood or body fluids.
- Wash hands after removing gloves and before working with the next SP.

B.3.4 Personal Protective Equipment

Personal Protective Equipment is used when occupational exposure remains after instituting engineering and work practice controls. Personal protective equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered personal protective equipment.

The selection of protective equipment depends on the nature of the potential exposure but generally includes gloves, lab coats, and gowns. If there is a chance for potentially infectious material to splash into the eyes or mouth, staff members are instructed to wear face protection in the form of a mask

and/or safety glasses with side shields. The employer provides all protective equipment in appropriate sizes and sufficient quantities for staff use. Hypoallergenic gloves or other alternatives are available to employees with allergic sensitivity to gloves.

Staff members other than those in Categories I or II are not expected to perform work procedures that carry risk for exposure to blood or body fluids but the following precautions are communicated to the staff in training and monitored:

- Staff should not perform any procedure or task for which they have not been trained.
- Gloves, disposable impervious lab jackets, and/or safety glasses are worn when performing venipuncture, and laboratory procedures. Personal protective equipment is provided to the staff. Disposable impervious lab jackets are provided to the medical technologists, phlebotomists, and health technologists performing the oral health examination. Reusable cloth lab coats are provided to the physician and MEC manager and are laundered by the employer if contaminated with blood or body fluids. Safety glasses are optional for the phlebotomist and are available onsite. Disposable, powder-free hypoallergenic non-latex powder-free gloves are provided to the medical technologists, phlebotomist, and dental examiners. Wear appropriate gloves if contact with blood, or other potentially infective materials is anticipated. Never wash or decontaminate disposable gloves for reuse.
- Gloves are changed after each sample person exam or when visibly soiled with blood and/or body fluids. Disposable impervious lab jackets worn by the laboratory and phlebotomy staff are discarded when soiled and at the end of each workweek. Disposable impervious lab jackets worn by the health technologists during the oral health examination are changed when visibly soiled with blood and body fluids. All disposable impervious lab jackets are removed before leaving the work area and after a garment become contaminated. Place used protective equipment in appropriately designated areas or containers when being stored or discarded.

B.3.5 Housekeeping

Under the OSHA standard, all areas must be kept clean and sanitary. A cleaning schedule that includes appropriate methods of decontamination procedures has been developed for every component and is included in the component-specific procedure manuals. These procedures are included in component training programs and are part of daily component procedures. Cleaning procedures are based on the type of surfaces, the type of contamination present, the tasks or procedures, and their location in the facility. Housekeeping staff also receive a written set of instructions for cleaning designated areas of the MEC.

The following housekeeping procedures must be observed and will be monitored by project staff:

- Clean and decontaminate all equipment and environmental and work surfaces contaminated with blood or other potentially infectious materials.
- Decontaminate work surfaces with an appropriate disinfectant after completion of procedures, immediately when overtly contaminated, after any spill of blood or other potentially infectious material, and at the end of the work shift when surfaces have become contaminated since the last cleaning.
- Remove and replace protective coverings such as plastic wrap.
- Inspect and decontaminate, on a regular basis, reusable receptacles such as bins, pails, and cans that have the likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as possible.
- Place other regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that prevent leakage.
- When discarding contaminated sharps, place them in containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom.
- Ensure that sharps containers are easily accessible to personnel and located as close as feasible to the use area. Keep sharps containers upright throughout use, replace routinely, close when moved, and do not allow to overfill.
- Never manually open, empty, or clean contaminated sharps disposable containers.
- Discard regulated waste into appropriate containers, labeled as biohazardous waste, and seal to prevent leakage during handling storage and transport. Regulated Waste means liquid or semiliquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semiliquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials. A hazardous waste company is responsible for the disposal of biohazardous waste from the MEC.

Specific methods and regular schedules for cleaning bench tops, equipment, and other environmental surfaces contaminated with potentially infectious materials are documented in the Infection Control Manual and in the respective component procedure manuals. The time required for cleanup may

be reduced if surfaces are covered before work with an impermeable, disposable covering such as plastic sheeting or absorbent bench pads.

Good housekeeping procedures are not limited to areas in which infectious materials are handled. Prudent safety practice dictates that halls and passageways are kept clear of obstructions such as carts, obsolete equipment, and shipping containers. Fire doors, other than those interconnected to smoke-detection systems, are kept closed. Stairs are not obstructed and exits are clearly marked.

Contaminated laundry is handled as little as possible and placed in labeled bags at locations where it is used. Leakproof bags are used to transport wet laundry. In addition, all employees who work with contaminated laundry wear gloves.

B.4 Hepatitis B Vaccine

The hepatitis B vaccine is made available to Category I and II MEC staff at no cost and at a reasonable time and place within 10 working days of initial assignment, and to any MEC staff following an exposure incident. Employees who refuse the hepatitis vaccine must sign the Declination Form, which is kept with the employee's medical records. Employees who have previously received the vaccine should provide evidence of antibody testing or completion of the vaccine series.

If an exposure incident occurs, the MEC manager and MEC physician must be notified immediately. The MEC physician must complete a Medical Incident Form, and the employee must receive an immediate medical evaluation to assess their level of vaccine protection, their level of exposure, and to recommend an appropriate treatment regimen per the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis* (MMWR, June 29, 2001),

B.4.1 Procedures for Evaluating Exposure Incidents

The OSHA standard requires that following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up. Exposure Incident means a specific eye, mouth, other mucous membrane, nonintact skin, or parenteral

contact with blood or other potentially infectious materials that results from the performance of an employee's duties. The exposure report must include at least the following elements:

1. Date and time of exposure;
2. Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;
3. Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;
 - a. The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV, HCV, and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.
 - b. Results of the source individual's testing shall be made available to the exposed employee's physician, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
4. Collection and testing of blood for HBV, HCV, and HIV serological status;
 - a. The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.
 - b. If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.
5. Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;
6. Counseling; and
7. Evaluation of reported illnesses.

It is important that the employee have access to treatment for possible HBV, HCV, or HIV exposure as soon as possible after the incident because HBIG (Hepatitis B immunoglobulin), hepatitis B vaccine, and HIV PEP (postexposure prophylaxis) are most likely to be effective if administered as soon after the exposure as possible. During training, the training supervisor, the Director of MEC Operations, Catherine Novak, and/or the Director of Examinations, Carla Maffeo, Ph.D., will oversee the response to

a needlestick or other exposure. During the examination period, the MEC physician is responsible for initiating the response, referring the employee to the nearest emergency department, notifying home office staff, and documenting the incident.

At a minimum, the evaluation and followup must include the following elements:

- Treatment of Exposure Site
 - Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen transmission; however, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.
- Exposure Report
 - Document the routes of exposure and how the exposure occurred on a Medical Incident Form and OSHA's Forms 300 and 301 (See Section 5.6 in Chapter 5 of the *Infection Control Procedures Manual*). The Medical Incident Form can be accessed from any exam room by clicking on the ambulance icon on the toolbar.
- Evaluation of the Employee and the Exposure
 - The employee should proceed immediately to the closest emergency department where they can be evaluated and counseled. Hospitals are available during all working hours, including nights and weekends. HBIG, hepatitis B vaccine, and antiretroviral agents for HIV PEP should be available for timely administration (i.e., either by providing access on site or by creating linkages with other facilities or providers to make them available off site). The evaluating emergency physician is responsible for providing postexposure management and counseling. They are familiar with evaluation and treatment protocols and the hospital has access to HBIG, hepatitis B vaccine, and antiretroviral drugs for HIV PEP.
 - The exposure will be evaluated by the hospital physician for the potential to transmit HBV, HCV, and HIV based on the type of body substance involved and the route and severity of the exposure. Blood, fluid containing visible blood or other potentially infectious fluid, can be infectious for bloodborne viruses. Exposures to these fluids through a percutaneous injury (i.e., needlestick or other penetrating sharps-related event) or through contact with a mucous membrane are situations that pose a risk for bloodborne virus transmission and require further evaluation. For HCV and HIV, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher risk exposure than exposure to a needle that was most likely used for giving an injection.

- The physician evaluating the employee must be provided with a copy of the OSHA bloodborne pathogen regulations, a description of the employee's duties relevant to the exposure incident, and documentation of the route and circumstances of exposure. Within 15 days after the evaluation of the exposed employee, the employer must obtain a copy of the report from the healthcare professional responsible for the postexposure evaluation and insure that the employee receives a copy of the written opinion. The evaluating physician must provide a written opinion regarding vaccination status and postexposure evaluation and followup. The written opinion to the employer is limited to whether the vaccine is necessary, documentation of administration, and whether the employee was informed of the results of the evaluation, including any medical conditions resulting from exposure which require further evaluation or treatment. However, all diagnoses not related to the exposure incident are protected by patient/physician confidentiality and should not be included in the written report to the employer.
- For skin exposure, followup is indicated only if it involves exposure to a body fluid previously listed and evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).
- Evaluation of the Exposure Source
 - The person whose blood or body fluid is the source of an occupational exposure should be evaluated for HBV, HCV, and HIV infection.
 - The HBV, HCV, and/or HIV infection status of the source is unknown. The source person should be informed of the incident and asked to undergo testing at the emergency department or to consent to have their blood tested by an independent reference laboratory. It will be explained to the SP that a blood test is needed to determine treatment options for the exposed person. Offer to use serum that has already been collected for testing so that a second venipuncture will not be necessary. The SP may also choose to go to their physician to obtain the test at NHANES project expense. The SP will be asked to consent to release the results of the tests to the exposed staff person by sending the results to the staff person's physician. The SP should sign the consent form (See Exhibit 5-3 in Chapter 5 of the *Infection Control Procedures Manual*.) and a copy of the consent should be provided to the SP. If the SP refuses to be tested, the MEC physician or other supervisor named above should document the refusal in writing.
 - Procedures should be followed for testing source persons, including obtaining informed consent, in accordance with applicable state and local laws. Any persons determined to be infected with HBV, HCV, or HIV should be referred for appropriate counseling and treatment. Confidentiality of the source person should be maintained at all times.
 - Testing to determine the HBV, HCV, and HIV infection status of an exposure source should be performed as soon as possible. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if

testing by EIA cannot be completed within 24--48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorescent antibody is not necessary to make initial decisions about postexposure management but should be done to complete the testing process and before informing the source person. Repeatedly reactive results by EIA for anti-HCV should be confirmed by a supplemental test (i.e., recombinant immunoblot assay [RIBA™] or HCV PCR). Direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV RNA or HCV RNA) for routine HIV or HCV screening of source persons are not recommended.

- If the exposure source cannot be tested or refuses to provide consent, information about where and under what circumstances the exposure occurred should be assessed epidemiologically for the likelihood of transmission of HBV, HCV, or HIV. Certain situations as well as the type of exposure might suggest an increased or decreased risk; an important consideration is the prevalence of HBV, HCV, or HIV in the population group (i.e., institution or community) from which the contaminated source material is derived.
- Testing of needles or other sharp instruments implicated in an exposure, regardless of whether the source is known or unknown, is not recommended. The reliability and interpretation of findings in such circumstances are unknown, and testing might be hazardous to persons handling the sharp instrument.
- The exposed employee's physician is provided with the source individual's test result and information about the applicable disclosure laws and regulations concerning the source identity and infectious status. (This will be accomplished through the evaluating physician and not through the employer.)

A copy of all documentation related to the incident, including the Medical Incident Form and OSHA's Forms 300 and 301, should be sent to the Director of Mobile Examination Center Operations, Catherine Novak, as soon as possible.

A more detailed description of these recommendations are in the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis* (MMWR, June 29, 2001). Copies of these guidelines are available in Appendix C of the *Infection Control Manual*.

B.5 Labeling

The OSHA standard requires that fluorescent orange and orange-red warning labels be attached to containers of regulated waste, to refrigerators and freezers containing blood and other potentially infectious materials, and to other containers used to store, transport, or ship blood or other potentially infectious materials. These labels are not necessary when (1) using red bags or red containers; (2) labels designate the contents of containers of blood, blood components, or blood products; and (3) individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, or disposal. The warning label must be fluorescent orange or orange-red, contain the biohazard symbol and the word BIOHAZARD, in a contrasting color, and be attached to each object by string, wire, adhesive, or other method to prevent loss or unintentional removal of the label.

In the MEC, labels are affixed to containers of infectious waste, centrifuges, refrigerators and freezers containing blood or body fluids and containers used to store, transport, or ship blood or body fluids.

B.6 Communication of Hazards to Employees - Training

All MEC employees, including those designated, as Category I and II will receive information and training during their working hours regarding the OSHA regulation and their exposure category at the time of initial assignment and at no cost to the employee. The training program will be provided at least once a year thereafter. Additional training will be provided as necessary when existing tasks are modified or tasks are added that affect the employee's exposure risk. Persons conducting the training will be knowledgeable about the subject matter, and the information will be appropriate in context and vocabulary to the education level, literacy, and language of the audience. All training programs for MEC staff will include instruction in the OSHA regulations, general infection control practices, and specific infection control procedures relevant to each examination component. The training must include the following elements:

- How to obtain a copy of the regulatory text and an explanation of its contents;
- Information on the epidemiology and symptoms of bloodborne diseases;
- Ways in which bloodborne pathogens are transmitted;

- Explanation of the exposure control plan and how to obtain a copy;
- Information on how to recognize tasks that might result in occupational exposure (categories of exposure);
- Explanation of the use and limitations of work practice and engineering controls, and personal protective equipment;
- Information on the types, selection, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment;
- Information on hepatitis B vaccination such as safety, benefits, efficacy, methods of administration, and availability;
- Information on who to contact and what to do in an emergency;
- Information on how to report an exposure incident and on postexposure evaluation and followup;
- Information on warning labels, and signs, where applicable, and color-coding;
- Information on other infectious disease concerns in the MEC; and
- Question and answer session on any aspect of the training.

B.7 Recordkeeping

The exposure control plan is reviewed and updated at least annually or whenever new tasks and procedures affect occupational exposure. A copy of the Exposure Plan is kept in every copy of the *Infection Control Manual*. Copies of this manual are kept in the staff lounge and in the physician exam room, and in each field office. The plan must be made available to the Assistant Secretary for OSHA and to the Director of the National Institute for Occupational Safety and Health for examination and copying if required.

Employers also must preserve and maintain for each employee an accurate record of occupational exposure. Under the OSHA bloodborne pathogens standard, medical records must include the following information:

- Employee's name and Social Security number;
- Employee's hepatitis B vaccination status including vaccination dates and any medical records relating to the employee's ability to receive vaccinations;

- Results of examinations, medical testing, and postexposure evaluation and followup procedures;
- Health care professional's written opinion; and
- A copy of the information provided to the health care professional.

Medical records must be kept confidential and maintained for at least the duration of employment plus 30 years.

Training records must also be maintained and kept accurate by the employer for 3 years and must include the following:

- Training dates;
- Content or a summary of the training;
- Names and qualifications of trainer(s); and
- Names and job titles of trainees.

Upon request, both medical and training records must be available to the Director of the National Institute for Occupational Safety and Health and to the Assistant Secretary of Labor for Occupational Safety and Health. Training records must be available to employees or employee representatives upon request. The employee or anyone having the employee's written consent can obtain an employee's medical records. In addition, if the employer ceases to do business, medical and training records must be transferred to the successor employer. If there is no successor employer, the employer must notify the Director, NIOSH, U.S. Department of Health and Human Services, for specific directions regarding disposition of the records at least 3 months before intended disposal.

B.8 Schedule and Methods for Implementing Sections of the Standard Covering the Methods of Compliance

Procedures for compliance with OSHA bloodborne pathogen recommendations are included in initial NHANES training programs and incorporated into all specific component procedures and operations procedures in the MEC. All procedures should be operational at the time of training and during the main study.

B.9 Sharps Injury Log

29 CFR Part 1904 – Recording and Reporting Occupational Injuries and Illnesses requires establishment and maintenance of a sharps injury log. All work-related needlestick injuries and cuts from sharp objects that are contaminated with another person’s blood or other potentially infectious material must be entered on the OSHA’s Forms 300 and 301 as an injury. The OSHA’s Forms 300 and 301 serve as the sharps injury log. Do not enter the employee’s name to maintain confidentiality. The sharps injury log must contain, at a minimum:

1. The type and brand of device involved in the incident,
2. The department or work area where the exposure incident occurred, and
3. An explanation of how the incident occurred.

The sharps injury log is maintained for the period required by 29 CFR 1904.03; the OSHA’s Forms 300 and 301 are maintained for five (5) years following the end of the calendar year that these records cover.

B1.10 Needlestick and other Sharps Injuries

In January 2001, the Occupational Safety and Health Administration revised the Bloodborne Pathogens (BBP) standard in conformance with the requirements of the Needlestick Safety and Prevention Act. The revisions to OSHA's BBP standard required under the Needlestick Safety and Prevention Act can be broadly categorized into four areas: modification of definitions relating to engineering controls, revision and updating of the Exposure Control Plan, solicitation of employee input, and recordkeeping.

The standard has been revised to add new requirements to the annual review and update of the Exposure Control Plan. Consideration and implementation of safer medical devices must be documented in the Exposure Control Plan by describing the safer devices identified as candidates for adoption, the method or methods used to evaluate devices and the results of evaluations, and justification for selection decisions. The revised standard requires that solicitation of input from employees be documented in the Exposure Control Plan. This information must be updated at least annually. The

recordkeeping requirements of the standard have been amended by adding a paragraph to require that employers maintain a sharps injury log to serve as a tool for identifying high risk areas and evaluating devices.

In November 1999, NIOSH published ALERT, Preventing Needlestick Injuries in Health Care Settings. A comprehensive plan and program to prevent transmission of bloodborne pathogens and to meet (and exceed, whenever possible) regulations was implemented to identify and evaluate various new safer needle technologies and devices. The intent was to replace the existing nonshielded blood collection needles.

Annual formal evaluations have been conducted since 2000. A notebook detailing each evaluation is kept at the Westat home office and is available for review and inspection.

The latest memo describing the process that was conducted in February 2004 follows.

TO: Catherine Novak
FROM: Barbara Lindstrom
SUBJECT: Annual 2004 Shielded Needle Evaluation

February 25, 2004

Background

In January 2001, the Occupational and Safety and Health Administration (OSHA) revised the Bloodborne Pathogens (BBP) standard in conformance with the requirements of the Needlestick Safety and Prevention Act. The revisions to OSHA's BBP standard required under the Needlestick and Safety Act can be broadly categorized into four areas: modification of definitions relating to engineering controls, revision and updating the Exposure Control Plan (ECP), solicitation of employee input, and recordkeeping.

The standard was revised to add new requirements to the annual review and update of the ECP. Consideration and implementation of safer medical devices must be documented in the ECP by describing the safer devices identified as candidates for adoption, the methods used to evaluate the devices and the results of the evaluation, and justification for selection decisions. This information must be updated annually.

Previous Evaluations

Products selected for evaluated are based on three sources of research: information provided by existing vendors, information provided by supply representative, and an Internet search. A variety of blood collection needles and sharps containers have been included in all previous evaluations. Preference is given to those products that use newer and safer technologies.

A variety of blood collection needles and sharps containers were evaluated during the first annual evaluation process that began in February 2000. Specific products were approved and put into use in August 2000. The evaluation process was repeated in July 2001, July 2002, and September 2002. The needles and sharps containers that are currently being used were approved during the July 2002 evaluation cycle and were reevaluated in September 2002. Documentation supporting each evaluation cycle is contained in previous versions of this memo.

The NHANES survey currently maintains one approved sharps container and four shielded blood collection needles:

- Becton Dickinson™ (BD) Vacutainer Eclipse Multi-sample needle (21G x 1 1/4")
- Becton Dickinson™ Butterfly Needle 19G Saf-T EZ Set and Luer Adapter
- Becton Dickinson™ Butterfly Needle 21G Safety-Lok Blood Collection Set
- Becton Dickinson™ Butterfly Needle 23G Safety-Lok Blood Collection Set
- Bio-Hazard Container (8 Gallon)

Candidates for Adoption – 2003-4

This year's research has yielded a newer shielding needle technology. BD Vacutainer Systems has introduced a Push Button™ Blood Collection Set (available in 21 and 23 G only) that is designed to make activating the safety mechanism easy. Its in-vein activation reduces risk of healthcare worker exposure to a contaminated needle, provides easy activation without patient discomfort, and is ideal for use in high-risk environments. The one-handed safety activation of the push button allows for activation of the safety mechanism while still attending to the participant/venipuncture site, and provides easier, safer blood collection for the healthcare worker, with no compromise to participant care.

Methods for Evaluation Devices

The MEC phlebotomists and back-up phlebotomists evaluated the 21 and 23 G BD Push Button™ Blood Collection Sets in both sizes at stands 172 and 173. The evaluation was conducted using samples provided by the manufacturer's representative.

- Part #367344 - BD Vacutainer Push Button™ Blood Collection Set, 21G 12" tubing, 0.75 needle w/Luer Adapter (50/Box 200/Case)
- Part #367342 - BD Vacutainer Push Button™ Blood Collection Set, 23G 12" tubing, 0.75 needle w/Luer Adapter (50/Box 200/Case)

The phlebotomist's evaluation took place during stands 172 and 173 in January 2004. They took the following actions:

1. Reviewed the hard copy instructions for use
2. Reviewed the hard copy wall chart
3. Reviewed the hard copy package insert
4. Reviewed the web-based training presentation
5. Selected the appropriate gauge needle for each participant (used the 21 gauge shielded blood collection set for most participants), performed the venipuncture, and completed an evaluation form (see attachment A.) They completed at least 6 evaluation forms on at least 1 SP in each age group, 1-2, 3-5, 6-11 and 12+.
6. Sent the evaluation forms and all unused needles back to the home office at the end of the stands.

Sharps Container Evaluation

The phlebotomists and medical technologists used the Sharps Disposal Evaluation Form (see Attachment B) to reevaluate the 8-gallon biohazard sharps container used in the lab and phlebotomy. Each medical technologist and phlebotomist completed at least one evaluation form for the 8-gallon container. The evaluation forms were sent back to the home office at the end of the stand.

Results of the Evaluation and Justification for Selection Decisions

The BD Eclipse continues to function as designed and no problems were noted by the evaluating staff. However, since the staff uses less than five per year, any change does not seem justified. The decision is to continue to maintain a supply of the Becton Dickinson™ Vacutainer Eclipse Multi-sample needle (21G x 1 1/4").

The phlebotomists use the 19 G needle on about one-half of all survey participants. Since BD does not currently manufacture the Push Button™ Blood Collection Set with a 19 G needle and the staff expressed continued satisfaction with the current BD™ Butterfly Needle 19 G Safe-T EZ Set and Luer Adapter the decision is to continue to maintain this needle for use in phlebotomy.

BD's new Push Button™ Blood Collection set in 21 and 23 G sizes was evaluated by the staff as directed in the evaluation plan. The BD Push Button™ Blood Collection Sets performed as described by the manufacturer. Review of the evaluation forms and verbal debriefings with the staff demonstrated that the technology increased their safety without compromising the survey protocol. The increased cost for this new device is \$0.11 each (\$1.14 vs. \$1.25.) The decision is to switch over to these new products as soon as the current inventory is exhausted.

The phlebotomists and medical technologists evaluated the 8-gallon biohazard sharps container used in the lab and phlebotomy. The evaluation forms revealed no problem with this item. The decision is to continue to use the existing sharps containers.

All evaluation forms will be kept in a notebook at the home office and are available for inspection at any time.

cc: B. Lewis
G. McQuillan

ATTACHMENT A
Safety Blood Collection Set
Evaluation Form – Stand 172 and 173

Date: _____ Tech ID: _____ Position: _____
 Manufacturer: _____ Number of
 Needle size: _____ times used: _____

- ✓ Indicate the degree to which you agree or disagree with each statement by circling the most appropriate number for each statement.
 ✓ Not applicable (N/A) may be used if the question does not apply to this product.

| DURING USE: | agree | | | | | disagree | |
|--|-------|---|---|---|---|----------|-----|
| 1. The safety feature can be activated using a one-handed technique | 1 | 2 | 3 | 4 | 5 | N/A | |
| 2. The safety feature <u>does not</u> interfere with normal use of this product | 1 | 2 | 3 | 4 | 5 | N/A | |
| 3. Use of this product requires you to use the safety feature | 1 | 2 | 3 | 4 | 5 | N/A | |
| 4. This product does not require more time to use than a non-safety device | 1 | 2 | 3 | 4 | 5 | N/A | |
| 5. The safety feature works well with a variety of hand sizes | 1 | 2 | 3 | 4 | 5 | N/A | |
| AFTER USE: | agree | | | | | disagree | |
| 6. There is a clear and unmistakable change (either audible or visible) that occurs when the safety feature is activated | 1 | 2 | 3 | 4 | 5 | N/A | |
| 7. The safety feature operates reliably | 1 | 2 | 3 | 4 | 5 | N/A | |
| 8. The exposed sharp is blunted or covered after use and prior to disposal | | 1 | 2 | 3 | 4 | 5 | N/A |
| TRAINING: | agree | | | | | disagree | |
| 9. The product <u>does not</u> need extensive training to be operated correctly | 1 | 2 | 3 | 4 | 5 | N/A | |

Did this needle interfere with your ability to complete the venipuncture protocol? Yes or No

Of the above questions, which three are the most important to your safety when using this product?

Are there other questions that you feel should be asked regarding the safety/utility of this product?

**ATTACHMENT B
Sharps Disposal
Evaluation Form**

Date: _____
Position: _____
Manufacturer: _____

Name: _____
Stand: _____
Capacity: _____

Indicate the degree to which you agree or disagree with each statement by circling the most appropriate number for each statement.

Not applicable (N/A) may be used if the question does not apply to this product.

| Please Rate: | agree | disagree |
|---|-----------|----------|
| 1. The container is puncture resistant | 1 2 3 4 5 | N/A |
| 2. The container does not leak | 1 2 3 4 5 | N/A |
| 3. The container is stable | 1 2 3 4 5 | N/A |
| 4. The container is accessible from any direction | 1 2 3 4 5 | N/A |
| 5. The container is located where the needles are used | 1 2 3 4 5 | N/A |
| 6. The container allows single handed use | 1 2 3 4 5 | N/A |
| 7. It is possible to drop sharps or tubes into the container vertically | 1 2 3 4 5 | N/A |
| 8. No force is required to put sharps or tubes into the container | 1 2 3 4 5 | N/A |
| 9. Needles/tubing do not get caught on the opening or interior shape | 1 2 3 4 5 | N/A |
| 10. The container opens and closes easily | 1 2 3 4 5 | N/A |
| 11. The container has a solid tight-fitting cover | 1 2 3 4 5 | N/A |
| 12. The box accommodates a range of sharp sizes or tubes | 1 2 3 4 5 | N/A |
| 13. The size of the container is appropriate for its use | 1 2 3 4 5 | N/A |
| 14. No one (including a child) can access the contents | 1 2 3 4 5 | N/A |
| 15. There is a permanent lock for final disposal that is not reversible | 1 2 3 4 5 | N/A |
| 16. The user can determine the fill level visually | 1 2 3 4 5 | N/A |
| 17. The container is appropriately labeled | 1 2 3 4 5 | N/A |
| 18. The box is not threatening to participants | 1 2 3 4 5 | N/A |
| 19. Use of this container does not compromise infection control practices | 1 2 3 4 5 | N/A |

Did this sharps container interfere with your ability to complete the venipuncture or blood processing protocol?
Yes or No

Are there other questions that you feel should be asked regarding the safety/utility of this product?

B.11 Laboratory and Phlebotomy Infection Control

This section contains a summary of all procedures used for infection control in the MEC laboratory and phlebotomy components. For detailed information regarding these procedures, refer to the component's manual of operation.

B.11.1 Glossary

| | |
|--------------------------------|---|
| Decontamination: | The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. |
| Detergent: | A cleansing agent used to facilitate the removal of gross debris from an object. |
| Disinfect: | To inactivate virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial endospores) on inanimate objects. |
| Engineering Controls: | Controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace. |
| Mucous membrane exposure: | Occurs from droplet contamination (splashes, spatters) of the eyes, nose, or mouth. |
| Parenteral exposure: | Piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions. |
| Personal Protective Equipment: | Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered personal protective equipment. |
| Regulated Waste: | Liquid or semiliquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semiliquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials. |

| | |
|---|--|
| Sharps with engineered sharps injury protections: | Non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident. |
| Sterilize: | The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores. |
| Universal precautions: | An approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. |
| Work Practice Controls: | Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique). |

In order to comply with Federal regulations, minimize the spread of infectious diseases, and provide a safe working environment, follow defined safety procedures at all times.

B.11.2 Laboratory Access

- Unauthorized people should not enter the MEC laboratory.
- All authorized persons must wear gloves when working with equipment, and when handling biological specimens such as blood, blood products, or urine in the laboratory. Examples are lab staff, biomedical engineers, Coulter technical representatives, NCHS or observers, coordinator, assistant coordinator, health techs, and MEC manager. People who visit the lab to observe should not touch countertops, equipment, or supplies if they are not wearing gloves.

B.11.3 Laboratory/Phlebotomy - Universal Precautions

A complete description of Universal Precautions is described in Section B.3.2. Laboratory staff, including the phlebotomist, observe Universal Precautions at all times.

B.11.4 Laboratory/Phlebotomy - Specific Engineering and Work Practice Controls

Engineering and work practice controls are described in Section B.3.3. Engineering controls eliminate hazards at their source. The biological safety cabinet and waste containers for sharps are examples of engineering controls used in the NHANES. A laminar flow biological safety cabinet is located in the laboratory in every MEC.

All health care workers take precautions to prevent injuries caused by needles and other sharp instruments or devices during procedures, when cleaning used instruments, during disposal of used needles, and when handling sharp instruments after procedures. It is mandatory and essential to use the shielded mechanism of the needle.

Specific measures of protection for the laboratory staff (including the phlebotomist) are described below.

Hang outside street clothing in a designated separate clean area.

Engineering Controls

- Do not eat, drink, smoke, handle contact lenses, or apply cosmetics or lip balm in the MEC laboratory or in the examination rooms.
- Do not keep food or drinks in refrigerators, freezers, shelves, cabinets, or work surfaces in the examination rooms. An employee lounge with a refrigerator is provided for personal food storage.
- Do not mouth pipette.
- Procedures involving blood or other potentially infectious materials are performed in such a manner as to minimize splashing, spraying, or aerosolizing. For example, the splattering of blood or serum that occurs when rubber stoppers are pulled out of specimen tubes is minimized by covering the stopper with gauze before removing it and performing this procedure under the biosafety hood.
- Perform all blood processing tasks in the LSBSC.
- Use Aerosolve containers when centrifuging blood tubes.
- Used needles must never be sheared, bent, clipped, broken, or recapped by hand. Discarded needles and other waste sharps must be placed in an “approved” sharps container. Either use a one-handed “scoop” technique or a mechanical device designed for holding the needle sheath.

- Use of the safety shielding mechanism on the blood collection needle is mandatory.
- Never point (direct) or move the unsheathed tip of a needle toward anyone.
- Always be alert and extremely cautious when handling unsheathed needles.
- Immediately after use, dispose of sharps in sharps containers.
- When discarding contaminated sharps, place them in containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom.
- Ensure that sharps containers are easily accessible to personnel and located as close as feasible to the use area.
- Keep sharps containers upright throughout use, replace routinely, close when moved, and do not overfill. Do not overstuff the biohazard waste containers by poking the trash down with another object. Shaking the container back and forth is acceptable.
- Never manually open, empty, or clean contaminated sharps disposable containers.
- Never discard needles directly into a container used for ordinary (“noninfectious”) waste.

B.11.5 Laboratory/Phlebotomy - Personal Protective Equipment

A complete description of personal protective equipment is contained in Section B.3.4.

- Wear impervious lab jackets when performing venipuncture and laboratory procedures. Disposable impervious lab jackets are provided to the medical technologists and phlebotomists.
- Remove protective equipment before leaving the work area and after a garment becomes contaminated.
- Place used protective equipment in appropriately designated areas inside the laboratory and place in designated biohazardous containers when being discarded.
- Discard lab jackets when soiled and at the end of each workweek.
- If the LFBSC is nonfunctional, then wear safety glasses when processing blood. Safety glasses are optional for the phlebotomist but safety glasses are available onsite.
- Wear appropriate face and eye protection such as a mask with glasses with solid side shields or a chin-length face shield when splashes, sprays, spatters, or droplets of

blood or other potentially infectious materials pose a hazard to the eye, nose, or mouth.

- It is mandatory to wear gloves when performing venipuncture, processing blood specimens, processing urine, processing vaginal swabs, and performing hematology testing. Disposable, powder-free hypoallergenic nonlatex powder-free gloves are provided to the medical technologists and phlebotomist.
- Change gloves after each sample person's exam or when visibly soiled with blood and/or body fluids.
- Never wash or decontaminate disposable gloves for reuse.
- Discard utility gloves at the first sign of deterioration.
- Remove gloves before leaving the laboratory or phlebotomy room.

Personal Hygiene – Infection Control

- Wash hands with soap and water after removing gloves or upon accidental skin contact with blood or body fluids, and before working with the next SP.
- Hand washing sinks are located in the bathrooms in trailers 1 and 4, in the hallways in trailers 1 and 2, in the laboratory, phlebotomy room, and staff lounge in trailer 3, and in the dental exam room in trailer 4. The laboratory and dental sinks include an electronic eye on/off mechanism.
- If using liquid soap for hand washing, replace with fresh product when empty. Do not add liquids to a partially full dispenser.

B.11.6 Laboratory/Phlebotomy - Waste Management

A complete description of the waste management procedures is described in Section B.3.5.

- Discard hazardous waste into appropriate containers. Biohazardous waste containers are labeled and sealed to prevent leakage during handling storage and transport. A hazardous waste company is responsible for the disposal of biohazardous waste from the MEC. Do not overstuff the biohazard waste containers by poking the trash down with another object. Shaking the container back and forth is acceptable.
- Dispose of all potentially infectious materials in a biohazard waste container.
- When discarding glass blood tubes, place them in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom.

- Place solid waste from the laboratory in biohazard bags and transport to an area designated to hold these bags. A single bag is adequate if the bag is sturdy (not easily penetrated) and if the waste can be put in the bag without contaminating the outside of the bag; otherwise, double bagging is indicated.
- To minimize the potential risk for accidental transmission of disease or injury, store infective waste waiting terminal processing in a pre-incineration storage area in the MEC accessible only to personnel involved in the disposal process.
- Place regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that prevent leakage.
- Transport closed sharps containers and biohazard bags destined for incineration or steam sterilization to the designated pre-incineration storage.
- Discard all regulated waste according to Federal, state, and local regulations.
- Refer to “infectious waste” in the glossary for any questions about identifying wastes for which special precautions appear prudent.
- Liquid Wastes
 - Pour urine down the sink connected to the sewer before discarding the cup into biohazard container.
 - Pour Coulter waste down the sink connected to a sewer. Add 1 3/4 cups (3.75-mL) undiluted bleach to the 10-gallon waste container and reattach to the instrument.

B.11.7 Laboratory/Phlebotomy - Labeling

In the MEC, labels are affixed to containers of infectious waste, centrifuges, refrigerators, and freezers containing blood or body fluids and containers used to store, transport, or ship blood or body fluids.

A complete description of the OSHA label requirements is described in Section B.5.

B.11.8 Laboratory/Phlebotomy - Housekeeping

A complete description of OSHA’s housekeeping requirements is described in Section B.3.5.

All housekeeping procedures must be observed and will be monitored by project staff:

- Wash work surfaces and or equipment contaminated with blood or body fluids with detergent and disinfected with a 1:10 dilution of bleach.
- At the end of every examination session, disinfect work surfaces with a 1:10 dilution of bleach.
- Check and decontaminate equipment before servicing and shipping.
- Remove protective coverings used to cover equipment and environmental surface and replace as soon as feasible when overtly contaminated with blood or body fluids during the exam session.
- Inspect and decontaminate all materials intended for reuse on a regular basis and clean and decontaminate immediately upon visible contamination.
- Inspect and decontaminate, on a regular basis, reusable receptacles such as bins, pails, and cans that have the likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as possible.
- Place other regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that prevent leakage.
- Clean and decontaminate all equipment and environmental and work surfaces contaminated with blood or other potentially infectious materials.
- Decontaminate work surfaces with an appropriate disinfectant after completion of procedures, immediately when overtly contaminated, after any spill of blood or other potentially infectious material, and at the end of the work shift when surfaces have become contaminated since the last cleaning.
- Remove and replace protective coverings such as plastic wrap and aluminum foil when contaminated.
- Clean and disinfect equipment and working surfaces, including keyboard covers, with a 1:10 bleach solution (5-mL bleach to 50-mL tap water) or 1:100 bleach solution (1-mL bleach to 100-mL water) after completion of procedures, when surfaces are overtly contaminated, immediately after any spill of blood or other potentially infectious materials, and at the end of the work shift.
- Remove and replace nonabsorbent paper used to cover equipment and environmental surfaces at the end of the work shift or when they become overtly contaminated.
- Check equipment routinely and decontaminate as necessary before servicing or shipping.

- Decontaminate reusable items contaminated with blood or other potentially infectious materials before washing and/or reprocessing. Routinely check equipment and decontaminate it before servicing and shipping.
- Clean and decontaminate all equipment and work surfaces contaminated with blood or other potentially infectious materials.
- On a regular basis inspect and decontaminate reusable receptacles such as bins, pails, and cans that have likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as possible.

B.11.9 Laboratory/Phlebotomy – Cleaning a Blood Spill

If a blood spill occurs, wear gloves, and if needed, a gown and facial protection during the cleanup procedure.

If spill contains broken glass use dustpan and broom to collect glass pieces. Dispose of broken glass and contaminated paper towels in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom. Disinfect dustpan and broom with bleach solution. Always use mechanical means such as forceps or a brush and dust pan to pick up contaminated broken glass; never pick up broken glass with hands even if wearing gloves. To minimize aerosol formation, broken glass is not dropped into a disposal container but gently placed in the container.

To clean a blood spill perform the following procedure:

- Wear gloves;
- Cover spill with disposable paper towels;
- Soak paper towels with 10% bleach solution;
- Let soak for at least 30 seconds;
- Dispose of blood/bleach soaked paper towels in biohazard container;
- Allow area to dry and then remove gloves; and
- Wash hands.

B.12 References

The following references were used to prepare the Exposure Plan:

1. *Occupational Exposure to Bloodborne Pathogens*, U.S. Department of Labor, Occupational Safety and Health Administration. OSHA 3127, 1996 (Revised). Title 29 Code of Federal Regulations, Part 1910.1030. [56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]
2. *Immunization of Health-Care Workers*, USPHS, CDC., MMWR 1997;46(No. RR-18).
3. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis* (MMWR, June 29, 2001)
4. *Occupational Exposure to Bloodborne Pathogens, Needlestick and other Sharps injuries: Final Rule*, U.S. Department of Labor, Occupational Safety and Health Administration. OSHA, 2000 (Revised).
5. Title 29 Code of Federal Regulations, Part 1904.
6. CDC. Guideline for Hand Hygiene in Health-Care Settings Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002:51(RR-16).

Copies of these materials are included in the Appendixes of the *Infection Control Manual*.

Appendix C

Specimen Protocol by Tube Type

APPENDIX C. SPECIMEN PROTOCOL BY TUBE TYPE

| 11/29/2004 | Lab | Shipping Freq | P 1-2 | P 3-5 | P 6-11 | P 12+ | | DR odd | P 6-11 | DR even | |
|--|-----------------------------------|---------------|-------|-------|--------|-------|------------------|--------|------------------|---------|------------------|
| Whole Blood | | | | | | | | | | | |
| CBC | | | 1.5 | 1.5 | 1.5 | 1.5 | | 1.5 | | 1.5 | |
| 1 Lead/Cad/HG | CASPIR | Weekly | 0.3 | 0.3 | 0.3 | 0.3 | | 0.3 | | 0.3 | |
| 2 Ery Proto | NYS DOH/Wadsworth CTR L&R | Weekly | | 0.4 | | 0.4 | 12 to 49 females | 0.4 | 12 to 49 females | | |
| 3 RBC Folate | CASPIR | Weekly | 0.1 | 0.1 | 0.1 | 0.1 | | | | 0.1 | |
| 4 Glycohem | NHANES Diabetes Laboratory | Weekly | | | | 0.4 | | 0.4 | | | |
| 5 Mercury | CASPIR | Weekly | 0.5 | 0.5 | 0.5 | 0.5 | | | | 0.5 | |
| 6 CD4 | CASPIR | End of stand | | | | 0.5 | 18-49 | | | | |
| Whole blood total | | | 2.4 | 2.8 | 2.4 | 3.7 | | 2.6 | | 2.4 | |
| EDTA tube size | | | 3 | 3 | 3 | 4 | | 3 | | 3 | |
| Number of EDTA | | | 1 | 1 | 1 | 1 | | 2 | | 2 | |
| EDTA Plasma | | | | | | | | | | | |
| 7 Homocys/MMA | CASPIR | Weekly | | | | 1.0 | 20+ | | | 1.0 | 20+ |
| 8 Xtra Plasma | CASPIR | End of stand | | | 0.5 | 0.5 | | | | | |
| EDTA Plasma total | | | 0.0 | 0.0 | 0.5 | 1.5 | | | | 1.0 | |
| EDTA tube size | | | | | 4 | 4 | | | | 3 | |
| Number of EDTA | | | | | 1 | 1 | | | | 2 | |
| Packed Cells | | | | | | | | | | | |
| 88 Acrylamide | CASPIR | Weekly | | 1.0 | 1.0 | 1.0 | | | | | |
| EDTA tube size | | | | 3 | | 3 | | | | | |
| Number of EDTA | | | | 1 | | 1 | | | | | |
| NaCit Plasma | | | | | | | | | | | |
| 9 Glucose | NHANES Diabetes Laboratory | Weekly | | | | 0.5 | morning only | 0.5 | morning only | 0.5 | morning only |
| 2-mL Gray | | | | | | 2 | | 2 | | 2 | |
| Number of gray | | | | | | 1 | | 2 | | 2 | |
| 98 OGTT | NHANES Diabetes Laboratory | Weekly | | | | 0.5 | morning only | | | | |
| 2-mL Gray | | | | | | 2 | | | | | |
| Number of gray | | | | | | 1 | | | | | |
| Potassium oxalate/sodium fluoride Plasma total | | | | | | 4 | | | | | |
| Serum | | | | | | | | | | | |
| 100 IgE | | Weekly | 0.5 | 0.5 | 1.0 | 1.0 | | 1.0 | | | |
| 81 Vitamin B6 | CASPIR | Weekly | 0.2 | 0.3 | 0.3 | 0.5 | | 0.5 | | | |
| 70 Vitamin D | CASPIR | Weekly | 0.3 | 0.5 | 0.5 | 0.5 | | 0.5 | | | |
| 12 Folate/B12 | CASPIR | Weekly | 0.7 | 0.8 | 1.0 | 1.0 | | 1.0 | | | |
| 13 CRP | Univ of Washington | Weekly | 0.2 | 0.3 | 0.3 | 0.3 | | | | 0.3 | |
| 14 Hep profile | CDC NCID Hepatitis Ref Lab | Weekly | | | 1.5 | 1.5 | | | | 1.5 | |
| 87 Hepatitis ab | CDC NCID Hepatitis Ref Lab | Weekly | 0.3 | 0.4 | | | 2-5 | | | | |
| 99 Fer/TFR | CASPIR | Weekly | 0.3 | 0.5 | | 0.5 | 12 to 49 females | 0.5 | 12 to 49 females | | |
| 11 Iron/TIBC | Collaborative Laboratory Services | Weekly | | 1.0 | | 1.0 | 12 to 59 females | | | 1.0 | 12 to 59 females |
| 17 Cotinine | CASPIR | Weekly | | 1.0 | 1.3 | 1.8 | | | | 1.8 | |
| 21 Lipids | Lipoprotein Analytical Lab/JHU | Weekly | | | 1.5 | 1.5 | | 1.5 | | 1.5 | |
| 104 Lp(a) | U of Washington - Michelle Mehan | Weekly | | | | 0.5 | morning only | 0.5 | | 0.5 | |
| 94 PTH2 | Univ of Washington | Weekly | | | 1.0 | 1.0 | | 1.0 | | | |
| 77 HPV Serum | CDC Kristi Singletary Meadows | Weekly | | | | 0.5 | 14 to 59 | | | | |
| 79 Vitamin C | CASPIR | Weekly | | | 0.1 | 0.1 | | 0.1 | | | |
| 18 Biochem | Collaborative Laboratory Services | Weekly | | | | 0.8 | | 0.8 | | 0.8 | |
| 23 Insulin | NHANES Diabetes Laboratory | Weekly | | | | 1.0 | morning only | 1.0 | | | |
| 22 HIV | CDC NCID AIDS Division | Weekly | | | | 0.8 | 18 to 49 | | | | |
| 24 HSV | Emory University | Weekly | | | | 0.2 | 14 to 49 | | | | |
| 75 PSA | Univ of Washington | Weekly | | | | 1.0 | 40+ males | | | | |

APPENDIX C. SPECIMEN PROTOCOL BY TUBE TYPE (continued)

| 11/29/2004 | Lab | Shipping Freq | P 1-2 | P 3-5 | P 6-11 | P 12+ | | DR odd | | DR even |
|---------------------|-------------------------------|---------------|-------|-------|--------|-------|---------------------------------------|--------|--|---------|
| 15 Vit A/E/Car | CASPIR | Weekly | | | 0.4 | 0.5 | | | | 0.5 |
| 32 Xtra serum | CASPIR | End of stand | | 0.5 | 0.5 | 0.5 | | | | |
| 33 Xtra serum | | | | | 0.5 | 0.5 | | | | |
| 34 Xtra serum | | | | | 0.5 | 0.5 | | | | |
| 35 Xtra serum | | | | | 0.5 | 0.5 | | | | |
| 36 Xtra serum | | | | | | 0.5 | | | | |
| 37 Xtra serum | | | | | | 0.5 | | | | |
| 38 Xtra serum | | | | | | 1.0 | | | | |
| 39 Xtra serum | | | | | | 1.0 | | | | |
| 40 Xtra serum | | | | | | 1.0 | | | | |
| Serum total | | | 2.5 | 5.8 | 10.9 | 22.0 | | 9.2 | | 7.9 |
| Serum yield | | | 2.4 | 5.6 | 10.8 | 24.0 | | 18.4 | | 16.0 |
| Red tube size | | | 3 | 7 | 10 | 15 | | 3 | | |
| Number of Red | | | 2 | 2 | 2 | 4 | | 2 | | |
| Red tube size | | | | | 7 | | | 10 | | 10 |
| Number of Red | | | | | 1 | | | 4 | | 4 |
| 29 Persis Pest | CASPIR/Dr. Wayman Turner | End of stand | | | | 4 | 1/3 subsample 4, 6, 8, 9 | | | |
| 89 Persis Pest2 | CASPIR/Dr. Wayman Turner | End of stand | | | | 4 | 1/3 subsample 4, 6, 8, 9 | | | |
| 90 Perfluor1 | CDC Dr. Antonia Calafat | End of stand | | | | 4 | 1/3 subsample 1, 2, 5, 11 | | | |
| 91 Srm Pest | CDC Dr. Dana Barr | End of stand | | | | 4 | 1/3 subsample 1, 2, 5, 11 | | | |
| 92 BFR1 | CASPIR/Dr. Wayman Turner | End of stand | | | | 4 | 1/3 subsample 0, 3, 7, 10 | | | |
| 93 BFR2 | CASPIR/Dr. Wayman Turner | End of stand | | | | 4 | 1/3 subsample 0, 3, 7, 10 | | | |
| 10-mL Red tube | | | | | | 10 | | | | |
| Number | | | | | | 2 | | | | |
| 54 VOC Blood | CDC Air Toxicant Branch | Weekly | | | | 10 | 12+ 1/2 subsample 4, 5, 6, 7, 8, 9 | | | |
| CDC 10-mL Gray | | | | | | 10 | | | | |
| Number of Gray | | | | | | 1 | | | | |
| Total blood draw | | | 9 | 20 | 34 | 105 | | 56 | | 56 |
| Urine | | | | | | | | | | |
| 45 Alb/Creat | Univ of Minnesota | Weekly | | | 3 | 3 | | | | 3 |
| 46 Chlam/GC | CDC NCID NCHSTD | Weekly | | | | 10 | 14 to 39 | | | |
| 69 Urn Iodine (UI) | CASPIR | Weekly | | | 3 | 3 | 1/3 subsample 4, 6, 8, 9 | | | |
| 86 Spc Arsenic (SA) | CASPIR | Weekly | | | 3 | 3 | 1/3 subsample 1, 2, 5, 11 | | | |
| 48 Prior Pest (PP) | CDC Dr. Dana Barr | End of stand | | | 10 | 10 | 1/3 subsample 4, 6, 8, 9 | | | |
| 49 Organophos (OP) | CDC Dr. Dana Barr | End of stand | | | 10 | 10 | 1/3 subsample 4, 6, 8, 9 | | | |
| 62 Urn Merc | CASPIR | Weekly | | | 5 | 5 | 1/3 subsample 1, 2, 5, 11 | | | |
| 50 Heavy Metal (HM) | CASPIR | Weekly | | | 10 | 10 | 1/3 subsample 1, 2, 5, 11 | | | |
| 65 Urn Phytoes (UY) | CASPIR/Dr. Christine Pfeiffer | End of stand | | | 3 | 3 | 1/3 subsample 0, 3, 7, 10 | | | |
| 66 PAH (UA) | CASPIR/Dr. Andreas Sjodin | End of stand | | | 3 | 3 | 1/3 subsample 0, 3, 7, 10 | | | |
| 67 Phthalates (UT) | CDC Dr. Antonia Calafat | End of stand | | | 3 | 3 | 1/3 subsample 0, 3, 7, 10 | | | |
| 102 Perchlorate | CDC Air Toxicant Branch | Weekly | | | 5 | 5 | | | | |
| 52 Xtra Urine | CASPIR | End of stand | | | 5 | 5 | | | | |
| 53 HIV Urine | CDC NCID AIDS Division | Weekly | | | | 3 | 18 to 49 | | | |
| Total urine mL | | | | | 63 | 76 | | | | 3 |
| 56 VOC Water | CDC Air Toxicant Branch | Weekly | | | | 10 | 12+ 1/2 subsample 4, 5, 6, 7, 8, 9 | | | |
| 103 PerchlorH2O | CDC Air Toxicant Branch | | | | | 10 | 12+ 1/2 subsample 1, 2, 3, 10, 11, 12 | | | |
| 78 HPV | CDC Ruth Ann Tucker | Weekly | | | | Swab | 14-59 females | | | |
| 101 Allergens | Air Quality Sciences | | Dust | Dust | Dust | Dust | | | | |

APPENDIX C. SPECIMEN PROTOCOL BY TUBE TYPE (continued)

| 11/29/2004 | VIP 1-2 | VIP 3-5 | VIP 6-11 | VIP 12+ | | G 1-11 | G 12+ | Surplus |
|--|---------|---------|----------|---------|--------------------------------------|--------|-------|---------|
| Whole Blood | | | | | | | | |
| CBC | 1.5 | 1.5 | 1.5 | 1.5 | | 1.5 | 1.5 | 1.5 |
| 1 Lead/Cad/HG | 0.3 | 0.3 | 0.3 | 0.3 | 12 to 49 females | | | |
| 2 Ery Proto | | 0.4 | | 0.4 | | | | |
| 3 RBC Folate | 0.1 | 0.1 | 0.1 | 0.1 | | | | |
| 4 Glycohem | | | | 0.4 | | | | |
| 5 Mercury | 0.5 | 0.5 | 0.5 | 0.5 | | | | |
| 6 CD4 | | | | | | | | |
| Whole blood total | 2.4 | 2.8 | 2.4 | 3.2 | | 1.5 | 1.5 | 1.5 |
| EDTA tube size | 3 | 3 | 3 | 4 | | 3 | 3 | 3 |
| Number of EDTA | 1 | 1 | 1 | 1 | | 1 | 1 | 1 |
| EDTA Plasma | | | | | | | | |
| 7 Homocys/MMA | | | | | | | | |
| 8 Xtra Plasma | | | | | | | | |
| EDTA Plasma total | | | | | | | | |
| EDTA tube size | | | | | | | | |
| Number of EDTA | | | | | | | | |
| Packed Cells | | | | | | | | |
| 88 Acrylamide | | | | | | | | |
| EDTA tube size | | | | | | | | |
| Number of EDTA | | | | | | | | |
| NaCit Plasma | | | | | | | | |
| 9 Glucose | | | | | | | | |
| 2-mL Gray | | | | | | | | |
| Number of gray | | | | | | | | |
| 98 OGTT | | | | | | | | |
| 2-mL Gray | | | | | | | | |
| Number of gray | | | | | | | | |
| Potassium oxalate/sodium fluoride Plasma total | | | | | | | | |
| Serum | | | | | | | | |
| 100 IgE | | | | | | | | |
| 81 Vitamin B6 | 0.2 | 0.3 | 0.3 | 0.5 | | | | |
| 70 Vitamin D | | | | | | | | |
| 12 Fol/B12 | 0.7 | 0.7 | 1.0 | 1.0 | | | | |
| 13 CRP | | | | | | | | |
| 14 Hep profile | | | | | | | | |
| 87 Hepatitis ab | | | | | | | | |
| 99 Fer/TfR | 0.3 | 0.5 | | 0.5 | 12 to 49 females 12 to 59 females | | | |
| 11 Iron/TIBC | | 1.0 | | 1.0 | | | | |
| 17 Cotinine | | | | | | | | |
| 21 Lipids | | | | | | | | |
| 104 Lp(a) | | | 1.5 | 1.5 | | | | |
| 94 PTH2 | | | 1.0 | 1.0 | | | | |
| 77 HPV Serum | | | | | | | | |
| 79 Vitamin C | | | 0.1 | 0.1 | | | | |
| 18 Biochem | | | | 0.8 | | | 0.8 | 0.8 |
| 23 Insulin | | | | | | | | |
| 22 HIV | | | | | | | | |
| 24 HSV | | | | | | | | |
| 75 PSA | | | | | | | | |

APPENDIX C. SPECIMEN PROTOCOL BY TUBE TYPE (continued)

| 11/29/2004 | VIP 1-2 | VIP 3-5 | VIP 6-11 | VIP 12+ | | G 1-11 | G 12+ | Surplus |
|---------------------|---------|---------|----------|---------|--|--------|-------|---------|
| 15 Vit A/E/Car | | | 0.4 | 0.5 | | | | |
| 32 Xtra serum | | | | | | | | |
| 33 Xtra serum | | | | | | | | |
| 34 Xtra serum | | | | | | | | |
| 35 Xtra serum | | | | | | | | |
| 36 Xtra serum | | | | | | | | |
| 37 Xtra serum | | | | | | | | |
| 38 Xtra serum | | | | | | | | |
| 39 Xtra serum | | | | | | | | |
| 40 Xtra serum | | | | | | | | |
| Serum total | 1.2 | 2.5 | 4.3 | 6.9 | | | 0.8 | 0.8 |
| Serum yield | 1.2 | 2.8 | 4.0 | 8.0 | | | 1.2 | 1.2 |
| Red tube size | 3 | 7 | 3 | 10 | | | 3 | 3 |
| Number of Red | 1 | 1 | 1 | 2 | | | 1 | 1 |
| Red tube size | | | 7 | | | | | |
| Number of Red | | | 1 | | | | | |
| 29 Persis Pest | | | | | | | | |
| 89 Persis Pest2 | | | | | | | | |
| 90 Perfluor1 | | | | | | | | |
| 91 Srm Pest | | | | | | | | |
| 92 BFR1 | | | | | | | | |
| 93 BFR2 | | | | | | | | |
| 10-mL Red tube | | | | | | | | |
| Number | | | | | | | | |
| 54 VOC Blood | | | | | | | | |
| CDC 10-mL Gray | | | | | | | | |
| Number of Grey | | | | | | | | |
| Total blood draw | 6 | 10 | 13 | 24 | | 3 | 6 | 6 |
| Urine | | | | | | | | |
| 45 Alb/Creat | | | 3 | 3 | | | | |
| 46 Chlam/GC | | | | | | | | |
| 69 Urn Iodine (UI) | | | | | | | | |
| 86 Spc Arsenic (SA) | | | | | | | | |
| 48 Prior Pest (PP) | | | | | | | | |
| 49 Organophos (OP) | | | | | | | | |
| 62 Urn Merc | | | | | | | | |
| 50 Heavy Metal (HM) | | | | | | | | |
| 65 Urn Phytoes (UY) | | | | | | | | |
| 66 PAH (UA) | | | | | | | | |
| 67 Phthalates (UT) | | | | | | | | |
| 102 Perchlorate | | | | | | | | |
| 52 Xtra Urine | | | | | | | | |
| 53 HIV Urine | | | | | | | | |
| Total urine mL | | | | | | | | |
| 56 VOC Water | | | | | | | | |
| 103 PerchlorH2O | | | | | | | | |
| 78 HPV | | | | | | | | |
| 101 Allergens | | | | | | | | |

Appendix D

Laboratory and Phlebotomy Inventory

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY

Laboratory Inventory

Consumable Items:

Exam Supplies

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|---------------------------------|--------------------------|------------------|-----------------|
| 56616-032 | Absorbent Bench Pad | each | 12 each | \$0.26 / each |
| FA201-10 | Absorbent Sheets (2" x 2") | pack | 4 packs | \$15.00 / pack |
| SO-AA | Absorbic Acid Vial | each | 10 each | No Charge / CDC |
| 24-54 | Cotton Tip Applicator Sticks | bag | 1 bag | \$0.60 / bag |
| 19-086333 | Wooden Applicator Sticks | box | 1 box | \$5.73 / box |
| SO-ZB | Quart Zip Lock Bag | box | 1 box | \$2.59 / box |
| 12-007-187 | Bench Kote Paper | case | 2 cases | \$67.05 / case |
| 9A-7793 | Bio-Hazard Bag (19" x 23") | box | 1 box | \$115.00 / box |
| 108M | Bio-Hazard Bag (25" x 35") | box | 1 box | \$31.20 / box |
| 14-830-132 | 8 Gallon Bio-Hazard Container | each | 20 each | \$14.12 / each |
| SO-Bleach | Regular Bleach | gallon | 3 gallons | \$0.88 / gallon |
| 1441266 | Bleach Rite Disinfectant Spray | bottle | 2 bottles | \$9.27 / bottle |
| 19050221D | Gloves, Nitrile (Lg.) | box | 15 boxes | \$13.90 / box |
| 19050221C | Gloves, Nitrile (Med.) | box | 10 boxes | \$13.90 / box |
| 19050221B | Gloves, Nitrile (Sm.) | box | 10 boxes | \$13.90 / box |
| 18999442C | Gloves, Maxxim Latexfree (Lg.) | box | 10 boxes | \$7.92 / box |
| 18999442B | Gloves, Maxxim Latexfree (Med.) | box | 10 boxes | \$7.92 / box |
| 18999442A | Gloves, Maxxim Latexfree (Sm.) | box | 12 boxes | \$7.92 / box |
| 34155 | Kimwipes (4 1/2" x 8 1/2") | box | 2 boxes | \$1.68 / box |
| SO-MA | Metaphosphoric Acid Vial 6% | vial | 10 vials | No Charge / CDC |
| 05-403-11 | Pipette Tips 1000uL | box | 2 boxes | \$55.34 / box |
| 05-403-09 | Pipette Tips 200uL | box | 1 box | \$55.34 / box |
| 05-403-62 | Pipette Tips 5mL (Bulk Pack) | case | 1 case | \$62.29 / case |
| RDR024 | Temperature Chart Pens | pack | 1 pack | \$66.00 / pack |
| RDR020 | Temperature Charts | pack | 1 pack | \$26.00 / pack |
| 86.1171 | 3.5mL Transfer Pipette | box | 2 boxes | \$34.00 / box |
| 15-235-61 | Terri Wipes (13" x 18") | box | 1 box | \$14.86 / box |

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

Office Supplies

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|-------------------------------|------------------------------|------------------|-----------------|
| DUR PC1604 | Durcell 9-Volt Battery | each | 3 each | \$2.43 / each |
| AVE 5160 | Copier Labels (1" x 2 5/8") | box | 1 box | \$40.78 / box |
| UVF 1x2625 | DataMax Labels | roll | 4 rolls | \$330.00 / roll |
| 107708 | Dymo Costar 1" x 2 1/8" Label | roll | 4 rolls | \$12.25 / roll |
| CLI 65001 | Laminating Sheets 9" x 12" | pack | 4 packs | \$21.00 / box |
| LBL-Cust | Sheet Labels (8 1/2" x 11") | pack | 1 pack | \$146.25 / pack |
| SAN 30001 | Sharpie Magic Marker | each | 2 each | \$1.09 / each |
| 95.954 | Felt Tip Waterproof Marker | each | 3 each | \$2.11 / each |
| MMM 670-5AU | Post-It Page Markers | pack | 3 packs | \$5.40 / pack |
| 48SRB-4PPL | DataMax Printer Ribbon | roll | 2 rolls | \$46.37 / roll |
| FJI2374C104 | Fujitsu Printer Ribbon | each | 1 each | \$10.65 / each |
| ALL 28335 | Rubber Bands # 33 | box | 1 box | \$3.19 / box |
| HEW C4127X | HP 4000 Toner Cartridge | each | 1 each | \$210.00 / each |

Hematology Supplies

| | | | | |
|---------|--------------------------|--------|-----------|-------------------|
| 7547002 | Coulter 5C Cell Control | pack | 2 packs | \$243.60 / pack |
| 8546930 | Coulter Clenz | box | 2 boxes | \$60.82 / box |
| 8546733 | Coulter Isoton III | box | 6 boxes | \$34.69 / box |
| 7546914 | Coulter Latron Control | pack | 1 pack | \$149.20 / pack |
| 7546915 | Coulter Latron Primer | pack | 1 pack | \$61.60 / pack |
| 8546983 | Coulter Lyse-S | bottle | 3 bottles | \$119.07 / bottle |
| 624519 | Coulter S-Cal Calibrator | pack | 1 pack | \$196.34 / pack |
| 8546917 | Coulter Scatter Pak | box | 2 boxes | \$131.06 / box |

Specialized Stickers

| | | | | |
|----------|-----------------------------------|------|---------|----------------|
| 8A-17697 | Bio-Hazard Sticker | roll | 1 roll | \$37.10 / roll |
| 8A-674 | Keep Frozen Sticker | pack | 2 packs | \$8.50 / pack |
| 8A-675 | Refrigerate-Do Not Freeze Sticker | pack | 1 pack | \$8.50 / pack |

**Pregnancy Test
Supplies**

| | | | | |
|----------|-----------------------------|------|---------|----------------|
| 22247114 | ICON 25 Pregnancy Test Kit | box | 9 boxes | \$33.29 / box |
| SA087712 | Sure-View hCG Serum Control | pack | 1 pack | \$28.14 / pack |
| SA087413 | Sure-View hCG Urine Control | pack | 1 pack | \$21.68 / pack |

Lab Jackets

| | | | | |
|----------|----------------------------------|------|---------|---------------|
| 1A-32187 | Disposable Lab Jacket, Lite Blue | box | 1 box | \$22.50 / box |
| 1721L | Lab Jacket, Large | each | 10 each | \$3.32 / each |
| 1721P | Lab Jacket, Petite | each | 20 each | \$3.32 / each |
| 1721XL | Lab Jacket, X-Large | each | 10 each | \$3.32 / each |

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

Tubes, Vials, & Filters

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|-------------------------------|--------------------------|------------------|-----------------|
| 62.559.001 | 50mL Red Top Conical Tube | bag | 16 bags | \$6.68 / bag |
| SO-14mL | Mercury Additive 14mL Tube | each | 100 each | \$0.24 / each |
| 14-959-11B | 14mL Falcon Culture Test Tube | bag | 20 bags | \$6.26 / bag |
| 679800-5840 | 2.0mL Non-Sterile Cryovial | case | 10 cases | \$126.00 / case |
| 5000-0020 | 2.0mL Sterile Cryovial | case | 2 cases | \$148.69 / case |
| 03-337-7H | 5.0mL Sterile Cryovial | case | 10 cases | \$56.10 / case |
| 02-681-50 | Serum Filter (13mm x 4") | pack | 2 packs | \$11.59 / pack |
| 02-681-52 | Serum Filter (16mm x 6") | pack | 17 packs | \$11.81 / pack |

Shipping Supplies

| | | | | |
|------------------|------------------------------------|------|----------|-----------------|
| 1A-55968 | Ziplock Bag (9" x 12") | case | 1 case | \$55.30 / case |
| BX-2-D | 2" Cardboard Box w/ 9 x 9 Grid | each | 275 each | \$2.25 / each |
| 36-6434-22 | 3" Cardboard Box w/ 9 x 9 Grid | each | 50 each | \$3.21 / each |
| 36-6434-52 | 3" Cardboard Box w/o Grid | each | 40 each | \$1.90 / each |
| | 5.25" Cardboard Box w/ Foam Insert | each | 20 each | \$4.75 / each |
| 95.064.925 | 3" Cell Dividers (5 x 5) | each | 40 each | \$1.00 / each |
| SO-CD | Combo. Bag Envelope System | case | 4 cases | \$160.78 / case |
| STP 730 | Combo. Bag Envelope System | case | 2 cases | \$102.70 / case |
| STP 710 | Combo. Bag Envelope System | case | 1 case | \$227.07 / case |
| STP 740 | Envelopes, Large Padded | each | 10 each | \$0.80 / each |
| SEL 01115 | FEDEX Airbill Pouch | pack | 2 packs | No Charge |
| (no part number) | FEDEX Blank Airbills | pack | 1 pack | No Charge |
| (no part number) | FEDEX Class 9 Dry Ice Label | roll | 1 roll | No Charge |
| (no part number) | FEDEX Large Shipping Box | each | 1 each | No Charge |
| (no part number) | FEDEX Preprinted FO Airbill | each | 300 each | No Charge |
| (no part number) | FEDEX Preprinted WHSE Airbill | each | 300 each | No Charge |
| 240-20 | News-Pak (Newsprint on roll) | each | 1 roll | \$34.20 / roll |
| 49-4886-36 | Medium Shipper 16" x 16" | each | 25 each | \$14.00 / each |
| 49-4886-15 | Small Shipper 14" x 14" | each | 70 each | \$7.27 / each |
| MMM 3710-2-TT | 2" Packing Tape | roll | 20 rolls | \$1.57 / roll |
| 03-528C | U-Tek Refrigerant Pack | case | 9 cases | \$12.47 / case |

Component Tools

| | | | | |
|---------|-------------------------|--------|----------|------------------|
| G31-500 | Glycerin - 500mL Bottle | bottle | 1 bottle | \$23.84 / bottle |
|---------|-------------------------|--------|----------|------------------|

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

**Non-Consumable
Items:**

Spare Parts & Tools

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|-------------------------------------|------------------------------|------------------|-----------------|
| 22-46-139-7 | Eppendorf Pipettor 100-5000uL | each | 1 each | \$394.00 / each |
| 22-46-138-9 | Eppendorf Pipettor 50-1000uL | each | 2 each | \$369.00 / each |
| 22-46-138-9 | Eppendorf Pipettor 5-100uL | each | 1 each | \$369.00 / each |
| 99833 | 16 oz. Claw Hammer | each | 2 each | \$7.92 / each |
| NC9818625 | Pipettor Battery (Spare) | each | 1 each | \$45.88 / each |
| 22-46-155-9 | Pipettor Charging Stand | each | 1 each | \$442.00 / each |
| 40822 | Screwdriver (4 in 1 Driver) | each | 1 each | \$2.96 / each |
| 66-039-6 | Screwdriver Set - 6 Piece Precision | each | 1 each | \$6.00 / each |

Shipping Supplies

| | | | | |
|------------|------------------------|------|--------|----------------|
| 14-241B | Aluminum Ice Scoop | each | 2 each | \$15.22 / each |
| 8A-18116 | Full Face Sheild | each | 1 each | \$15.40 / each |
| 11-394-200 | Cryo Gloves - Large | pair | 1 pair | \$77.14 / pair |
| 11-394-305 | Cryo Gloves - Medium | pair | 1 pair | \$77.14 / pair |
| 1E-24039 | Leather Utility Gloves | pair | 1 pair | \$5.20 / pair |
| SPR 01750 | Tape Gun 2" | each | 2 each | \$9.95 / each |

Component Tools

| | | | | |
|-----------------------|--|------|----------|----------------|
| 03-337-7E | Plastic Cryovial Blood Rack | each | 100 each | \$17.31 / each |
| BPT-12+(1-2/3-5/6-11) | Blood Processing Template Age (12+)(Age 1-2/3-5/6-11) | each | 100 each | \$5.00 / each |
| 21-102-52 | Cube Rack - 4 Way Flipper Rack | each | 2 each | \$10.49 / each |
| OA-9188 | Flashlight | each | 1 each | \$13.45 / each |
| 08-572-7C | Graduated Cylinder 50mL | each | 1 each | \$4.51 / each |
| 60985-444 | Multicolor 4 Way Flipper Rack (4/set) | set | 1 each | \$38.00 / set |
| 14-809-101 | Nalge 13mm Half Rack | each | 3 each | \$6.80 / each |
| 14-809-134 | Nalge 16mm Full Rack | each | 4 each | \$9.37 / each |
| 14-809-117 | Nalge 16mm Half rack | each | 5 each | \$7.62 / each |
| 03-409-11E | Distilled Water Bottle | each | 2 each | \$3.00 / each |
| 415S0023BY | NOTRAX Floor Mat | each | 1 each | \$21.00 / each |
| 9A-33810 | Protective Eyewear | each | 3 each | \$3.70 / each |
| 15-078J | Thermometer, Calibration | each | 1 each | \$19.58 / each |
| 15-077-19 | Thermometer, Solar | each | 2 each | \$18.44 / each |
| 06-662-51 | Timer | each | 1 each | \$8.80 / each |
| 06-662-3 | Timer, Triple Display | each | 2 each | \$18.20 / each |

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

Phlebotomy Inventory

Consumable Items

Exam Supplies

| <u>Part Number</u> | <u>Description</u> | <u>Unit</u> <u>Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|---------------------------------|------------------------------------|------------------|-----------------|
| 7000HP | Air Sickness Bags | each | 5 each | \$1.26 / each |
| 58-104 | Alcohol Wipes | box | 6 boxes | \$1.85 / box |
| 17-98797E | Ammonia Ampules | box | 1 box | \$1.36 / box |
| SO-BO | Baby Oil | bottle | 1 bottle | \$1.99 / bottle |
| AB95 | Band-aids - Cartoon Characters | box | 6 boxes | \$8.95 / box |
| 4434 | Band-aids 3/4" x 3" | box | 3 boxes | \$4.27 / box |
| 387359 | Butterfly Needle 19g EZ-Set | box | 5 boxes | \$54.05 / box |
| 465268 | Push Button 21g Needle | box | 10 boxes | ??????? |
| 465269 | Push Button 23g Needle | box | 1 box | ??????? |
| 19-003-428D | Co-Flex NL Cohesive Bandage | case | 1 case | \$27.37 / case |
| 107708 | Dymo CoStar Labels 1" x 2 1/8" | roll | 7 rolls | \$12.25 / roll |
| 7632 | Gauze Pads (2" x 2") | pack | 10 packs | \$3.20 / pack |
| 209269 | Heel Warmers | each | 5 each | \$1.04 / each |
| ????????? | Liquid Band Aid | pack | ????????? | \$8.95 / pack |
| 367290 | Luer Adapters | box | 3 boxes | \$29.49 / box |
| SO-MO | Mineral Oil | bottle | 1 bottle | \$1.99 / bottle |
| 18-917 | Pillow Covers | each | 10 each | \$0.23 / each |
| P1723-20 | Pillow | each | 1 each | \$2.50 / each |
| 530212 | Squeeze Ball | each | 4 each | \$1.75 / each |
| Cartoon Sticker | Kids Cartoon Stickers | roll | 4 rolls | \$3.75 / roll |
| TB-1-18 | Latex Tourniquets | each | 10 each | \$0.11 / each |
| 02-6576 | Stretch Tourniquets (non-latex) | box | 20 boxes | \$9.50 / box |
| 1530-0 | Transpore Paper Tape | roll | 1 roll | \$0.34 / roll |
| 1527-0 | Transpore Tape | roll | 1 roll | \$0.69 / roll |

Forms

| | | | | |
|------------------|------------------------|------|---------|---------------|
| (no part number) | List of Reported Tests | each | 50 each | \$0.03 / each |
|------------------|------------------------|------|---------|---------------|

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

VOC Supplies

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|--------------------------|--------------------------|------------------|-----------------|
| (no part number) | VOC 10mL Blood Draw Tube | each | 300 each | No Charge / CDC |

Fasting Snacks

| | | | | |
|-----------------------|------------------------------|--------|-------------|-----------------|
| Austin Cracker | Animal Crackers (kosher) | bag | 75 bags | \$0.19 / bag |
| 132-745 | Apple Juice Box | box | 150 boxes | \$0.38 / box |
| Minute Maid | Orange Juice Box | box | 150 boxes | \$0.35 / box |
| Trutol – Cola | Glucose Drink – Orange | bottle | 60 bottles | \$1.13 / bottle |
| Trutol – Lemon / Lime | Glucose Drink – Lemon / Lime | bottle | 96 bottles | \$1.13 / bottle |
| Trutol – Orange | Glucose Drink – Orange | bottle | 144 bottles | \$1.13 / bottle |
| Peanut Butter Cracker | Peanut Butter Cracker | pack | 240 packs | \$0.12 / pack |
| Drinking Straw | Plastic 10” Drinking Straw | box | 3 boxes | \$1.19 / box |

Tubes, Vials, & Filters

| | | | | |
|------------|----------------------------------|------|----------|-----------------|
| 367921 | BD Hemogard 2mL Gray Top Tube | tray | 5 trays | \$30.43 / tray |
| 367856 | BD Hemogard 3mL EDTA Tube | tray | 2 trays | \$27.32 / tray |
| 369612 | BD Hemogard 3mL Red Top Tube | tray | 1 tray | \$17.33 / tray |
| 367861 | BD Hemogard 4mL EDTA Tube | tray | 10 trays | \$27.32 / tray |
| 369615 | BD Hemogard 7mL Red Top Tube | tray | 2 trays | \$ 17.82 / tray |
| 366430 | BD Vacutainer 10mL Red Top Tube | tray | 6 trays | \$18.72 / tray |
| 366432 | BD Vacutainer 15mL Red Top Tube | tray | 10 trays | \$19.78 / tray |
| 368607 | BD Vacutainer Eclipse 21g Needle | box | 1 box | \$19.53 / box |
| 22-289-953 | BD Vacutainer Yellow Tube Holder | each | 700 each | \$0.11 / each |

Non-Consumable Items

Emergency Supplies

| | | | | |
|----------|------------------|------|--------|----------------|
| 1A-16896 | CPR Mask - Adult | each | 1 each | \$20.00 / each |
|----------|------------------|------|--------|----------------|

Component Tools

| | | | | |
|-------------|-------------------------|------|--------|----------------|
| 20-373030-3 | 2 Step White Step Stool | each | 1 each | \$15.99 / each |
| 14-809-130 | Nalge 13mm Full Rack | each | 1 each | \$6.80 / each |
| 14-809-101 | Nalge 13mm Half Rack | each | 2 each | \$6.80 / each |
| 14-809-117 | Nalge 16mm Half Rack | each | 7 each | \$7.62 / each |
| 415S0023BY | NOTRAX Floor Mat | each | 1 each | \$21.00 / each |
| 30-1310-05 | Lister Bandage Scissors | each | 1 each | \$13.50 / each |
| 15-077-19 | Thermometer, Solar | each | 1 each | \$18.44 / each |

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

**Body Measurement
Component**

PAM Inventory

Exam Supplies (Items Placed Into Kits)

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|-------------------------------|------------------------------|------------------|-----------------|
| SEL 01110 | Bubble Mailer 6" x 10" | each | 1 each | \$0.35 / each |
| (no part number) | Direction Sheet - Light Green | each | 1 each | \$0.01 / each |
| (no part number) | PAM Color Letter | each | 2 each | \$0.03 / each |
| Monitor | PAM Monitor | each | 1 each | \$300.00 / each |
| 12979 | Black 80" Velcro Belt | each | 1 each | \$1.20 / each |

****** NOTE******

Physical Activity
Monitor Kits are part of
the Body Measurement
Component. The items
listed above are included
in each kit prepared by
the warehouse.

The current par level
for each site is 300 kits.

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

VOC Inventory

Exam Supplies (Items Placed Into Kits)

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|--------------------|--|--------------------------|------------------|-----------------|
| (no part number) | VOC Water Tube | each | 1 each | No Charge / CDC |
| 63-4-05W | Write On Ziplock Bag | each | 1 each | \$0.03 / each |
| (no part number) | VOC Water Collection Instruction Sheet | each | 1 each | \$0.02 / each |

**** **NOTE** ****

VOC Water Collection Kits are part of the Field Office Inventory. The items listed above are included in each kit prepared by the warehouse.

The current par level for each Field Office is 325 kits

APPENDIX D. LABORATORY AND PHLEBOTOMY INVENTORY (continued)

HPV Inventory

Exam Supplies

| <u>Part Number</u> | <u>Description</u> | <u>Unit Distribution</u> | <u>Par Level</u> | <u>Price</u> |
|-----------------------|---------------------------------|------------------------------|------------------|---------------|
| OA-56084 | Mini-Grip Bag 4" x 8" | each | 1each | \$0.05 / each |
| HPV Instruction Sheet | HPV Age 14-59 Instruction Sheet | each | 1 each | \$0.03 / each |
| QEC 091H | Catch-All Collection Swaube | each | 1each | \$1.28 / each |

****** NOTE ******

HPV are created for female SP's between the ages of 14 & 59.