National Health
and Nutrition
Examination Survey

LABORATORY PROCEDURES MANUAL

April 2001

TABLE OF CONTENTS

For fast and easy navigation, press F5 to show Bookmarks

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

List of Appendixes

List of Figures

List of Exhibits

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

TABLE OF CONTENTS (continued)

List of Exhibits (continued)

1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

This chapter provides a general description of the health examination surveys conducted by the National Center for Health Statistics (NCHS) and the current National Health and Nutrition Examination Survey (NHANES). It also provides an overview of the tasks that staff perform during the survey.

1.1 History of the National Health and Nutrition Examination Programs

This NHANES is the eighth in a series of national examination studies conducted in the United States since 1960.

The National Health Survey Act, passed in 1956, gave the legislative authorization for a continuing survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. In order to fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) the people themselves by direct interview; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) places where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, between 1960 and 1984, 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 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)
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 had become increasingly important 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 monitor nutritional 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). Four 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)

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 to 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. Hispanic HANES (HHANES), conducted from 1982 to 1984, produced 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 of minority groups is often different than the health status and characteristics of nonminority groups, so black Americans and Mexican Americans were selected in large proportions for NHANES III. Each group comprised 30 percent of the sample. NHANES III was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. To obtain generalizeable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate than previously. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure levels of pesticide exposure, presence of certain trace elements in the blood, and amounts of carbon monoxide present in the blood. A home examination was incorporated for those persons who were unable or unwilling to come to the exam center but would agree to an abbreviated examination in their homes.

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 Epidemiologic Follow-up Survey, a multiphase survey conducting follow-up interviews with the NHANES I population in order to provide longitudinal data on the health of the U.S. population.

1.2 Overview of the Current NHANES

This NHANES follows in the tradition of past NHANES surveys, continuing to be a keystone in providing critical information on the health and nutritional status of the U.S. population.

The major difference between the current NHANES and previous surveys is that NHANES is intended to become a **continuous annual survey**. NHANES is also linked to the National Health Interview Survey following the Survey Integration Plan proposed by DHHS. NHANES collects data from a representative sample of the U.S. population every year. 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 will be about the same as in previous NHANES, about 5,000 randomly selected subjects 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.

1.2.1 NHANES Pilot and Dress Rehearsal

During 1998 and 1999 two comprehensive tests were conducted in the Washington, DC area in preparation for the main study—a pretest and a dress rehearsal. In both tests, respondents were interviewed in their home and then asked to participate in a physical examination in the MEC. Data collected during the pretest and dress rehearsal are not included in the main survey database and no analyses were performed.

The pretest evaluated household interviewing procedures and MEC procedures, including the physical exams, the examination center interviews, the field office and exam center, and the Integrated Survey Information System (ISIS). The dress rehearsal was the final trial run for all survey procedures.

1.2.2 Data Collection for NHANES Main Survey

Data collection on the NHANES main survey began early in 1999 and will continue for approximately 6 years at 88 locations (stands) across the United States. Each year approximately 7,000 individuals of all ages, in households across the United States, will be randomly selected to participate in the main survey. The study respondents include whites as well as an oversample of blacks and Mexican Americans. The study design also includes a representative sample of these groups by age, gender, and

income level. Adolescents and older persons will also be oversampled. The overall goals of data collection are to:

- Estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factor;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposure;
- Analyze risk factors for selected diseases;
- Study the relationships between diet, nutrition, and health; and
- Explore emerging public health issues and new technologies.

Randomly selected persons are invited to take part in the survey by first being interviewed in their homes. Household interview data are collected via computer-assisted personal interviewing (CAPI) and include demographic, socioeconomic, dietary, and health-related questions. Upon completion of the interview, respondents are asked to participate in a physical examination. The examination is conducted in a specially equipped and designed Mobile Examination Center (MEC), consisting of four trailers. The MEC houses the state-of-the-art exam equipment and is divided into rooms to assure the privacy of each study participant during the exams and interviews. The examination includes a physical and dental examination conducted by a physician and a dentist, laboratory tests, a variety of physical measurements, and other health interviews conducted by highly trained medical personnel.

Participants who are 50 years and older or less than 1 year old and are unable or unwilling to travel to the MEC will be offered a home examination administered by an examiner from the MEC. The household interviews and MEC exam combined will collect data in the following important health-related areas:

- Cardiovascular and respiratory disease;
- Vision;
- Hearing;
- Mental illness;
- Growth;
- Infectious diseases and immunization status in children;
- Obesity;

- Dietary intake and behavior;
- Nutritional status;
- Disability;
- Skin diseases;
- Environmental exposures;
- Physical fitness; and
- Other health-related topics.

1.3 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 U.S. 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) 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.

1.4 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 Staff** – The field staff consists of three groups of employees: Stand office staff, the interviewers, and the MEC staff.
  - **Stand Office Staff** – For the main survey, an office will be opened in every stand. Each stand office will include a study manager, an office manager (OM), a field manager (FM), three assistant office managers (AOMs), and a data manager (DM).

    The **study manager** is responsible for the overall management of operations at a stand.

    The **office manager** 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. S/he will supervise one or more local office clerks hired to assist with office activities.

    The **field manager** has primary responsibility for the supervision of the household interviewers (health representatives).

    The **assistant office managers** are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. They report to the office manager.

    The **data manager** assists in the setup and testing of computer systems and telecommunications hookups in the field. S/he also coordinates the maintenance and repair of all field computer systems with the home office and external venders and acts as the field “help desk” person.

  - **Interviewers** – This staff is primarily responsible for identifying and enrolling the survey participants, conducting the household interviews, and appointing the study participants for the MEC exam. Specifically, 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, interviewers visit the stand 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** – This staff of health professionals conducts the health exams. The main study includes two exam teams.

  There are 17 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 1 licensed dentist, 3 medical technologists, 4 health technicians, 2 MEC interviewers, 2 dietary interviewers, 1 phlebotomist, and 1 home examiner. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff.

The following section describes the steps that are always completed prior to the opening of a stand and an overview of the tasks that interviewers are expected to perform. Highlighted items are basic concepts critical to the conduct of the study.

Steps completed prior to interviewing include:

- 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.

- Twelve weeks before data collection begins, NHANES staff list the segments. 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.

- 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.

- 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 inform the household that an interviewer will contact them in the near future.

The tasks interviewers perform when they arrive at a stand include:

1. After the successful completion of training, interviewers are given an assignment of sampled dwelling units to contact. Each assignment consists of prelabeled Household Folders, prelabeled Neighbor Information Forms, and the appropriate Segment Folder.

2. Using addresses on the Household Folders and listing/mapping materials in the Segment Folder, interviewers locate these dwelling units.

3. If a selected address is not a dwelling unit or is not occupied, interviewers complete the “Vacant/Not a DU Section” on the Screener Non-Interview Form.

4. In an occupied residential dwelling unit, interviewers contact an adult who lives in the selected household 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.

5. If all persons in a household are ineligible, no further work is done with the case. When eligible household members are identified, interviewers continue to conduct all the necessary tasks associated with the case.

6. In eligible households, the interviewer obtains a signed interview consent form prior to completing the medical history and/or the family questionnaire.

7. Next, the appropriate medical history CAPI interview is administered to eligible respondents. The questions asked depend on the age of the SP.

8. In each household containing children aged 1-5, floor and window sill dust samples are obtained. These samples provide information on lead levels in the household environment.

9. A Family questionnaire is also administered to one adult family member from each eligible family in the household.

10. Next, an appointment is scheduled for each SP, coordinating the MEC schedule and the SP schedule.

11. Interviewers then obtain signed consent form(s) for each SP for the examination, call the field office to confirm the examination appointment(s), and give each SP an appointment slip.

12. If there is more than one eligible family in a household, this process is repeated with each additional family.

13. Interviewers record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.

14. Interviewers also support the survey by conducting field reminders prior to MEC appointments and reschedule broken, cancelled, or no-show MEC appointments.

15. If an interviewer is unable to complete any of the questionnaires or procedures for any SP, an SP Card is completed. This card documents the problems encountered in completing one or more tasks.

16. Interviewers check for missed DUs and/or structures when instructed to do so. If any are found, the Missed DU or Missed Structure Procedures is implemented and appropriate forms will be completed.

17. When an interview has been completed, interviewers edit their work, carefully reviewing all forms for completeness and legibility.

18. Interviewers report in person to the FM 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.

19. To insure 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.

20. At the end of each stand field period, interviewers return all interviewing materials to the supervisor.

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

Examinations and interviews are conducted in Mobile Examination Centers (MEC), which is composed of four specially equipped trailers. Each trailer is approximately 45 feet long and 10 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.

Exhibit 1-1. Floor plan of the MEC

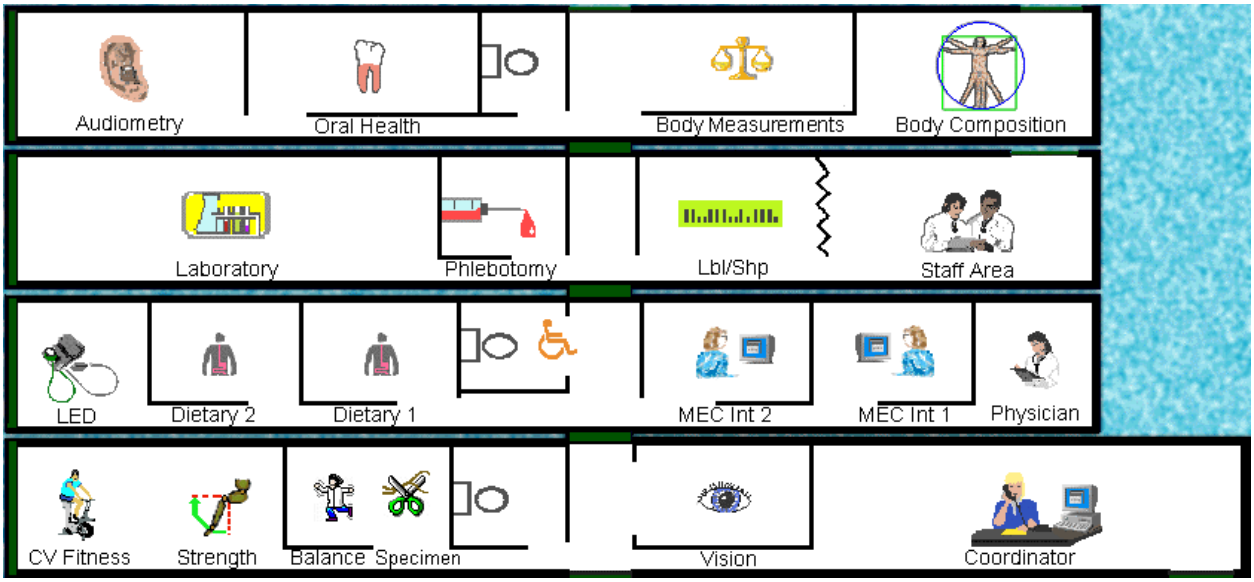
Audiometry
Oral Health
Body Measurements
Body Composition
Laboratory
Phlebotomy
Lbl/Shp
Staff Area
LED
Dietary 2
Dietary 1
MEC Int 2
MEC Int 1
Physician
CV Fitness
Strength
Balance
Specimen
Vision
Coordinator

Exhibit 1-2. MEC exams and rooms

Trailer	Room	Room Use
Trailer 1	Reception area	Welcoming and waiting area for SPs
	Vision room	Vision tests
	Balance/Specimen Collection	Balance test, hair, and MRSA collection
	Fitness	Cardiovascular fitness and muscle strength
Trailer 2	Physician	Physical examination
	MEC Interview	Health interview
	MEC Interview	Health interview
	Dietary Interview	Dietary interview
	Dietary Interview	Dietary interview
	Lower Extremity Disease	Testing for lower extremity pulses and sensitivity
Trailer 3	Venipuncture	Drawing of blood samples
	Laboratory	Processing of urine and blood samples
	Label/shipping area	Lab area for labeling and shipping specimens
	Staff lounge	Staff area that houses main computer system
Trailer 4	Total Body Composition	Total body composition scans and bioimpedance
	Body measures	Body measurements
	Dental	Dental exam
	Audiometry/Tympanometry	Hearing tests

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 SPs per session. During a stand, work weeks rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

Exam Team Responsibilities. There are 17 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.

- One dentist conducts the dental exam and calls the results to a health technician who records the findings.

- Two health (MEC) interviewers administer questionnaires for physical and mental 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 certified radiologic technicians take and record body measurements, perform balance tests, vision tests, cardiovascular fitness tests, muscle strength assessments, lower extremity measures, total body composition (DEXA) scans, bioimpedance (BIA) tests, administer hearing tests, and collect hair and MRSA specimens. In addition, the technicians record findings for the dental examiner.

- 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 administers the phlebotomy questionnaire draws blood from SPs, and recruits SPs for special studies.

- One home examiner performs home exams for SPs aged 50 years and older or under 1 year old who are unable or unwilling to travel to the MEC. The home exam lasts approximately 1 hour and includes the following:

  - Height;
  - Weight;
  - Skinfold measures;
  - Blood pressure;
  - Near vision;
  - Blood samples and nasal (MRSA) swab collection; and
  - Reproductive history for females.

  The home examiner assists the MEC laboratory and phlebotomy staff when not performing home exams.

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.

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:

- **Anthropometry**

  The purpose of the anthropometry component is to provide: (1) nationally representative data on selected body measures, (2) estimates of the prevalence of overweight and obesity, (3) data to study the association between body measures and such health conditions and risk factors as cardiovascular disease, diabetes, hypertension, and activity and dietary patterns, and (4) data to monitor growth and development in children. A total of 11 body measurements are collected, but the number and type of measures varies with the age groups.

Exhibit 1-3. Examination components

Component	Ages
Anthropometry	All
Audiometry/Tympanometry	20-69
Balance	40+
BIA	8-49
Cardiovascular Fitness	12-49
Dietary Interview	All
Hair Collection	1-5 years, females 16-49
Muscle Strength	50+
Lower Extremity Disease	40+
MEC Interview	8+
Mental Health	8-19 years, 20-59 years (half-sample with audiometry)
MRSA sample collection	1+
Oral Health	2+
Physician Exam	All
Total Body Composition	8+
Urine Collection	6+
Venipuncture	1+
Vision	12+
VOC	20-59

- **Balance**

  Balance disorders, disequilibrium, and dizziness from vestibular disorders constitute a major public health problem. Primary disorders may be hidden by their consequences, such as falls, while subtle dysfunction may underlie difficulties in learning, writing, reading, and in everyday activities. The main objectives of the balance test are to obtain prevalence data, examine the relationship between balance disorders and other factors, and to characterize normal and disordered balance and spatial orientation. The standard Romberg test is used to measure postural sway.

- **Bioelectrical Impedance Analysis (BIA)**

  The purpose of the BIA exam is to monitor secular trends in overweight prevalence, describe the prevalence of obesity, and examine the relationship between overweight and obesity and other examination measures. BIA measures the electrical impedance of body tissues and is used to assess fluid volumes, total body water, body cell mass, and fat-free body mass.

- **Cardiovascular Fitness and Muscular Strength**

Evaluation of physical fitness provides nationally representative data on measures of physical fitness, estimate the prevalence of persons at risk due to sedentary habit and poor physical fitness, and provide data to study the relationship between leg strength, lower extremity function, and activity limitations. Cardiovascular fitness is assessed with a submaximal treadmill test on examinees aged 12 through 49 years. Lower body strength is assessed using a timed measured walk and isokinetic strength testing of the knee extensors and flexors in examinees aged 50 and older.

- **Dietary interview**

  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 is obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system.

- **Hair collection**

  The purpose of the hair component is to obtain a suitable biological sample that can be used for the determination of total mercury levels in hair. Approximately 100 strands are collected from SPs aged 1-5 years and women aged 16-49 years.

- **Hearing**

  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.

- **Laboratory**

  The laboratory component includes the collection and processing of various biological and environmental specimens including blood for subjects 1 year and older, urine for subjects 6 years and older. On-site pregnancy testing excludes pregnant women from other examination components such as DEXA, BIA, and cardiovascular fitness testing. 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.

- **Lower Extremity Disease (LED)**

  The purpose of this component is to determine the prevalence of LED and its risk factors. Simple and reproducible measures of lower extremity arterial disease are obtained. Peripheral neuropathy is evaluated by measurement of cutaneous pressure sensation in the feet. Foot deformities permit the estimation of prevalence of those at high risk for the late-stage complications of LED.

- **MEC Interview**

  The MEC Interview consists of questionnaire sections designed to obtain information on health behaviors, specific conditions, medical history, and risk factors. The information collected in the interview is intended to assist researchers in analyzing the data collected in the other examination components. The interview is administered to all age-eligible subjects, or a suitable proxy, using computer-assisted interviewing software.

- **Mental Health**

  The mental health assessment is used to estimate the prevalence of selected disorders in the U.S. and to describe the degree of comorbidity between mental health disorders and other medical conditions and biological risk factors. Assessments are made during the MEC Interview using relevant portions of the Diagnostic Interview Schedule for Children (DISC) and the Composite International Diagnostic Interview (CIDI) for adults.

- **Methicillin-Resistant *S. Aureus* (MRSA) Sample Collection**

  A nasal swab specimen collection for Methicillin-Resistant Staphylococcus aureus (S. aureus) is obtained on SPs aged 1+ years for the purpose of estimating the prevalence of MRSA in the population. Antimicrobial resistance to S. aureus has increased so dramatically, particularly in the hospital setting, that currently only one treatment option exists for this organism. NHANES is the first population-based prevalence study of MRSA. No other population-based studies or national surveillance efforts are available to provide reliable national estimates for this problem.

- **Oral Health**

  This component monitors oral health status, risk factors for disease, and access to preventive and treatment services. The exam consists of a series of subcomponents which assess dentition and periodontal disease.

- **Physicians' Exam**

  Blood pressure assessment and discussion of testing for sexually transmitted disease are the primary elements of the physician's exam. The purpose of assessment of blood pressure is to monitor prevalence and trends in major cardiovascular conditions and risk factors and to evaluate prevention and treatment programs targeting cardiovascular disease. The physician discusses the purpose of STD testing and arranges for SPs to select a unique password with which to phone NCHS and obtain test results.

- **Total Body Composition**

  This component is composed of the BIA and Dual Energy X-ray Absorptiometry (DEXA). The purpose of the DEXA scan is to gain insights into age, gender, and racial/ethnic differences in the skeleton relative to other measures of body composition such as total muscle and fat mass, as well as behavioral factors such as diet and activity. A total body scan using dual energy X-rays is performed to provide measures of bone mineral content, bone mineral density, muscle and fat mass.

- **Vision**

  The vision examination consists of a near vision acuity test, a distance vision acuity test, an eyeglass prescription determination (when appropriate), and an automated refraction measurement. Information from the component may be used to estimate the prevalence of visual acuity impairment and distribution of refractive error in the U.S. population. Data are also used to evaluate screening strategies for visual impairment and eye disease, and evaluate functional impairment related to vision.

- **Volatile Organic Compounds (VOC)**

  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. Participants receive sampling badges to wear for 48 hours and return to the MEC with the badge for a second blood draw in 48-72 hours. An additional remuneration is paid for this test.

Second Exams

Approximately 5 percent of SPs aged 12-69 who are examined in each stand are asked to return for a second MEC exam. Data from the second exam is used to obtain quality control data of survey procedures. The second exam components are similar, but modified versions of the original MEC exams. SPs who return for a second exam are included as a convenient VOC sample. Two additional VOC blood tubes are drawn and a questionnaire is administered. Also, not all components are repeated. Exams are generally conducted by the same examiner who obtained the first exam.

An additional 5 percent of SPs aged 2 and older are invited to repeat only the dietary interview, either in the MEC or by telephone.

SPs who return for second exams receive remuneration for their visit and transportation.

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 includes an

extra incentive if the SP fasts prior to the exam. Additional, remuneration is offered for the VOC component, the home exam, and the second MEC exam.

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 for the SP on the day of their examination and includes results that are immediately available and require no further evaluation or interpretation. Just prior to the examinee's departure from the MEC, the coordinator prints a report that includes height, weight, and body mass index, complete blood count, blood pressure, and results from the audiometry, cardiovascular fitness, lower extremity disease, vision, and dental exams. The MEC physician reviews the blood pressure and complete blood count test results for abnormalities and discusses any problems with the SP (or their parent). The dentist also discusses the dental recommendations with the SP. 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, syphilis, Herpes simplex 1 and 2, bacterial vaginosis, and Trichomoniasis) and human immunodeficiency virus (HIV) are released only to the sample person using a specially devised procedure requiring a unique password.

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.

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 prior to the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. Any problems are corrected quickly before the "real" examinations begin. 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 actual 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.

1.6 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 procedure consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw and to determine fasting status, (2) a blood draw, and (3) recruiting participants for special studies.

The purpose of urine collection and processing is to collect sufficient urine from participants aged 6 and older to be able to (1) perform a pregnancy test on selected females aged 8 to 17 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 eventual transport to approximately eight laboratories for analysis, (3) allocate urine into vessels for future studies, and (4) hold and process urine as a back up for the HIV blood test where the amount of blood collected was insufficient.

The purpose of blood collection and processing is to collect sufficient blood from participants aged 1 and older to be able to (1) perform a complete blood count, (2) allocate blood into vessels for storage and transport to approximately 15 laboratories across the United States for analysis, (3) allocate plasma and serum into vessels for future studies, and (4) process blood tubes and clots for genetic testing.

The purpose of collecting and processing lead dust wipes, hair, and vaginal and nasal swabs is to be able to store and transport these samples to various laboratories for 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 8-59 from participating in the dual-energy x-ray absorptiometry (DXA), bioelectrical impedance analysis (BIA), and cardiovascular fitness (CV Fitness) components of the MEC exam.

The purpose of conducting the special study is to determine the prevalence of exposures to certain chemicals called Volatile Organic Compounds (VOCs).

2.2 The Laboratory Team

Each laboratory team includes four certified medical 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 including quality control, equipment calibration, and maintenance. On a routine basis, the chief medical technologist performs the same duties as the other medical technologists.

The home examiner is a medical technologist who serves as back up in phlebotomy and the laboratory. The home examiner conducts a modified MEC exam including venipuncture in the SP's home, processes home examination specimens in the MEC laboratory, conducts special study exams in SP's homes, and assists the field office and MEC staff as requested.

2.3 Tasks

The tasks of the phlebotomist include recording MEC equipment QC activities and readings, conducting venipuncture and special studies, assisting the medical technologists as needed, and managing the component inventory.

The tasks of the medical technologists include recording MEC equipment QC activities and readings, printing labels and labeling vessels, performing complete blood counts (CBCs), conducting pregnancy testing, processing blood, urine, hair, nasal swabs, genital swabs, lead dust and lead dust QC specimens, blood tubes, air monitoring badges, tap water samples, shipping specimens to contact laboratories, assisting the phlebotomist as needed, and managing 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.

The phlebotomist collects blood and recruits participants for special studies and collects their specimens in the phlebotomy room. 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.

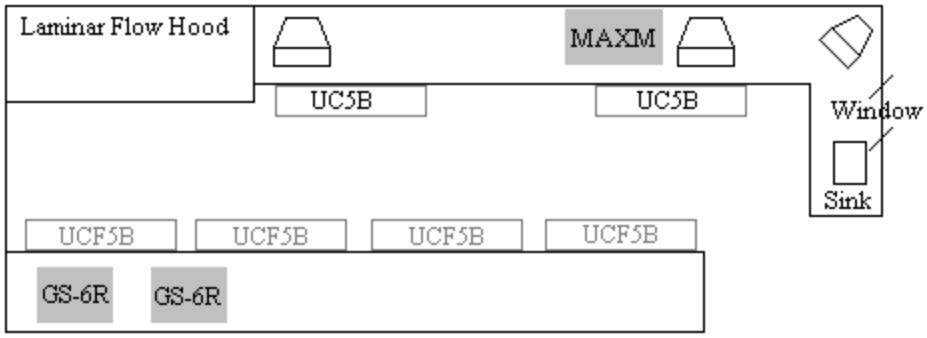

Figure 2-1. Laboratory area

Laboratory Area Floor Plan

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

Printing labels, labeling blood-processing racks and shipping occur at workstation 3; this is located in the label/ship area. Packing shipments may also occur at workstation 1.

2.5 Tasks – Phlebotomy Room

- Set up supplies and check expiration dates of Vacutainer® tubes.

- Maintain the Supply Use Control Log.
- For each SP, administer the Venipuncture Questionnaire, perform the venipuncture, and recruit participants for special studies.
- Enter blood collection results.
- Label and transfer all blood specimens to the laboratory area.
- Conduct special study exams including collecting biological and environmental specimens.
- Disinfect all counters at the beginning and end of each day.
- Record QC readings.
- Maintain appearance of the venipuncture area and the equipment.
- Conduct daily and start and end of stand inventory.
- Assist in labeling and assembling blood-processing racks, centrifuging specimens, shipping specimens, setup, teardown and cleaning the laboratory at the beginning and end of stand, and clerical activities as time allows.

2.6 Tasks – Workstation 1

- Stock blood processing and storage supplies.
- Receive blood specimens.
- Select correct prelabeled rack and age appropriate template.
- Set red top blood tubes aside to clot.
- Pipette whole blood for vessel 1(lead/cadmium), vessel 2 (erythrocyte protoporphyrin), vessel 3 (RBC Folate), and vessel 5 (mercury) on all SPs from 3-mL or 5-mL EDTA lavender tube.
- Transfer 3-mL or 5-mL EDTA tube to workstation 2 technologist for hematology.
- Make dilutions for RBC Folate.
- Pipette whole blood for vessel 4 (glycohemoglobin) and vessel 6 (CD4) from the 5-mL EDTA tube.
- Centrifuge the 5-mL EDTA tube in refrigerated centrifuge.
- Centrifuge 3-mL gray and 3-mL light blue tubes.
- Check label and store the ACD tubes at room temperature.

- Centrifuge red top tubes.
- Pool serum from all 15-mL red tubes and mix well.
- Aliquot plasma and serum into appropriate storage vessels.
- Pour clots into appropriate storage vessel.
- Enter blood processing results.
- Refrigerate or freeze designated tubes and vessels.
- Access HIV urine processing module and process urine.
- Check contents of blood and HIV urine storage boxes using the box maps module at the end of each session.
- Disinfect all counters and laminar flow hood at the beginning and end of each session.
- Maintain appearance of the blood processing area, the equipment, and the daily inventory.
- Assist in labeling and assembling blood processing racks, shipping specimens, setup, teardown and cleaning the laboratory at the beginning and end of stand, completing the beginning and end of stand inventories of laboratory materials, and clerical activities as time allows.

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.
- Maintain the Supply Use Control Log.
- Prepare ascorbic acid.
- Stock supplies for urine processing, hematology, pregnancy testing, pH and gram stains.
- Enter urine collection results.
- Run pregnancy test controls.
- Conduct pregnancy test and enter results.
- Perform start-up procedures and run quality control materials on Coulter® MAXM.
- Run SP specimens on the Coulter® MAXM.
- Label and aliquot urine into storage vessels.

- Enter urine processing results.
- Freeze urine vessels.
- Process lead dust, hair, nasal and genital specimens.
- Check contents of urine, lead dust, hair, nasal, and genital storage boxes and bags using the box maps module at the end of each session.
- Disinfect all counters at the beginning and end of each session.
- Maintain appearance of the urine processing/hematology area, the equipment, and the daily inventory.
- Assist phlebotomist with venipuncture.
- Assist in labeling and assembling blood processing racks, centrifuging specimens, shipping specimens, setup, teardown, and cleaning the laboratory at the beginning and end of stand, completing the beginning and end of stand inventories of laboratory materials, and clerical activities as time allows.

2.8 Tasks – Workstation 3

- Print blood, urine, hair, nasal swab, genital swab, and pregnancy labels.
- Pre-label blood processing racks.
- Generate container IDs at the start of stand.
- Close open containers, create airbills, assign containers to shippers.
- Prepare shipping manifests and send electronic files.
- Prepare blood (whole blood, serum, and plasma), urine, hair, nasal swab, genital slide and swab, special study samples, and lead dust specimens for shipping.
- Pack, weigh, label, and ship shippers.
- Open all new containers after shipping.
- Run FedEx tracking daily.
- Assist phlebotomist with venipuncture.
- Assist in centrifuging specimens, setup, teardown, and cleaning the laboratory at beginning and end of stand, completing the beginning and end of stand inventories of laboratory materials, and clerical activities as time allows.

3. BIOSAFETY

3.1 OSHA (Occupational Safety and Health Administration) Bloodborne Pathogens Regulations

The Occupational Safety and Health Administration has established the Bloodborne Pathogens Regulations. The Bloodborne Pathogens Regulation applies to all persons who may reasonably anticipate contact with blood or other potentially infectious materials in the course of their employment. The focus of this regulation is the creation of a written Exposure Control Plan that describes how the employer will protect employees from exposure. The exposure control plan contains the following components: exposure determination, procedures for evaluating the circumstances surrounding an exposure incident, schedule and methods for implementing sections of the standard covering the methods of compliance, hepatitis B vaccination and postexposure followup, communication of hazards to employees, and recordkeeping. The plan is reviewed and updated at least annually and kept accessible.

3.2 Exposure Categories

The exposure determination is based on a review of job classifications within the work environment. Employees with occupational exposure are identified and hazards are communicated to these employees.

MEC staff are classified as Category 1 when it is determined they may be routinely exposed to bloodborne pathogens. This category includes the dentist, phlebotomist, and medical technologists. Staff are classified as Category 2 exposure when it is determined they are not usually exposed to blood, but may be exposed under certain circumstances. This category includes the physician and MEC manager.

3.3 Preventive Measures

The employer must make the hepatitis B vaccine and vaccine series available to all employees who have occupational exposure and followup to all employees who experience an exposure incident.

Hepatitis B vaccine is available at no cost to the employee. If previously vaccinated, the employee must provide evidence of antibody testing or completion of the vaccine series. If the employee

refuses the vaccine, they must complete a Declination Form. Notify the MEC manager immediately if an exposure incident occurs.

3.3.1 Universal Precautions for Prevention of Transmission of HIV and other Bloodborne Infections

"Universal precautions," (UP) as defined by CDC, are a set of precautions intended to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens when providing first aid or health care. Universal precautions consider blood and other body fluids (containing visible blood, semen, and vaginal secretions) from all participants potentially infectious for HIV, HBV, and other bloodborne pathogens.

Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear, which can reduce the risk of exposure of the health care worker's skin or mucous membranes to potentially infective materials. In addition, universal precautions recommend that all health care workers take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices.

Pregnant health care workers are not at greater risk of contracting HIV infection than are health care workers who are not pregnant. However, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with, and strictly adhere to, precautions to minimize the risk of HIV transmission.

As mandated by the Needlestick Safety and Prevention Act, OSHA has revised its bloodborne pathogens standard to clarify the need for employers to select safer needle devices as they become available and to involve employees in identifying and choosing the devices. The updated standard also requires employers to maintain a log of injuries from contaminated sharps.

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.

Thus, the additional provisions require that employers, in their written Exposure Control Plans, account for innovations in procedure and technological developments that reduce the risk of exposure incidents. This would include, but would not be limited to, newly available medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Consideration and implementation of safer medical devices could 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. This information must be updated at least annually.

The revised Exposure Control Plan requirements make clear that employers must implement the safer medical devices that are appropriate, commercially available, and effective.

The sharps injury log must include the specified minimum information regarding the device involved (if known), the location of the incident, and the description of the events that resulted in the injury. The level of detail presented should be sufficient to allow ready identification of the device, location, and circumstances surrounding an exposure incident (e.g., the procedure being performed, the body part affected, objects or substances involved and how they were involved) so that the intended evaluation of risk and device effectiveness can be accomplished.

3.4 Methods of Control

Engineering and work practice controls are the primary methods used to prevent occupational transmission of HBV and HIV. Personal protective clothing and equipment are also necessary when occupational exposure to bloodborne pathogens remains even after instituting these controls.

Engineering controls reduce employee exposure by removing or isolating the hazard or worker from exposure. One example is the provision and mandated use of puncture resistant disposal

containers for contaminated sharp instruments. Work practice controls alter the manner in which a task is performed. Comply with the following work practice controls:

- Restrict eating, drinking, applying cosmetics or lip balm, and handling contact lenses to the staff area of the MEC.
- Mouth pipetting is prohibited.
- Storage of food and/or drink in refrigerators or other locations where blood and other potentially infectious materials reside is prohibited.
- Use the laminar flow safety cabinet for blood processing.
- Use hand-washing facilities in the laboratory and phlebotomy rooms.
- Use the eyewash station in case of a splash.
- Routinely check and decontaminate equipment and counters.

3.4.1 Engineering Control - Needle Precautions

All health care workers should 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.

- When discarding contaminated sharps, place them in sharps containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leakproof on the sides and bottom.
- Never recap used needles, or otherwise manipulate them using both hands, or use any other technique that involves directing the point of a needle toward any part of the body; rather, use either a one-handed “scoop” technique or a mechanical device designed for holding the needle sheath.
- Never shear or break contaminated needles.
- Do not remove used needles from disposable syringes.
- Keep puncture-resistant sharps containers upright throughout use, replace routinely, close when moved, and do not overfill.
- Never manually open, empty, or clean contaminated sharps disposable containers.

3.4.2 Work Practice Controls - Personal Protective Equipment

Use personal protective equipment if occupational exposure remains after instituting engineering and work practice controls or if those controls are not feasible. All category 1 MEC staff should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure during contact with any SP's blood or body fluids that require universal precautions. These barrier precautions include gloves, gowns, and other protective apparel and masks.

Hand Washing

Wearing gloves does not replace the need for hand washing, because gloves may have small defects or may tear during use, and hands can become contaminated during removal of gloves. Hand washing is the vigorous, brief rubbing together of all surfaces of lathered hands, followed by rinsing under a stream of water. Hand washing with plain soaps or detergents (in bar, granule, leaflet, or liquid form) suspends microorganisms and rinses them off. In addition, hand washing with antimicrobial containing products kills or inhibits the growth of microorganisms. Hand washing is an important component of the personal hygiene of all MEC personnel. Perform hand washing whenever you are in doubt about the necessity for doing so.

- For most activities, vigorously but briefly (at least 10 seconds) rub together all surfaces of lathered hands and rinse under a stream of water. Times of 15 seconds or less are effective in removing most transient contaminants from the skin. If soil on the hands is visible, increase time for hand washing.
- Use plain soap for hand washing unless otherwise indicated.
- Wash hands when reporting to the MEC at the beginning of the session, at the completion of each session, immediately after removing gloves, and when leaving the laboratory or phlebotomy to go to other parts of the MEC.
- Wash hands and other skin surfaces immediately or when SP safety permits if contaminated with blood or body fluids requiring universal precautions.
- Wash hands before eating, before, between, and after SP contact, after blowing or wiping of nose, and after personal use of the toilet.

Gloves

Gloves play an important role in reducing the risk of transmission of microorganisms. Wear gloves for three important reasons. First, gloves provide a protective barrier to prevent gross

contamination of the hands when touching blood, body fluids, secretions, excretions, mucous membranes, and nonintact skin. OSHA mandates the wearing of gloves in specified circumstances to reduce the risk of exposures to bloodborne pathogens. Specifically, OSHA requires wearing gloves when it is reasonably possible that an employee will have contact with blood, or other potentially infectious materials; when performing vascular access procedures; and when touching contaminated items or surfaces. Second, gloves reduce the likelihood that microorganisms present on the hands of personnel will transfer to SPs during invasive or other SP-care procedures that involve touching an SP's mucous membranes and nonintact skin. Third, gloves reduce the likelihood that hands of personnel contaminated with microorganisms from a SP or an inanimate object can transmit these microorganisms to another SP.

Failure to change gloves between SP contacts is an infection control hazard. Wear gloves when touching blood and body fluids requiring universal precautions, mucous membranes, or nonintact skin of all SPs, and for handling items or surfaces soiled with blood or body fluids to which universal precautions apply.

- Wear appropriate gloves when there is the possibility of contact with blood, other potentially infective materials, when performing vascular access procedures, and when handling or touching contaminated items or surfaces.
- It is mandatory to wear gloves when performing phlebotomy, processing blood specimens, processing urine, and performing hematology testing.
- Never wash or decontaminate disposable gloves for reuse.
- Change gloves before and after contact with each SP.
- Gloves should reduce the incidence of blood contamination of hands during phlebotomy, but they cannot prevent penetrating injuries caused by needles or other sharp instruments.
- Remove gloves before leaving the laboratory or phlebotomy room.

Gowns

Various types of gowns and protective apparel provide barrier protection and reduce opportunities for transmission of microorganisms in health care settings. Gowns prevent contamination of clothing and protect the skin of personnel from blood and body fluid exposures. OSHA mandates wearing gowns and protective apparel under specified circumstances to reduce the risk of exposures to bloodborne pathogens. Specifically, OSHA requires the use of such equipment only if it does not permit blood and other potentially infectious materials to pass through or reach employees' work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal use.

- Wear a disposable lab jacket when performing phlebotomy or working in the laboratory.
- Remove protective equipment before leaving the work area and after a garment becomes contaminated.
- Place used protective equipment in appropriately designated areas or containers when being stored or discarded.
- Hang outside street clothing in a designated separate clean area.

Masks

In addition to the laminar flow biological safety cabinet, various types of masks, goggles, and face shields are available alone or in combination to provide barrier protection. Wear a mask that covers both the nose and the mouth, and goggles or a full face shield during activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions to provide protection of the mucous membranes of the eyes, nose, and mouth from contact transmission of pathogens. The OSHA bloodborne pathogens final rule mandates wearing masks, eye protection, and a face shield in specified circumstances to reduce the risk of exposure. Perform all blood processing tasks in the LSBSC. Use Aerosolve containers when centrifuging blood tubes. 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.

3.5 Housekeeping

Under the OSHA standard, each place of employment must keep work areas clean and sanitary. The employer must develop and implement a cleaning schedule that includes appropriate methods of decontamination and the tasks or procedures to be performed. The employer also must ensure that employees follow these procedures:

- 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 including keyboard covers.
- Decontaminate work surfaces with a 1% (1:100) bleach solution after completion of routine procedures, at the end of the work shift, and when surfaces have become contaminated since the last cleaning.

- Decontaminate work surfaces with a 10% (1:10) bleach solution or with a 10% Hype Wipe immediately when surfaces become overtly contaminated and after any spill of blood or other potentially infectious material.

- On a regular basis inspect and decontaminate 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.

- 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.

- If using liquid soap for hand washing, replace or clean the dispenser and fill with fresh product when empty. Do not add liquids to a partially full dispenser.

- 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.

- 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.

    - Wash hands.

    - If spill contains broken glass use dust pan 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 dust pan and broom with bleach solution.

3.6 Identification of Infectious Waste

Consider laboratory wastes, blood and blood products, and sharp items (especially needles) as potentially infectious. Handle and dispose of waste using with special precautions.

3.6.1 Waste Management

A precise definition of infectious waste that is based on the quantity and type of etiologic agents present is virtually impossible to develop. The most practical approach to infective waste management is to identify those wastes that represent a sufficient potential risk of causing infection during handling and disposal and for which some special precautions appear prudent. MEC wastes for which special precautions appear prudent include blood and blood products. Moreover, consider the risk of either injury or infection from certain sharp items (for example, needles) contaminated with blood when disposing of such items. Besides the above guidelines, local and state environmental regulations may also exist.

3.6.2 Infectious Waste Labels

The OSHA Bloodborne Pathogens standard requires that fluorescent orange or 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.

3.6.3 Handling, Transport, and Storage of Infectious Waste

It is often necessary to transport or store infectious waste within the health care setting before terminal treatment. Do this safely by using proper and common sense procedures. Inform personnel involved in the handling and disposal of infectious waste of the potential health and safety hazards and train in the appropriate handling and disposal methods.

- 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.

3.7 Recordkeeping

Employers must preserve and maintain an accurate record of occupational exposure for each employee. Medical records are kept confidential and maintained for at least the duration of employment plus 30 years.

Exposure Management

An "exposure" that may put a health care worker at risk for HIV infection and therefore requires consideration of postexposure prophylaxis is defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object), contact of mucous membrane or nonintact skin (e.g., when exposed skin is chapped, abraded, or afflicted with dermatitis), contact with intact skin when the duration of contact is prolonged (i.e., several minutes or more), or involves an extensive area, with blood, tissue, or other body fluids.

In the event of an exposure follow the steps listed below:

- Notify training or technical supervisor, Director of MEC Operations, and/or MEC physician immediately because postexposure prophylaxis is most likely to be effective if implemented as soon after exposure as possible.

- Treat exposure site by washing wounds and skin sites with soap and water and flushing mucous membranes with water.

- The circumstances and postexposure management are recorded in the health care worker's confidential medical record. Relevant information includes date and time of exposure, details of the procedure being performed, details of the exposure, details about the exposure source, and details about counseling, postexposure management,

and followup. Document route of exposure and how the exposure occurred on a MEC Incident/Emergency Report form.

- The source-person and the exposed health care worker are evaluated to determine the need for HIV postexposure prophylaxis and followup for hepatitis B virus and hepatitis C virus is also conducted. Assessment of infection risk is conducted by evaluating exposure and testing exposure source.

  - Evaluation of exposure – The exposure is evaluated for potential to transmit HIV based on type of body substance involved and the route and severity of the exposure.

  - Evaluation and testing of an exposed source – The person whose blood or body fluids are the source of an occupational exposure is evaluated for HIV infection. If the HIV serostatus is unknown, the source person should be informed of the incident and, if consent is obtained, tested as soon as possible for serologic evidence of HIV infection.

  - Clinical evaluation and baseline testing of exposed health care workers – Exposed health care workers will be evaluated for susceptibility to bloodborne pathogen infections. Baseline testing for HIV and HBV is performed.

- HIV postexposure prophylaxis – When a health care worker has had an exposure to a source person with HIV or where information suggests that there is a likelihood that the source person is HIV-infected, recommendations for chemoprophylaxis is explained to the health care worker.

- Followup of health care worker exposed to HIV – Health care workers with occupational exposure to HIV will receive followup counseling, postexposure testing, and medical evaluation. HIV-antibody testing is performed for at least 6 months post-exposure (e.g., at 6 weeks, 12 weeks, and 6 months).

- Evaluating physician provides written opinion to employer that includes whether vaccine for HBV is necessary, and documentation of administration and statement that employee was informed of results of evaluation and further treatment, if any.

Training Records

The employer must maintain training records for 3 years. This record must include training dates, content or a summary of training, names and qualifications of trainer(s), and names and job titles of trainees.

3.8 References

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16. Rutala WA, Stiegel MM, Sarubbi FA. Decontamination of laboratory microbiological waste by steam sterilization. *Appl Environ Microbiol* 1982;43:1311-6.

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20. CDC. Public Health Service Guidelines for the Management of Health-Care Workers Exposed to HIV and Recommendations for Postexposure Prophylaxis. *MMWR* 1998;47(RR-7).

4. VENIPUNCTURE

4.1 Introduction

The phlebotomist conducts an interview to screen SPs for conditions that excludes them from the blood draw. The phlebotomist also administers a fasting questionnaire to determine fasting compliance. The venipuncture protocol is dependent on the SPs age, person type, and session time. Exhibits 4-1 through 4-4 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 entering the results of the blood draw, 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 after offering refreshments.

Exhibit 4-1. Venipuncture protocol – primary

Age in Years	1-2	3-5	6-11	12+
Tube Type – Priority				
3-mL Lavender	1	1	1	1
5-mL Lavender		1	1	2
3-mL Gray (Morning sessions only)				1
3-mL Blue (40+)				1
3-mL Red	2			
7-mL Red		2		
15-mL Red			2	4
10-mL Red				1
8-mL ACD (20+)				2

Exhibit 4-2. Venipuncture protocol – second exam

Age in Years	12-19	20-59	60-69
Tube Type – Priority			
5-mL Lavender	2	2	2
3-mL Gray (Morning sessions only)	1	1	1
3-mL Blue (40+)		1	1
15-mL Red	2	2	2
7-mL Gray		2	

Exhibit 4-3. Venipuncture protocol – VIP guest

Age in Years	1-11	12+
Tube Type – Priority		
3-mL Lavender	1	1
3-mL Red	1	1

Exhibit 4-4. Venipuncture protocol – guest and surplus

Age in Years	1+
Tube Type – Priority	
3-mL Lavender	1
3-mL Red	1

If the veins of a SP appear too fragile to accommodate the size of the large red top tubes, substitute smaller red top tubes as an alternative protocol. Exhibit 4-5, alternative venipuncture protocol – primary, illustrates the alternative size and number of tubes in bold with the original tube protocol in parenthesis. When the alternative protocol is substituted for the original protocol, a comment must be recorded. This protocol constitutes a deviation from the established standard and it should only be used in rare circumstances.

Exhibit 4-5. Alternative venipuncture protocol - primary

Age in Years	3-5	6-11	12+
3-mL Red	**4**		
7-mL Red	*(2)*	**4**	**9**
15-mL Red		*(2)*	*(4)*
10-mL Red		**3**	

(#) Represents the standard protocol

4.2 Equipment and Supplies

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

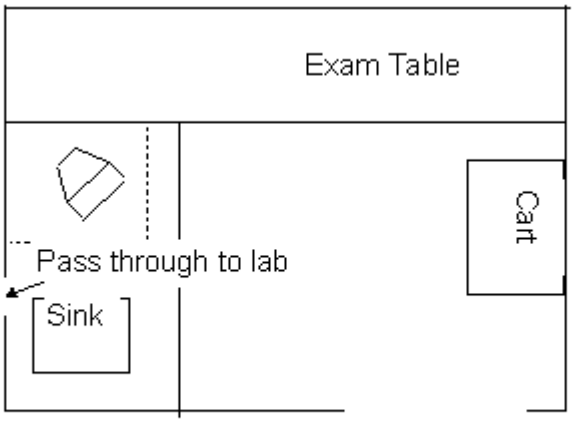


Figure 4-1. Floor plan for phlebotomy room

The equipment and supplies used in venipuncture are listed in Exhibit 4-6.

Exhibit 4-6. Equipment and supplies - phlebotomy

BD Hemogard Vacutainer® 3-mL EDTA	Stretch disposable tourniquet
BD Hemogard Vacutainer® 3-mL Red	Latex tourniquet
BD Hemogard Vacutainer® 5-mL EDTA	Alcohol wipe
BD Hemogard Vacutainer® 3-mL Gray	Iodine prep pad
BD Hemogard Vacutainer® 7-mL Red	2 x 2 Gauze square
BD Vacutainer® 15-mL Red	Adhesive bandage
BD Vacutainer® 8-mL ACD	Adhesive bandage – children
BD-Vacutainer® 10-mL Red	Transpore tape
BD-Vacutainer® 3-mL Blue	Surgical paper tape
Butterfly blood collection set 19 gauge with adapter	Cartoon sticker
Butterfly blood collection set 21 gauge with adapter	Kleenex
Butterfly blood collection set 23 gauge with adapter	Antibacterial hand soap
BD Vacutainer® multiple sample 21 gauge needle	Hand cream
BD Vacutainer® needle holder – single use	Ammonia inhalant packet
Air sickness bag	Sharps container 8 gallon
Heel warmer	Pillow and disposable pillow cover
Labels for Intermec printer	Phlebotomy cart
Nonsterile, powder-free, latex (nonlatex for use by latex allergic staff) gloves -- small, medium, large	Hype-Wipe 10% bleach solution
Juice and crackers	Squeeze ball
Biohazard bags 19 x 23	

4.2.1 Inventory Procedures

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.

- Verify the correct counting
- Enter only one name in the “Counted By” field. This is the person responsible for taking and verifying the inventory count.
- Do not write any notes, comments, etc. on the count sheet. Only write one name in the “Counted By” field and place a number in the “Count” box. Do not redefine or re-iterate the Unit of Measure. Address questions to the MEC manager.
- Do not count partial units; record whole numbers only in the “Count” field.
- If the PAR for an item is more than one and the box or container is open, do not count that container.
- If the PAR for an item is only one unit and if it is more than one-half empty, place a 0 in the count unit.

- Lot #'s and expiration dates – all applicable active lot #'s and expiration dates are on the count sheets. If there is a lot # and expiration date, put a count (even if it is 0) in this field. Use items with older expiration dates first.

Start of Stand Counting Procedures

- Verify the End of Stand Count and the Ship to Stand amount to ensure that the component is at or above PAR level. Address any concerns to the MEC manager.
- Restocking Supplies – remember to use items in the rooms and items in the belly compartment first. Many items such as gloves, alcohol prep pads, electrodes, etc. deteriorate over time.

Consumables vs. Non-Consumables

Inventory items are broken out into two categories - consumable and nonconsumable. Inventory 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.

Shipping Excess Inventory Back to the Warehouse

When shipping excess inventory back to the warehouse, use the "Transfer Inventory to Warehouse Manifest" which is found on the intraweb. The MEC manager or data manager have the ability to access and print this form. This form looks similar to the "End of Stand Count Sheets." Enter one name in the "Count By" field and indicate next to each item how many units are being shipped back to the warehouse. The warehouse manager enters this information into the system, which adjusts the stand inventory and usage information as well as increases the warehouse inventory counts.

Tracking of Expired and Broken Inventory

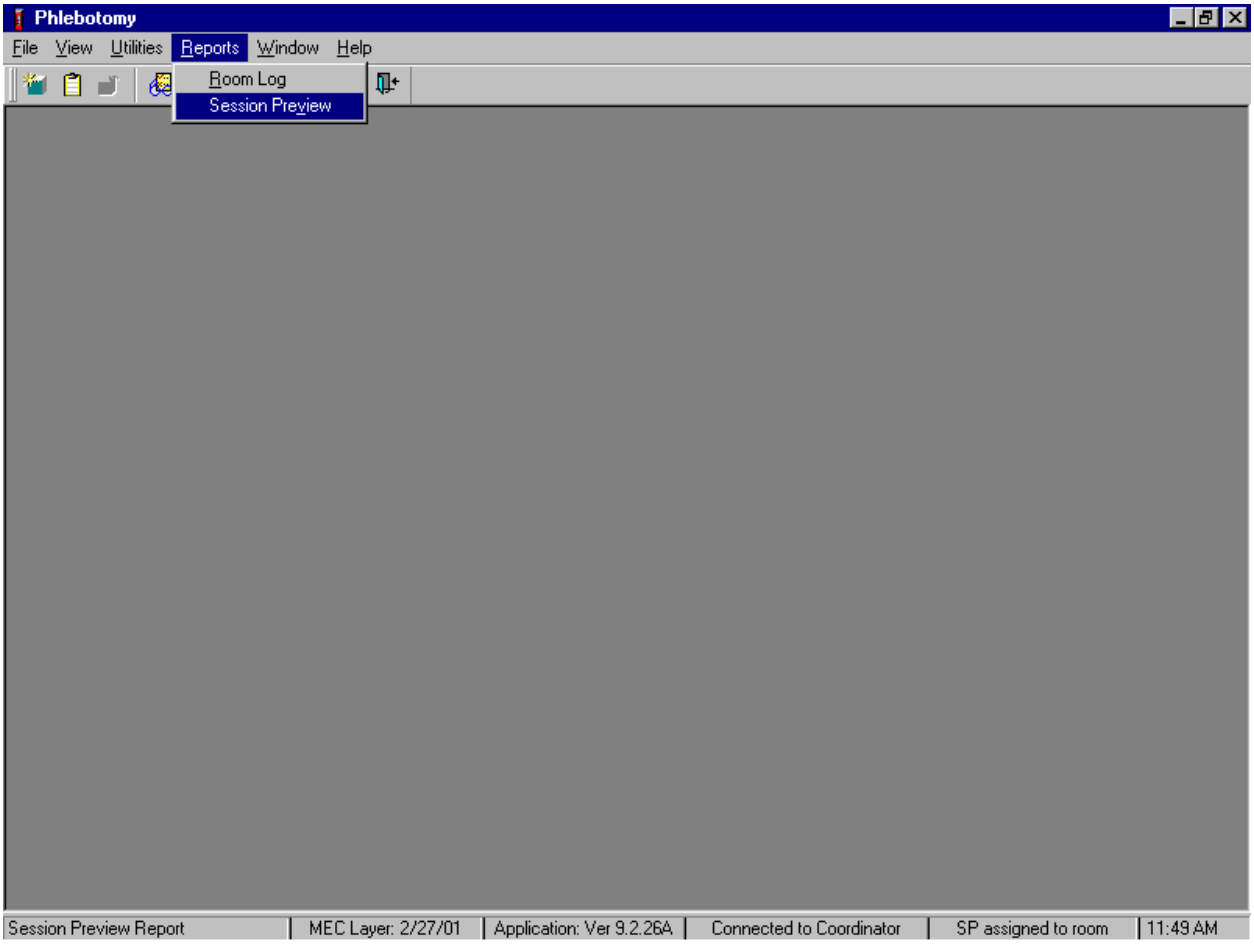
Complete a "Delete Expired/Broken Inventory Report" whenever inventory has expired and must be destroyed or has broken and is no longer usable. Locate this report on the intraweb, complete, and forward it to the warehouse manager so that he or she can remove the expired or broken inventory from the stand inventory.

DO NOT BORROW ANY SUPPLIES FROM ANY OTHER COMPONENTS – Usage is tracked by stand and inconsistencies and trends are tracked by tech. Everyone is accountable for his or her component counts.

REMEMBER – Everyone is responsible for ensuring that there are enough supplies to perform an exam. Notify the MEC manager as soon as possible if additional supplies are required.

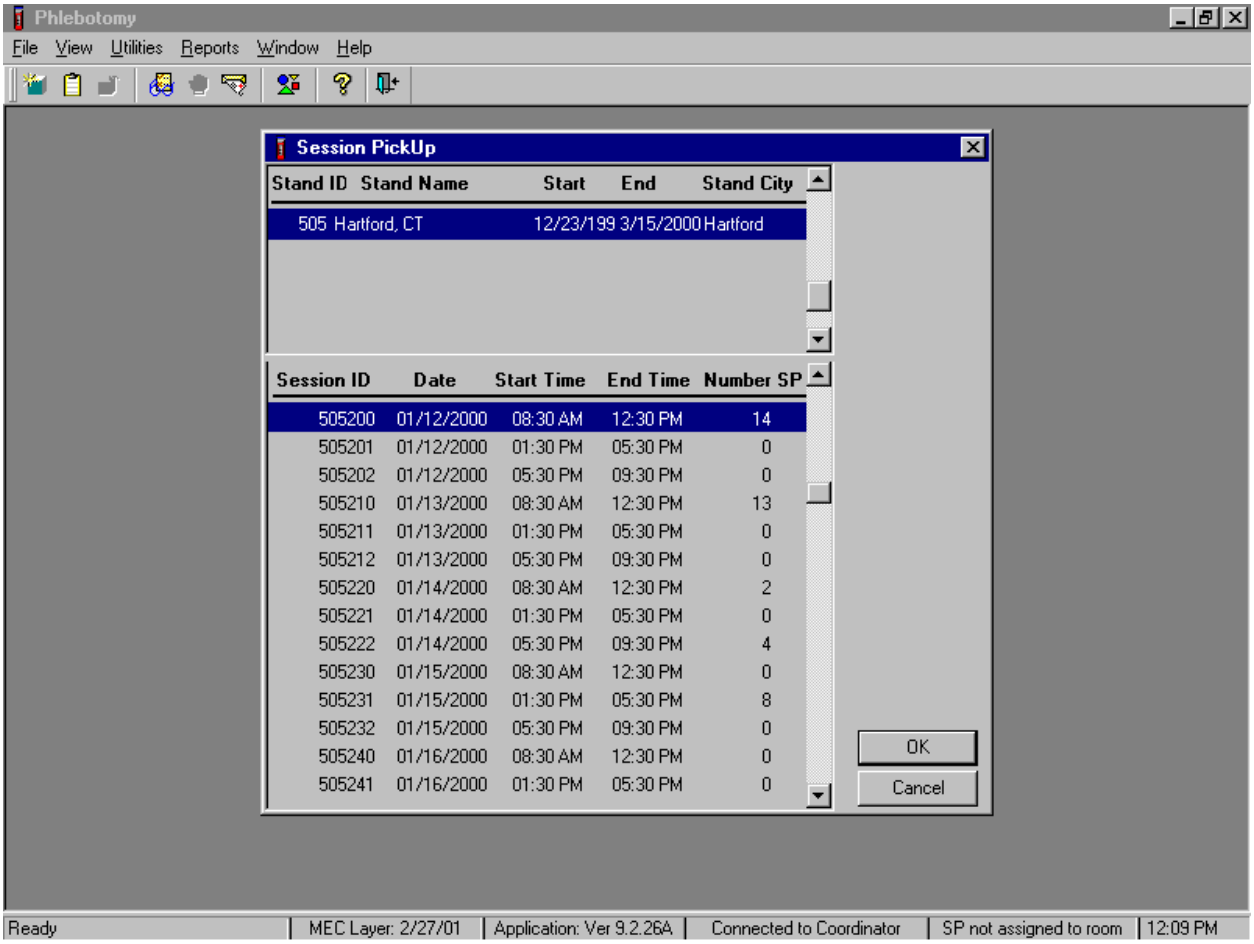
4.3 Session Preview, Show Results, and Room Log Reports

Access the Session Preview report to view all SPs scheduled into any session including the current session.



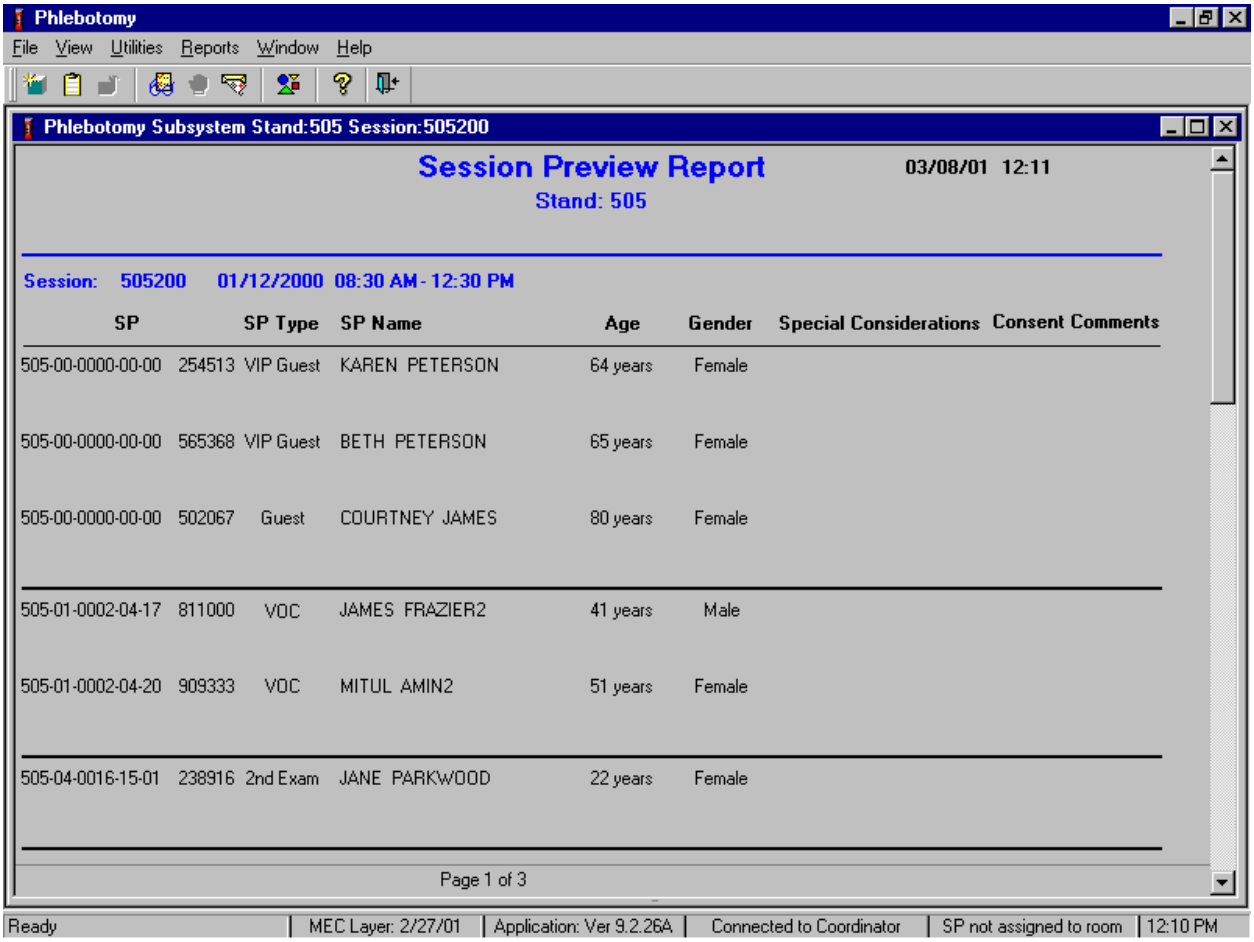
To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, left click, drag the mouse arrow to {Session Preview} and left click, or type [Alt] [R/r], [V/v].

Select the session.



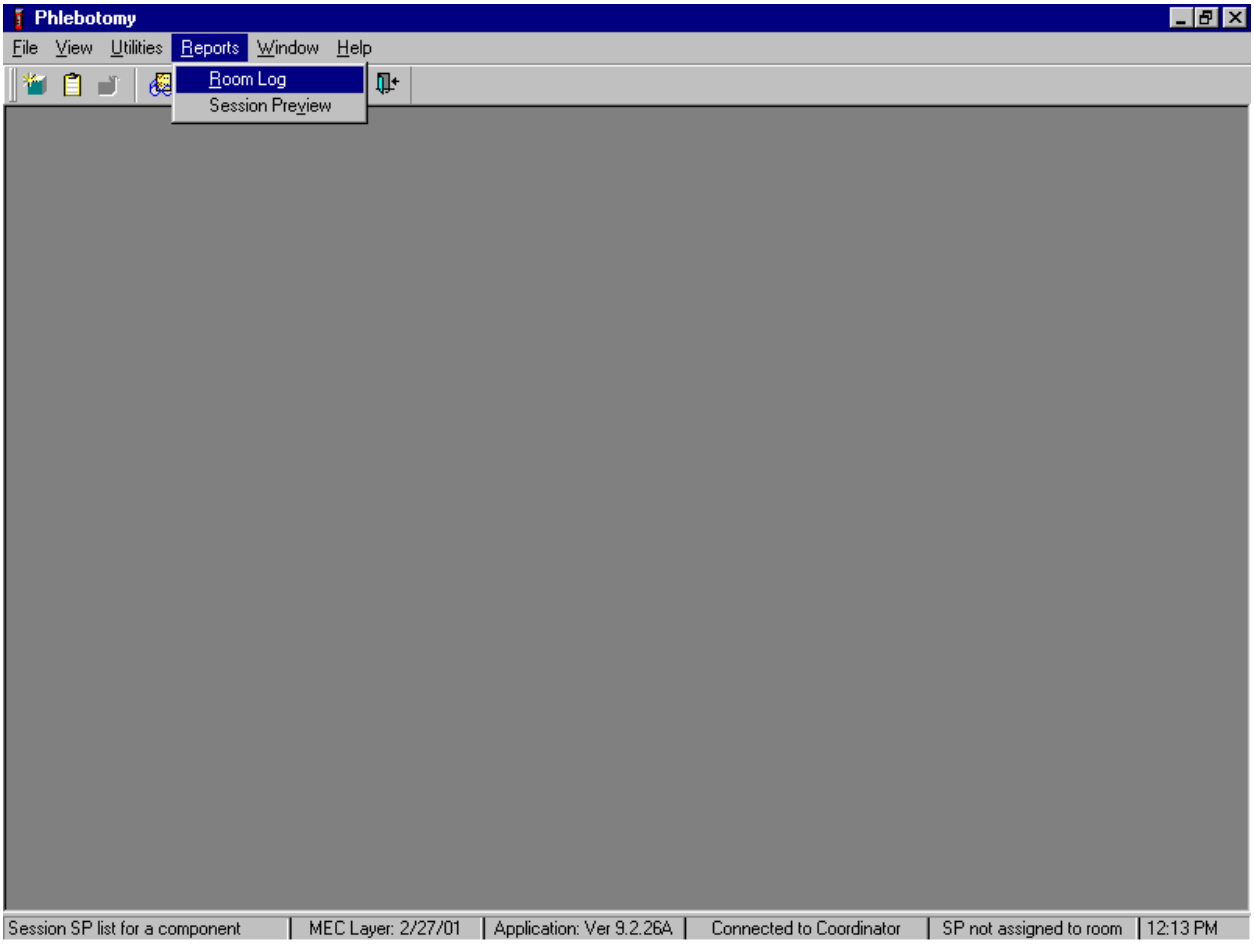
The Session PickUp list displays and defaults to the current session. To select a different MEC session, use the mouse to drag the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the OK button and left click, or press [Enter]. To cancel, use the mouse to direct the mouse arrow to the Cancel button and left click.

The Session Preview Report displays.



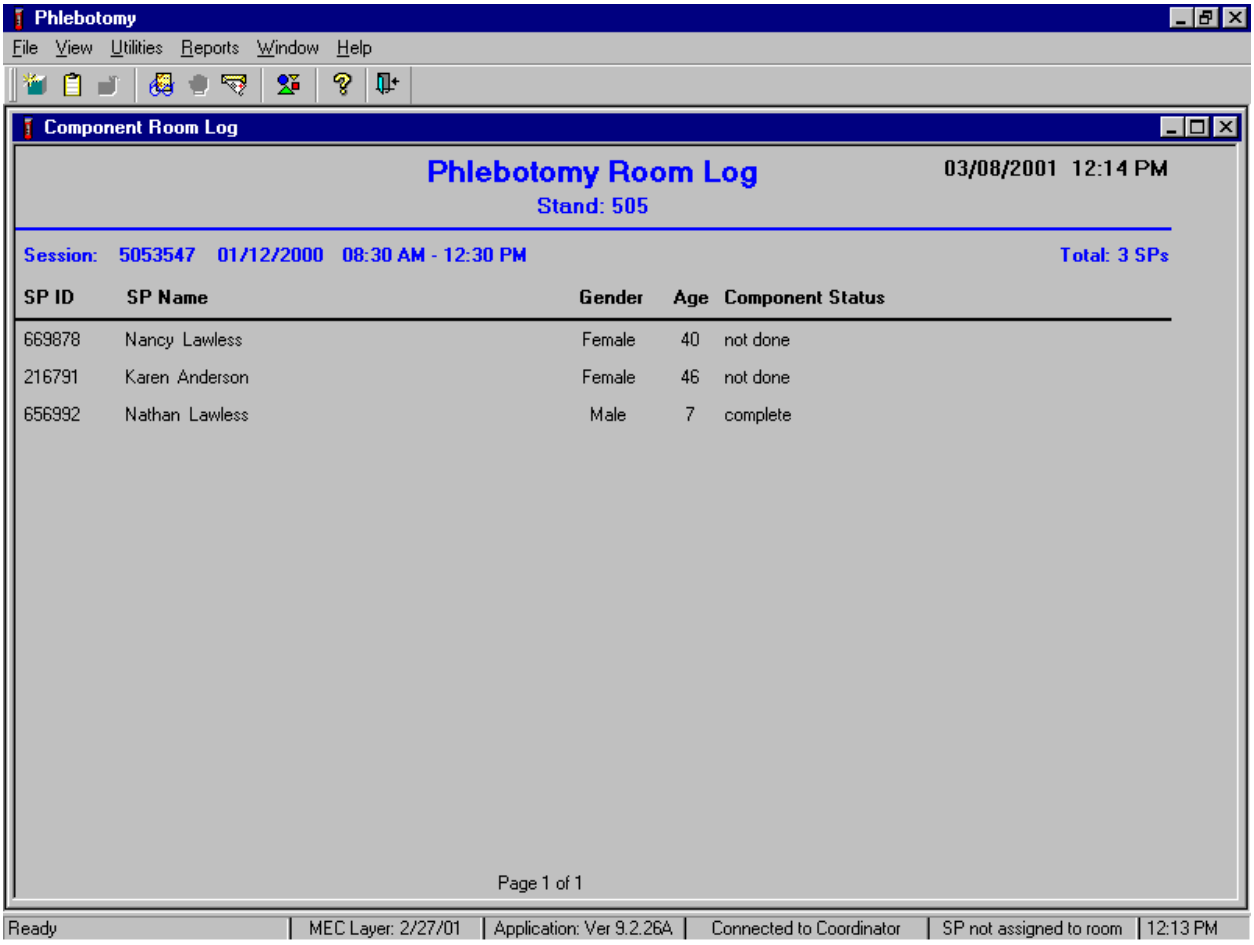
The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last), Age, Gender, and any Special Considerations or Consent Comments. A blue asterisk (*) in front of a name indicates that the SP is eligible for the VOC component. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Session Preview Report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Session Preview Report, use the mouse to direct the mouse arrow to the _ box in the upper right corner of the Session Preview Report (minimize window button) and left click.

The Room Log report provides detailed information about all SPs who have been through the phlebotomy exam and their exam status.



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

The Phlebotomy Room Log displays the SPs in the current session and their component status. The status is listed as Complete, Partial, or Not Done. Use this report to assess the session status.



The Phlebotomy Room Log lists the stand number, session number, session date and time, current date and time, SP's ID, first and last name, gender, age, SP status, and component status. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Room Log report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Room Log report, use the mouse to direct the mouse arrow to the _ box in the upper right corner of the Room Log report (minimize window button) and left click.

4.4 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.

Each SP receives a bar coded ID bracelet when they arrive 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.

The phlebotomist is responsible for completing entries for the following procedures:

- Venipuncture
- VOC special study

Set up the appropriate blood collection cart in advance making sure there are sufficient supplies for all SPs in the session. For each SP, the phlebotomist requires the following materials:

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

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.

4.5 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 239 different biochemical tests (SPs 12+), which provide detailed information about the SP's health and nutritional status. NHANES data produces 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. There is a variety of blood collection needles 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, 22-mL (0.7 ounces), 1.5 tablespoons

  6-11 years primary SP, 38-mL (1.3 ounces), 2.5 tablespoons

  12+ years primary SP, 102-mL (3.4 ounces), 6.8 tablespoons

  12-19 years second exam, 60-mL (2.0 ounces), 4.0 tablespoons

20-59 years second exam, 74-mL (2.5 ounces), 5.0 tablespoons

60-69 years second exam, 60-mL (2.0 ounces), 4.0 tablespoons

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

3-5 years VIP guest, 10-mL (0.4 ounces), 0.7 tablespoons

6-11 years VIP guest, 18-mL (0.6 ounces), 1.0 tablespoon

12+ years VIP guest, 23-mL (0.8 ounces), 1.5 tablespoons

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

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

1+ years surplus, 3-mL (0.1 ounces), 0.2 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 their own blood before their surgery. This consists of one unit per week for up to six 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 participating in the venipuncture component of the NHANES exam.

Gaining the cooperation of a 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/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.

4.5.1 Refusal Conversion

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

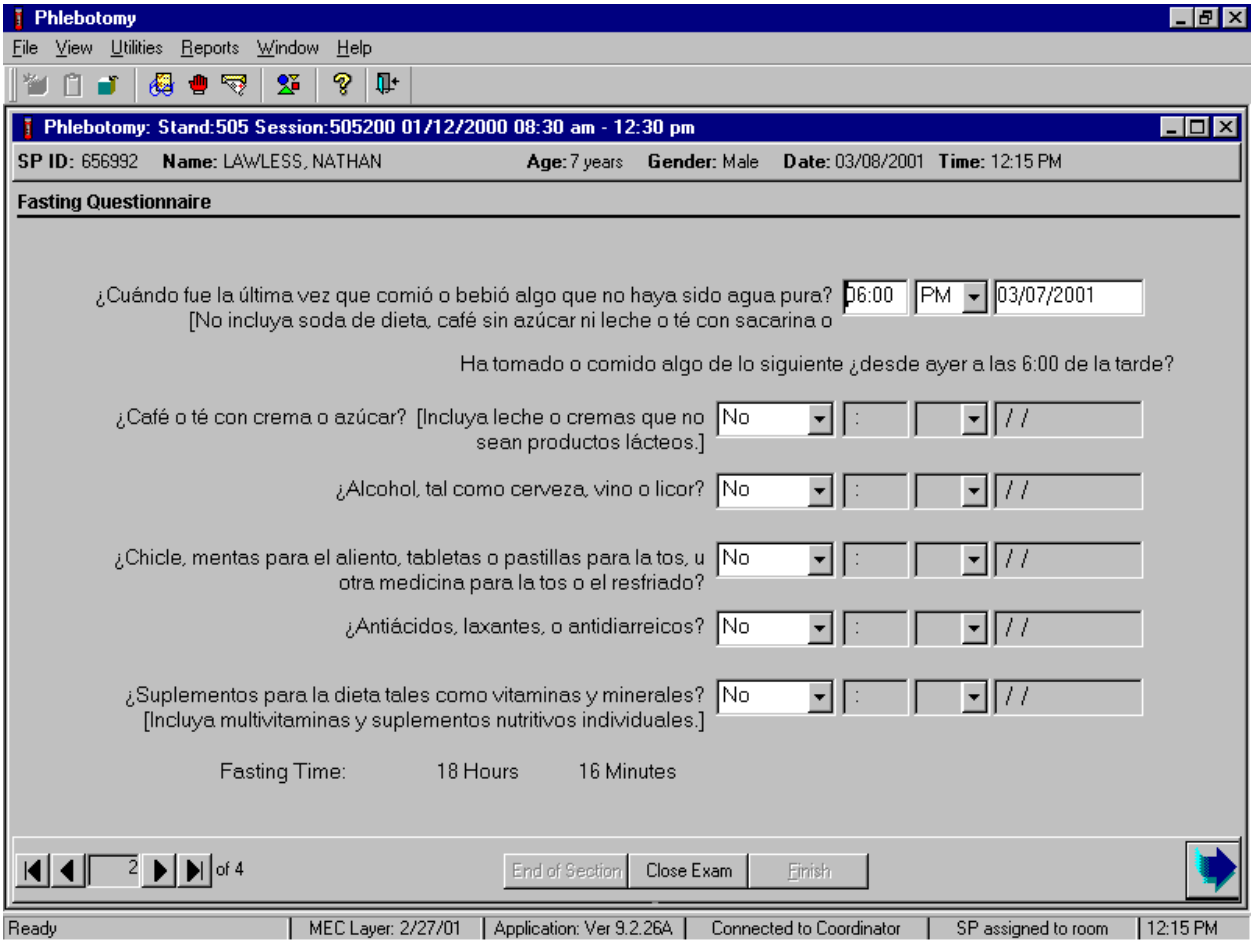
The phlebotomist should discuss the condition of the SP's refusal with the coordinator before he/she attempts a conversion. If the coordinator indicates that the SP is an adamant refusal, the phlebotomist should not attempt to approach the SP or conduct the phlebotomy interview. If, however, the coordinator 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 technician, and/or the MEC physician when attempting to convert refusals.

4.6 Performing the Venipuncture on SPs Who Do Not Speak English

When the phlebotomist must administer the venipuncture procedure to a 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.

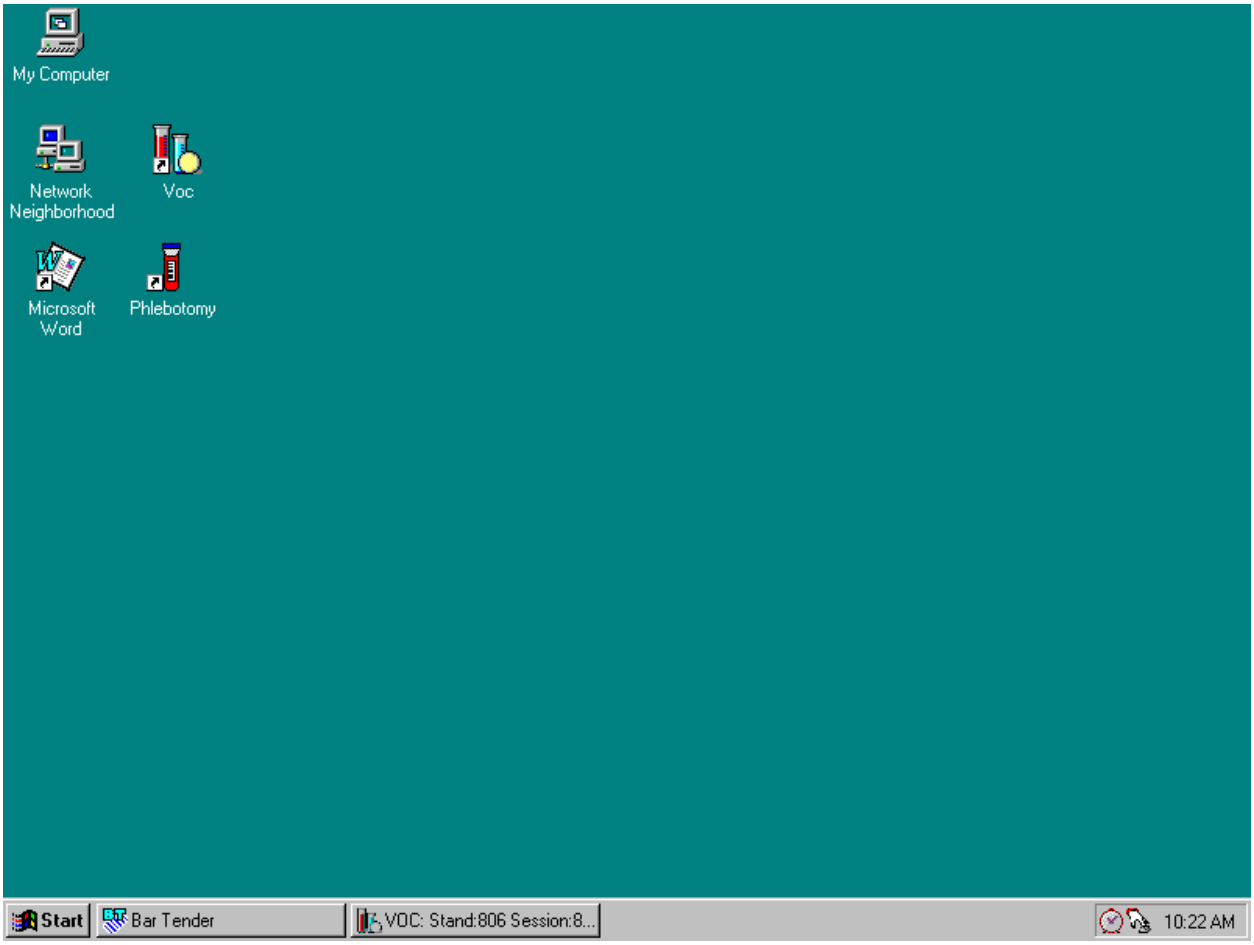
Convert the phlebotomy interview and fasting questionnaire text from English to Spanish or from Spanish to English at any time before, during, or after an exam.



To view the phlebotomy interview and fasting questions 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 the phlebotomy interview and fasting questions 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].

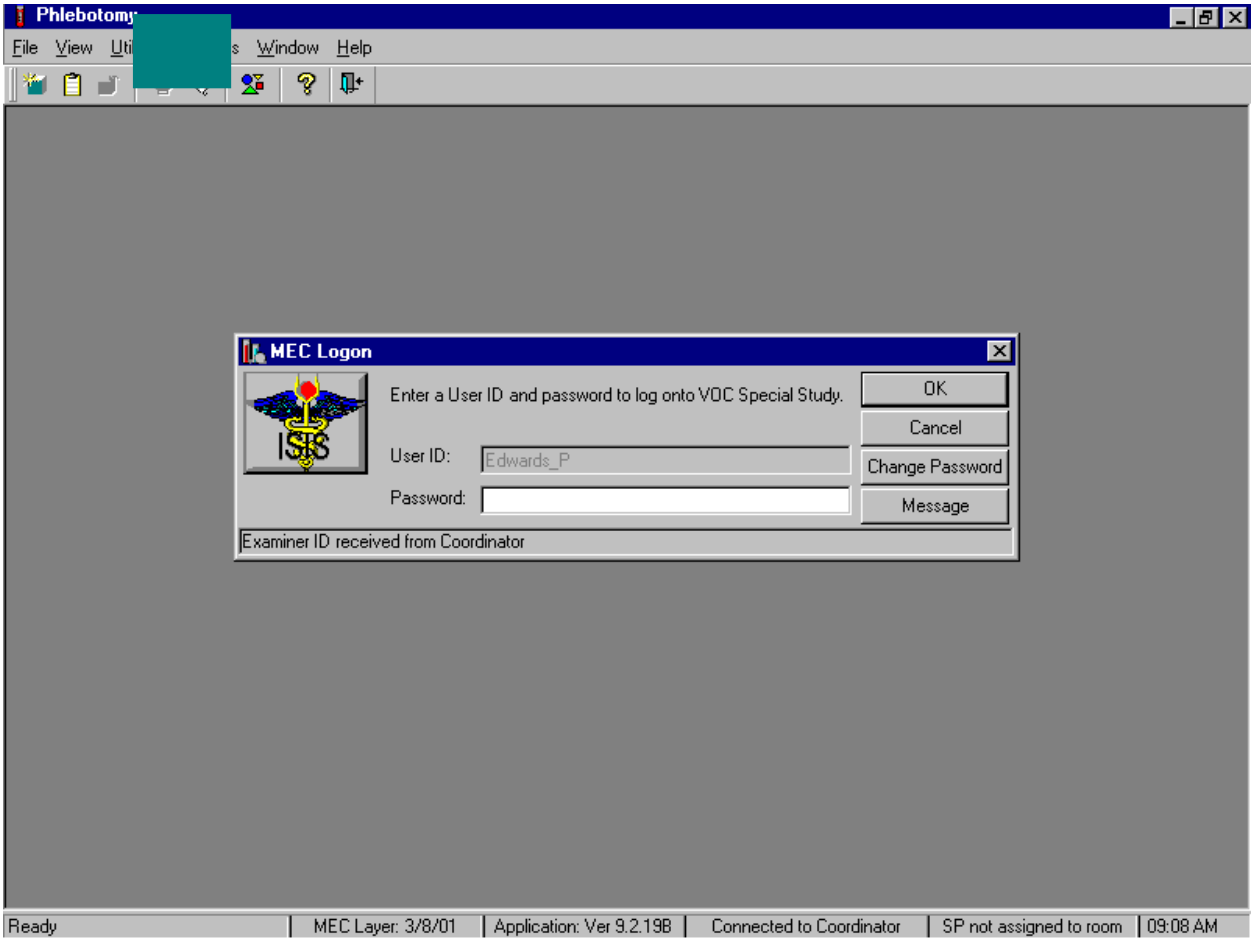
4.7 Begin the Exam and Logon

Open the phlebotomy application.



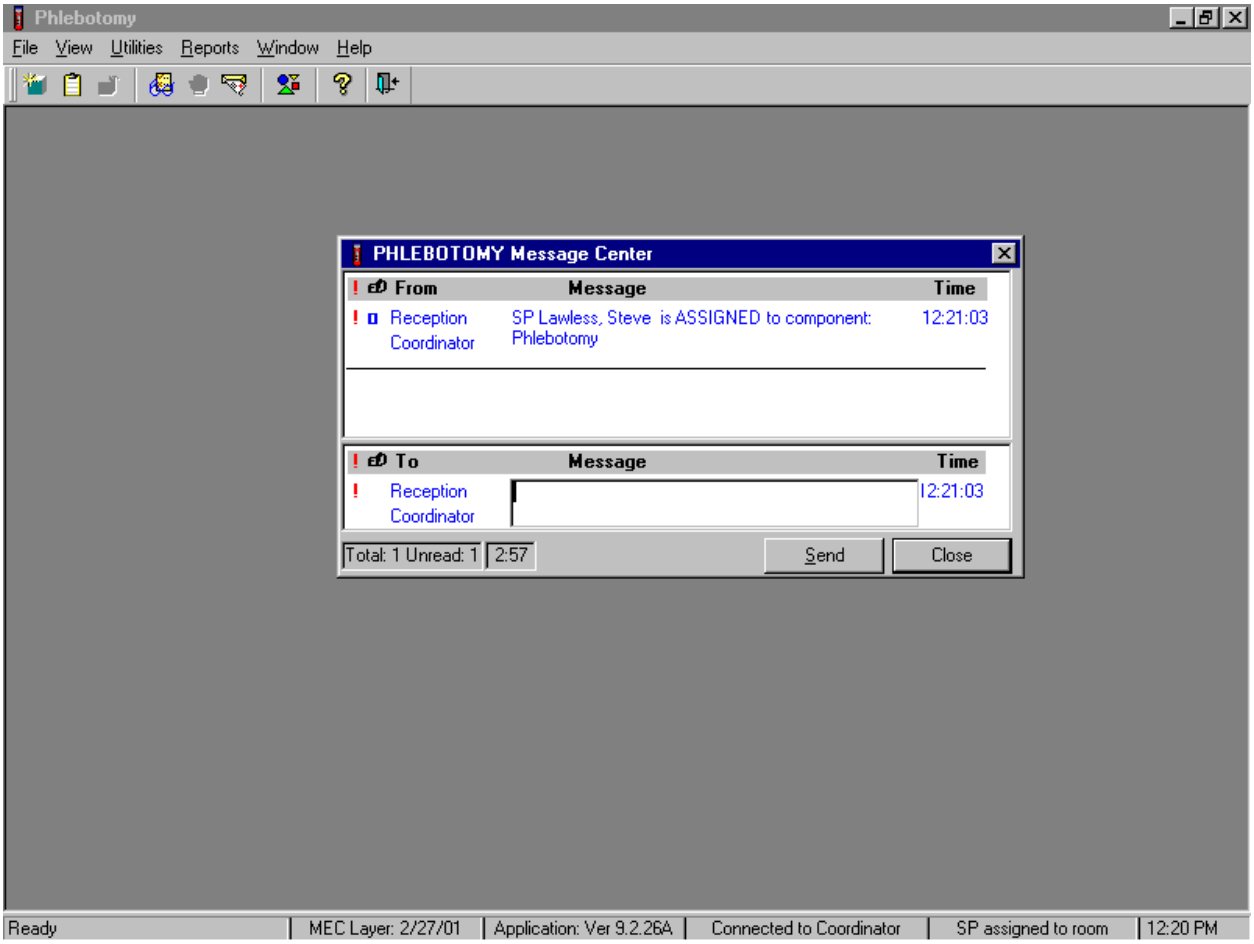
To access the phlebotomy application, use the mouse to direct the mouse arrow to the Phlebotomy icon on the desktop and double left click.

Log onto the Phlebotomy application.



The MEC Logon window displays. Type the password using the keyboards numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the OK button and left click. To exit this screen without entering a password, use the mouse to direct the mouse arrow to the Cancel button and left click. To send a message to the coordinator, use the mouse to direct the mouse arrow to the Message button and left click.

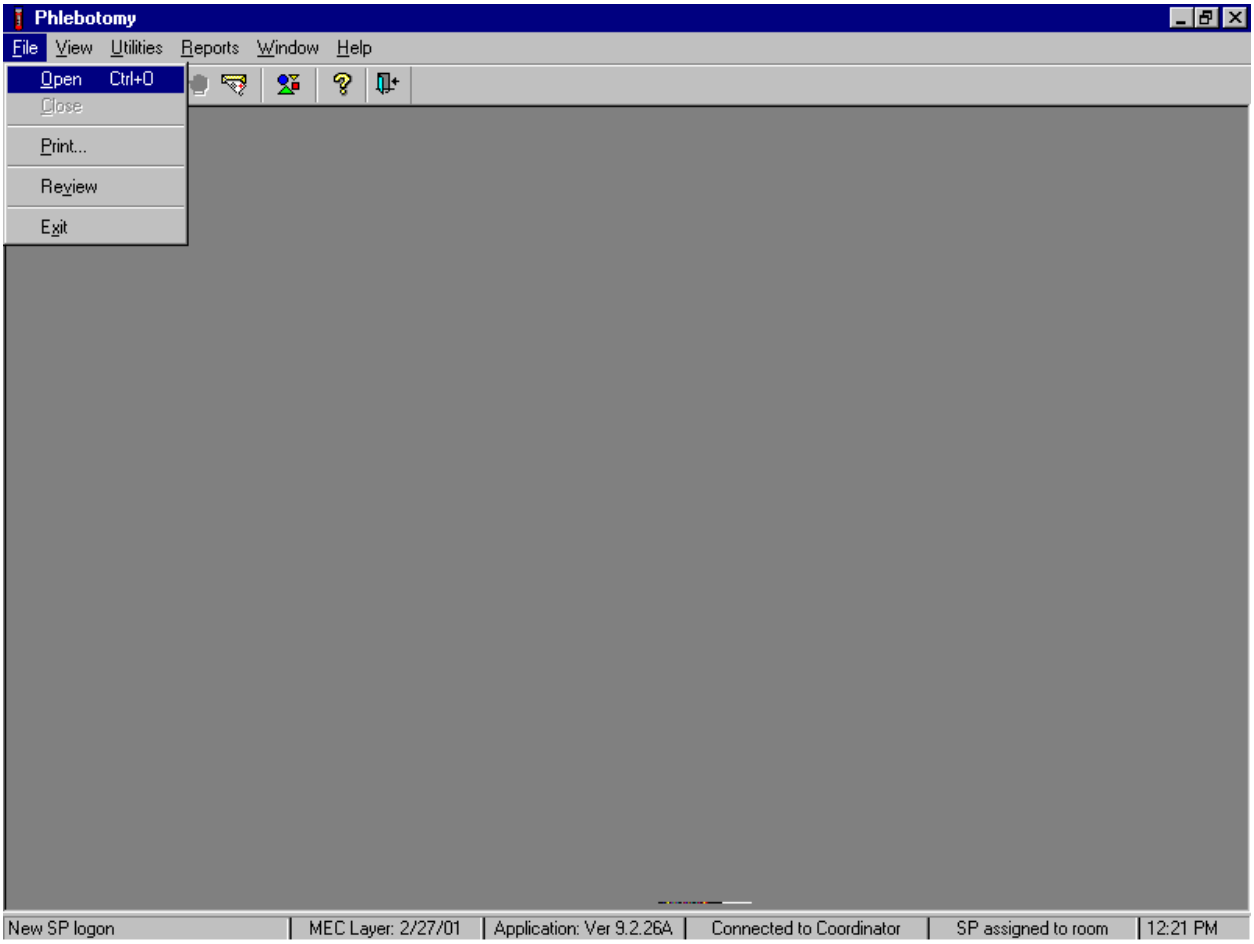
The message center window identifies the SP assigned to phlebotomy.



A Message Center message text box containing a message from the coordinator indicating the name of the SP who is assigned to the phlebotomy component displays. 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].

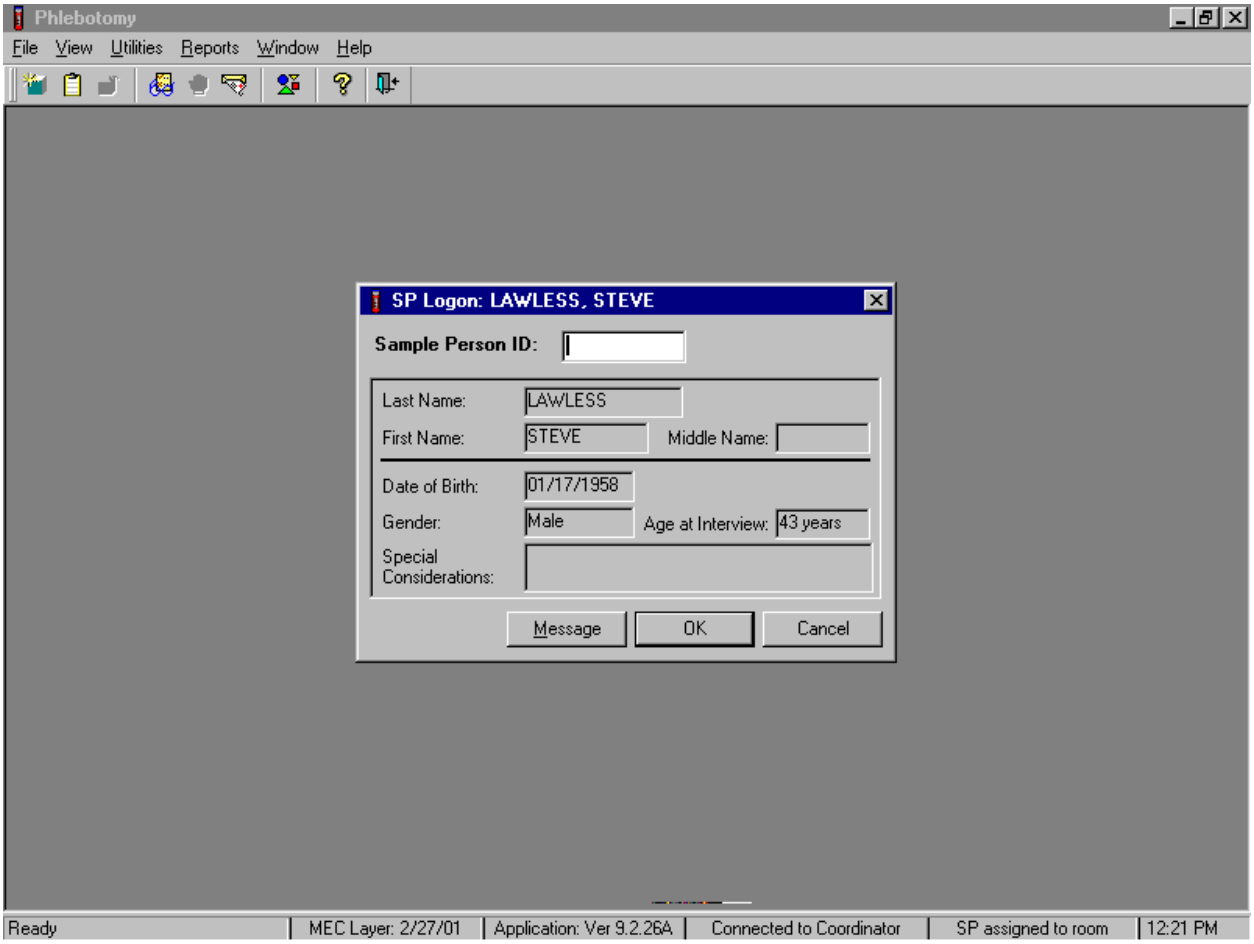
4.8 Open the Exam and Log the SP into the Exam

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.



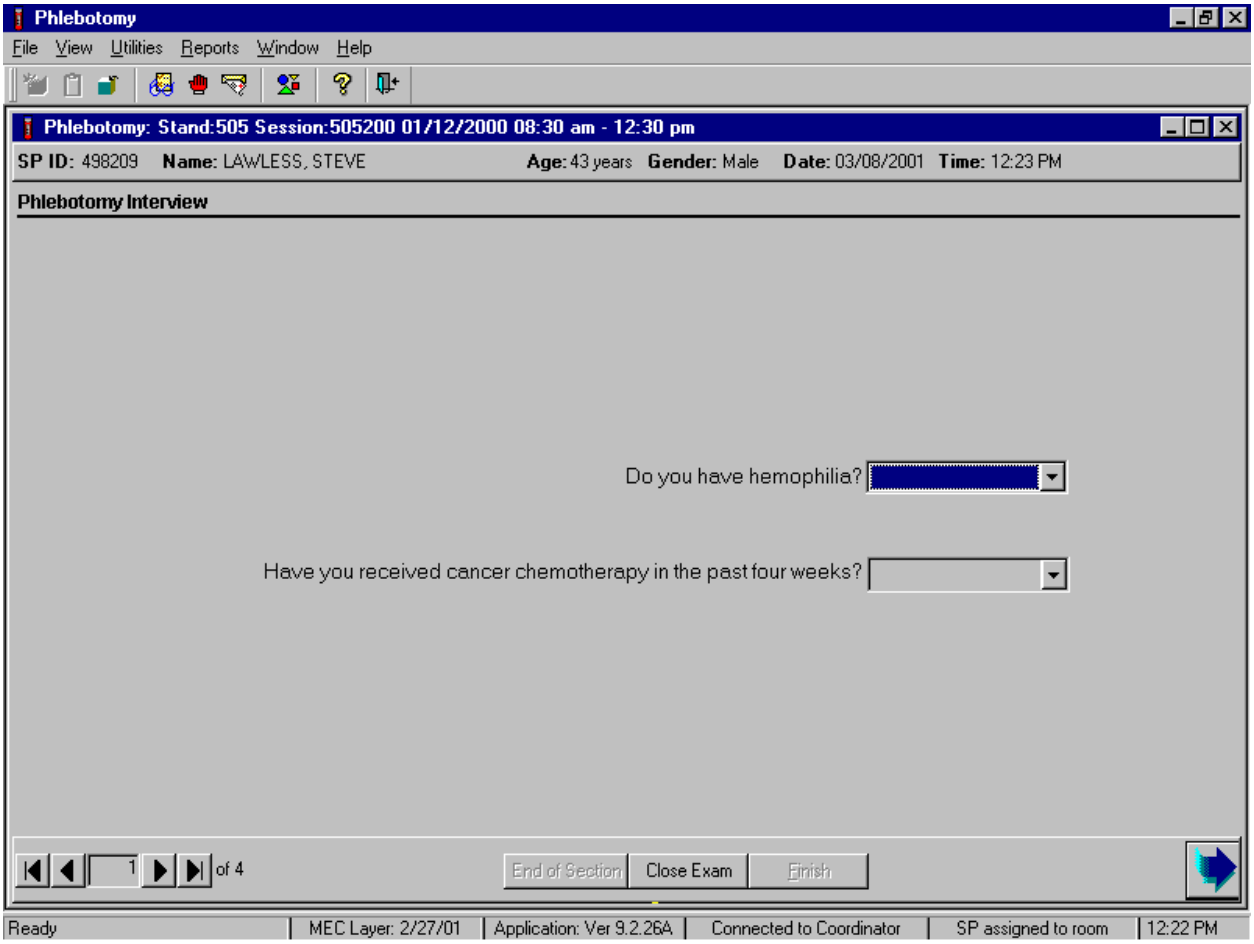
The SP Logon window displays for the SP assigned to the component. To log the SP into the component either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use 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.

4.9 The Phlebotomy Interview

The phlebotomy interview screens the SP for safety exclusions. There are only two reasons to exclude a 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 18 or administer the interview questions (and fasting questionnaire) to the SP's parent or guardian for SPs under age 18.

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

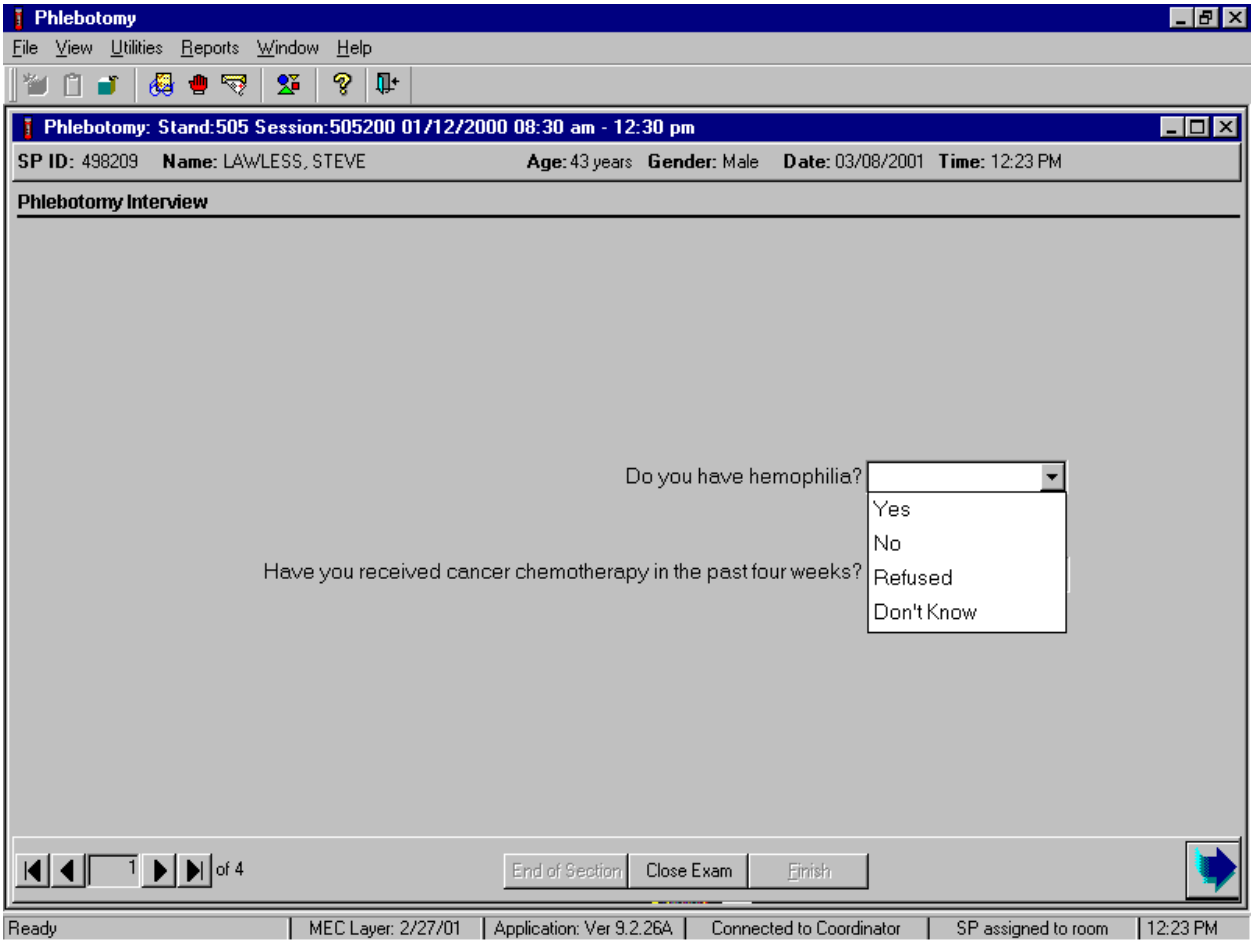


Conduct the phlebotomy interview by asking the question displayed on the screen, "Do you have hemophilia?"

Q1: Do you have hemophilia?

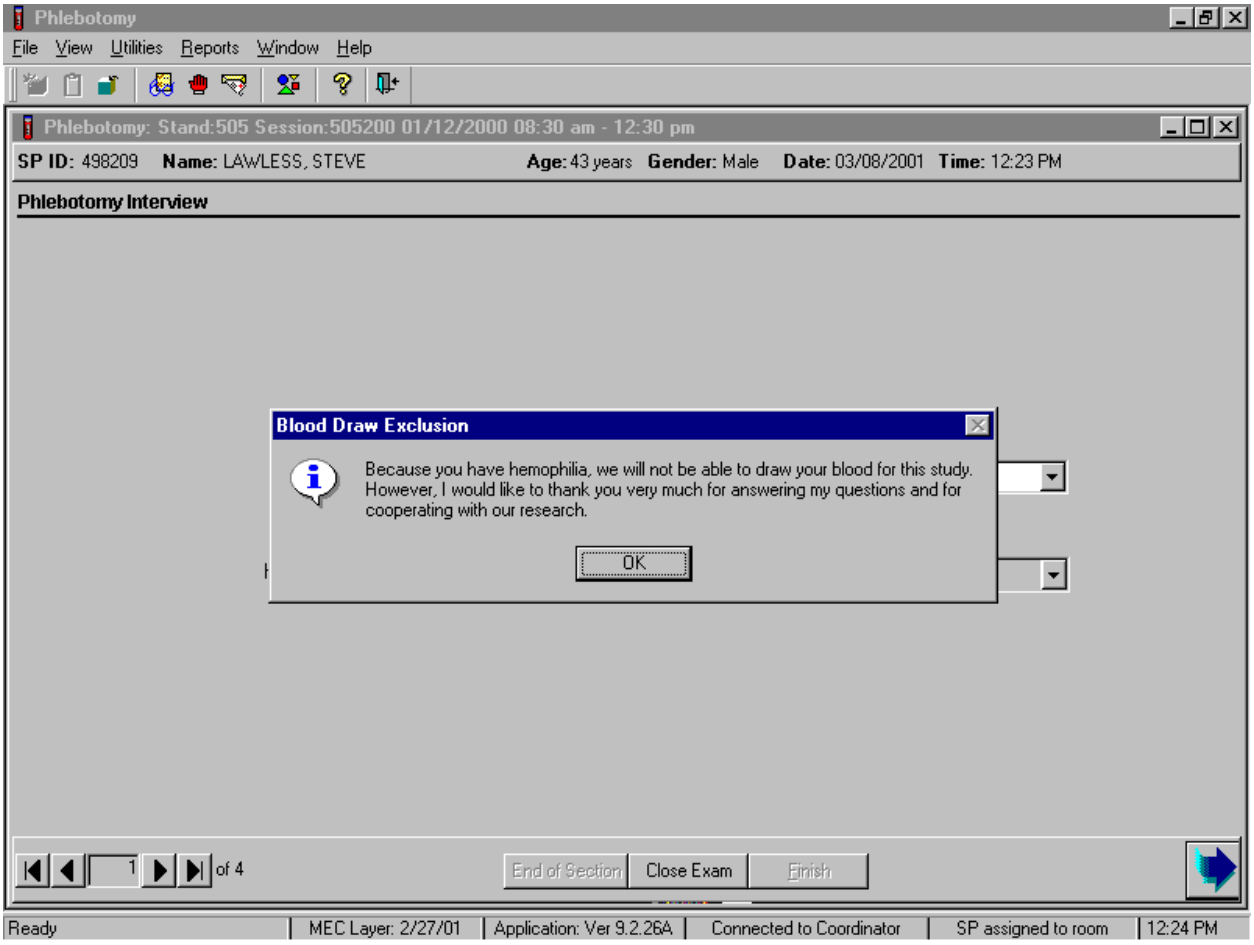
Q1: This question asks whether the SP has hemophilia, which is an exclusion criterion for this procedure.	Explain that we cannot perform phlebotomy on participants who have hemophilia. Hemophilia is a rare disease where an individual's blood does not clot. If a SP's relative has hemophilia but the SP 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 them back to the coordinator station.

Record the exact response.



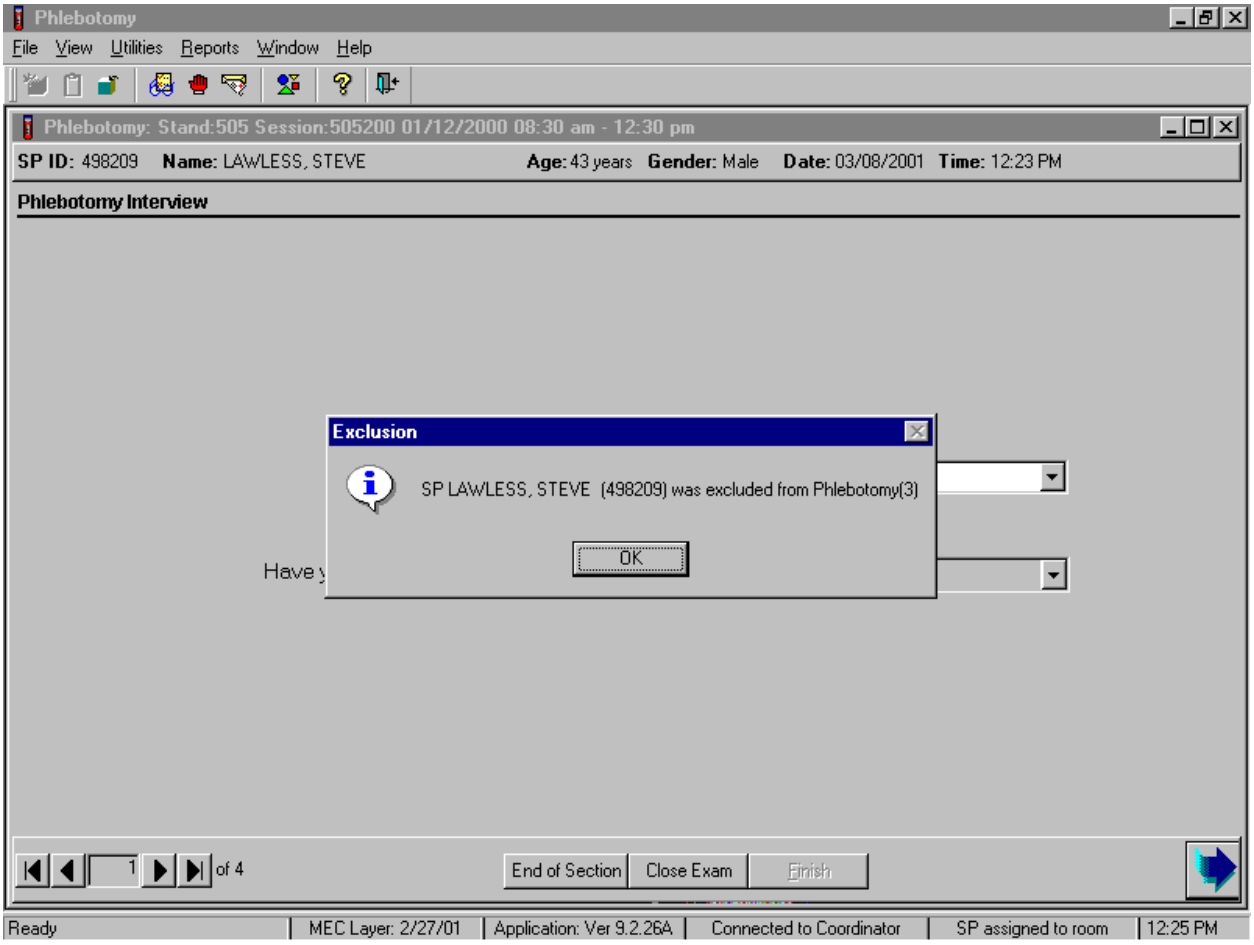
Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” “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.



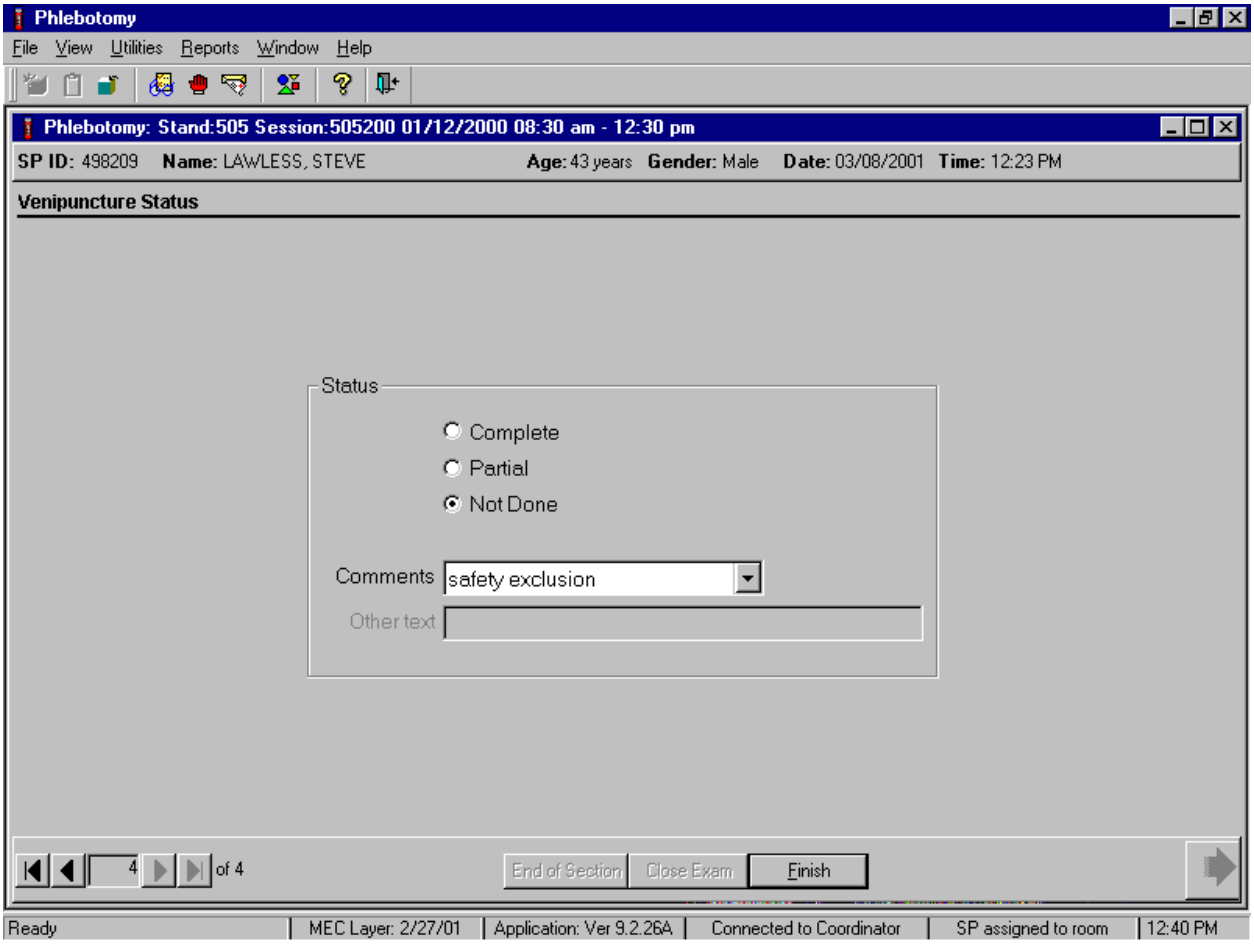
Read the script to the SP. To remove the Blood Draw Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

If the SP is excluded from the phlebotomy component due to hemophilia, an Exclusion message text box displays.



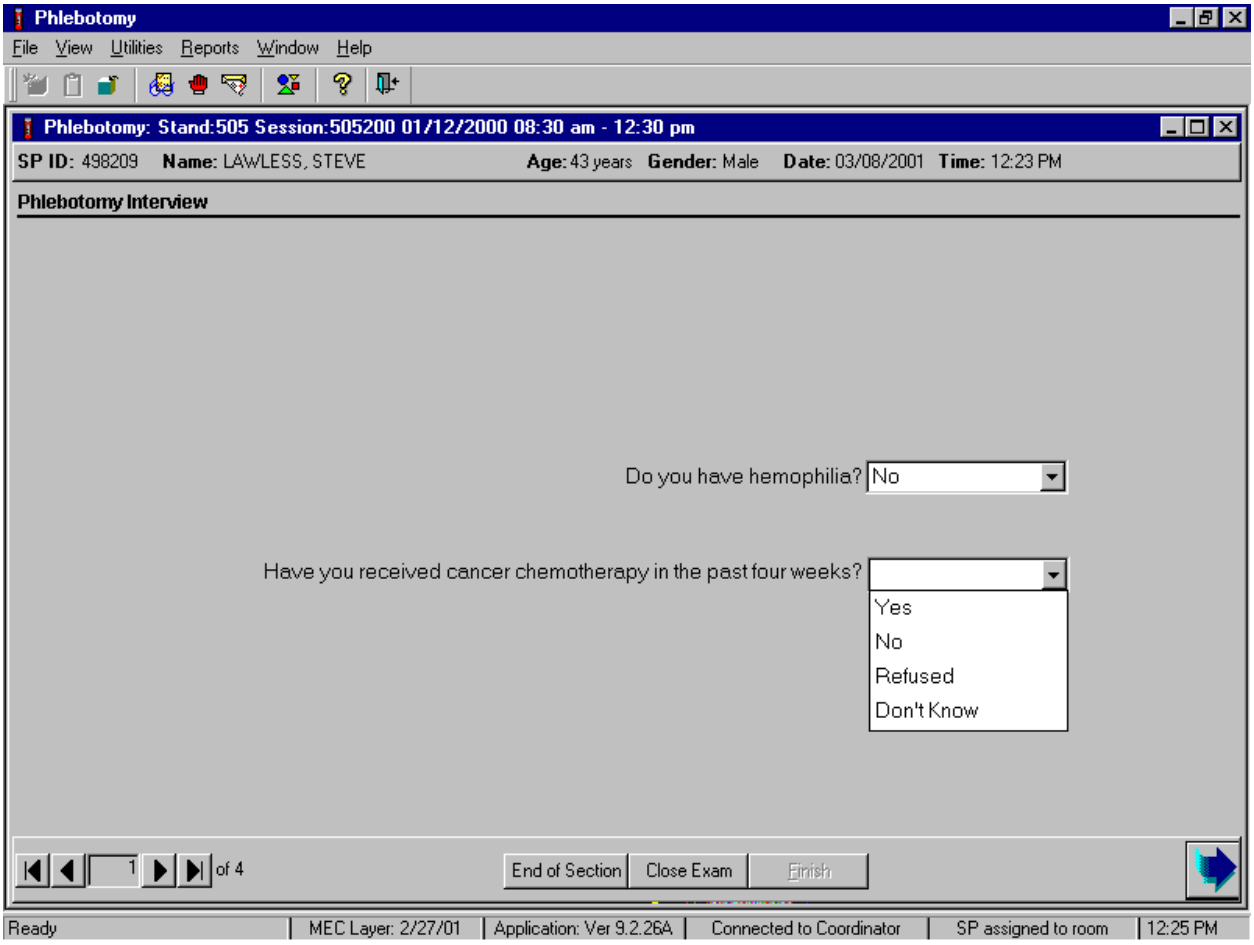
To remove the Exclusion message text box, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter].

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 their 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?"

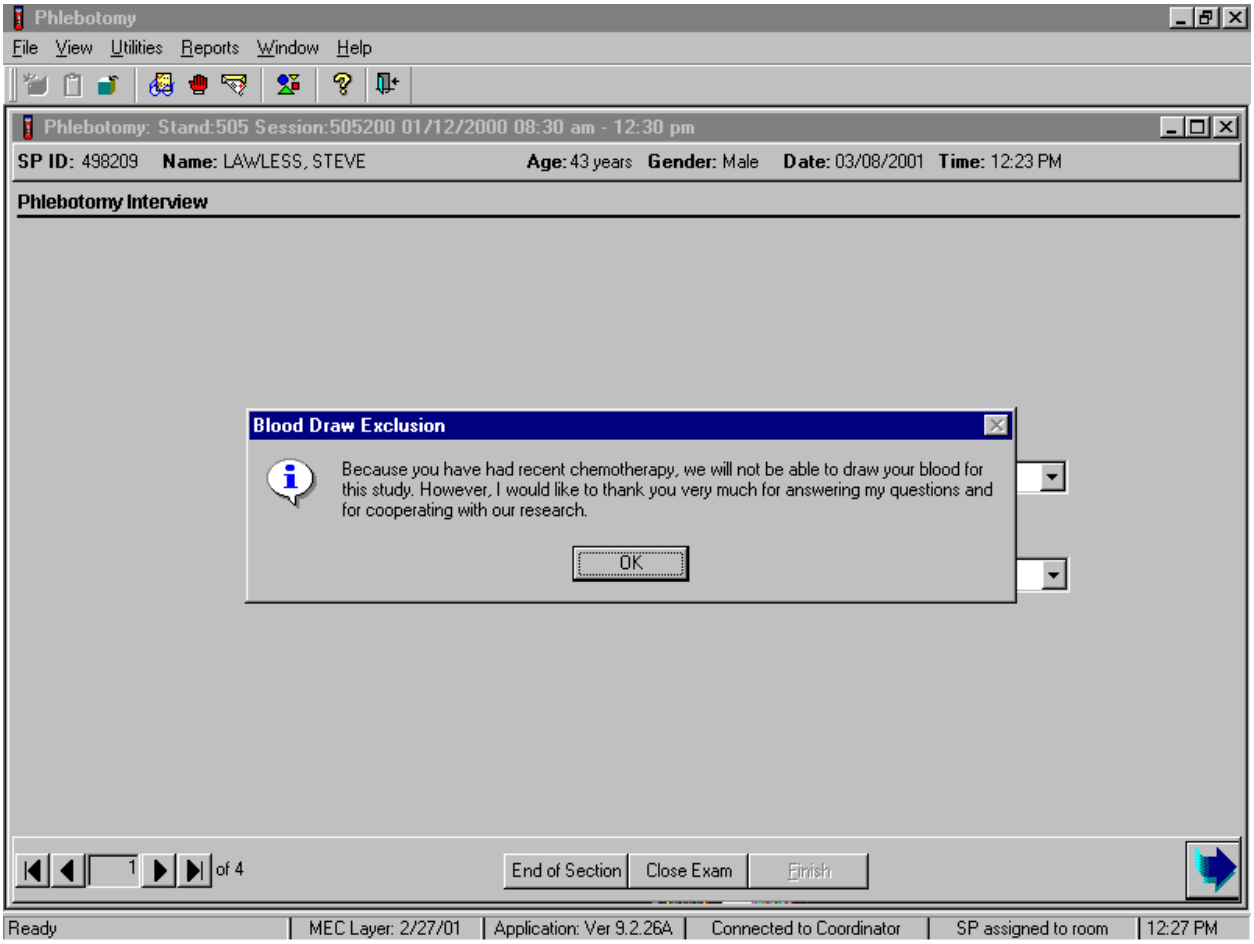


Q2: Have you received cancer chemotherapy in the past four weeks?

Q2: This question asks whether the SP has received chemotherapy in the past 4 weeks. This situation excludes the SP from this procedure.	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 them back to the coordinator station.

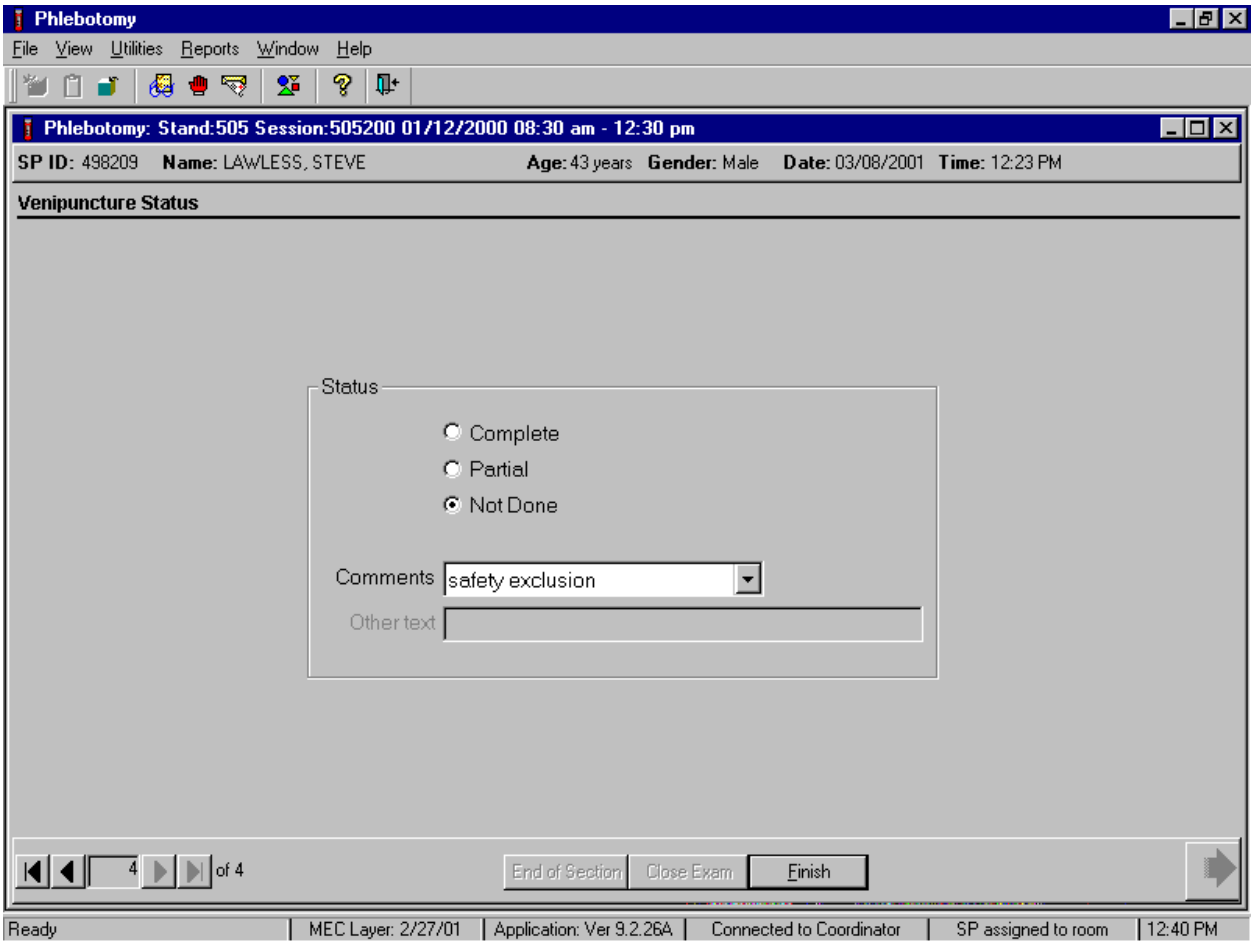
Record the response by typing [Y/y] for "Yes," [N/n] for "No," [R/r] if they refuse, or [D/d] for "Don't know." Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to "Yes," "No," "Refused," or "Don't Know" and left click. If the response is "Yes," "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. 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 their next component as directed by the Message Center.

4.10 Administering the Fasting Questionnaire

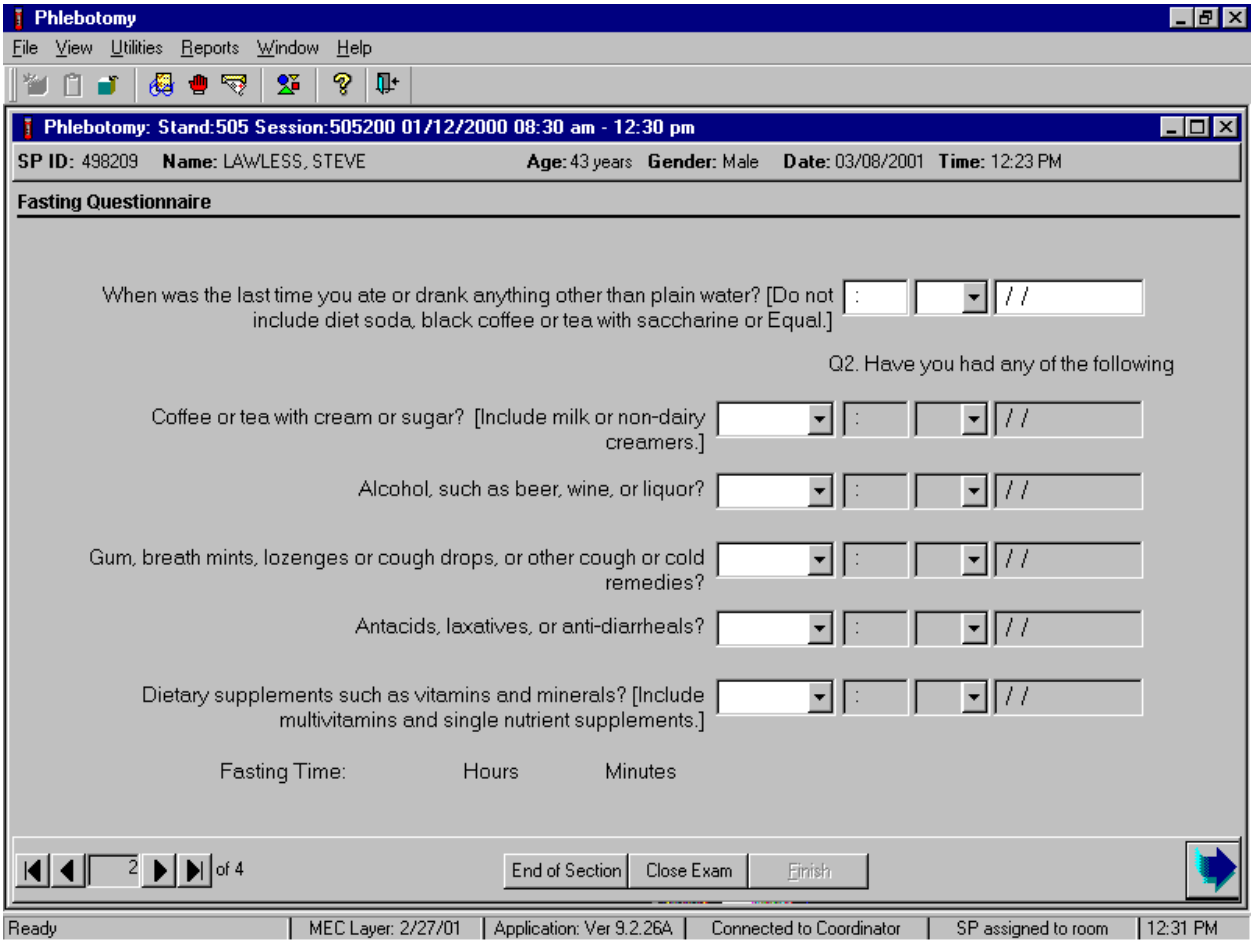
Fasting is critical to many of the laboratory analytes and fasting data is required for correct interpretation of laboratory results. No primary SP age 1-11 or diabetics taking insulin by injection are required to fast. All other primary SPs age 12+ have required fasting times based on the examination session to which they are appointed. SPs appointed to a morning session are asked to fast for 9 hours while SPs appointed to an afternoon or evening session or a home exam session are asked to fast for 6 hours. 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 performs the venipuncture if the SP meets the fasting requirement. If the SP has not met the fasting requirement but will meet the required fast within 30 minutes of the end of the session, the SP is asked to continue with other examination components and return to phlebotomy once the fast has been met. The coordinator reassigns the SP to phlebotomy.

The overall objective is to perform phlebotomy on SPs who have met their fast but SPs can be reassigned to phlebotomy at any time, whether they have met the fasting requirement or not. Base the decision to reassign a 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 a SP insists on leaving the MEC and it is preferable to get blood from a SP who has not met their fast than not to obtain any blood on the SP. The coordinator and MEC manager are able to provide the best overall assessment of the status of a particular SP and the coordinator and/or the MEC manager should make the decision to reassign an SP to phlebotomy before the fasting period ends. The coordinator and/or the MEC manager should include the phlebotomist in their discussion whenever possible so everyone understands the situation.

Guest, dry run, VIP guests, and surplus participants do not have a required fast.

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

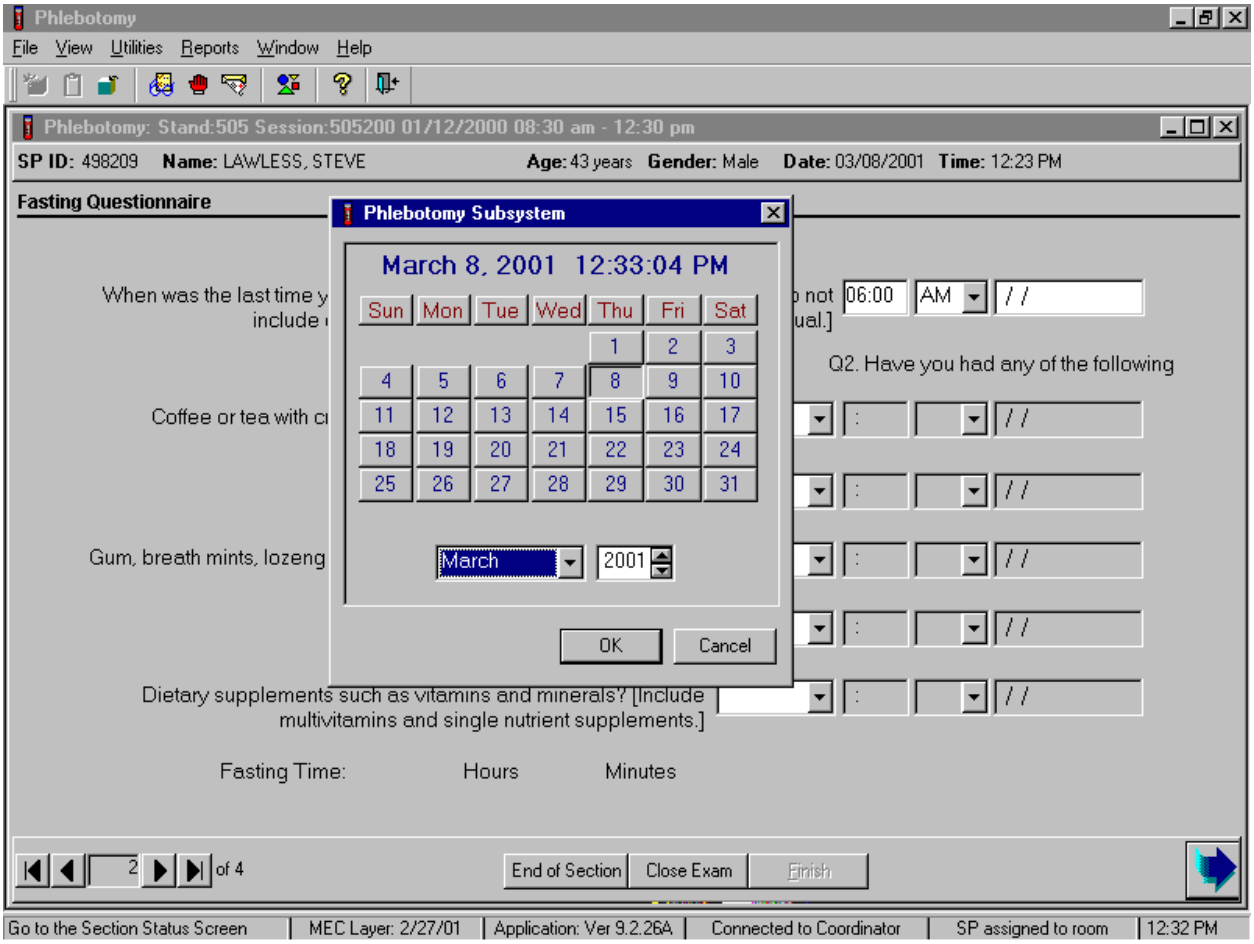
Read the text exactly and record the time.



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.]

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

Enter the response.

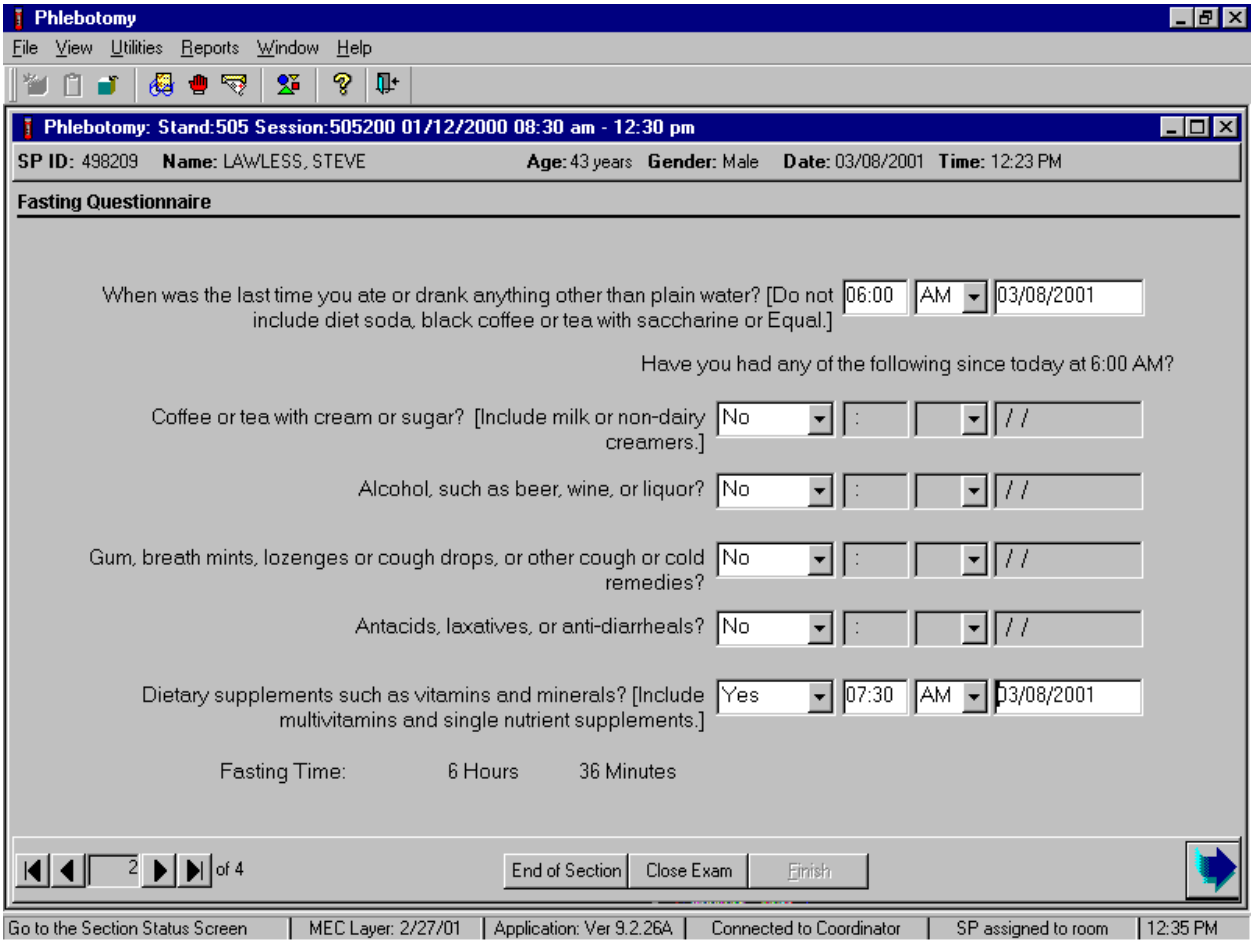


Type in the reported time using the numeric keys and select [Tab] to move to the AM/PM space. Type in [A/a] for times between midnight and 11:59 a.m. or [P/p] for times between 12:00 noon and 11:59 p.m. and select [Tab]. Alternatively, to select AM or PM, use the mouse to direct the mouse arrow to the 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.



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

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.]	Black coffee is acceptable but coffee with any additives other than saccharine or Equal are unacceptable. Include all milk products such as half and half, light cream, nonfat milk, and all other non-dairy creamers like Creamora or Coffee-Mate.
Alcohol, such as beer, wine, or liquor?	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.

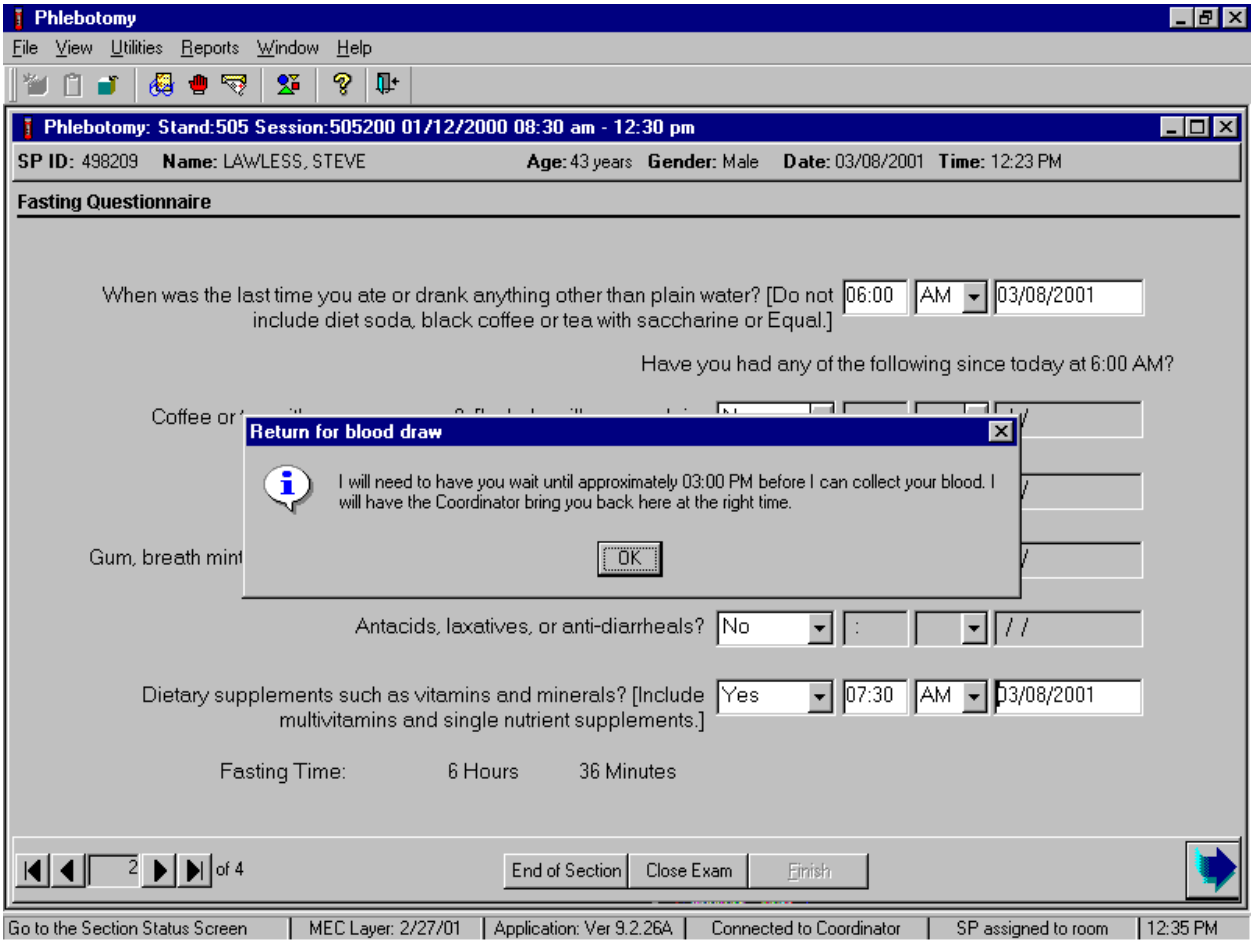
Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?	Include sugar-free gum and mints in this category. Give the SP the laminated card that lists common over-the-counter cough drops and cough and cold remedies to refresh their memory if they appear unsure about these items. If the answer is, "Yes" clarify the response. Ask the SP to describe the activity, item consumed and the correct time.
Antacids, laxatives, or anti-diarrheals?	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 their memory if they appear 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.
Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]	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 mulitvitamin-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 their memory if they appear 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.

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.

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].

If the SP does not meet their fast, but will meet their fast within 30 minutes before the end of the session, the Return for blood draw informational text box displays.



Read the text to the SP. To remove the Return for blood draw text box, use the mouse to direct the mouse arrow to direct the mouse arrow to the OK button and left click or select [Enter].

When s/he returns to phlebotomy, open the exam, wand the SPs ID bracelet and proceed with the interview questions. If the fasting requirement will not be met by the end of the session, proceed with the venipuncture. Continue to administer the questionnaire.

4.11 Venipuncture Procedures

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 and then mix well to distribute the additive.

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. Use expired tubes if 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 Supply Use Control Log. Keep a separate line in the log for each type of Vacutainer®. When opening a new box, record the date, the lot number of the box, date in use, the expiration date, and tech ID number.

4.11.1 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 a 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 a 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 arm on the armrest or a pillow so that the veins are readily accessible and the phlebotomist is able to work in a comfortable position. Dispose of the pillow weekly for hygiene purposes. Change the pillowcase frequently. Be sure that the arm is in a downward position with the elbow lower than the heart to prevent backflow.

- Inspect the arm. Use the left arm unless unsuitable. The veins of choice are those located in the antecubital area. Do not draw blood from any arm with an arterial access, such as a fistula or shunt. Also, do not draw blood from a swollen or edematous arm or an arm that has a rash or open sore.

- If the veins in the antecubital space are not suitable, look for suitable veins on the forearm.

- 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 technique 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.

4.11.2 Venipuncture Technique for the Sherwood Kendall Monoject Angel Wing™ Blood Collection Set

1. Prepare the blood collection set. Open the package and attach the needle holder. Grasp the Angel Wing Safety Blood Collection Set between thumb and forefinger so the opposing wings are pinched together. While holding the wings, remove the protective needle sheath and ensure the needle bevel is up. Alternatively, hold the wing section in one hand and remove the protective sheath. Check to ensure the needle bevel is up. Grasp the base section of the device behind the tethers so the wings are in their normal flat position.

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 the phlebotomist's 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. Push the needle firmly and deliberately into the vein. 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 three 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, gray, blue, and ACD tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender, gray, and light blue top tubes on the rocker. Gently invert the ACD tubes 5-6 times and place in rack. 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. Using one hand, place the index finger on the wing section immediately behind and slightly to one side of the wing tabs; grasp the base section/tubing interface between the thumb and middle finger. Hold the wing section in place with gentle pressure, and then slowly begin to pull back on the assembly until the tethers are fully extended and a slight resistance is met. A faint click may be heard. This indicates the locking device has been actuated and the contaminated needle tip is now shielded behind a stainless steel barrier.

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.

4.11.3 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 the phlebotomist's 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, gray, blue, and ACD tubes to ensure proper mixing of blood and anticoagulant or additive. Place the lavender, gray, and light blue top tubes on the rocker. Gently invert the ACD tube 5-6 times and place in rack. Do not invert or agitate the red top tubes.

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.

4.11.4 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. Label each tube collected with the computer generated bar code labels. The time prints on the label.

3. Dispose of all visibly contaminated waste in a biohazard bag.

4. Check the venipuncture site for clotting. 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.

5. Report any adverse reaction to the venipuncture to the physician immediately and document it by entering an explanation in the Comments section of the Venipuncture Data Entry Screen and by recording the event in the Unusual Occurrence Log.

6. If the SP has been fasting, offer them a snack and juice. Escort them back to the coordinator.

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

8. If a 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.

4.12 Pediatric Venipuncture

Pediatric venipuncture requires special techniques. Because the phlebotomist 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, that is with a doll, 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/she was after the draw. Give the child realistic choices, such as which arm to choose. The phlebotomist 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 old 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 the adolescent that the best technique is being used. It is very important that the adolescent maintains control of the situation; therefore, give the child some

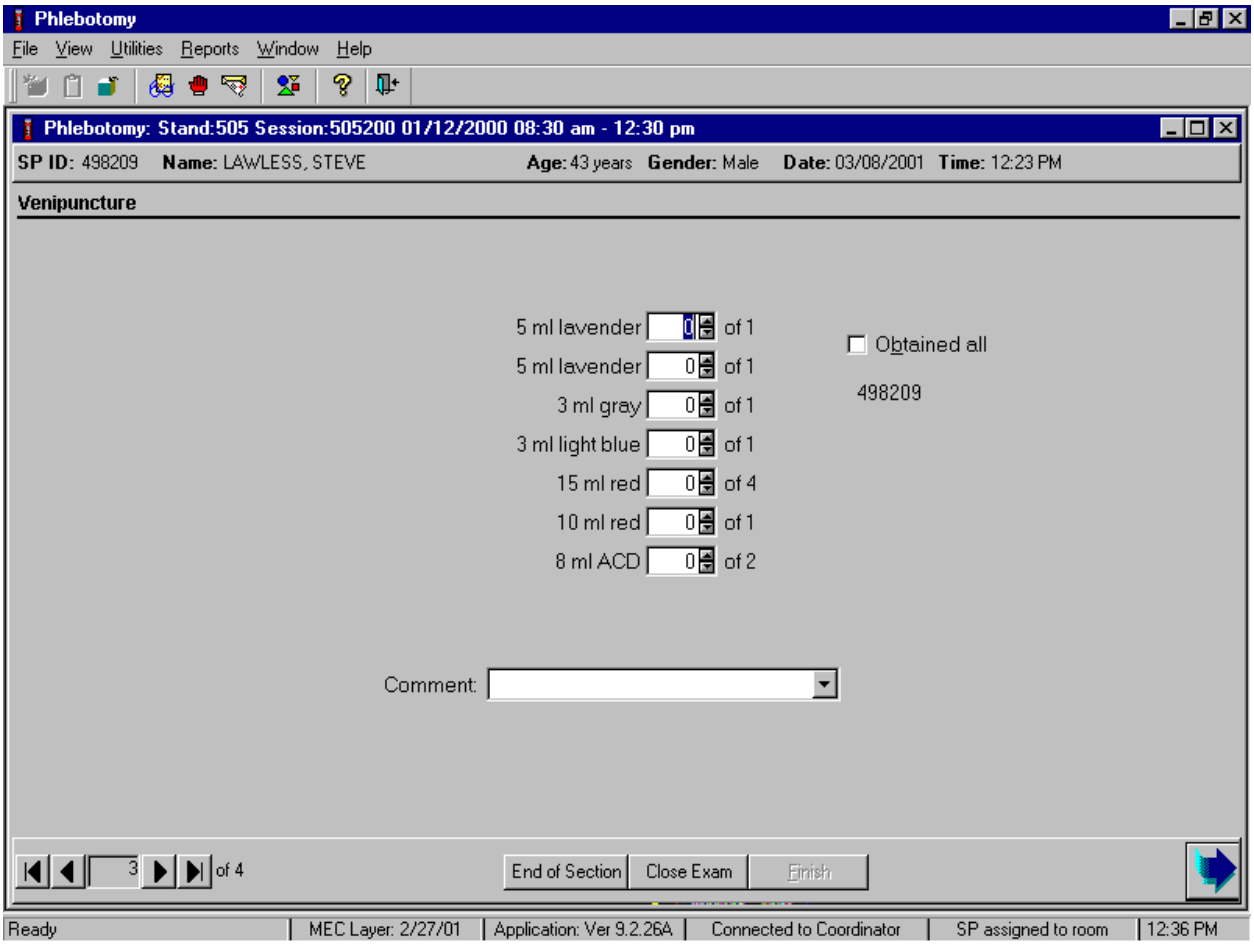
choices as well as allow him or her to help if offered. Be very clear about rules, such as remaining motionless, but do not restrain the child.

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 4.11 for performing venipunctures.

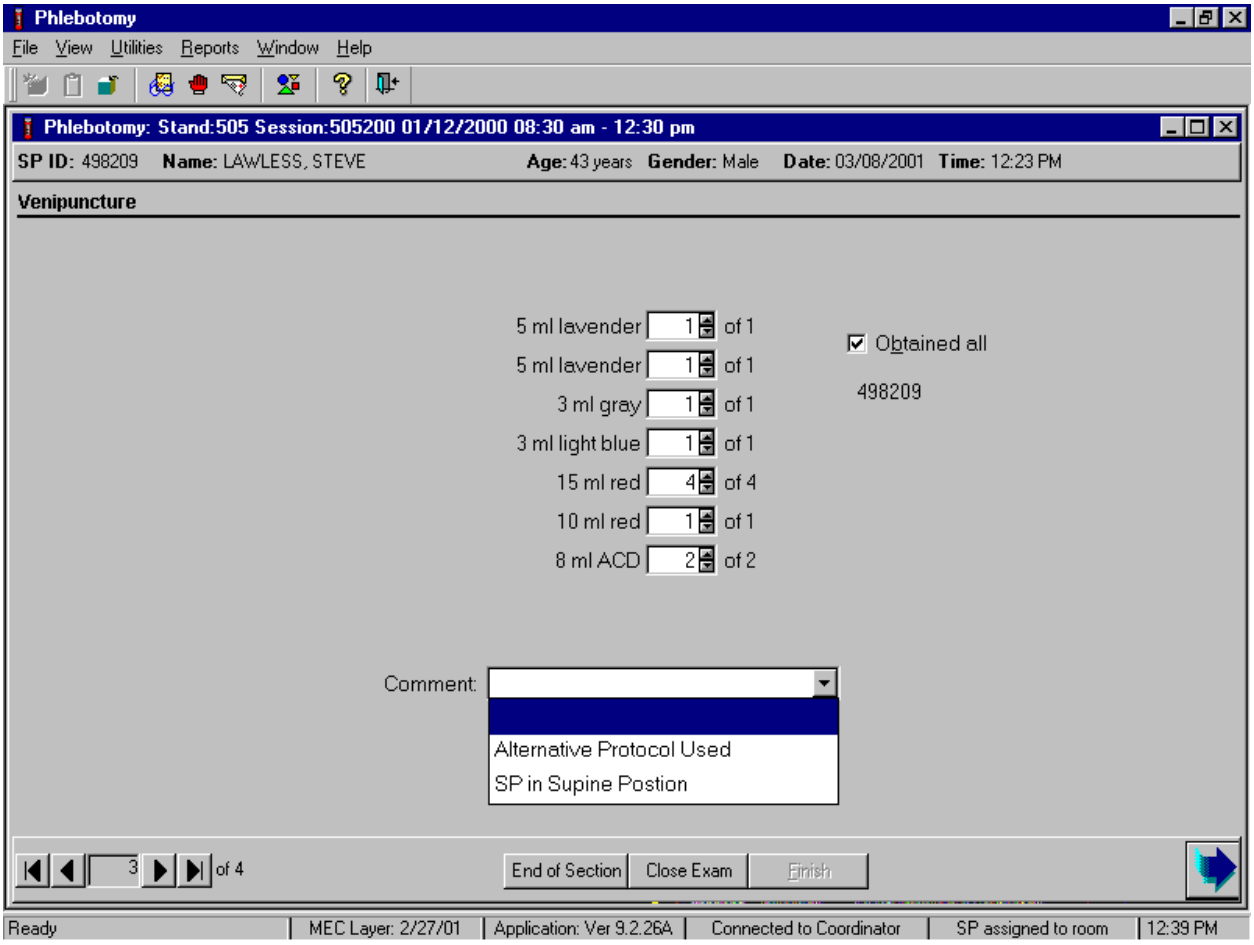
4.13 Recording the Results of the Venipuncture Procedure

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.



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.

4.14 Final Venipuncture Procedures

Corresponding labels automatically print for the tubes drawn. Label the ACD tubes with the label containing the Vessel ID. Label all other tubes with bar coded labels with the bar code vertical on the tube.

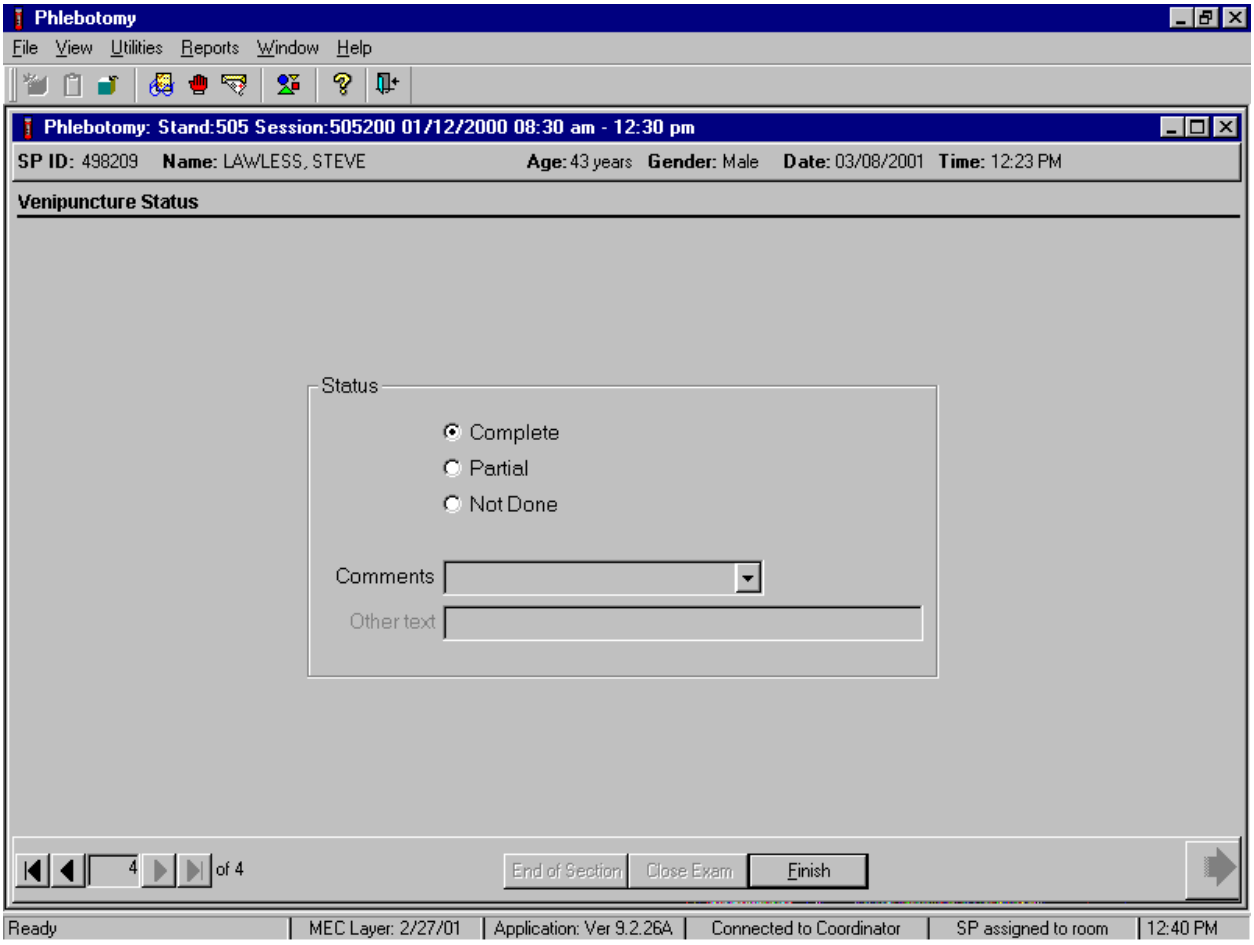
Place the rack containing the blood collection tubes in the pass through window located over the sink. Alternatively, deliver the rack to the laboratory, and distribute as described below:

- Place the lavender, gray, and blue tubes on the rocker located next to the centrifuge.
- Place the red top and ACD tubes upright in the test tube rack located next to the centrifuges in the laboratory.

Place all used needles in a sharps container and all soiled supplies in a biohazard bag. If blood has spilled on the table or the arm board, wash the area with a Hype-Wipe (10% solution of bleach and water) then prepare the workstation for the next SP. Routinely disinfect the table or arm board with 1% bleach solution. Wash hands and change gloves before approaching the next SP.

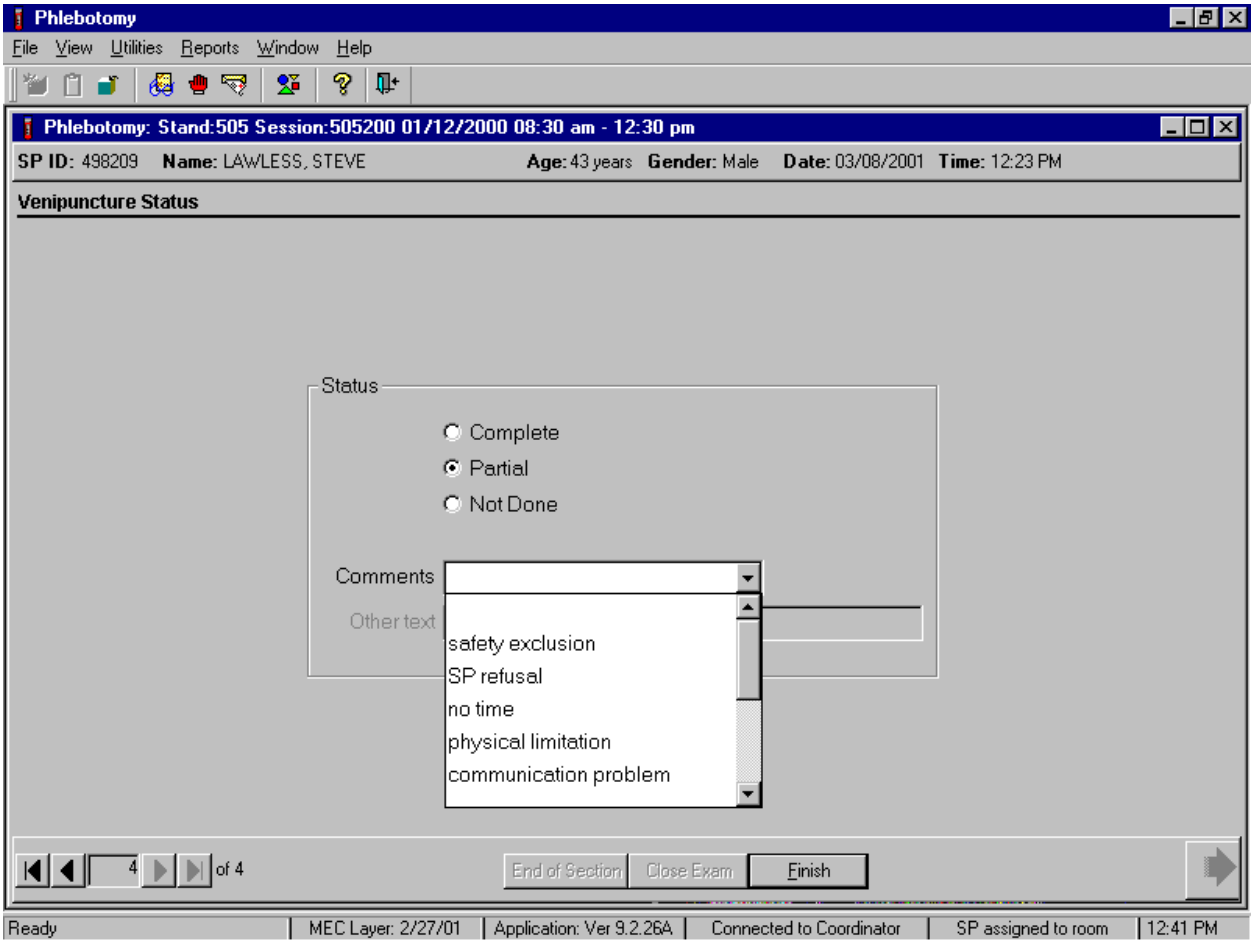
4.15 Venipuncture Status

Verify the venipuncture status.



The venipuncture status is complete if all tubes were collected.

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

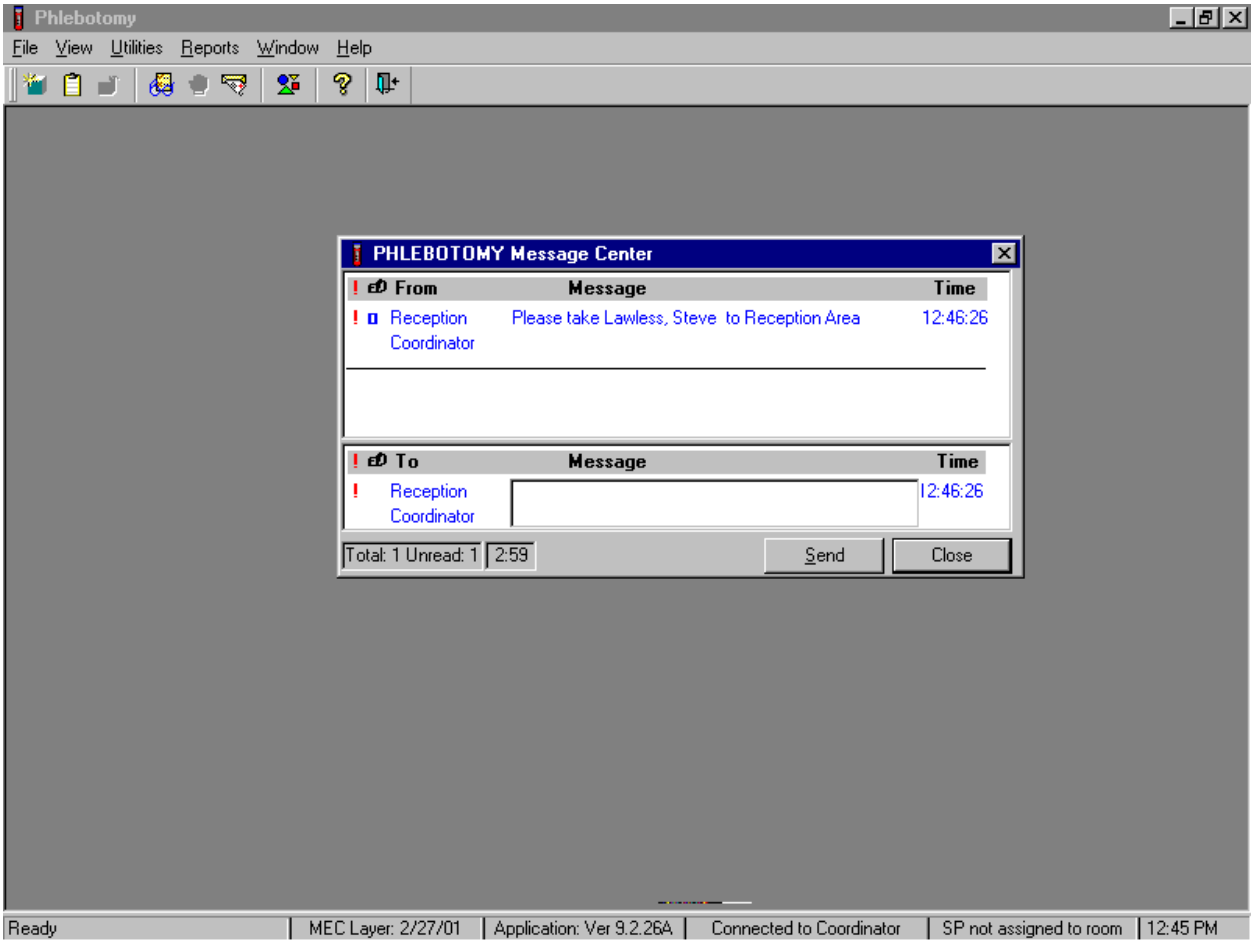


Choose and enter the appropriate comment code when the venipuncture section status is Partial or Not Done. To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice and left click. 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 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	Use this comment to codes exams as not done (no tubes drawn) when the SP does not have an accessible vein, any arms available, casts on both arms, or they have a rash over the entire area, or the blood draw was started but there was no blood in the tubing. Use this comment to code exams as partial when one or more tubes were successfully drawn but blood flow stops before all tubes are drawn or when the veins collapse.
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.
SP did not meet fast	Not applicable. This is reserved for instances when the SP did not meet the required fasting time but may meet the requirements 30 minutes before the end of the session and it is automatically coded by the application.
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.

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 to progress to the next section (VOC) or select [Enter] when this blue arrow is highlighted.

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

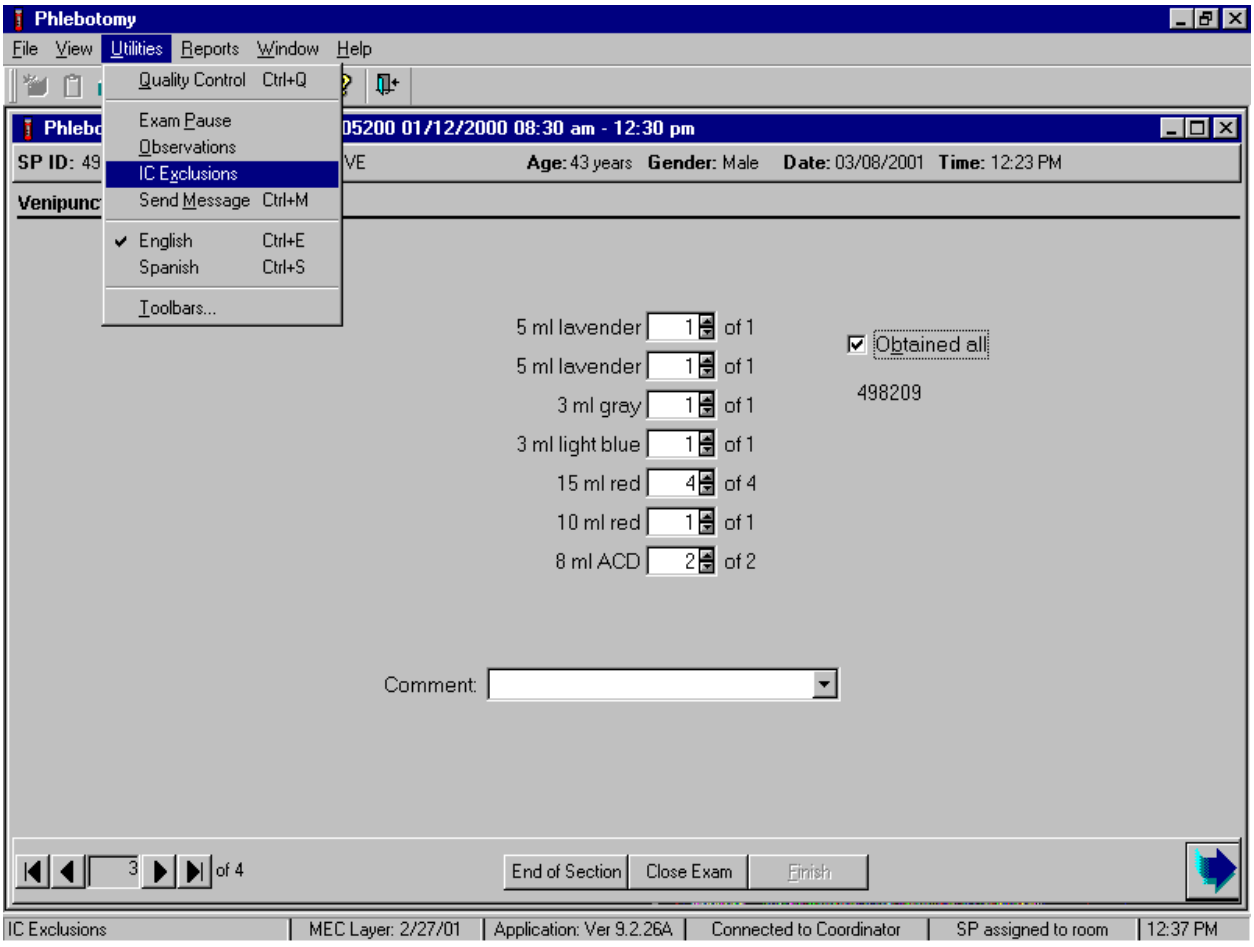


Review the instructions in the Message Center text box and follow the directions.

4.16 Informed Consent Exclusions

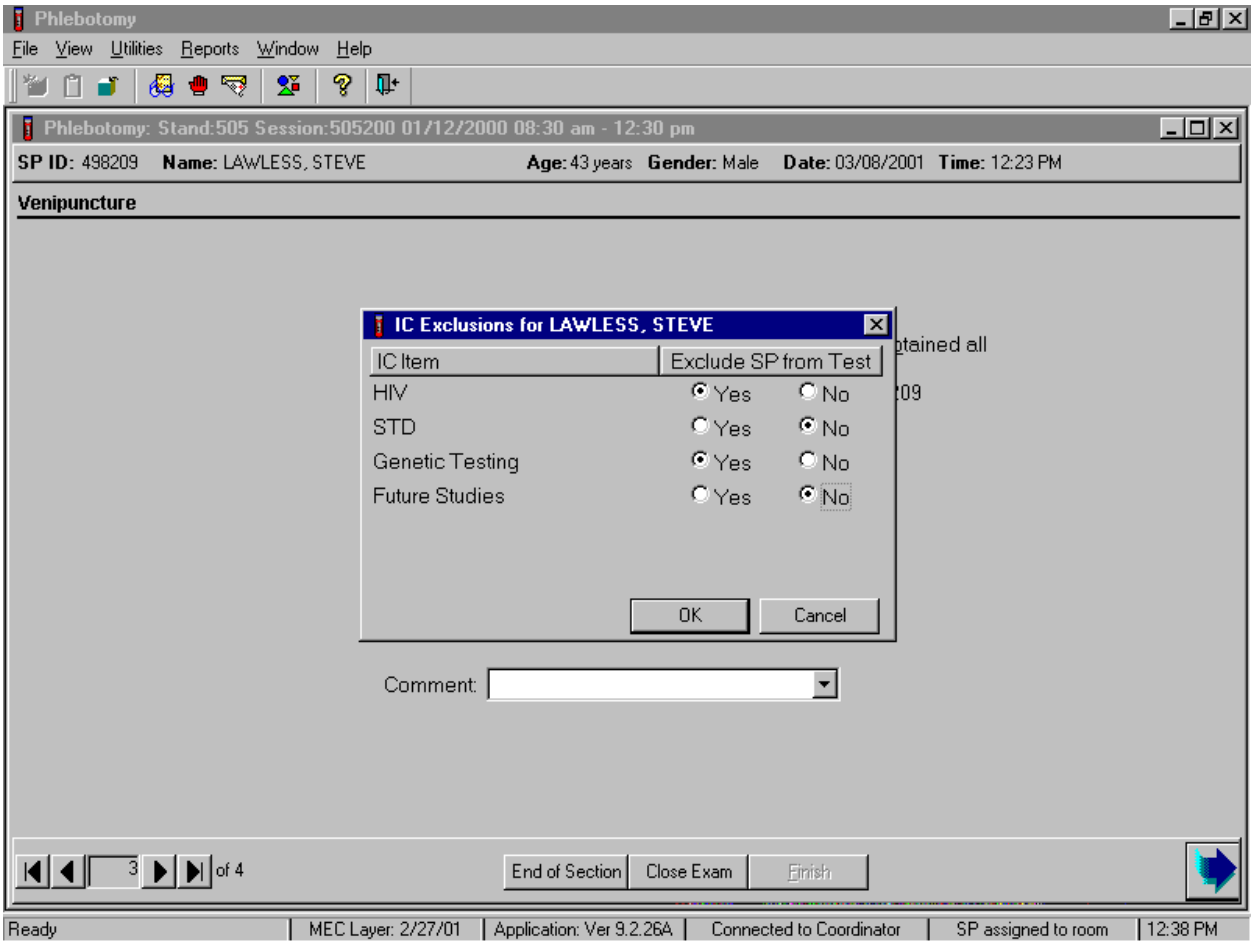
If at any time during the venipuncture procedure the SP indicates he/she does not want his/her blood tested for HIV (AIDS), STD (sexually transmitted diseases include chlamydia, gonorrhea, herpes, and syphilis), genetics testing, or future studies, enter this information using the Exclusions module.

Access the IC Exclusions module.



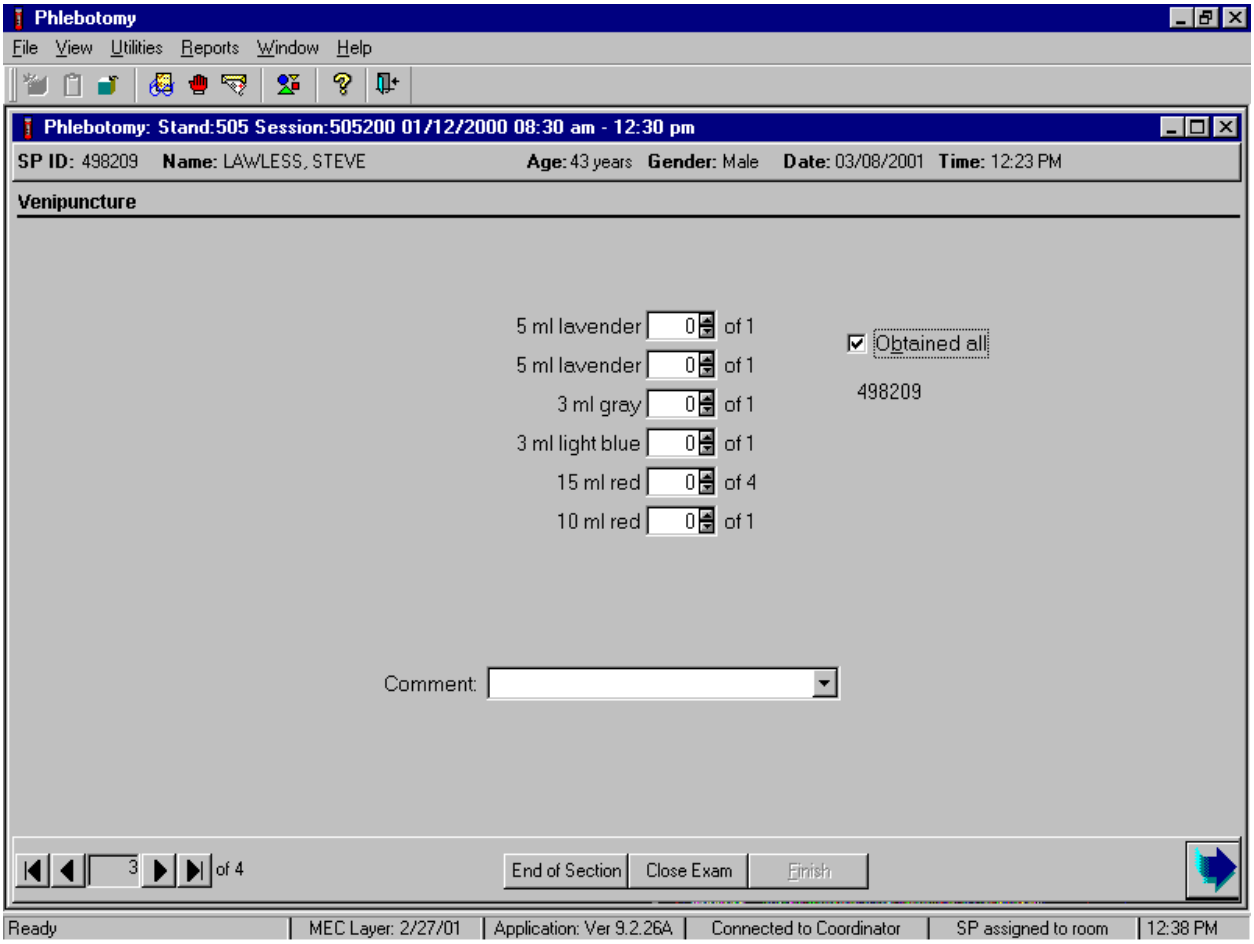
To access the IC (informed consent) Exclusions module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {IC Exclusions}, and left click, or type [Alt] [U/i], [X/x].

The IC Exclusions window displays.



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.

The venipuncture protocol updates if the tubes have not been drawn.

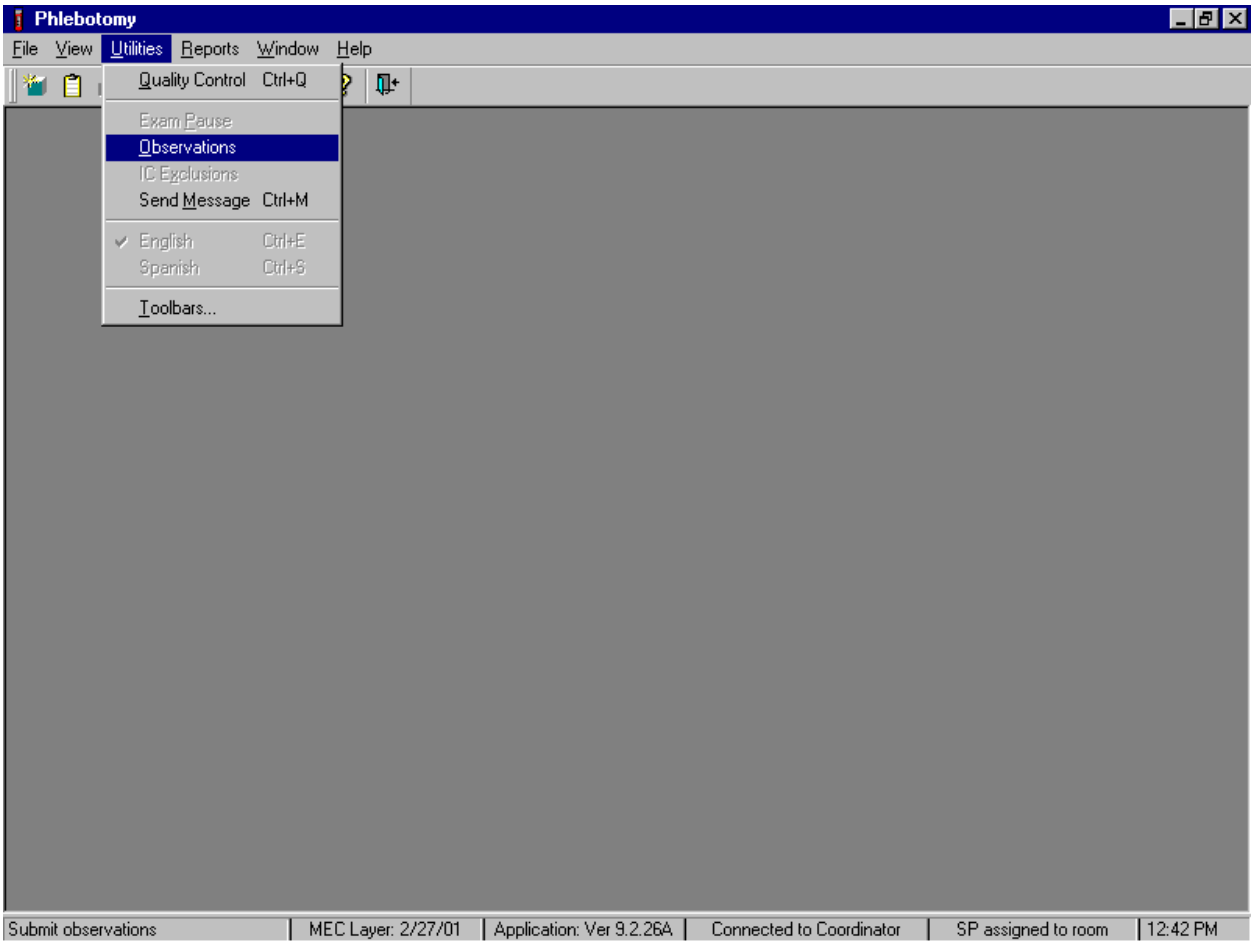


The venipuncture protocol updates if the SP opts out of the genetic testing before the blood tubes are drawn; the tubes are removed from the display. Draw the tubes displayed on the screen.

4.17 Observations

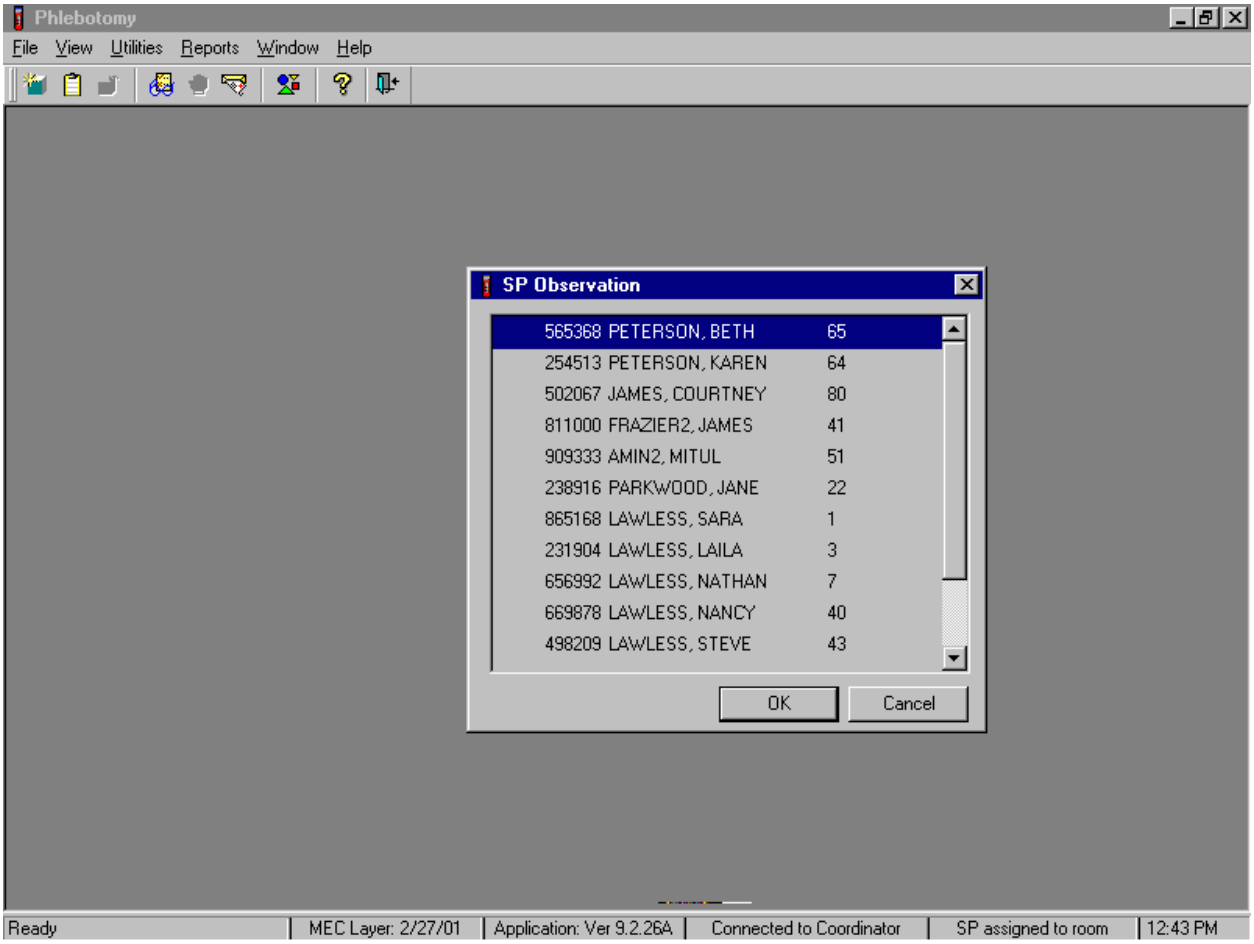
Send confidential observations to the MEC physician. Send an observation on any SP scheduled into the MEC session or the SP currently assigned to the component.

Send an observation on any SP scheduled into the MEC session. Access the observation function.



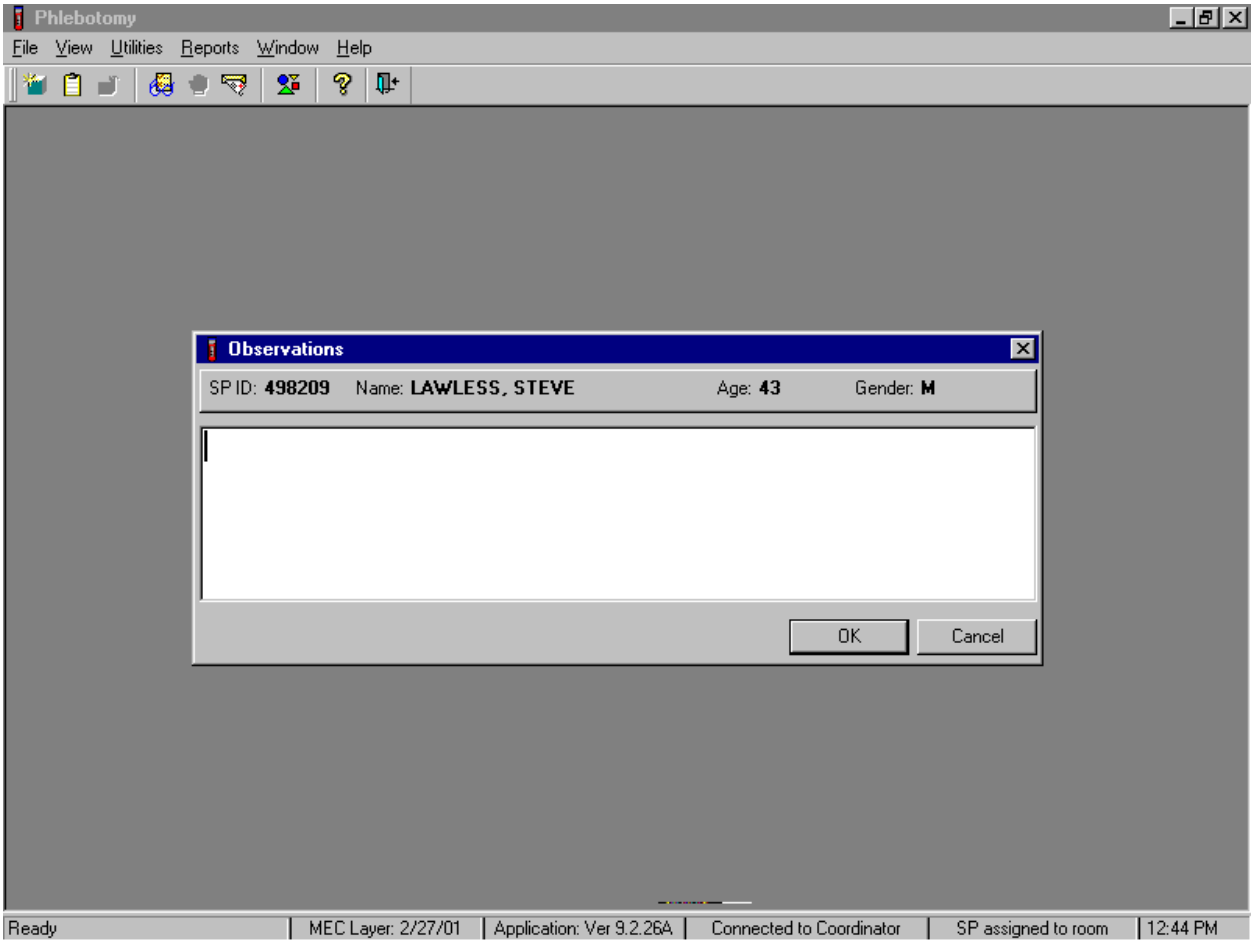
To access the observation function, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the mouse arrow to {Observations}, and left click, or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



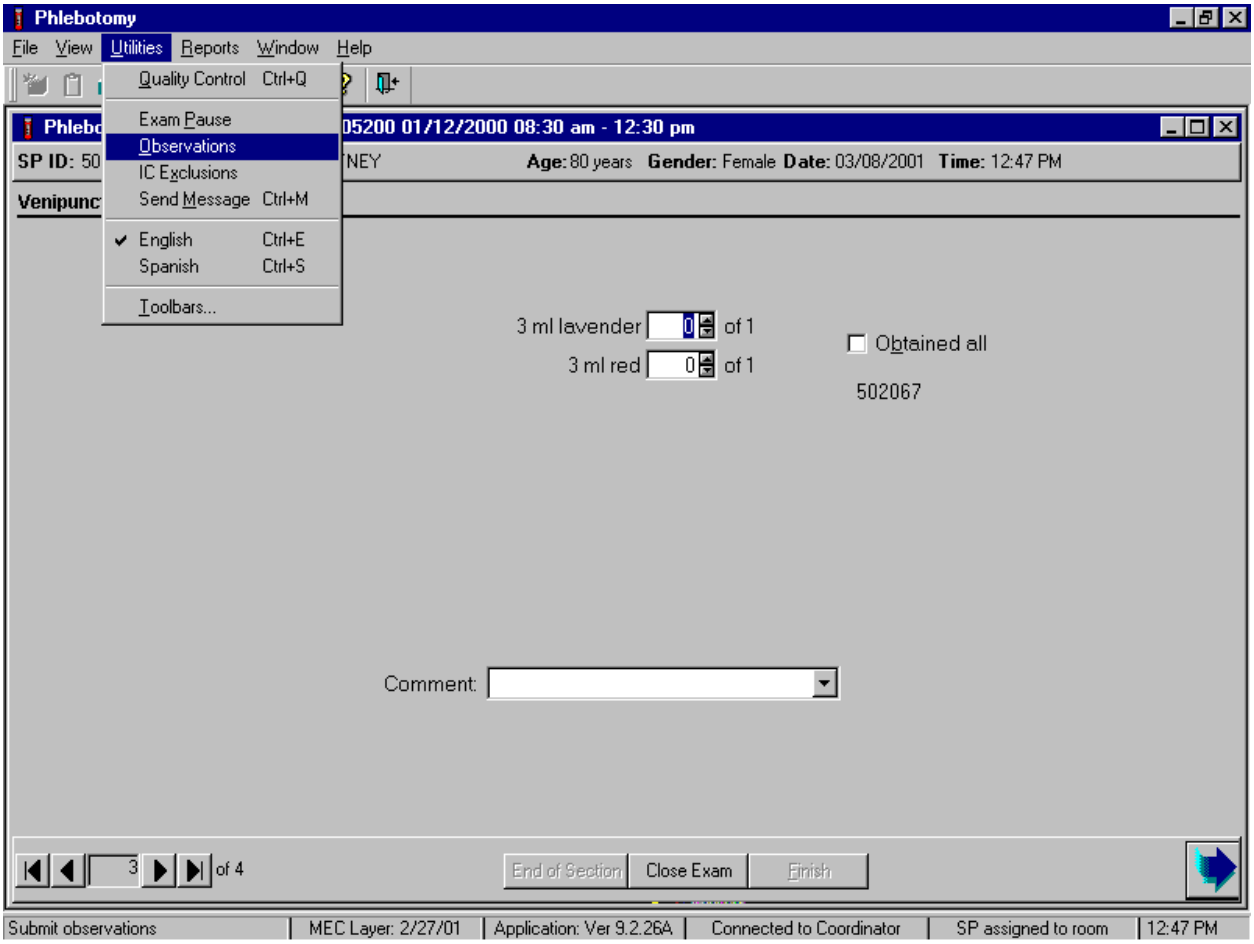
To select or highlight a SP, drag the mouse arrow to the correct SP and left click or use the up and down arrows to move up and down the list. Verify that the SP ID, name, and age are correct. Use the scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to 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.



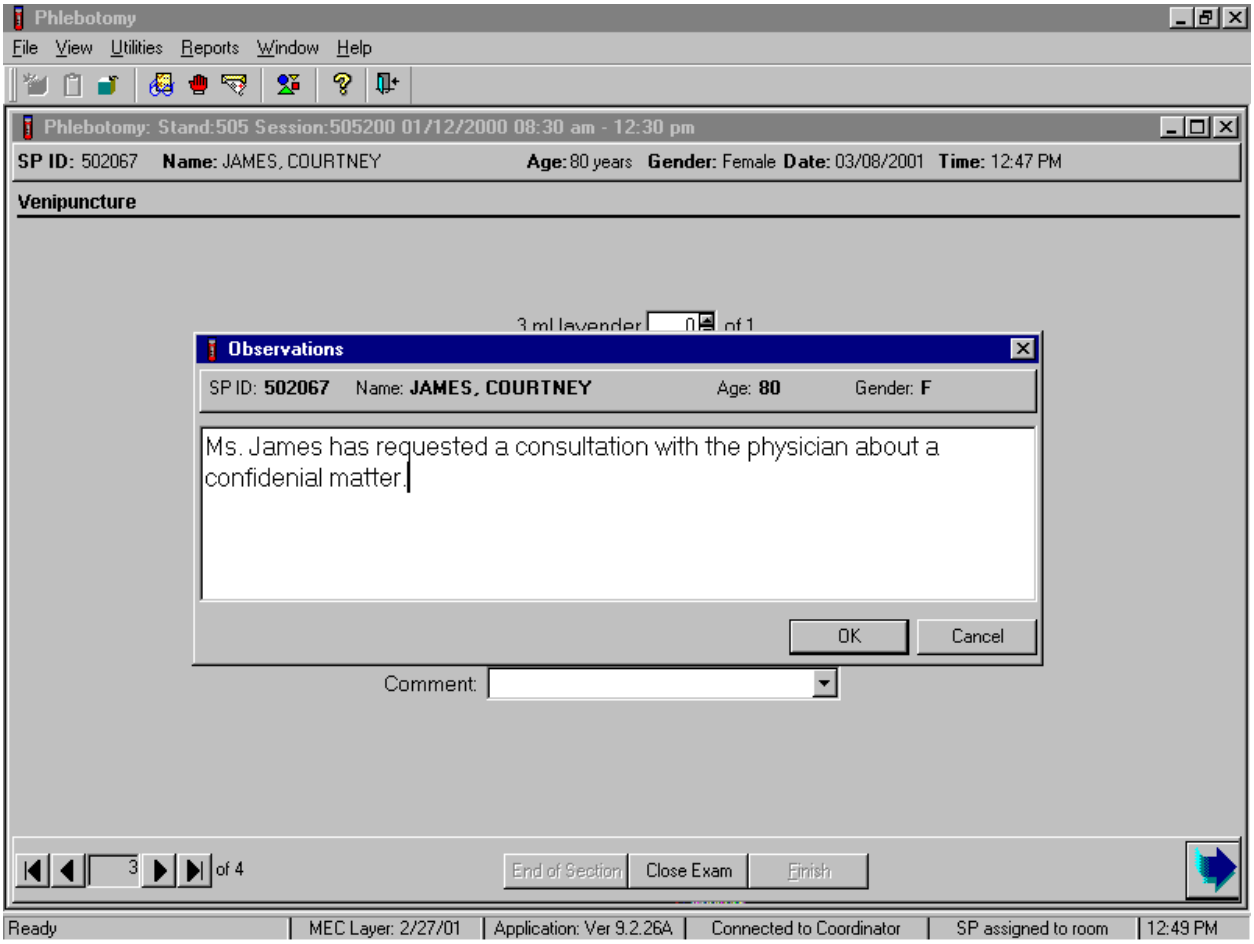
The observation window contains the SP ID, name, age, and gender. Type the observation using the keyboard. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click, or select [Enter]. To cancel these actions or to exit the observation window without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

Enter an observation on the SP currently assigned to the component.



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].

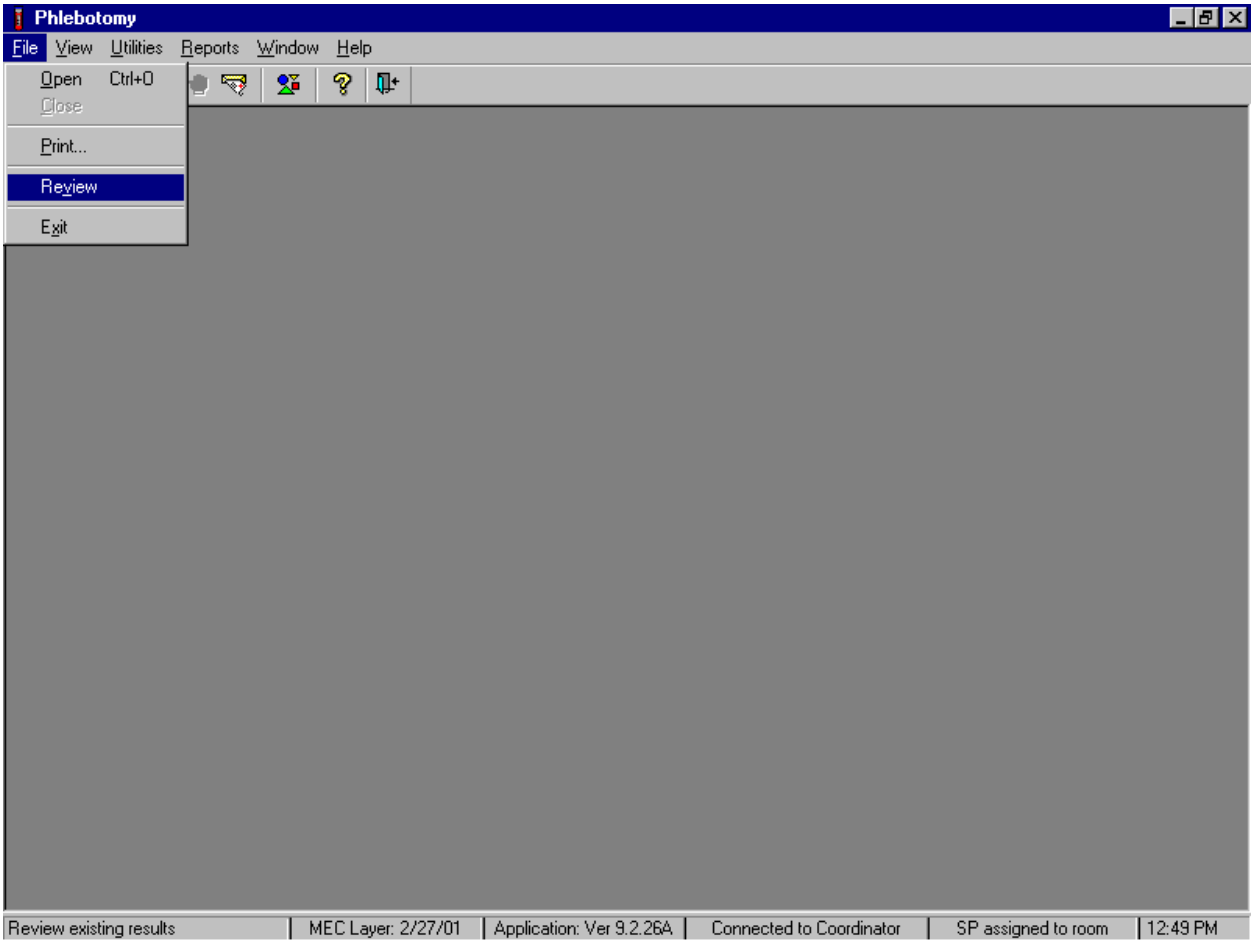
The observation window displays.



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.

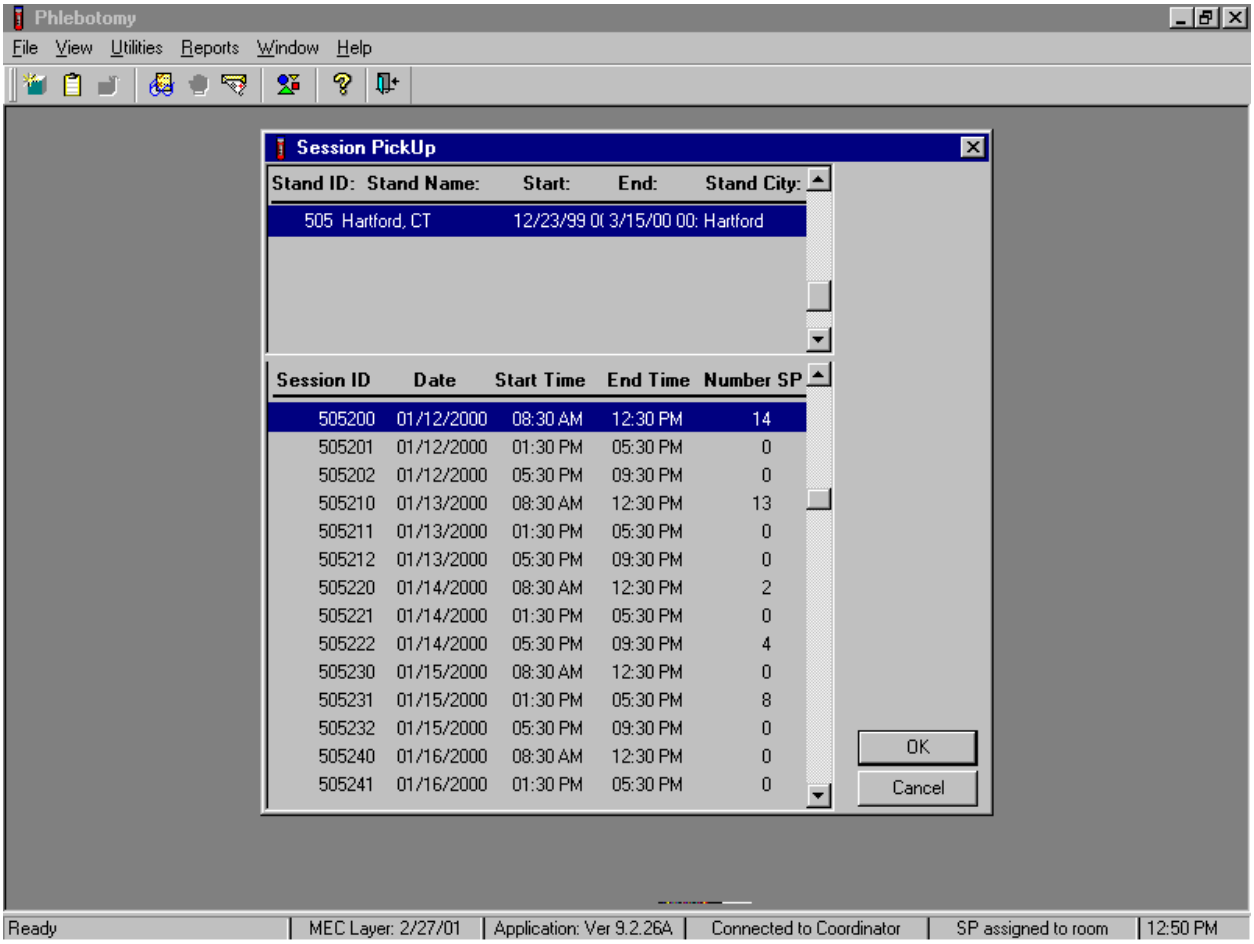
4.18 Review an Exam

Review a completed exam. Access the Review module.



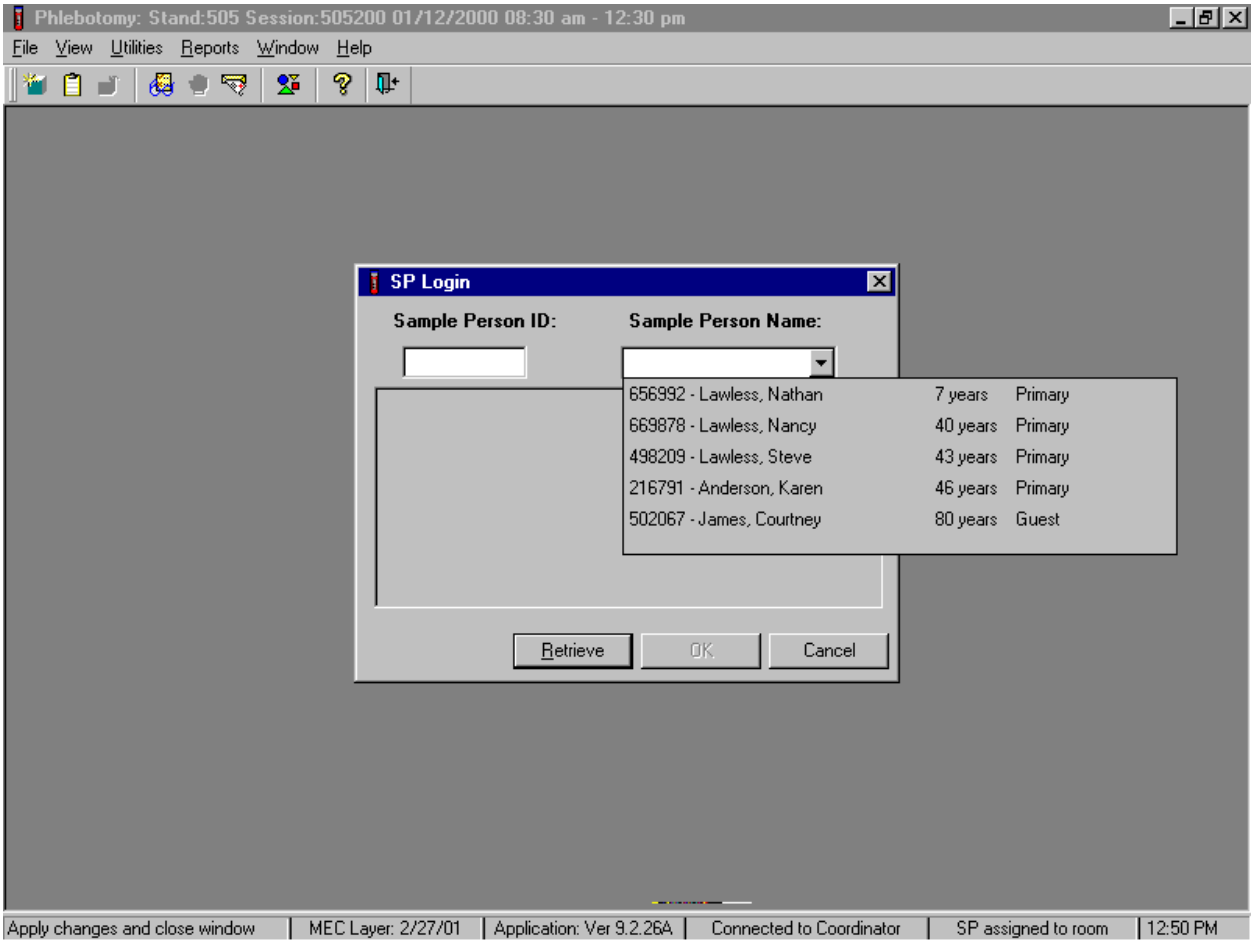
To access the Review module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Review} and left click, or type [Alt] [F/f], [V/v]. The Session PickUp list displays.

Select the session.



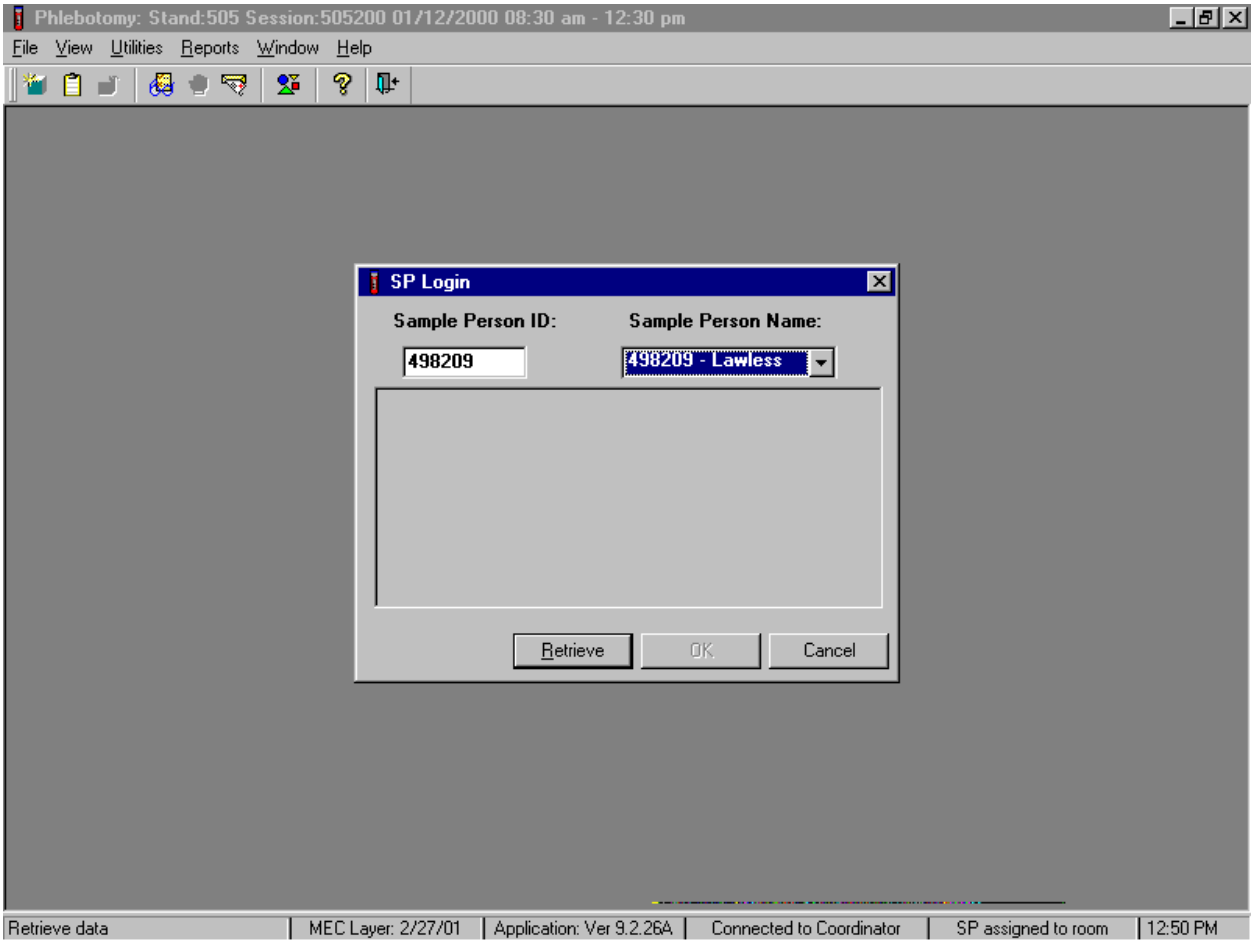
The Session PickUp list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection or use the up and down arrows to move up and down the list and press [Enter]. To proceed, use the mouse to direct the mouse arrow to the OK button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the Cancel button and left click.

Select the SP.



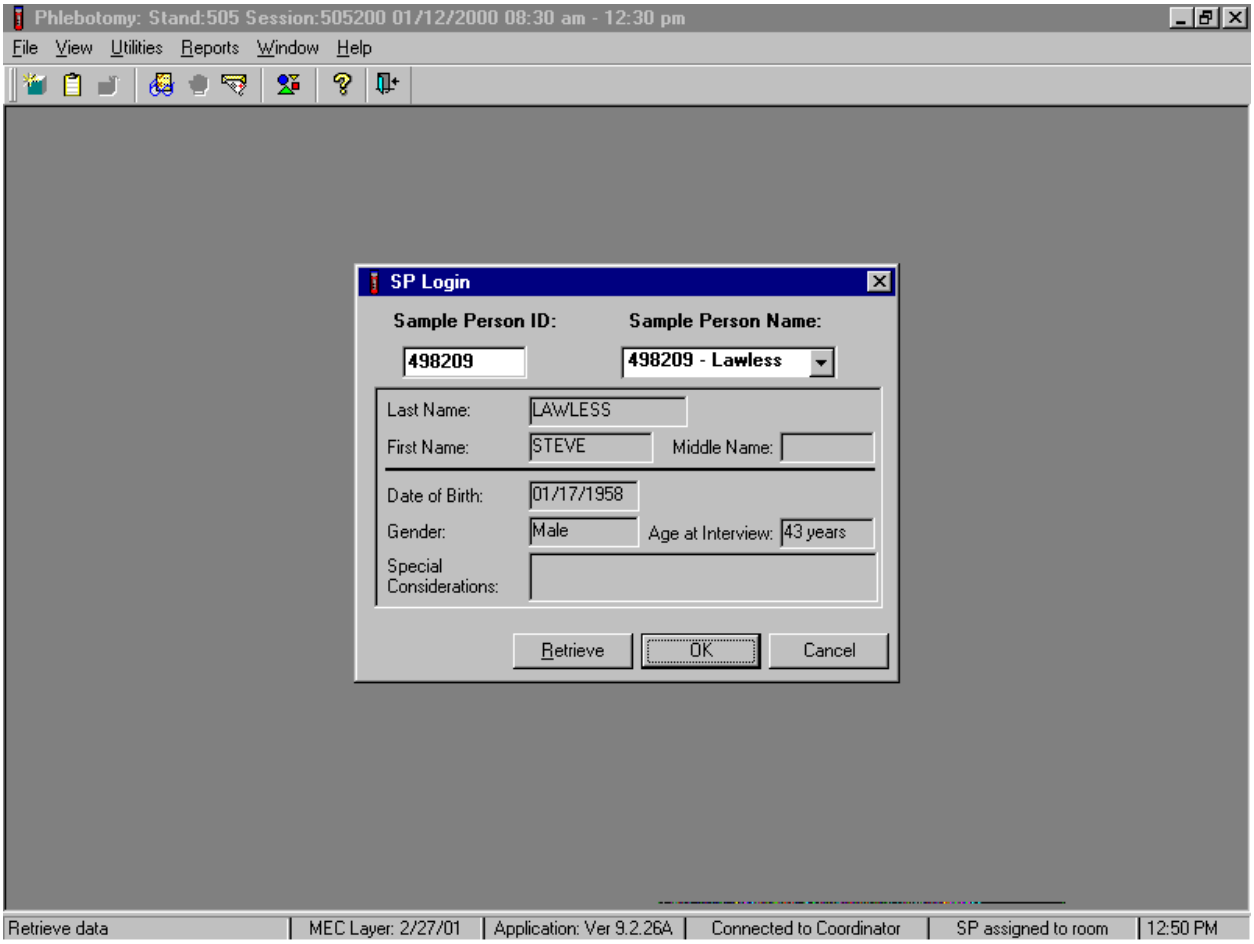
The SP Login window displays. To view a list of previously examined SPs, use the mouse to direct the mouse arrow to the drop-down arrow on the Sample Person Name text box and left click. To select or identify a specific SP, drag the mouse arrow to the correct SP and left click.

Continue to select the SP.



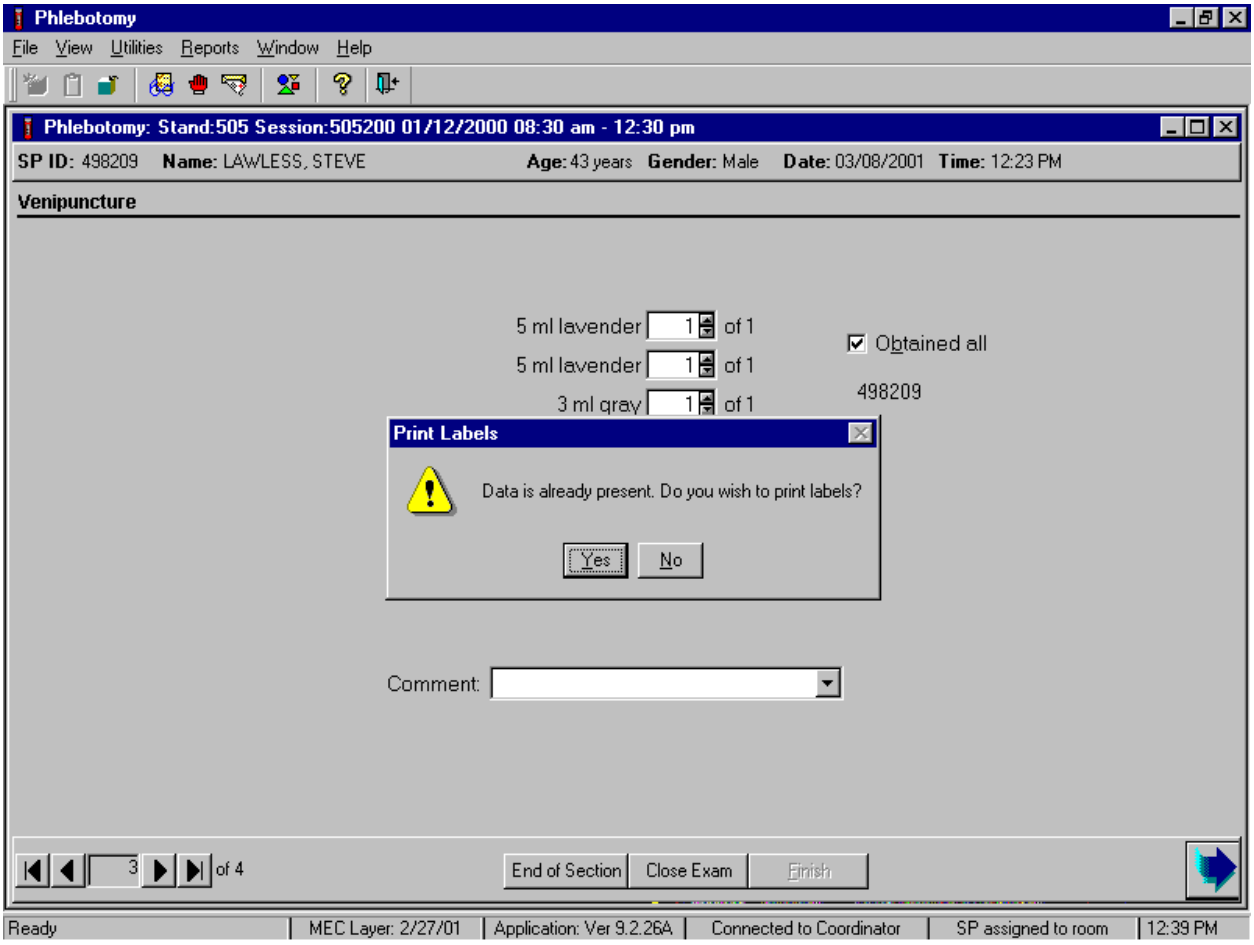
The Sample Person ID and Sample Person Name text boxes fill in with the SP ID and the SP ID and last name. To continue, use the mouse to direct the mouse arrow to the Retrieve button and left click, or select [Enter]. To exit, use the mouse to direct the mouse arrow to the Cancel button and left click.

Continue to select the SP.



Once the Retrieve button is selected, the remaining data in the SP Login box fills in. To move forward and to review the exam, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. The phlebotomy exam screens with results are displayed. To progress through the screens, 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.

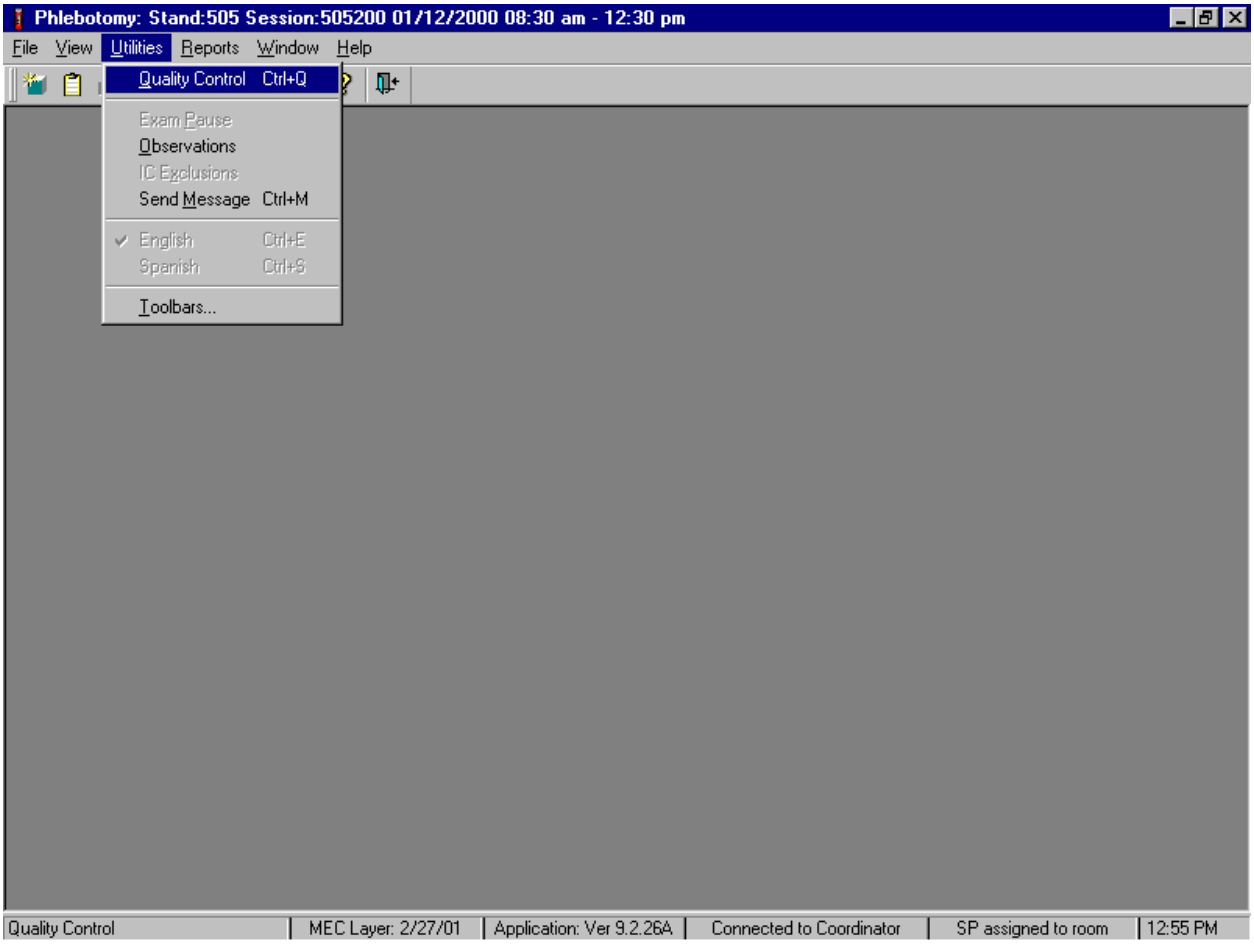
After the venipuncture protocol screen is displayed and the bright blue arrow in the bottom right hand corner is selected, a Print Labels message text box displays.



The Print Labels informational message text box displays the following message; “Data is already present. Do you wish to print labels?” To reprint the labels, use the mouse to direct the mouse arrow to the Yes button and left click, or select [Enter]. To decline the opportunity to reprint labels, use the mouse to direct the mouse arrow to the No button and left click. The venipuncture status window displays. To finish, select [Enter] or use the mouse to direct the mouse arrow to the End of Section button and left click.

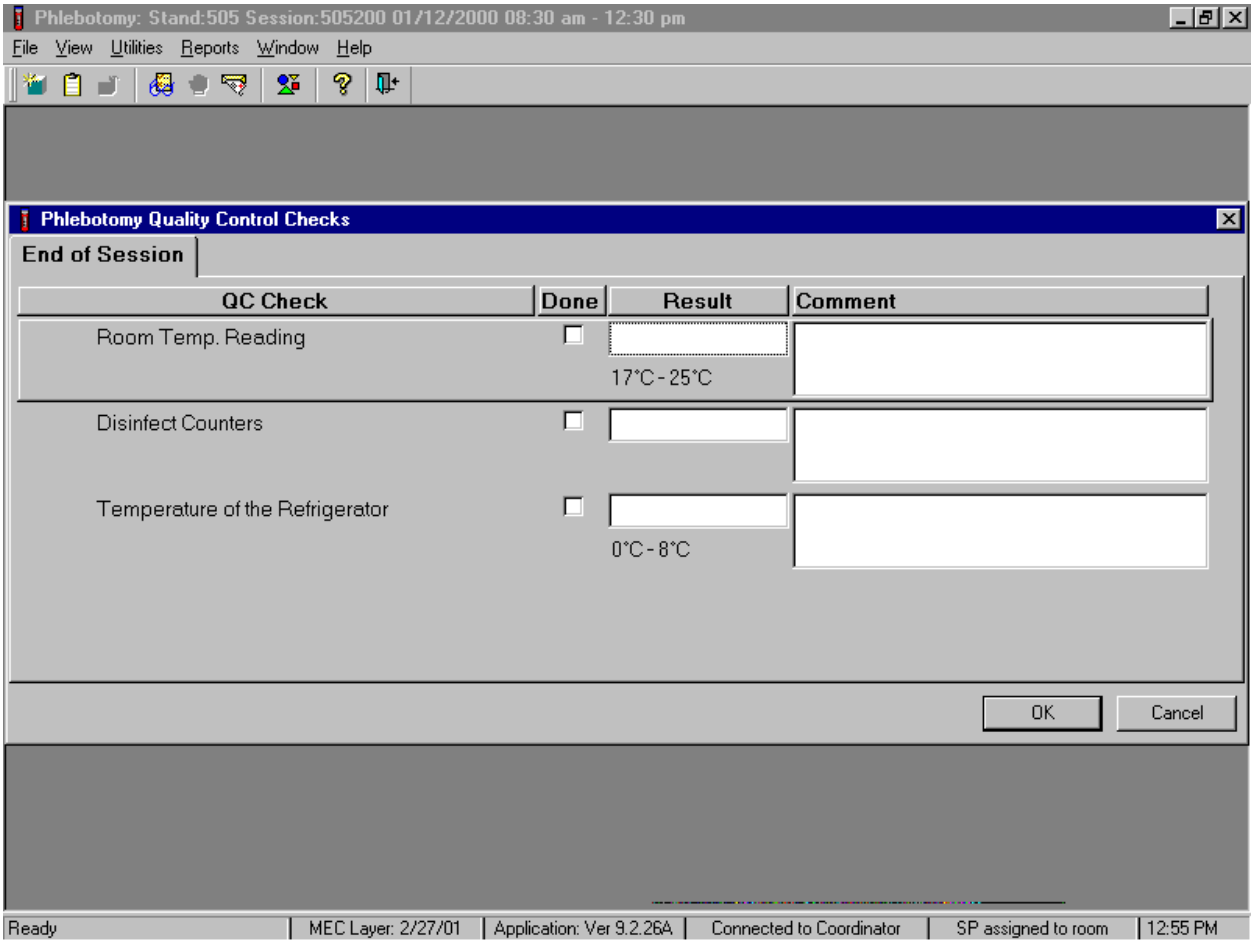
4.19 Phlebotomy Quality Control

Perform phlebotomy quality control at the end of each session.



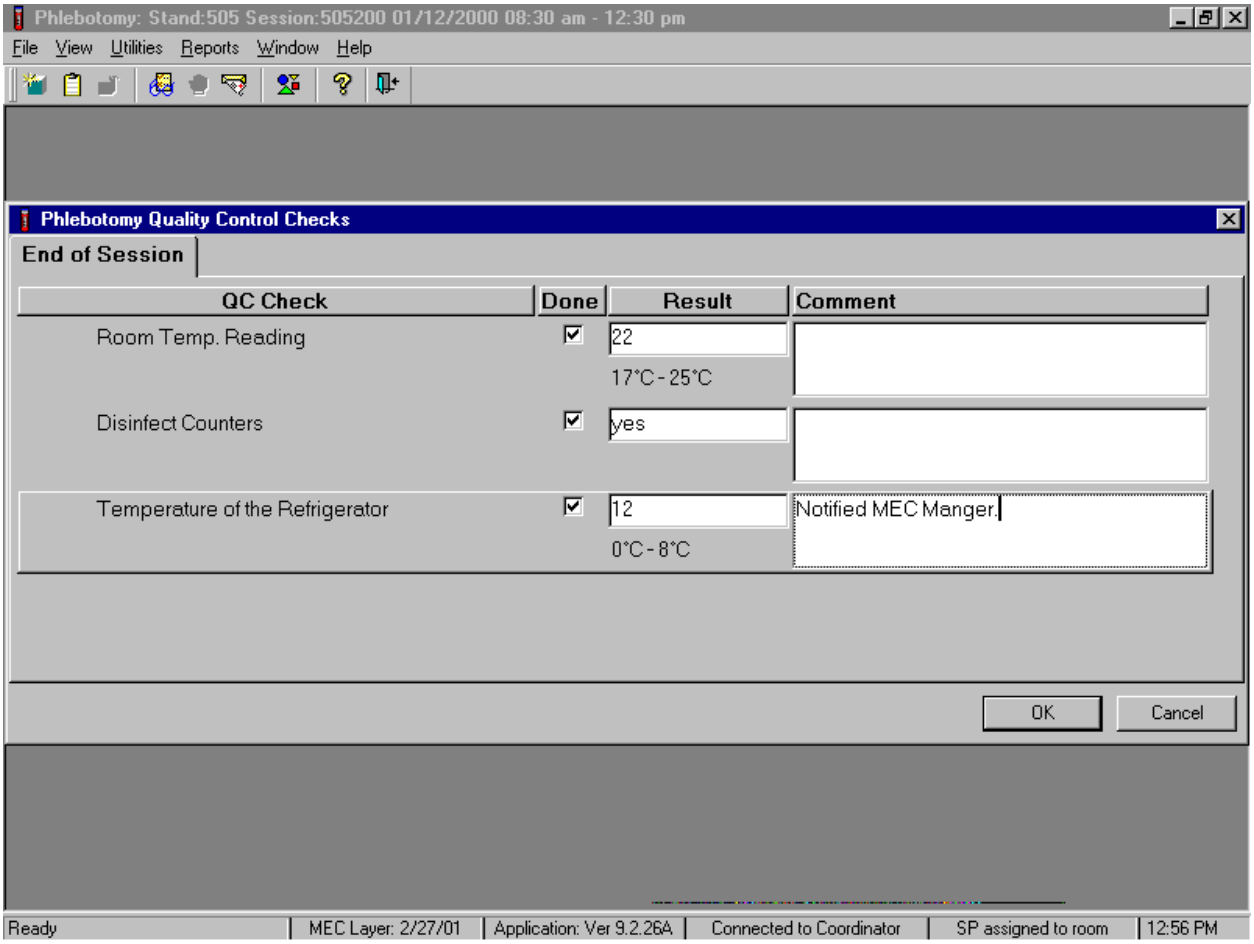
To access the phlebotomy QC module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Quality Control} and left click, or select [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

Record the quality control activities. Mark each done check box with a check mark.



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.

Continue entering the QC.



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 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. To record a check mark in Temperature of the Refrigerator 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 box. Enter the Result text box and select [Tab] to move to the Comment text box. If the reading is outside the established range (4-8°C), document the actions taken to resolve the situation in the Comment text box. To save these actions 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.

4.20 Conducting the Venipuncture as Part of a Home Exam

4.20.1 Introduction

Collect a small amount of blood as part of the home exam (HE). Schedule the venipuncture so that the blood is transported and processed within 4 hours of the draw, whenever possible.

The home examiner administers a questionnaire to screen home exam SPs for conditions that excludes them from the blood draw. The home examiner also administers a fasting questionnaire to determine fasting compliance. After administration of the screening questions and the fasting questionnaire, the blood draw venipuncture protocol displays. Exhibit 4-7, Home exam venipuncture protocol, illustrates the HE venipuncture protocol. This protocol illustrates the types and numbers of tubes in priority order. It is extremely important to perform the venipuncture protocol as described for each home exam SP.

Exhibit 4-7. Home exam venipuncture protocol

Age in Years	50+
Tube Type - Priority	
5-mL Lavender	2
3-mL Blue	1
7-mL Red	3

If the veins of a home exam SP appear too fragile to accommodate the size of the 7-mL red top tubes, substitute the alternative protocol. Exhibit 4-8, Home exam alternative venipuncture protocol, illustrates the alternative size and number of tubes in parenthesis with the original tube protocol in **bold**. When the alternative protocol is substituted for the original protocol, a comment is required. Since this protocol constitutes a deviation from the standard protocol, its use should be limited to circumstances.

Exhibit 4-8. Home exam alternative venipuncture protocol

Age in Years	50+
3-mL Red	*(7)*
7-mL Red	**3**
10-mL Red	*(2)*

Bold represents the standard protocol

4.20.2 Equipment and Supplies

The venipuncture equipment and supplies are listed in Exhibit 4-9.

Exhibit 4-9. Equipment and supplies – home exam venipuncture

BD Hemogard Vacutainer® 5-mL EDTA	Stretch disposable tourniquet
BD Hemogard Vacutainer® 7-mL Red	Latex tourniquet
BD Hemogard Vacutainer® 3-mL Red	Alcohol wipe
BD-Vacutainer® 3-mL Blue	2 x 2 Gauze square
BD-Vacutainer® 10-mL Red	Band-Aid
Butterfly blood collection set 21 gauge with adapter	Ammonia inhalant packet
Butterfly blood collection set 23 gauge with adapter	Plastic drape
BD Vacutainer® needle holder – single use	Small biohazard bag
Sharps container	Emesis bag
Reusable ice packets	Hand cream
Thermos® 1.5 Pint Stainless Steel Wide Mouth Food Tote	Non-sterile, powder-free, latex gloves -- small, medium, large
Transport case	Antibacterial hand soap
Thermometer	Bleach towelette
Hard-sided blood transport container	Reusable refrigerant pack

For each SP's venipuncture, the home examiner requires the following materials:

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

4.20.3 Overview

The home examiner is responsible for completing the venipuncture procedure.

Print the blood tube labels in advance. Collect the appropriate blood collection supplies in advance making sure there are sufficient supplies for each home exam visit. Administer the venipuncture interview and fasting questionnaire. The screen displays the appropriate venipuncture protocol. Draw the appropriate tubes, and enter the number of tubes collected next to the expected values. Use comments to describe differences between the actual tubes drawn and the established protocol. Label the blood tubes with the preprinted labels. Verify that the phlebotomy completion status is correct. The phlebotomy section 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. Place one 5-mL EDTA tube in the refrigerated Thermos® container with sufficient reusable ice packets to maintain the temperature at 2-8°C. Transport the blood tubes back to the MEC.

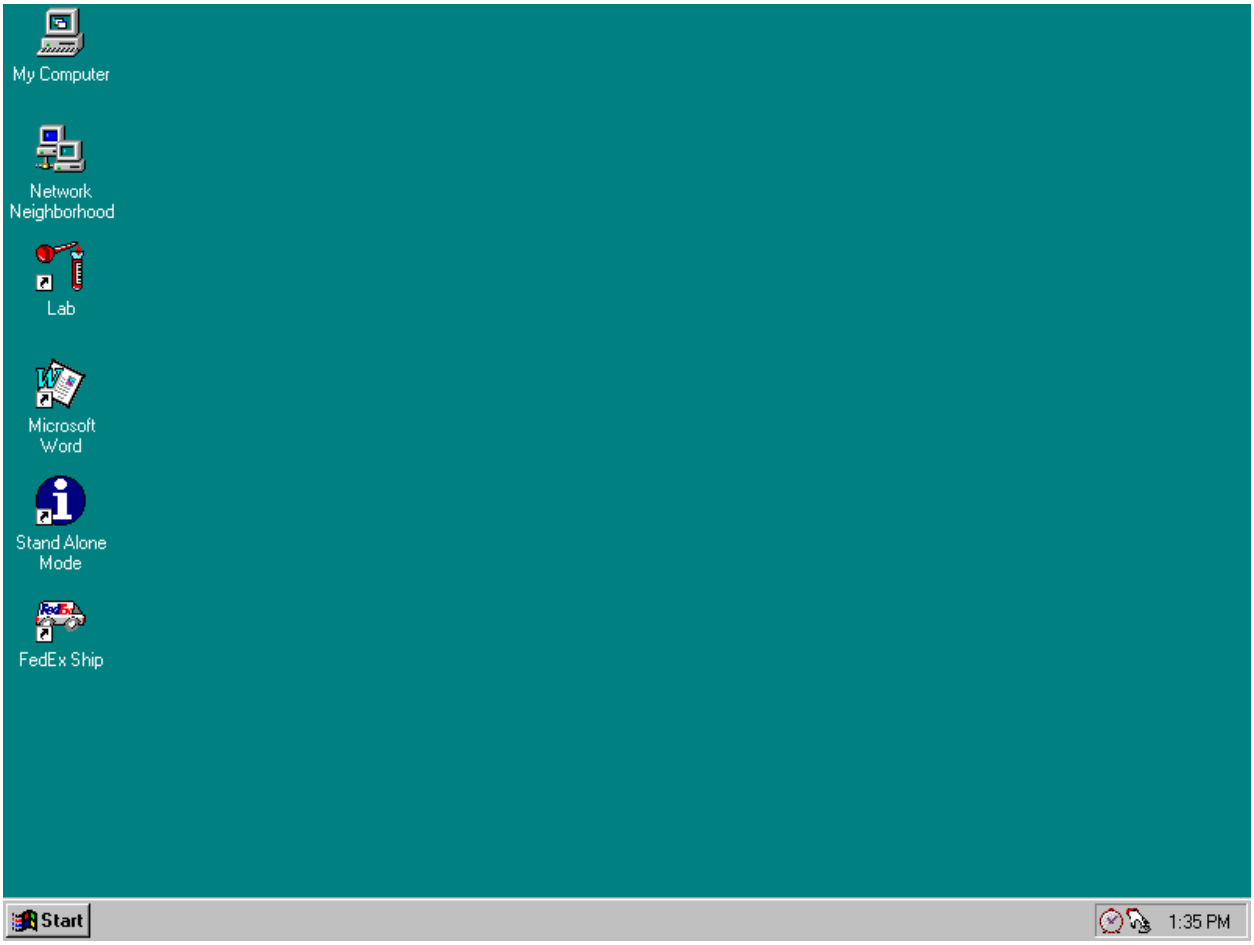
Be prepared to answer all the questions the SP poses about the venipuncture procedure. In addition, the home examiner must convince the SP of the importance of cooperation in the venipuncture component of the examination. Use the information provided in Section 4.5 to assist in gaining the SP's cooperation. The venipuncture procedure withdraws 34-mL, which is 1.1 ounces, or 2.3 tablespoons of blood.

- Perform venipuncture in a well-lit noncarpeted area. Set up venipuncture equipment and supplies on a flat surface, such as a tabletop. Make sure there is enough surface space for adequate support of the SP's arm and for easy access to all supplies.

4.20.4 Preparing for the Home Exam - Printing Venipuncture Tube Labels and Collecting Supplies

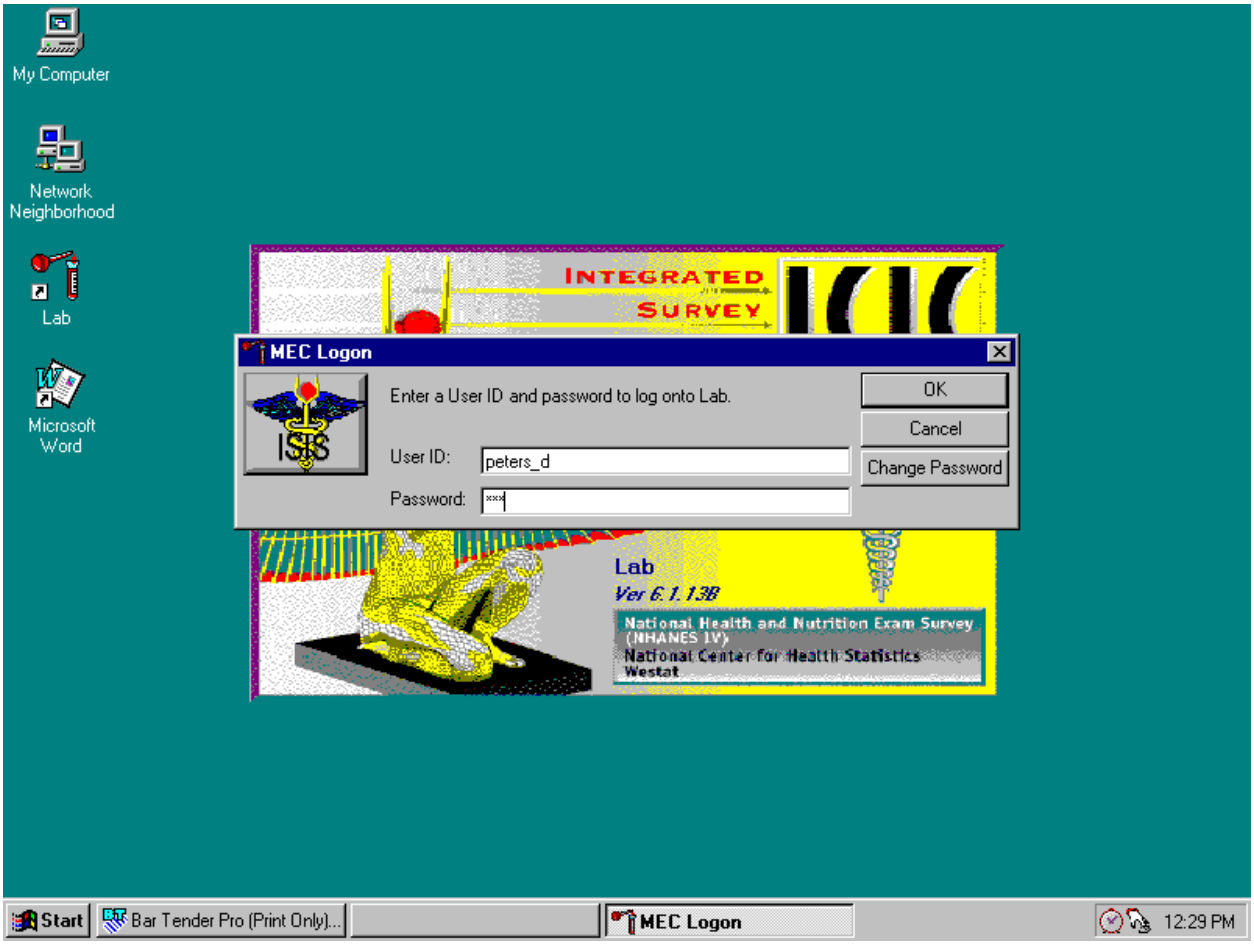
Print venipuncture tube labels in advance of the home examination.

Open the Laboratory application.



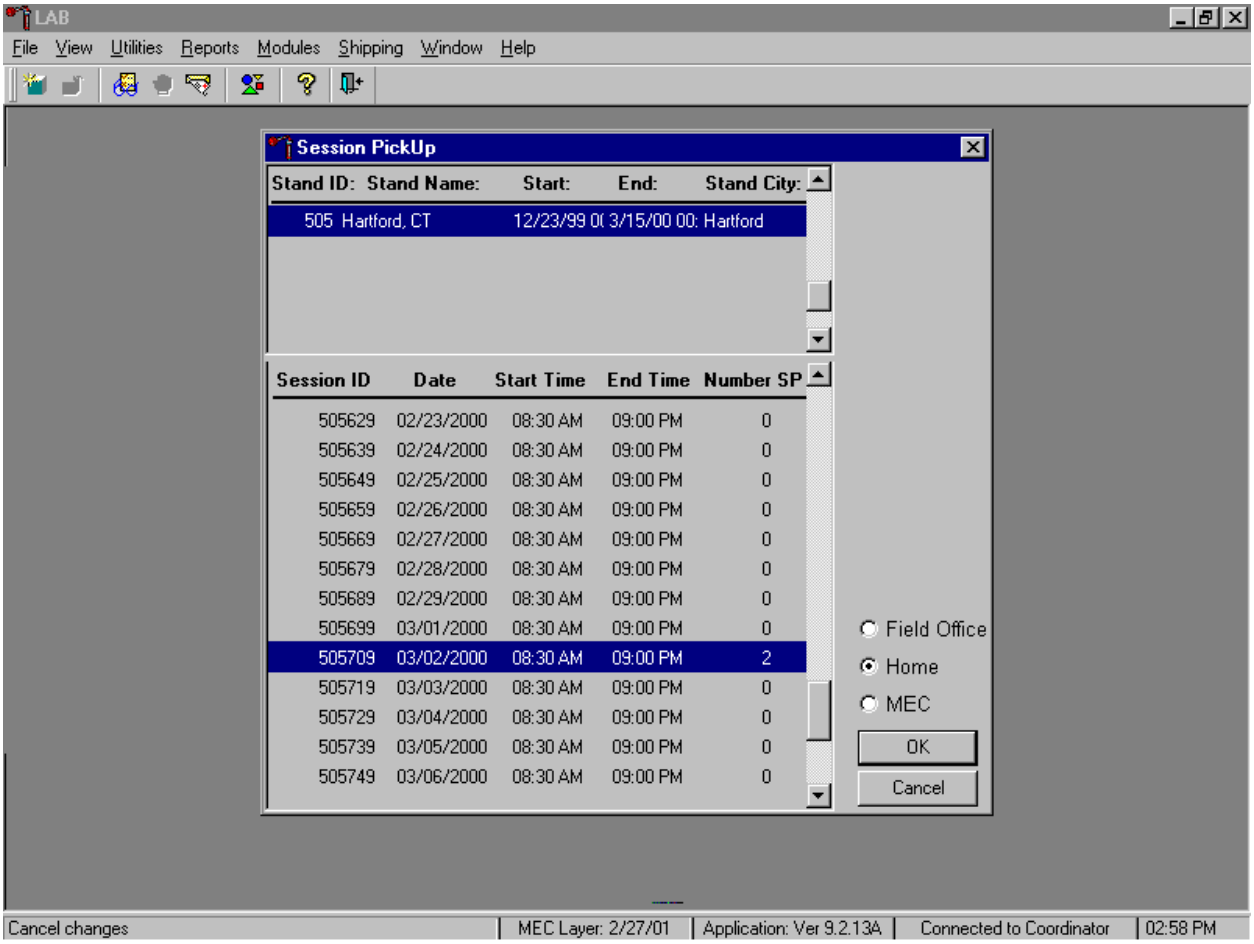
To open the Laboratory application, use the mouse to direct the mouse arrow to the Laboratory (Lab) icon on the desktop and double click.

Sign onto the computer terminal if the staff is not conducting a MEC session.



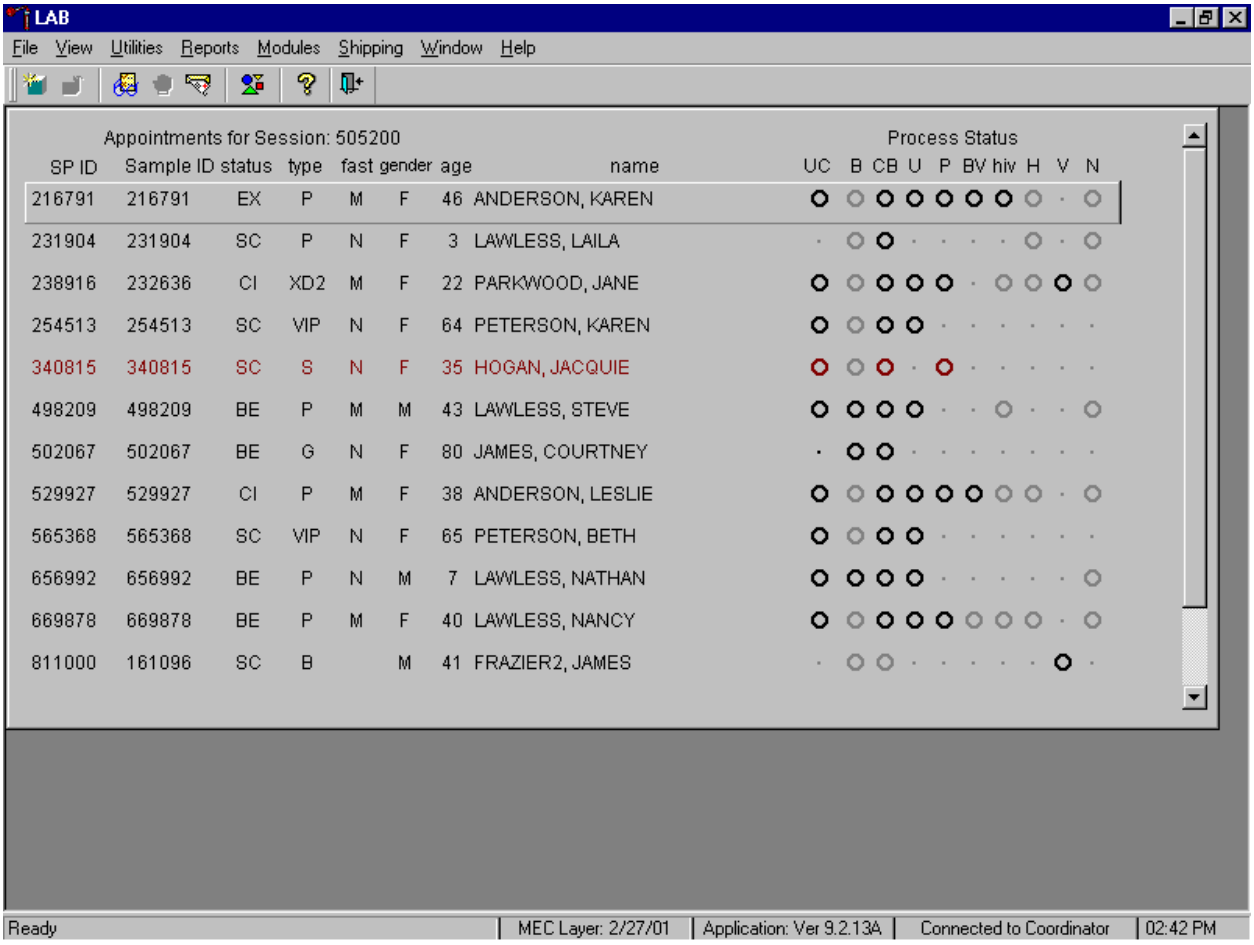
The MEC Logon screen displays. Type last name, underscore, and first initial in the User ID box and [Tab] or [Enter]. Enter password and press [Tab], [Enter], or use the mouse to direct the arrow to the OK button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the Cancel button and left click.

Select the correct filter, and session, if the staff is not conducting a MEC session.

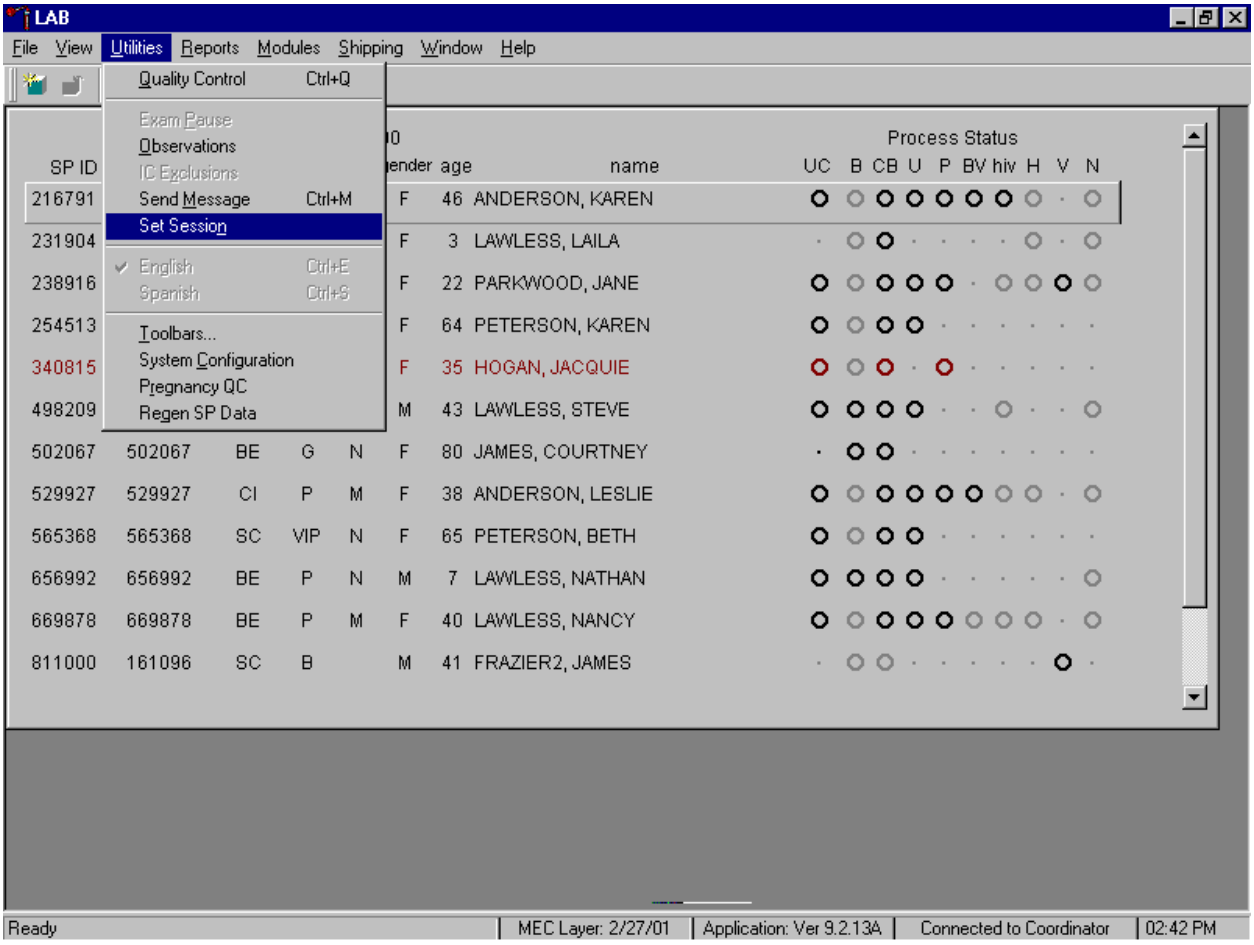


To select the correct filter, use the mouse to direct the mouse arrow to the Home radio button and right click to pick up (or filter on) home exam sessions. To select or highlight the correct home session, use the mouse to direct the mouse arrow to the correct session date and time and right click. To 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.

If the staff is conducting a MEC session, the Laboratory application defaults to the current MEC session.

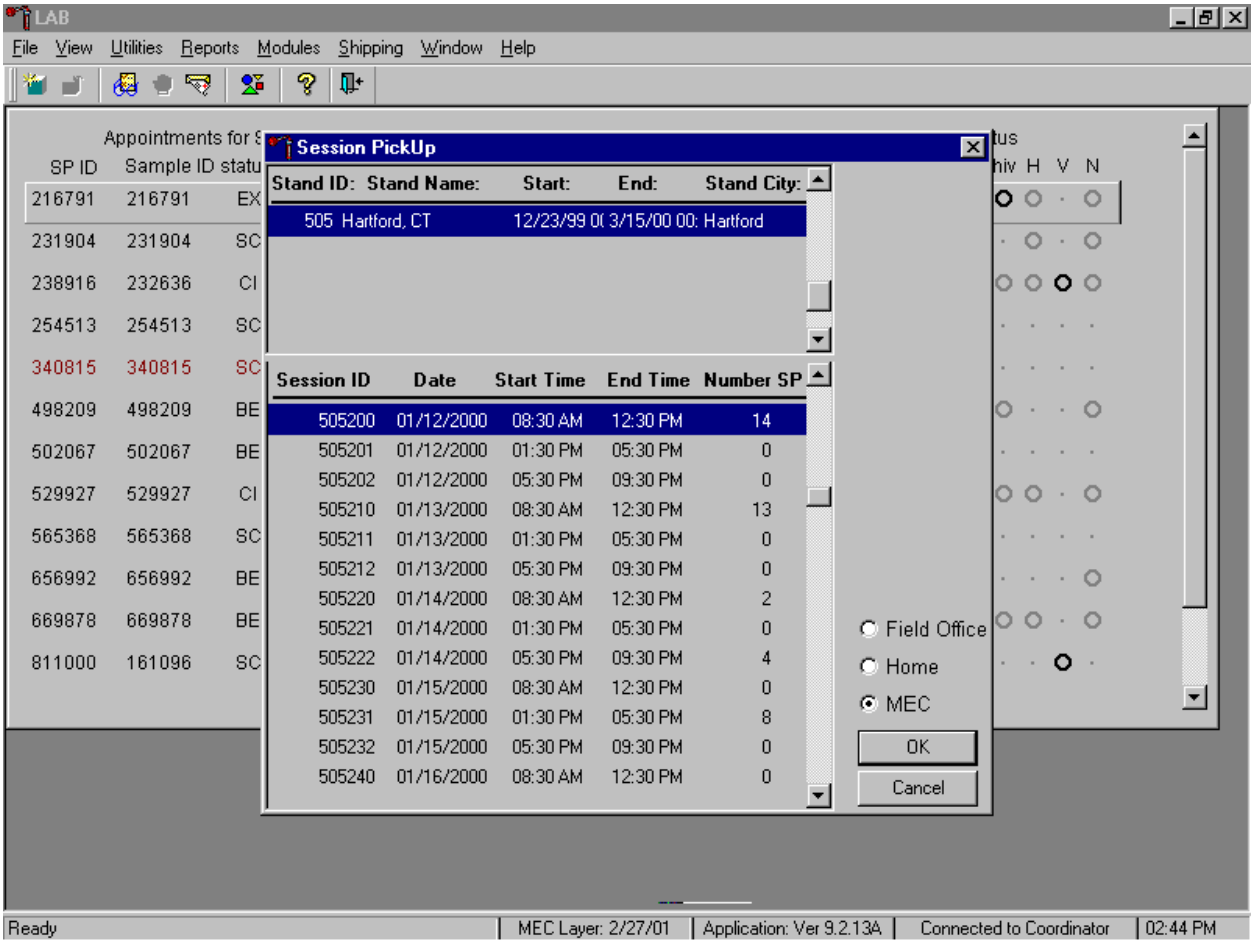


Use the Set Session laboratory module to access a home examination session when the staff is conducting a MEC session.



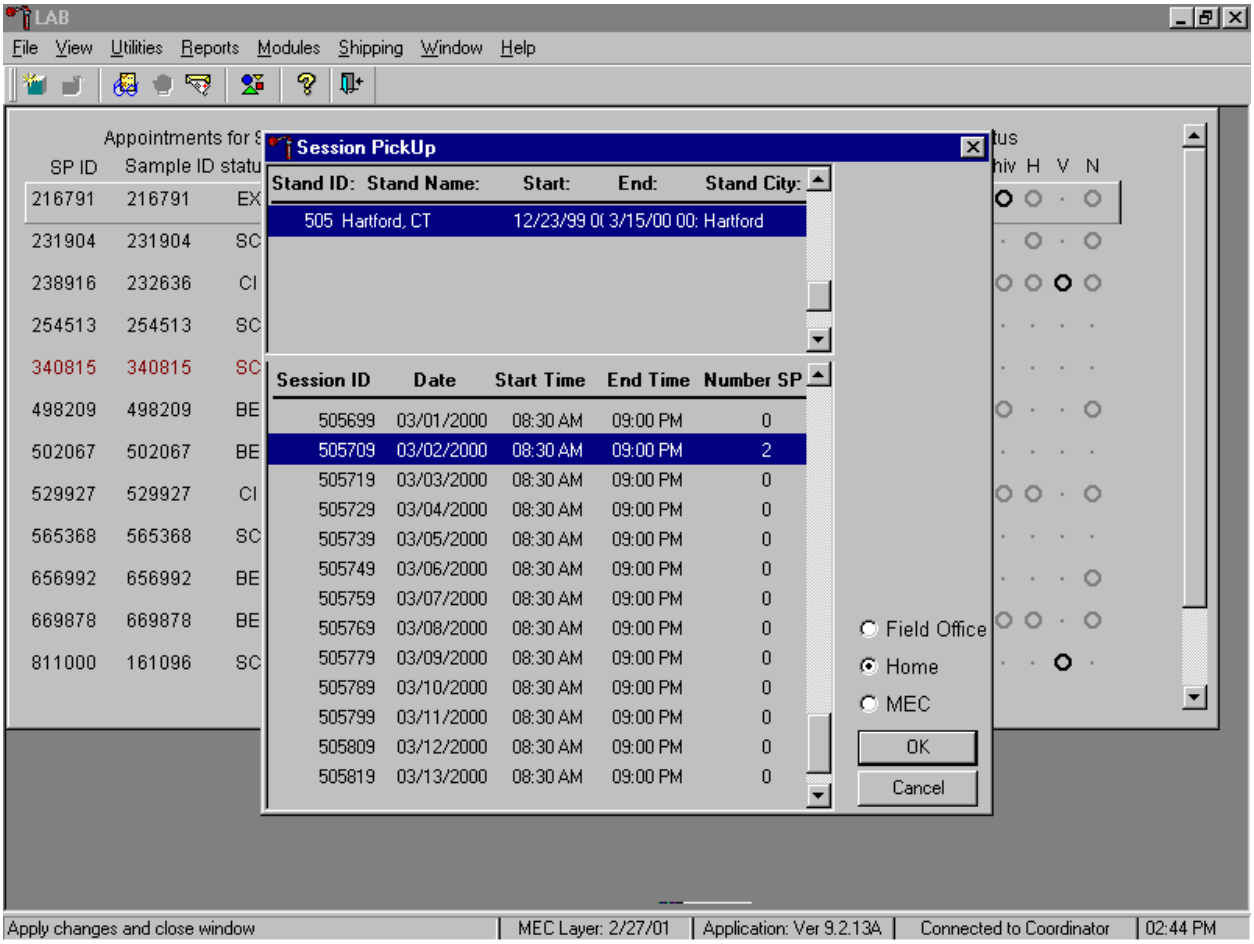
To access a home examination session when the staff is conducting a MEC session, use the mouse to direct the mouse arrow to the {Utilities} module in the top tile bar, drag the mouse arrow to {Set Session}, and left click or type [Alt] [U/u], [N/n].

Select the correct Session PickUp filter.



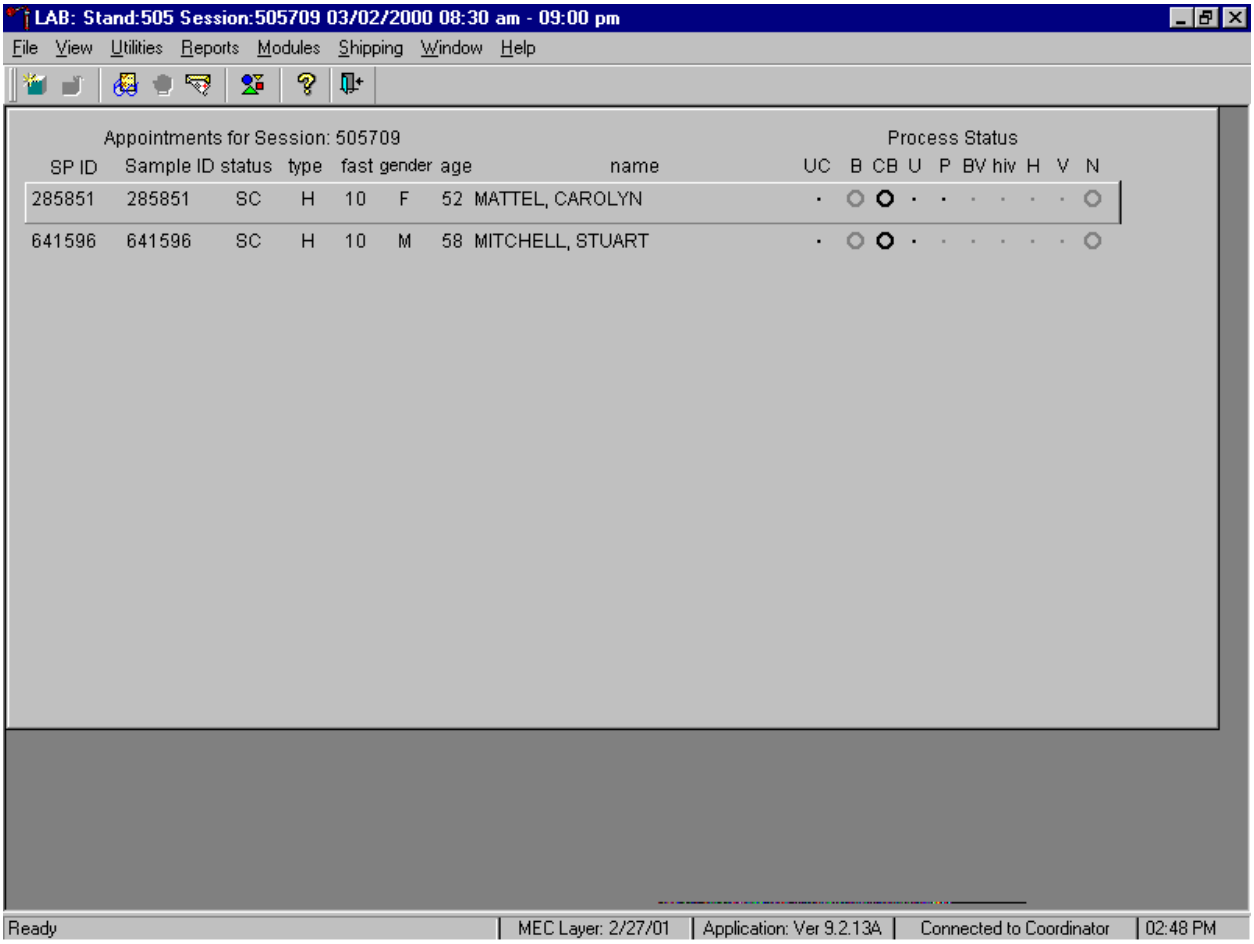
The Session Pickup list displays. To filter on home examination sessions, and not MEC sessions, use the mouse to direct the mouse arrow to the Home radio button and left click.

Select the correct home exam session.



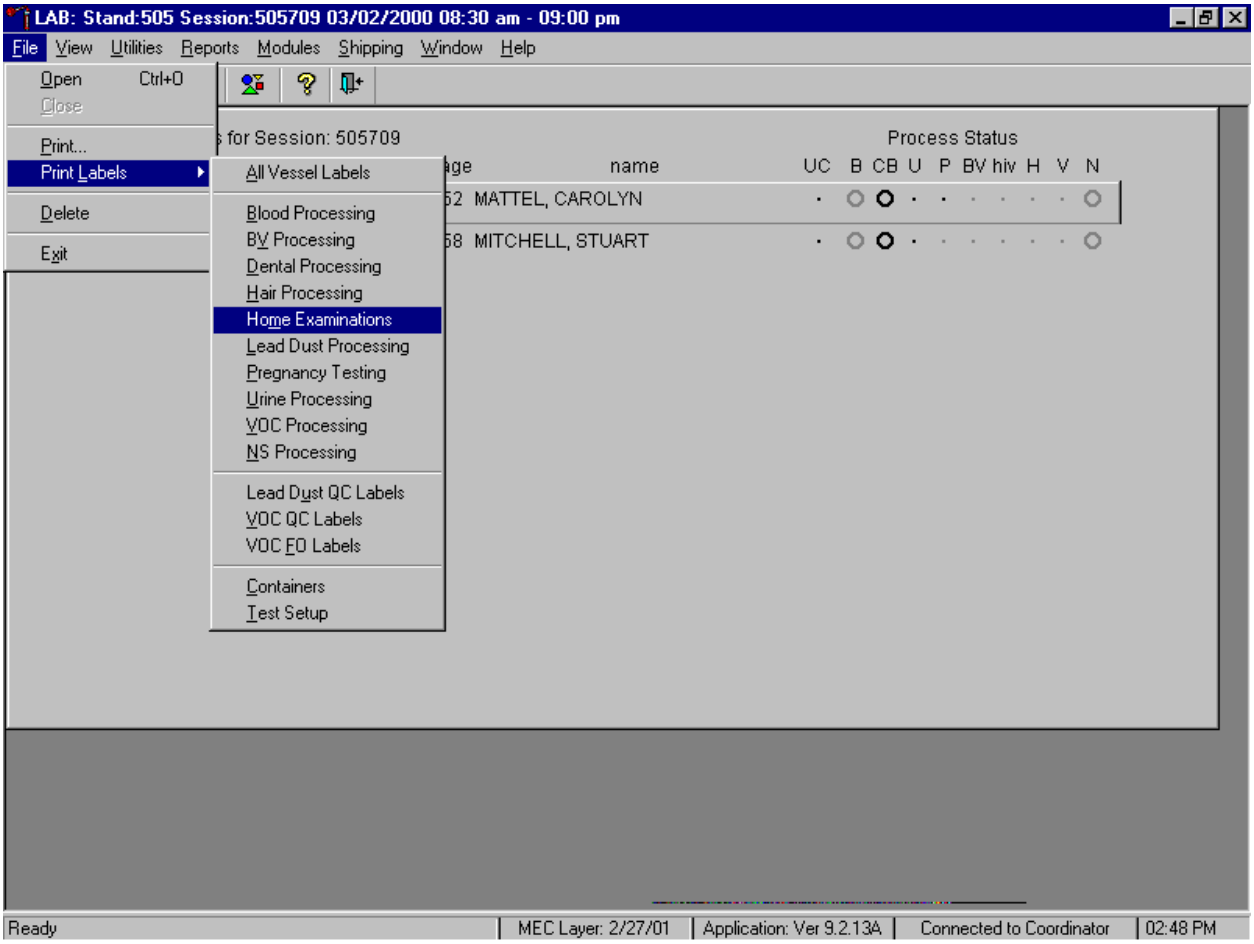
To select or highlight the correct home session, use the mouse to direct the mouse arrow to the correct session date and time. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

The selected home exam session displays.



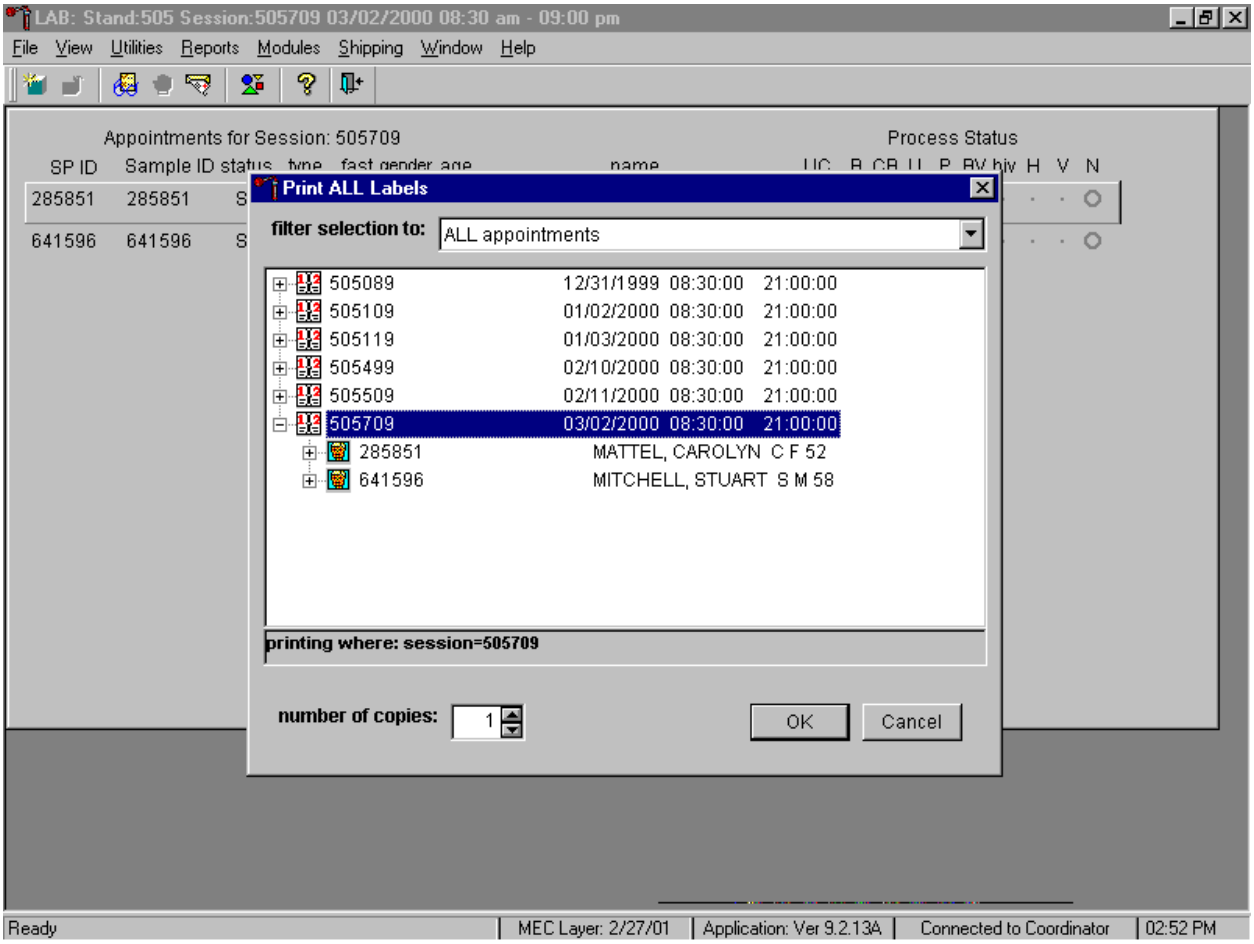
Review the Heads-up screen. Verify that the home examination SP is scheduled in this session.

Access the Print Labels module.



To access the Print Labels module, use the mouse to direct the mouse arrow to {File}, drag the mouse arrow to {Print Labels}, {Home Examinations}, and left click or type [Alt] [F/f], [L/l] [M/m].

Print venipuncture tubes labels for all SPs scheduled into a home exam session.

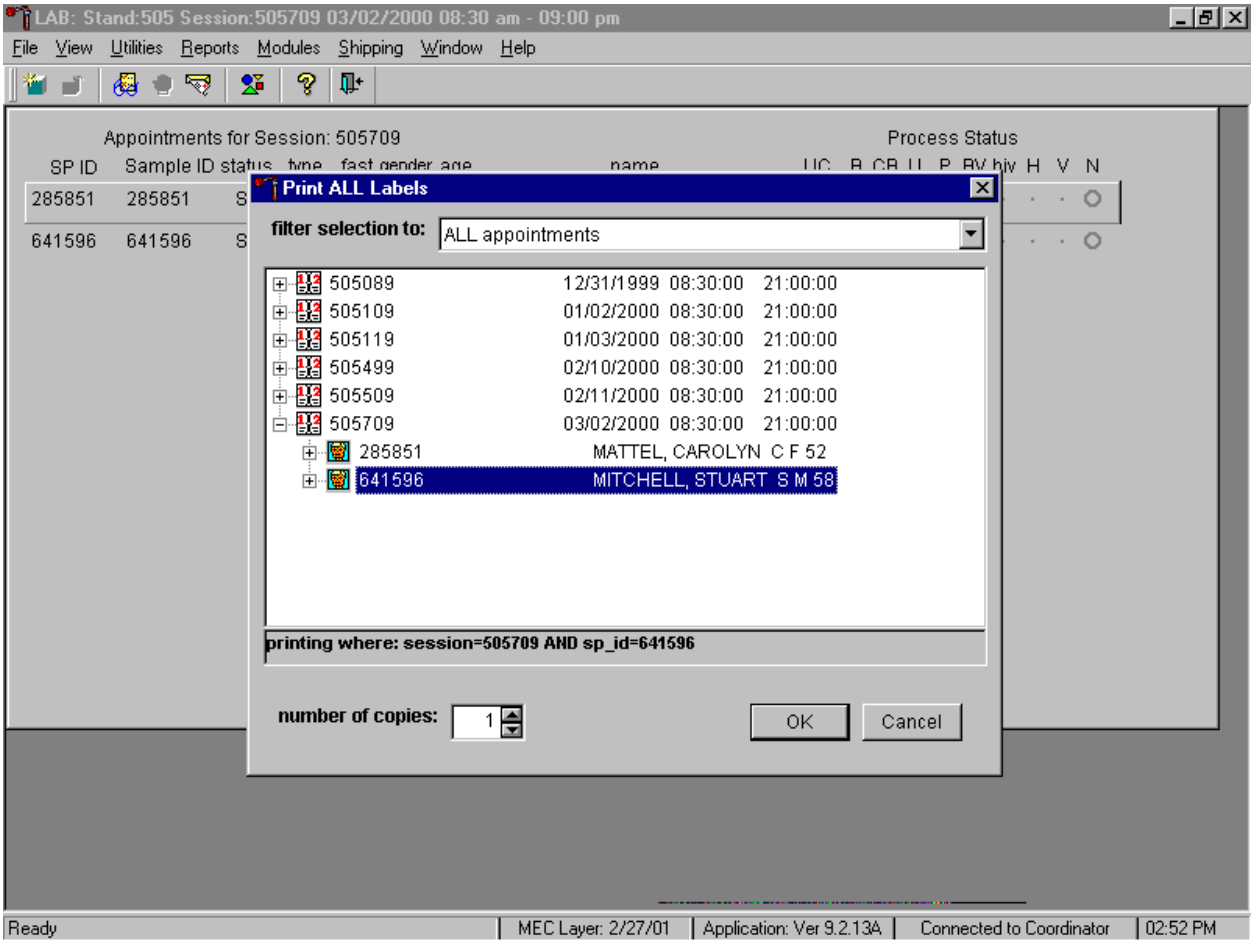


The Print ALL Labels window displays. This window contains a list of all home examination sessions and includes, a plus or minus sign, a calendar icon, session number, date, and time. The plus or minus indicates that there is additional (+) or no additional (-) information for the session. To view the additional information, use the mouse to direct the mouse arrow to the plus sign and left click. A list of SPs scheduled into this session displays below the session information line. This additional information displays a line for each SP and includes a plus or minus sign, SP icon (SPs with a "?" are less than 1 year and not eligible for venipuncture), SP ID, SP name (last, first), SP gender, and SP age.

To select or highlight a session, use the mouse to direct the mouse arrow to the session number and left click. All SPs scheduled for the home exam session are displayed below the session number. Select the number of copies (ten labels print for each home exam) by using the mouse to direct the mouse arrow to the up and down arrows on the right side of the number of copies box. Use the mouse arrow to toggle the number on the spin box up and down or highlight the field and type the desired number using the numeric keys. To print the labels for all home exam SPs scheduled into this session, use

the mouse to direct the mouse arrow to the OK button and left click. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click. The screen returns to the Heads-up display.

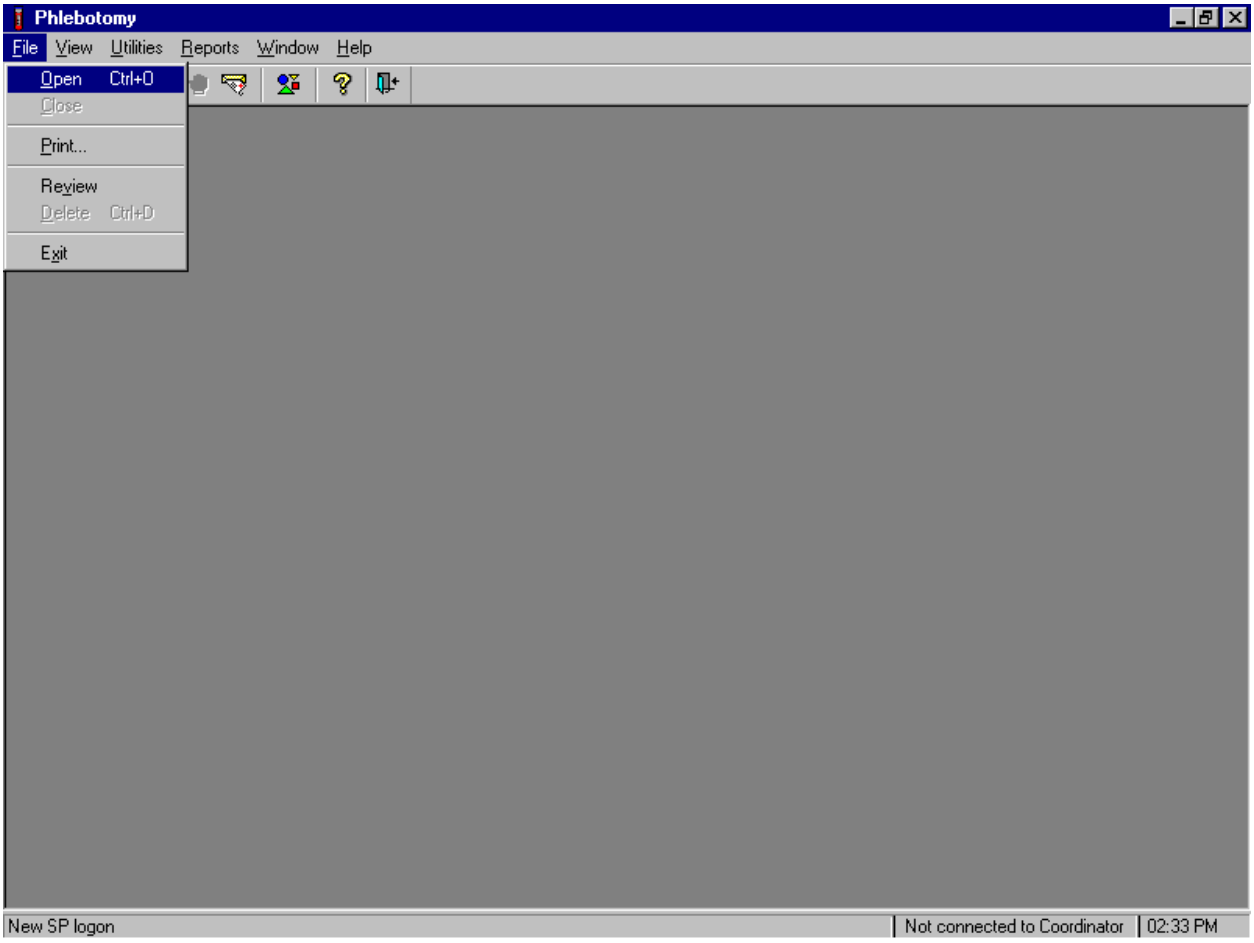
Print venipuncture tube labels for one home exam SP.



To select or highlight the session, use the mouse to direct the mouse arrow to the session number and left click. All SPs scheduled for the session are listed below the session number. To select or highlight a specific SP, use the mouse to direct the mouse arrow to correct SP and left click to highlight only the SP of interest. Select the number of copies (ten labels print for the SP) by using the mouse to direct the mouse arrow to the up and down arrows on the right side of the number of copies box. Use the mouse arrow to toggle the number on the spin box up and down or highlight the field and type the desired number using the numeric keys. To print the labels, use the mouse to direct the mouse arrow to the OK button and left click. To exit without printing any labels, use the mouse to direct the mouse arrow to the Cancel button and left click.

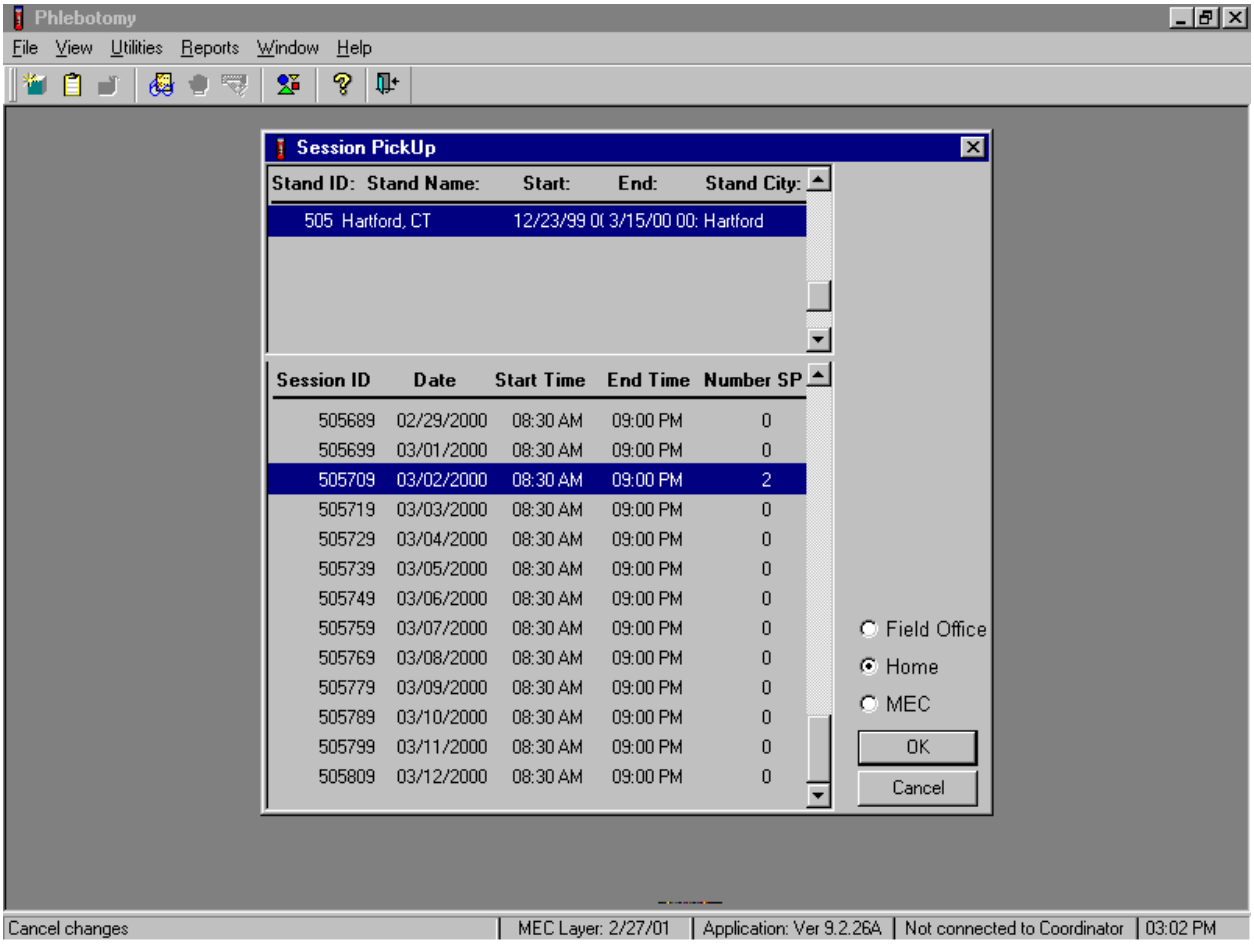
Ten bar-coded labels print for each home exam SP. Collect the labels from the Datamax printer in the label/ship area. Stock the transport case with sufficient supplies to complete the venipuncture procedure on at least two home exam SPs. Remove the Thermos® tote from the transport case. Examine the thermometer for any visible damage and place 5 frozen ice cubes in the Thermos tote. Remove one frozen refrigerant pack from the freezer and place in the transport case.

Access the Phlebotomy application using procedures described in Section 4.7. Open the phlebotomy exam.



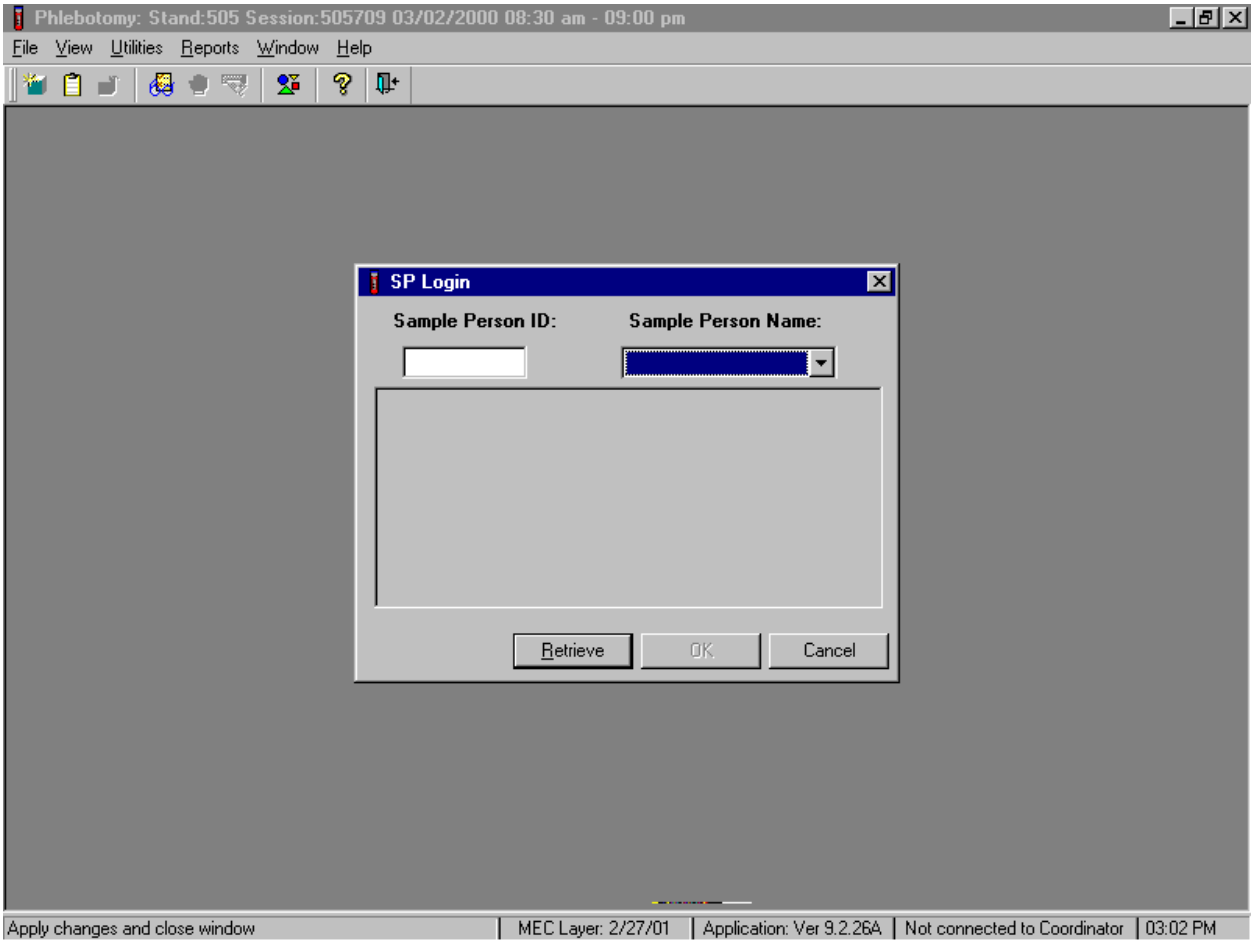
To open the phlebotomy examination, use the mouse to direct the mouse arrow to {File} in the top tile bar, drag the arrow to {Open} and left click. Alternatively, to open the phlebotomy examination, use the mouse to direct the mouse arrow to the {Open} icon in the top toolbar and left click or type [Alt] [F/f] [O/o] or [Ctrl] [O/o].

Select the correct filter, stand, and session.



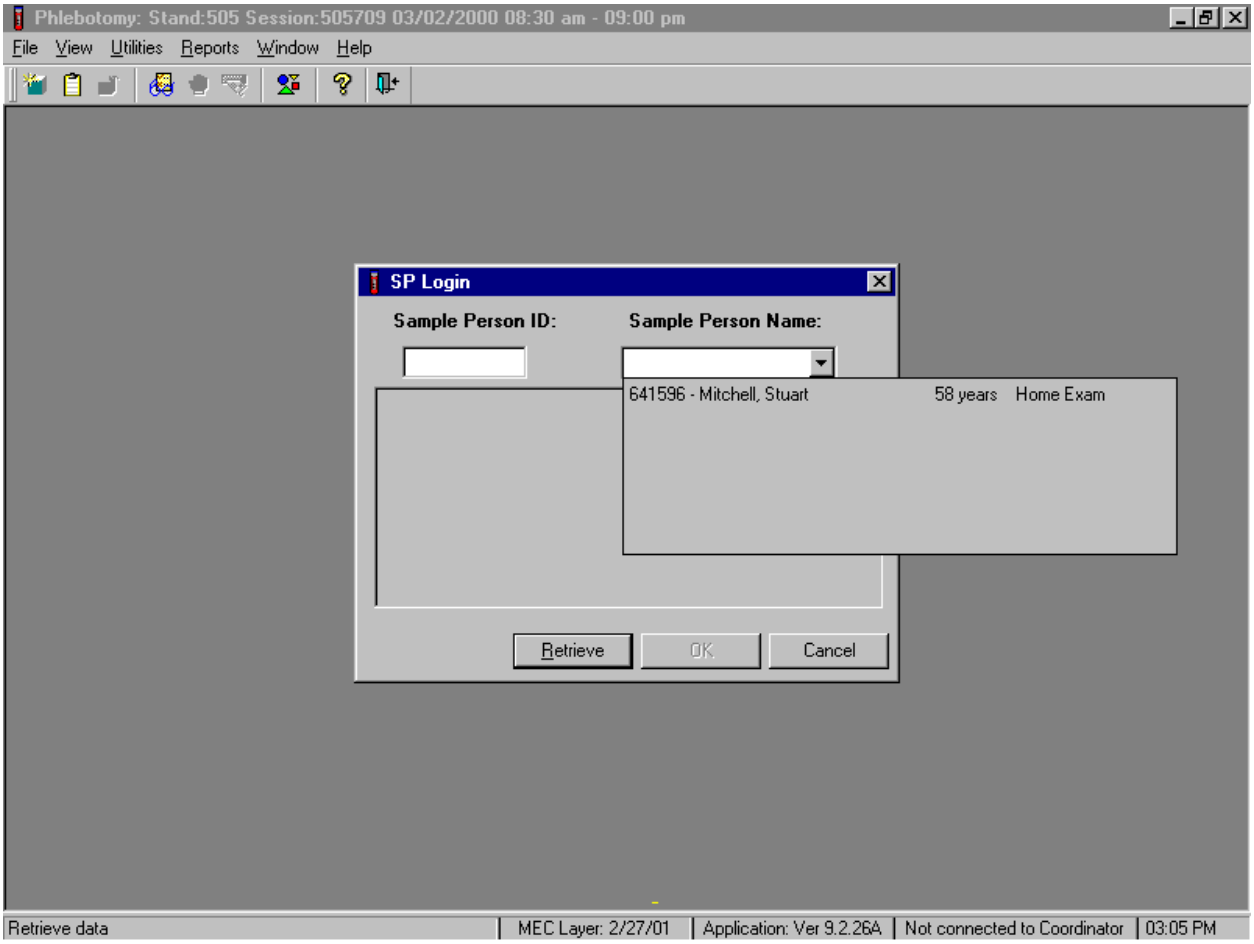
To select the correct filter, use the mouse to direct the mouse arrow to the Home radio button and right click to pick up (or filter on) home exam sessions. To select the correct stand, use the mouse to direct the mouse arrow to the correct stand and right click to highlight the selection. To select the correct home session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the OK button and right click. To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

Log the SP into the exam.



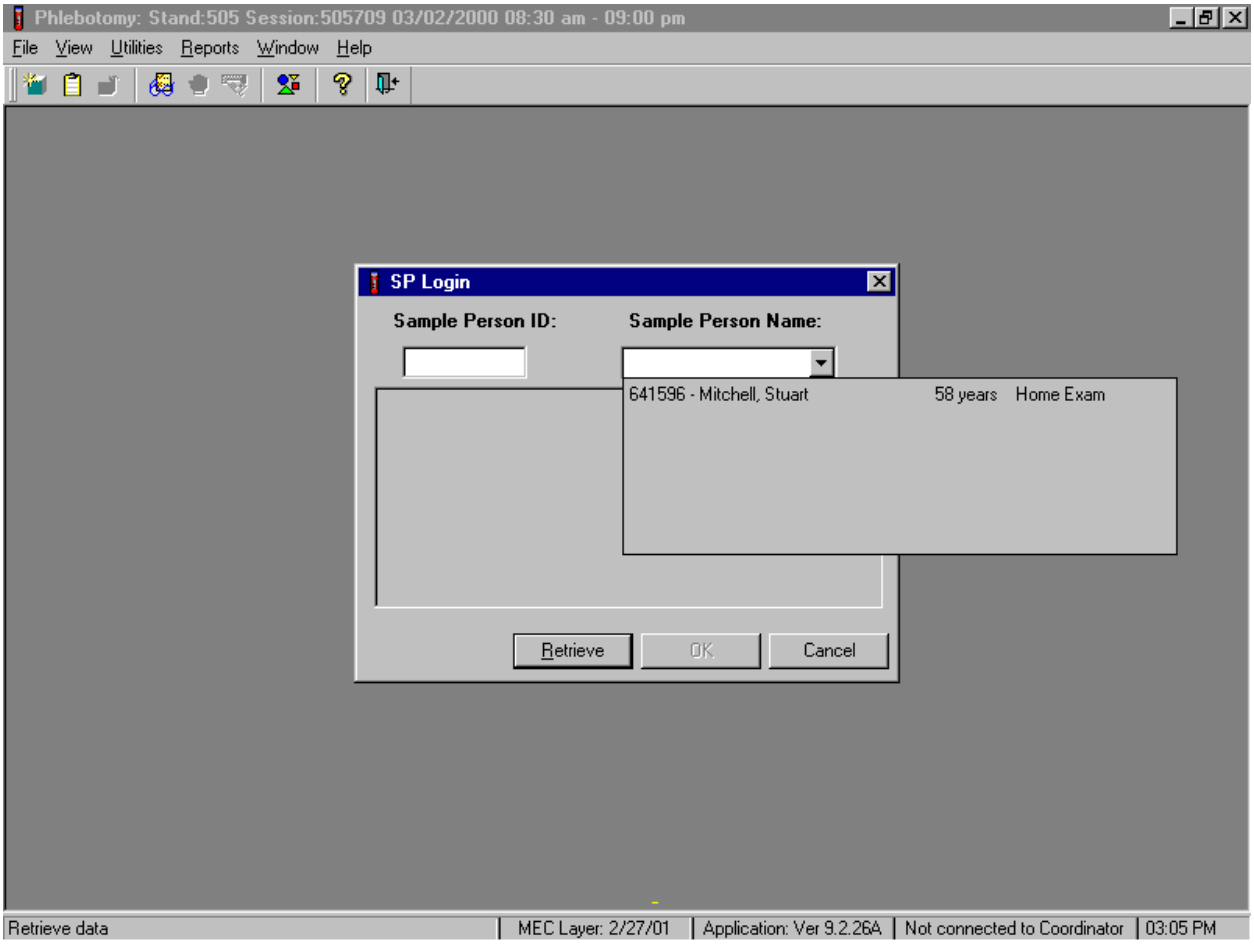
The SP Login window displays.

Continue to log the SP into phlebotomy.



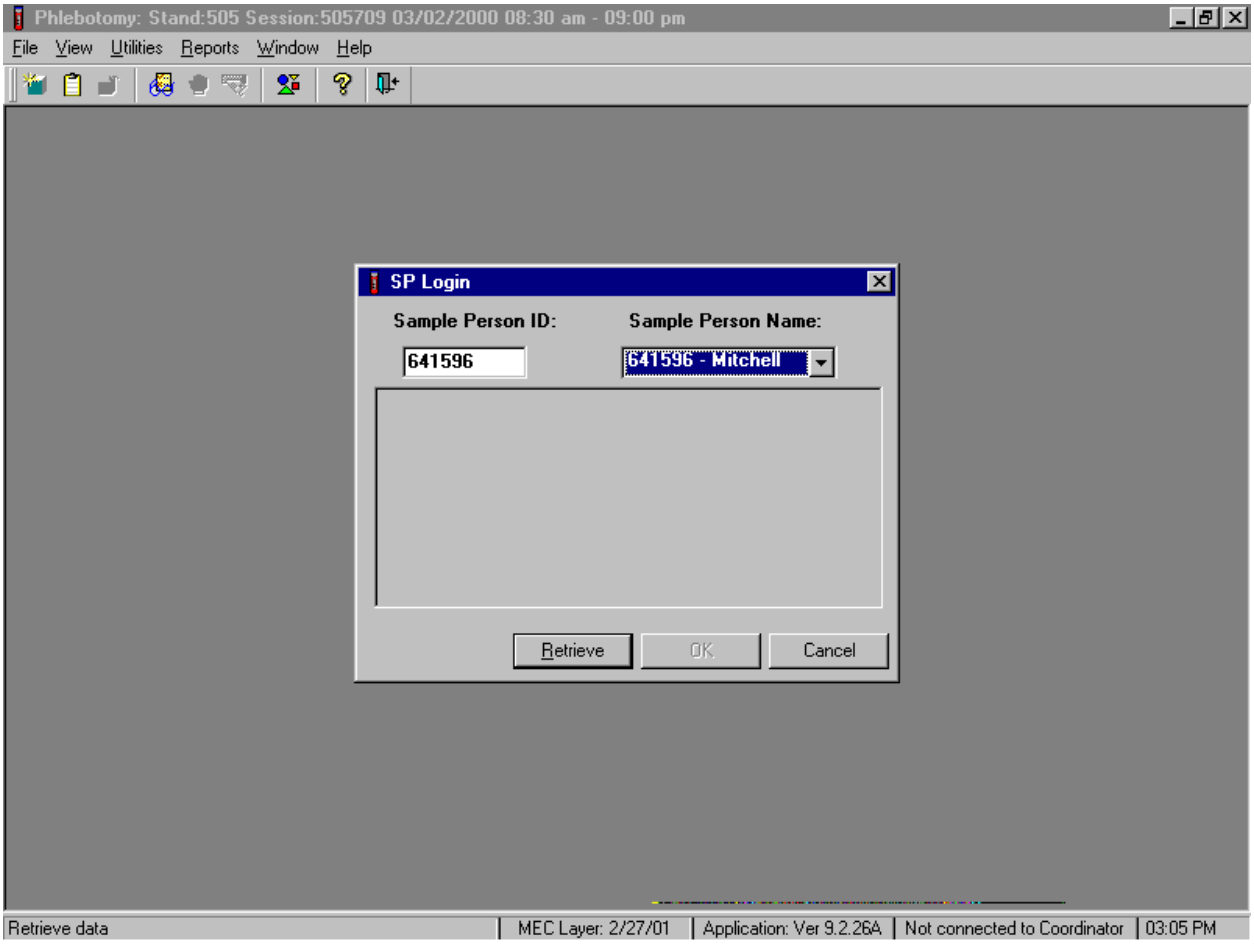
To view the list of eligible SPs, use the mouse to direct the mouse arrow to the pull down menu on the right side of the Sample Person Name: box and right click.

Continue to log the SP into phlebotomy.



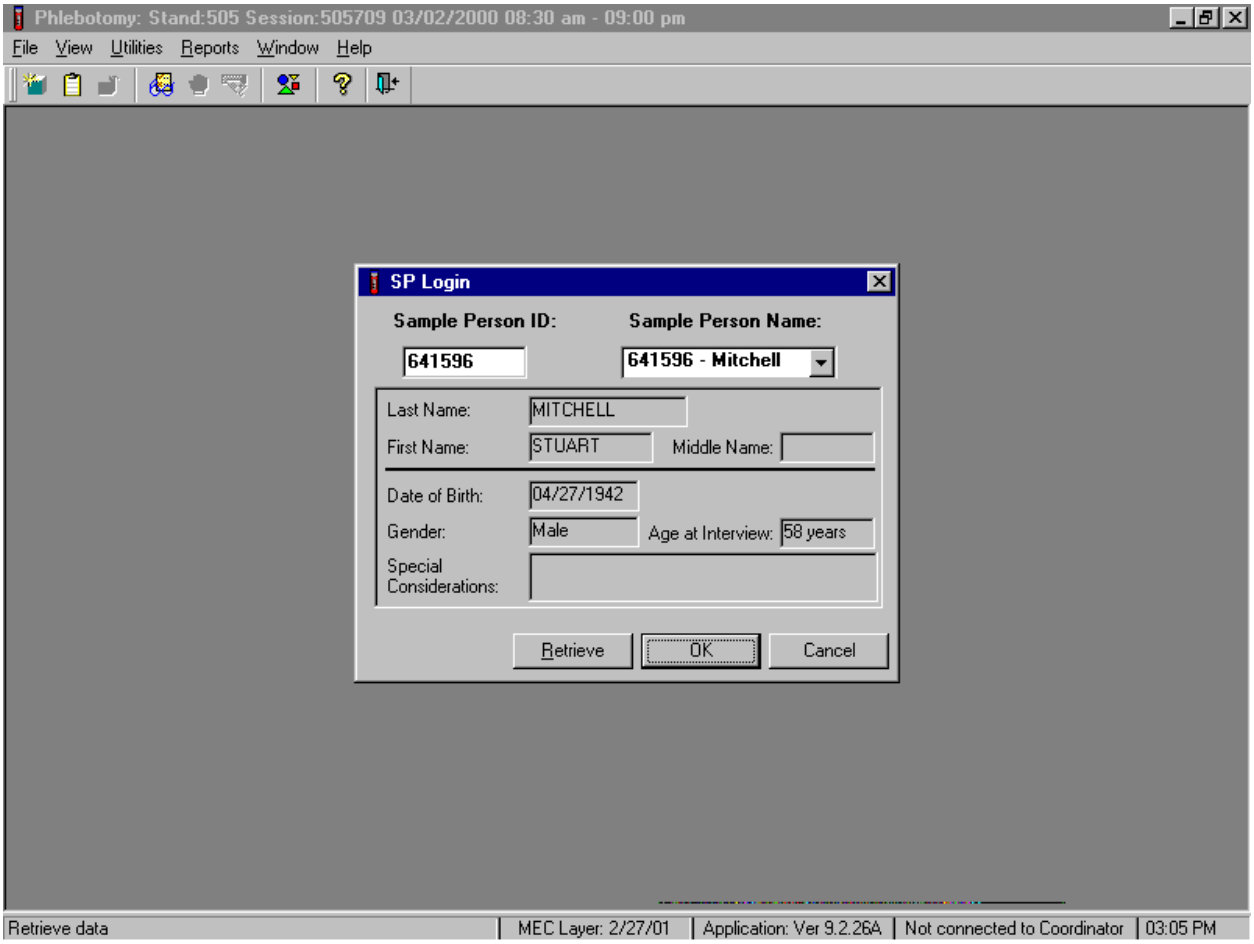
To select (highlight) the correct SP, use the mouse to drag the mouse arrow to the correct SP and left click. The Sample Person ID: and the Sample Person Name: boxes fill in for the highlighted choice.

Continue to log the SP into phlebotomy.



To retrieve the remaining information on the SP, use the mouse to direct the mouse arrow to the Retrieve button and left click or press [Enter].

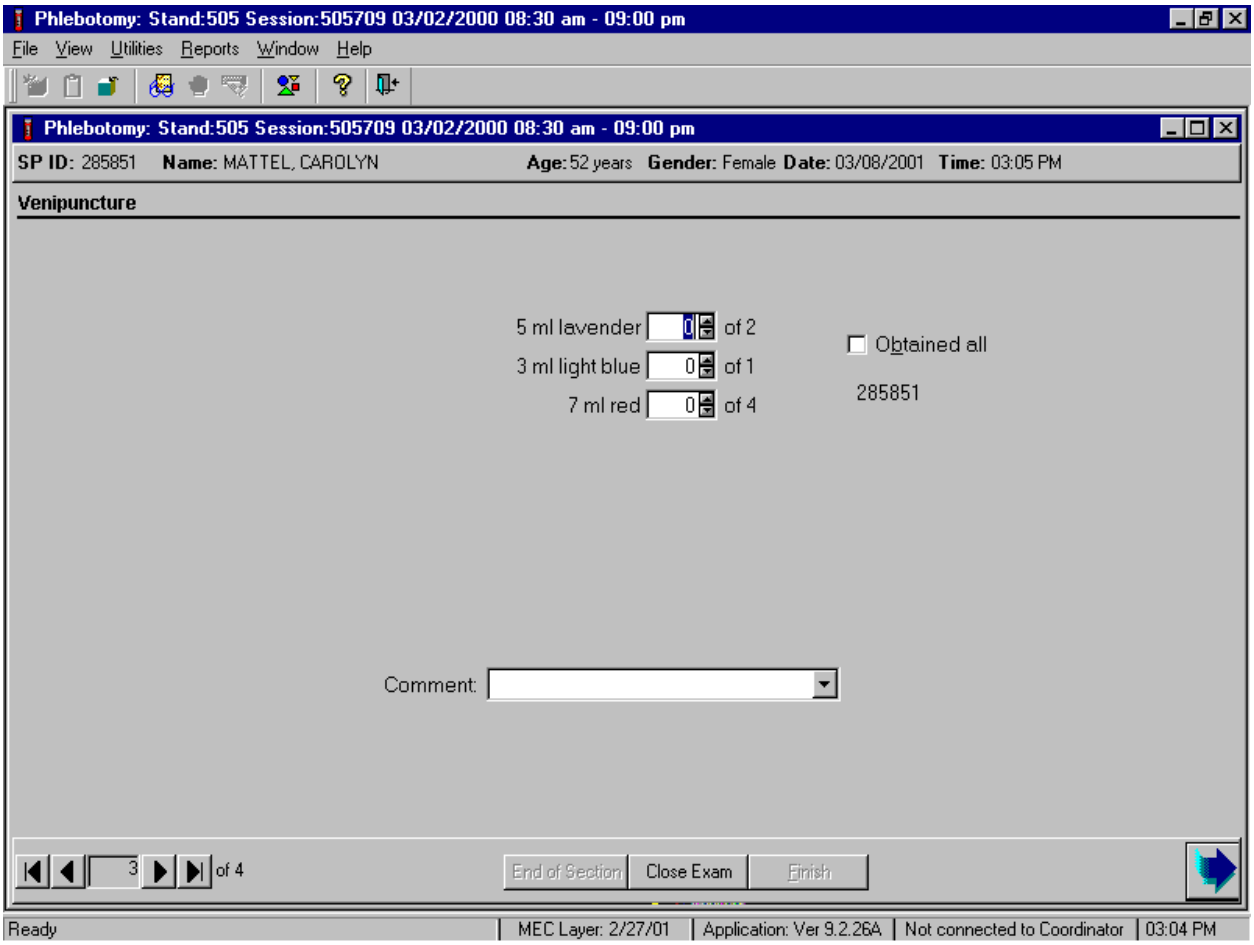
Continue to log the SP into phlebotomy



The remaining SP information displays. To move forward to the phlebotomy interview questions, press [Enter] or use the mouse to direct the mouse arrow to the OK button and left click. To cancel the SP login process, use the mouse to direct the mouse arrow to the Cancel button and left click.

4.20.5 Conducting the Exam

Conduct the phlebotomy interview and administer the fasting questionnaire using procedures described in Sections 4.9 and 4.10. Conduct the venipuncture using procedures described in Section 4.11.

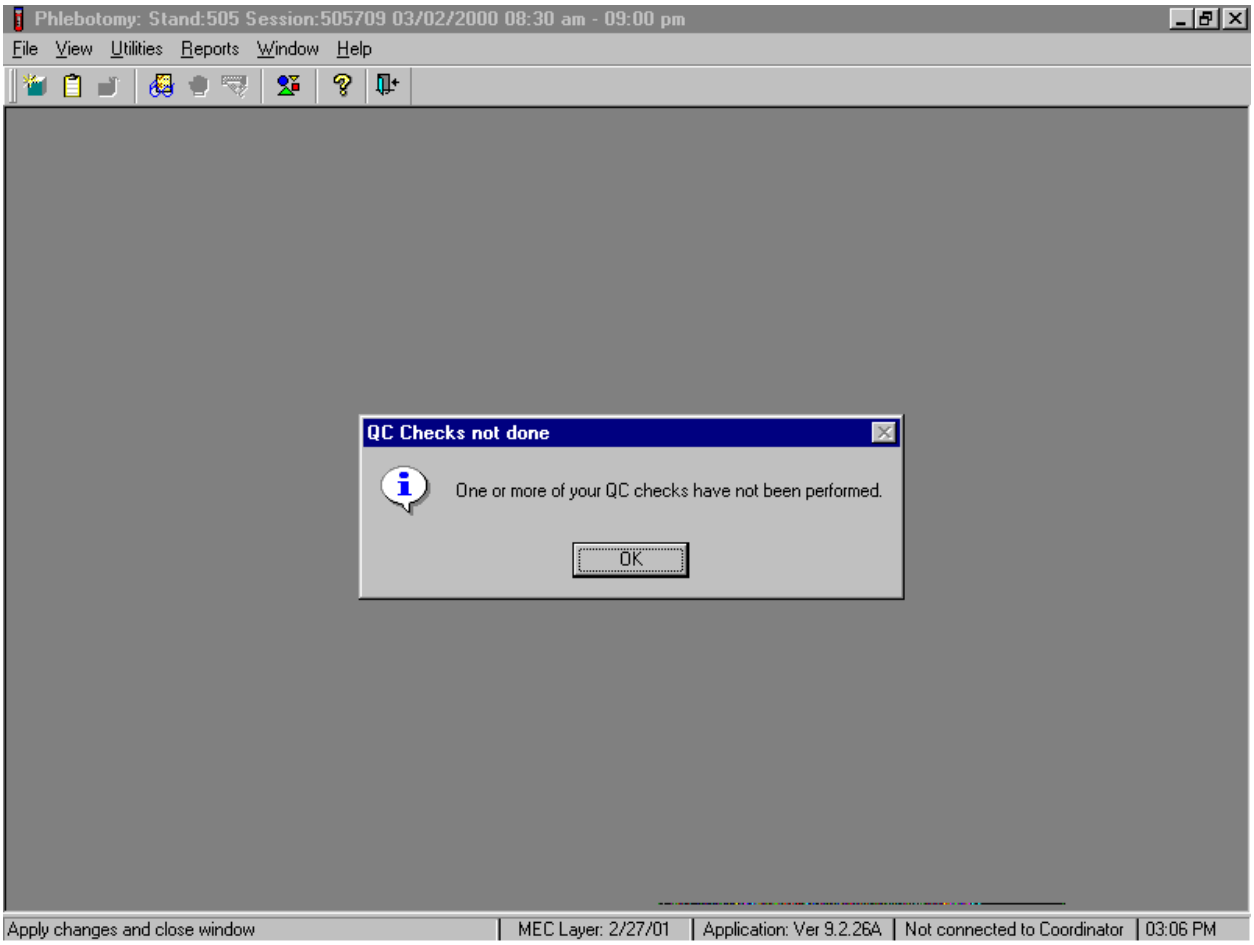


Label all tubes with bar-coded labels with the bar-code vertical on the tube and record the current time on each tube. Place the second 5-mL EDTA tube in the Thermos tote. Place all other blood collection tubes in the hard-sided blood transport container. Use the frozen refrigerant pack when necessary to maintain near room temperature conditions for the blood tubes in the transport case. Place all used needles in the sharps container and all soiled supplies in a biohazard bag. If blood has spilled on the table, wash the area with a bleach towelette. Record the results of the venipuncture using procedures described in Section 4.13. Verify that the correct exam status. Choose and enter the appropriate comment code when section status is Partial or Not Done.

When performing venipuncture on SPs who do not speak English, a translator who does speak the SP's language assists the home examiner and stays with the SP and the home examine for the entire procedure.

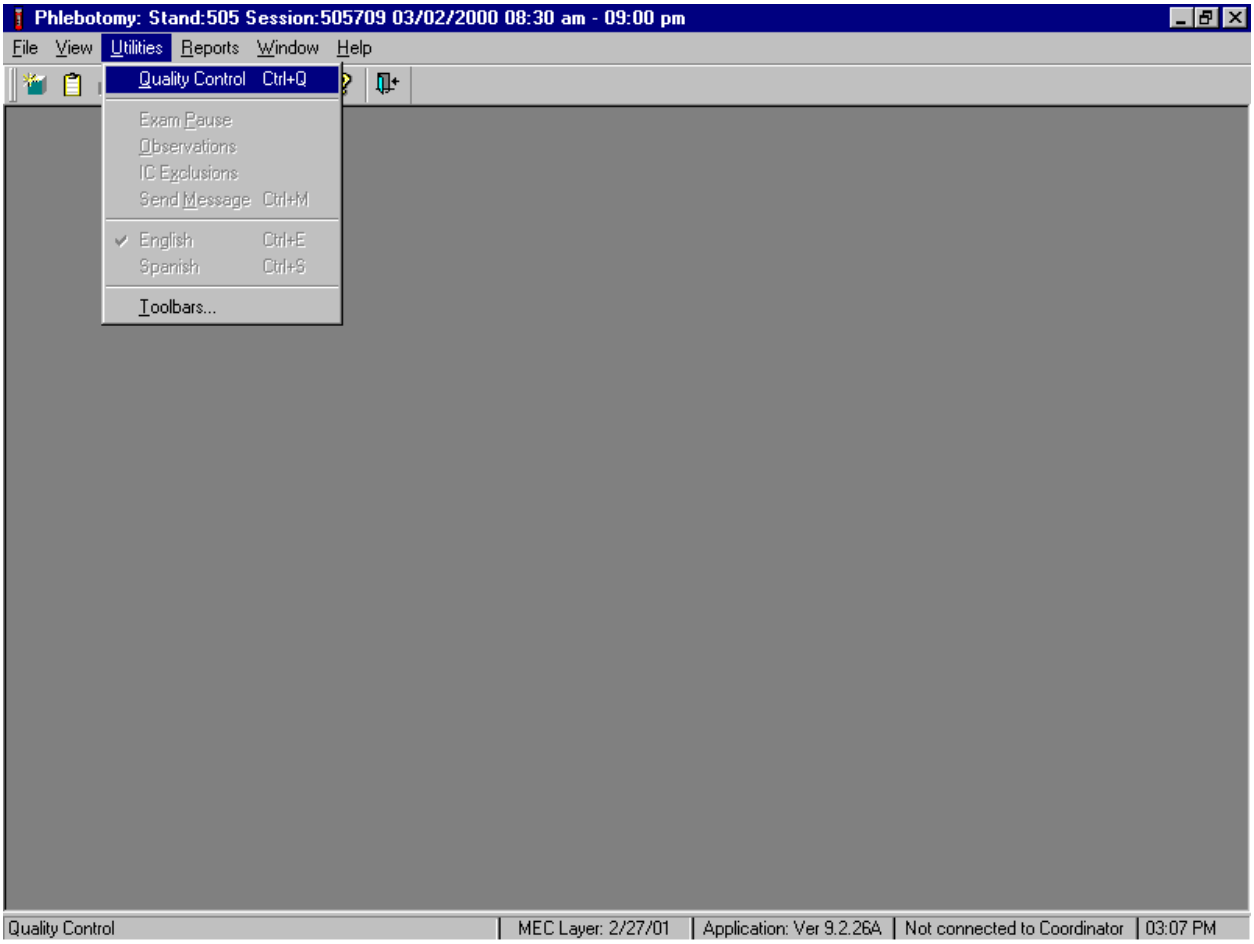
4.20.6 Entering Phlebotomy Home Exam Quality Control

Conduct home exam phlebotomy quality control after returning to the MEC.



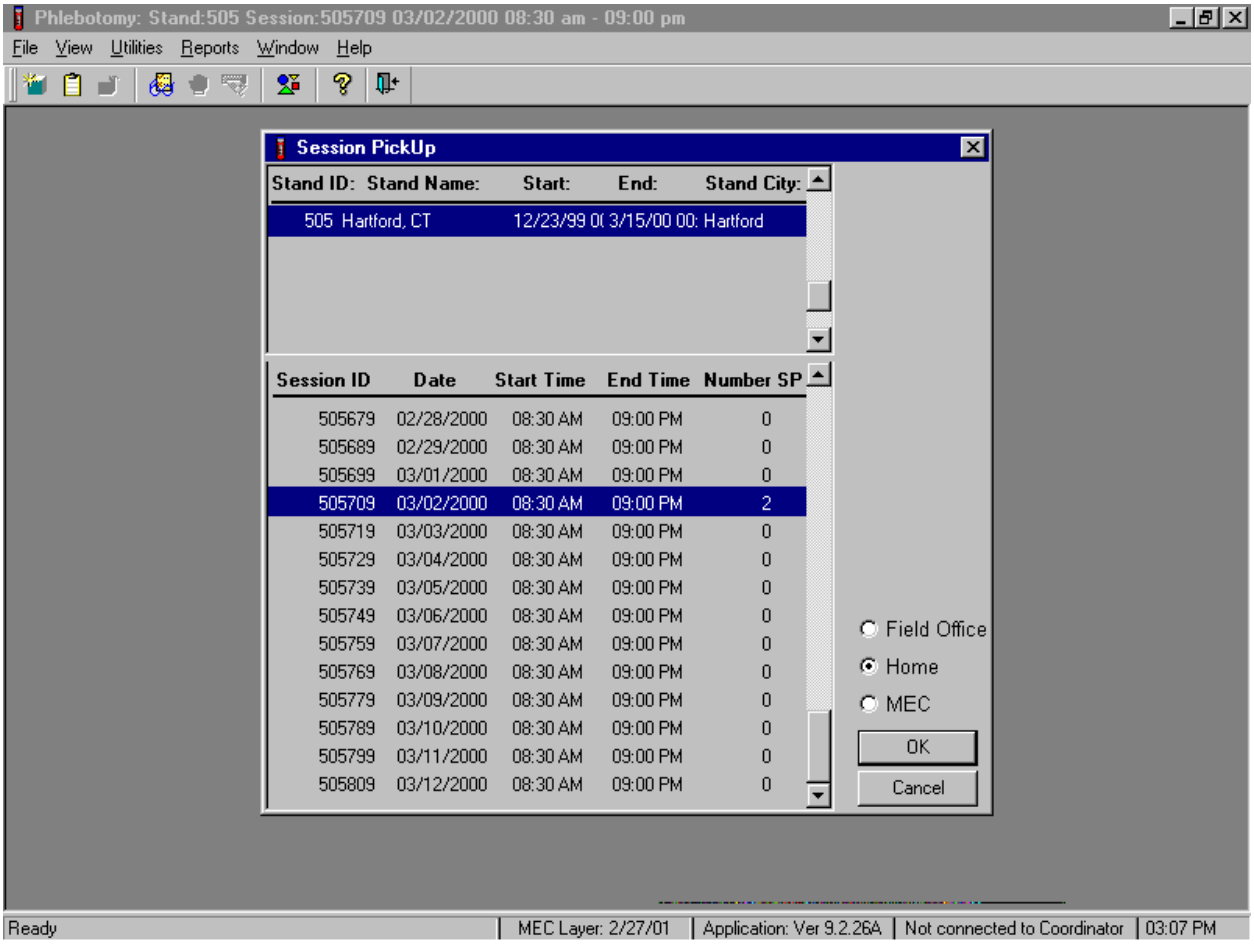
If the QC from the previous home session was incomplete, a QC Checks not done message box displays. To remove the message box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

Access the QC module.



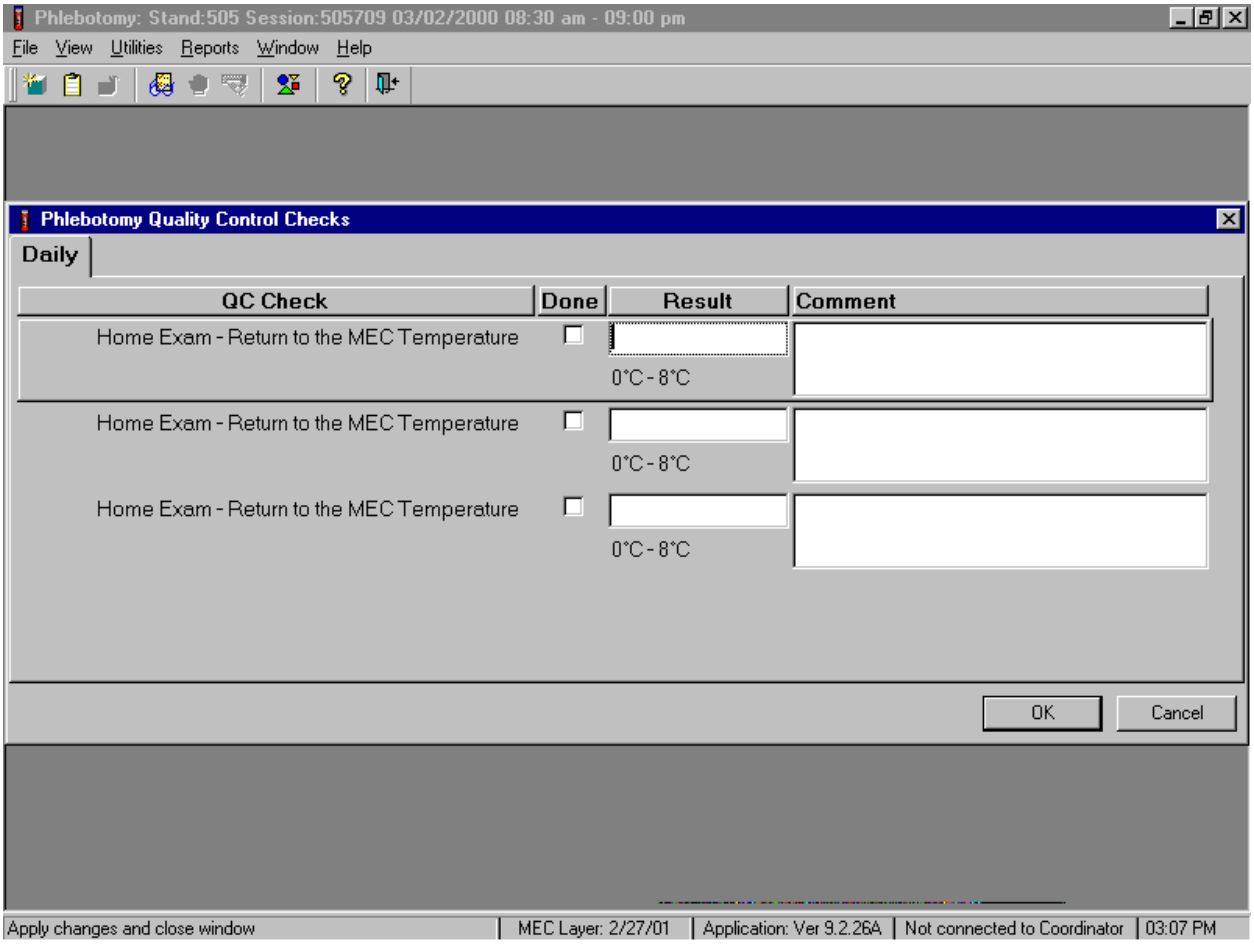
To access the phlebotomy QC module, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Quality Control} and left click, or select [Alt] [U/u], [Q/q] or [Ctrl] [Q/q].

Select the session.



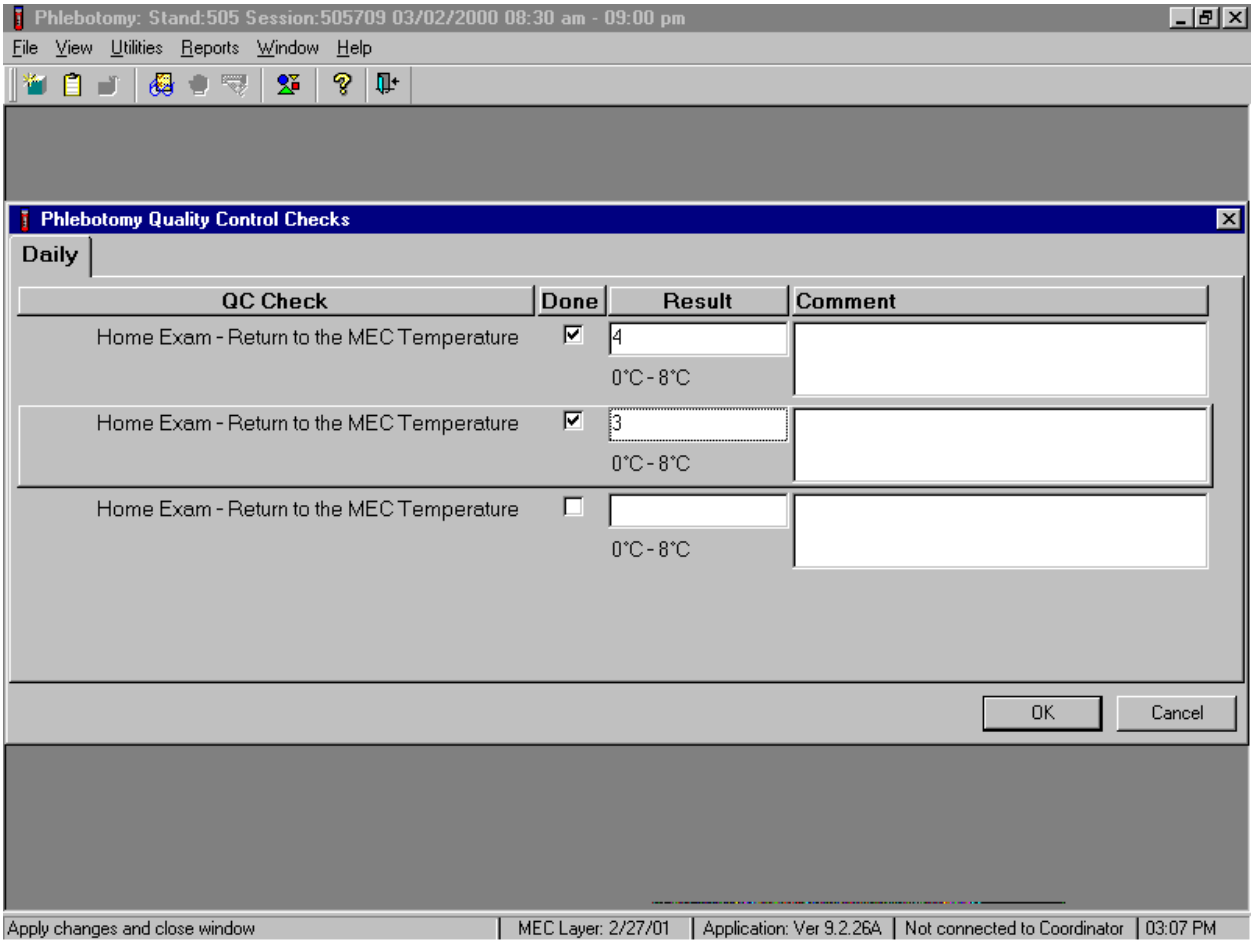
To select the correct filter, use the mouse to direct the mouse arrow to the Home radio button and right click to pick up (or filter on) home exam sessions. To select the correct stand, use the mouse to direct the mouse arrow to the correct stand and right click to highlight the selection. To select the correct home session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the OK button and right click. To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

Record the quality control activities. Mark each done check box with a check mark.



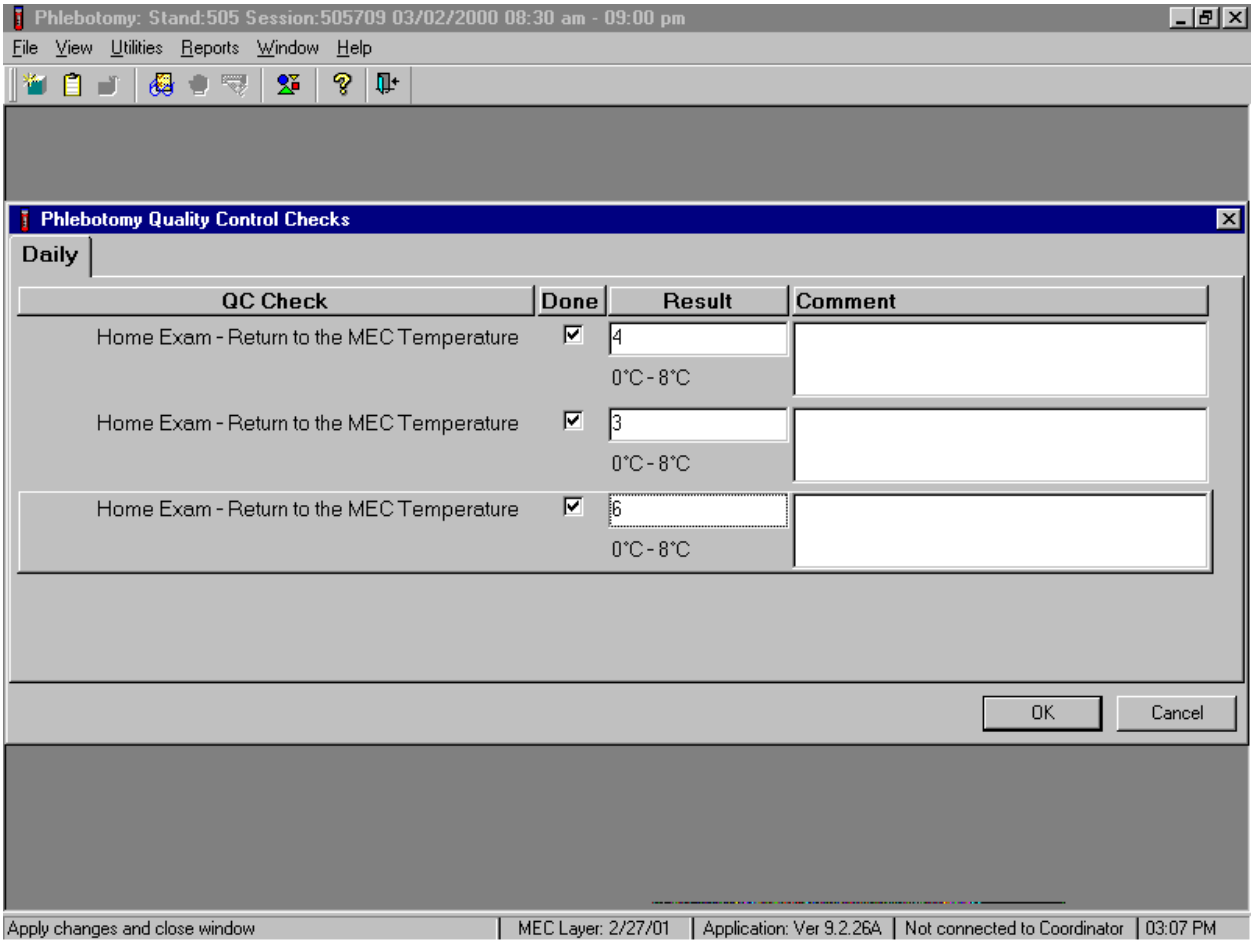
Each time a new home exam session is conducted a new line is added to the home exam quality control utility. Record the temperature of the thermometer inside the Thermos when opening the Thermos to remove the blood for processing.

Enter the QC results.



To record a check mark in the Home Exam – Return to the MEC Temperature 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.

Continue to enter the results.



Enter the Result text box and select [Tab] to move to the Comment text box. If the reading is outside the established range (0-8°C), document the actions taken to resolve the situation in the Comment text box. To save these actions 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.

4.21 Red Cross Procedures for Handling Vasovagal Reactions

"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 head at the level of his 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.

If the SP vomits, roll him/her onto his/her side or turn his/her head to the side and, if necessary, wipe out his/her mouth with your fingers, preferably wrapped in cloth.

- Maintain an open airway.
- **Do not** pour water over the SP's face because of the danger of aspiration; instead, bathe his/her face gently with cool water.
- **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.

4.22 How to Deal With System Failure

If the computer system fails, record results on a preprinted Phlebotomy Worksheet (Exhibit 4-10). Complete a Phlebotomy worksheet for each SP while conducting the exam. Enter the results after the system is operational.

Exhibit 4-10. Phlebotomy worksheet – English Primary or Second Exam SP

PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

PRIMARY or SECOND EXAM 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 Yes, No	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 multi-vitamins and single nutrient supplements.]			
Primary SP Protocol	**Second Exam SP Protocol**	# Filled	Not Filled ✔
3 mL lavender (1 age 1-11)			
5 mL lavender (1 age 3-11, 2 age 12+)	5 mL lavender (2 age 12-69)		
3 mL gray (morning only 1 age 12+)	3 mL gray (morning only 1 age 12-69)		
3 mL light blue (1 age 40+)	3 mL light blue (1 age 40-69)		
3 mL red (2 age 1-2)			
7 mL red (2 age 3-5)			
15 mL red (4 age 6-11)	15 mL red (2 age 12-69)		
10 mL red (1 age 12+)			
8 ml ACD (2 age 20+)			
	7-mL gray (2 age 20-59)		
Comments:			

Exhibit 4-11. Phlebotomy worksheet – Spanish Primary or Second Exam SP

PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

PRIMARY or SECOND EXAM 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	**Second Exam SP Protocol**	# Filled	Not Filled ✔
3 mL lavender (1 age 1-11)			
5 mL lavender (1 age 3-11, 2 age 12+)	5 mL lavender (2 age 12-69)		
3 mL gray (morning only 1 age 12+)	3 mL gray (morning only 1 age 12-69)		
3 mL light blue (1 age 40+)	3 mL light blue (1 age 40-69)		
3 mL red (2 age 1-2)			
7 mL red (2 age 3-5)			
15 mL red (4 age 6-11)	15 mL red (2 age 12-69)		
10 mL red (1 age 12+)			
8 ml ACD (2 age 20+)			
	7-mL gray (2 age 20-59)		
Comments:			

Exhibit 4-12. Phlebotomy worksheet – English Home Exam SP

PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

HOME EXAM 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 Yes, No	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 multi-vitamins and single nutrient supplements.]		
Home Exam SP Protocol	# Filled	Not Filled ✔
5 mL lavender (2 age 50+)		
3 mL light blue (1 age 40+)		
7 mL red (3 age 50+)		
Comments:		

Exhibit 4-13. Phlebotomy worksheet – Spanish Home Exam SP

PHLEBOTOMY INTERVIEW, FASTING INTERVIEW, and PROTOCOL

HOME EXAM 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.]		
Home Exam SP Protocol	# Filled	Not Filled ✔
5 mL lavender (2 age 50+)		
3 mL light blue (1 age 40+)		
7 mL red (3 age 50+)		
Comments:		

5. URINE SPECIMEN COLLECTION AND URINE PROCESSING AND STORAGE

5.1 Introduction

The purposes of urine collection and processing are to collect sufficient urine from primary SPs age 6 years and older to be able to (1) perform a pregnancy test for selected females aged 8-11 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, surplus, and second exam person 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 urine specimens from all SPs who are 6 years of age and older. At least 54-mL of urine is required for primary SPs aged 6-13 and 66-mL from most SPs aged 14+ years and older. These volumes include an additional 0.5-mL for the pregnancy test. 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, surplus, and second exam person 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 will explain 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.
- Close container to minimize exposure to air.

5.2 Supplies

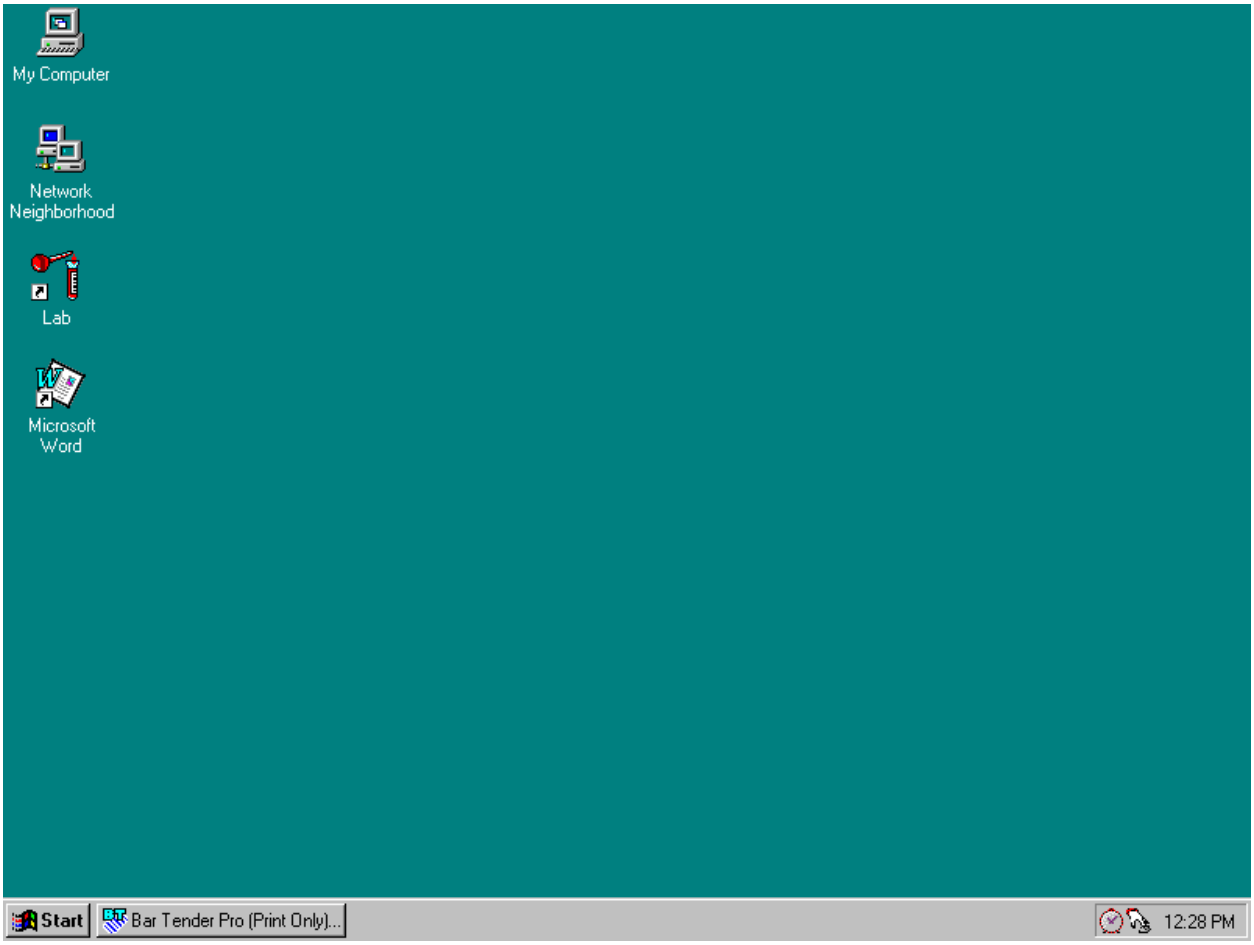
The supplies needed for urine collection and urine processing and storage are listed in Exhibit 5.1

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)	2-mL cryovial non-sterile
Bench Kote paper	Caps for 2-mL cryovial
Cube rack – 4 way flipper rack	Transfer pipette
Nonsterile, powder-free, latex (non-latex for use by latex allergic staff) gloves -- small, medium, large	Kimwipes
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

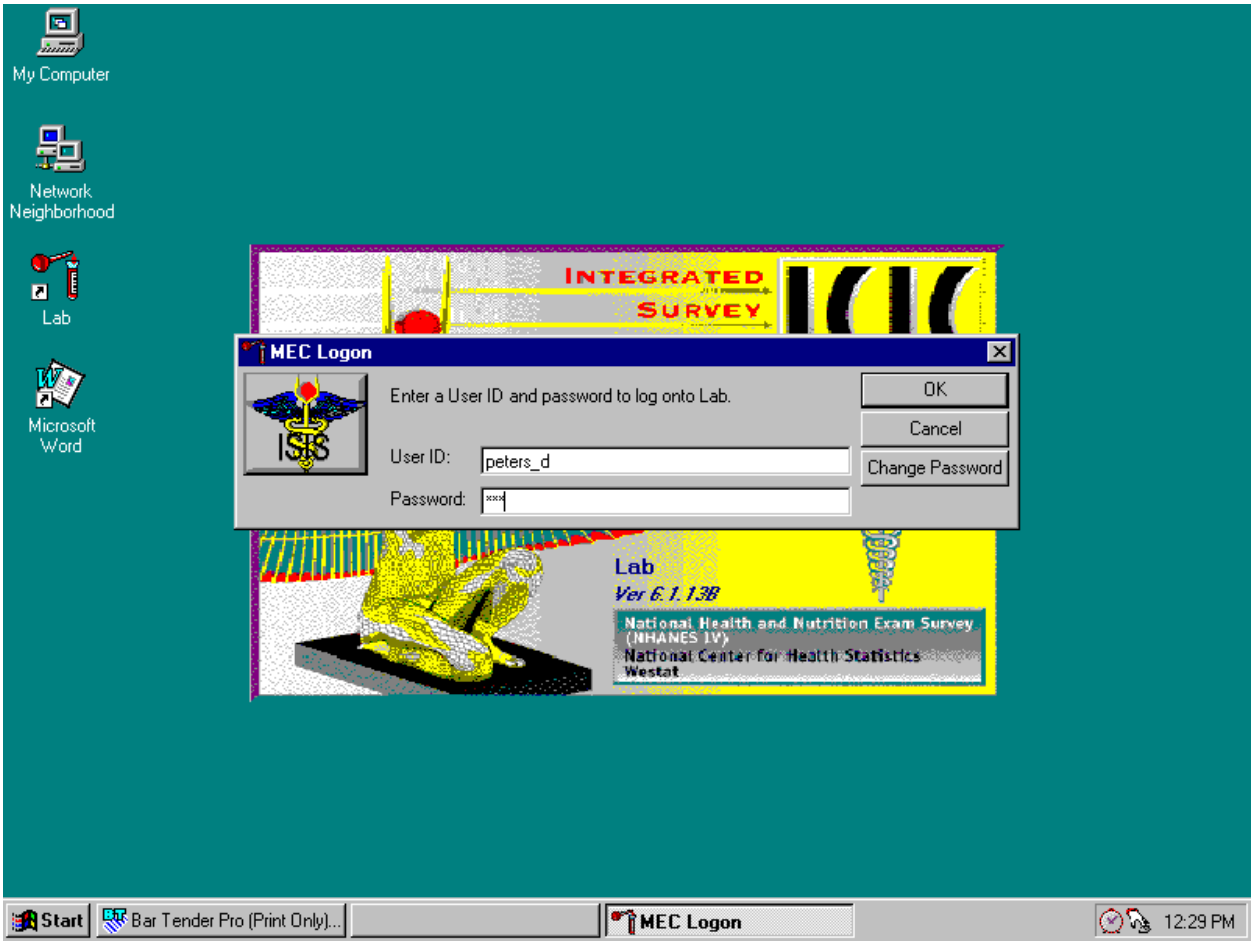
5.3 Document Urine Collection

Open the Laboratory application.



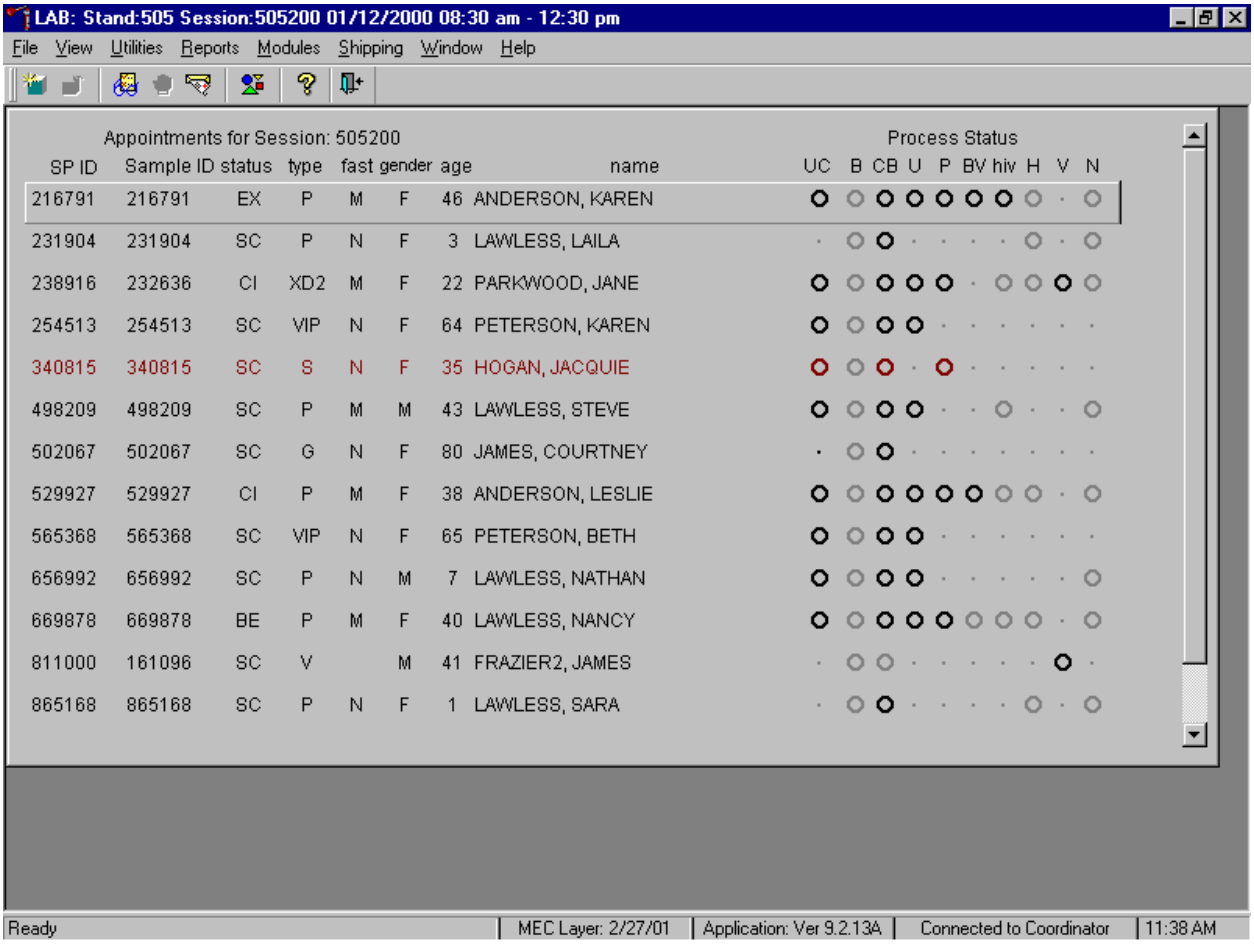
To open the laboratory application, use the mouse to direct the mouse arrow to the Laboratory icon on the desktop and double click.

Log onto the laboratory application.



The MEC Logon window displays. Type last name, underscore first initial in the User ID space, and [Tab] or [Enter]. Enter 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.

Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status.



The heads-up display lists all SPs with appointments for the current session. It includes the SP ID, Sample ID, Status (SC=scheduled, CI=checked-in, BE=being examined, EX=exited), Type (P=primary, G=guest, VIP=VIP guest, XD2=second exam, S=surplus, D=dry run, V=VOC), fast (M=morning, A=afternoon, E=evening, N=none), Gender (M=male, F=female), Age, and Name (last, first.)

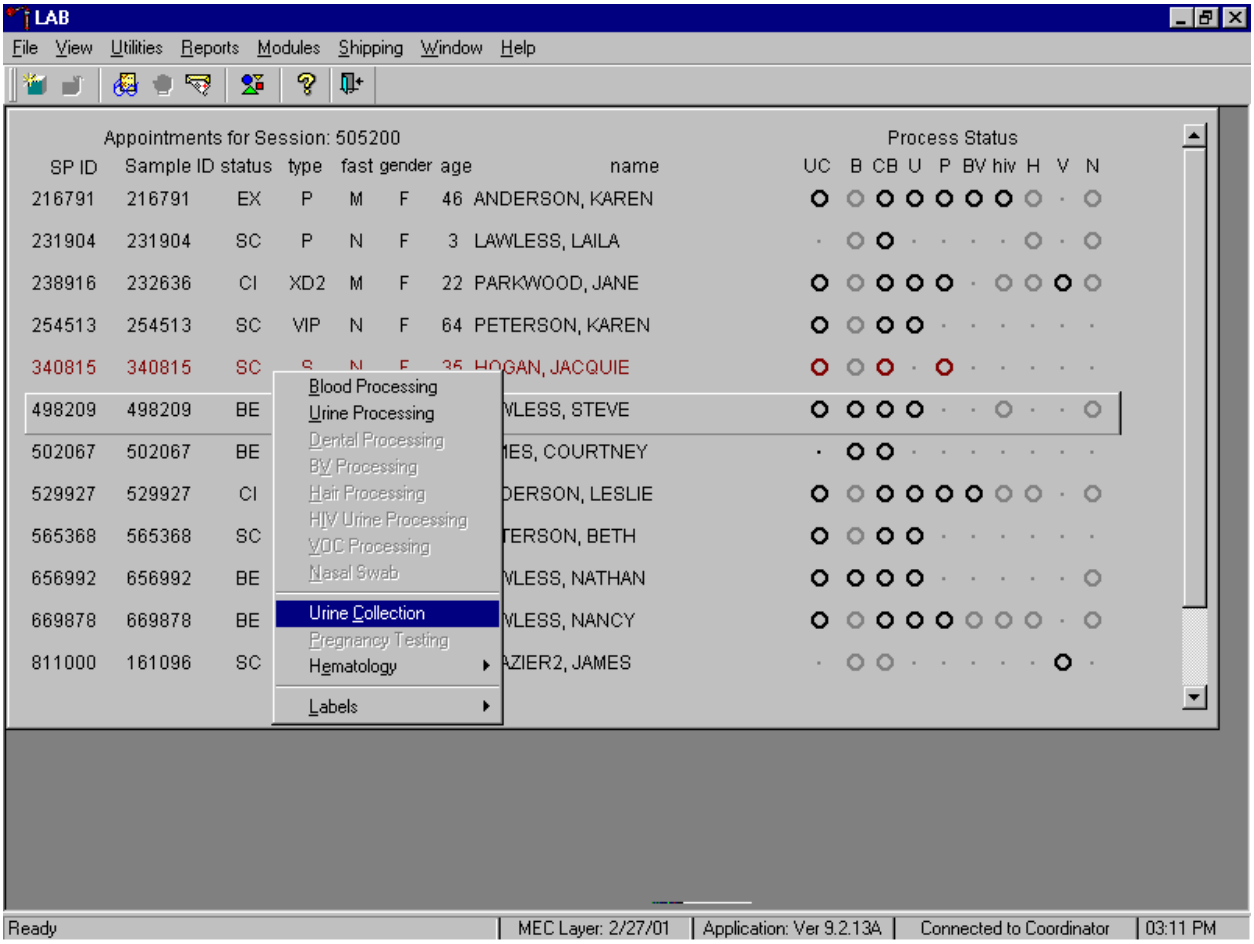
The heads-up display provides the Process Status for the following modules: UC (urine collection), B (blood processing), CB (complete blood count), U (urine processing), P (pregnancy testing), BV (bacterial vaginosis), hiv (HIV urine processing), H (hair), V (VOC), and N (nasal swab). The SP is ineligible 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 but

the process status is O until the SP's blood, hair, and nasal swab samples are recorded as collected. Once the sample is collected, the process status changes from O to **O**. 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 quantity of HIV serum is insufficient, the status changes from O to **O**. The process status 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 for urine collection. Select a different SP if active SP is not the SP of choice.

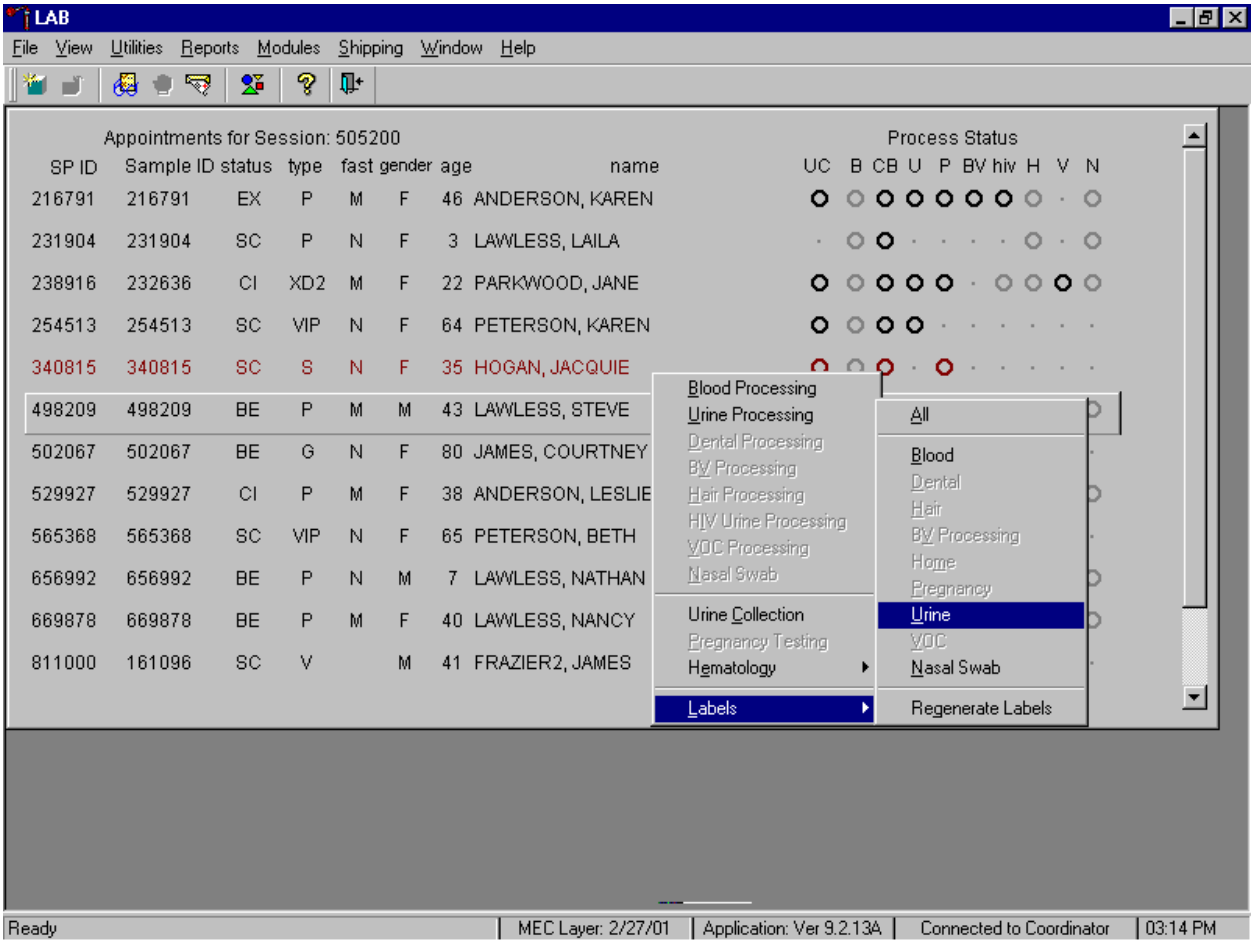
To view all SPs, the modules for which they are eligible, and their process status use the mouse to direct the mouse arrow to the vertical scroll bar, left click, and drag the bar up or down. Alternatively, to view all SPs use the mouse to direct the mouse arrow to the bottom of the heads-up display,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

Select the correct SP and access the Urine Collection module.



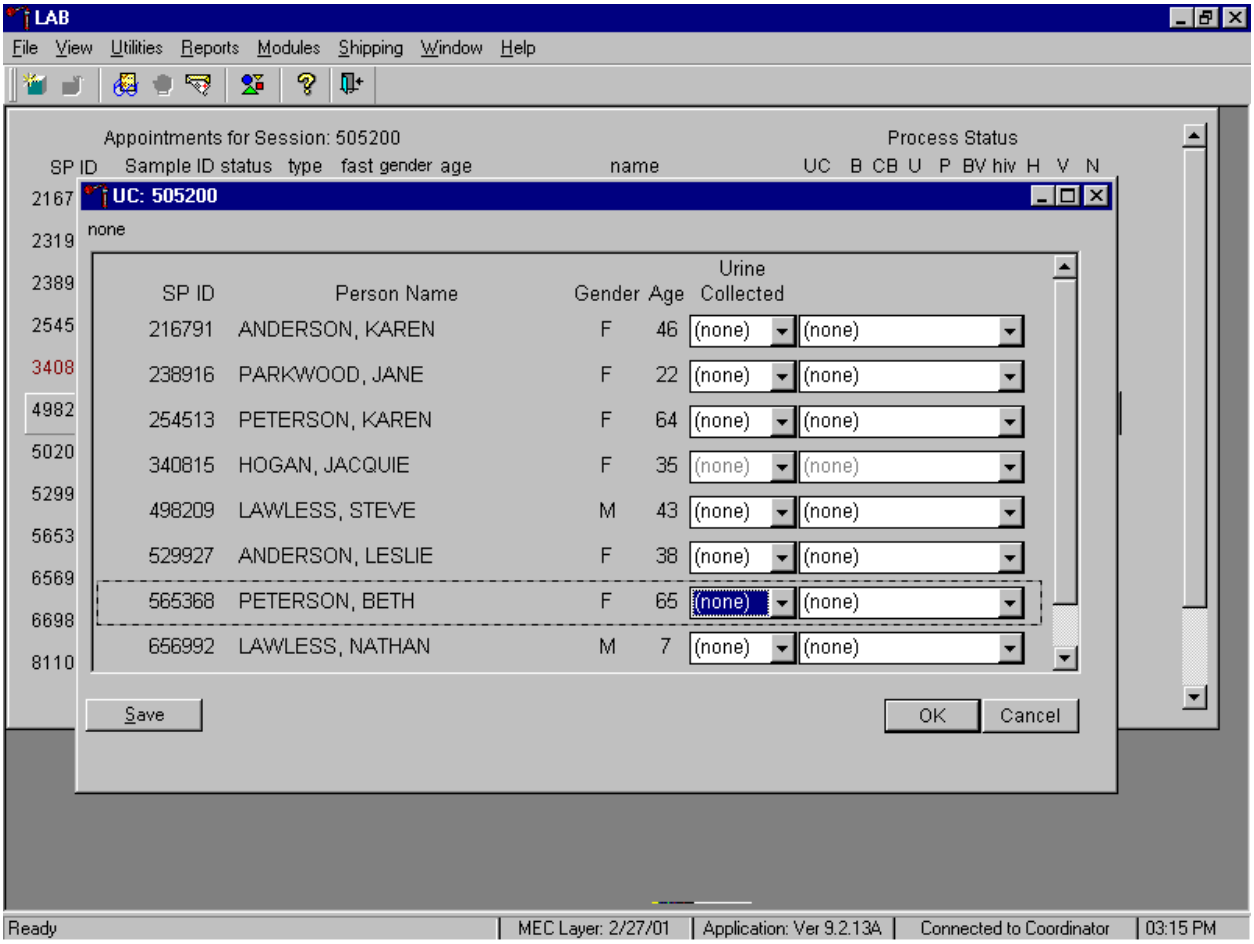
To select a SP, use the up and down keys to move up and down the list until the correct SP is highlighted or drag the mouse arrow to the correct SP and right click. To access the Urine Collection module, drag the mouse arrow to {Urine Collection} and left click or left click and type [C/c].

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 {Urine} and right click or right click on the correct SP, and type [L/l][U/u]. Urine processing labels print for the SP in the Label/Ship area.

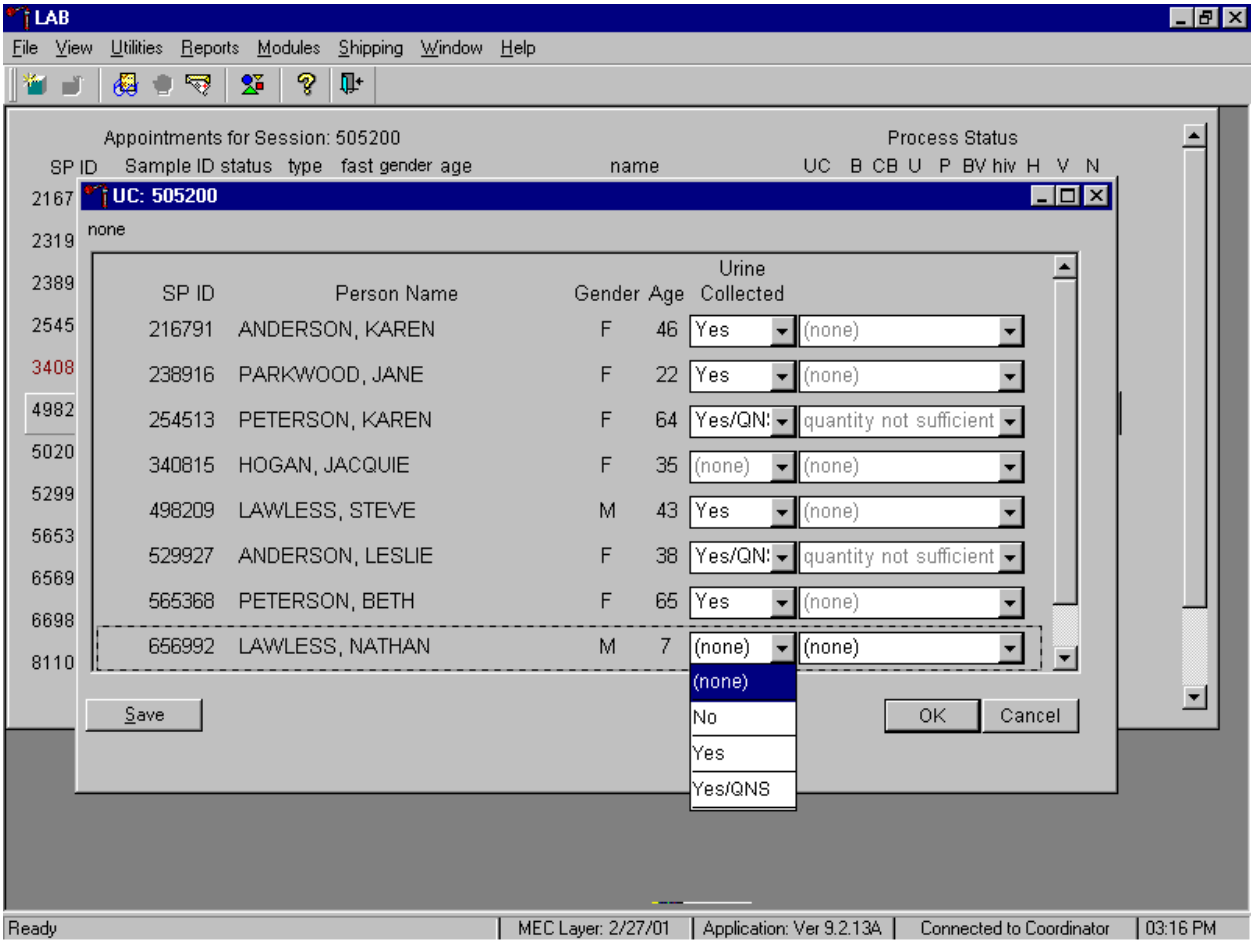
The urine collection window displays.



The urine collection window contains columns for the SP ID, Person Name (last, first), Gender, Age, Urine Collected, and Comment result fields. Only SPs who have checked into the MEC session are available for processing. 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 are 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. Use the gradations on the urine collection cup to estimate the amount of urine.

Record the urine collection result for each SP.

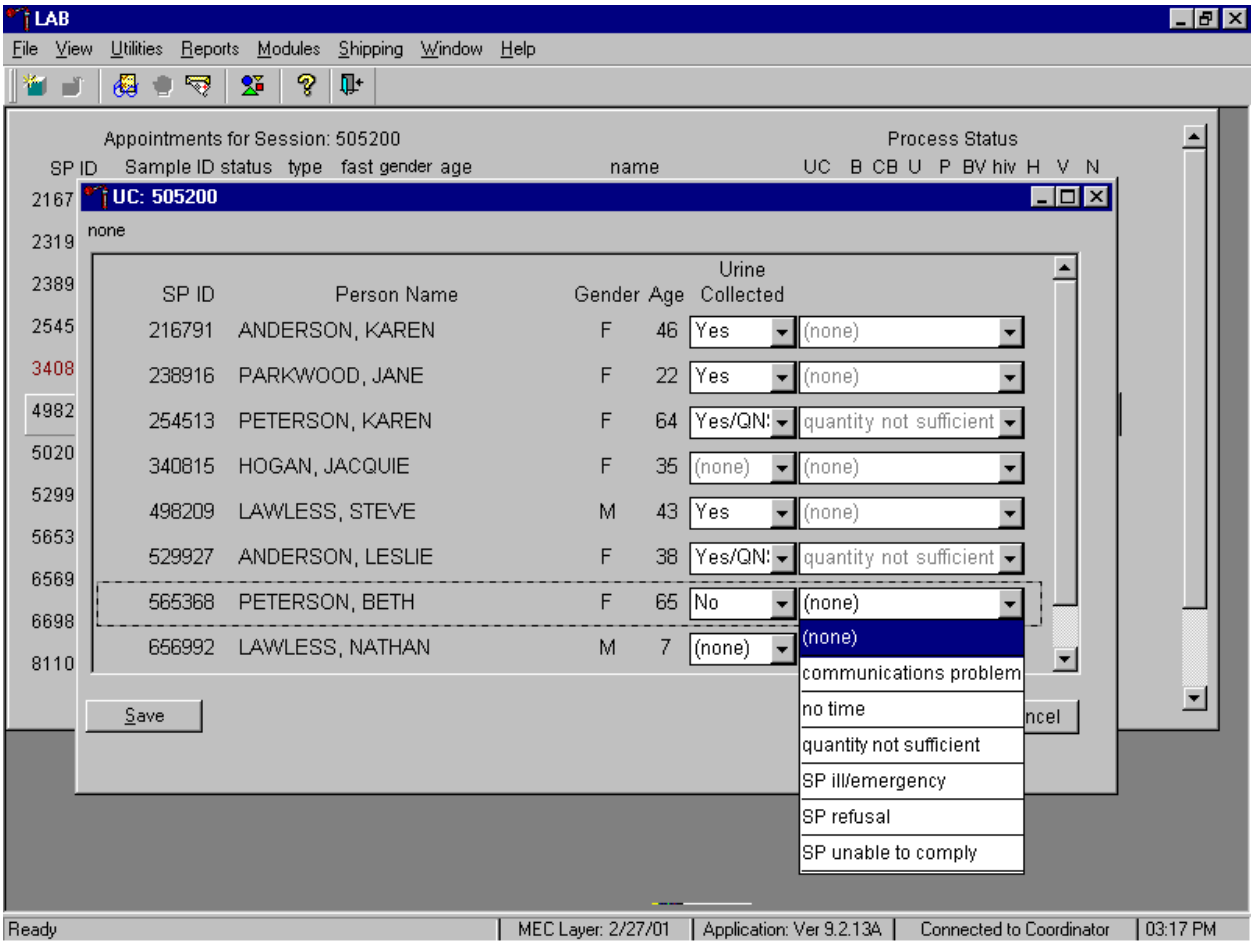


Record the urine collection result for each SP by typing [Y/y] for "Yes," [N/n] for "No," or [Y/y] a second time for "Yes/QNS." Alternatively, use the mouse to direct the mouse arrow to the drop-down list, left click to display the responses, drag the mouse arrow to "Yes," "No," or "Yes/QNS" and left 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.

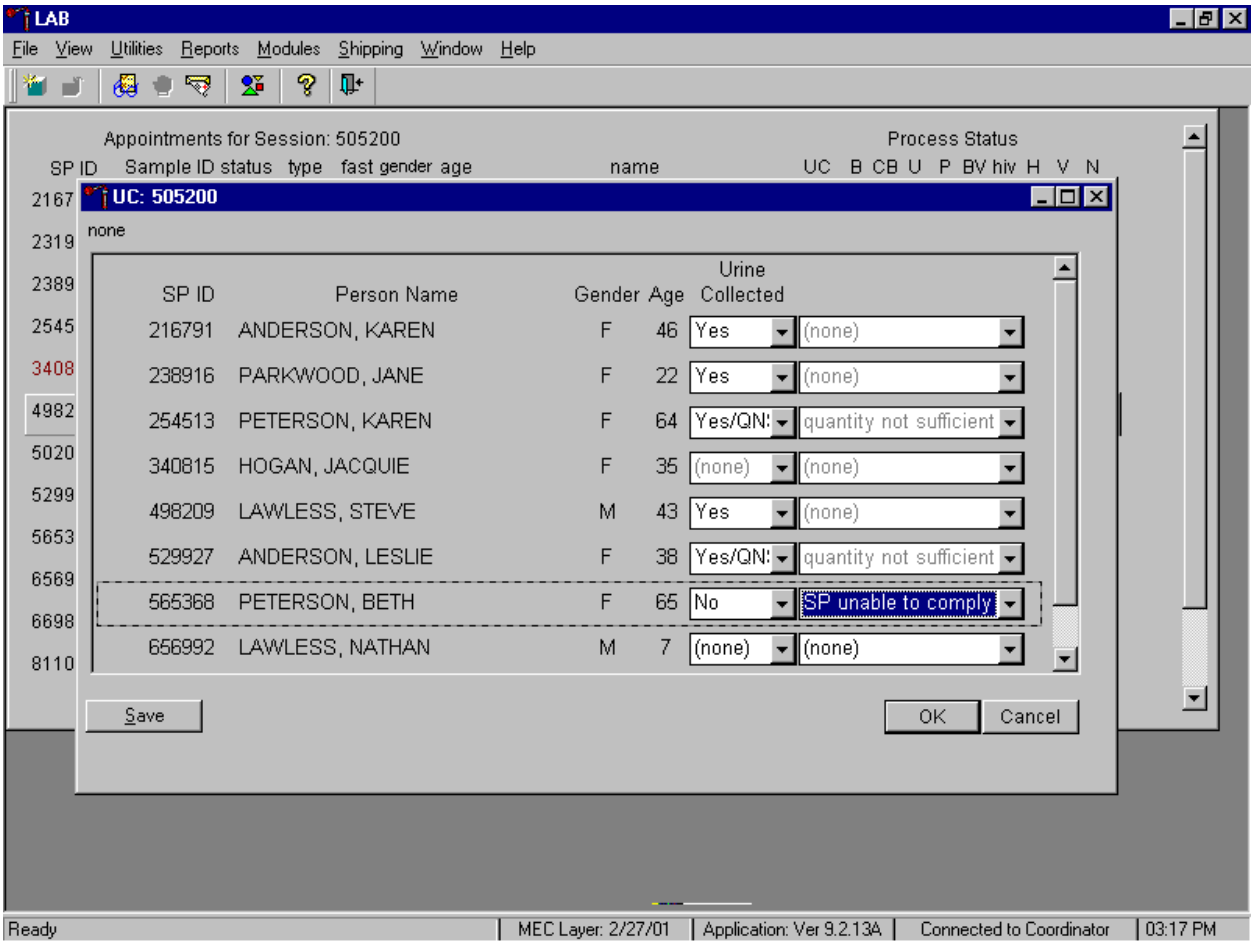
Record a coment for all insufficient urine collections.



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 X 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 all SPs 6+ years old
- Chlamydia/Gonorrhea (Chlam/GC) on SPs 14-39 years old
- NTX on SPs 8+ years old
- Urinary Iodine (Urn Iodine) on selected SPs 6+ years old
- Priority pesticide (Prior Pest) on selected SPs 6+ years old
- Organophosphates (Organophos) on selected SPs 6+ years old
- Urine Mercury (Urn Merc) on female SPs 16-49 years old
- Heavy Metal on selected SPs age 6+ years old
- Phytoestrogens (Urn Phytoes) on selected SPs age 6+ years old
- Polyaeromatic hydrocarbons (PAH) on selected SPs age 6+ years old
- Phthalates on selected SPs age 6+ years old
- Extra urine (Xtra Urine) on SPs age 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

Exhibit 5-2 summarizes the urine processing protocol for primary SPs. Process urine in priority order with vessel 45 filled first, 46 second, etc.

Exhibit 5-2. 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	4	5-mL Cryovial
47	NTX	8+	1	2-mL Cryovial
69	Urn Iodine	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	16-49 Females	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
51	Xtra Urine	6+	5	5 mL Cryovial
52	Xtra Urine	6+	5	5 mL Cryovial
53	HIV	18-49	3	5 mL Cryovial

Exhibit 5-3 summarizes the urine processing protocol for the VIP guest person type

Exhibit 5-3. NHANES urine processing protocol – VIP guest

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

Exhibit 5-4 summarizes the urine processing protocol for the second exam person type

Exhibit 5-4. NHANES urine processing protocol – second exam

Vessel No	Assay	Age in years	Sample size mL	Vessel
45	Alb/Creat	6+	3	5-mL Cryovial
47	NTX	8+	1	2-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, person 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.

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.

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 (or carefully pipette) 4-mL of the specimen for Chlam/GC into 5-mL vessel
47. Pour 1-mL of the specimen for NTX into 2-mL vessel
69. Pour 3-mL of the specimen for Urn Iodine 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

51. Pour 5-mL of the specimen for Xtra Urine into a 5-mL vessel

52. Pour 5-mL of the specimen for second 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)

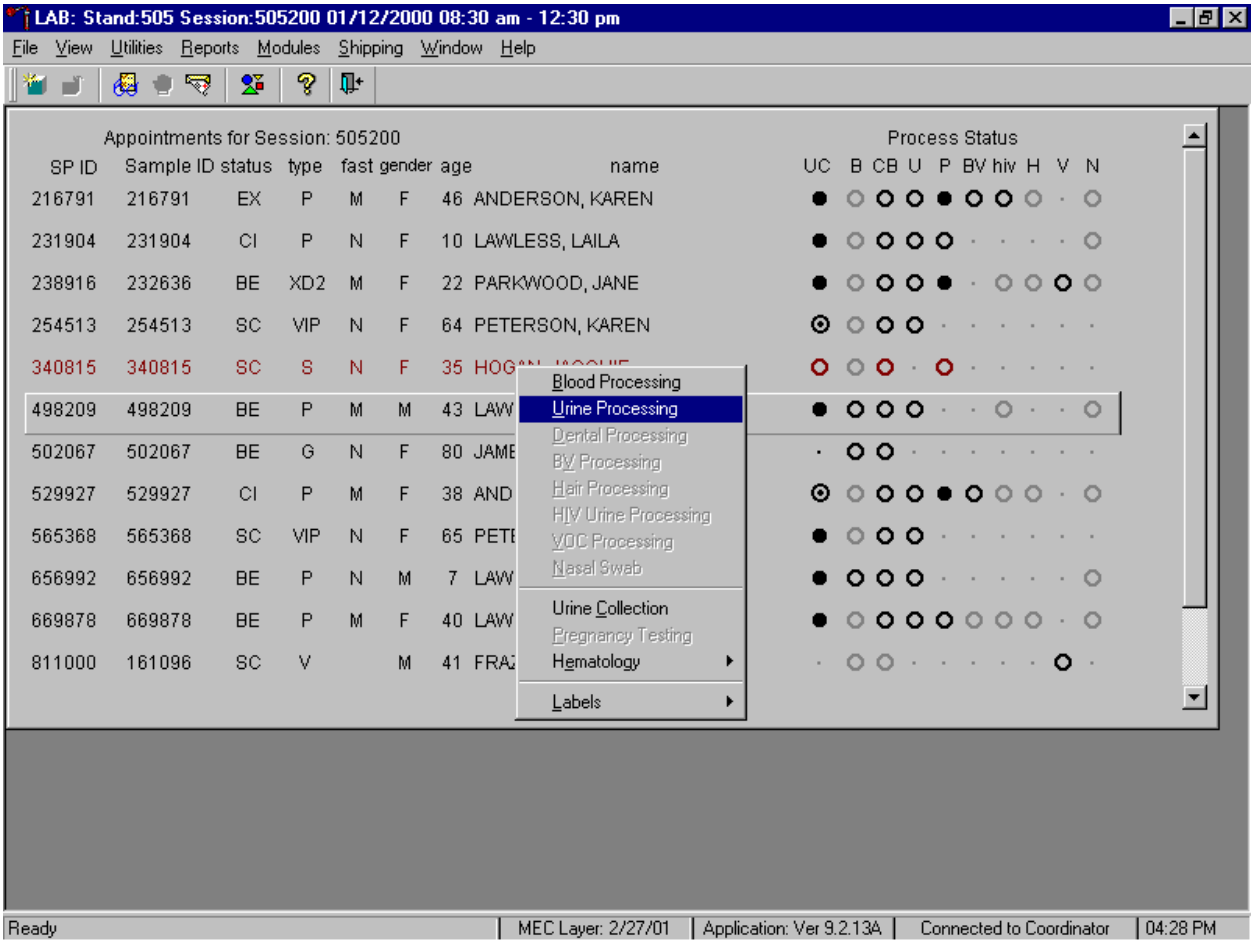
Discard any remaining urine specimen at the end of each session. Pour urine down the drain in the laboratory sink. Flush the sink with water. Discard urine cup in the biohazard trash.

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

5.8 Record the Results of Urine Specimen Processing

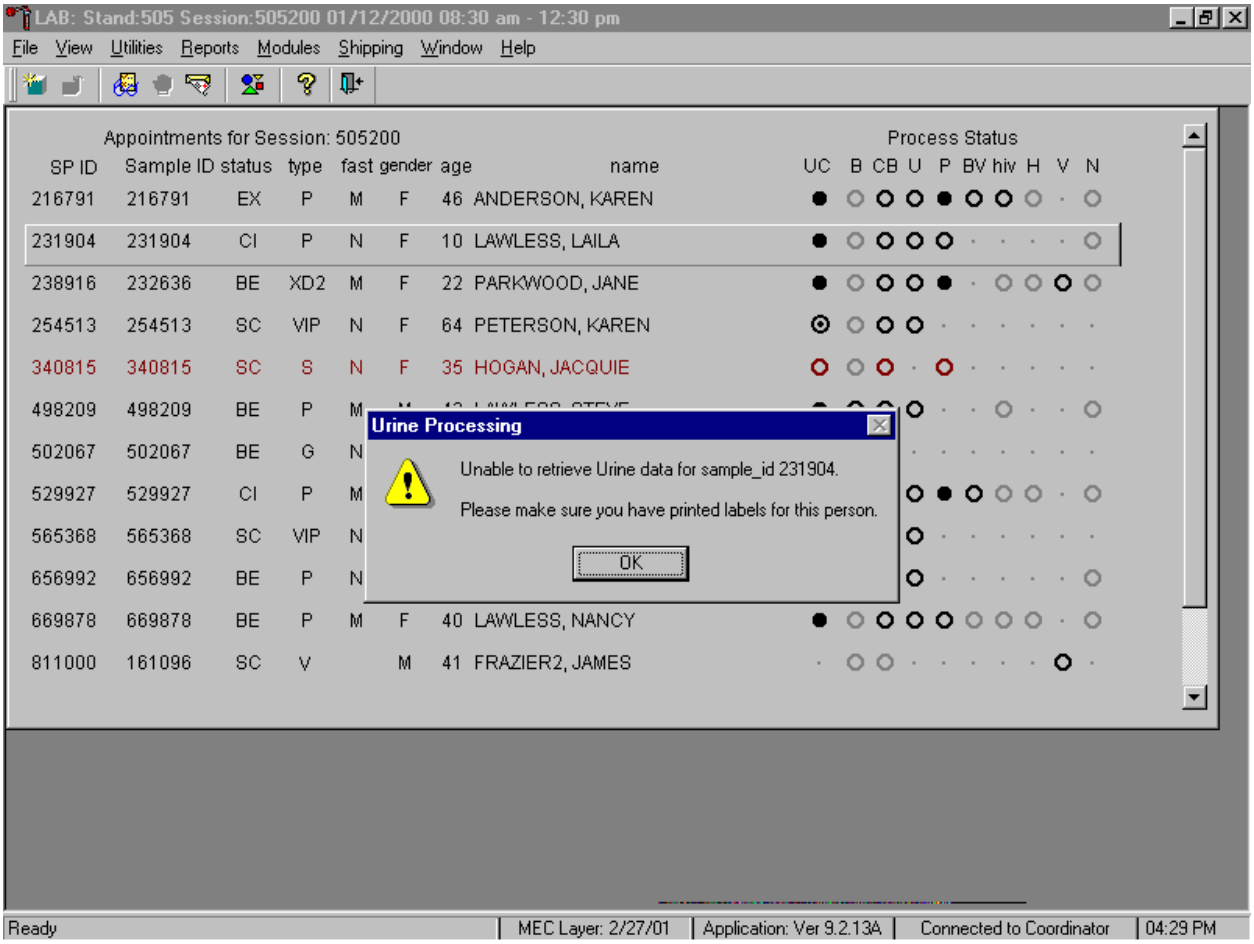
After filling the urine specimen vessels for each SP, use the Urine Processing module to enter the results of urine processing.

Access the Urine Processing module.



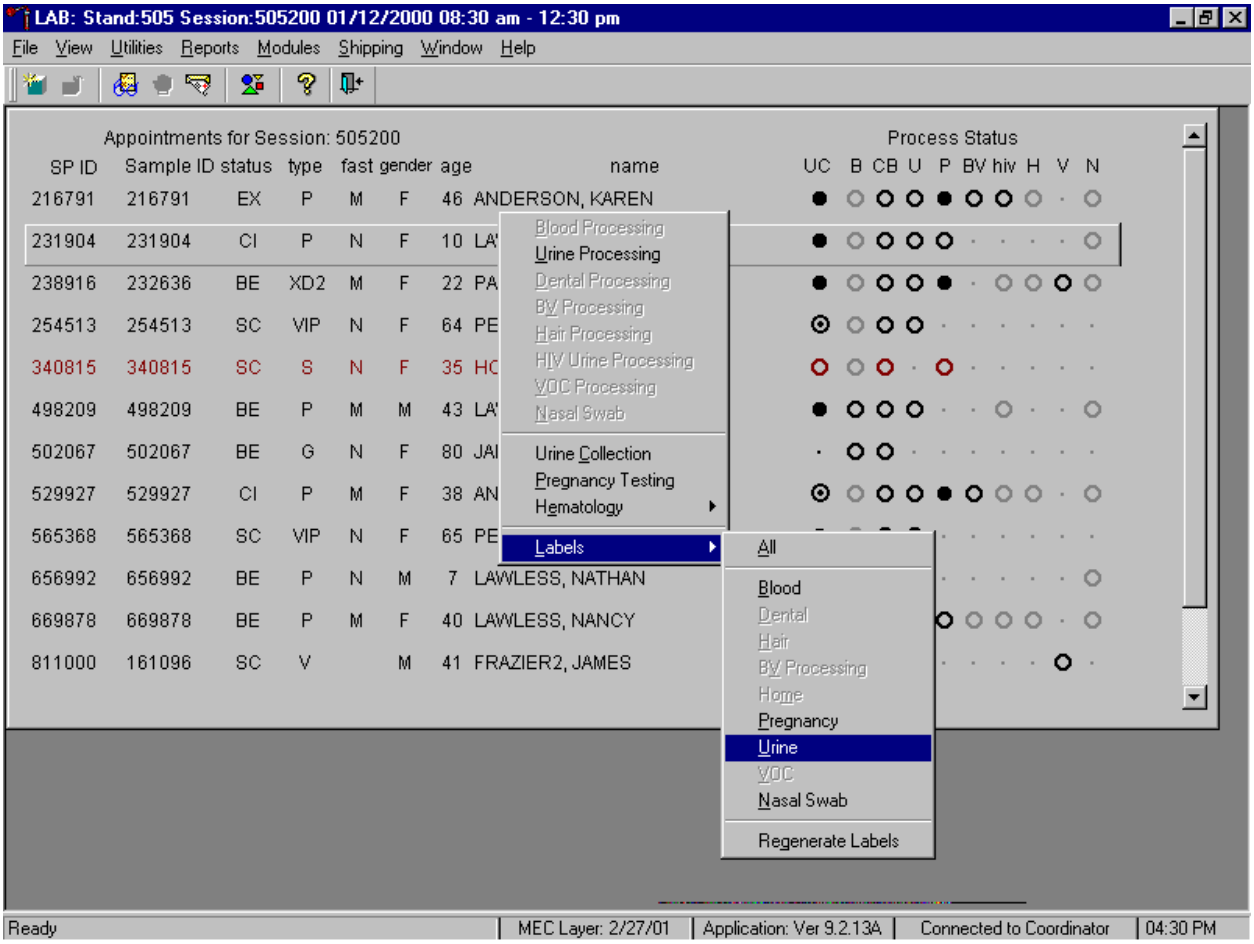
To access the Urine Processing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Urine Processing} and right click or right click and type [U/u]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted,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

If labels have not been printed in advance, a Urine Processing message box displays.



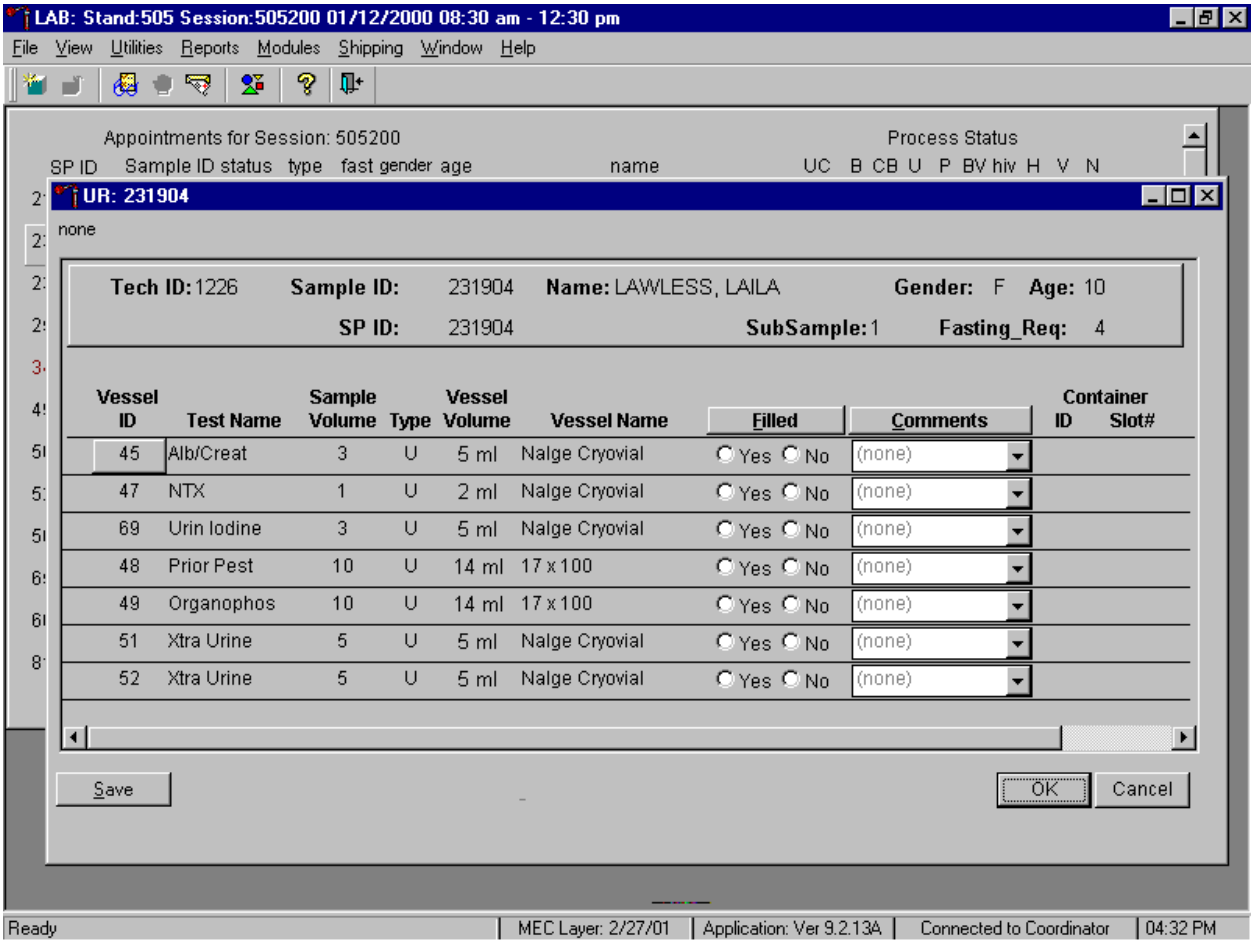
Urine processing cannot occur unless labels have been printed in advance. To remove the Urine Processing message box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. Print the labels for each SP.

Print labels for an individual SP using the heads-up display.



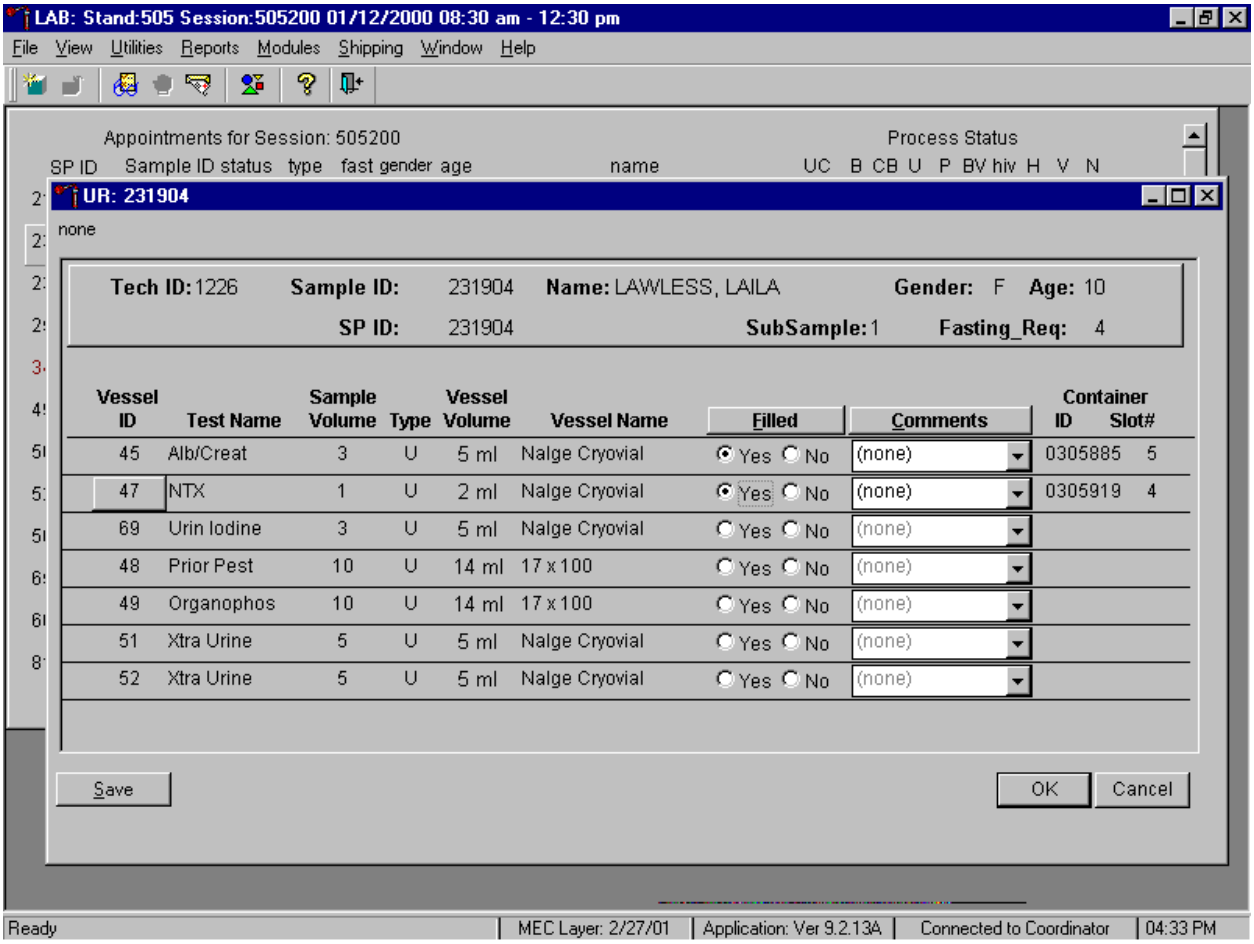
To print labels for a SP, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Labels}, then {Urine} and left click or left click and type [L/l] [U/u]. Labels print in the label/ship area. Continue processing urine on this SP.

The SP's urine processing window displays.



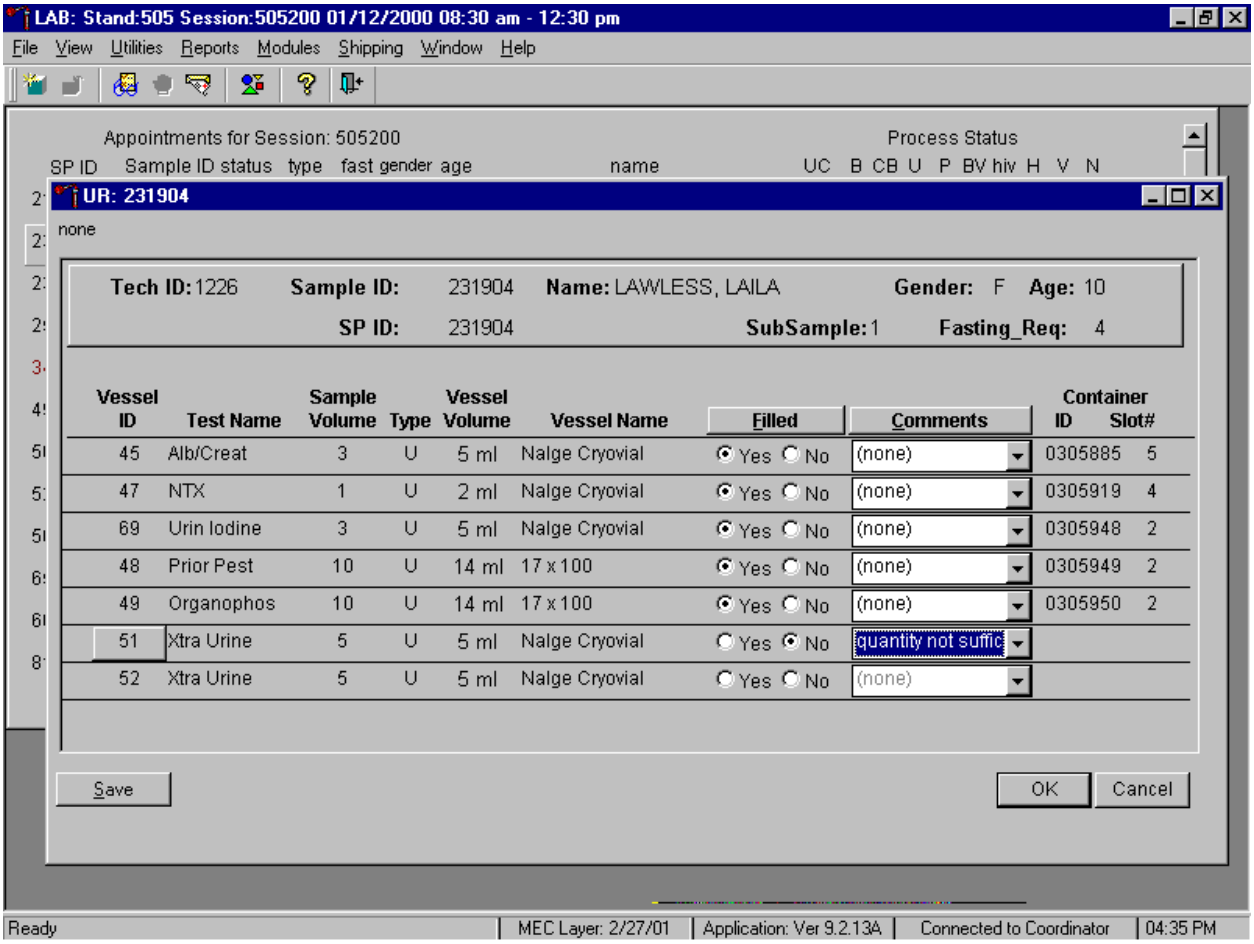
The urine processing window for a SP contains the following information: Tech ID, Sample ID, SP ID, Name (last, first), Gender, Age, SubSample, Fasting_Req, columns for Vessel ID, Test Name, Sample Volume, Type, Vessel Volume, Vessel Name, Container ID/Slot #, and Filled and Comments buttons.

Individually mark each vessel as Filled - “Yes.”



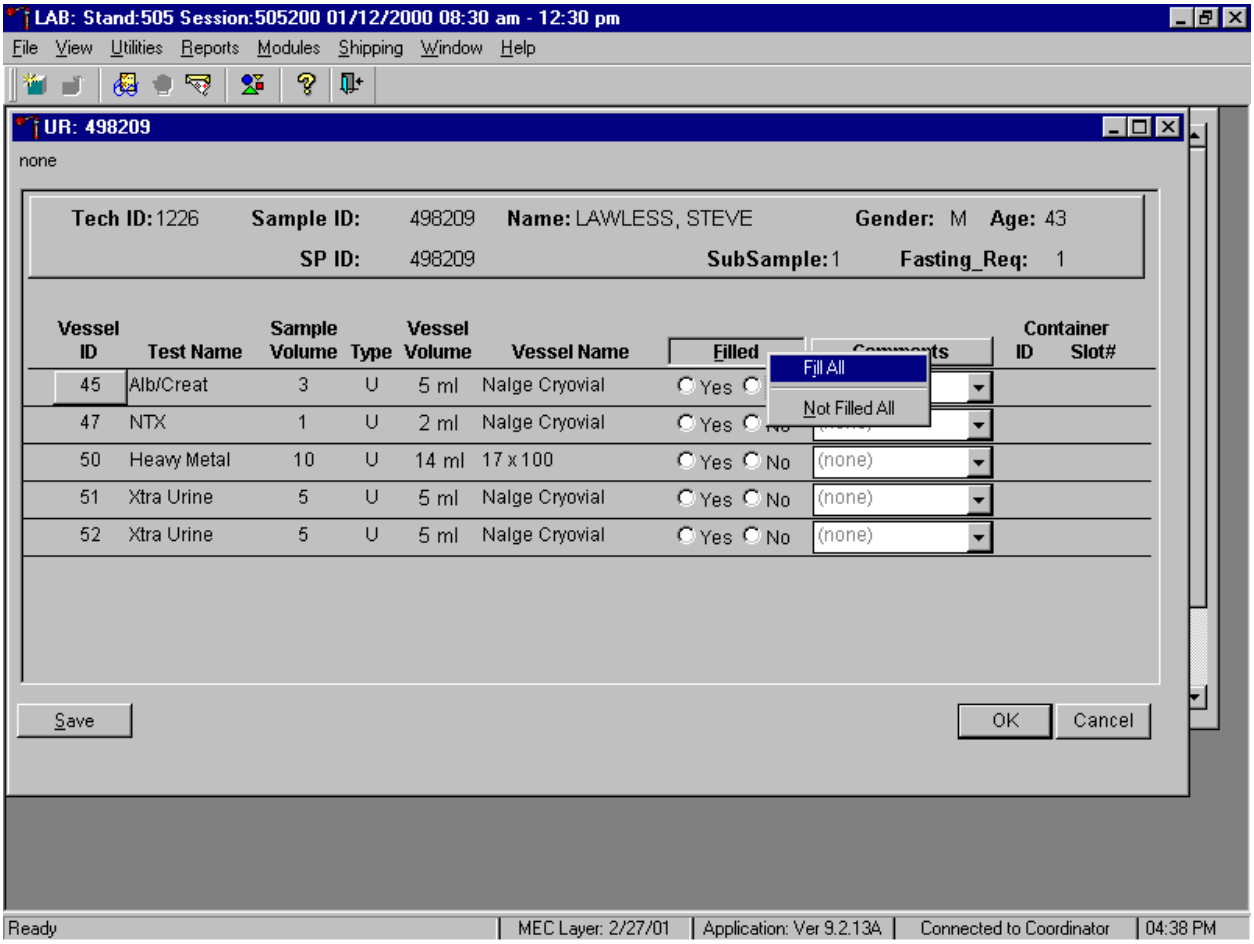
To mark an individual urine vessel as collected or Filled – “Yes” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As each vessel is marked as Filled – “Yes,” it is automatically assigned to a slot in an existing (open) container.

Individually mark each vessel as Filled - “No.”



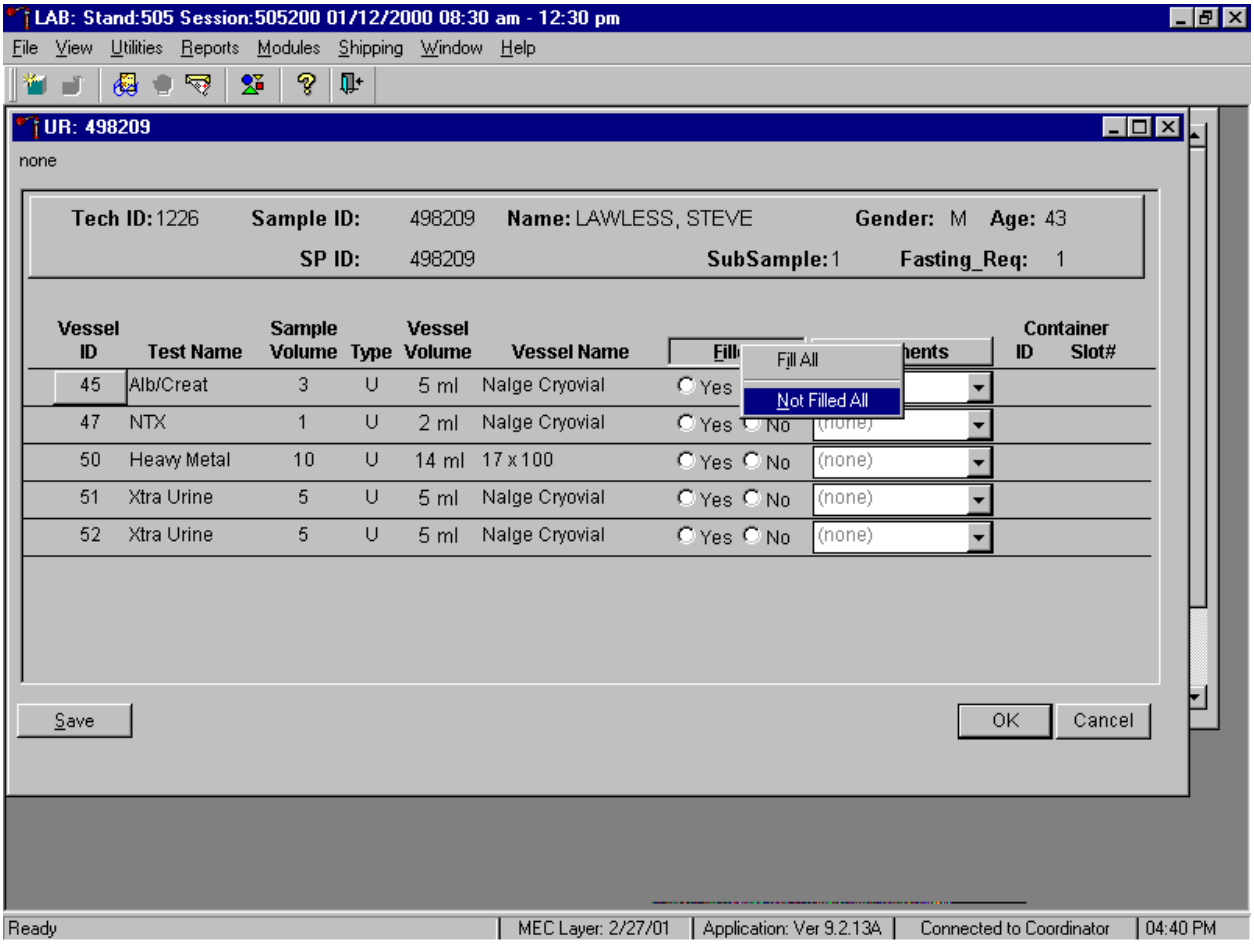
To mark an individual urine vessel as not collected or Filled - “No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. As each vessel is marked as Filled “No,” the comment, “quantity not sufficient” is automatically entered in the Comments column.

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.”

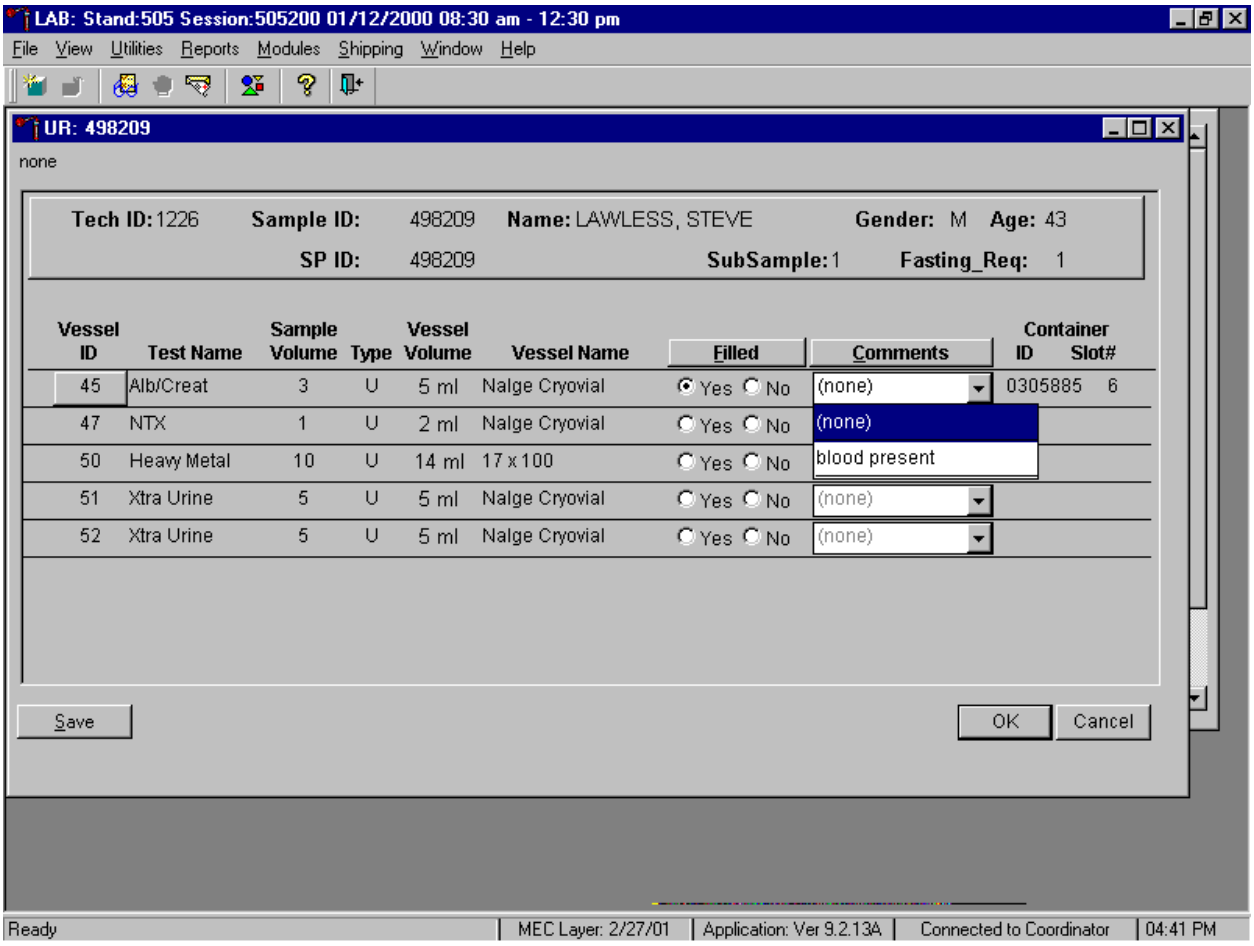


To mark all vessels as Filled - “No”, use the mouse to direct the mouse arrow to the Filled box, left click, drag the mouse arrow to {Not Filled All} and left click or type [Shift] [F/f], [N/n.]

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

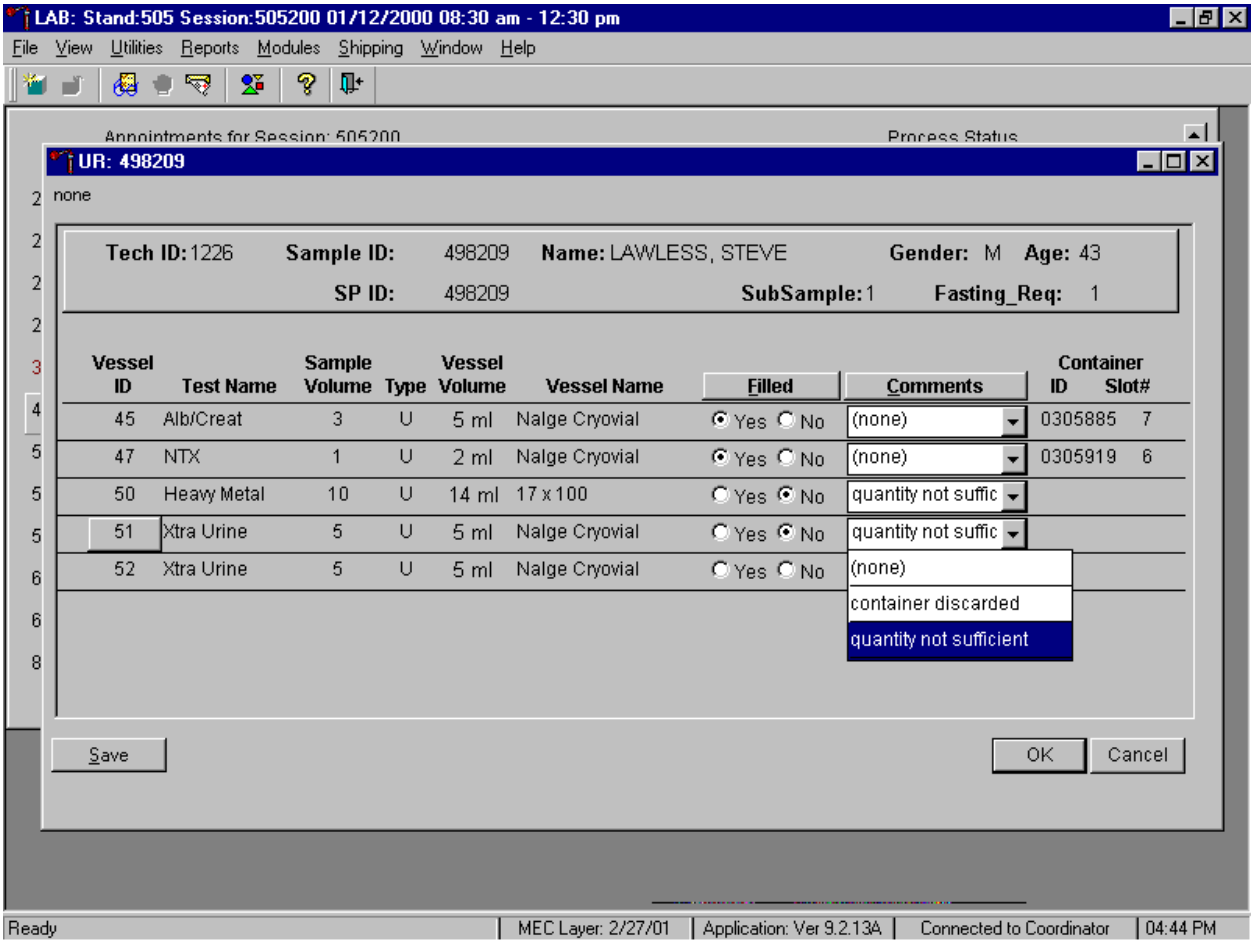
Comment Code	Use when:
Blood present	Blood is visible in the specimen.

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



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.

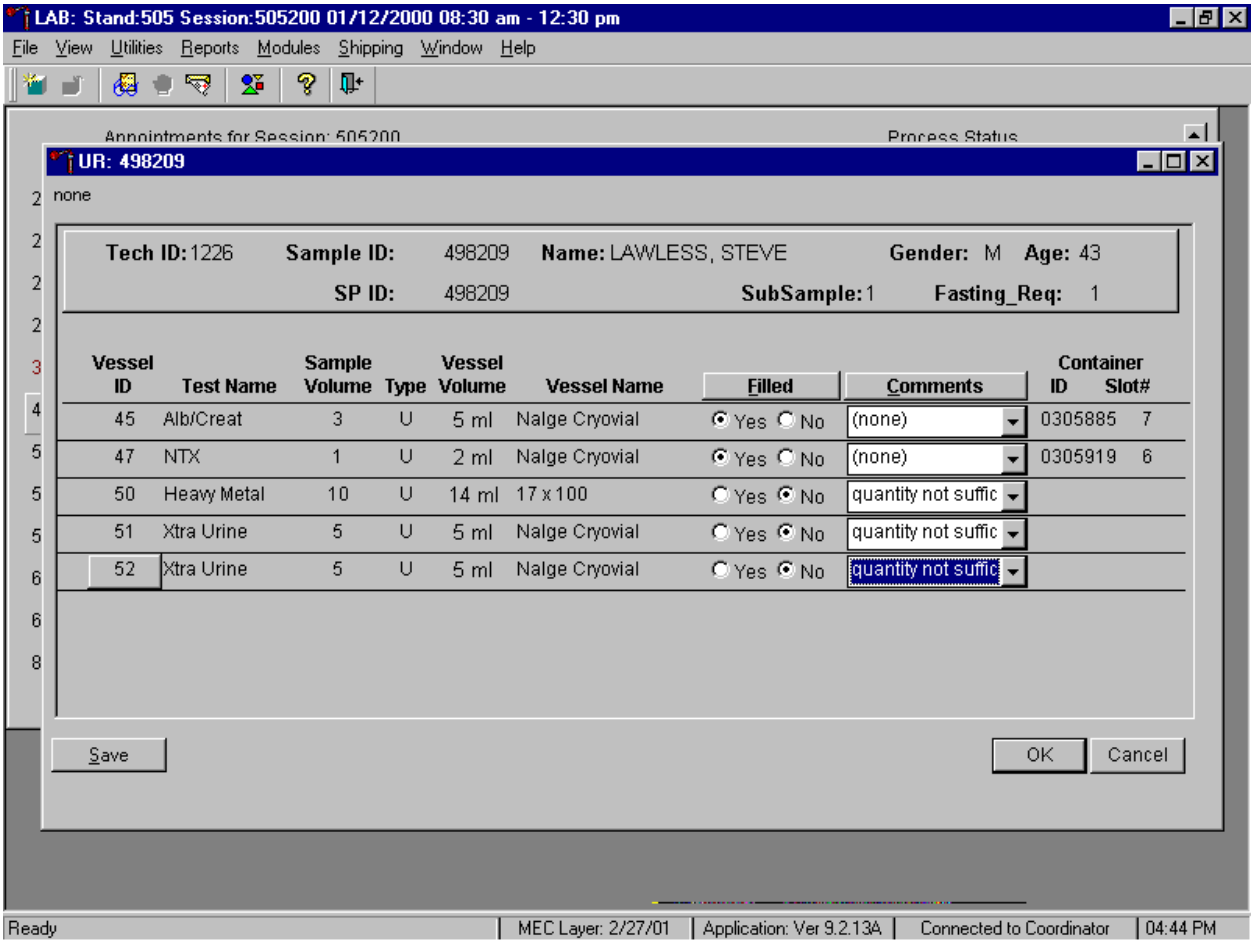
If a vessel is marked as Filled – "No," the comment "quantity not sufficient" is automatically entered. Review the comment for all insufficient urine collections.



Comment Code	Use when:
container discarded	Not applicable
quantity not sufficient	The amount of urine received in the lab is insufficient to fill this vessel

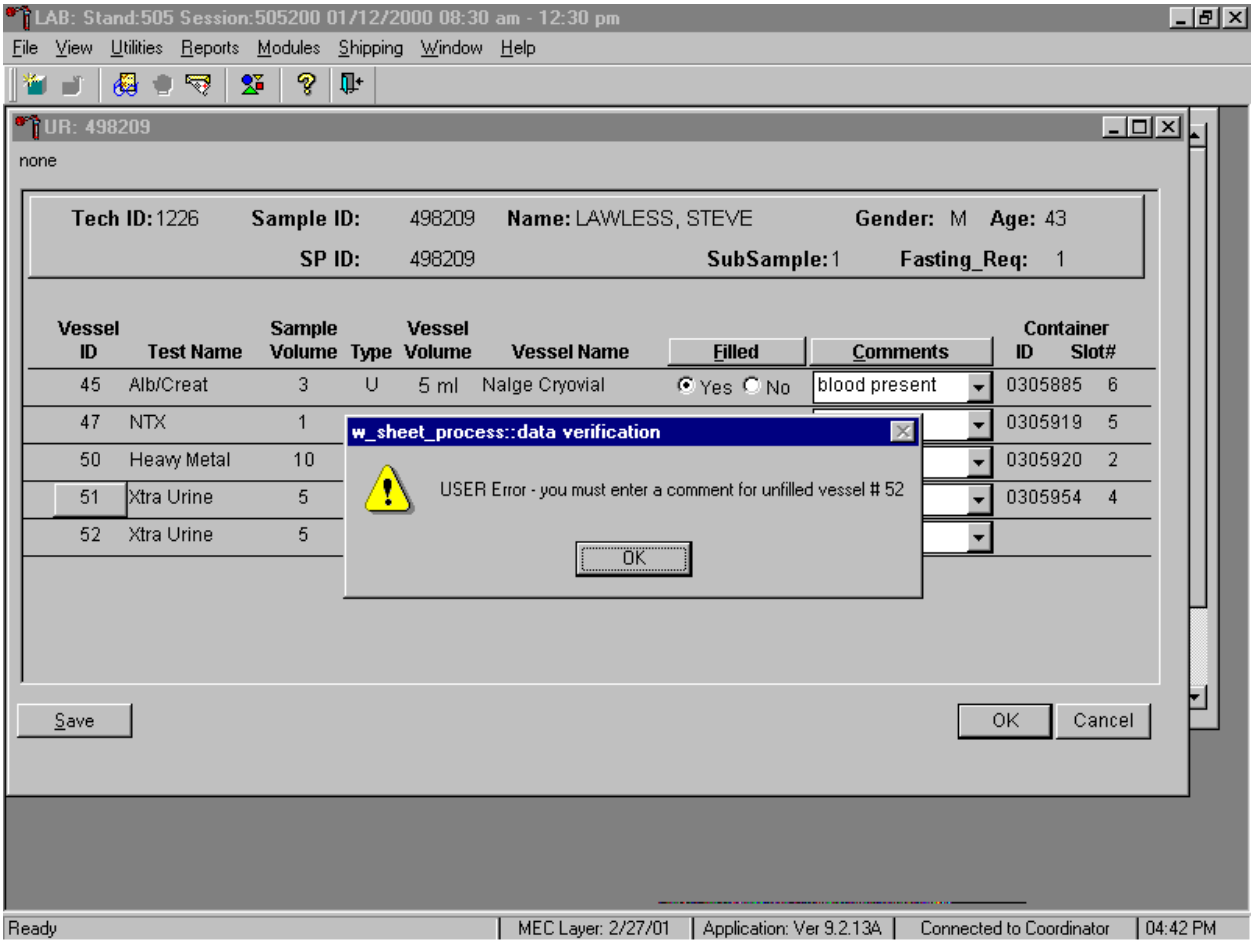
Continue recording and updating urine collection results as specimens are delivered to the laboratory.

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



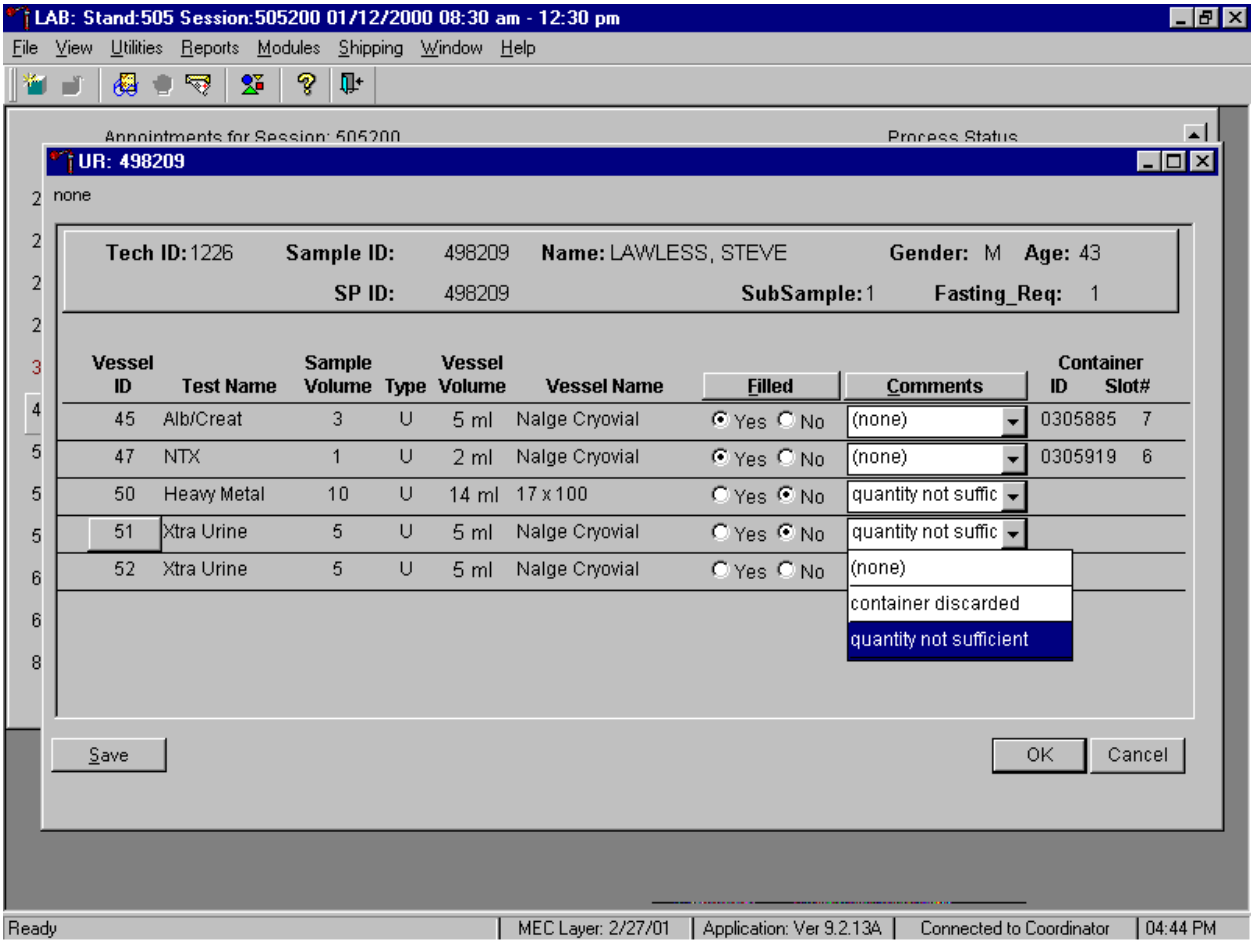
Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse 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.

All vessels marked as Filled – "No" require 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. Enter a comment for all unfilled vessels and save the result.

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



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

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 addition 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 Exhibit 5-5.

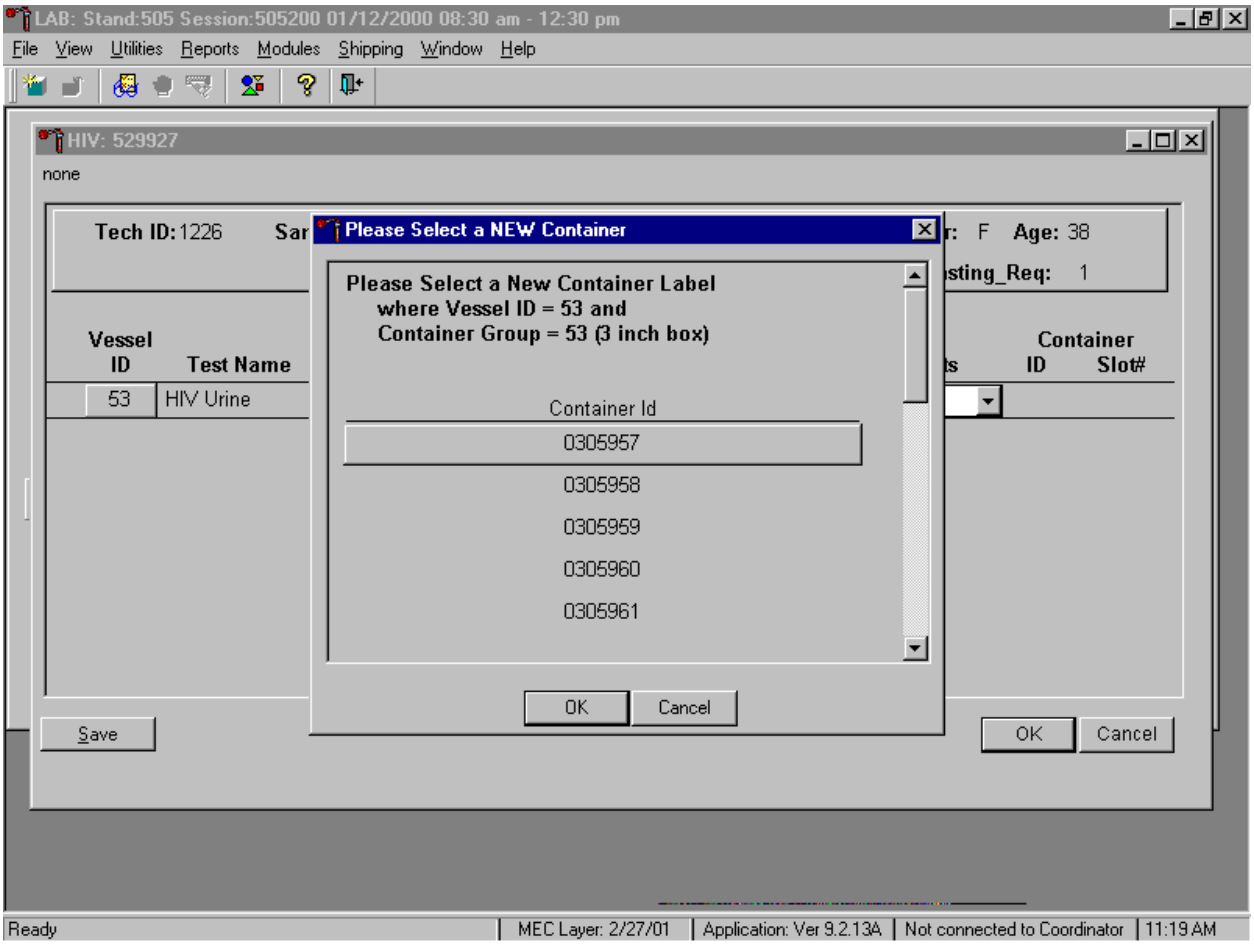
At the beginning of each stand, generate and print a series of bar coded, numbered labels for storage containers as described in Chapter 9. Use the shipping module to assign a bar code label to a specific storage container (test). This process "opens" a storage box. Each vessel is assigned to a specific 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.

Exhibit 5-5. Storage protocol for urine

Shipping Location	Vessels	Conditions	Vessel Storage
University of Minnesota	45 Alb/Creat	Frozen	9 x 9 three inch box
CDC,NCID NCHSTD	46 Chlam/GC	Frozen	9 x 9 three inch box
University of Washington	47 NTX	Frozen	9 x 9 two inch box
CASPIR	69 Urn Iodine	Frozen	9 x 9 three inch box
CDC/Dr. Dana Barr	48 Prior Pest	Frozen	5 x 5 three inch box
CDC/Dr. Dana Barr	49 Organophos	Frozen	5 x 5 three inch box
CASPIR	62 Urn Merc	Frozen	5 x 5 three inch box
CASPIR	50 Heavy Metal	Frozen	5 x 5 three inch box
CDC/Dr. Dana Barr	65 Urn Phytoes	Frozen	9 x 9 three inch box
CASPIR/Dr. James Grainger	66 PAH	Frozen	9 x 9 three inch box
CDC/Dr. John Brock	67 Phthalates	Frozen	9 x 9 three inch box
CASPIR	51 & 52 Xtra Urine	Frozen	9 x 9 three inch box

5.10.1 Opening New Containers

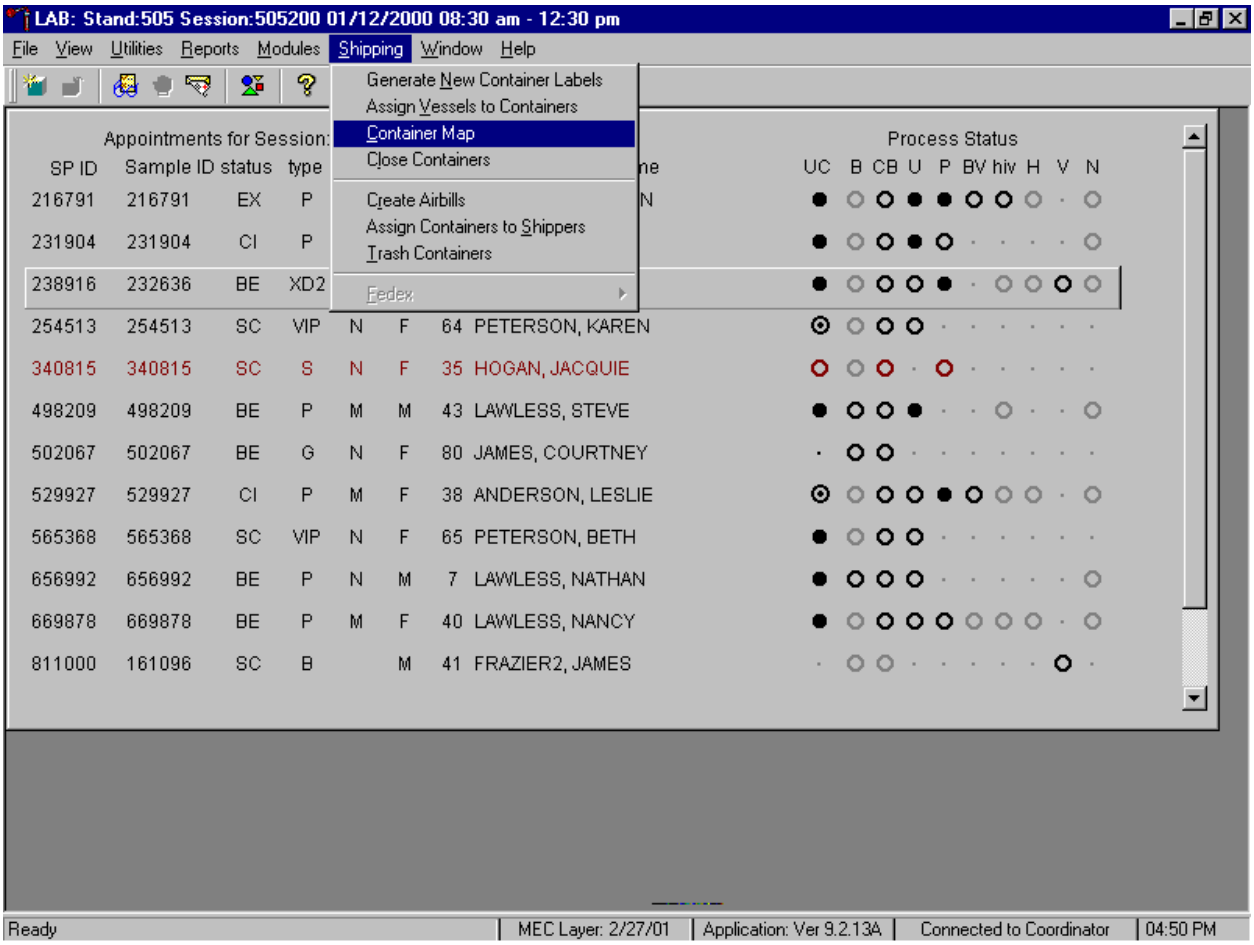
When a container is full, the container will automatically "close." Open a new container when prompted.



When a container is full, an opportunity to open a new container is automatically displayed on the "Please Select a NEW Container" window. The next available container ID is assigned to the new container. To accept this assignment, use the mouse to direct the mouse arrow to the OK button and left click or type [Enter]. To exit the screen without opening a new container or to cancel the action, use the mouse to direct the mouse arrow to the Cancel button and left click.

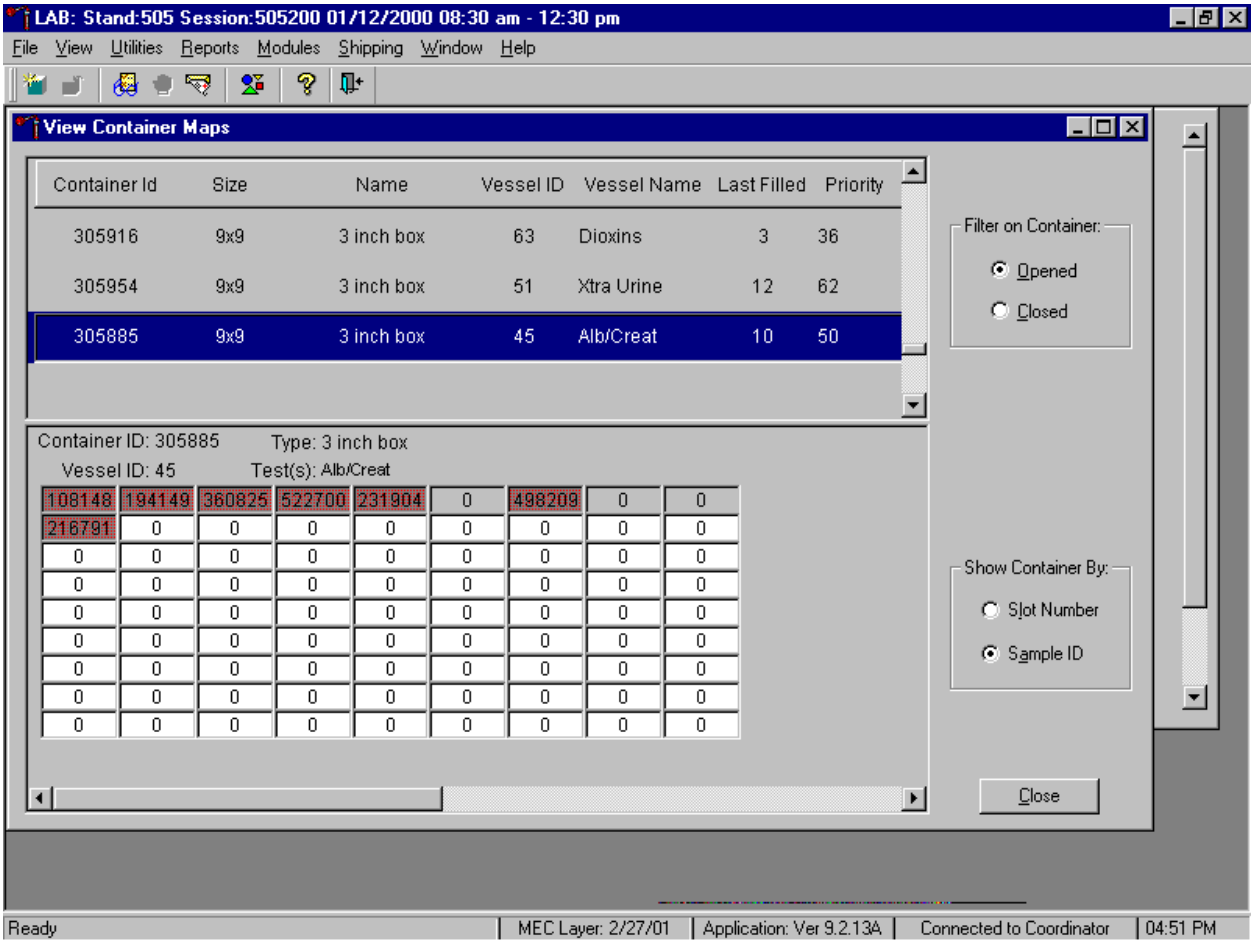
5.10.2 Check Storage Containers

Check the slot assignment of containers associated with vessels 45-51, 62, 65-67, and 69 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.

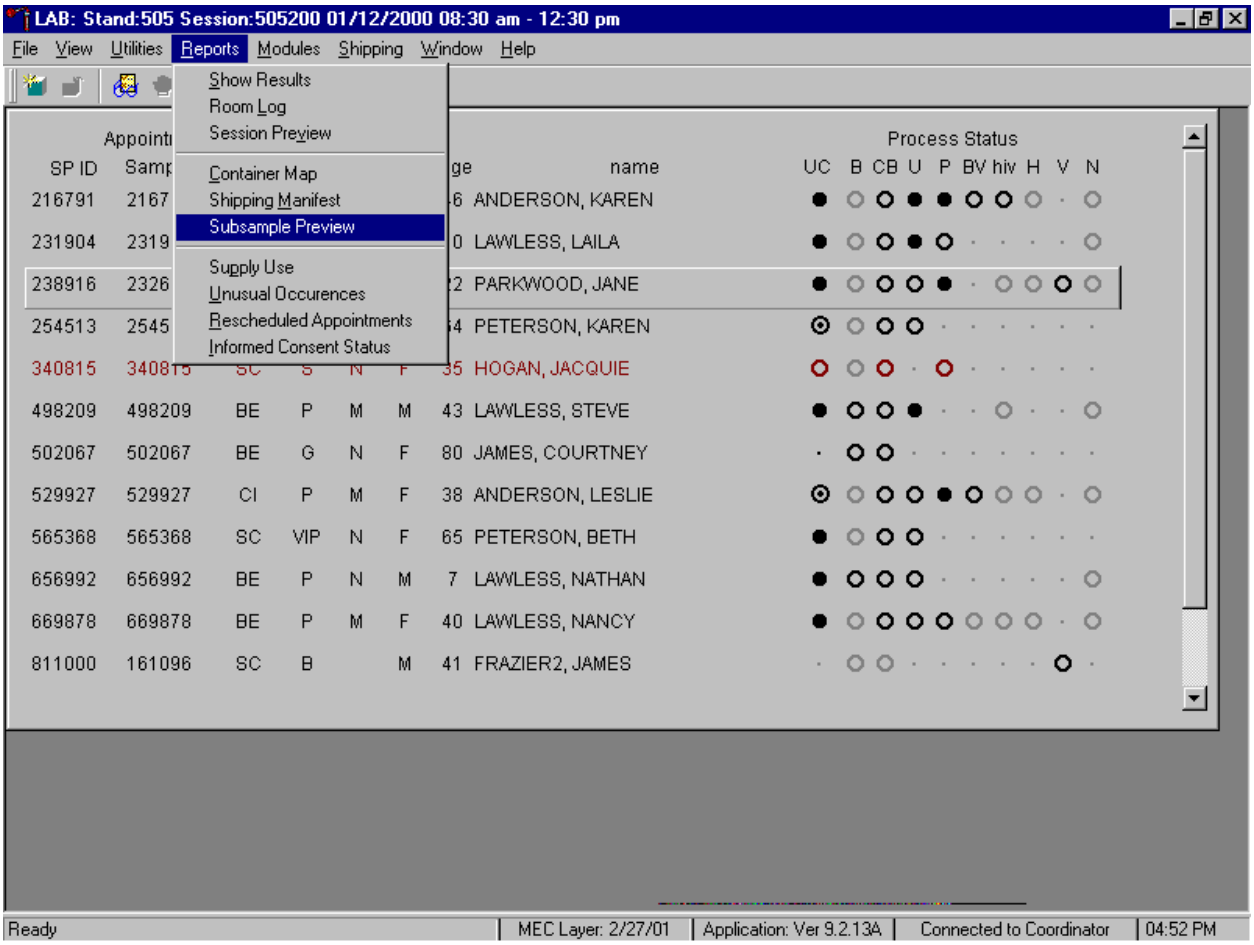


- Set the Filter on Container to “Opened” by using the mouse to direct the mouse arrow to “Opened” and left click.
- Set the Show Container By to “Sample ID” by using the mouse to direct the mouse arrow to “Sample ID” and left click.
- Highlight or select the first container ID for vessel 45 by using 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 Vessel ID 45.
- 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.
- Place a black mark with a waterproof marker on the last vessel. When subsequently checking the Container Map Report for this container, begin checking at the first filled slot after the black mark.
- Continue checking each container map report for all remaining urine containers.

- To exit the Container Map report, use the mouse to direct the mouse arrow to the Close button and left click.

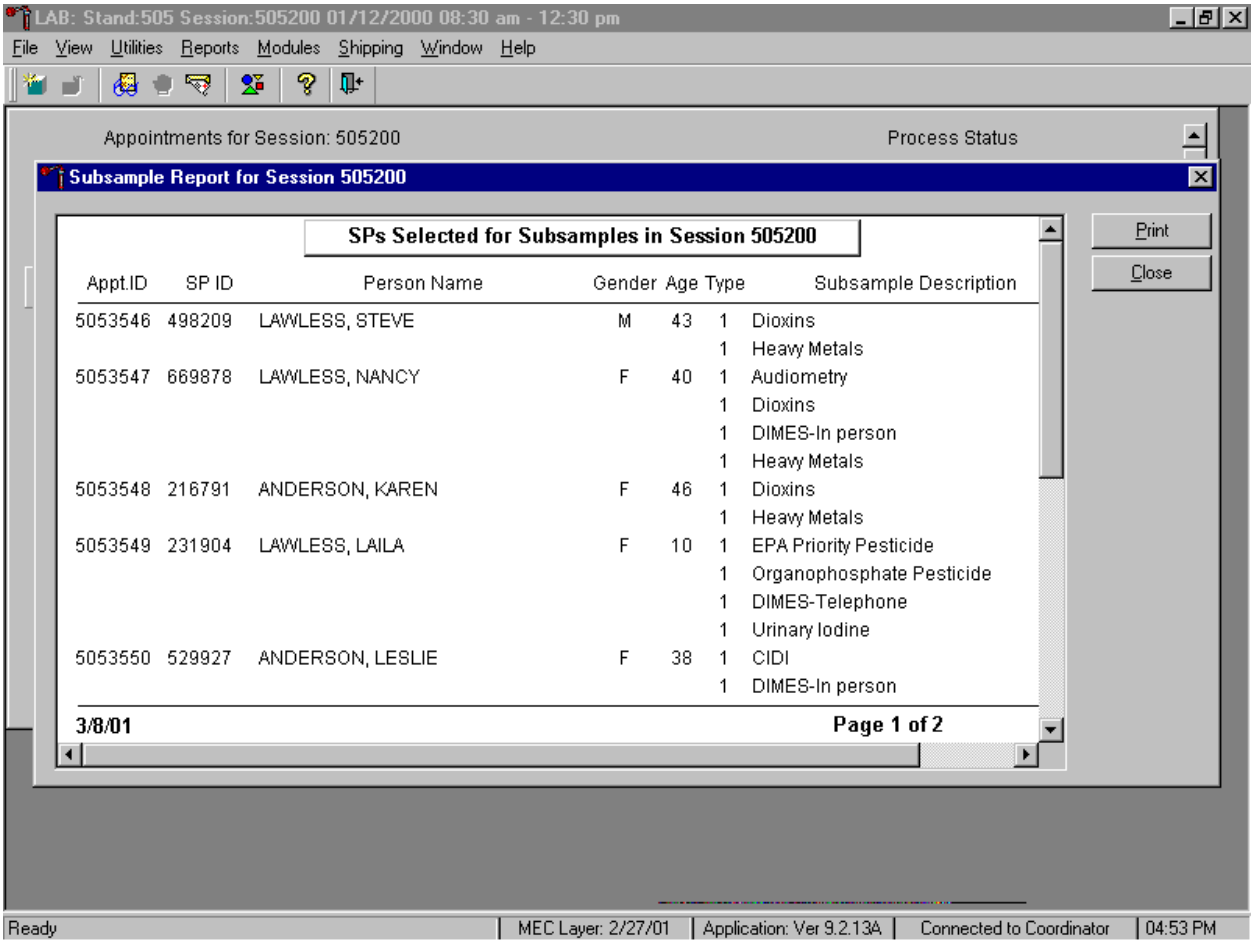
5.11 Subsample and Session Previews

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



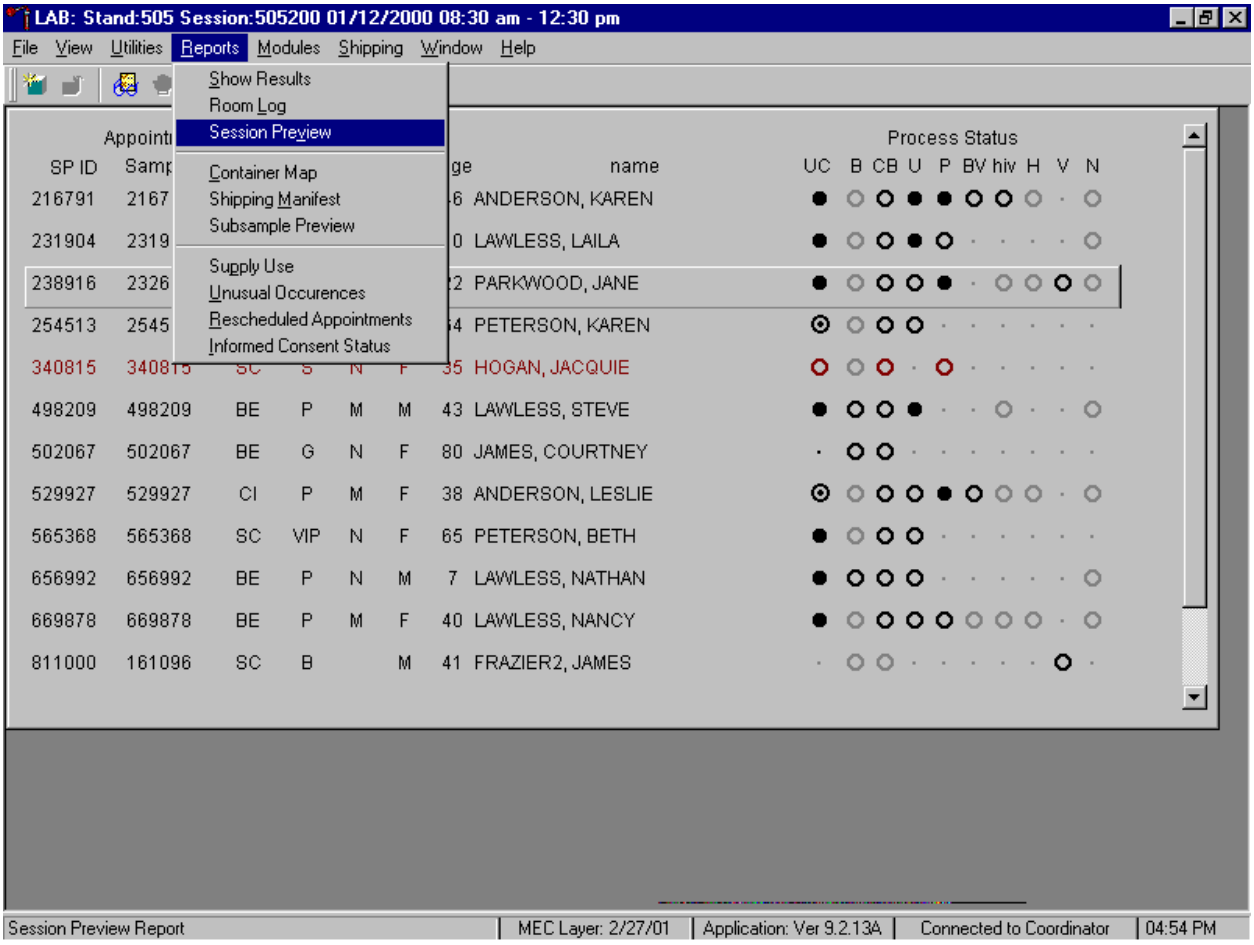
To access the Subsample Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Subsample Preview}, and left click.

Review the Subsample Preview.



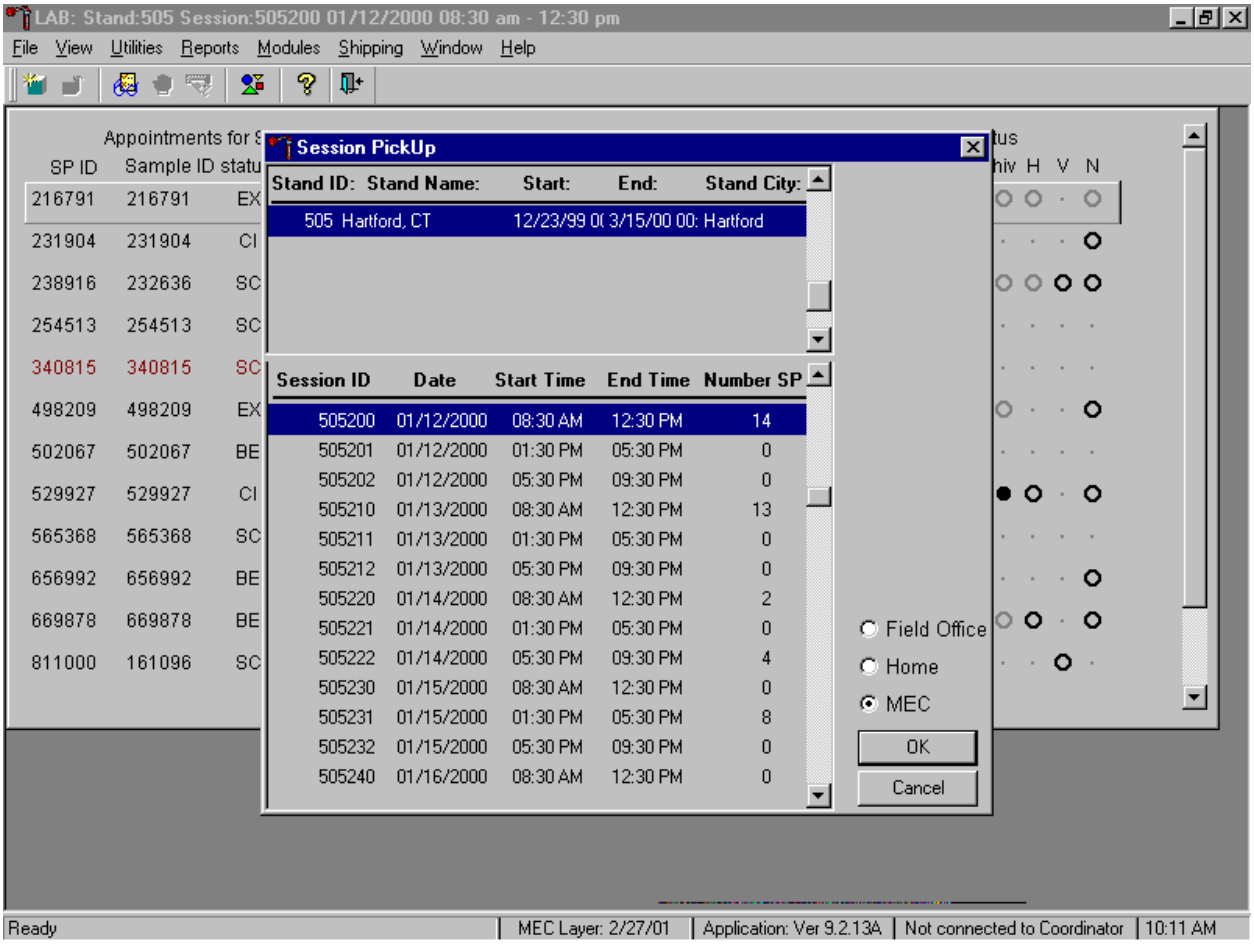
The Subsample Preview report includes all SPs assigned to the current session and the subsamples for which they are eligible. This report contains the appointment ID, SP ID, person name, gender, age, person type, and subsample description. Only SPs selected for inclusion in specific subsamples are eligible 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.

Access the Session Preview report to view all SPs scheduled into any session including the current session.



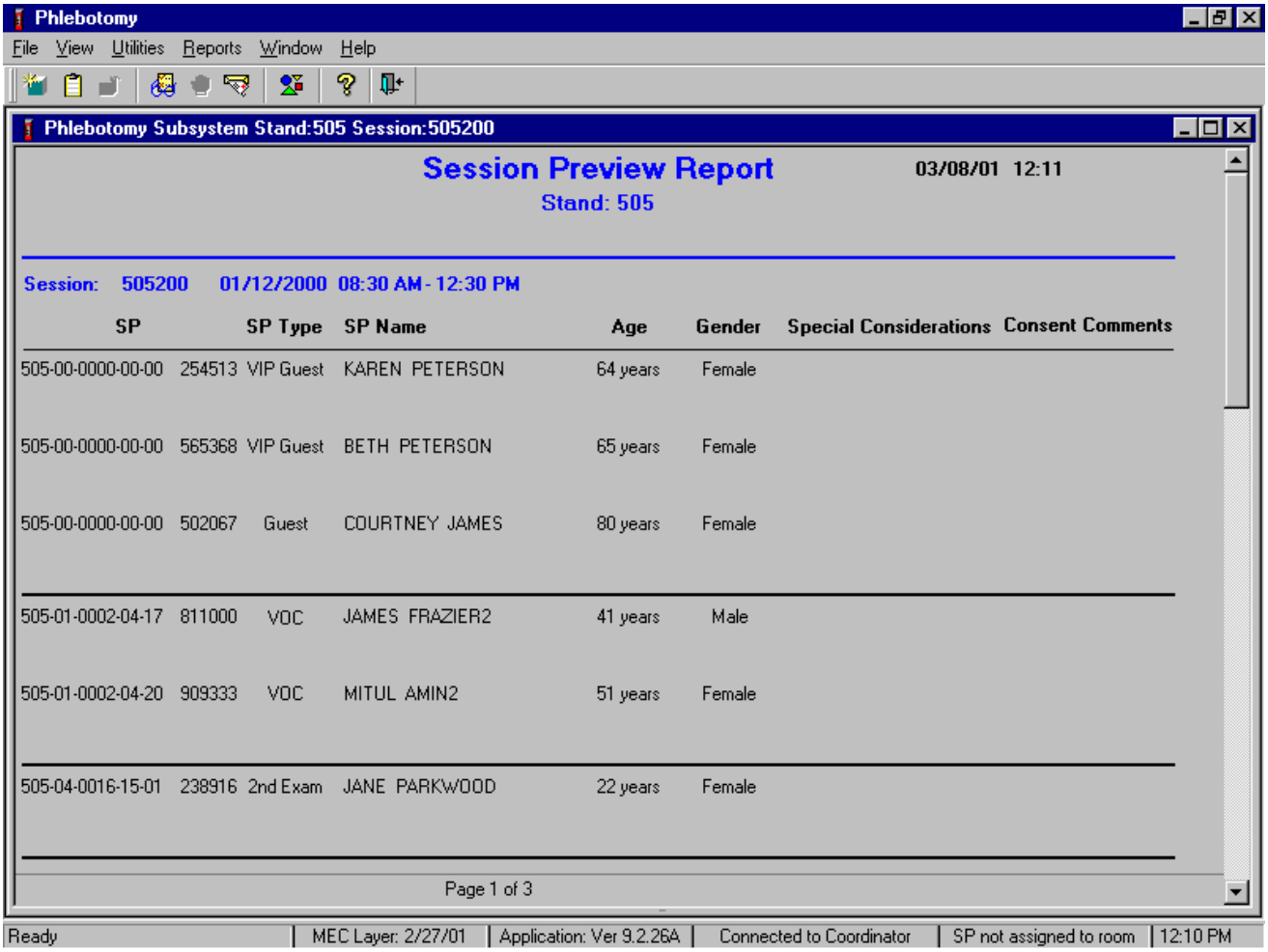
To access the Session Preview report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Session Preview} and left click or type [Alt] [R/r], [V/v].

Select the session.



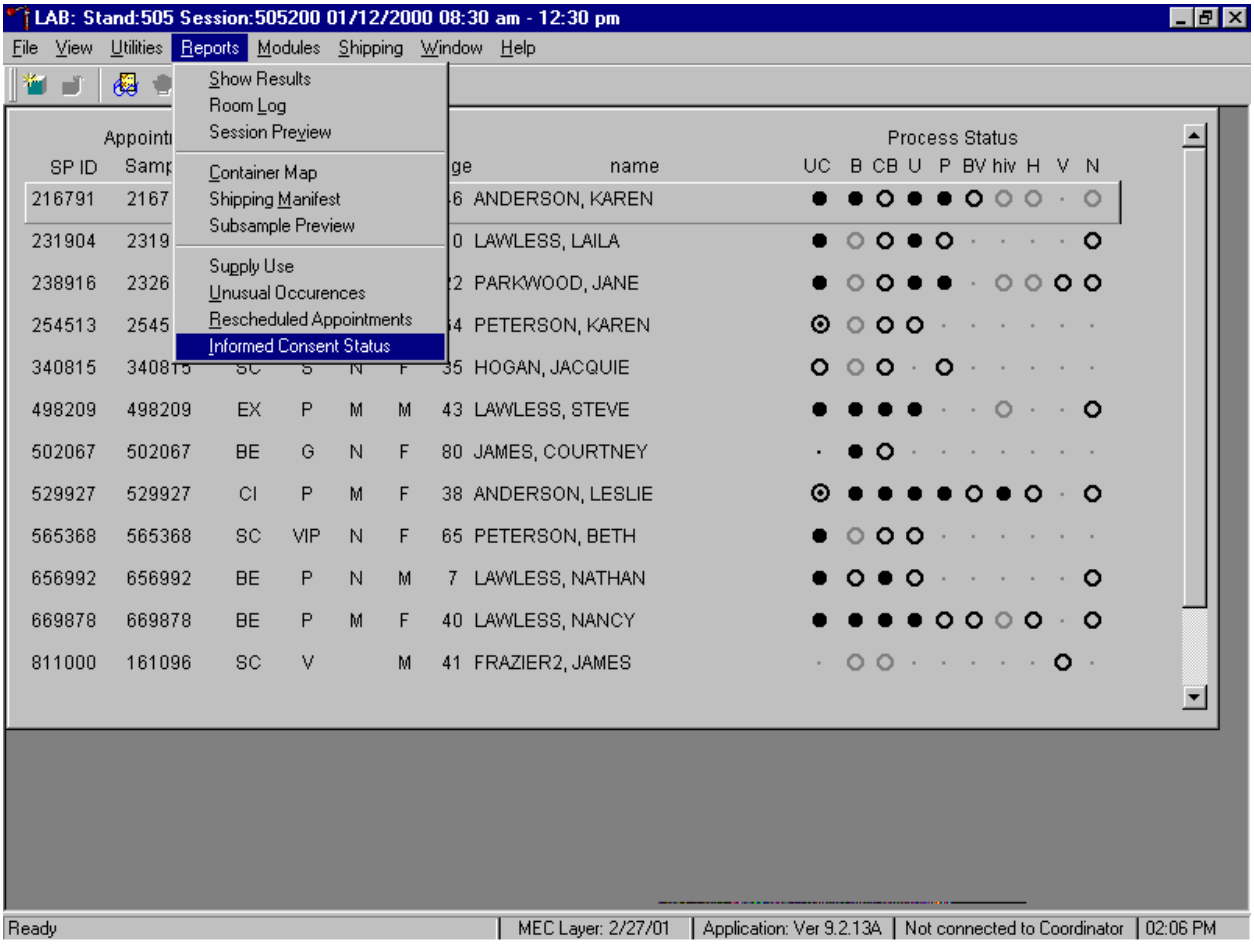
The Session PickUp list displays and defaults to the current session. To select a different MEC session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the OK button and right click or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the Cancel button and right click.

The Session Preview Report displays.



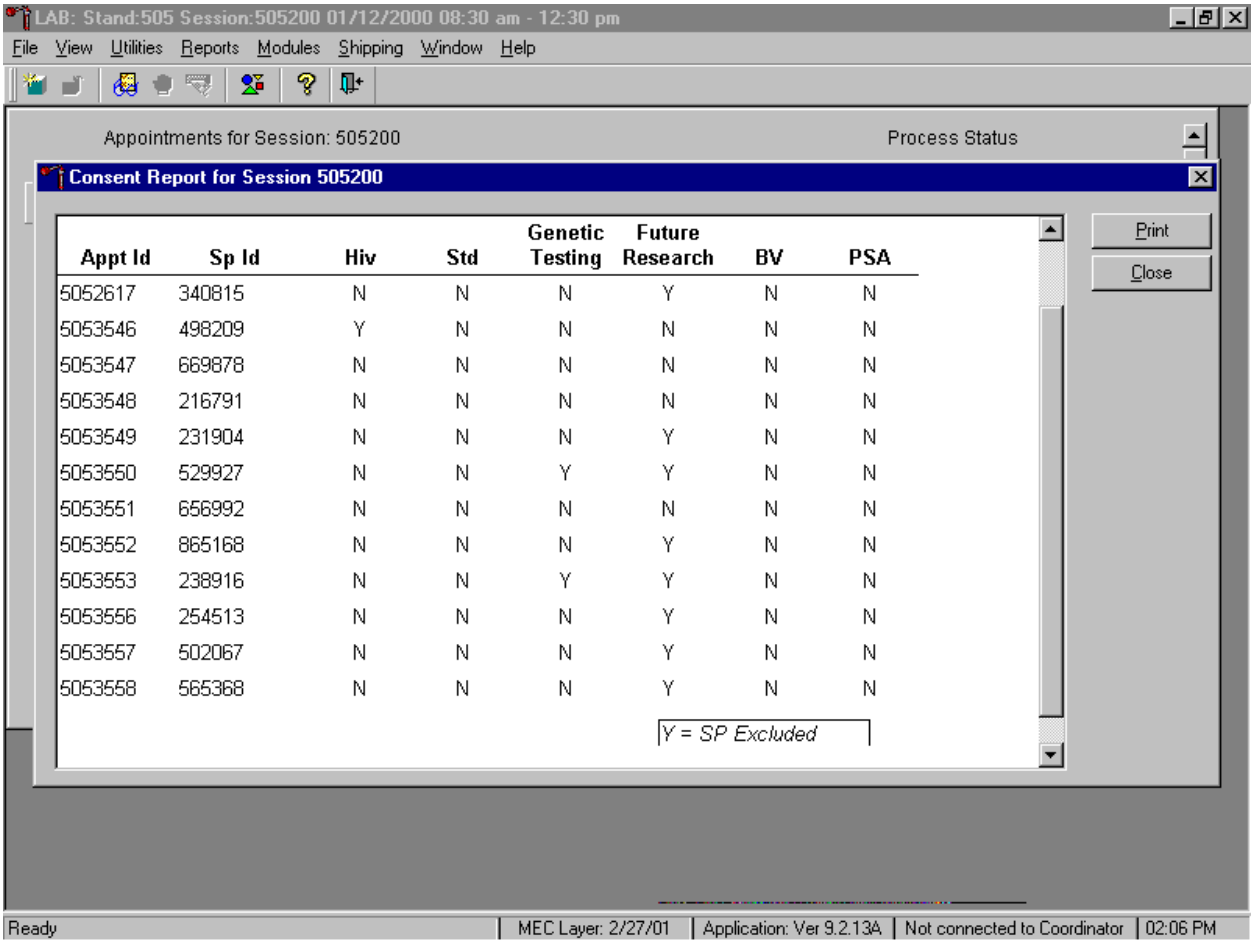
The Session Preview Report includes the session number, date, and time and lists the SP ID, SP Type, SP Name (first, last), Age, Gender, and any Special Considerations or Consent Comments. A blue asterisk (*) in front of a name indicates that the SP is eligible for the VOC component. To close the screen, use the mouse to direct the mouse arrow to the X box in the upper right hand corner of the Session Preview Report (close window button) and left click. Be careful not to select the X in the extreme top right corner (this closes the phlebotomy application.) To minimize the Session Preview Report, use the mouse to direct the mouse arrow to the _ box in the upper right corner of the Session Preview Report (minimize window button) and left click.

Access the Informed Consent Status report to view SPs and the status of the informed consent 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	Genetic Testing	Future Research	BV	PSA
5052617	340815	N	N	N	Y	N	N
5053546	498209	Y	N	N	N	N	N
5053547	669878	N	N	N	N	N	N
5053548	216791	N	N	N	N	N	N
5053549	231904	N	N	N	Y	N	N
5053550	529927	N	N	Y	Y	N	N
5053551	656992	N	N	N	N	N	N
5053552	865168	N	N	N	Y	N	N
5053553	238916	N	N	Y	Y	N	N
5053556	254513	N	N	N	Y	N	N
5053557	502067	N	N	N	Y	N	N
5053558	565368	N	N	N	Y	N	N

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 22 – HSV, 46 – Chlam/GC, 74 – Syphilis)
- genetic testing (vessels 44 and 71 – ACD tubes, 43 – clot)
- future research (vessels 8 – plasma, 32-42 – serum, 51-52 – urine)
- BV (vessel 72 – bacterial vaginosis, 73 – T. *vaginalis*)
- PSA (vessel 75)

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

5.12 How to Deal With System Failure

If the computer system fails, record results on a preprinted Workstation 2 Processing Worksheet (Exhibit 5-6). 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 5-6. Workstation 2 worksheet

URINE COLLECTION, PREGNANCY TEST, URINE PROCESSING

SP ID _____

	Urine Collected Age 6+	Yes ✔	Yes/QNS ✔	No ✔	Comments: communication problem no time 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 *QNS* *Blood Present*	Slot #
45	Alb/Creat	6+	3	Urine			
46	Chlam/GC	14-39	4	Urine			
47	NTX	8+	1	Urine			
69	Urn Iodine	6+	3	Urine			
48	Prior Pest	6+	10	Urine			
49	Organophos	6+	10	Urine			
62	Urn Merc	16-49	5	Urine			
50	Heavy Metal	6+	10	Urine			
65	Urn Phytoes	6+	3	Urine			
66	PAH	6+	3	Urine			
67	Phthalates	6+	3	Urine			
51	Xtra Urine	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

Prepared by _____ Date Adopted _____

Approved by _____
Director

Signed _____
Director

Dated _____
Director

Reviewed by _____ 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 person types except home exam who are aged 12-59, and girls aged 8-11 who report that they are menstruating when asked during the home interview. This test excludes pregnant women aged 8-59 from participating in the dual-energy x-ray absorptiometry (DXA), bioelectrical impedance analysis (BIA), and cardiovascular fitness (CV Fitness) components 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, 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 levels of hCG 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 kit is intended 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% 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 build-up. This reagent is harmful if swallowed. Contact with acids liberates very toxic gas. If there is accidental contact with skin, wash the area 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 is 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 except home exam who are aged 12-59 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 the 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

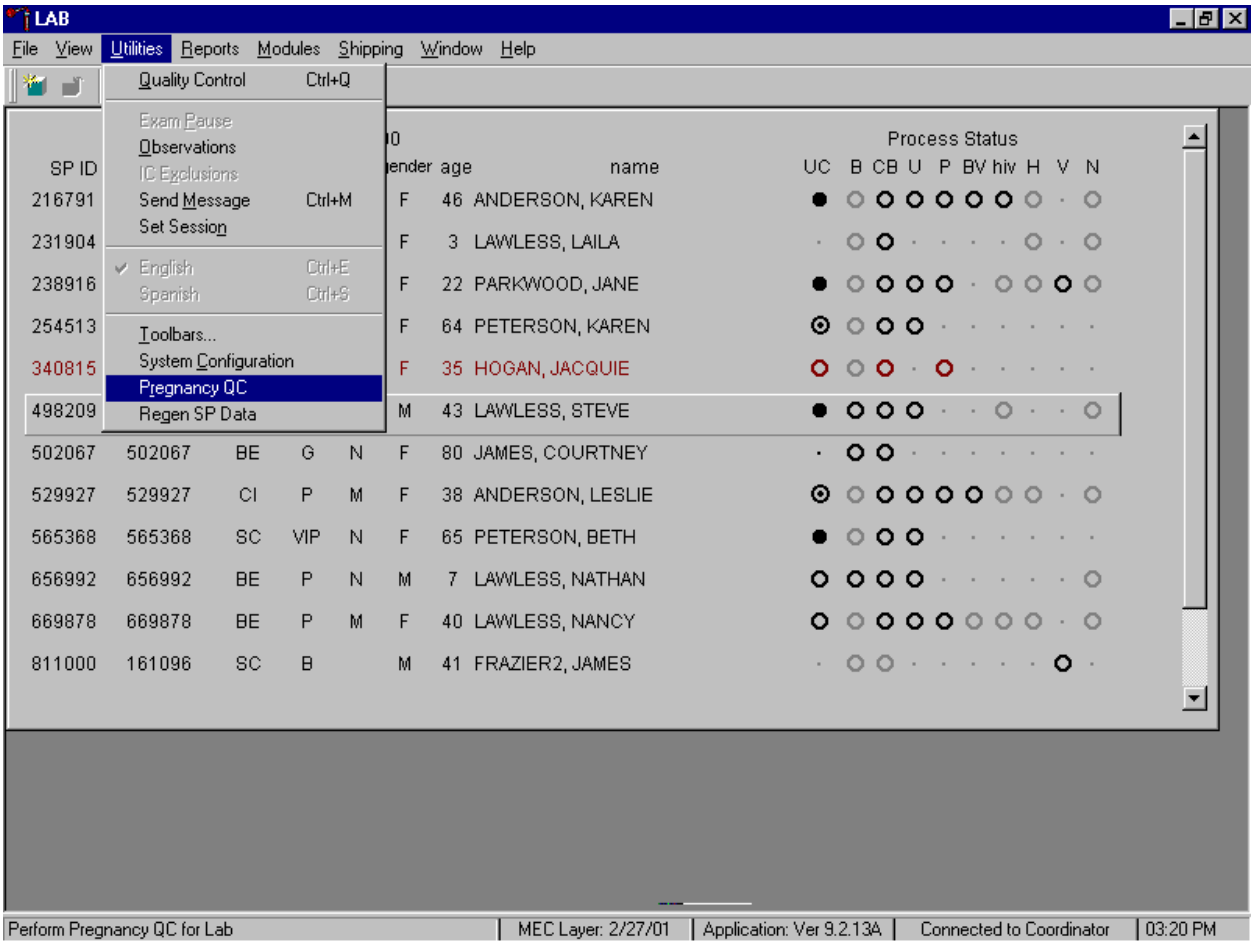
CAP Proficiency Testing

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.

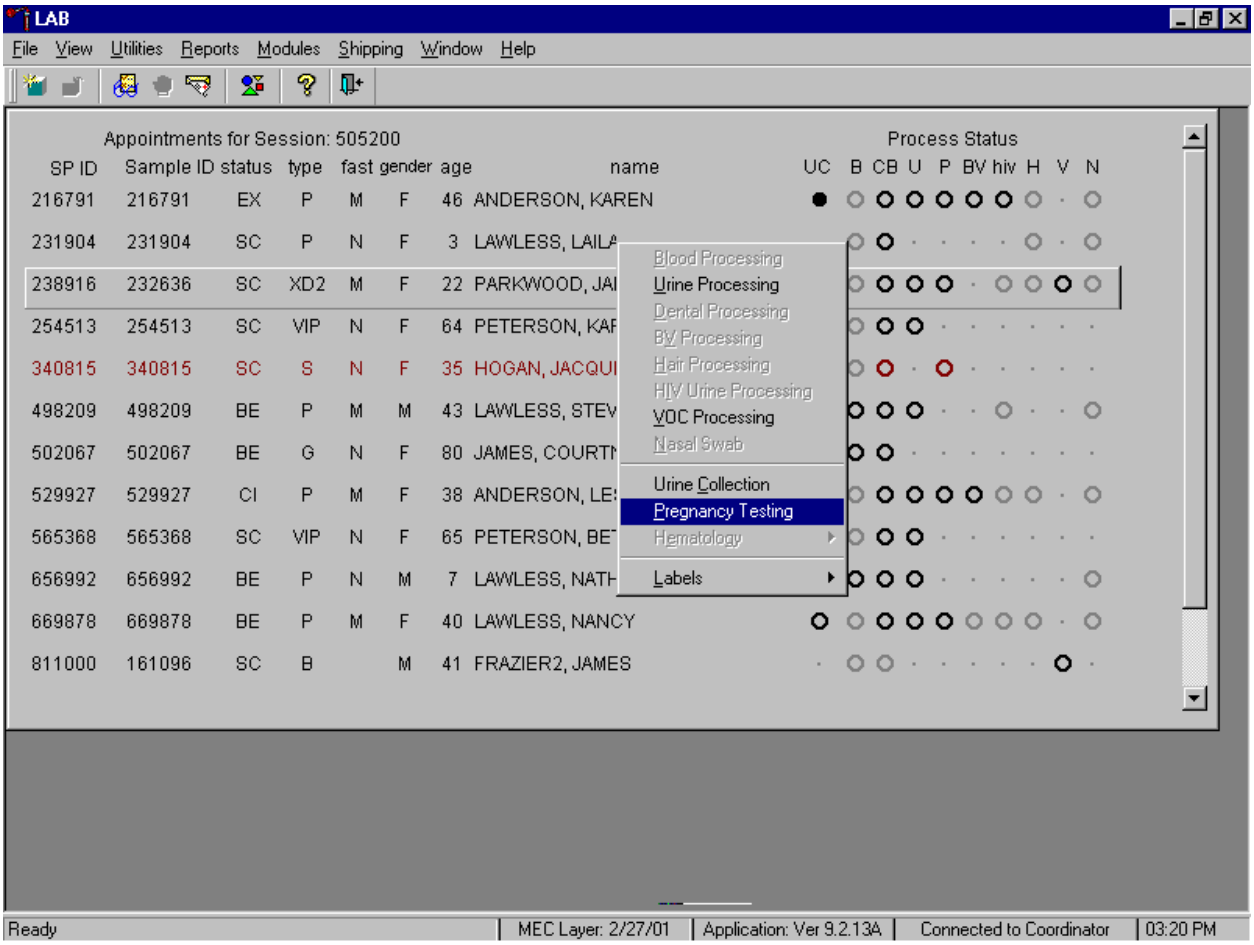
CAP sends samples three times a year for qualitative serum hCG. Each shipment includes five lyophilized sera specimens. Handle and analyze these samples in a manner identical to SP samples. Record results on the CAP forms and send to the address specified by CAP Surveys Program Support. Send a copy of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

Open the Pregnancy QC module.



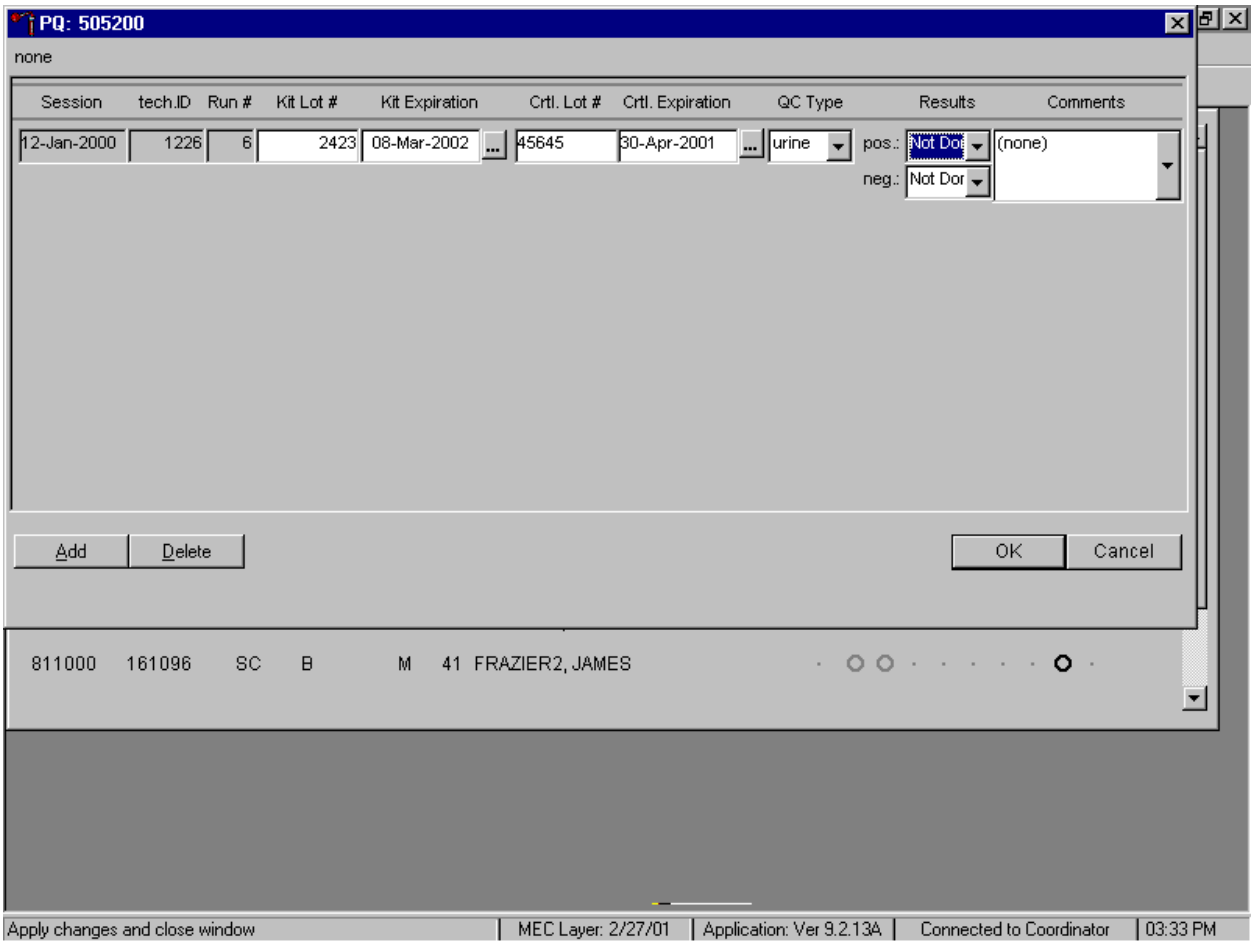
To open the pregnancy QC module, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the arrow to {Pregnancy QC}, and left click or type [Alt] [U/u], [R/r].

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



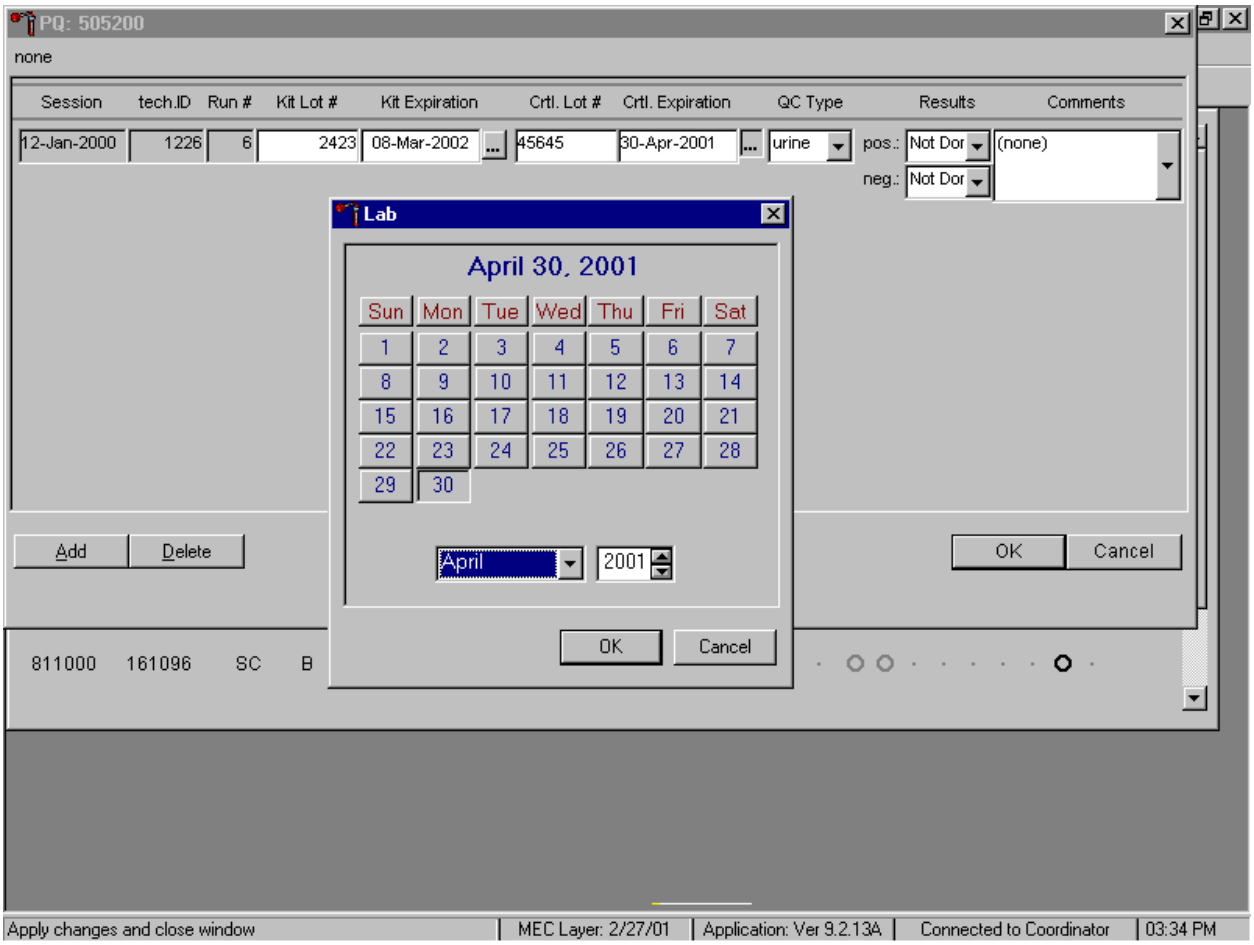
To access the Pregnancy QC module from the heads-up screen, use the up and down keys to move up and down the list until the correct SP is highlighted or use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing}, and left click or left click and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

The Pregnancy QC window displays.



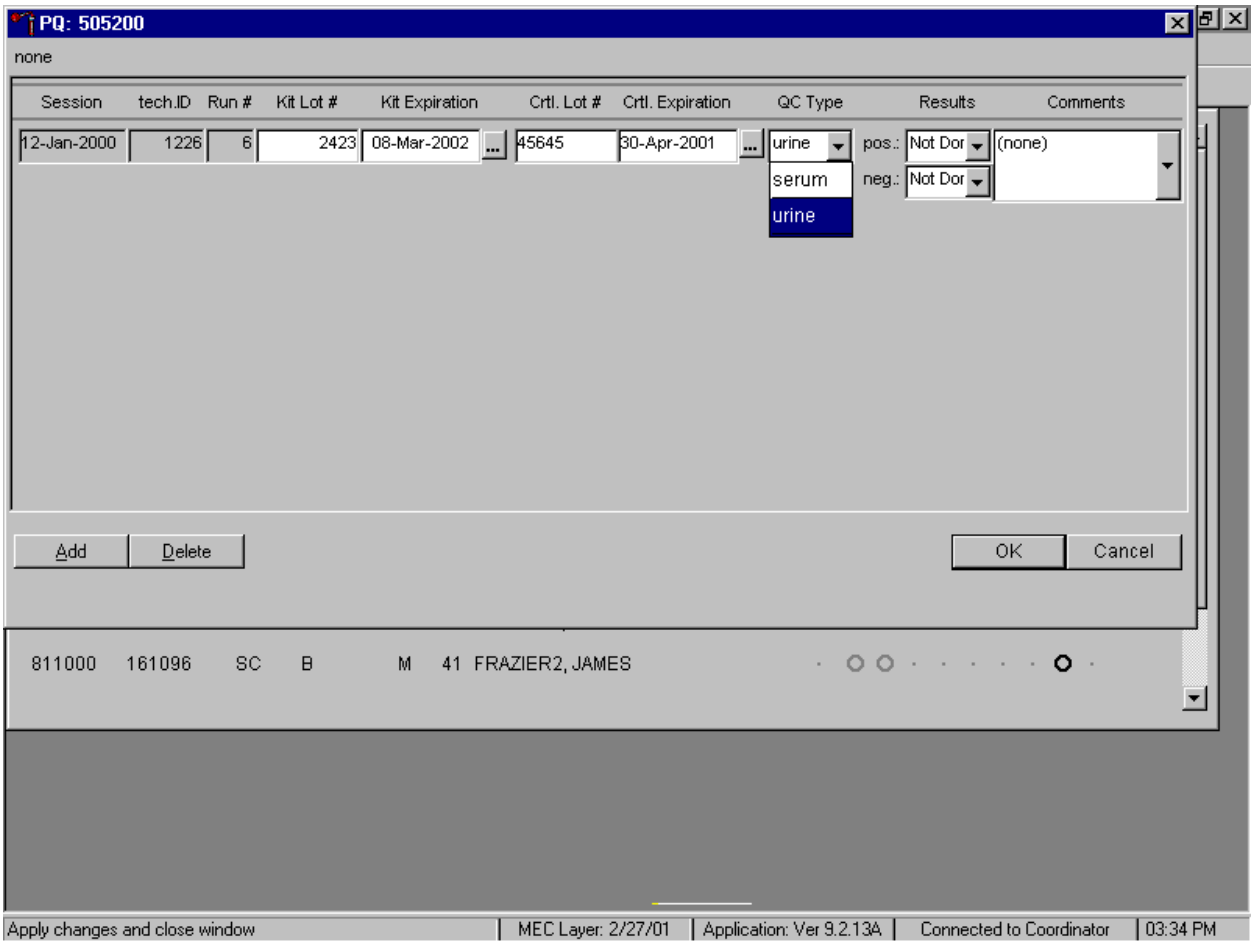
The Pregnancy QC module automatically captures the session date and technologist ID and assigns the run number. The module defaults to the last kit lot number, kit expiration date, Ctrl (control) lot number, Ctrl expiration date, and the QC type - urine. If the window defaults to the current kit, verify the existing 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.



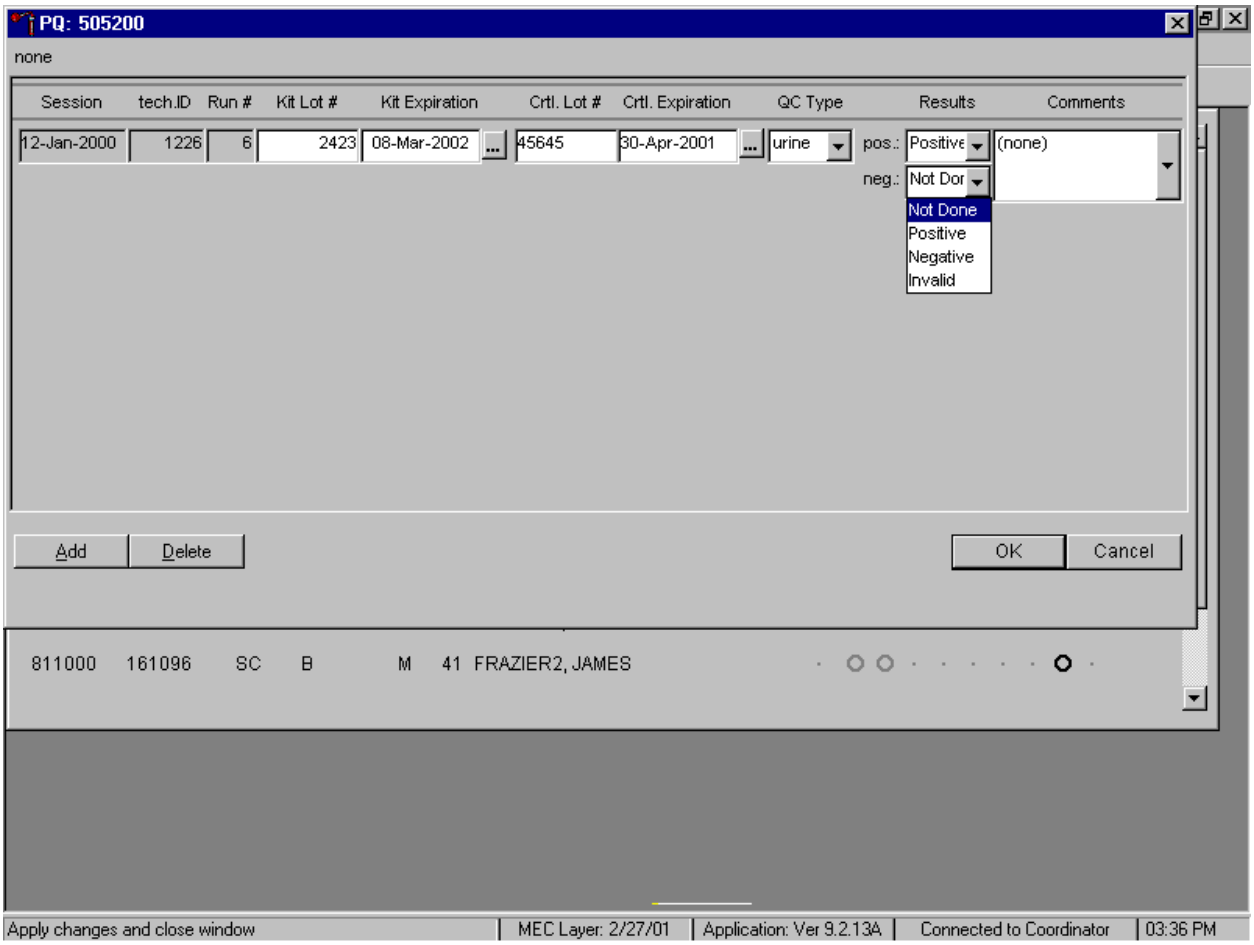
Type in the date using the keyboard's numeric keys and the dd/mm/yyyy format and select [Tab] or use the calendar to enter the date. To access the calendar, use the mouse to direct the mouse arrow to the ellipsis and left click. To select the correct month, use the mouse to direct the mouse arrow to 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, or 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.



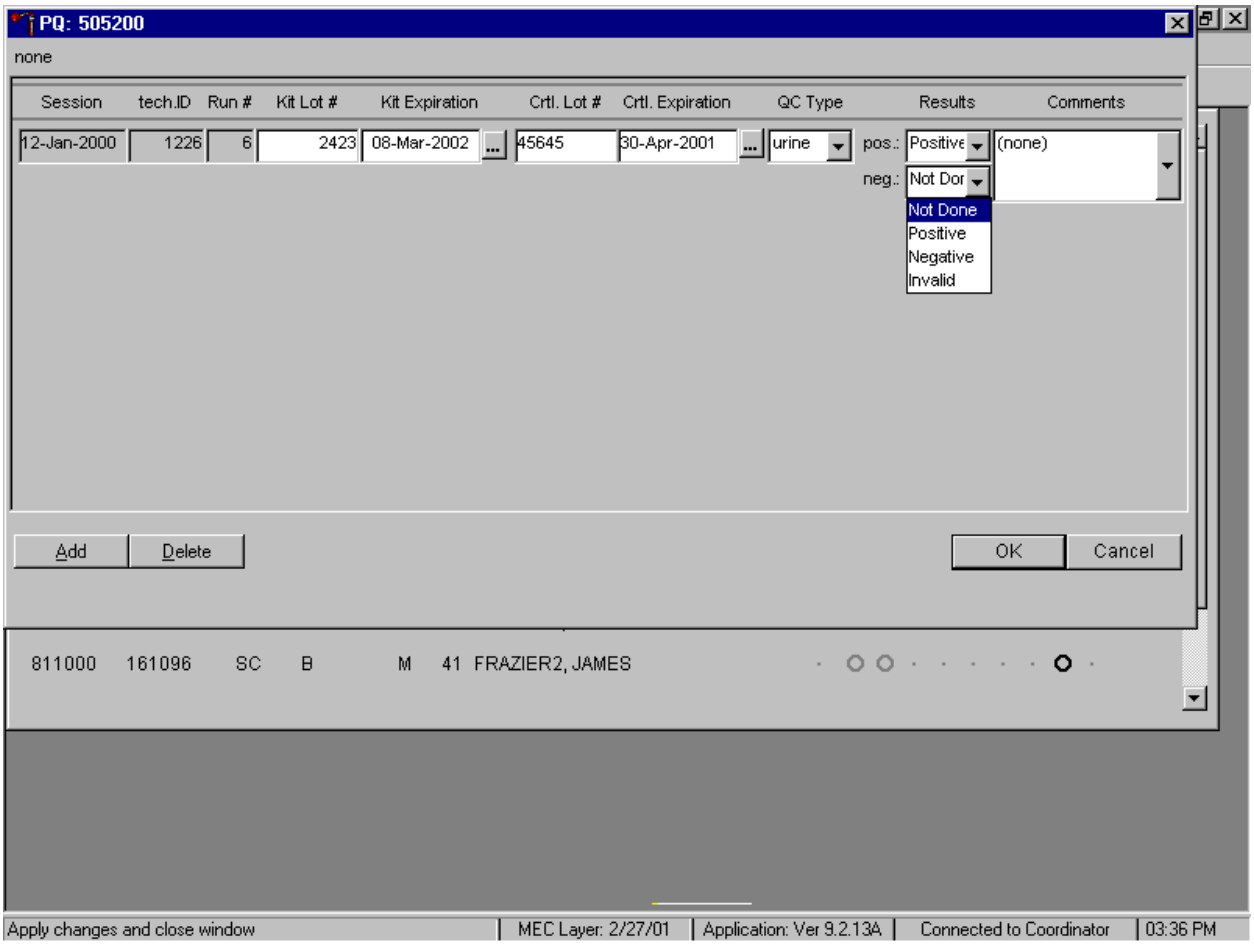
The QC control type default is "Urine." To change the QC type to serum or to select urine, use the mouse to direct the mouse arrow to the drop down list, drag the mouse arrow to either serum or urine and left click. Alternatively, highlight the QC type text box and type [S/s] for serum or [U/u] for urine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

Record the Positive and Negative control results.



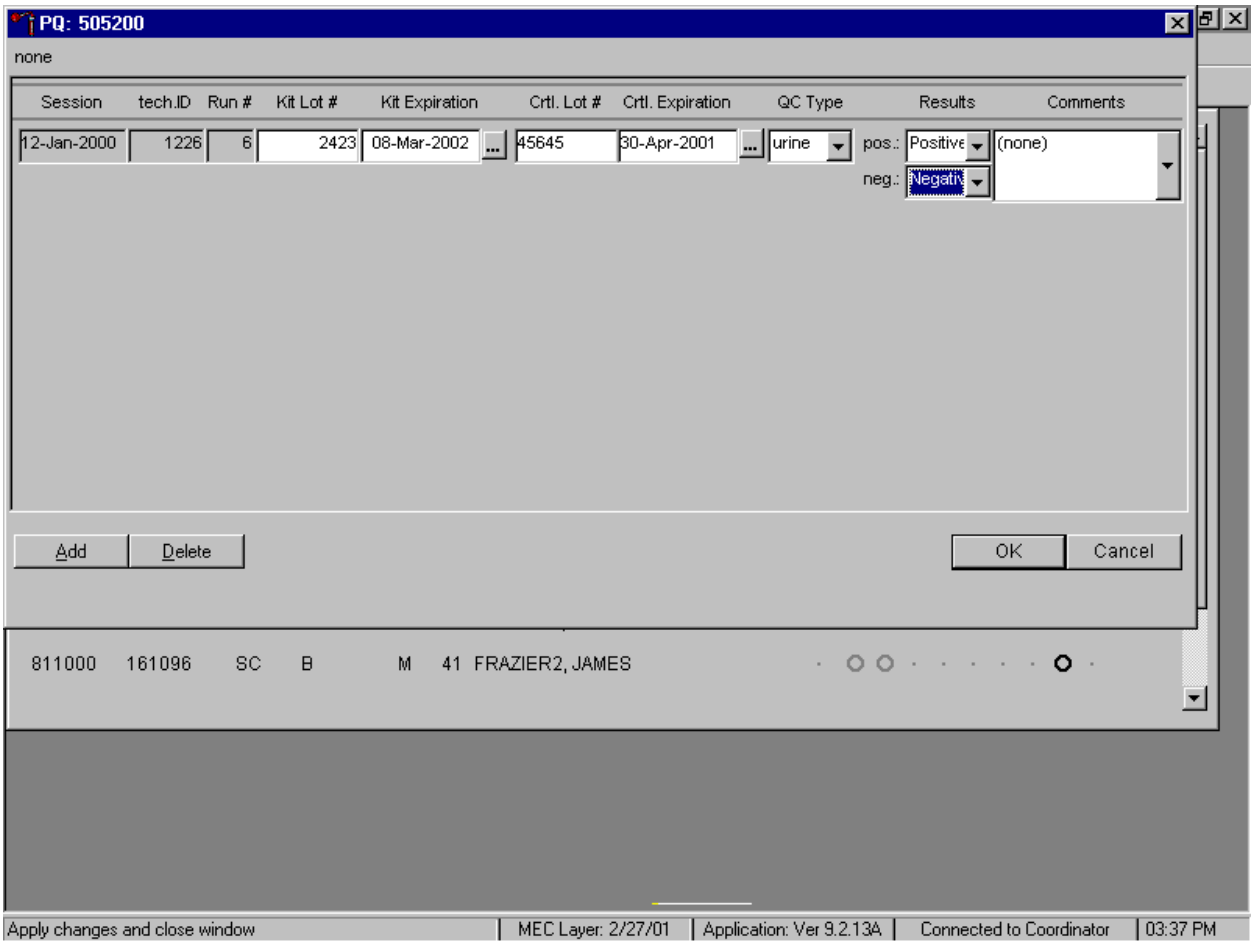
To enter a result in the Positive result text box, type [P/p] for "Positive," [N/n] for "Negative," or [I/i] for "Invalid" or use the up and down arrow keys to toggle between the three choices; Positive, Negative, and Invalid and select [Tab]. Alternatively, use the mouse to direct the mouse arrow to 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.



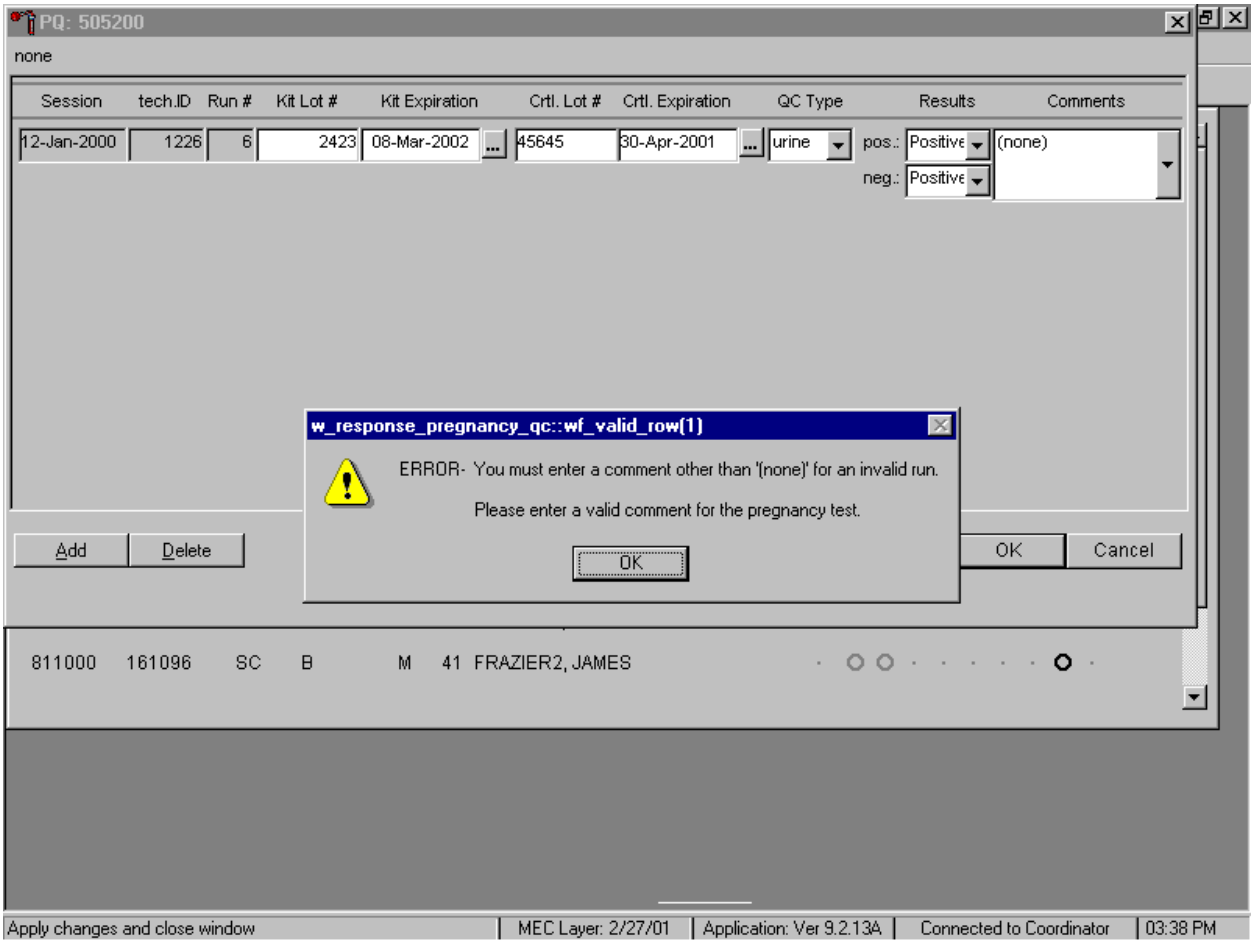
To enter a result in the Negative result text box, type [P/p] for "Positive," [N/n] for "Negative," or [I/i] for "Invalid" or use the up and down arrow keys to toggle between the three choices; Positive, Negative, and Invalid and [Tab]. Alternatively, use the mouse to direct the mouse arrow to drop down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

Save results when Positive and Negative controls demonstrate the expected result.



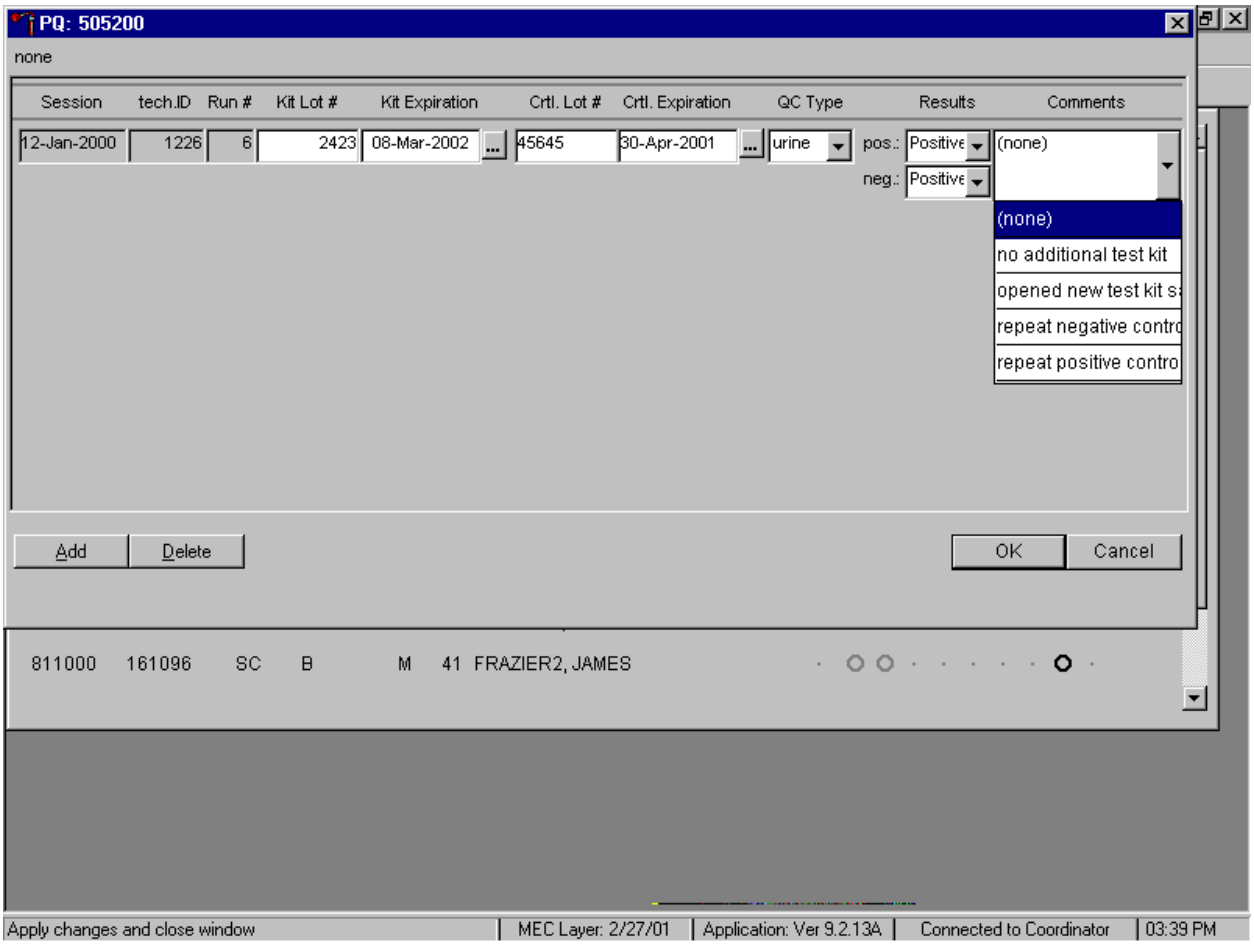
If the Positive and Negative controls demonstrate the expected result, use the mouse to direct the mouse arrow to the OK button and left click to save these results and to proceed with pregnancy testing. To cancel and exit the module without recording or saving any QC results to the database, use the 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.



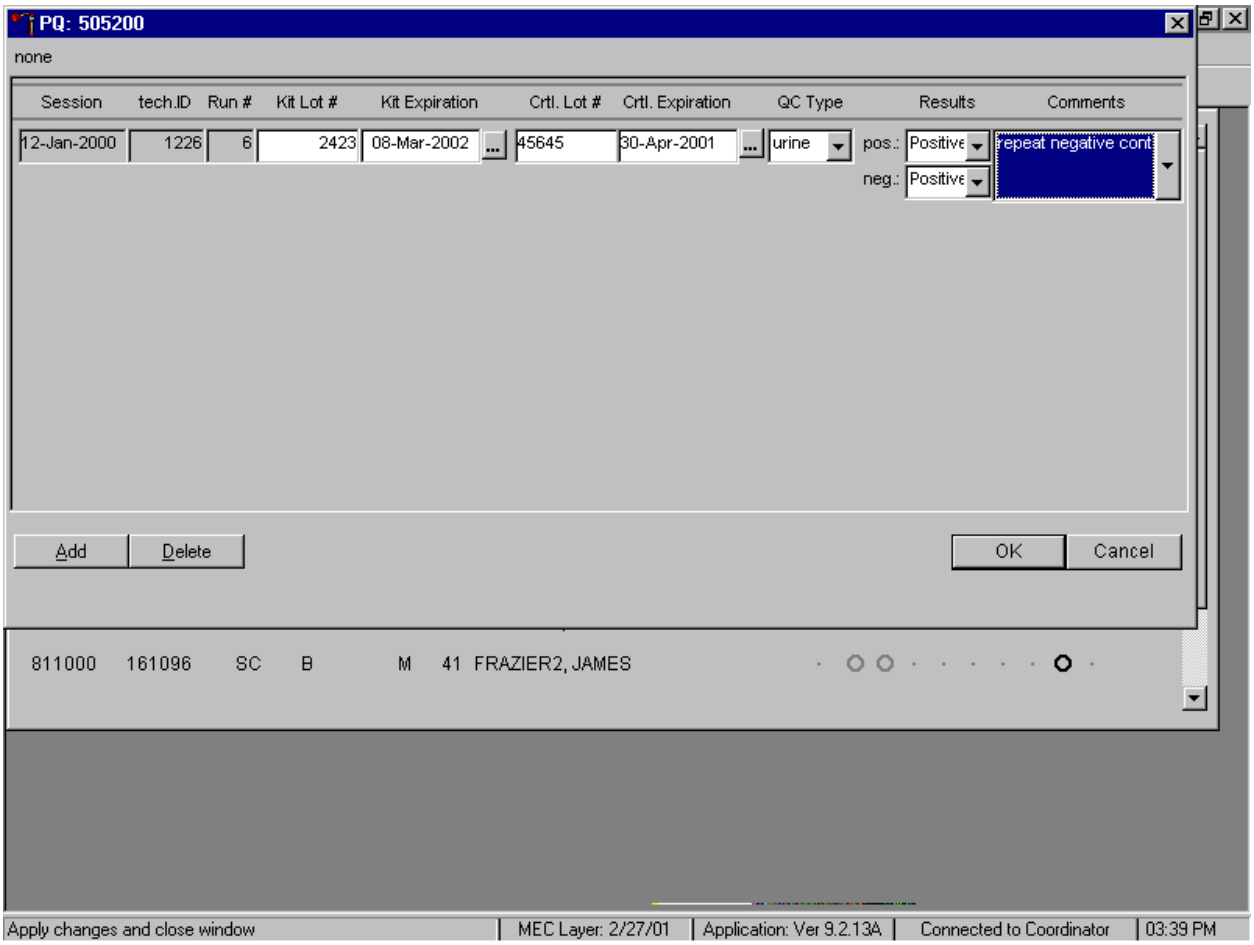
To close the box, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter].

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



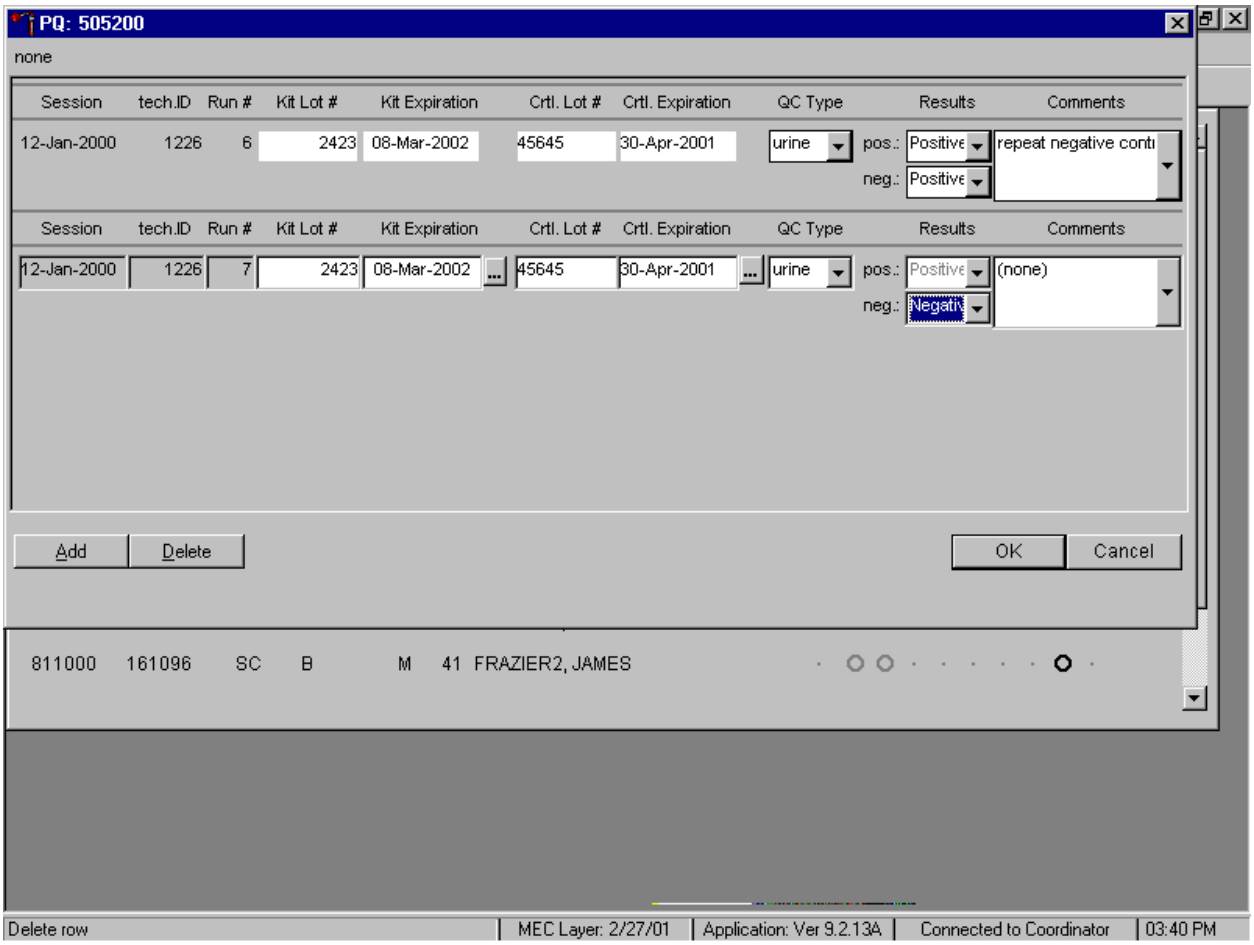
Enter the appropriate comment in the "Comments" column by using the mouse to direct the mouse arrow to the drop down list, left click to display the choices, drag the mouse arrow to the most appropriate choice, and left click when the correct choice is highlighted. Alternatively, use the up and down 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.

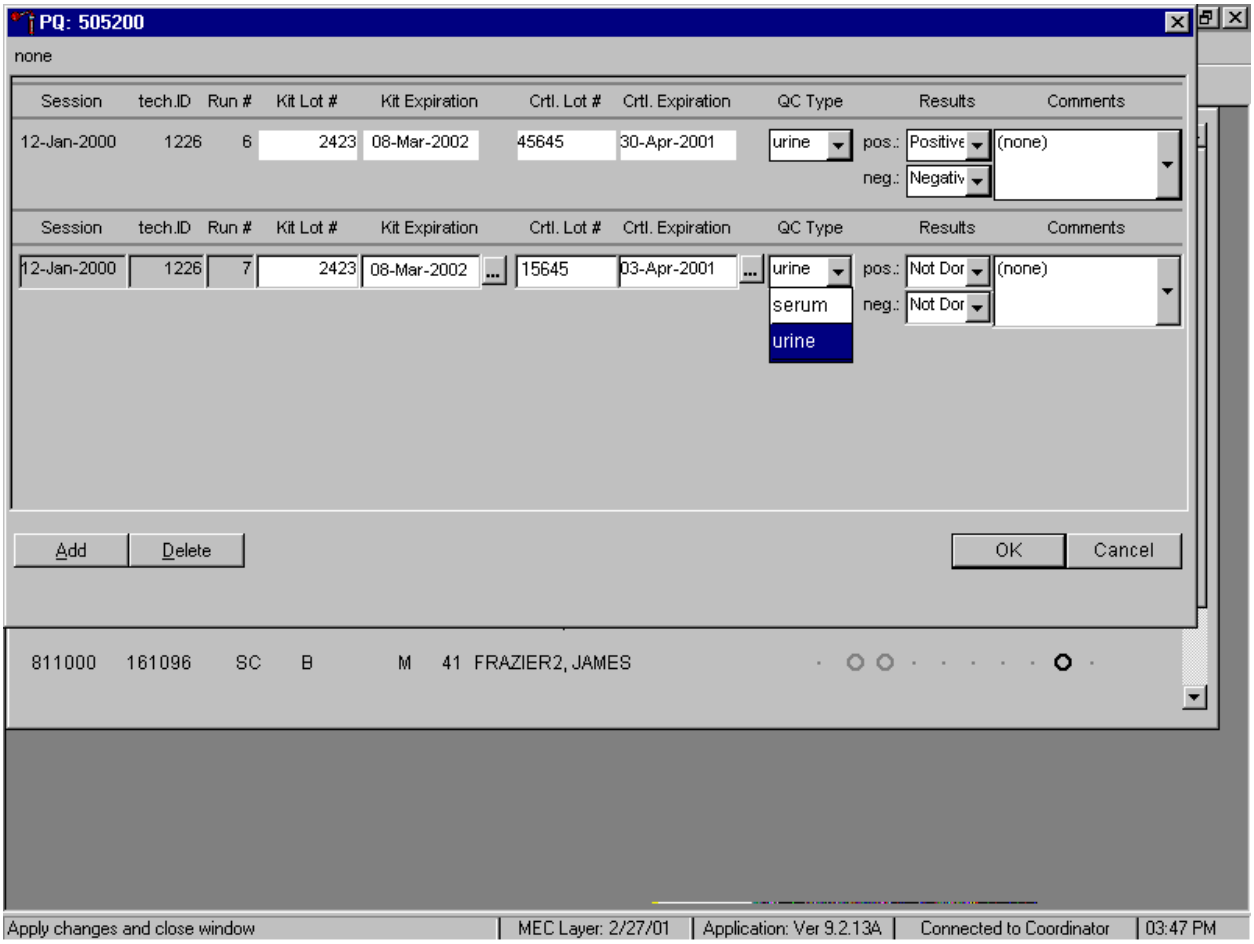
Add a new QC record and repeat the control for invalid or unexpected results.



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.

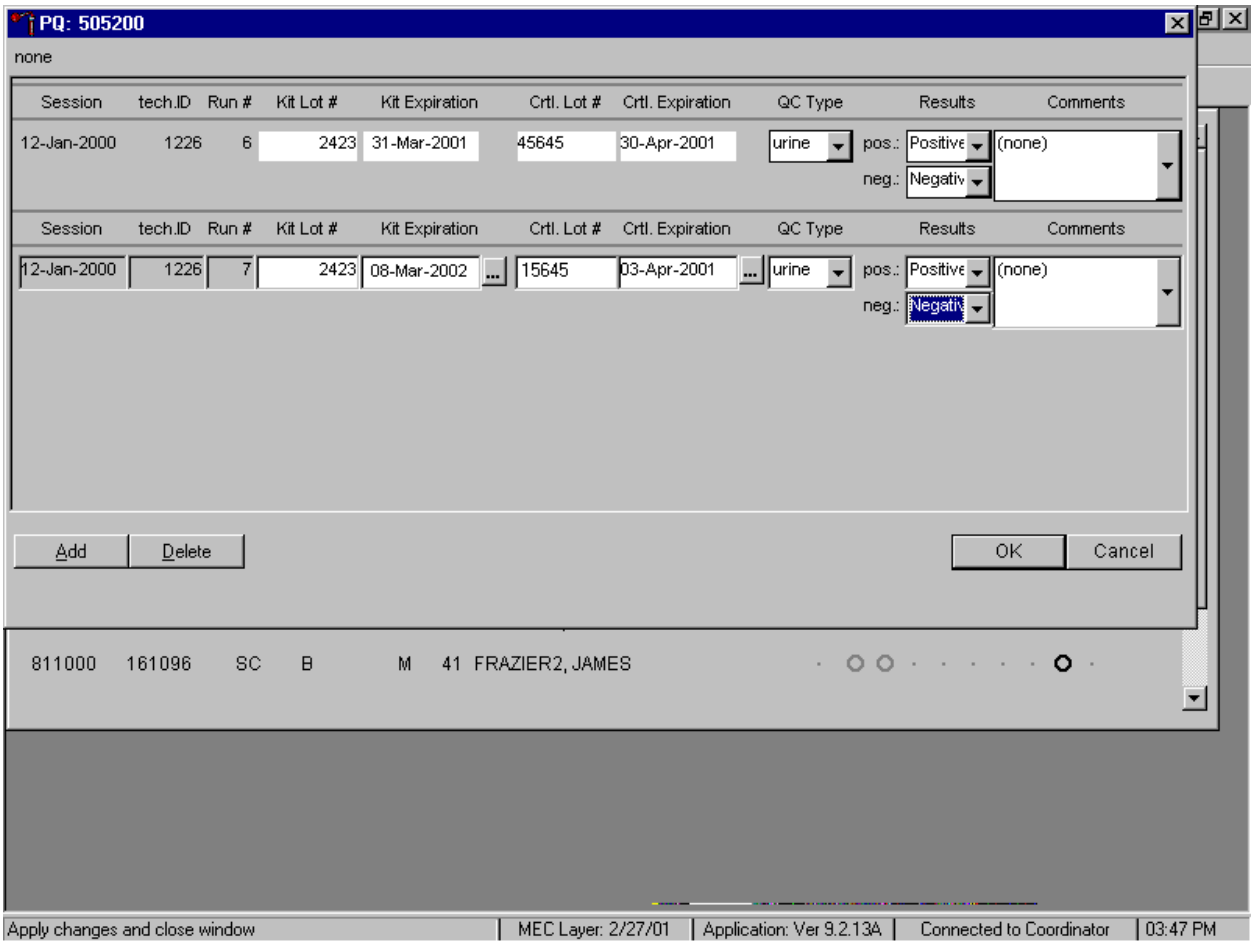
If this does not resolve the situation, repeat the procedure with a different lot of controls. If this fails to resolve the problem, discard the entire lot of pregnancy test kits and test a new lot.

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.



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

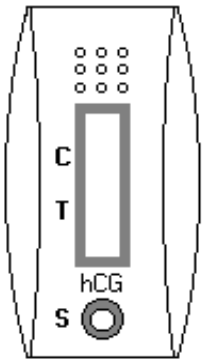


Figure 1

ICON 25 test device

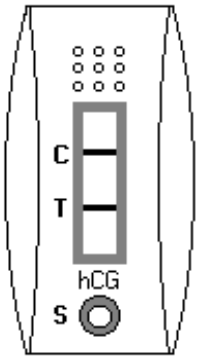


Figure 2
Positive Result
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

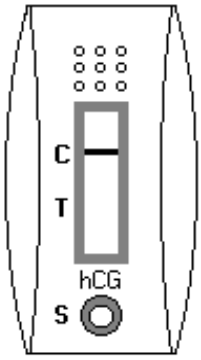


Figure 3
Negative Result
One red line appears in the control region (C). No apparent red or pink line appears in the test region.

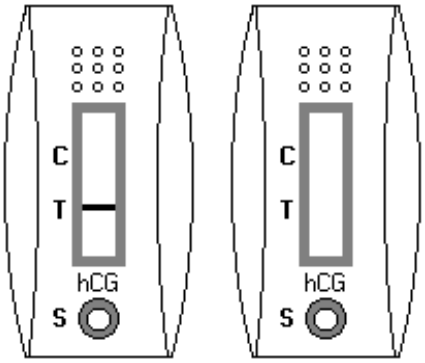


Figure 4
Invalid Result
Control line fails to appear.

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.

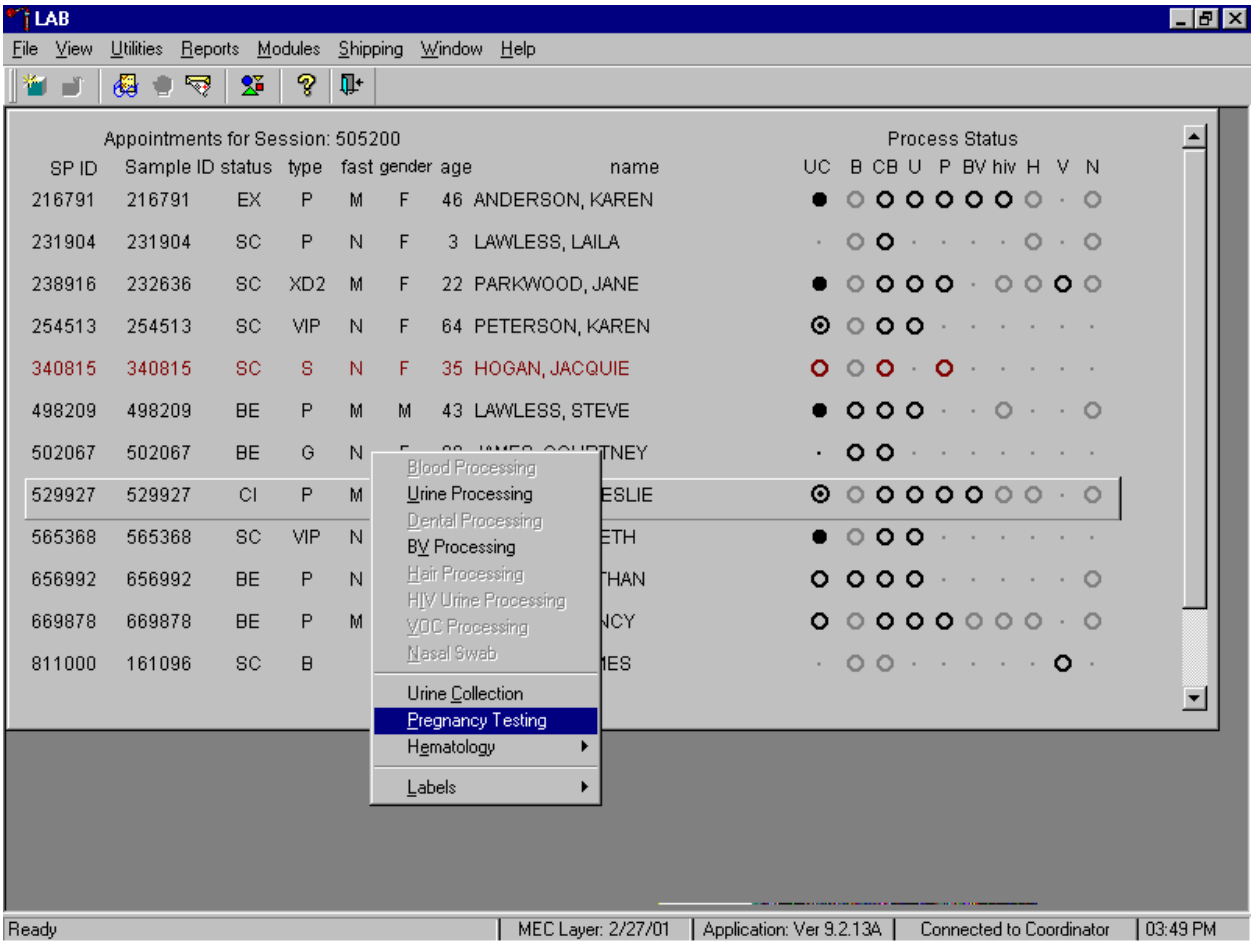
Negative Result:

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

A. Recording Results

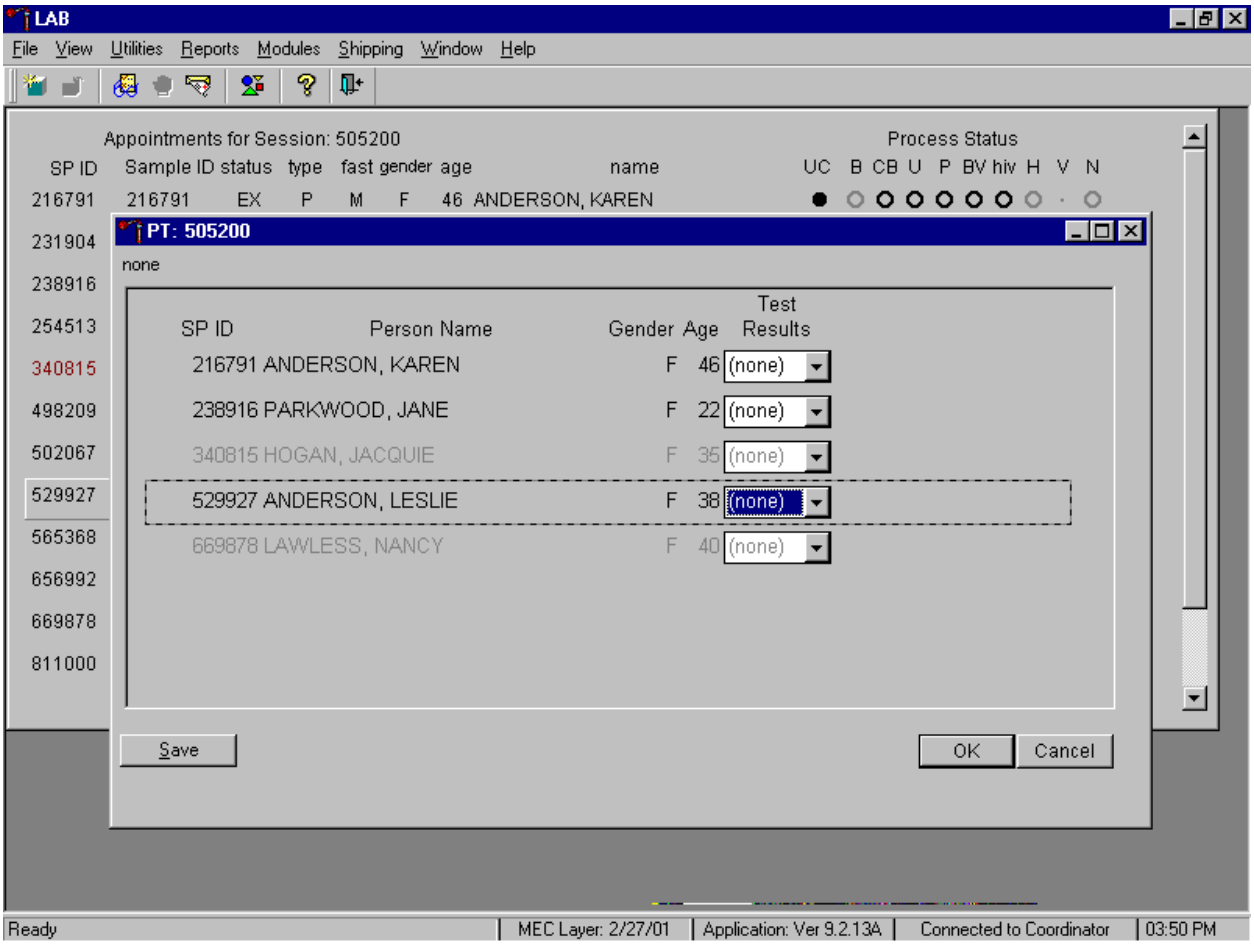
Use the heads-up display and the Pregnancy Testing module to enter the results of the ICON® 25 hCG test kit pregnancy test result for each SP.

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



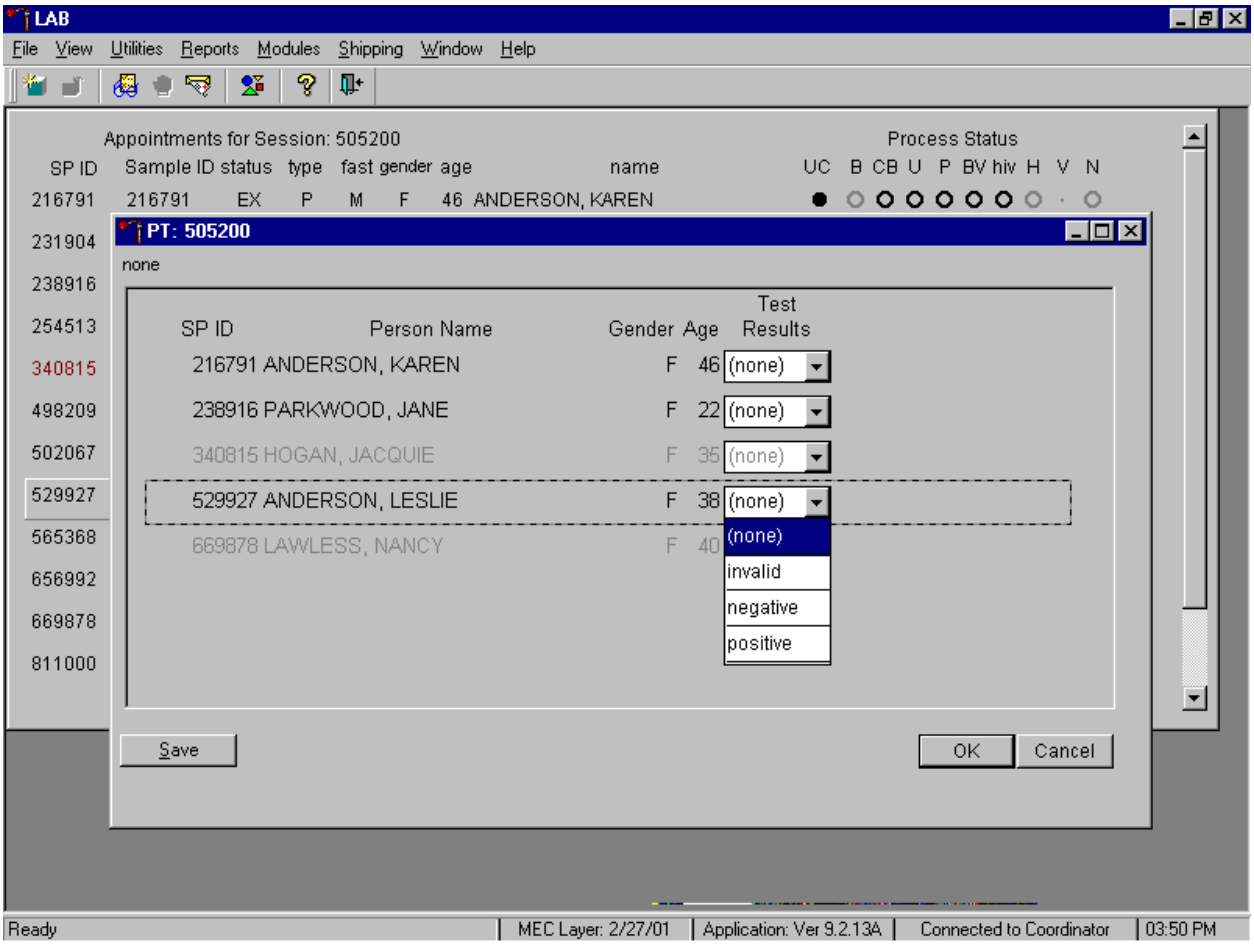
To access the Pregnancy Testing module, use the mouse to direct the mouse arrow to the correct SP, right click, drag the mouse arrow to {Pregnancy Testing}, and left click, or left click and type [P/p]. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted,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

The Pregnancy Testing window displays.



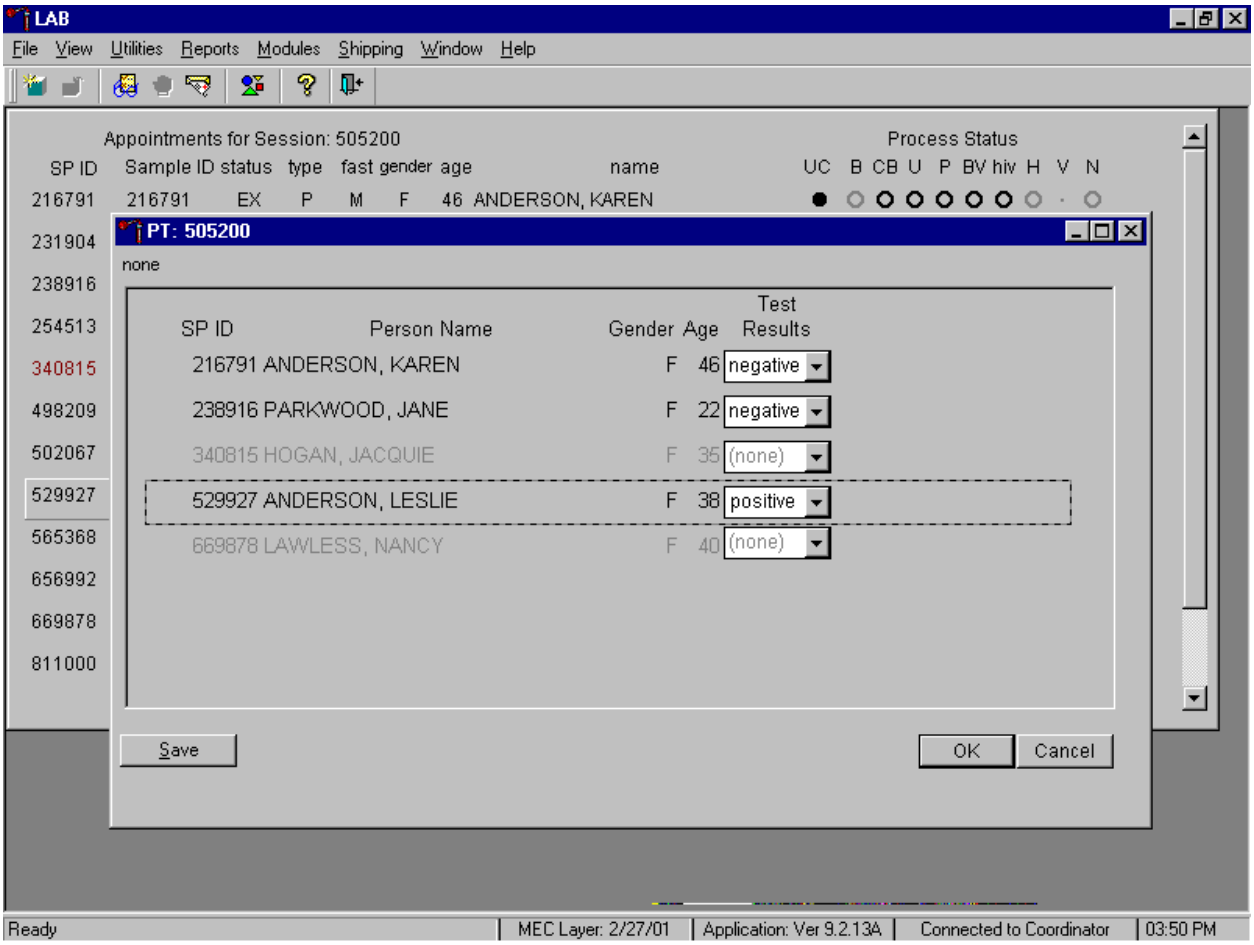
SPs who have urine collection results recorded as “yes” or “yes/QNS” appear black in the window. SPs who do not have urine collection results recorded appear gray in the window. The window lists the SP ID, Person Name, Gender, Age, and includes a Test Results column.

Report the results for each SP as Positive, Negative, or Invalid.



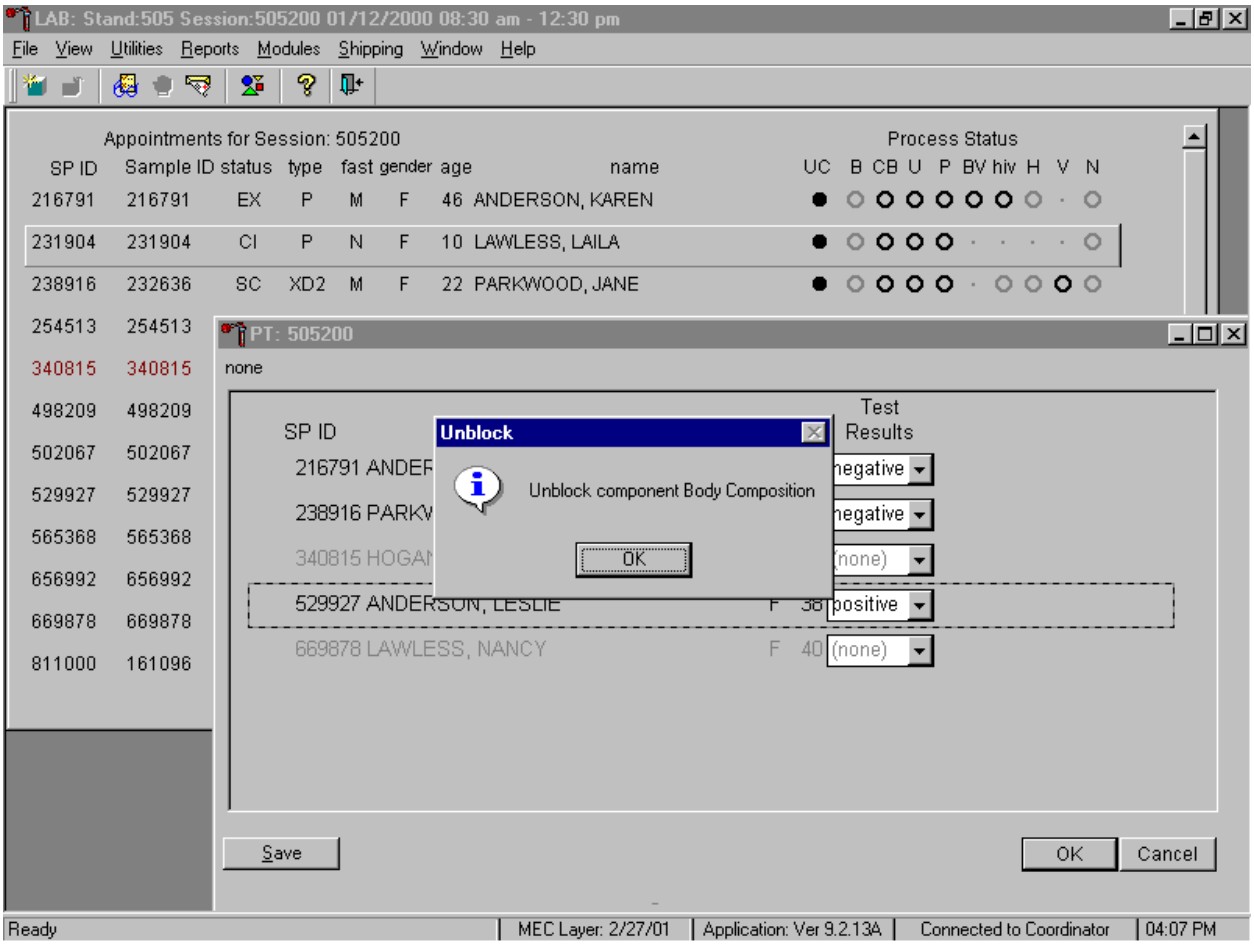
If the Test Result field is black or highlighted, record the result by typing [P/p] for Positive, [N/n] for Negative, or [I/i] for an invalid result. Alternatively, to record a result, use the mouse to direct the mouse arrow to the drop down list, drag the arrow to the correct choice and left click. 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.

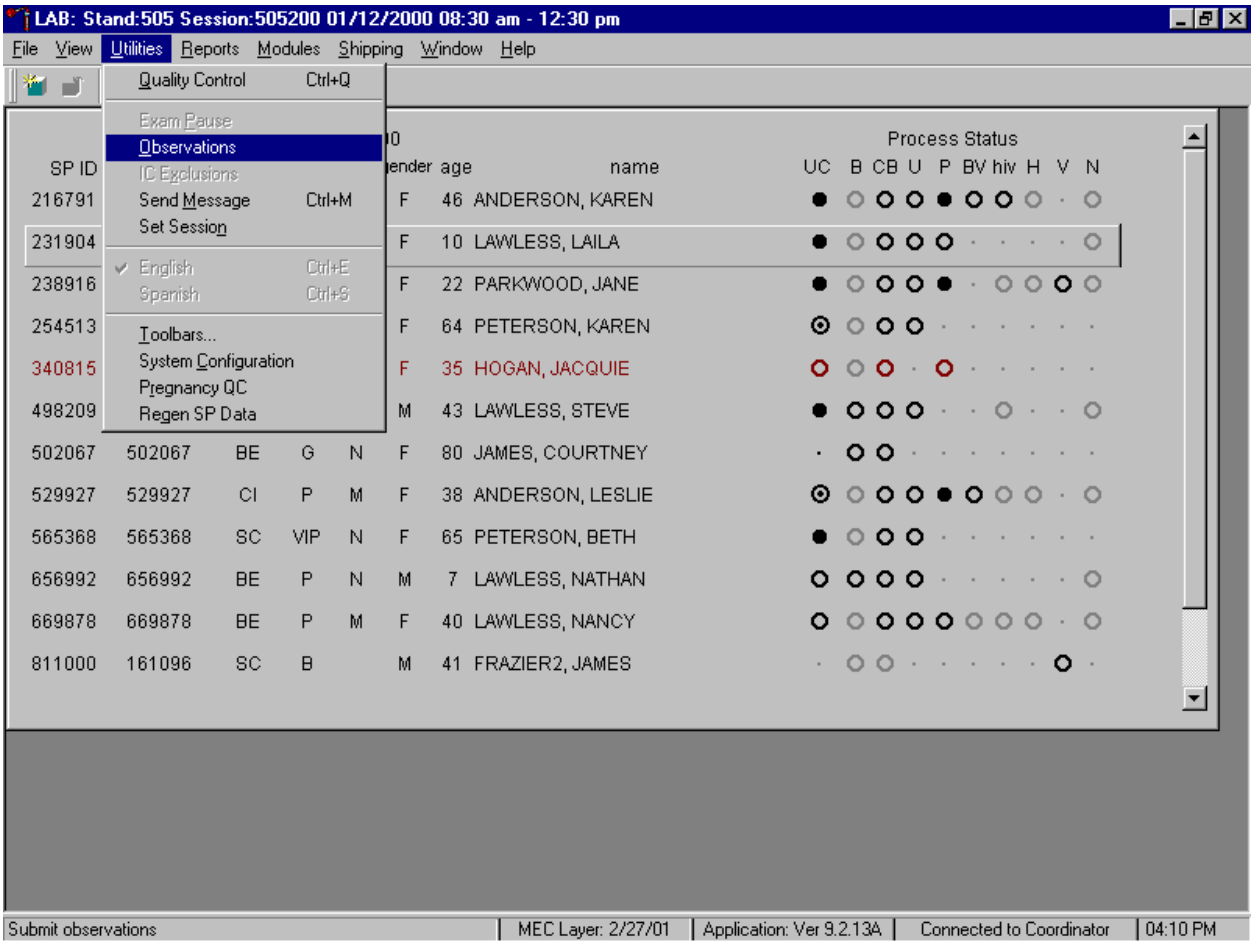
After each negative result is saved to the database, an unblocking message box displays.



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

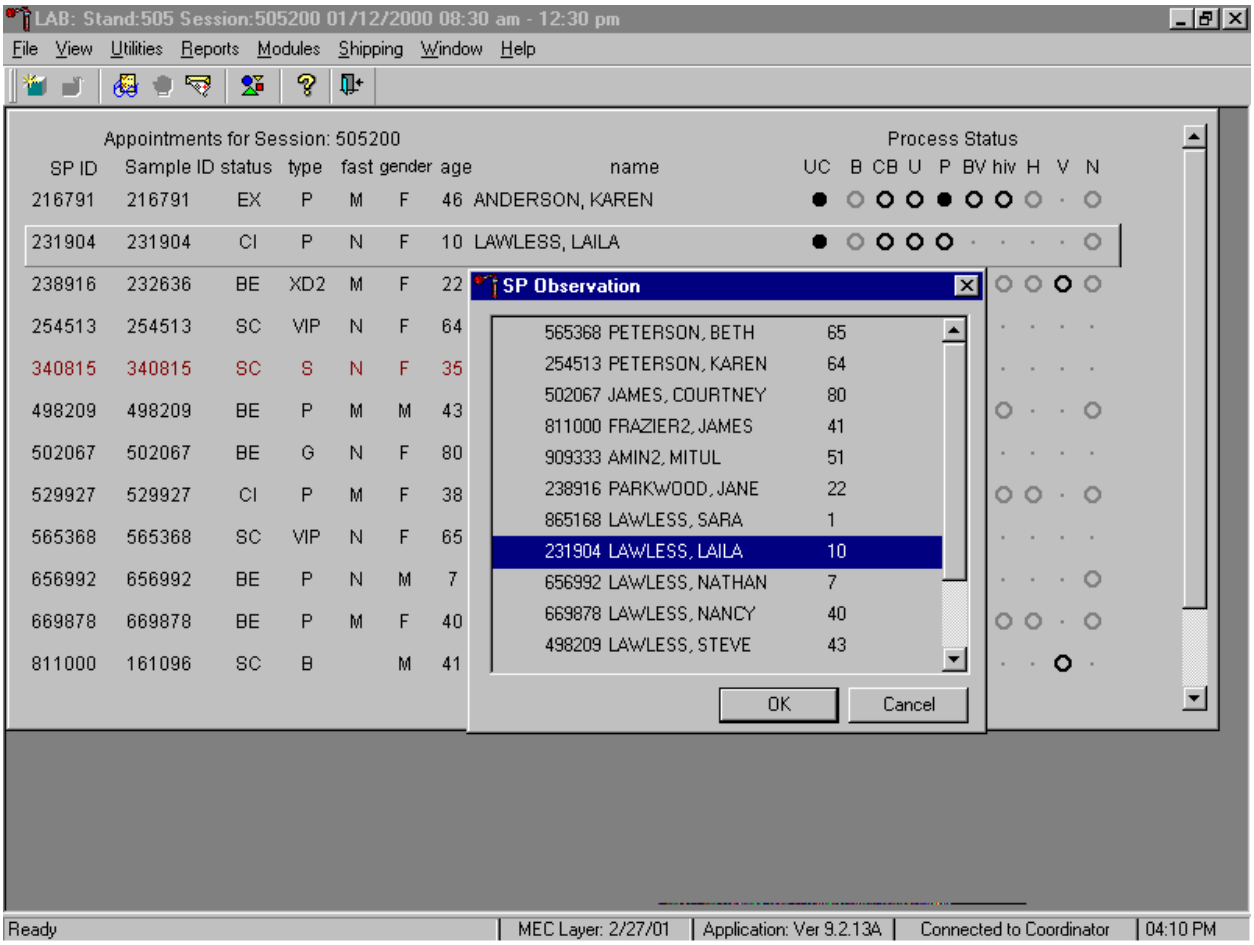
If a urine pregnancy test is positive on any female SPs aged 8-17, confirm the result using serum. If no blood is drawn, repeat the urine test. Notify the physician of the second positive or negative confirmatory test or the inability to perform a confirmation test using the observation function.

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



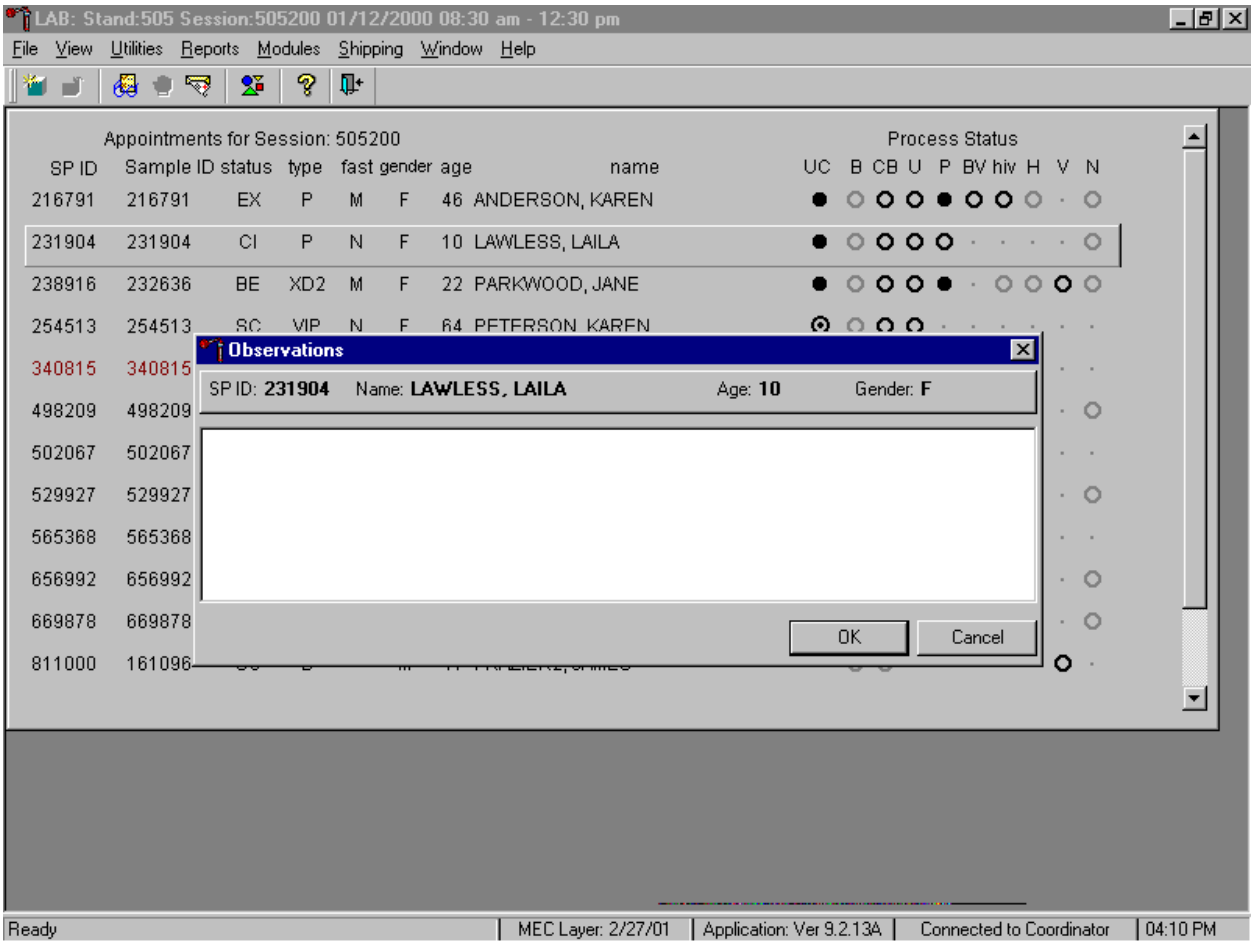
To send an observation to the physician, use the mouse to direct the mouse arrow to {Utilities} in the top menu bar, drag the mouse arrow to {Observations} and left click or type [Alt] [U/u], [O/o].

Select or highlight the correct SP.



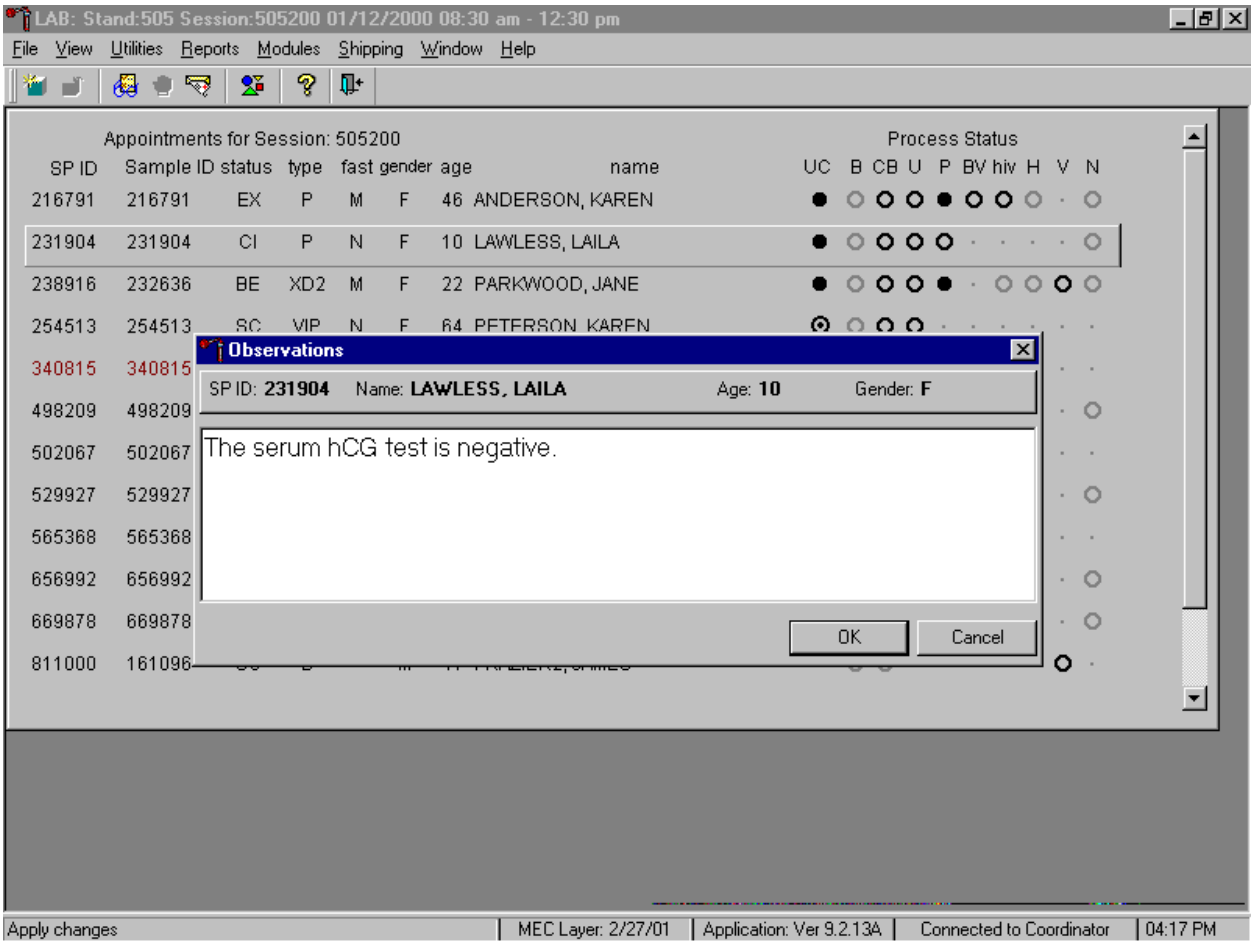
To select or highlight a SP, drag the mouse arrow to the correct SP and left click. Verify that the SP ID, name, and age are correct. Use the vertical scroll bar to view the complete list of SPs. To continue, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To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



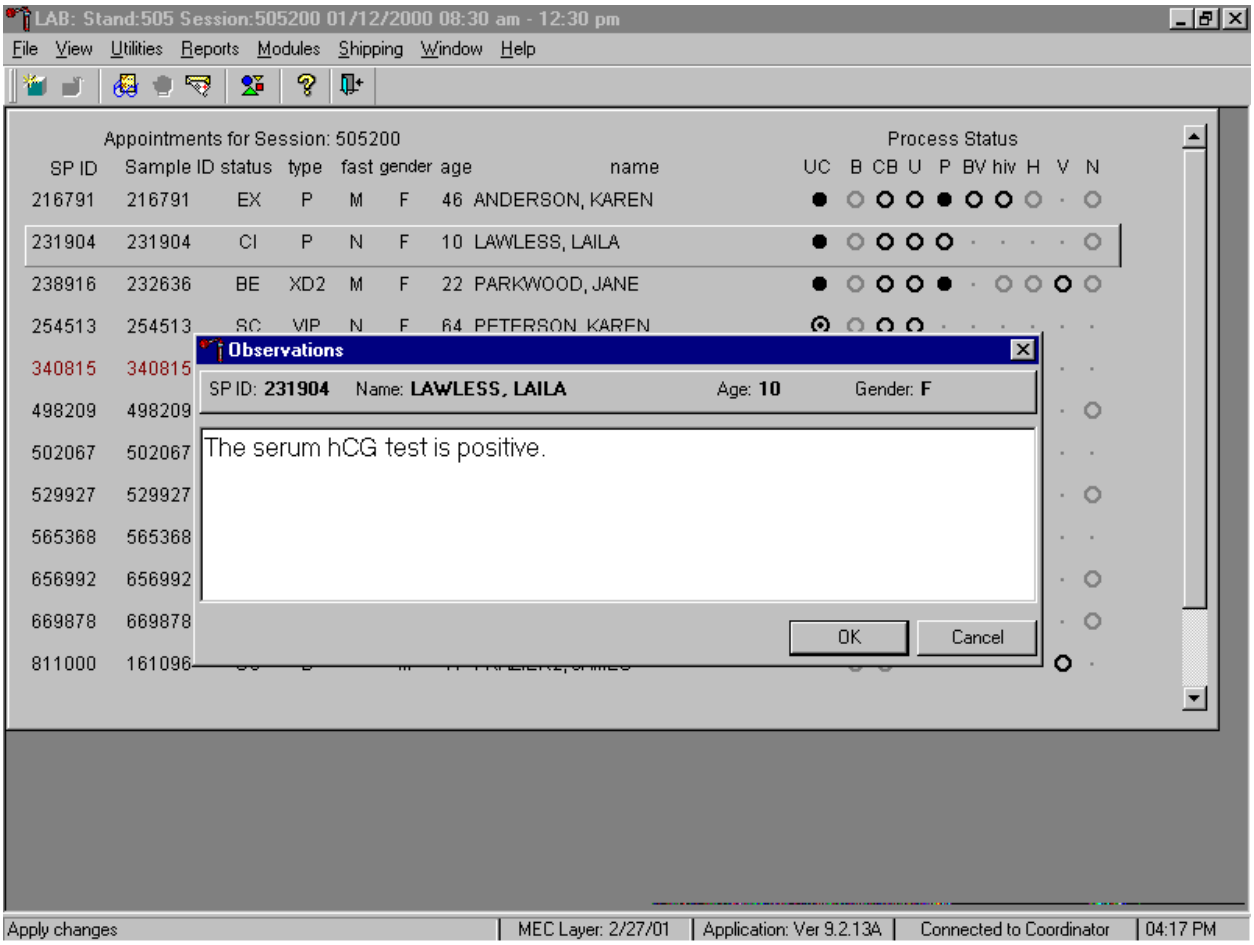
The observation text window contains the SP ID, name, age, and gender. Type the observation using the keyboard's keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions or to exit the observation 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.



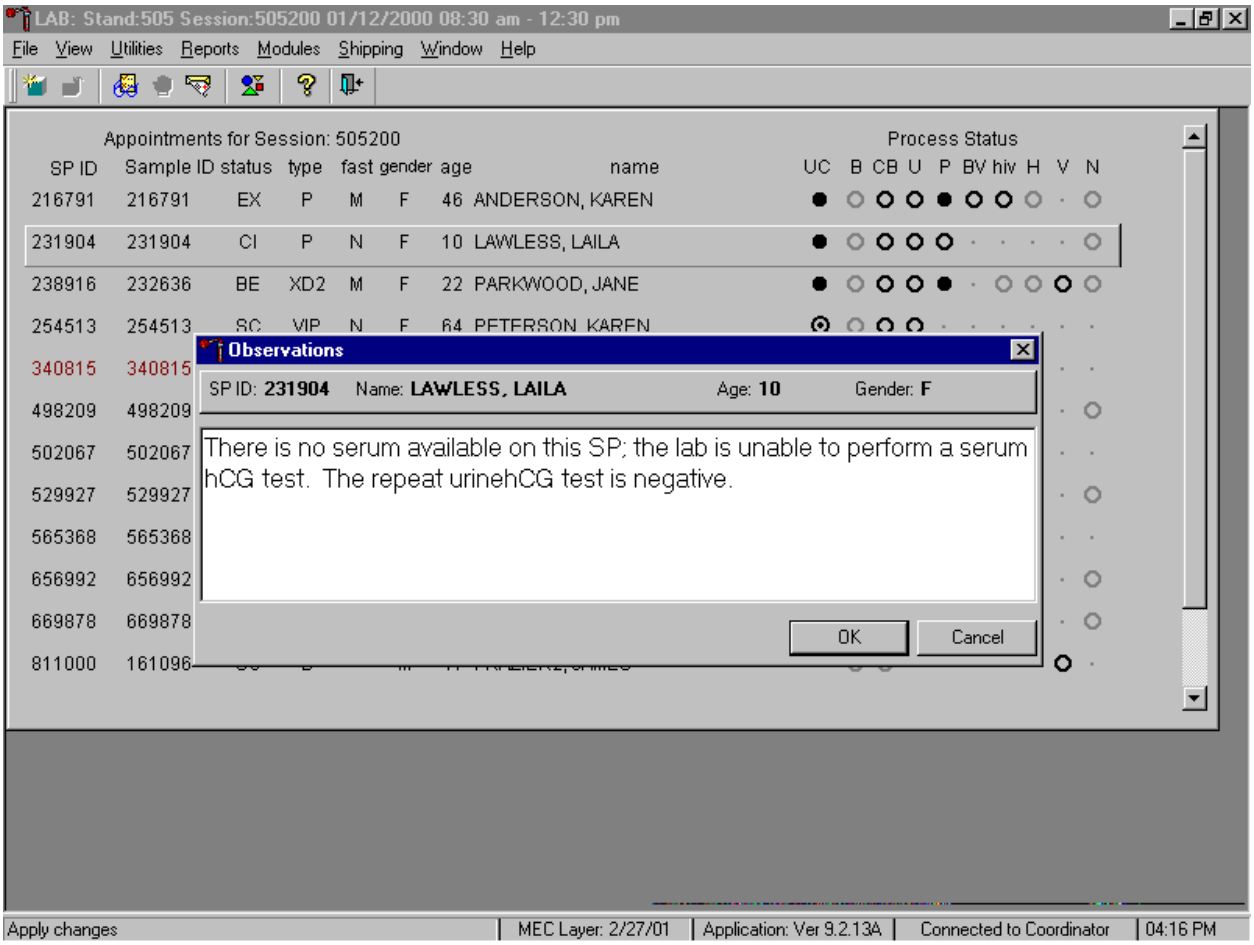
The observation window contains the SP ID, name, age, and gender. Type the observation, "The serum hCG test is negative," using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions 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.



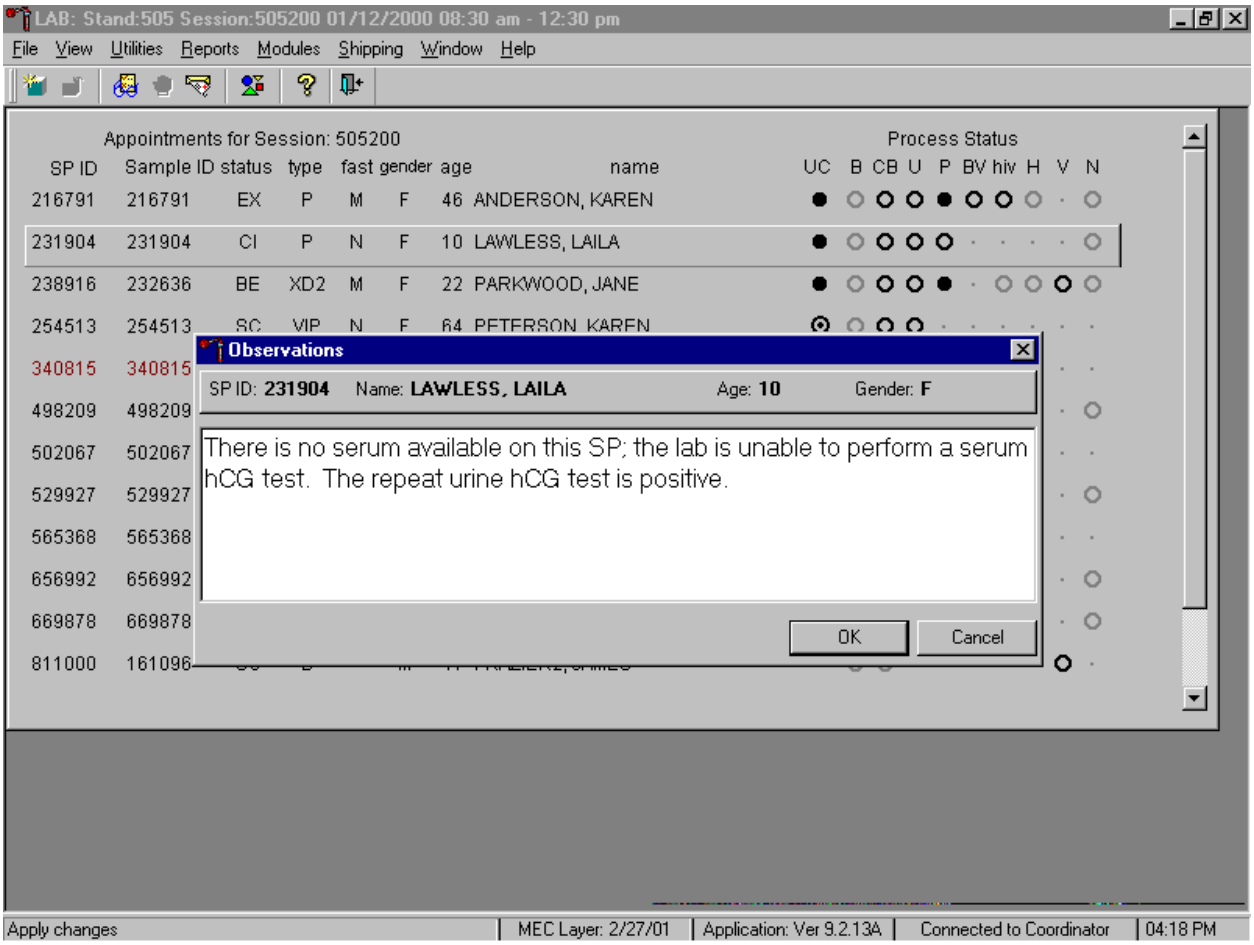
The observation window contains the SP ID, name, age, and gender. Type the observation, "The serum hCG test is positive," using the keyboard keys. To send the observation to the physician, use the mouse to direct the mouse arrow to the OK button and left click or select [Enter]. To cancel these actions 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.



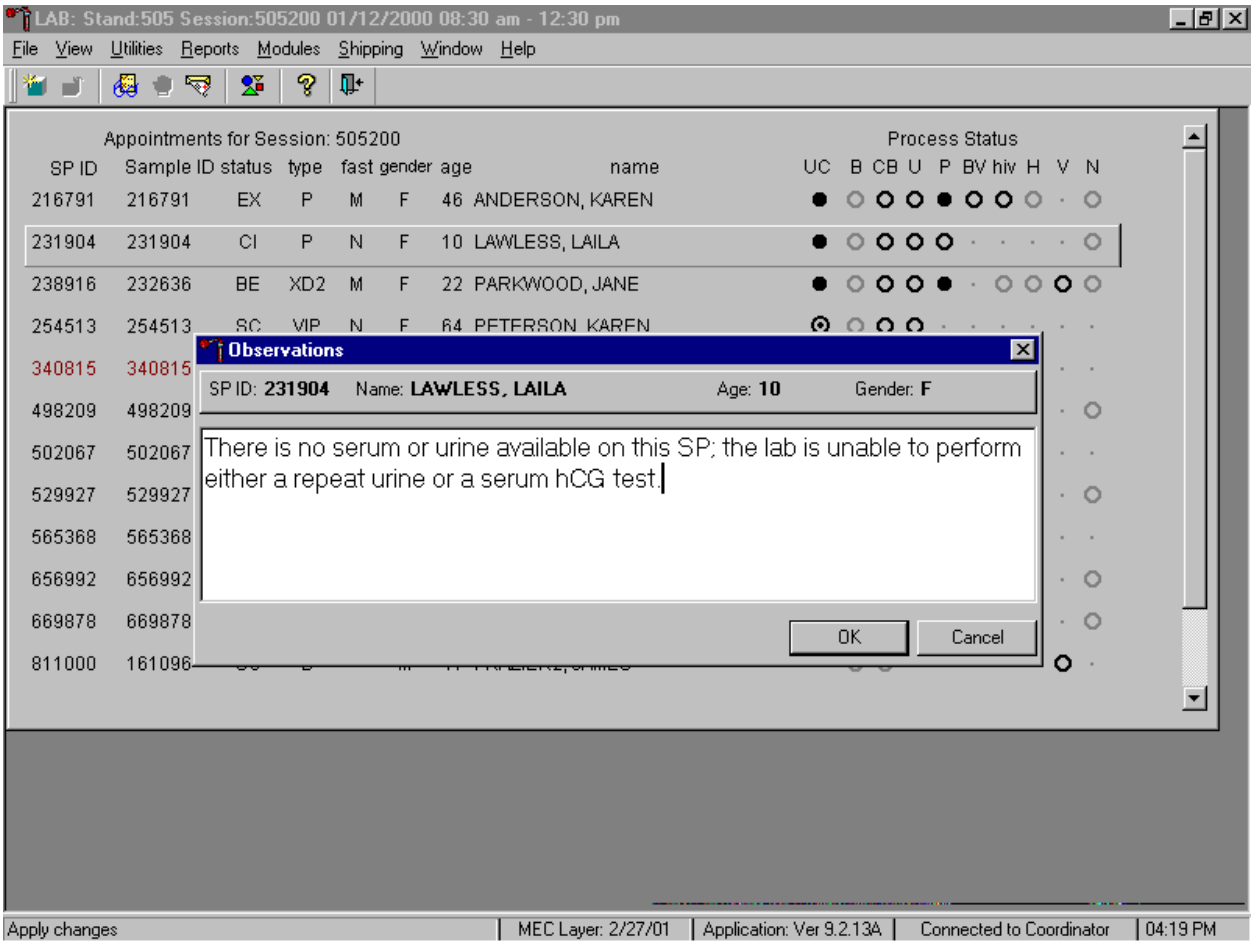
The observation window contains the SP ID, name, age, and gender. Type the observation, "There is no serum available on this SP; the lab is unable to perform a serum hCG test. The repeat urine hCG test is negative." using the keyboard keys. To send the observation to the physician, use the mouse to direct 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.



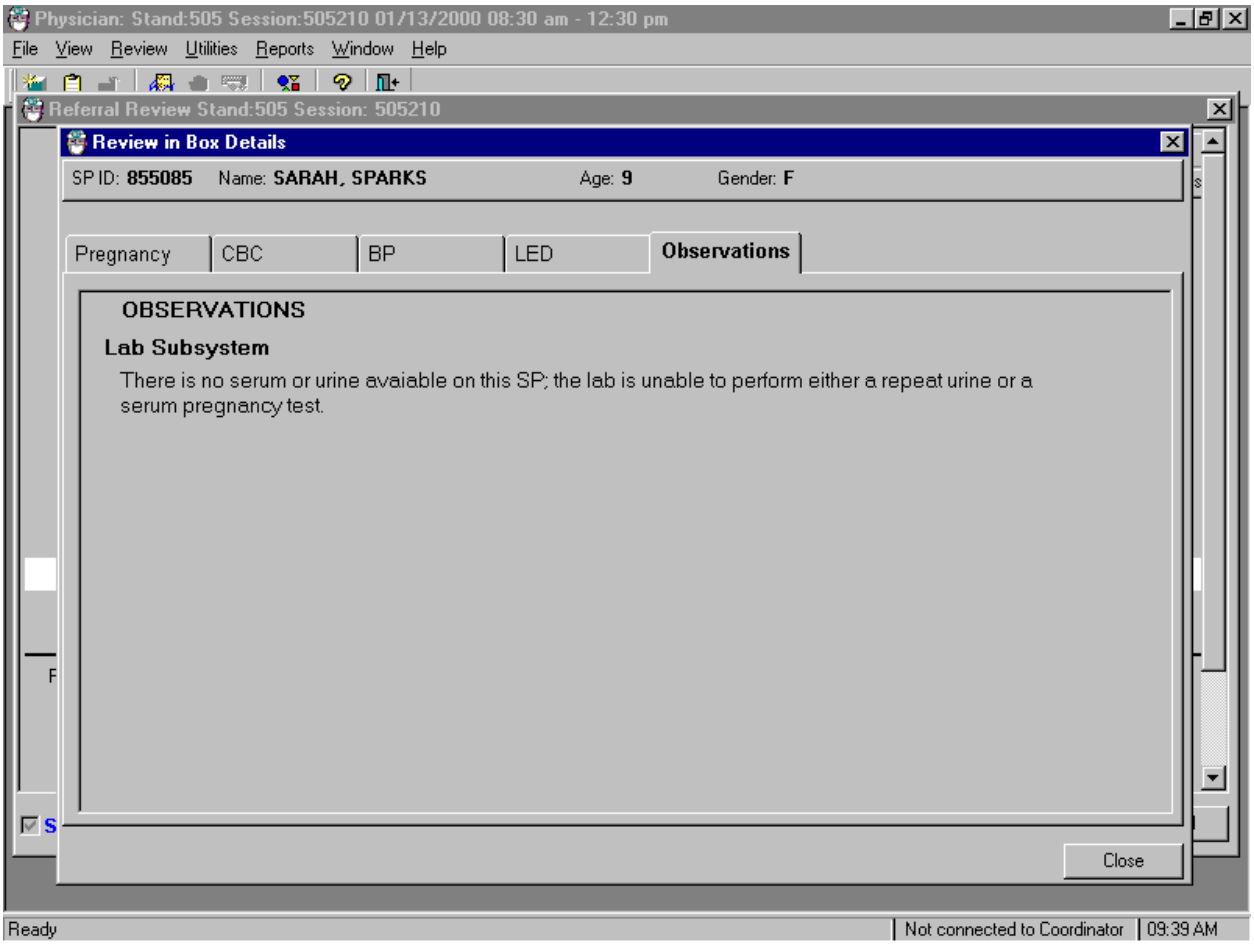
The observation window contains the SP ID, name, age, and gender. Type the observation, "There is no serum available on this SP; the lab is unable to perform a serum hCG test. The repeat urine hCG test is positive." using the keyboard keys. To send the observation to the physician, use the mouse to direct 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.



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.

XII. 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 mIL/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 mIL/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-Vue™ hCG Urine and Serum Control Sets

- These controls are formulated for use as a quality control specimen 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.

XIII. Reference Ranges

Not applicable.

XIV. Action Limits

Not applicable.

XV. 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.

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

There is no alternative method for testing.

XVII. Test Results Reporting System Protocol for Reporting Action Limits

Not applicable.

XVIII. Specimen Accountability and Tracking

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

XIX. Quality Control Summary Statistics and Graphs

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

XX. References

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