NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY III, CYCLE 2

MANUAL FOR MEDICAL TECHNICIANS

Revised February 1992

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1. OVERVIEW OF THE NHANES III

1.1 Introduction and Purpose of the Survey

The Third National Health and Nutrition Examination Survey (NHANES III) is being conducted by the National Center for Health Statistics (NCHS) of the United States Public Health Service. Data collection began in September 1988 and will continue for approximately 6 years (two 3-year rounds) at 88 locations across the U.S. The main survey was preceded by three pretests which were held between September 1987 and March 1988 in Los Angeles, California, Washington, D.C. and Tampa, Florida. Another pretest called the "Dress Rehearsal" was conducted in October 1988, just prior to the start of the main survey.

Approximately 40,000 individuals two months of age and older will be randomly selected from households across the U.S. to participate in the survey. Selected persons will be invited to take part in the survey by completing interviews in their homes and by receiving examinations at the Mobile Examination Center (MEC). The detailed interview includes demographic, socioeconomic, dietary, and health-related questions. Upon completion of the interview, respondents will be asked to voluntarily participate in additional interviews, extensive physical and dental examinations and biochemical tests, all conducted by highly trained medical personnel in a mobile examination center (MEC).

The purpose of NHANES III is to assess the health and nutritional status of adults and children in the United States. NCHS will use the data collected in this survey to define the normative distribution of:

- Specifically-defined diseases and other conditions of ill health;
- Nutritional disorders;
- Potential risk factors; and
- Normative health-related measurements, such as height, weight, and blood pressure.

At the conclusion of the study, prevalence rates will be computed for blacks, Mexican-Americans, Puerto Ricans, and other groups including whites, by age, sex, and income level. To assist in obtaining these rates, the survey will oversample blacks, Hispanics, the elderly and children.

The diseases and other medical conditions to be studied include, but are not limited to, the following:

- Cardiovascular disease (heart disease);
- Cancer;
- Chronic obstructive lung disease, including:
  - Asthma;
  - Chronic bronchitis; and
  - Emphysema;
- Diabetes;
- Kidney disease and other urologic disorders;
- Gallbladder disease;
- Osteoporosis;
- Arthritis and related musculoskeletal conditions, including:
  - Rheumatoid arthritis; and
  - Osteoarthritis;
- Infectious diseases, including:
  - Immunization to childhood diseases;
  - Exposure to hepatitis A or B;
  - Exposure to human immunodeficiency virus (HIV); and
  - Exposure to sexually transmitted diseases, such as herpes simplex 1 and 2;

- Oral health problems, such as:
  - Caries;
  - Periodontal disease;
  - Tooth loss;
  - Soft-tissue lesions;
  - Trauma assessment;
  - Occlusal and dentofacial characteristics; and
  - Tooth restoration and prosthesis conditions;
- Allergies to:
  - Certain foods, animals, insects and molds;
- Mental health conditions, for example:
  - Depression;
- Hearing loss;
- Retinal Disease; and
- Nutritional disorders, such as vitamin and mineral deficiencies.

Risk factors are those aspects of a person's lifestyle, constitution, heredity or environmental exposures which may increase his/her chances of developing a certain disease or condition. Some of the risk factors to be included in this study are:

- Tobacco usage;
- Alcohol consumption;
- Physical activity;
- Sexual practices;
- Occupational exposures;

- Reproductive health, such as oral contraceptive use and breastfeeding practices;
- Weight;
- Dietary intake; and
- Stress.

The results of this survey will benefit the American people in two important ways. First, data on the distribution of health problems and potential risk factors in the population provide researchers with important clues to the causes of disease development. This survey will provide the data researchers need to establish hypotheses of disease causation which can be tested in future epidemiologic and clinical research studies. Secondly, information collected from this survey will be compared to information collected in previous HANES surveys and future HANES surveys in which study participants will be asked to be examined and interviewed again sometime in the future. This will allow researchers to determine the extent to which various health problems and risk factors have changed in the U.S. population over time. By identifying the health care needs of the population, agencies of the government and private sector can establish policies and plan research, education, and health-promotion programs which will help improve the current health status of the population and prevent future health problems.

By computing prevalence rates for the population as a whole and for specific age-race-sex groups (e.g., 30-35 year old white females), researchers can determine which subgroups of the population would benefit most from specific programs and policies. For example, information collected in this survey will help FDA decide whether to implement calcium fortification regulations for the nation's food supply and how best to implement the fortification program, if needed. Data from this survey will be used to revise the growth charts which are used widely by pediatricians to monitor the growth of children.

Study participants are first interviewed at their homes and asked detailed demographic, socioeconomic, and health-related questions. Extensive physical examinations by highly trained medical personnel, additional health interviews, dietary interviews, and biochemical tests on biological specimens are then conducted in specially equipped mobile examination centers (MECs). Persons who cannot or will not come to the MEC for the full-scale examination are asked to undergo certain parts of the exam at their homes.

In addition to using these data as a baseline for future follow-up studies and analysis, some blood and urine specimens collected in this survey will be stored. Biological specimen banking will be of value in the future as new techniques are developed to measure exposure to environmental contaminants or disease agents or when new health problems are recognized. Biological specimen banking will be used to permit future laboratory analyses for:

- Estimating the prevalence of factors of current interest but for which acceptable testing protocols do not yet exist (e.g., pesticides);
- Estimating the prevalence of factors of emerging importance (e.g., chlamydia subtypes, various types of non-A, non-B hepatitis); and
- Conducting studies to look for the specific causes of diseases (e.g., bacteria, viruses, toxic materials).

Four areas have been selected for special emphasis in NHANES III: child health; health of older Americans; occupational health; and environmental health.

Child Health. NHANES III will help researchers assess the physical and emotional health status of children in the U.S. Communicable diseases, such as influenza, measles, and chickenpox, are not the only causes of illness and disability in the young. The focus of the childhood component of NHANES III will be on:

- Chronic diseases (heart and lung diseases);
- Allergic conditions;
- Immunity to various infectious diseases;
- Nutritional status;
- Cognitive functioning (ability to function in the activities of daily life);
- Physical growth;
- Disorders of hearing and dentition; and
- Blood lead levels.

Older Americans. The U.S. has experienced dramatic growth in the number of older people during this century. These demographic changes have major implications related to health care needs, public policy, and changing research priorities associated with older Americans. Recognizing this, NCHS is working with a consortium of public health service agencies to improve information on the health of the elderly. NHANES III is designed to fill many of the gaps in our knowledge of the health of older people. The survey component for older persons focuses on physical health status and aspects of functional health status. The key components for this part of the survey are:

- Osteoporosis and the evaluation of lower extremity function, including risk of falls and fractures;
- Musculoskeletal function, focusing on osteoarthritis, as a major cause of disability in older persons;
- Nutrition, including the evaluation of obesity;
- Cardiopulmonary diseases, which are major causes of illness and death in older persons;
- Physical function (individual's capacity for self-care);
- Cognitive function (ability to function in the activities of daily life); and
- Social function (ability to live independently).

Occupational Health. This component of the survey will focus on exposures in the workplace, such as noise, chemicals, and dust, which may be associated with specific health problems, such as neurological problems, lung disease, and musculoskeletal injuries.

Environmental Health. The environmental health research topic for NHANES III focuses primarily on studying exposure to toxic metals and chemicals, such as pesticides, by examining blood specimens for levels of various metals and chemicals in the blood.

Westat is a survey research firm which has been awarded a contract by NCHS to carry out data collection activities for the survey. Westat is responsible for selecting the survey sample, scheduling and

planning study procedures, developing the survey materials, such as manuals and forms, hiring and training field personnel, making advance arrangements for each stand, conducting community outreach activities, setting up and maintaining field offices and Mobile Examination Centers (MECs), scheduling and conducting screening interviews and extended interviews in the household, conducting interviews and physical examinations in the MECs, designing and carrying out quality control procedures, transmitting data to NCHS, and shipping biological specimens to various laboratories in the U.S. The examination and interview components of this survey have been designed in close collaboration with the Federal agencies which will use the resulting data for program planning and regulatory and research purposes. The following agencies have been involved in designing NHANES III:

Agencies of the National Institutes of Health, Public Health Service

- National Heart, Lung and Blood Institute (NHLBI);
- National Cancer Institute (NCI);
- National Institute of Child Health and Human Development (NICHD);
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK);
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMSD);
- National Institute of Dental Research (NIDR);
- National Institute of Mental Health (NIMH);
- National Institute of Neurological and Communicative Disorders and Stroke (NINCDS); and
- National Institute on Aging (NIA).

Other Federal Agencies

- Environmental Protection Agency (EPA);
- Food and Drug Administration (FDA);
- National Institute of Occupational Safety and Health (NIOSH); and
- National Institute of Environmental Health and Safety (NIEHS).

1.2 History of the Health and Nutrition Examination Survey

The National Health Survey Act, passed in 1956, provided the legislative authorization for a continuing survey to collect 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: the people themselves by direct interview; clinical tests, measurements, and physical examinations on sample persons interviewed; and places where persons received medical care such as hospitals, clinics, and doctors' offices.

To collect data by interview and physical exam, NCHS conducted four separate examinations surveys between 1959 and 1976. The first Health Examination Survey (HES I) focused mainly on selected chronic diseases of adults aged 18 - 79. HES II and HES III, conducted between 1963 and 1970, focused primarily on the growth and development of children.

The fourth survey introduced a new emphasis: the study of nutrition and its relationship to health status. This had become increasingly important as researchers began to discover links between dietary habit and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutritional Surveillance System was undertaken by NCHS. The purpose of this system was to measure changes in nutritional patterns over time. However, a special task force recommended that the continuing surveillance system be expanded to include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutritional Surveillance System was combined with the Health Examination Survey to form the National Health and Nutrition Examination Survey, NHANES.

NHANES I, the first cycle of the NHANES studies, was conducted between 1971 and 1974. This survey obtained a national sample of about 21,000 persons between the ages of 1 and 74 years of age. Extensive data on health nutrition were collected by interview, physical examination, and a battery of clinical measurements and tests from all members of the sample.

The planning process for NHANES II was carried out in 1974 and 1975 in collaboration with other Federal agencies. Throughout the planning stage there was continual awareness of the necessity of making the data collection for NHANES II comparable to the first NHANES survey so that NHANES I data could serve the purpose of providing a baseline for assessing changes overtime. This means that many of the same measurements had to be taken the same way on the same age segment of the U.S. population in both surveys. The NHANES II survey began examinations in February 1976 with the goal of interviewing and examining 21,000 persons between the ages of 6 months and 74 years. This survey was completed in 1980.

In addition to NHANES I and NHANES II, a special survey of the U.S. Hispanic population, HHANES, was undertaken to provide information on the health and nutrition status of Hispanics comparable to that obtained for the general U.S. population. The survey was completed in 1984. A fourth NHANES project, the NHANES Epidemiologic Followup Survey, was recently completed. This study was an effort to conduct followup interviews with the sample population, now aged 35-84, who were interviewed and examined in NHANES I between 1970 and 1974.

NHANES III is the third cycle in the NCHS series of surveys to collect data on the health and nutrition of the people of the United States through interviews and physical examinations. As in previous NHANES cycles, the survey's primary purpose will be to produce descriptive statistics that can be used to measure and monitor the health and nutritional status of the civilian, noninstitutionalized U.S. populations.

The plan is to administer a household interview and a 4-hour examination consisting of medical procedures, biochemical tests, and questionnaires to 40,000 sample persons aged 2 months and older over a period of approximately 6 years. The survey will be conducted in 2 rounds of about 3 years each in approximately 88 locations across the country.

NHANES III will serve to collect public health data for use in evaluating the health status of the U.S. population and determining how health status is affected by social and economic conditions. The wide range of statistics produced will be valuable for:

- Estimating the prevalence of selected diseases and conditions;
- Assessing health and nutritional status;
- Determining needs for health care;
- Analyzing relationships between health measures and risk factors; and
- Evaluating aspects of health and nutrition.

A number of longitudinal studies which use NHANES III data as baseline data are planned. These studies will follow the sample persons interviewed and examined during NHANES III over a period of years to attain measures of changes in health status and to study human growth and development in detail.

1.3 About Westat

Westat is an employee-owned research firm founded in 1961 and located in the Metropolitan Washington, DC area (Rockville, Maryland). Westat is recognized as one of the leading research firms engaged in survey research, program evaluation, mathematical and statistical analysis, and computer applications. Although primarily involved in conducting surveys for agencies of the Federal Government, the company has also served local government agencies, universities, professional societies, nonprofit institutions, and commercial enterprises.

The professional staff of more than 450 includes statisticians, epidemiologists, psychologists, sociologists, survey managers, market research analysts, economists, and computer systems analysts with specialized knowledge in health, labor, housing, and education. A highly trained nationwide field staff of supervisors, interviewers, and survey assistants provides additional support to the organization.

A large number of the studies Westat manages are concerned with the health of various subgroups of the population. The success of these projects can be attributed in part to the company's ability to enlist the cooperation of individuals and groups in the communities where the studies are conducted. For instance, it may be necessary to obtain cooperation from state or local government officials, professional associations, hospital administrators, citizen groups, and individuals.

Many of Westat's studies in the area of health involve nationwide data collection efforts in hundreds of different communities. For example, in 1979-80, Westat enlisted 38,000 U.S. school children in a study to estimate the prevalence of dental caries (cavities) and other oral health problems in that population. A second dental survey conducted in 1986-87 involved 45,000 school children. Fourteen teams, each with a dentist, a data recorder, and 2 coordinators, traveled to schools across the U.S. to collect data from students via dental examinations and interviews.

1.4 Pretest and Main Survey Schedules

1.4.1 Pretests

1.4.1.1 Purpose of the Pretests

Before any large-scale data collection effort is started on a survey, one or more pretests are conducted. During a pretest, field procedures and data collection instruments are tested and evaluated, then refined by the researchers. Field procedures are carried out just as they would be in the main study, but during the pretest a much smaller group of sample persons is selected. After the completion of a pretest, a series of meetings is held and suggestions for improving the field procedures and data collection instruments are incorporated into the plans for the main study. In this way, potential problems are resolved before the main survey begins, although it is inevitable that some unanticipated problems will arise as the study progresses.

1.4.1.2 Summary of the Pretests

Since NHANES III is so large and complex, four pretests were scheduled from September 1987 through December 1988. The first three pretests were conducted at different sites to evaluate the performance of the field procedures in various locations. The fourth pretest, or "Dress Rehearsal" was conducted in October 1988 and was intended to provide a final practice of all procedures before the main survey was initiated. Following is a summary of the pretests, the locations, the number of sampled persons (SPs), and the procedures tested.

Pretest I

LOCATION: Los Angeles, California
DATE: October 1987
DURATION: Six weeks
NUMBER OF SPs: 450
Questionnaires and interviewer field procedures were tested and evaluated.

Pretest II

LOCATION: Washington, D.C.
DATE: October - December 1987
DURATION: 9 weeks
NUMBER OF SPs: 600
MEC procedures and examinations tested.

Pretest III

LOCATION: Tampa, Florida
DATE: February - March 1988
DURATION: Six weeks
NUMBER OF SPs: 500
All office, interviewing and MEC procedures tested.

Pretest IV ("Dress Rehearsal")

LOCATION: College Park, Maryland
DATE: October 1988
DURATION: 6 weeks
NUMBER OF SPs: 450
Final testing of all procedures

1.4.2 Schedule for the Main Survey

Data collection for the main survey of 40,000 sample persons (SPs) began in September l988 and will be conducted in 2 cycles of approximately 3 years in length. Field office staff, interviewers, and 2 examination teams will travel to approximately 44 locations throughout the U.S. in each cycle. The average stand size will be about 450 SPs (within a range of 300-600 SPs). At any given time during the survey, examinations will be conducted at two stands simultaneously for 10 1/2 months of the year. There will be breaks of about 2 weeks around Christmas and about 2 weeks during the summer.

1.5 Sample Design

A sample is defined as a representative part of a larger group. Surveys involve studying a sample of persons rather than conducting an expensive and time-consuming census whereby every person in the population of interest is studied. Since it is impossible to interview and examine everyone in the U.S. for NHANES III, a representative sample is taken of the nation's population. At the conclusion of the study, estimates will be made of the prevalence of various health conditions and risk factors for the entire U.S. population, based on what is learned from the sample of people studied in the survey. 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 such a way that it accurately represents the whole population. Statisticians must calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population such as age, sex, race, and income.

After a decision has been made on the size and characteristics of the sample, the next step is to determine the method of drawing the sample. For NHANES III, a multi-stage approach is being used.

Stage 1: Sampling PSU's.

The U.S. is divided into geographic regions called Primary Sampling Units (**PSU's**). Each PSU is a county or small group of contiguous counties. At the home office, Westat statisticians randomly select 88 PSU's to be included in this study. The probability (likelihood) of a PSU being selected depends on its size (i.e., the more people who live in the PSU, the more likely it will be sampled). Each PSU that is selected is called a **stand**. Exam teams will travel to each of the 88 stands to conduct exams and interviews in the MECs.

Stage 2: Sampling BG/ED's.

Each selected PSU is comprised of block groups (**BGs**), defined by the Census Bureau, or enumeration districts (**ED's**). The home office randomly selects BG/ED's to be included in the study. Similar to Stage 1, the probability of a BG/ED being selected depends on its size.

Stage 3: Sampling segments.

Each BG/ED is comprised of **segments** which are clusters of homes. Segments are randomly selected to be included in the study. The larger the segment the more likely it is to be selected. Project staff called listers go to each segment and, using special forms, list the addresses of all dwelling units (houses, apartments, mobile homes) in that area.

Stage 4: Sampling households from the field listing.

Not all households in a stand are selected for the study. Home office project staff randomly select households from the field listings.

Stage 5: Selecting eligible persons (screening).

Field interviewers go to each sampled household identified in Stage 4. The interviewer administers a 10-minute screening questionnaire (Household Screener Questionnaire) to determine the household composition and sex/race/age/ethnicity characteristics of the household members. Depending on the characteristics of the household, only certain households are selected for the final sample. Interviewers have written instructions from the home office on how to conduct this stage of sampling.

Stage 6: Choosing Sample Persons in the selected households.

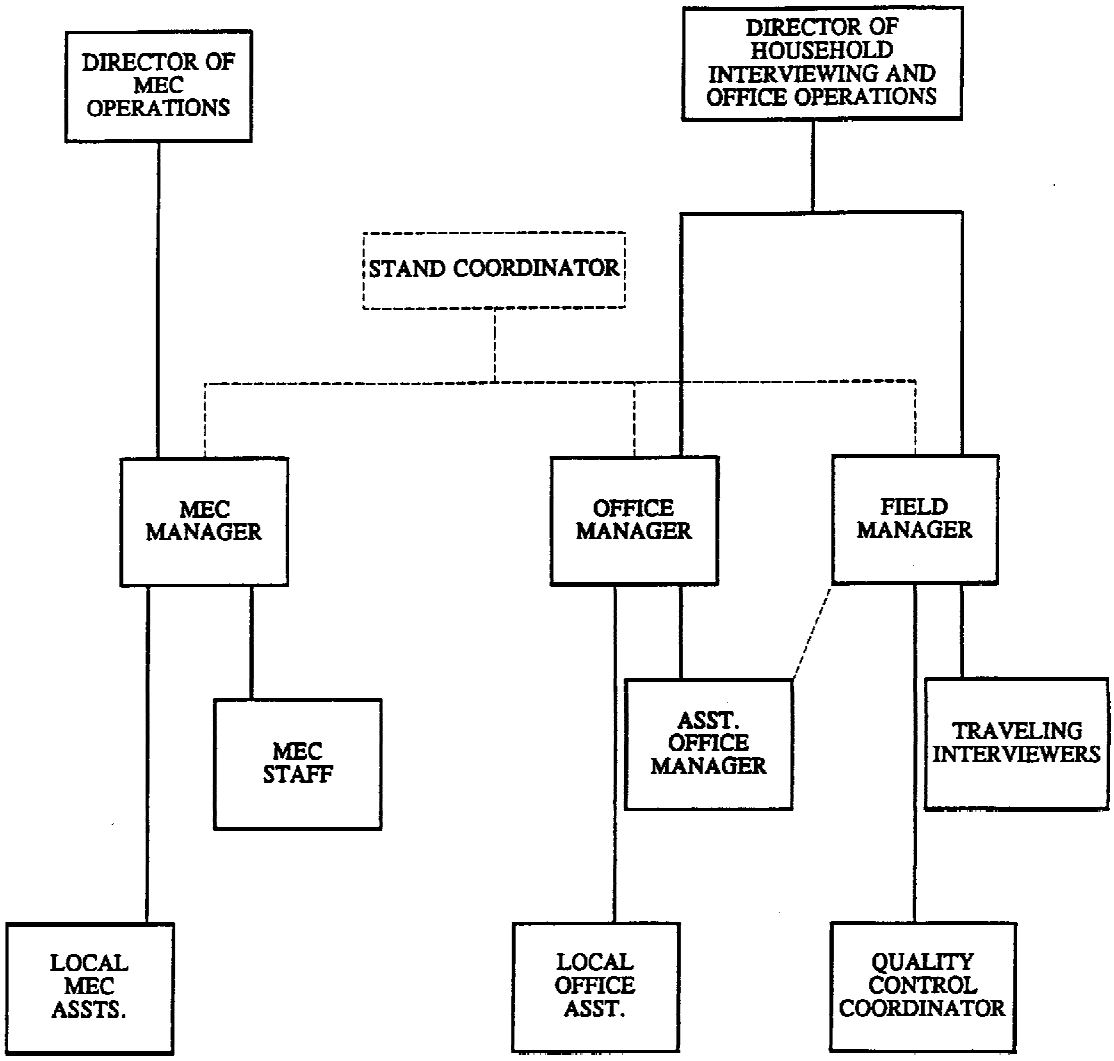
Following the screener sampling instructions, in a typical household 2-3 persons will be selected. However, in some households we may select none and in others as many as 10. Each individual selected for the study is called a **Sample Person (SP)**.

1.6 Personnel and Reporting Relationships

There are two different organizations conducting NHANES III. The National Center for Health Statistics (NCHS) is the government agency sponsoring, and ultimately responsible for, the survey. NCHS has contracted with Westat to conduct the field operations for the survey. NCHS staff and consultants from both NCHS and Westat participate in staff training programs and pretest activities, and periodically visit the field operations during the main survey.

As a member of the exam team staff, you are an employee of Westat and will report directly to Catherine Novak, Director of MEC operations for the Westat staff. Exhibit 1-1 shows the formal reporting relationships for the project. Renee Slobasky serves as the NHANES project director for the Westat home office. Dr. Carla Maffeo, technical director for examinations at Westat's home office, is responsible for technical issues, such as how an exam procedure or biochemical test should be done. Exam or personnel matters should be discussed with the Director of MEC operations. The MEC manager, who is responsible for day-to-day activities of the MEC at the stand, should be consulted for such questions regarding the automated system, equipment, supplies, data collection, sterilization of instruments, storage and shipment of data and specimens, and administrative issues.

Exhibit 1-1. Reporting relationships



A Stand Coordinator is also designated for each stand and will be responsible for coordinating stand activities with the other on-site managers.

1.7 Advance Arrangements for a Stand

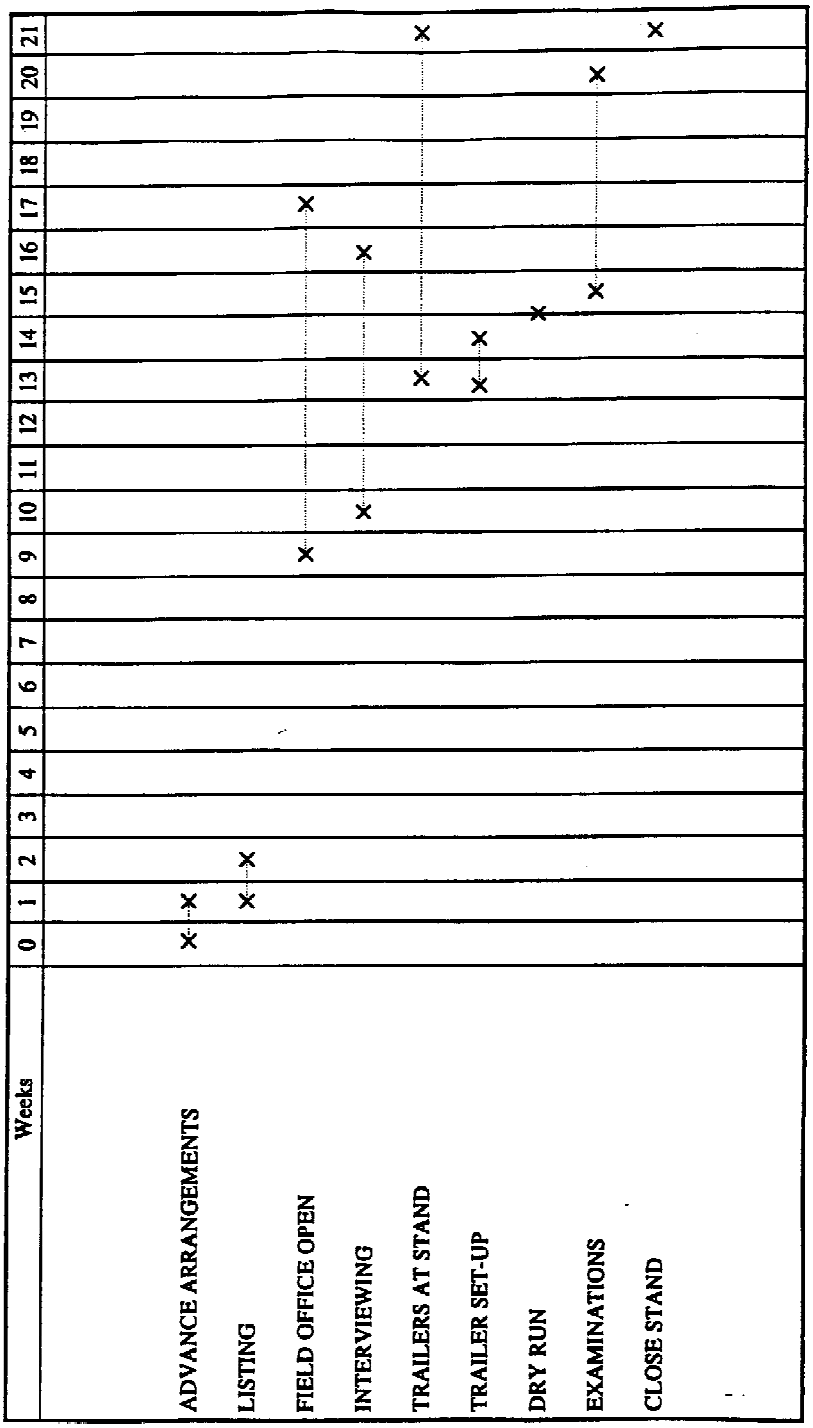
1.7.1 Schedule for Advance Arrangements

Exhibit 1-2 summarizes the schedule for a stand. Advance arrangements begin in Westat's home office at least 10 weeks prior to the start of interviewing at a stand. Members of the advance arrangements team study maps and familiarize themselves with the layout of a stand, location of sampled segments, major highways and arteries, public transportation, and sites that appear appropriate for location of the MEC. Once they have a basic knowledge of the layout of the area, they contact local officials identified by our outreach program as prospective knowledgeable informants and make arrangements to visit the prospective stand.

The field office is opened at least 1 week prior to the start of household screening and interviewing. During that week the rental furniture and office equipment arrive, supplies shipped to the site from the home office are unpacked, telephones are installed, and computer systems are tested. A member of the advance arrangements team is at the stand during this period.

At least 1 week before examinations begin, the MEC is delivered to the prearranged site. The MEC manager will be on hand to receive the trailers and direct their location and leveling by the shipping firm, to oversee the hookup of electricity and plumbing lines by local contractors, and to verify the presence of the previously arranged security. After the trailers are set up, examination staff members unpack, calibrate and test the equipment. Medical and laboratory supplies delivered to the MEC are unpacked and stored. These preparations are scheduled and managed so that the MEC is ready for its dry run prior to the first scheduled examinations.

Exhibit 1-2. Stand schedule



1.7.2 Community Outreach Activities

Westat and NCHS have developed a comprehensive and effective outreach program. This program is directed from the Westat home office under the supervision of the Director of Advance Arrangements, Jack Powers. Outreach activities are initiated prior to entering a stand and continue throughout the period of interviewing and examinations.

The purpose of the outreach activities is to inform public officials and potential participants about NHANES III. In informing public officials, regardless of whether their active support is sought, it is hoped that by providing information the study will be recognized as a legitimate and important research effort. The goal of outreach programs directed to potential sample persons is not only to provide information, but to encourage them to take part in an important study.

Westat directs the outreach program to audiences at the national, regional, state and local levels. Through Westat, public officials receive a letter from NCHS describing the survey, a fact sheet explaining technical aspects of the study, and a brochure.

It is important to establish a positive relationship with local health officials and other community representatives as their active support will help legitimize the survey. These persons can also assist during advance work by providing an introduction to other community officials whose cooperation may be important to the survey.

Westat has developed a community outreach program to be activated in each stand incorporating various types of media. The goal is to reach as many of the target populations as possible via radio, television and newspapers in each community. Posters and flyers, in English and Spanish, will be distributed and posted in highly frequented areas, such as churches and community centers, shopping centers and high-rise apartment buildings.

Another purpose of the outreach program is to identify local physician’s and dentist’s offices or clinics to which the examination reports of findings may be sent for those SPs who are referred for immediate medical or dental care but who report no regular source of health care.

1.8 Data Collection

Data for NHANES III are collected in two phases:

- Household interviews in which SPs are asked detailed demographic, socioeconomic, and health-related questions; and
- Extensive physical examinations, dental examinations, health and dietary interviews, and laboratory tests on biological specimens conducted in mobile examination centers (MECs).

The household component and MEC component are discussed in more detail in the following section.

1.8.1 The Automation System

An automated system has been developed for survey control and capture of interview and examination data in the field. In the MEC, this system will collect, record, account for and transmit examination and interview data. In addition, the computerized flow system will process examinees through the MEC. A more detailed explanation of the MEC Automation System is given in The NHANES III Laboratory Automation System Manual.

1.8.2 Household Interviews

The field interviewers conduct all household interviews and schedule appointments for examinations in the MEC.

1.8.2.1 Advance Letter

As mentioned in Section 1.5, certain households are sampled for the survey. Before an interviewer contacts a household, the Westat home office mails an advance letter to the household.

The advance letter is an important tool for introducing and legitimizing the study. The letter clearly states the purpose and importance of the study, a respondent's rights as a participant, including the confidentiality of information given and the voluntary nature of participation, and indicates that an interviewer will be coming to the household in the near future.

1.8.2.2 Household Screening Interview

Upon arriving at a home, interviewers are instructed to show the advance letter at the door (if the respondent has not seen or does not remember the letter), the screener brochure, and his/her survey I.D. badge.

- **The Household Screener Questionnaire** is administered to one eligible respondent living in the selected dwelling unit who is at least 17 years of age and preferably the head of the household. It includes an introduction, a household enumeration section (including a series of questions identifying secondary families), and an eligibility criteria section collecting information on age, sex, and race or ethnic background. The Screener takes about ten minutes to administer. Once the interviewer has determined that at least one person in the household is eligible to participate in the survey, he/she attempts to administer the family questionnaire, the medical history interview and make an examination appointment. During this process, each selected respondent receives a sample person brochure.

- **The screener brochure** contains a brief description of the study and provides answers to typical questions a respondent might have during initial contact.

- **The sample person brochure** contains more detailed information on the extended interview and examination component of the study. The interviewer distributes this brochure to eligible respondents upon completion of the screening. The brochure describes the examination to be conducted in the MEC and, like the screener brochure and advance letter, emphasizes the purpose and importance of the study, voluntary participation and confidentiality of the information provided. It also includes the Informed Consent Form.

1.8.2.3 Informed Consent

- **Consent form**. The last page of the Sample Person Brochure contains the consent form. The SP must sign the form as an indication of his/her willingness to participate in the study. If the SP does not wish to sign the consent form at that time, he/she may bring the signed form to the MEC at his/her scheduled exam time, or may have additional questions answered at the MEC before signing the form. A refusal to sign the consent form is considered a refusal to participate in the examination phase of the study. Examinations will not be conducted on sample persons who do not return a signed consent form. To participate in the household interviews, an SP only needs to give verbal consent.

For minors the signature of a parent or guardian is required on the consent form. Minors over the age of 12 years are also asked to sign the form as an indication of agreement to participate.

By signing a consent form, a person gives permission for the SP to have the extensive physical exam in the MEC (or the home health examination). A copy of the Home Health Exam Fact Sheet will be given to each SP who is offered the home examination option.

1.8.2.4 Extended Household Interviews

- **The Family Questionnaire** is administered to one eligible respondent in each family who is at least 17 years of age and preferably the head of the household. Information is collected on family relationships, demographics, health insurance, housing, and income. It also contains instructions for within household sampling.

- **The Sample Person Questionnaire** is administered to each sample person or an eligible proxy. A detailed health history is collected on each sample person. The extended interviews require about 40 minutes for each SP. There are two versions of the SP Questionnaire, one for adults and one for youths. Information about SPs who are 2 months to 16 years old is obtained through direct interviews with a proxy, such as the child's parent.

1.8.2.5 Exam Appointments

Interviewers make appointments for SPs to receive physical examinations at the MEC. The interviewer calls the field office to obtain an exam appointment time. If the SP agrees to the time, the information is entered into the field office Automated Survey Management System.

1.8.2.6 English and Spanish Study Materials

The advance letter, brochures, consent form, and household questionnaires are printed in both English and Spanish. Bilingual interviewers use the language with which the respondent feels most comfortable.

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

1.8.3.1 The MEC

Examinations and interviews are conducted in specially equipped and designed mobile examination centers (MECs) each consisting of four trailers. Each trailer is approximately 45 feet long and 8 feet wide. The trailers are drawn by detachable truck tractors when moving from one geographic location to another. At an examination site, such as a hospital parking lot, the four trailers are set up side-by-side and connected by enclosed passageways. At any given time during the survey, there are two MECs set up at two different stands and a third MEC is either in transit or in for maintenance.

Exhibit 1-3 shows a floor plan for the MEC. The interior of each MEC is designed specifically for this survey and incorporates many customized features. For example, the trailers are divided into specialized rooms to assure the privacy of each study participant during the exams and interviews. Also, the audiometry room is soundproofed and the X-ray room shielded with lead. The MEC houses all of the state-of-the-art equipment and supplies necessary for the exams and biochemical tests conducted in the MEC.

1.8.3.2 Exam Sessions

The MEC remains at a stand for approximately 6 weeks (range 4-8 weeks). During that period, the MEC operates 5 days a week including weekday, evening and weekend sessions. Two 4-hour sessions are scheduled each day with 10 examinees per session.

Exhibit 1-3. Floor plan of MEC

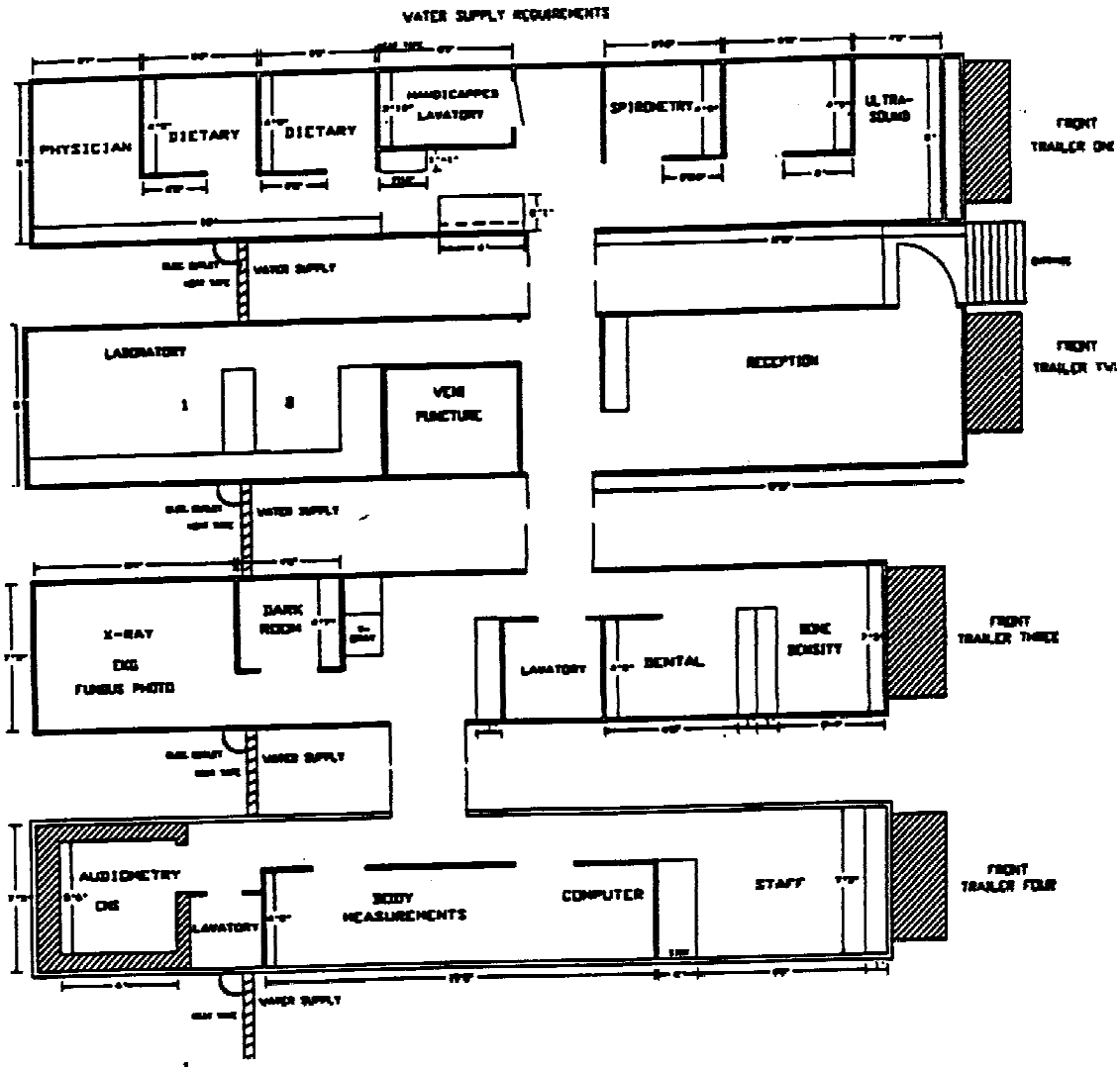


Exhibit 1-3. Floor plan of MEC (continued)

Trailer	Room	Room Use
Trailer I	Physician	Physical examination by a physician
	Dietary	Dietary and food frequency interview
	Dietary	Dietary and food frequency interview
	Interview	Cognitive test and neurological tests
	Spirometry	Tests lung function
	Ultrasound	Ultrasound exam for gallstones
Trailer II	Waiting Area	Waiting area for sample persons
	Reception	Welcoming station and public waiting room
	Venipuncture	Drawing of blood samples, GTT
	Lab	Centrifugation preparation and analysis, blood processing, hematology and blood chemistry laboratory
Trailer III	X-ray/ECG/	X-rays of hand, knee; test heart function
	Fundus Photography	Photo of the fundus of the eye
	Dental	Dental exam by a dentist
	Bone Densitometry	Measures bone density
Trailer IV	Audiometry	Hearing tests
	Body Measurements/ Allergy	Height, weight, and other physical measurements/Allergy testing
	Computer	Storage of collected data
	Lounge	Staff

1.8.3.3 Exam Team Responsibilities

The two exam teams travel from stand to stand to conduct the exams and interviews in the MECs. There are 16 individuals on each traveling team. In addition, a local assistant will be recruited, trained, and employed at each stand to assist the exam staff. The duties of the exam team members are summarized below.

- One coordinator directs the flow of SPs through the MEC examination process. The coordinator manages all SP appointments, prepares the SP examination folders, and verifies that all exam components have been conducted and recorded before the SP leaves the MEC.

- One physician reviews the SP's medical history, conducts the medical examination, and records the results of the exam. The physician also reviews the X-rays, the results of the blood test (CBC) and the ECG.

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

- One health interviewer administers questionnaires for cognitive and neurological tests and records the results.

- Two dietary interviewers administer the SP dietary questionnaire. During the interview the interviewer records (a) a 24-hour dietary recall of the types and amounts of all foods and beverages consumed by the SP in the last 24 hours and, on selected SPs, (b) food frequency information regarding how often certain types of foods were consumed by the SP in the past month.

- Four certified radiologic health technologists take and record body measurements, X-rays, bone densitometry, pulmonary function tests (spirometry), ECGs, photos of the fundus of the eye, administer audiometry and allergy exams, and record the dental exam findings. The duties of the health technicians are assigned on a rotating basis.

- One certified ultrasonographer performs sonography of the gallbladder, and also assists health technicians in performing selected other tests such as allergy, audiometry, spirometry and body measurements.

- Three certified medical technicians/technologists conduct clinical laboratory tests on blood and urine specimens, record the results of tests, and prepare and ship specimens to various laboratories.

- One certified phlebotomist administers the phlebotomy questionnaire, draws blood from SPs, and administers Trutol for the glucose tolerance test (GTT).

- One home health technician conducts home exams, and works as a health technologist and a laboratory technologist when there are no home exams scheduled.

Each MEC 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 National Health and Nutrition Examination 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 any 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. Team members will rotate periodically to prevent the introduction of bias into the exam results due to "team effects" .

1.8.3.4 Exam Components

Each SP exam takes up to 4 hours. The actual length of time depends on the age of the SP, as some exam components are only done on certain age groups (adult SPs tend to receive more extensive exams). Exhibits 1-4 and 1-4a present lists of exam components for each age group. Exhibit 1-5 presents an estimate of the number of minutes for each exam component.

Some blood specimens are analyzed in the MEC by the medical technologists while other specimens are sent to various laboratories in the U.S., such as the Centers for Disease Control (CDC), and have special storage and shipping specifications.

1.8.3.5 Sample Person Remuneration

SPs who complete all or part of the exam in the MEC are given a monetary token of appreciation for their time and effort. This remuneration is in addition to the payment for transportation expenses. Adult examinees will receive $30 or $50, depending on whether they accept an appointment at a particular time. Also adults who receive special components, such as the volatile toxicants study, will receive additional remuneration. Children will receive $30.00.

Exhibit 1-4. Examination components by age groups

2-11 mos.	1-5 yrs.	6-19 yrs.	20 yrs. +
Physician exam	Physician exam	Physician exam	Physician exam
Body measurements	Body measurements	Body measurements	Body measurements
Dietary interview	Dietary interview	Bioelectrical impedance	Bioelectrical impedance
Dental exam	Dental exam	Dietary interview	Dietary interview
	Venipuncture	Dental exam	Dental exam (up to 74)
		Tympanic impedance	Venipuncture
		Venipuncture	Urine collection
		Audiometry	Cognitive tests (60+)
		Urine collection	Neurological tests (20-59)
		Cognitive tests	Allergy skin test (20-59)
		Allergy skin test	Spirometry
		Spirometry	Joint X-ray (60+)
		MEC questionnaire	Electrocardiogram (40+)
			Glucose tolerance test (40-74)
			Ultrasound (up to 74)
			Bone densitometry
			Physical function (60+)
			Fundus photography (40+)
			MEC questionnaire

Exhibit 1-4a. NHANES III Examination Components

Components	Ages
Physician exam	all
Phlebotomy	1+
GTT	40-74
Body measures	all
24-hour recall	all
Food frequency	6-19
ECG	40+
Bioelectrical impedance	12+
Spirometry	8+
Dental	2 mos-74
Bone densitometry	20+
Ultrasound	20-74
Allergy (adult half sample)	6-59
Physical function	60+
Cognitive function	60+
MEC questionnaire-adult + Dis	20+
MEC questionnaire - youth	6-19
MEC questionnarie - proxy youth	20-39
CNS (half sample)	20-59
Cognitive testing-child	6-19
Joint X-ray	60+
Audiometry/tympanometry	6-19
Urine collection	6+
Fundus photography	40+

Exhibit 1-5. Estimated number of minutes for each exam component

EXAM COMPONENTS	SAMPLE PERSON LENGTH OF TIME (IN MINUTES)
Physical Exam	10
Body Measurements	9
Bioelectrical Impedance	3
Dietary Interview	19
Food Frequency (12-16)	12
Fundus Photography	6
Dental exam	8
Tympanic Impedance	5
Venipuncture, GTT	19
Audiometry	10
Cognitive and Neurological Tests and Health Interview	30
Allergy Skin Test	7
Spirometry	11
X-rays of Hand, Knee	8
Electrocardiogram (ECG)	13
Ultrasound	10
Bone Densitometry	16

1.8.3.6 Report of Exam Findings

For each SP examined in the MEC, the routine blood pressure and dental findings will be reported to the examinee prior to his/her leaving the MEC. A report of all other findings will be generated by the automated system at NCHS summarizing the findings of the physical exam and biochemical tests. This Report of Findings form will be produced **after** the stand is closed, and **mailed** to the SP. The dentist completes a report of the dental exam findings which is alsogiven to all SPs. Additionally, for SPs who are referred for immediate medical or dental care, a report is sent to the SP's personal physician, dentist or clinic. If the SP does not have a personal physician, dentist or clinic, a list of community clinics will be shown to the SP by the MEC coordinator who will encourage the SP to choose one; the report of the physician's/dentist's findings is then sent to that clinic. If the SP refuses to choose a health care provider, the report of the physician or dentist's findings is given to the SP.

In the MEC, in those instances when the physician or dentist finds a condition that warrants immediate attention from the ECG, hematology, X-ray, dental, or blood pressure results, or from an unexpected incident, the physician or dentist will contact the SP's health care provider by telephone.

1.8.3.7 Dry Run

At the beginning of each stand, members of the MEC staff will devote one-half day to calibrating instruments and practicing MEC procedures. Since the MEC will be moving from one stand to another, it is important to check the equipment before exams begin to make sure everything is working properly. If there are problems with any of the equipment, including the automated system, the stand manager must be informed so that malfunctions can be repaired before the real exams begin. In addition to calibrating instruments, the dry run will give MEC staff an opportunity to practice their assigned duties, including setting up equipment and supplies, verifying instrument quality control results, sterilizing instruments, processing examinees through the MEC, interacting with other MEC staff members and examinees, performing exam procedures, recording exam results on the automated system, completing required forms, and shipping data and specimens to Westat and various laboratories. All procedures in the dry run will be completed as though the actual study were being conducted. The only difference is that in the dry run the examinees will be volunteers who are not part of the actual sample for the main

study or pretests. To solicit volunteers from the community, someone from the field office may post an advertisement at a local grocery store. Other volunteers may include local officials who want to see first-hand the type of exams to be conducted, field office staff, field interviewers, and MEC staff.

Problems identified during the dry run will be discussed by the MEC manager and MEC staff. Based on the results of the dry run, certain procedures may need to be modified or additional quality control procedures may be instituted by the home office in order to overcome or alleviate identified problems.

1.8.4 Home Exams

An examination in the home will be available for selected SPs who are wheelchair or bed-bound or unable or unwilling to go to the MEC for an examination. The household interviewers will determine when an SP should be offered the home exam, and the field office will schedule the appointment. If the SP is reluctant to participate in a MEC exam, every attempt will be made to persuade the SP to agree to an exam, either at the MEC or in his/her home. Because of equipment and staffing considerations, only certain exam components can be conducted in the home. For instance, any equipment required for the home exams must be portable and relatively compact when packed. Exhibit 1-6 lists the exam components which are conducted in the homes of SPs. As with the full-scale MEC exam, the components of the exam depend on the SP's age.

The home examiner conducts the examination of SPs in the home. All tests are completed on-site with the exception of the blood tests, which are prepared and shipped from the MEC. After completing an SP exam, the home examiner will return to the MEC with the blood tubes and enter the results of the home examination phlebotomy into the automated system in the laboratory. The blood is processed and shipped with the blood collected in the MEC.

SPs who complete the home exam are given $15 as a token of appreciation for their time and effort. This is less than the remuneration for the MEC exam because the home exam is less extensive.

Exhibit 1-6. Home exam components

	AGE		
	2-11 months	20-59 years	60+ years
COMPONENTS			
Body Measurement (Height, Weight, Mid-Arm Girth & Tricep Skinfold)	X	X	X
Head Circumference	X		
Venipuncture		X	X
Spirometry		X	X
Cognitive Tests			X
Physical Function Exam			X
Infant Food frequency	X		
Selected Conditions/Medicine, Vitamin & Mineral Usage/Tobacco/ Reproductive Status		X	X
TIME (Minutes)	10	40	50

1.8.5 Special Studies

At times during the study, special projects may be implemented to obtain information about a specific area of interest, as NHANES III provides an unusual opportunity to capture large amounts of data in an efficient manner. The volatile toxicant study is one such special study.

1.8.5.1 Volatile Toxicants Study

The volatile toxicant study is being sponsored by the toxicology branch of the CDC as an additional component of NHANES III. Extra blood and urine samples are to be collected from 45 volunteers at each stand and analyzed by CDC for selected variables. Volunteers are paid $10 for participating in the study.

Recruitment for the study will begin on the first day of exams at each stand and continue until 45 sample persons have volunteered. Only sample persons between the ages of 20 and 59 are eligible for the study. The phlebotomist is responsible for recruiting sample persons at the time of the first venipuncture. Because the MEC itself may be a source of some of the chemicals CDC is measuring in this study, the blood and urine samples must be collected as soon as possible after the sample person enters the MEC.

If a sample person agrees to participate in the study, one 10 ml gray top tube and one 10 ml non-silicone coated red top tube are obtained on the first draw. If this is not possible, the sample person will be asked if a second stick can be performed. If the SP is over the age of 40 years and will have a second venipuncture for the glucose tolerance test, the additional blood may be drawn at that time.

The required 45 ml of urine is obtained from the urine specimen which is collected when the sample person first enters the MEC, assuming that the first specimen is of sufficient volume to allow this. If the required amount of urine cannot be obtained from the initial sample, a second urine specimen will be collected.

The sample person is also asked to complete a self administered questionnaire as part of the volatile toxicants study. The phlebotomist collects the questionnaires from the coordinator at the end of the session and mails the questionnaire with the urine samples to CDC.

1.9 Confidentiality and Professional Ethics

All information collected for this study must be kept strictly confidential except as required by law. 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 study 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 study.

When the study is finished, all of the collected information will be summarized by NCHS in a report. No participant names will be included in any reported results. Neither NCHS nor Westat 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. Westat expends a great deal of effort in obtaining cooperation from national, regional, state, and local officials and the general public. It is the responsibility of each person working for Westat to build on the company's reputation of integrity so that we can continue to have access to study participants during current and future studies; therefore, professional conduct both on and off the job is very important.

As you travel across the country for this study, you may find yourself to be very much in the public eye, particularly in the smaller towns where your presence is easily recognized. Each staff member has a responsibility to the Public Health Service and to Westat for promoting good public relations. The Public Health Service and Westat will be judged by the actions of the staff both on and off duty; consequently, you must be discreet in speech and actions. Your personal appearance and behavior must be governed by these same considerations. Be aware of the customs of the area and avoid any actions which might be interpreted unfavorably by the public, for example, parking a Westat vehicle in a questionable location. Please be aware of your "audience" at all times and try to avoid statements or actions that could shed an unfavorable light on Westat, the Public Health Service, or the survey.

You will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that you understand that you are prohibited by law from disclosing any information obtained while working on the study to anyone except authorized staff of NCHS and Westat and that you agree to abide by the Assurance of Confidentiality.

This chapter of the manual was designed to provide you with general information about the study, including the advance work that Westat and NCHS completed prior to your joining the study staff. The remainder of this manual explains in detail your responsibilities in this study.

2. ROLE OF THE LABORATORY TEAM

2.1 Medical Policy Regarding the Exams

The purpose of NHANES III is to collect data on the health of the population. The intent of the study is not to provide medical care or treatment, and the MEC laboratory team should not offer such care. There are several reasons for this. First of all, we are not equipped to treat medical problems. The standardized MEC exam is not like a full-scale exam that would be done in a health professional's office. For example, the examiners do not have access to the SP's medical records, which are helpful in diagnosing medical problems. Second, in most instances the MEC examiner will not be licensed within the state in which the examinations are being conducted. Third, the liability insurance obtained for the Westat examiners covers only protocol activities and not any type of treatment procedure. Fourth, providing treatment would interfere with the primary purpose of the study, which is to collect data on the population.

The only time medical care will be provided is when there is an immediate medical emergency. This is discussed in Chapter 3, which covers venipuncture, and in Appendix C, which covers Emergency Procedures.

Further, it is not necessary to discuss exam findings with an SP unless referral is needed. A single examination often does not allow an adequate interpretation of findings nor provide enough information so that specific advice can be given. The SP's personal physician or dentist, who has the SP's records and is involved with his/her long-term care and follow-up, should interpret the findings and decide what to tell the SP. The SPs are encouraged to discuss the results with their health care providers.

Referral of examinees has been included in the MEC procedures for ethical reasons, even though it is not one of the purposes of the study. NCHS has developed several forms for reporting test results to examinees' physicians.

The Report of Physical Findings I contains all findings from the NHANES III examination that are available after a two-month period. The Report of Physical Findings II contains those results which cannot be furnished at the end of the two-month period, including the results of laboratory analyses performed at the Centers for Disease Control and other NCHS contract laboratories.

These two reports are generated and mailed to the SP from NCHS headquarters. As relevant, the report for each examinee will include a copy of the hand, wrist, knee and feet X-rays, the ECG tracing, and results of laboratory work.

It is important to keep in mind that as individuals and as a health research organization we have no control over local health care systems. Any involvement beyond routine referral is ineffective and interferes with the purpose of the study. If the data collected during the survey indicate that substandard care is being delivered to people in particular communities, this may provide the impetus for local health planners to improve the delivery of health care there.

2.2 HIV Positive Sample Persons

NCHS has prepared the following procedures to be observed when sample persons who report themselves to be HIV positive participate in the examination.

- The MEC Manager will be notified of the sample person's status and will inform the appropriate staff persons of this information on the day prior to the SP's appointment;
- MEC staff members will not discuss this person's status, nor treat the SP differently from other sample persons. If staff members choose to take extra precautions such as double gloving, be sure these practices are applied to every sample person in the session without exception;
- If in the performance of your duties it is necessary to mention the HIV status of the sample person, any conversation should be discreet and conducted in a secure area. It is important that other sample persons do not learn of this sample person's status;
- MEC staff should not inform other contractors (such as contract labs) of the SP's status;

- No written record or note should be made of the SP's status;
- The HIV status of the SP should not be entered into the computer system; and
- All written records kept by the Field Office pertaining to the SP's status will be destroyed after the SP has been examined.

All staff members should be aware of the importance of their confidentiality pledge and sensitive to SPs reported to be HIV positive.

2.3 Organization of the Laboratory Team

Each laboratory team includes three certified medical technologists who are experienced in venipuncture, hematology and serology and one certified phlebotomist who is experienced 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, quality control, equipment calibration and maintenance. On a day-to-day basis, the chief medical technologist performs the same duties as the other medical technologists.

Medical technologists rotate among three work stations in the MEC. Each work station has specific tasks associated with it, and each medical technologist is trained to perform all of these tasks. The tasks of the technologists can be briefly listed as follows:

- Specimen centrifugation, blood specimen processing;
- Hematology, urine processing and pregnancy testing;
- Specimen shipment, labeling vials and floating (assisting with all tasks as needed); and
- Assisting the phlebotomist as needed.

The phlebotomist's responsibilities are as follows:

- Venipuncture and GTT; and
- Assisting with labeling vials and specimen centrifugation as time allows.

A more detailed breakdown of the tasks to be done by each laboratory team member at each work station follows:

Phlebotomist, Phlebotomy Room: Venipuncture and GTT

- Arrive for work at least 15 minutes before the first scheduled SP to set up supplies and to check expiration dates of vacutainer tubes;
- Administer the Venipuncture Questionnaire;
- Recruit volunteers for the volatile toxicants study and record results;
- Perform the first venipuncture;
- Administer glucose tolerance test (GTT) to eligible SPs;
- Perform the second venipuncture on GTT subjects;
- Collect blood from volatile toxicant volunteers;
- Enter data on all blood specimens collected;
- Transfer all blood specimens to the main laboratory;
- Maintain appearance of the venipuncture area, the equipment and the daily inventory of supplies, including Trutol;
- Receive completed Chemical Exposure Questionnaires from the coordinator; reconcile questionnaires with list of volunteers on the Daily Appointment Schedule;
- Set up and tear down phlebotomy room;
- Complete begin and end stand inventory of phlebotomy supplies and materials; and

- Assist the laboratory techs in labeling storage vials, assembling blood processing racks, centrifuging specimens, completing the begin and end inventories of laboratory materials, cleaning the laboratory during the stand setup and tear down, preparing laboratory forms for end of stand shipments, and clerical activities as time allows.

Technologist 1, Work Station 1: Specimen Centrifugation and Specimen Processing

- Arrive for work 45 minutes after the first scheduled SP to set up equipment;
- Inventory blood processing and storage supplies;
- Do QC check on the biological safety cabinet and record the results;
- Receive blood specimens;
- Set aside red top and SST blood tubes to clot; then cool SST tube in wet ice before spinning;
- Centrifuge 3 ml gray, red, SST, light blue and leukoprep tubes;
- Pour out whole blood specimen for lead and erythrocyte protoporphyrin for age groups A-C before transferring lavender tubes to Technologist 2 for hematology;
- Transfer EDTA (lavender) tubes to Technologist 2 for hematology;
- Label and refrigerate the 10 ml gray top tubes;
- Aliquot plasma/serum into assay/storage vials;
- Prepare serum for Vitamin C assay;
- Enter blood processing/condition data;
- Notify the physician of any abnormal conditions, e.g., lipemia;
- Refrigerate/freeze designated vials;
- Check contents of blood and urine storage boxes/bags at the enD of each session; and
- Assist in shipping specimens.

Technologist 2, Work Station 2: Hematology, Urine Processing and Pregnancy Testing

- Arrive for work at least 15 minutes before the first SP is scheduled to set up equipment;
- Do QC checks on refrigerators and freezers in the phlebotomy room and lab and record results;
- Inventory equipment and supplies for hematology, urine processing and pregnancy test kit;
- Check to see that the urine specimens have been received; if not, report back to the coordinator;
- Verify calibration and run controls on Coulter S-Plus Jr. and record results;
- Run SP specimens on the Coulter S-Plus Jr. and give printed copy of results to the physician;
- Prepare blood smears;
- Perform spun hematocrit;
- Aliquot urine into storage vials;
- Run pregnancy test controls;
- Conduct pregnancy test and enter results;
- Notify coordinator of all positive and invalid pregnancy test results;
- Enter urine processing data;
- Enter hematology data;
- Assist phlebotomist as necessary; and
- Assist in shipping specimens.

Technologist 3, Work Stations 1 and 2: Shipping, Labeling and Floating

- Arrive for work 1 hour after the first scheduled SP;
- Label vials and setup processing racks;
- Prepare transmittals, floppy diskettes and labels for shipping;
- Prepare blood and urine specimens for shipping;
- Prepare blood smears for shipping;
- Pack, weigh, and label shippers;
- Assist the phlebotomist with the second venipuncture; and
- Assist with blood specimen processing.

3. VENIPUNCTURE AND GTT

3.1 Introduction

Venipuncture and GTT are two of the most critical data collection activities for NHANES III. In Exhibit 3-1 we provide the venipuncture protocol for NHANES III. This protocol indicates which types of tubes you are to draw for each age group. This information is also presented in a poster located on the wall in Work Station 1.

Notice that the tubes to be drawn from each subject are listed in priority order, according to which assays have the highest priority for NHANES III. It is extremely important that you draw the tubes in this order since it affects the assays which can be done on the specimens.

3.2 Equipment and Supplies

Work Station 1 contains a sink and a cabinet in which supplies for venipuncture are stored. This work station also includes a data terminal and a refrigerator. The floor plan for this work station is shown in Figure 3-1.

The equipment and supplies used in venipuncture are listed in Exhibit 3-2. At the beginning of a session you should check to make sure that all equipment is functioning and that you have sufficient supplies at your work station to perform venipuncture on 10 SPs.

For each SP you will need the following materials:

- Alcohol wipes;
- 2"x 2" sterile gauze squares;
- Vacutainer tubes of the appropriate type (see Exhibit 3-1);
- Adult and pediatric tourniquets;

Exhibit 3-1. NHANES III venipuncture protocol

	Age of SP in Years				
	1-3	4-5	6-11	12-19	20+
Color Code	Red	Green	Yellow	Blue	Orange
Tube Type (in priority order)					
4 ml SST	0	0	0	1	1
2 ml lavender	0	0	0	1	1
3 ml lavender	1	1	1	1	1
3 ml gray	0	0	0	0	1/1*
4 ml SST	1	0	0	0	0/1*
10 ml red	0	1	1	1	0
15 ml red	0	1	2	3	5
2 ml light blue	0	0	0	0	1**
8 ml leukoprep	0	0	0	1	1
10 ml gray	0	0	0	0	1***
10 ml red+	0	0	0	0	1***

* Drawn at the time of the second venipuncture if SP is 40-74

** Drawn if SP is 40+

*** Drawn if SP is 20-59 and volunteers for this component for which he/she will be paid extra

\+ Non-silicone coated; screened and provided by CDC

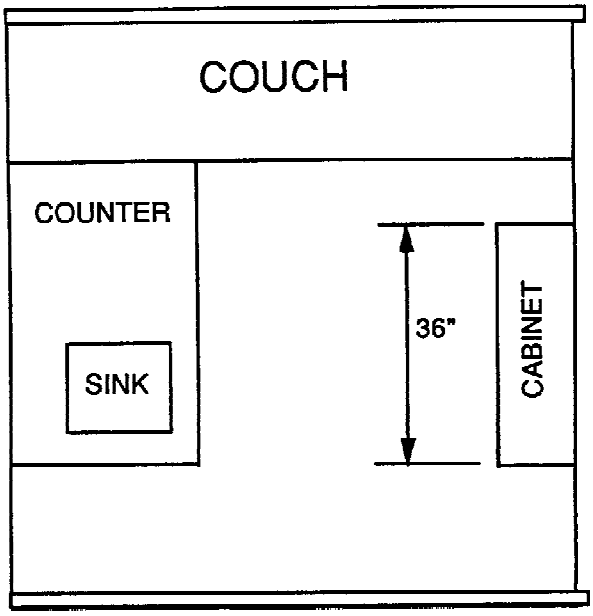


Figure 3-1. Floorplan for the phlebotomy room

Exhibit 3-2. Equipment and supplies used at Work Station 1 (Phlebotomy Room)

Daily Appointment Schedule

Control Record (for each SP)

Venipuncture Questionnaire

Data Terminal

BD Vacutainers:
Lavender - Liquid
K_3EDTA
2.0 ml*,+
3.0 ml*,+

8 ml Leukoprep Top+

Red top - Prelabeled
10 ml+
15 ml+

4 ml SST+

2 ml Light Blue Top+

3 ml Gray Top+

10 ml Gray Top*,+

10 ml Red Top - non silicone coated*,+

B.D. Butterfly
21g - 1" x 12" multisample with adapter
23g - 1" x 12" multisample with adapter
19g - 1" x 12" multisample with adapter

B.D. needle
20 g 1 1/2" multisample
21 g 1 1/2" multisample

B.D. Vacutainer holder
standard
small

Luer Adapter BD
Pediatric holder/adapter

Needle Disposal Unit - No Cut
needle container

Hemostat

Blood Collection tray

Tourniquet
Latex 1"x18"
Pediatric

*Each lot must be prescreened by CDC
+Monitor and document use

Infant heel warmer

Alcohol wipes

2"x2" gauze pad
Steri-Pads J&J
individ. wrapped

3M Transpore tape

Bandaids, J&J

Ammonia inhalant packets

Trutol+ (for SPs aged 40+)

Paper cups

Nonsterile disposable latex gloves
Small
Medium
Large

Waterproof pens

Wall Chart

Antibacterial soap

Hand Cream

Paper drapes

Kleenex

Labels-S.P. (for Vacutainers)

Cartoon Labels (for children)

2-Hr. Draw Labels (for SPs aged 40+)

Foam Rubber Pad

Pillow

Disposable Pillow Cases

Emergency Bell

Fruit

Emesis Basin

Bedsheet

- Needle assembly; and
- Trutol (for SPs aged 40-74).

The setup of the blood collection tray differs according to the age of the SP.

3.3 Receiving Assignments

3.3.1 Daily Appointment Schedule

At the beginning of a session, check the Daily Appointment Schedule (Exhibit 3-3), which will be available in printed form. The schedule lists the appointment time, sample disposition code, ID number, age, sex, language and name of each SP scheduled for an appointment. By consulting this schedule you will be able to plan the setup of the blood collection trays you will need for each session. You will also get an idea of what your work flow will be like. At the end of a session you can use the schedule to verify that you have entered data for each scheduled SP. You should also use the schedule to keep track of the volunteers for the volatile toxicants study and the SPs who are to receive the 2 hour draw. File all Daily Appointment Schedules in the MEC laboratory files.

3.3.2 SP Control Record

An SP Control Record (Exhibit 3-4) is generated for each SP. This record provides certain demographic information about the SP. It also documents the examination procedures in which the SP has yet to participate and which procedures have already taken place and at what times they started and ended. The coordinator uses this form to direct the SP to the appropriate work stations in the MEC and to determine whether or not all the appropriate examinations have been completed.

Exhibit 3-3. Sample daily appointment schedule

06/22/88

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY
DAILY APPOINTMENT SCHEDULE FOR STAND 998
FOR FRIDAY FEBRUARY 12, 1988

APPT TIME	NCHS NUMBER	AGE/SEX /LANGUAGE	NAME	TRANS	RMS
08:15 AM	S 998 232 9	84 F E	LOIS K. BOYD	T	
08:15 AM	S 998 228 0	84 F E	VERA SMITH DATA RETRIEVAL: SCR FAM	S	*
08:30 AM	U 998 488 7	2 F E	ALEXIS T. BRIDGEMAN	T	
08:30 AM	S 998 300 7	90 M E	JAMES STUART FOLEY	T	
08:30 AM	S 998 074 1	68 M E	PHILIP FRANCIS LAREAU DATA RETRIEVAL: SP	S	
08:30 AM	U 998 203 5	2 M S	HUMBERTO JR. DEJESUS	T	
08:30 AM	S 998 189 6	83 F E	MAUDE H. BRIGGS	T	*
08:30 AM	S 998 446 1	80 M E	LEWIS W. WINN	T	

Exhibit 3-4. SP control record

OMB No. 0920-0237
Approval Expires

CONTROL RECORD

NOTICE - Information contained on this form which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated for this study, and will not be disclosed or released to others without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m)

Sample No.	a. Age ☐ Mos. ☐ Yrs.	b. ☐ Male ☐ Female	c. Coordinator	d. Examination Date Month Day Year
e. Date of Birth Month Day Year	f. Temperature	g. GTT priority	PREGNANT: ☐ YES - NO BONE SCAN ☐ DK - NO BONE SCAN ☐ NO	

Name (First, Middle, Last)

Procedure	Age Group	Time In	Time Out	Staff
Physician's Exam	All			
Body Measurements	All			
MEC Interview	All			
24-hour Recall	All			
Venipuncture	1 and older			
Dentist's Exam	1-74			
Urine Specimen	6 and older			
Allergy Test	20-59 Even 6-19 All			
Audiometry/Tympanometry	6-19			
WISC and WRAT	6-16			
Spirometry	8 and older			
Bioelectrical Impedence	12 and older			
Exit Interview	12 and older			
Food Frequency	12-16			
Bone Densitometry	20 and older			
Gallbladder Ultrasound	20-74			
CNS	20-59 Odd			
ECG	40 and older			
Fundus Photography	40 and older			
Glucose Challenge	40-74			
Venipuncture 2	40-74			
Joint Radiographs	60 and older			
Performance Test	60 and older			

PHS 6300
Rev 5/99

TIME IN: _____ TIME OUT: _____

Column 1 lists the procedures that may be administered to an SP. The phlebotomist is responsible for completing entries for the following procedures:

- Venipuncture: 1 and older
- Glucose Challenge: 40-74
- Venipuncture 2: 40-74

At the beginning of each venipuncture session, check the Daily Appointment Schedule to verify that the SP is in fact scheduled for venipuncture as an examination component. Note that if the SP is to receive a GTT, the second blood draw must be scheduled for two hours after you administer Trutol.

To complete the Control Record, record the time in hours and minutes when you begin and end each of these examination procedures: "Time In," in Column 2, refers to the time you begin the procedure; "Time Out," in Column 3, refers to the time you end the procedure. Also enter your **4-digit** ID number in column 4.

- Venipuncture 1: Record the time the SP enters the Phlebotomy room for the initial venipuncture and the time the SP exits the Phlebotomy Room.
- Glucose Challenge: Record the time you administer the Trutol. The coordinator will record the time the SP finishes the Trutol.
- Venipuncture 2: Record the time you begin the venipuncture for the 2-hour draw procedure and the time you complete the venipuncture.

At the end of each venipuncture session, double check this record to ensure that the information it presents with regard to the venipuncture and the GTT corresponds to the information you have entered at the conclusion of the venipuncture session using the automated Venipuncture Questionnaire (see Section 3.4 of the Laboratory Automation Manual).

3.4 Gaining Cooperation

The coordinator introduces the SP to the examination and briefly explains the examination process. The coordinator is also trained to answer any general questions the SP has about venipuncture. However, as the phlebotomist, you must be prepared to answer all the questions an SP poses about the venipuncture and GTT components of the examination. Also you must be prepared to convince the SP of the importance of cooperation in the venipuncture component of the examination. Finally, you must be prepared to convince an eligible examinee to participate in the volatile toxicants study.

In order to address subjects' concerns effectively, you must be familiar with the following information about the procedures to be used for the study:

- Although the SP has provided much useful information in the household and individual interviews, the successful completion of the venipuncture and GTT components of NHANES III is critical to the success of the study. Using the blood specimen we are able to perform over 60 different biochemical tests (SPs 40-74) which provide us with detailed information about the SP's health status
  -- information which would not be available to us in any other way.

- Venipuncture causes only minimal discomfort. It is performed by a licensed phlebotomist, well-experienced in blood drawing. One venipuncture is done for those under 40 years of age. Two are done for those 40-74. For adults 40-74, 121 ml of blood, or about 4 ounces, are drawn in total. This amounts to about 25 percent of the amount drawn from regular donors by the Red Cross. The body manufactures blood daily and this volume of blood will be completely replaced within 24 hours.

- The supplies used for venipuncture are completely sterile, and they are used only once. After use they are destroyed. There is absolutely no possibility of the SPs being infected by any blood-borne disease, such as hepatitis or AIDS, as a result of participating in the venipuncture component of the NHANES III exam.

In Appendix A we provide answers to frequently asked questions regarding venipuncture. Familiarize yourself with this material so that you are prepared to answer SPs' questions as clearly and as concisely as possible.

Gaining the cooperation of an SP will be 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 disease, such as hepatitis and AIDS.
- Be aware of your 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 and you are not interested in performing the venipuncture.
- Avoid nervous behaviors, such as squirming and tapping, that can distract you and the SP. The SP may begin to feel nervous, hurried, and anxious as a result of such behaviors.

3.4.1 Refusal Conversions

The coordinator should notify the phlebotomist of all (phlebotomy) refusals so that the phlebotomist will have the opportunity to 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 and should not be approached, the phlebotomist should not attempt to administer the venipuncture questions. If, however, the coordinator and the phlebotomist decide that the SP is a good candidate for a refusal conversion attempt, the phlebotomist may administer the venipuncture questions as part of the conversion attempt. If appropriate, the phlebotomist should enlist the help of the coordinator, the laboratory technicians and/or the MEC physician to help convert refusals. The phlebotomist enters the exit code for all phlebotomy results into the automation system including those where the SP does not answer the venipuncture questions.

3.4.2 Performing the Venipuncture on SPs Who Do Not Speak English

When the phlebotomist must administer the phlebotomy procedure to an SP who does not speak English and the phlebotomist does not speak the language of the SP, the phlebotomist must be assisted by a translator who does speak the language of the SP.

The translator should stay 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.

Because the phlebotomy procedure can be time consuming, and the MEC staff members, especially the coordinator, are needed to perform other tasks, a priority order has been established for staff members who should act as a translator for the phlebotomist. This priority order is, of course, dependent on the language of the SP and the language capabilities of each staff member.

Depending on the ability of each staff member to speak Spanish, the priority of the staff members who should assist the phlebotomist with Spanish-speaking SPs is as follows:

- Local Translator;
- Assistant coordinator;
- MEC interviewer;
- Dietary Interviewer;
- Health technicians; or
- Coordinator.

3.4.3 Protocol for the Volatile Toxicants Study

The phlebotomist should recruit 45 SPs per stand for the volatile toxicants study. Recruitment should begin on the first examination day and continue until 45 people have volunteered. Only 4-5 people may be recruited each day.

After administering the Venipuncture Questionnaire and before beginning the venipuncture procedures, you are to invite all SPs between the ages of 20 and 59 years to participate in the volatile

toxicants study. The following script is suggested for recruitment:

- "The Centers for Disease Control is conducting another study in conjunction with NHANES III. This study tests to see if you have been exposed to certain chemicals called volatile toxicants."
- "We would like to invite you to volunteer for this study. It involves giving a small additional amount of blood and urine and filling out a short questionnaire."
- "Your participation in this study is strictly voluntary and you will be paid an extra sum of $10.00 for your cooperation."
- "If you would like to participate in the study, I will collect the additional blood now, along with the blood I am going to collect for the other tests."
- "You will be asked to complete a short questionnaire and you may be asked to give another urine sample sometime later during the exam."
- "This is the only opportunity you will have to join this special study group. I would like to include you as a volunteer now."

If the SP refuses the invitation to volunteer for the study at this time, enter this information on the Venipuncture Data Entry Screen (Exhibit 3-5) and continue with the venipuncture procedures.

If the SP volunteers for the study, collect one 10 ml gray top tube and one 10 ml non-silicone coated red top tube after all of the other required tubes are filled. If you cannot collect the extra blood on the first stick and the SP is 20 to 39 years of age, you may, with the SP's permission, attempt another stick. If the SP is 40-59 and is scheduled for a GTT, you may collect the extra blood at the time of the 2 hour draw, but this is not recommended.

Exhibit 3-5. Venipuncture data entry screen

Name _____ Nchs # _____ Age ____ Sex __ Group __

Venipuncture Time __:__

Is SP a volatile toxicant volunteer? ___ (1 = yes, 2 = no)
Vial 20? __ (1 = yes, 2 = no vial20)

TUBES DRAWN EXACTLY AS LISTED (1 = yes)

4ml	SST	Need to Draw __	.....Drew	__
2ml	Lavender.....	Need to Draw __	.....Drew	__
3ml	Lavender	Need to Draw __	.....Drew	__
3ml	Grey	Need to Draw __	.....Drew	__
4ml	SST	Need to Draw __	.....Drew	__
10ml	Red	Need to Draw __	.....Drew	__
15ml	Red	Need to Draw __	.....Drew	__
2ml	Light blue	Need to Draw __	.....Drew	__
8ml	Leukoprep	Need to Draw __	.....Drew	__
10ml	Grey (vol.tox).....	Need to Draw __	.....Drew	__
10ml	Red (vol.tox)	Need to Draw __	.....Drew	__

Comments Code __ _____

Screen:Blood_Draw PRESS < NEXT SCREEN > KEY FOR NEXT SCREEN V5.1

Tell the hematology technologist that the SP is a volunteer for the volatile toxicants study. The technologist will process the SP's urine accordingly, and if necessary, submit a request for a second urine specimen to the coordinator.

Place a red sticker in the upper right hand corner of the SP's control record to notify the coordinator that the SP has volunteered for the study. The coordinator will give a Chemical Exposure Questionnaire to the SP and answer any of the SP's questions about the form. (See Appendix B for copies of the English and Spanish versions of the Chemical Exposure Questionnaire.) He/she will give the completed questionnaires to you at the end of the session. If necessary, he/she will instruct the SP to collect a second urine specimen. He/she will also pay the SP an extra $10 dollars for his/her participation.

Document that the SP is a volatile toxicants volunteer on the Daily Appointment Schedule and on the Venipuncture Data Entry screen. You will need to keep track of the number of volunteers recruited each day so you will know when you have collected specimens on 45 SPs. At the end of the session, check the Chemical Exposure Questionnaires against the Daily Appointment Schedule to make sure that there is a completed questionnaire for everyone who volunteered. Record the results of the volatile toxicants blood draw in the upper left hand corner of the questionnaire. Then photocopy the questionnaire and file the copy in the MEC.

3.4.3.1 Use of Replicate SPs for the Volatile Toxicants Study

The phlebotomist should offer the volatile toxicant study to a replicate SP if:

- The SP agreed to participate in the volatile toxicant study during the first MEC examination; and
- Blood was collected for the volatile toxicant study during the first visit.

The phlebotomist will have to establish a system to keep track of the SPs and the replicate SPs that volunteer for the volatile toxicants study. The following system is suggested:

- Record the results of the blood draw for the volatile toxicants study on the SP's Chemical Exposure Questionnaire in the upper left corner.

- Photocopy each of the Chemical Exposure Questionnaires. File the copies in the laboratory. Keep them in order by NCHS number.

- Before the beginning of each session, review the Daily Appointment Schedule to identify replicate SPs.

  - Obtain from the coordinator, the original NCHS number for each of the replicate SPs.

  - Search the Chemical Exposure Questionnaire file for a questionnaire with the original NCHS number.

  - If you find a questionnaire with the replicate SP's original NCHS number, check the upper left corner of the questionnaire for the results of the blood draw.

  - If the 10 ml non-silicone red and the 10 ml gray tops were filled, make a note on your Daily Appointment Schedule to recruit the replicate SP for the volatile toxicant study.

- When a replicate enters the phlebotomy, check the Daily Appointment Schedule to see if he/she should be recruited for the volatile toxicant study.

- If the replicate volunteers for the study:

  - Collect the extra blood;

  - Notify the coordinator and the hematologist that the replicate SP is a volatile toxicant volunteer; and

  - Place a red label on the replicate SP's control record.

- At the end of the session obtain the SP's Chemical Exposure Questionnaire from the coordinator and write replicate in the upper right hand corner.

3.5 Administering the Venipuncture Questionnaire

You administer the Venipuncture Questionnaire (Appendix C) immediately prior to performing venipuncture. The questionnaire is designed to screen the SP for all phlebotomy procedures, including venipuncture and the glucose tolerance test, to determine fasting compliance, and to aid the analysis of

the results of the assays performed on the specimens collected. There are only two reasons to exclude an SP from venipuncture: hemophilia and having received chemotherapy within the past 4 weeks. Only receiving insulin therapy excludes otherwise eligible SPs, those aged 40 to 74, from receiving the glucose tolerance test. Note that you administer the questionnaire directly to SPs over the age of 12. For SPs under age 12, you administer the questionnaire to a parent or guardian. Inform the MEC manager if a parent or legal guardian does not accompany an SP under 12 years on the MEC. The questionnaire will be administered to the parent/guardian by phone whenever possible. Refer to Chapter 3, Phlebotomy, in the Laboratory Automation Manual, for specific instructions on how to administer the automated version of the Venipuncture Questionnaire.

Prior to initiating the phlebotomy, you are to verify all information which appears on the phlebotomy screens. If there is an error in any of this information, you are to inform the coordinator immediately. The coordinator will verify what the correct information should be and will enter the corrected information into the automated system as necessary.

If the automated system fails, you must administer the paper version of the Venipuncture Questionnaire. Appendix C contains the hard copy English and Spanish versions of the Venipuncture Questionnaire and detailed specifications for asking each questionnaire item.

3.6 Venipuncture Procedures

The Vacutainer system used to collect blood specimens for diagnostic analyses is composed of glass tubes with color-coded stoppers containing a pre-measured vacuum to provide a controlled draw. The tubes required for each SP are specified by the Venipuncture Questionnaire in Appendix C. Tubes are to be drawn in the order designated by the Venipuncture Data Entry Screen as Exhibit 3-5 or if the data terminal is not functioning by the Venipuncture Protocol in Exhibit 3-1.

The exact quantity of blood drawn into each tube may vary slightly with altitude, ambient temperature, and venous pressure. It is important that tubes with additives should be completely filled to assure proper ratio of blood to additive and then mixed well to distribute the anticoagulant for maximum effectiveness.

Vacutainers should be at room temperature at time of use. They must be protected from extreme temperatures and stored at a constant temperature in a cool place. It is important to note the expiration date printed on vacutainer tubes. Expired tubes should not be used. However, if the only tubes on hand have expired, you may try them and use them if they still work.

All vacutainer tubes except the 10ml grey and the 10ml non-silicone coated red top tubes will be sent to you from Westat at the beginning of each stand. The 10ml grey tubes and the 10ml non-silicone coated red top tubes to be used for the volatile toxicants study will be sent to you directly from CDC, also at the beginning of each stand. These red top tubes will be specially labeled and packaged to differentiate them from the silicon coated red top tubes, sent from Westat, that are used for the regular venipuncture protocol.

Document the use of each type of vacutainer on a Supply Use Control Log (Exhibit 3-6). Keep a separate log for each type of vacutainer. When a new box is opened, record the date, the lot number of the box, the expiration date and your tech ID number.

3.6.1 Preparation of the Puncture Site

It is extremely important that the anticipated puncture site and all necessary equipment, including needles, tubes, tourniquet, etc., be kept absolutely sterile and free from contamination. Extreme caution must be exercised throughout the collection of blood and pooling of sera so that the data are valid.

Follow the steps outlined below to prepare the puncture site.

- Place your venipuncture equipment where it is readily available but not in danger of being upset. Keep extra equipment within easy reach.
- Thoroughly wash your hands.
- Put on gloves.
- Prepare appropriate blood collection tubes (Exhibit 3-1), placing them in a test tube rack in the order in which they will be used until you are ready to use them. If an SP exhibits nervousness, keep the tubes covered.

Exhibit 3-6. NHANES III supply use control log

NHANES III Supply Use Control Log

MEC _____

Year _____

Supply Name* _____

Date Opened	Lot #	Expiration Date	Tech ID #

*Multisample needles (20 g, 21 g); butterfly needles (19 g, 21 g, 23 g); lavender tops (2.0 ml, 3.0 ml); 8 ml leukoprep top; prelabelled red tops (10 ml, 15 ml); 4 ml SST; 2 ml light blue top; gray tops (3 ml, 10 ml); Trutol; urine specimen cups; 15 ml Falcon conical tubes; ICON pregnancy test kit; and urine controls.

- Instruct the SP to sit down on the couch. **Never** attempt a venipuncture on a standing

subject. Having the subject sit helps guard against any injury that might result if the subject faints. See Section 3-12 and Appendix D for procedures on how to handle SPs who have problems. Do not draw if the SP requires CPR after a venipuncture. For SPs in age group B-E, place them in a prone position if it is impossible to perform the procedure sitting up. Instruct the SP to extend the arm palm up and straight at the elbow. If the SP is a child, you should position the arm. If the SP is an infant, have a medical technologist hold the infant in the proper position for you.

- Position the arm on your work table so that the veins are readily accessible and you are able to work in a comfortable position. Be sure that the arm is in a downward position with the elbow lower than the heart to prevent backflow.

- Inspect the arm you plan to use for venipuncture. 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 an arm which has a rash or open sore or is swollen or edematous.

- If the veins in the antecubital space are not useable, look for suitable veins on the forearm or the back of the hand.

- Apply the appropriate latex strip tourniquet several inches above the selected site.

- Select a vein that is palpable and well-fixed to surrounding tissue. Palpate even when the vein can be seen. If the veins do not distend rather quickly, the following techniques may be used:

  - Massage the arm from wrist to elbow to force blood into the veins;

  - Tap the area sharply with the index and second finger two or three times to cause the veins to dilate;

  - Apply an infant heel warmer to the antecubital area to help the veins dilate;

  - Have the arm to be used for venipuncture hang at the SP's side without a tourniquet to allow the veins to fill to their capacity; and

  - Examine the SP's other arm; sometimes the veins in one are larger than in the other.

- If the tourniquet has been applied for more than 1 minute while you search for a vein, release the tourniquet for 2 to 3 minutes. Prolonged obstruction of blood flow by the tourniquet is unnecessary and uncomfortable for the SP and may alter certain results (e.g., cholesterol).

- Check carefully for scar tissue or the presence of tendons near the vein.

- Cleanse the area with an alcohol wipe. Hold the alcohol wipe so that you do not touch the side 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 sterile 2x2 gauze pad. The area should be completely dry before the venipuncture is done in order to reduce the burning sensation caused by alcohol penetrating the skin.

- After the puncture site is cleansed, determine the correct needle size to be used. A 19g, 21g or 23g butterfly or a 20g or 21g multisample needle may be used depending on the condition of the SP's veins. The 19g butterfly should be suitable for most SPs. If the SP's veins appear to be fragile or small, you may use a 21g or 23g butterfly. If the SP is obese, use a 20g or 21g multisample needle.

3.6.2 Venipuncture Technique for the Vacutainer System With a Butterfly Needle

- Open the needle package. Do not remove the needle shield.

- Attach the butterfly with the Luer adapter to the vacutainer holder by screwing the threaded end of needle onto the holder.

- Prepare the tape.

- Ask the SP to make a fist. Do not have the SP pump his/her fist since this action may alter certain results.

- Remove the shield from the needle.

- Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of your nondominant hand.

- Using a 19g, 21g or 23g butterfly needle, 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.

- 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 butterfly tubing. Put tape over the butterfly to hold it in place. If no blood enters the tube but no bruise is forming, probe the vein until entry is indicated by blood flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place a gauze square over the puncture site and apply firm pressure to the puncture site for three minutes. Switch to the other arm using a new needle. If you must use the same arm for a second try, wait ten minutes before beginning the procedure again.

- 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 with its attendant possibility of adverse reactions to the SP.

- As the vacutainer tube is filling, transfer the shield support to your left (nondominant) hand, leaving the right (dominant) hand free to pick up and change the tubes.

- Use your left hand to hold the Luer adapter steady. Use your right hand to pull out the filled tube and place it in the rack. Note: all tubes should be **completely filled**. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.

- Immediately invert the anticoagulated lavender, 3ml and 10ml grays, light blue and leukoprep tubes to ensure proper mixing of blood and anticoagulant or additive. Place on the rocker. Also invert the SST tubes 8-10 times to activate ground glass material and thixotropic gel. DO NOT PUT SST TUBE ON ROCKER. Do not invert or agitate the red top tubes.

- Insert the next tube and push it down gently onto the adapter.

- Because prolonged application causes vasoconstriction, remove the tourniquet after two minutes to ensure valid test results. If necessary (i.e., if the blood flows more slowly), reapply the tourniquet after two minutes.

- Fill tubes in this order, according to the protocol: SST, lavender, 3ml gray, red, light blue, leukoprep, 10ml gray and 10ml non-silicone coated red.

- If this is the last tube to fill, loosen the tourniquet as soon as the tube begins filling and remove it as the last tube fills.

- When the last tube has filled, remove the needle in a smooth quick motion, and after the needle is withdrawn immediately press a clean gauze square over the venipuncture site. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein.

3.6.3 Venipuncture Technique for the Multisample Needle

- Open the multisample needle package. Do not remove the shield from the needle.

- Assemble the vacutainer holder and the multisample needle by screwing the threaded end of the needle onto the holder.

- Place the first tube to be drawn into the holder, securing it slightly, but not penetrating the stopper.

- Ask the SP to make a fist. Do not have the SP pump his/her fist since this may alter certain results.

- Remove the shield from the needle.

- Fix the vein about one inch below the proposed point of entry by pulling the skin taut with the thumb of your nondominant hand.

- Using a 20g or 21g multisample needle, 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.

- 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. If no blood enters the tube but no bruise is forming, probe the vein until entry is indicated by blood flowing into the tube. If no blood enters the tube and a bruise is forming, remove the needle. Place a gauze square over the puncture site and apply firm pressure to the puncture site for three minutes. Switch to the other arm using a new needle. If you must use the same arm for a second try, wait ten minutes before beginning the procedure again.

- 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 with its attendant possibility of adverse reactions to the SP.

- As the vacutainer tube is filling, transfer the shield support to your left (nondominant) hand, leaving the right (dominant) hand free to pick up and change the tubes.

- Use your left hand to hold the Luer adapter steady. Use your right hand to pull out the filled tube and place it in the rack. Note: all tubes should be **completely filled**. Make sure the tube contents do not touch the stopper or the end of the needle during the procedure.

- Immediately invert the anticoagulated lavender, 3ml and 10ml grays, light blue and leukoprep tubes to ensure proper mixing of blood and anticoagulant or additive. Place on the rocker. Also invert the SST tubes 8-10 times to activate ground glass material and thixotropic gel. DO NOT PUT SST ON ROCKER. Do not invert or agitate the red top tubes.

- Insert the next tube and push it down gently onto the adapter.

- Remove the tourniquet after two minutes. If necessary (i.e., if the blood flows more slowly), reapply the tourniquet after two minutes.

- Fill tubes in this order, according to the protocol: SST, lavender, 3ml gray, red, light

blue, leukoprep, 10ml gray, and 10ml non-silicone coated red.

- If this is the last tube to fill, loosen the tourniquet as soon as the tube begins filling and remove it as the last tube fills.

- Remove the last tube from the holder.

- When the last tube has filled, remove the needle in a quick, smooth motion, and after the needle is withdrawn immediately press a clean gauze square over the venipuncture site. Avoid heavy pressure as the needle is being withdrawn because it may cause the point of the needle to cut the vein.

3.6.4 Concluding the Venipuncture

- Have the SP place two fingers on the gauze to hold it 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 two to three minutes to help prevent hematomas.

- Remove the last tube and discard the needle in the needle disposal unit. Do not recap the needle.

- Label each tube collected with the paper adhesive SP ID number labels found in the SP's chart.

- Write the time of collection on one red top tube and on the tubes for the volatile toxicants.

- Dispose of all contaminated waste in a biohazard bag.

- Check the venipuncture site. If it is adequately clotted, apply a bandaid 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 five minutes or more.

- 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 of the Quality Control Notebook.

- Once the SP is feeling well enough, escort the SP to the coordinator.

- Two attempts for a successful venipuncture are allowed with the SP's verbal consent or with the parent's consent if an SP is a child or an infant.

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

3.6.5 Pediatric Phlebotomies

Pediatric phlebotomies require special techniques. Because you will be dealing with children of different age ranges and levels of understanding, it is important that you be able to recognize 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. Children of this age must be restrained by either a laboratory technician, a parent or a bedsheet. (Refer to Figure 3-2 for methods of restraining infants with bedsheets.) 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 as quickly as possible. Be sure to reassure the child after the procedure is completed and to use cartoon bandaids when you are finished.

Preschoolers, aged 2 to 6 years, think concretely and in absolutes; things are either 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 words "take" which implies remove, "test" which implies pass or fail, and "fix" which implies that the child was 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 bandaids. Distractions, such as holding something, counting things in the room, and breathing deeply, may also work with the older children in this age group. You may, however, need to consider restraining 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, i.e., this will all be over soon, and relative terms, such as this will hurt a little or a lot. Detailed explanations of the procedure work extremely well. Again, always be honest. Include demonstrations, i.e., with a doll, whenever possible. Having the child help during the

procedure distracts the child as well as lets him or her feel some control. Be sure to reinforce how big a help he/she was after the draw is completed. Give the child realistic choices, such as which arm to choose, not whether or not the blood should be drawn. You may need to consider restraining some children even at this stage. Bandaids continue to be important.

Although adolescents, ages 12 to 18 years, are beginning to think abstractly they often regress when placed in stressful situations. It is best to assume that they will act younger than their chronological age. However, it is still very important that you address the adolescent as an adult and not as a child. Along with providing detailed explanations, you should inform the adolescent that you are using the best technique and that you will not harm him/her. It is very important that the adolescent feel in control; therefore, give the child some choices as well as allow him or her to help if offered. Be very clear about rules, such as no moving, but do not restrain the child.

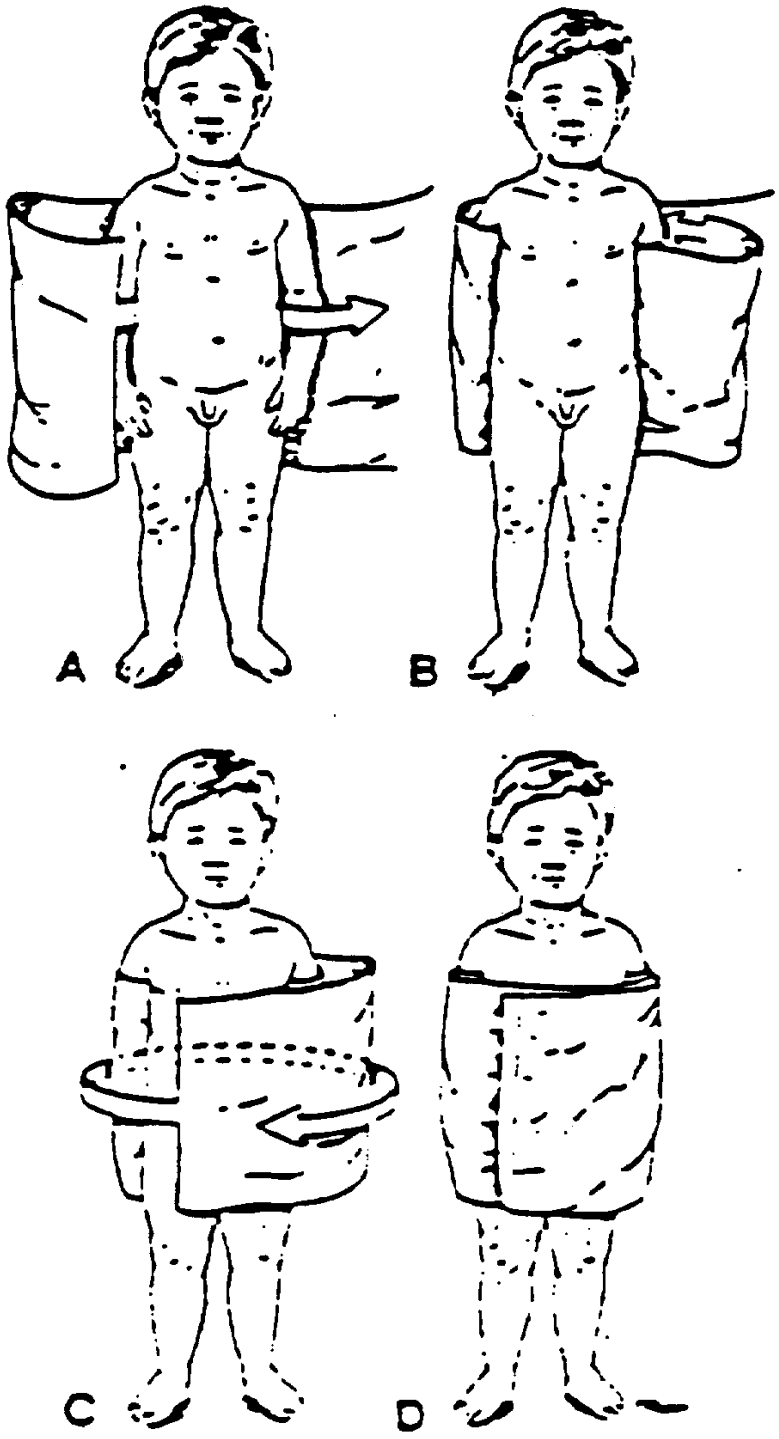


Figure 3-2. Method for restraining the upper body using a hospital bed sheet

Pediatric phlebotomies are most successful when children are immobilized, 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; however, if an adequate vein cannot be located in this site, sites in the hand or foot may be used (see Figure 3-3 Pediatric Venipunctures Sites). Most venipunctures in children can be performed using a 21 or 23-gauge butterfly needle. Follow the general Guidelines 3.6.1-3.6.4 for performing venipunctures.

3.6.6 Recording the Results of the First Venipuncture

Immediately after completing the first venipuncture, you must use the Venipuncture Data Entry screen (Exhibit 3-5) to enter the results of the blood draw, the reasons for a tube not being drawn according to the protocol, and any comments you have about the venipuncture. Use the screen to record whether or not the SP is a volunteer for the volatile toxicants study. Also, if at any time during the administration of the Venipuncture Questionnaire or the venipuncture procedures, the SP tells you he/she does not want his/her blood tested for HIV I or AIDS, you must enter this information into the MEC database using the Venipuncture Data Entry Screen. Refer to Chapter 3, Phlebotomy, in the Laboratory Automation Manual for specific instructions on how to enter the results of the first venipuncture.

You must also record the appropriate exit code on the exit screen for the first blood draw for all SPs who are age eligible. The list of exit codes for the first venipuncture is given in Exhibit 3-7. Please note that the "safety exclusion" code applies only to situations where the SP is excluded on the basis of protocol screening questions. If the SP is excluded by the physician for

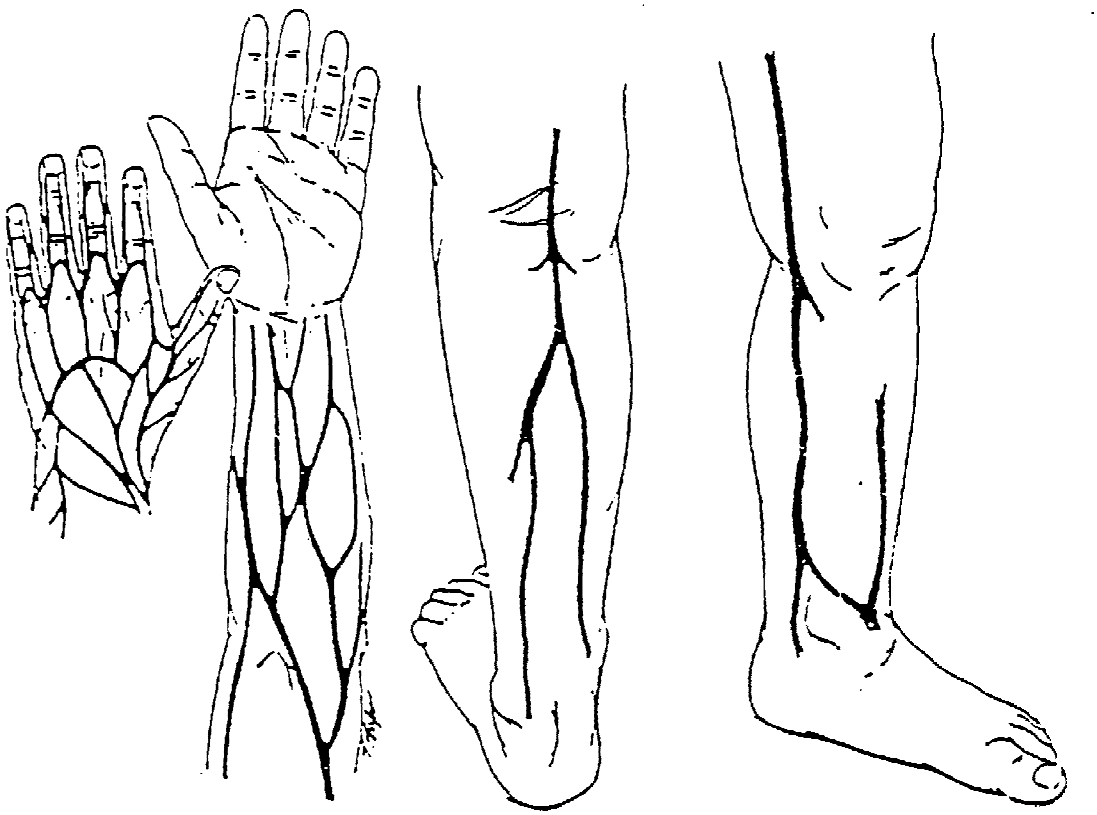


Figure 3-3. Pediatric Venipuncture Sites

Exhibit 3-7. First blood draw exit codes

1st BLOOD DRAW

Result Codes	Category	Instructions
110	Blood Drawn, All Tubes	All tubes fully and partially filled (not including volatile toxicant tubes.)
111	Blood Drawn, Some Tubes	Only a few tubes filled.
112	Safety Exclusion	SP excluded only for safety reasons, per protocol (e.g., hemophiliacs or SP on cancer chemotherapy).
113	Refused/Uncooperative	SP initiated non-response (e.g., SP refused, SP or family member sick, SP leaves early, SP comes late and no blood drawn).
114	Out of Time	SP comes on time; adequate staff in MEC; it's the end of session and no time to draw blood.
115	Unable to Puncture Vein	Phlebotomy attempted but the draw was unsuccessful.
116	SP Unable to Understand Instructions	SP is unable to understand instructions due to language, cognitive impairment or other communication problems and no blood drawn.
117	Equipment/Supply Problems	Venipuncture equipment malfunction or tubes not available to draw blood.
118	Other Reasons	Limit use on this code only to reasons that cannot be coded with above categories (e.g., SP sent home or excluded by the physician or inadequate staff to draw blood). Explain in comments.
210	Done at Prior Session	SP rescheduled and 1st blood draw was completed at the previous visit.

reasons other than a protocol specific problem, or if the reason for exclusion is not provided in the existing codes, exit code 118 -- "other reasons" -- should be used and a comment should be recorded to explain the situation. If the venipuncture is incomplete or unsuccessful, use the comment codes to further explain the results (see Exhibit 3-11).

In times of automated system failure, use the paper form of the Venipuncture Questionnaire (see Appendix C) to record the results of the first venipuncture. Record the appropriate exit code on the SP's Control Record in the space between the procedure and age category. When the system is working again, enter the results recorded on paper into the system using the instructions given in Section 10.2 of the Laboratory Automation Manual. Note that this must be done **before** you ship the specimens.

3.7 Administering Trutol for the Glucose Tolerance Test (GTT)

All adults aged 40 to 74 who provide a "fasting" blood sample and who do not take insulin will be asked to participate in the glucose tolerance test (GTT). Before administering the Trutol, you must administer the Venipuncture Questionnaire to determine that the SP:

- Is not taking insulin; and
- Has followed the fasting instructions. (SPs who have not followed the fasting instructions are still eligible for the GTT.)

Adults taking oral medications other than insulin to control diabetes **are** eligible for the GTT. The GTT poses **no** risk to these SPs. SPs taking pills for diabetes are instructed to bring their pills to the MEC on the day of their exam and to take them after the GTT is finished. If the 2-hour draw cannot be completed before the end of the session, do not administer the Trutol. Escort the SP to the reception area and notify the coordinator that the GTT must be rescheduled.

If the SP is eligible for the GTT, escort the SP to the reception area and administer one 10-ounce bottle of Trutol to each eligible adult immediately after the first venipuncture has been conducted. The coordinator will make sure that the **entire** dose of Trutol is consumed within 10

minutes. If the entire bottle of Trutol is not consumed **do not** draw the 2 hour draw. Should an SP vomit or have a diarrheal episode after ingesting the Trutol, do not repeat the Trutol. Do attempt the second draw as long as the SP appears fine. Use the Trutol Data Entry Screen (Exhibit 3-8) to enter the results of the Trutol administration, the time that the Trutol was administered, and any comments you may have concerning the procedure. Refer to Chapter 3, Phlebotomy, in the Laboratory Automation Manual for detailed instructions on how to enter the results of the Trutol procedure. Also, record the time that the SP is to return for the 2-hour draw next to the SP's name on the Daily Appointment Schedule as well as on a label which you should ask the SP to affix to the top of the paper gown he/she is wearing.

If the automated system is not working, record the time that the Trutol was administered on the Venipuncture Questionnaire (Appendix C). Note that once the system is working again, you will have to enter these times in the automated system.

Direct any questions from SPs about payment for the GTT or the 2 hour venipuncture to the MEC coordinator.

3.8 Conducting the Second Venipuncture for GTT

The second venipuncture for the GTT is to be done 2 hours after the Trutol is administered. You will use the Daily Appointment Schedule to remind yourself of the time at which an SP is to receive the second venipuncture. When the schedule indicates it's time for a 2-hour draw, you are to check with the coordinator and ask him/her to locate the SP and direct the SP to the venipuncture area. The coordinator will either escort the SP to your work station or let you know when the SP will be available for the second venipuncture. If necessary, you may perform the second venipuncture in a room other than the phlebotomy room.

You will always draw a 3ml gray top tube and a 4ml SST on the second venipuncture. If the SP is aged 40-59 and a volunteer for volatile toxicants but did not have extra blood for volatile toxicants collected on the first draw, you will also draw one 10ml gray top and one 10ml non-silicone coated red top. The SP's folder and the data terminal will indicate whether or not he/she is a

volunteer for volatile toxicants. If you were unable to fill the 2ml light blue or the 8 ml leukoprep with the first venipuncture, you may collect them during the 2-hour draw.

Exhibit 3-8. Trutol data entry screen

Name _____ Nchs# _____

Glucose Tolerance Test GROUP E (ORANGE) AGE 20+

Trutol given ..... __1. Yes
__2. No

Time given ..... _____

Comments Code __ _____

(Press <Next Screen> key for next screen.)

Screen: Trutol_given

Name _____ Nchs# _____

__ GTT CAN NOT BE DONE.
DO NOT GIVE TRUTOL
DO NOT DRAW 2 HOUR SAMPLE.

(Press the <Next Screen> key for next screen.)

Screen P1.8

In conducting the second venipuncture you should use the same procedures you use for the first venipuncture to prepare the puncture site. You should also use the opposite arm that you used for the first venipuncture unless that arm is unsuitable. Inspect the arm and the veins carefully before you begin. If you find that you cannot use the arm or if in your judgment the veins in the arm will be very difficult, you should explain the situation to the SP, saying something like: "The veins in this arm are not as good as those in the arm I've done already. I don't want to cause you any unnecessary discomfort, so I suggest that I use the original arm again." In this case, unless the SP refuses to allow you to use the original arm, you would perform the venipuncture on it. If necessary, you may use the same area and the same vein you used for the first venipuncture unless (a) the first puncture site is bruised; b) the first puncture site is still bleeding; or c) the SP specifically requests that you use the other arm.

If the first puncture site is bruised, you may use the same arm but not the same vein for the second venipuncture. If the first puncture site is still bleeding, you must use the other arm for the second venipuncture.

Follow the same phlebotomy technique outlined in Sections 3.6.1 through 3.6.4 to perform and conclude the second venipuncture. After conducting the second venipuncture, offer the SP eight ounces of juice or water. Remind the SP on oral medication for diabetes to take their pills. Also, label each tube correctly with the appropriate labels. Each tube must be labeled with the SP's ID number. The tubes for volatile toxicants should also be labeled with the time of the second venipuncture.

3.9 Recording the Results of Second Venipuncture and GTT

Immediately after completing each venipuncture, you must use the 2-Hour Draw Screen (Exhibit 3-9) to indicate which tubes you filled and to record the time you did the second venipuncture, the reasons for a tube not being drawn according to the protocol, any comments you have about the venipuncture, and your Tech ID number. If the SP vomited or had a diarrheal episode after ingesting the Trutol, enter the time elapsed from ingestion of Trutol to the vomiting or diarrheal episode. Refer to Chapter 3, Phlebotomy, in the Laboratory Automation Manual for specific

instructions on how to enter the results of the 2-hour venipuncture.

Exhibit 3-9. Two-hour draw data entry screen

Name _____ NCHS # _____

Glucose Tolerance Test Group E (ORANGE) Age 40+

Current Time _____ Trutol given at: _____ Volatile Toxicant volunteer ___

Protocol	Enter number of tubes (0 or 1)		
1 3ml Grey (2-Hour sample)	___	Time drawn ___:___	___ 1. AM 2. PM
1 4ml SST (2-Hour sample)	___		

	Enter # of tubes (0, 1, or 2)	already drawn
1 2ml Light Blue	___	___
1 8ml Leukoprep.....	___	___
1 10ml Grey (Volatile Toxicants).....	___	___
1 10ml Red (Volatile Toxicants).....	___	___

Comments Code ___ _____

(Press <Next Screen> key for next screen)

Screen: Two_hour

You must also record the appropriate exit code on the exit screen for the second blood draw for all SPs who are age eligible for the GTT and who complete the fasting blood draw. The list of exit codes for the second venipuncture is given in Exhibit 3-10. Please note that the "safety exclusion" code applies only to situations where the SP is excluded on the basis of protocol screening questions. If the SP is excluded by the physician for reasons other than a protocol specific problem, or if the reason for exclusion is not provided in the existing codes, exit code 118 -- "other reasons" -- should be used and a comment should be recorded to explain the situation. Also, if you are completing the first draw protocol during the 2-hour draw, select the exit code that also describes the final results of the first draw. If the 2-hour draw is unsuccessful or incomplete, use the secondary comment codes to further explain the results (Exhibit 3-11).

In times of automated system failure, use the Venipuncture Questionnaire (Appendix C) to record the results of the 2-hour blood draw. On the SP's Control Record enter the appropriate exit code in the space between venipuncture and age group. When the system is working again, enter the results recorded on paper into the system using the instructions given in Section 10.2 of Laboratory Automation Manual.

3.10 Rescheduled GTT

If, for some reason, the GTT cannot be done during the SP's initial visit, i.e., it is too late in the session, notify the coordinator, who will reschedule the GTT. When the SP returns to the MEC for a rescheduled GTT, you must administer the Venipuncture Questionnaire, draw the fasting blood samples (i.e., draw one 3 ml grey top tube and one 4 ml SST), administer the Trutol, perform the 2 hour draw collecting one 3 ml grey tube and one 4 ml SST, and record the results using the automated system (see Chapter 3, Laboratory Automation System Manual.)

3.11 Cleaning Up the Phlebotomy Room

Place all used needles in a needle box and all used supplies in a biohazard bag. If blood has spilled on the couch or the arm board, wash with a solution of bleach and water and prepare the

work station for the next SP. Change your gloves before approaching the next SP.

Exhibit 3-10. Second blood draw exit codes

2nd BLOOD DRAW

Result Codes	Category	Instructions
110	Blood Drawn, All Tubes	Drew 2 hour 3 ml grey tube and 2 hour 4 ml SST and completed the incomplete 1st draw protocol.
111	Blood Drawn, Some Tubes	Drew one or both 2-hour tubes and did not complete incomplete 1st draw protocol.
112	Safety Exclusion	SP excluded only for safety reasons, per protocol (e.g., SP currently using insulin).
113	Refused/Uncooperative	SP initiated non-response. SP refused Trutol or the 2nd draw for any reason and no blood drawn (e.g., SP or family member sick, SP leaves early, SP comes late).
114	Out of Time	SP comes on time; adequate staff in MEC; it's the end of session and no time to administer Trutol and draw blood second time for GTT.
115	Unable to Puncture Vein	Phlebotomy attempted but the draw was unsuccessful.
116	SP Unable to Understand Instructions	SP is unable to understand instructions due to language, cognitive impairment or other communication problems.
117	Equipment/Supply Problems	Venipuncture equipment malfunction, tubes not available to draw blood, or no Trutol available.
118	Other Reasons	Limit use on this code only to reasons that cannot be coded with above categories (e.g., SP sent home or excluded by the physician or inadequate staff to draw blood). Explain in comments.
210	Done at Prior Session	SP rescheduled and 2nd blood draw was completed at the previous visit.

Exhibit 3-11. Venipuncture comment codes

CODE	CATEGORY	INSTRUCTIONS
01	SP refusal	SP or parent/guardian of SP refused venipuncture/Trutol
02	SP ill/faints	SP becomes ill or faint in reaction to the procedures
03	SP in prone position	SP reclining during venipuncture
04	Multistick required	Two attempts; venipuncture procedure unsuccessful (no blood)
05	SP uncontrollable	Unable to control SP; venipuncture procedure unsuccessful (no blood)
06	Veins not palpable	Unable to palpate veins; venipuncture procedure unsuccessful (no blood
07	Condition of veins	Venipuncture unsuccessful (some or no blood) due to condition of SP's veins, e.g., too small, fragile, too deep, rolling, etc.
08	Medical exclusion	Physician excluded SP from venipuncture/Trutol
09	Glove deterrent	Venipuncture unsuccessful (some or no blood) because appropriate gloves are not available
10	Dry run	Subject examined during dry run session; not a regular SP
11	Problems with needle	Venipuncture incomplete (some or no blood) due to problems with the needle, e.g., improper selection -- wrong size or type; improper handling -- pushed needle through vein or needle slipped out of vein; malfunction -- defective sheath, etc.
12	Problems with vacutainer	Venipuncture incomplete (some or no blood) due to problems with the vacutainer, e.g., no vacuum, or cracked
99	Other reasons	Limit use of this code only to reasons that cannot be coded with one of the above categories

3.12 Transporting Specimens to the Laboratory

Place the rack containing the blood collection tubes in a closeable, leakproof container and carefully carry it to the main lab where the specimens will be processed.

- Place the lavender top tubes and 10 ml gray tube on the rocker.
- Place the red tops, the SST, and the 10 ml non-silicone red top tubes upright in a test tube rack and leave the rack in an area where the specimens will not be exposed to extreme heat or cold.
- Place the 3 ml gray and 2 ml light blue in the small table top centrifuge, set the timer and inform the technologist who is processing bloods. If the centrifuge is full, place the tubes on the rocker.
- Place the 8 ml leukoprep top tube in the large centrifuge and spin at **2,900 rpm** for 20 minutes. If the centrifuge is in use, place the tube in the test tube rack.
- Inform the blood processor of any SP in age groups B-E who was lying down during the venipuncture.

3.13 Red Cross Procedures for Handling Vasovagal Reactions

"Fainting" is a partial or complete loss of consciousness due to a reduced supply of blood to the brain for a short time. Occasionally, a person collapses suddenly without warning. Recovery of consciousness almost always occurs when the victim falls or is placed in a reclining position. 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 are usually preceded or accompanied by:

- Extreme paleness;
- Sweating;
- Coldness of the skin;
- Dizziness;

- Numbness and tingling of the hands and feet;
- Nausea; or
- 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.

- Leave the SP lying down.
- 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 whether or not he/she has suffered injury from falling.
- Seek medical assistance. The SP should be carefully observed afterward because fainting might be a brief episode in the development of a serious underlying illness[1].

See Appendix D, the NHANES III Emergency Procedures Manual for Health Technicians, for NCHS policy and procedures for dealing with medical emergencies at the NHANES mobile examination centers.

[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. BLOOD SPECIMEN PROCESSING AND STORAGE

4.1 Introduction

A variety of assays will be performed on each SP's blood specimen. The purpose of blood processing is to allocate blood to processing and storage vials for transport to contract laboratories where samples will be analyzed for a variety of compounds, including lead, vitamins, and hormones. In addition, a hematologic workup will be done on each SP's blood sample. Exhibit 4-1 illustrates the hematology processing protocol. Exhibit 4-2 illustrates the protocol for blood chemistry processing. It is extremely important that the processing procedures outlined in these protocols and in this manual be followed exactly. If they are not, we will experience specimen loss or biased results.

4.2 Equipment and Supplies

The laboratory area is organized into two work stations, one of which is used for separating and processing blood specimens, for storing blood and urine specimens, and for packing blood and urine specimens for shipment (Station 1), and the other which is used for conducting hematology analyses, processing urine specimens and performing pregnancy tests (Station 2).

The laboratory area includes a sink, refrigerator, three freezers, four centrifuges, two data terminals, the Coulter S-Plus Jr., a biosafety hood with a work table, work benches for processing blood and urine, and cabinets in which supplies for blood/urine processing and hematology are stored. The floor plan for the laboratory is shown in Figure 4-1.

The equipment and supplies for the laboratory area are listed in Exhibits 4-3 and 4-4.

4.3 Setting Up Blood Processing Racks

The phlebotomist and the technologist assigned to shipping are responsible for labeling vials and assembling the blood processing racks. It is very important to the success of the

Exhibit 4-1. NHANES III hematology processing protocol

Step no.	Age group	Tube type	Test name	Sample size	Vial type	Analyzed by	Other remarks
1.	A (1-3)	3-ml Lav	CBC/RDW/Plat. Automat. Diff.	0.20 ml	--	MEC	Use Coulter S+ Jr.
2.	A (1-3)	3-ml Lav	Differential smear	0.05 ml	Glass slide	CDC	Make backup for automated diff.
1.	B-C (4-11)	3-ml Lav	CBC/RDW/Plat. Automat. Diff.	0.20 ml	--	MEC	Use Coulter S+ Jr.
2.	B-C (4-11)	3-ml Lav	Differential smear	0.05 ml	Glass slide	CDC	Make backup for automat. diff.
1.	D-E (12+)	2-ml Lav	CBC/RDW/Plat. Automat. Diff.	0.20 ml	--	MEC	Use Coulter S+ Jr.
2.	D-E (12+)	2-ml Lav	Differential smear	0.05 ml	Glass slide	CDC	Make backup for automat. diff.

Exhibit 4-2. NHANES III blood processing protocol for biochemistry specimens

Test ID Number	Test Name	Age Group	Sample Size, ml	Specimen Type	Collection Type	Vial Type	Analyzed By	Other Remarks
1.	Lead	A-E	0.50	EDTA-WB	3 ml lavender	2.0 ml	CDC/EHLS	Aliquot first.
2.	Erythrocyte Protoporphyrin	A-E	0.5/1.0	EDTA-WB	3 ml lavender	2.0 ml	CDC/EHLS	Aliquot 0.5 for Group A and 1.0 for Groups B-E.
3.	RBC Folate	B-E	0.1	EDTA-WB	3 ml lavender	2.0 ml	CDC/EHLS	0.1 ml EDTA plus 1 ml 1% ascorbic acid.
4.	Glycosylated Hemoglobin	B-E	≥0.5	WB	3 ml lavender	3 ml lavender	U. of Mo.	Refrigerate EDTA tube. Ship twice a week on wet ice.
5.	Glucose	E (20-39, 75+)	1.0	P	3 ml gray	2.0 ml	U. of Mo.	Spin and aliquot plasma.
5.A/B	Glucose (GTT)	E (40-74)	1.0	P	3 ml gray/3 ml gray	2.0 ml	U. of Mo.	Spin and aliquot plasma.
6.	Insulin/ C-peptide	E (20-39, 75+)	1.5	S	10/15 ml red	2.0 ml	U. of Mo.	
6.A/B	Insulin/C-peptide	E (40-74)	1.5	S	10/15 ml red/4 ml SST	2.0 ml	U. of MO.	
7.	(Iron/TIBC/Ferritin)	A	All	S	4 ml SST	2.0 ml		
	Iron/TIBC	B-E	1.25	S	10/15 ml red	2.0 ml	CDC/EHLS	
8.	Ferritin/ Folate	B-E	1.5	S	10/15 ml red	2.0 ml	CDC/EHLS	
9.	NHLBI Lipids	B-E	2.5-5.5	S	10/15 ml red	6.0 ml	Hopkins	
10.	Vitamins A/E/ Carotene	B-E	1.25	S	10/15 ml red	2.0 ml	CDC/EHLS	Retinyl esters on subset.
11.	Cotinine	B-E	2.0	S	10/15 ml red	2.0 ml	CDC/EHLS	
12.	C-Reactive Protein/RF	B-E	0.5/1.0	S	10/15 ml red	2.0 ml	U. WA	Aliquot 0.5 ml for adults less than 60 and 1.0 ml for adults 60+.
13.	SMAC profile	D-E	1.0	S	10/15 ml red	2.0 ml	White Sands	
14.	Vitamin C	C-E	0.1	S-extr	10/15 ml red	2.0 ml	CDC/EHLS	0.1 ml serum plus 0.4 ml 6% MPA.

Exhibit 4-2. NHANES III blood processing protocol for biochemistry specimens (continued)

Test ID Number	Test Name	Age Group	Sample Size, ml	Specimen Type	Collection Type	Vial Type	Analyzed By	Other Remarks
15.	Vitamin D Total/Ionized Calcium	D-E	All	S	4 ml SST	SST	CDC/EHLS	Spin down after clotted; chill 60 min; freeze on side; ship unopened, frozen.
16.	Tetanus	B-E	0.5	S	10/15 ml red	2.0 ml	MUSC	
17.	Hepatitis	C-E	1.0	S	10/15 ml red	2.0 ml	CDC-1	
18.	Herpes	D-E	1.0	S	10/15 ml red	2.0 ml	CDC-2	
19.	Selenium	D-E	0.5	S	10/15 ml red	2.0 ml	CDC/EHLS	
20.	HIV I	D-E (18+)	0.5	S	10/15 ml red	2.0 ml	CDC-3	
21.	Thyroid	D-E	1.0	S	10/15 ml red	3.5 ml	USC	
22.	FSH & LH hormones	E	0.75	S	15 ml red	2.0 ml	U.MASS.	Women 35-60.
23.	Fibrinogen	E	All	P	2 ml blue	2.0 ml	White Sands	Age 40 + only.
TO.	Toxoplasmosis	D-E	0.5	S	10/15 ml red	2.0 ml	CDC/EHLS	
RU.	Rubella	C-E	0.5	S	10/15 ml red	2.0 ml	CDC	
IE.	IgE	C-E	0.5/1.0	S	10/15 ml red	2.0 ml	Bratton	0.5 ml for Group C, 1.0 ml for Groups D and E.
24.-27.	Storage #1-4	C-E	1.0/2.0	S	10/15 ml red	Multiple 2.0 ml	CDC/EHLS	One vial has 1.0 ml; others have 2.0 ml.
28.	Volatile toxicants	E(20-59)	All	P	10 ml gray	10 ml gray	CDC/EHLS	Do not spin. Refrigerate; ship on wet ice
29.	Volatile toxicants	E(20-59)	All	S	10 ml red non-silicone coated	5.0 ml Wheaton		Ship on dry ice with Vol. Tox. urines.
C1.	DNA/HGB Adducts	C-E	clot	clot	10/15 ml red	8.0 ml Sarstedt	SRA	Ship on dry ice.
C2.	DNA/HGB Adducts	C-E	clot	clot	10/15 ml red	8.0 ml Sarstedt	SRA	Ship on dry ice.
31.	Genetic Analyses	D-E	All	WB	8 ml Leukoprep	8 ml leukoprep	CDC	Refrigerate; ship on wet ice

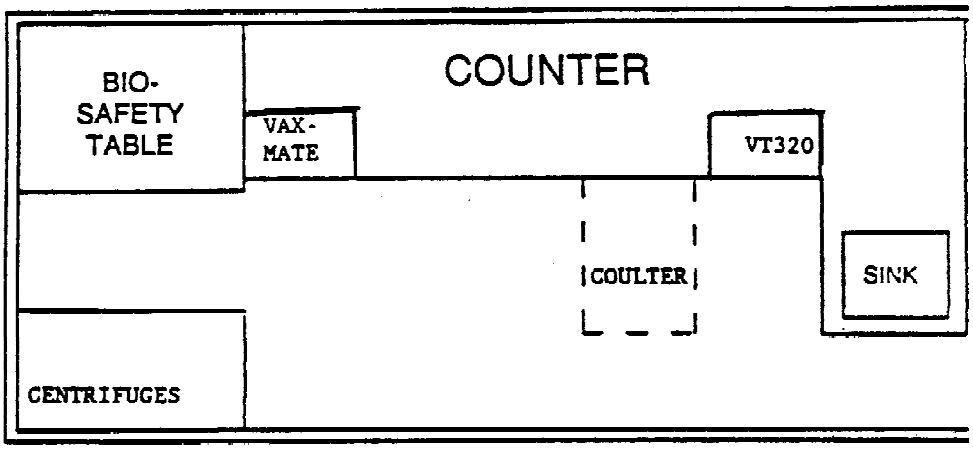


Figure 4-1. Floor plan for the laboratory blood and urine processing facilities

Exhibit 4-3. Equipment for the laboratory

Biological safety hood

2 Rockers

Two Sorvall centrifuges

Small table top centrifuge

2 Data terminals

3 Freezers

Coulter S + Jr.

Hematocrit centrifuge

Refrigerator

Exhibit 4-4. Supplies for the laboratory

Blood Processing & Storage

MLA micropipettors
0.1 ml
1.0 ml
0.4 ml

MLA pipette tips
Micro
0.1 ml 100 ul (microliter)
1.0 ml 1000 ul

MLA pipette holder

Tube Lubricant

Cryo tubes
2.0 ml Nalgene*
3.5 ml Sarstedt
5.0 ml Wheaton vials, stoppers and seals
6.0 ml flat bottom - (Sarstedt)
8.0 ml flat bottom - (Sarstedt)

Crimper

Cryo storage boxes

Inventory racks
Large - 100 place
Small - 20 place

Test tube rack (16mm)

Biohazard bags
and ties - 8 1/2"x11"

Benchtop Bio-Hazard
Bag holder

Sterile plastic
transfer pipettes

Bench covers for hood

Plastic aprons

Gloves - latex
Small
Medium
Large

Face masks

Conical tubes, 50 ml. Falcon

Hemostat - Long Nosed

Deionized water (regular ok)

Graduated cylinders
Large (100 ml)
Small (50 ml)

Metaphosphoric acid 3gm/vial
(pre-measured)

Ascorbic acid, 0.5 gm/vial
(pre-measured)

Wooden applicator sticks

Serum separators
For 10/15 ml tubes

Hematology, Urine Processing, Pregnancy Test

Coulter cuvettes

Isoton III+

Coulter Clenz +

Lyse-S III:diff +

4C+ controls, dated +

S-Cal, dated +

Coulter tool kit
Extra tubing
bulbs
fuses
batteries

Coulter printer paper

Printer ribbon

Pocket calculator

Urine specimen cups*,+

Conical tubes, 15 ml Falcon*,+

4.5 ml vials

*Prescreende by CDC
+Monitor and document use

Exhibit 4-4. Supplies for the laboratory (continued)

60 ml Wheaton vials, stoppers and seals

Crimper

2.0 ml Nalgene vials

ICON Pregnancy Test Kit +

Urine Controls +

Microhematocrit
Cap. tubes -
non-heparin - glass
Plain (Blue top)

Microhematocrit sealant
(clay)

Microscope slides
1"x3"

Slide box -
100 slide capacity

Mailer bags for slides

Wash bottles

Miscellaneous

Bleach

Rubber gloves

Spray bottles

Kim Wipes

4" x 4" Gauze pads

Timers

+Monitor and document use

Biohazard bags
large
small

Biohazard box

Pencil sharpener

Pencils

Pens

Antibacterial soap

Paper towels

Rubber bands

Paper clips

Hand lotion

Sponges

Self-stick labels
ID labels
Vial labels
HIV labels

Waterproof pens

Tissues - Kleenex

Paper lab coats

Cotton swabs

Tackle box

Playmate cooler

Safety glasses

Exhibit 4-4. Supplies for the laboratory (continued)

Shipping

Polyfoam shippers
- Large
- Small

Insul-ice Mat
- 1 box @ 37 1/2 ft
- singles

Cryo gloves
- Size med
- 14" mid arm

Strapping tape

Scissors

Dry ice

Ziplock bags

Shippers

Hammer

Scotch Tape & Dispenser

Unprinted Newsprint

Shipping transmittals

Labels which state:
- Keep Frozen
- Refrigerate
- Contains Dry ice
- Human Blood
- Blood Specimens for Medical Use

Fed. Ex. labels (typed)
to all contract labs.
(List destinations)

Address labels (typed)
to all Contract labs.

Field Office return address labels

Formatted Diskettes

Diskette mailers

Westat Business Reply Labels

laboratory operation that the blood vials be set up in the appropriate rack and be labeled correctly with the appropriate vial label and subject ID number. If a vial is placed in a rack in the incorrect position, if a vial is labeled with the incorrect ID or vial number, or if the wrong type of rack is set up for a particular subject, the validity of the laboratory results is jeopardized. Thus, you must be very careful in setting up the blood vial racks and in labeling the vials with the appropriate vial number and SP number.

4.3.1 Materials and Supplies

To set up and label blood vials you will use the following materials:

- Daily Appointment Schedule for future examination days (Exhibit 3-3);
- Color-coded Styrofoam racks for the blood vials;
- Uncapped blood vials of the following sizes:
  - 2.0 ml Nalgene
  - 3.5 ml Sarstedt
  - 5.0 ml Wheaton
  - 6.0 ml Sarstedt
  - 8.0 ml Sarstedt;
- Capped, prescreened (by CDC) 2 ml Nalgene vials to be used only as Vial 1 for blood lead;
- Bar-coded subject ID labels, each containing a 7 digit ID number;
- Bar-coded subject ID labels containing a randomly ordered 7 digit ID number (Z labels); and
- Color-coded vial labels, each containing a vial number, matched to the colors of the racks for the blood vials.

4.3.2 Preparing the Blood Vial Racks

One Styrofoam blood vial rack should be prepared for each study subject. The set-up of

the rack depends on the subject's age. Both the racks and the vial labels are color-coded to reflect this.

The racks must be prepared at least one day before the study subject is scheduled for examination. Check the Daily Appointment Schedule (Exhibit 3-3) for the next examination day for which no racks have yet been prepared.

- Determine which type of rack you need to prepare for each subject. You determine this by referring to the study subject's age on the Daily Appointment Schedule and to the chart below.

SP's Age	Type of Rack
1-3	Red
4-5	Green
6-11	Yellow
12-19	Blue
20+	Orange
20+ (Home Exam)	Purple

- Locate the appropriate type of rack for the first subject on the Daily Appointment Schedule.
- Locate the appropriate bar-coded ID labels for the subject, referring to the ID number on the Daily Appointment Schedule.
- Locate the appropriate color-coded vial labels for the subject. (The labels match the color of the rack.)
- Locate blood vials of the appropriate size for this rack by referring to Exhibits 4-5 through 4-9. For example, a red rack for a 1-3 year old requires three 2 ml vials, one capped 2 ml vial for Vial 1 and two uncapped prescreened 2 ml vials for Vials 2 and 7. A yellow rack for a 6-11 year old requires one capped prescreened 2 ml vial for Vial 1, 16 uncapped 2 ml vials for Vials 2-3, 7-8, 10-12, 14, 16, 17, RU, IE and 24-27, one 6 ml Sarstedt vial for Vial 9 and two 8 ml Sarstedt vials for Vials C1 and C2. You will also have to leave a blank space in the rack for a 3 ml lavender tube (Vial 4).

- Label each vial with the appropriate vial number, according to the protocol. Place the label lengthwise on the vial rather than wrapping it around the vial horizontally. Place the label so that the first digit of vial number is at the top of the vial.

- In addition, label each vial (except Vial 20 for HIV) with one ID number for the SP, again placing the label lengthwise on the vial with the first digit at the top of the vial. **Note that it is extremely important that you do not label Vial 20 with an SP ID label.** This vial will contain the specimen to be tested for the AIDS virus, and in order to protect the anonymity of the sample person it is essential that no SP ID label be applied to this vial. Vial 20 should be labeled with one of the randomly ordered 7 digit ID number labels that begin with "Z." Refer to Appendix G for instructions on assigning "Z" numbers.

  Note: Some vial positions indicate a type of blood tube. For example, in a rack for adults 20+, some vial positions will indicate "LAV" or "SST." These refer to blood tubes rather than vials. You will be provided with the vial labels for these positions. Simply place the vial label over the appropriate vial position in the rack.

- When you have labeled and inserted all the vials in the rack, put all of the extra vial labels, ID labels and "Z" labels in the center of the rack. These labels will be used for the urine vials.

- Continue with the rack for the next subject.

- If, for any reason, blood is not processed for an SP by the end of the stand, recycle the vials by removing the ID labels and Z labels from the vials. Leave the color coded vial labels on and reuse the vials when you set up the next appropriate rack.

4.4 Specimen Labeling

The phlebotomist and the technologist assigned to shipping are responsible for labeling the vials and setting up the color coded racks. (See Section 4.3 above.) However, as the blood processor, you must verify that each vial is labeled before you fill it. Because you will be preparing a large number of vials for most SPs, you must not rely only upon your memory or the positioning of the vials in a rack to indicate which vials you have filled. Always double check:

- The SP's ID number on the bar coded label;
- The SP's assigned "Z" number on the barcoded label;
- The color of the vial label;
- The vial number on the label; and
- The adhesion quality of the labels.

In this way you will help to ensure that we do not lose specimens due to incorrect or missing labels. Exhibits 4-5 through 4-9 illustrate how the vials or tubes will be labeled for each type of SP.

Please note: Any extra SP ID labels should be placed in the storage bags containing Vials 31 to be sent to the CDC Genetics Laboratory.

4.5 Blood Specimen Processing Procedures

4.5.1 Introduction

All blood specimens are to be centrifuged unopened, then transported to the biological safety cabinet, uncapped and processed under the hood. The biological safety cabinEt provides a HEPA filtered, recirculated mass airflow within the workspace and protects you from any spattering that may occur when opening the vacutainer tubes or when pouring or pipetting the specimens. It also prevents the drawing of contaminated air or dust over the specimens. It is mandatory that you use the blower at all times when using materials prescreened by CDC for trace metal contamination.

You must wear gloves at all times when you are handling specimens. Check your gloves for small holes or tears. Change your gloves if they become visibly contaminated with blood. Soak visibly contaminated racks in 1:100 bleach solution.

Inspect the tubes drawn for the SP. Refer to the Daily Appointment Schedule (Exhibit 3-3) and the Venipuncture Blood Processing Data Entry Screen (Exhibit 4-10). Verify that the number of tubes and the amount of blood collected that appear on the log are, in fact, what you have received. If not, enter a comment to explain the situation.

4.5.2 Processing Lavender Top (EDTA) Tubes and Blue-Black (Leukoprep) Tubes

The well-mixed lavender EDTA tube is used for the hematology profile and for certain biochemical tests. The EDTA (tripotassium salts of ethylene diamine-tetracetic acid) acts

Exhibit 4-5. Vials for age group A (1-3)

Age Group A: 1-3 years
Label Color: Red

Source: 3 ml EDTA-lavender top-WB

Vial	Assay	Amount	Contents	Vial
01	Lead	0.50 ml	WB	2.0 ml N
02	Erythrocyte Protoporphyrin	0.50 ml	WB	2.0 ml N

Source: 4 ml SST

Vial	Assay	Amount	Contents	Vial
07	Iron/TIBC/Ferritin	all	S	2.0 ml N

Exhibit 4-6. Vials for age group B (4-5)

Age Group B: 4-5 years
Label Color: Green

Source: 3 ml lavender top, WB

Vial	Assay	Amount	Contents	Vial
01	Lead	0.5 ml	WB	2.0 ml N
02	Erythrocyte Protoporphyrin	1.0 ml	WB	2.0 ml N
03	RBC Folate	0.1 ml	WB	2.0 ml N
04	Glycoslyated hemoglobin	≥0.5 ml	WB	3.0 ml Lav

Source: One 10 ml red-top and one 15 ml red top, serum

Vial	Assay	Amount	Contents	Vial
07	Iron/TIBC	1.25 ml	S	2.0 ml N
08	Ferritin/Folate	1.5 ml	S	2.0 ml N
09	NHLBI Lipids	2.5-5.5 ml	S	6.0 ml S
10	Vitamins A/E/Carotene	1.25 ml	S	2.0 ml N
11	Cotinine	2.0 ml	S	2.0 ml N
12	C-reactive protein	0.5 ml	S	2.0 ml N
16	Tetanus	0.5 ml	S	2.0 ml N

Exhibit 4-7. Vials for age group C (6-11)

Age Group C: 6-11 years
Label Color: Yellow

Source: 3 ml EDTA, lavender top, WB

Vial	Assay	Amount	Contents	Vial
01	Lead	0.5 ml	WB	2.0 ml N
02	Erythrocyte Protoporphyrin	1.0 ml	WB	2.0 ml N
03	RBC folate	0.1 ml	WB	2.0 ml N
04	Glycosiyated hemoglobin	≥0.5 ml	WB	3.0 ml Lav

Source: One 10 ml and two 15 ml red top, serum

Vial	Assay	Amount	Contents	Vial
07	Iron/TIBC	1.25 ml	S	2.0 ml N
08	Ferritin/Folate	1.5 ml	S	2.0 ml N
09	NHLBI Lipids	2.5-5.5 ml	S	6.0 ml S
10	Vitamin A/E/Carotene	1.25 ml	S	2.0 ml N
11	Cotinine	2.0 ml	S	2.0 ml N
12	C-reactive protein	0.5 ml	S	2.0 ml N
14	Vitamin C	0.1 ml	S	2.0 ml N
16	Tetanus	0.5 ml	S	2.0 ml N
17	Hepatitis	1.0 ml	S	2.0 ml N
RU	Rubella	0.5 ml	S	2.0 ml N
IE	IgE	0.5 ml	S	2.0 ml N
24-27	Storage	1.0/2.0 ml	S	2.0 ml N

Source: Two 15 ml red tops, clots

Vial	Assay	Amount	Contents	Vial
C1-C2	Clot	All	Clot	8.0 ml Sarstedt

Exhibit 4-8. Vials for age group D (12-19)

Age Group D: 12-19 years
Label Color: Blue

Source: 3 ml lavender top

Vial	Assay	Amount	Contents	Vial
01	Lead	0.5 ml	WB	2.0 ml N
02	Erythrocyte Protoporphyrin	1.0 ml	WB	2.0 ml N
03	RBC folate	0.1 ml	WB	2.0 ml N
04	Glycosylated Hb	≥0.5 ml	WB	3.0 ml Lav

Source: One 10 ml red top, three 15 ml red tops, serum

07	Iron/TIBC	1.25 ml	S	2.0 ml N
08	Ferritin/Folate	1.5 ml	S	2.0 ml N
09	NHLBI Lipids	2.5-5.5 ml	S	6.0 ml S
10	Vitamins A/E/ Carotene	1.25 ml	S	2.0 ml N
11	Cotinine	2.0 ml	S	2.0 ml N
12	C-reactive protein	0.5 ml	S	2.0 ml N
13	SMAC profile	1.0 ml	S	2.0 ml N
14	Vitamin C	0.1 ml	S	2.0 ml N
16	Tetanus	0.5 ml	S	2.0 ml N
17	Hepatitis	1.0 ml	S	2.0 ml N
18	Herpes	1.0 ml	S	2.0 ml N
19	Selenium	0.5 ml	S	2.0 ml N
*20	HIV I	0.5 ml	S	2.0 ml N
21	Thyroid	1.0 ml	S	3.5 ml S
TO	Toxoplasmosis	0.5 ml	S	2.0 ml N
RU	Rubella	0.5 ml	S	2.0 ml N
IE	IgE	1.0 ml	S	2.0 ml N
24-27	Storage	1.0/2.0 ml	S	2.0 ml N

Source: Two 15 ml red tops, clot

C1-C2	Clot	All	Clot	8.0 ml Sarstedt

Source: 4 ml SST

15	Total/Ionized calcium/Vitamin D	All	S	4.0 ml SST with 2.0 ml N

Source: 8 ml leukoprep top

31	Genetic Analyses	All	P	8.0 ml leukoprep

* Done only for those 18+

Exhibit 4-9. Vials for age group E (20+)

Age Group E: 20+
Label Color: Orange

Source: 3 ml EDTA lavender tube

Vial	Assay	Amount	Contents	Vial
01	Lead	0.5 ml	WB	2.0 mlN
02	Erythrocyte Protoprophyrin	1.0 ml	WB	2.0 ml N
03	RBC folate	0.1 ml	WB	2.0 ml N
04	Glycosylated Hgb	≥0.5 ml	WB	3.0 ml Lav

Source: Two 3 ml gray-tops

*05 or 05A/B	Glucose	1.0 ml	P	2.0 ml N

Source: Five 15 ml red tops, serum

*06 or 06A	Insulin/C peptide	1.5 ml	S	2.0 ml N
07	Iron/TIBC	1.25 ml	S	2.0 ml N
08	Ferritin/Folate	1.5 ml	S	2.0 ml N
09	NHLBI Lipids	2.5-5.5 ml	S	6.0 ml S
10	Vitamins A/E/ Carotene	1.25 ml	S	2.0 ml N
11	Cotinine	2.0 ml	S	2.0 ml N
**12	C-reactive protein/RF	0.5/1.0 ml	S	2.0 ml N
13	SMAC profile	1.0 ml	S	2.0 ml N
14	Vitamin C	0.1 ml	S	2.0 ml N
16	Tetanus	0.5 ml	S	2.0 ml N
17	Hepatitis	1.0 ml	S	2.0 ml N
18	Herpes	1.0 ml	S	2.0 ml N
19	Selenium	0.5 ml	S	2.0 ml N
20	HIV	0.5 ml	S	2.0 ml N
21	Thyroid	1.0 ml	S	3.5 ml S
***22	FSH & LH hormones	0.75 ml	S	2.0 ml N
TO	Toxoplasmosis	0.5 ml	S	2.0 ml N
RU	Rubella	0.5 ml	S	2.0 ml N
IE	IgE	1.0 ml	S	2.0 ml N
24-27	Storage	1.0/2.0 ml	S	2.0 ml N

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* 05 and 06 for adults 20-39 and 75+; 05A and 06A and 05B and 06B for adults 40-74
** 0.5 for adults <60; 1.0 for adults 60+
*** Only for women 35-60

Exhibit 4-9. Vials for age group E (continued)

Vial	Assay	Amount	Contents	Vial
Source: Two 15 ml red tops, clot				
C1-C2	Clot	All	Clot	8.0 ml Sarstedt
Source: 4 ml SST				
15	Total/Ionized calcium/Vitamin D	All	S	4 ml SST with 2.0 ml N
Source: One 2 ml light blue top				
****23	Fibrinogen	All	P	2.0 ml N
Source: 8 ml leukoprep top				
31	Genetic analyses	All	P	8 ml leukoprep
Source: 4 ml SST				
6B	Insulin/C-Peptide	1.5 ml	S	2.0 ml N
Source: One 10 ml gray top				
*****28	Volatile toxicants	All	WB	10 ml gray
Source: One 10 ml non-silicone coated red top				
*****29	Volatile toxicants	All	S	5.0 ml Wheaton vial

**** Only for males and females 40+
***** Only for special sample of 45 SPs

as a chelating agent to combine with calcium in the blood and prevent coagulation. Determinations should be made between 30 and 60 minutes after the blood is drawn. If circumstances arise which make it impossible to proceed after one hour, EDTA blood should be stored in the refrigerator after the smears have been made and after aliquots for biochemistry assay vials 1, 2 and 3 have been removed. The maximum time the EDTA blood may be stored is 24 hours for WBC, RBC, HgB and HCT. Beyond this time the blood will undergo changes which will render the results inaccurate.

After proper identification and labeling, aliquot the blood lead, the erythrocyte protoporphyrin and the RBC folate specimens under the hood. Then give the tube to the hematologist who will check each EDTA tube for small clots by stirring the blood gently with a wooden applicator stick. Small clots which would invalidate test results will adhere to the stick. If clots are present, the specimen will not be used for CBC analysis and the hematologist will return the tube to you for further processing. If no clots are present, the hematologist will perform the hematology tests before returning the tube to you for further processing. Continue to process the lavender top tubes following the instructions given in Appendix H (Exhibits H-1 to Appendix H-5).

The blue-black leukoprep tube is drawn for age groups D and E to be used for genetic testing. The tube should be kept upright at room temperature until centrifuged. Mix the blood specimen by gently inverting the tube 8-10 times. The leukoprep tube is then centrifuged at 2,900 rpm for 20 minutes to separate peripheral blood mononuclear cells from erythrocytes and granulocytes. When the separation is complete, resuspend the mononuclear cells in the plasma by gently inverting the tube 5-10 times. The tube is refrigerated until it is shipped, following the instructions given in Appendix H (Exhibits H-1 to H-5).

4.5.3 Processing Light Blue and 3 ml Gray Top Tubes

- Centrifuge and separate the plasma from the 3 ml gray top tubes and the 2 ml light blue top tubes as soon as possible.
- If the contents of the gray tube are clotted, process the sample. Document in the automated system.
- If the blue tube is clotted, process the sample only if the clot is minute. Otherwise,

discard. Document in the laboratory automated system.

- Place the tubes in the centrifuge carrier of the table top centrifuge. Balance using water-filled tubes if necessary and centrifuge at 2,900 rpm (RCF=1115) for 15 minutes.

- Using a plastic transfer pipette, remove the plasma from the glucose tubes (grey tops) and place in the appropriately labeled 2.0 ml Nalgene vials.

- Using a plastic transfer pipette, remove the plasma from the light blue top tube and place in a 2.0 ml Nalgene vial.

4.5.4 Processing Red and Tiger Top (SST) Tubes

- Allow the blood in each red and tiger top tube to clot for 30 to 40 minutes at room temperature.

SST (for Vial 15 - Vitamin D)

- Cool the SST tube 3-5 minutes in wet ice.

- To centrifuge the specimens, place all tubes in the centrifuge carriers.

- Balance using water-filled tubes if necessary and centrifuge at 2,900 rpm (RCF=1115) for 15 minutes.

- Do not open the SST tubes. Refrigerate them **between 30 minutes to two hours**. Freeze horizontally in the appropriate storage bags by end of day.

SST/Red Tops - Serum

- Do not allow the serum to remain in contact with the clot for more than one hour after the specimen is collected.

- Inspect the serum in the 4 ml SST/red-top tubes to determine whether or not it is hemolyzed, turbid, lipemic or icteric.

  - If the serum is grossly turbid, lipemic or icteric, report this information to the physician immediately. Also, enter a comment to describe the serum when entering the results of the processing into the automated system.

  - If the serum in any one red-top tube from one SP is grossly hemolyzed, do not pool it with serum from the remaining tubes. Save it for the storage vials.

- If the serum in all of the red top tubes for one sample person is turbid, lipemic, or icteric, pool it and allocate as usual.

- Using a serum separator, carefully remove serum from the 4 ml SST or all the red-top tubes. Push the serum separator to the clot barrier gently to ensure cell-free separation. If the separator is pushed too hard, some flow through may occur.

- Pool the serum from all red-top tubes except the 10 ml red top for volatile toxicants into a 50 ml polypropylene centrifuge tube. Label with SP ID #. Hold the tube and the separator level while you decant the serum. Be careful to avoid introducing any cellular debris. Discard the tubes and separators in a biohazard bag.

- Stopper the 50 ml polypropylene tube and mix its contents by gentle inversion.

- Aliquot immediately, following the instructions given in Section 4.6 on specimen allocation.

- If the serum cannot be aliquoted immediately, you may refrigerate it at 4°C for no longer than four hours.

Red Tops-Clots

- After the serum has been decanted and processed, loosen the clot specimen with a stirring rod.

- Choose the clots with the least amount of fibrin. Decant the loosened clot specimens from the 15 ml red tops into separate 8.0 ml flat bottom Sarstedt vials. Do not fill the vials to the top even if you have enough material to do so. If the blood draw is short and you do not have two 15 ml red tops, decant the clot from a 10 ml red top rube and make a note in the automated system.

- Discard the red top vials and the stirring rod in a biohazard bag.

- Freeze the specimens upright in the appropriate storage box immediately.

4.5.5 Processing 10 ml Gray Top Tubes and 10 ml Non-silicone Coated Red Top Tubes for the Volatile Toxicants Study

The 10 ml gray top tubes, drawn for adults in age group E, aged 40-59, who volunteer for the volatile toxicants study, are to be labeled and refrigerated following the instructions given in

Appendix H (Exhibit H-5).

The 10 ml non-silicone coated red top tubes, drawn for adults who volunteer for the volatile toxicants study, are to be processed following the instructions given in Appendix H (Exhibit H-5).

4.5.6 Reagent Preparation

CDC will supply pre-measured ascorbic acid used for the RBC folate assay and the metaphosphoric acid used for the Vitamin C assay. These reagents must be prepared in advance of processing the blood samples and added to the appropriate vials using the MLA pipettor. Reagent grade distilled water is not required if none is available.

- The ascorbic acid powder, supplied in a 50 ml Falcon tube, is dissolved in 50 ml of distilled water and mixed gently. The reagent must be prepared daily. Date and label the Falcon tube each time you prepare the reagent. If the powder or the solution appears cloudy or discolored, discard and prepare fresh reagent.

- The metaphosphoric acid crystals are transferred to a sterile urine specimen container and dissolved in 50 ml of distilled water. Protect the reagent from light by wrapping the container with aluminum foil. This can be stored in the refrigerator and used for up to one week. Write the expiration date on the container when you prepare the reagent.

4.6 Specimen Allocation

4.6.1 Serum

- Confirm that all vials are labeled with the appropriate SP's barcoded ID label and the appropriate color coded vial label before you fill them.

- Using clear serum only, fill as many vials as possible in the order of priority shown in Exhibit 4-2. Pool all clear sera. The order of allocation and specific procedures to follow for each type of SP are summarized in Appendix H (Exhibits H-1 through

H-5).

- Securely close all vials to prevent leakage and evaporation.
- All leftover serum is to be aliquoted into storage vials 24-27 and then into additional vials if more serum is available.

4.7 Recording the Results of Blood Specimen Processing

You will use the Enter Blood Vial Data Screen (Exhibit 4-10) to enter the results of the blood specimen processing. After you have processed all of the specimens for one SP, access this screen and enter the SP's ID number, your own ID number and the results of the processing. If the specimens were not processed according to protocol, you will need to enter the appropriate reason. Codes for comments that describe reasons for deviating from the protocol are listed along with specific instructions on how to enter blood processing data in Chapter 7, Blood Processing, of the Laboratory Automation Manual. Enter codes for all reasons that apply. Also, enter any other comments you have in the space provided for comments.

4.8 How to Deal With System Failure

If the automated control system fails at any time and the results of blood processing cannot be entered into the computer, the results must be recorded on the preprinted Blood Processing Worksheet (Exhibit 4-11). You must complete a Blood Processing Worksheet for each SP for whom a blood sample was processed. After you have processed all of the specimens for one SP, complete the Blood Processing Worksheet as follows:

- Tech No.: Record your four-digit Tech ID number.
- Date: Record today's date in the space provided.
- Session: Check the appropriate box to indicate the session number. Check box 1 for the morning session, 2 for the afternoon session or 3 for the evening session.
- NCHS#: Record the SP's seven-digit NCHS ID number in the space provided.
- Age: Record the SP's age in years. Obtain the SP's age from the Daily Appointment Schedule on the Control Record (Exhibit 3-4).
- Sex: Check one box to indicate the SP's sex. Obtain the SP's sex from the Daily Appointment Schedule. Check box 1 if the SP is male; check box 2 if the SP is female.

Exhibit 4-10. Blood processing data entry screen

BLOOD VIALS Lavender _ Red _ SST _ Blue _ Red/Grn _

Tech #_____ _____ 3ml Grey _ VT(1) _ VT(2) _ Two Hour _

Nchs #_____ Age___Months/Years ___ Sex ___ Group Color _____

Last vial filled ___ Code for vials not filled ___ _____

Vial #	Filled	Code	Comment	Box #

Screen C-2.1 _ _ _ V1.5 _ _

NHANES III blood processing worksheet

NHANES III

NHANES III Blood Processing Worksheet

Tech No. _ _ _ _
Date _ _/_ _/_ _
Session _ 1 Morning
2 Afternoon
3 Evening
4 Home Exam

NCHS #	Age	Sex	Blood Vials Filled
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			
_ _ _ _ _ _ _ _ _	_ _	☐ 1 male ☐ 2 female	1 2 3 4 5 5A 5B 6 6A 6B 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 TO RU 24 25 26 27 28 29 C1 C2 31
Comments			

Comment Codes
B01 - No specimen drawn
B02 - QNS
B03 - Broken tube
B04 - Hemolysis
B05 - Icteric
B06 - Lipemia
B07 - MLA Pipet malfunction
B08 - No MPA
B09 - No ascorbic acid
B10 - Tube or vial thawed
B11 - Prone position
B99 - Other

- **Blood Vials Filled:** Circle the number which corresponds to each vial that you filled that you filled. Circle each number individually. If you did not fill a particular vial, do not circle the corresponding number on the form.

- **Comments:** If you did not fill a designated vial, you must record in the Comments section the vial number followed by the comment code which best explains the reason for the deviation from the protocol. For example: If you drop and break the light blue top tube, write 23-B03 in the Comments section. Codes and corresponding comments are given at the bottom of the Blood Processing Worksheet. If you use code B99, you must specify the reason you were unable to fill the vial.

4.9 Blood Specimen Storage

4.9.1 Blood Specimen Storage Protocol

After you fill the vials and enter the blood processing data, you must prepare to store the vials. Vials are stored in numbered storage boxes or bags according to the site to which they will be shipped. Store the vials as indicated in Exhibit 4-12.

At the beginning of each stand you will be given a series of barcoded, numbered labels to be used in ascending consecutive order for storage containers and shippers. You must label a storage box or bag for each destination as specified in Exhibit 4-12. You will use the automated system to assign a barcoded label to a specific storage container. This process is called "initializing" or "opening" a storage box/bag. The automated system will keep track of open storage containers. Each time you enter blood processing information, it will assign the blood vials to the appropriate storage containers. Each time you fill and close a box/bag or ship a box/bag to a specific destination, you must "initialize" and label a new box/bag for that destination. See Chapter 7, Blood Processing, of the Laboratory Automation Manual for specific procedures on how to initialize a storage bag/box.

Exhibit 4-12. Storage protocol for processed bloods

Recipient	Vials	Destination Code	Storage Arrangements
CDC-EHLS	1-3, 7-8, 10-11, 14-15, 17-19, 24-27, TO	A	Place vials from one SP together, upright in a plastic storage bag. Write the SP ID number on the bag. Freeze. Refrigerate tube 15 (SST) for 30 min - 2 hours before placing it on its side in the bag. Place all SP bags from one session in a gallon storage bag. Label it with date and session.
University of Missouri	4	I	Place specimens upright in serpentine order in a numbered 3" storage box. Refrigerate.
	5, 5A & 5B	J	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
	6, 6A & 6B	K	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
Hopkins	9	H	Place vials upright in serpentine order in a numbered 3" storage box. Freeze.
University of Washington	12	L	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
White Sands	13	N	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
MUSC	16	M	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
CDC-EHLS	20	C	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
USC	21	P	Place specimens upright in serpentine order in a numbered 3" storage box. Freeze.

Exhibit 4-12. Storage protocol for processed bloods (continued)

Recipient	Vials	Destination Code	Storage Arrangements
University of Massachusetts	22	Q	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
White Sands	23	R	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
CDC-EHLS	28	D	Place specimens upright in a rack; order by session and refrigerate. Wrap separately. Place all tubes from one session in a whirl bag labelled with date and session number. Place whirl bags in a numbered plastic bag for shipping. Add one gray top tube to every shipment.
CDC-EHLS	29	X	Place specimens upright in serpentine order in a numbered 3" storage box. Freeze. Use 5x5 divider. Add one empty capped and crimped 5.0 ml Wheaton vial and one empty 10 ml nonsilicon coated red top to every shipment.
SRA	C1, C2	C1	Place specimens upright in serpentine order in a numbered 3" storage box. Use a 7x7 divider, leaving one slot empty on each line. Freeze.
CDC-EHLS	31	F	Place specimens upright; refrigerate. Wrap Separately. Place all tubes from one session in a whirl bag labeled with the date and session number. Place the whirl bags in a numbered plastic bag for shipping. You may store whirl bags from several sessions in one storage bag.
CDC	RU	RU	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.
Bratton	IE	IE	Place specimens upright in serpentine order in a numbered 2" storage box. Freeze.

4.9.2 Arrangement of Vials in Storage Boxes

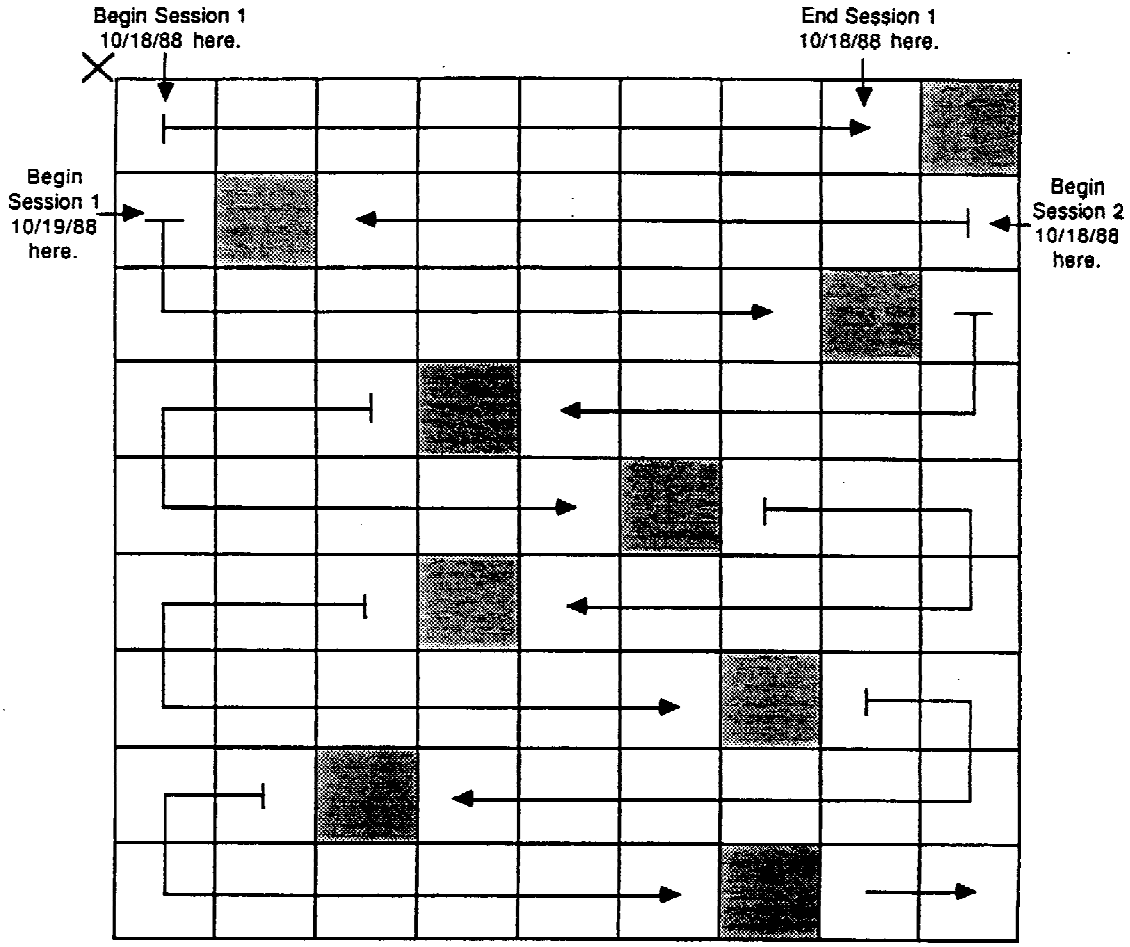
All vials that are to be stored in boxes should be arranged in their respective storage boxes in serpentine order (Exhibit 4-13) as described below.

- Use the automated system to initialize (assign a number to) a storage box. (See the Blood Processing Section of the Laboratory Automation Manual.)
- Label a new storage box with the contract laboratory destination and the designated barcoded label.
- Using a waterproof marker, draw a large "X" on an inside corner of the numbered storage box.
- Position the box so that the "X" is in the top left corner of the box.
- Begin filling a new box by placing the first vial in the top left corner space of the box (next to the "X").
- Continue to add vials as they are processed filling the spaces from left to right in the top row of the box.
- Fill the second row from right to left.
- Leave one space between the last vial of one session and the first vial of the next session so that you can easily find and check the vials collected during one session.
- Store vials from home exam SPs as a separate session (Session 4) after sessions 1 and 2 or 1 and 3.
- Continue adding vials to the box in serpentine order until it is full or until it is closed and shipped.

4.9.3 Check Storage Boxes and Bags

It is very important that the order of the vials in the storage boxes match exactly the order of the vials as they appear on the corresponding shipping transmittals. At the end of each session you must check each open storage box to see that it contains the appropriate vials and arrange them in ascending numerical order by SP ID number to match the order in which the vials will be listed on the shipping transmittals.

Exhibit 4-13. Serpentine arrangement of blood vials in a storage box



There are two methods you can use to check your work at the end of each session. The first method uses the computer terminal CRT to display the vials processed by destination. The second method uses the computer to print a report of the vials processed by destination. Both methods are described in more detail below.

CRT Method

- Remove an open storage box from the freezer or refrigerator.
- Arrange the vials processed during the session in ascending numerical order by SP ID #. Keep paired vials, such as 5A and 5B, together for one SP, with 5A placed before 5B.
- Enter the code for the contract lab destination code of the storage box. The computer will display the number of vials in each open storage box for the selected destination.
- Select the storage box number of the box you wish to check.
- The computer will call up the Show Blood Screen, which will display SP ID numbers of the vials in the storage box you selected. The numbers will be in ascending numerical order for each session beginning with the most recent session.
- Locate the first vial placed in the storage box during the session. It should have the same SP ID number as the first vial listed on the terminal monitor.
- Following the serpentine order of the box, the next vial should correspond to the second vial on the list, and so on until all of the vials placed in the box for that session and all of the SP ID numbers displayed for the session are accounted for.

Session Summary Printout Method

- Remove an open storage box from the freezer or refrigerator.
- Arrange the vials processed during the session in ascending numerical order by SP ID. Keep paired vials, such as 5A and 5B, together for one SP, with 5A placed before 5B.
- Use the automated system to print a session summary. From the Main Menu select "Summary for a Session". From the submenu select "Blood Processed for a Session." Choosing the item will call a screen used for entering the date and session for the report.
- Check the vials in the box against the printed report of the vials processed for that

destination.

The contents of the storage bags should also be checked at the end of each session. Although the vials cannot be stored in numerical order in a storage bag, each vial in the bag can be checked against either the Display Contents of Storage Boxes screen and the Show Blood screen (the CRT method) or the Summary for a Session printout to ensure that what has been entered into the automated system reflects exactly the number and identity of the vials in the storage bag.

Detailed instructions for using the automated system to check the contents of storage boxes and bags are given in Section 7.4 of the NHANES III Automation System Manual.

4.9.4 How to Handle Automated System Failure

In the event that the automated system fails, you should continue to label storage containers with barcoded labels. Always use the barcoded labels in ascending consecutive order. Do not skip numbers or use any numbers that are lower than the highest number on an open storage box. Label each storage box with the contract laboratory destination.

Store vials as specified in Exhibit 4-12, storage protocol for processed bloods. Hopefully the automated system will be repaired before you must ship the specimens to the contract laboratories and you will be able to use it to enter the blood processing data and to check the contents of the storage containers. However, if the automated system is still down when the specimens must be shipped, then the technologist who is handling shipping will complete the Shipping Transmittals and check the contents of the storage boxes.

5. HEMATOLOGY USING THE COULTER S-PLUS JR. AND THE HEMATOCRIT CENTRIFUGE

5.1 Introduction

The Coulter Counter Model S-Plus Jr. with Coulter histogram differential, hereafter referred to as the Model S-Plus Jr., is a quantitative, automated hematology analyzer. It is intended for determining the following 18 hematologic parameters:

- White Blood Cell (WBC) or leukocyte count $*10^3$;
- Lymphocyte percent (LYMPH percent) %;
- Mononuclear cell percent (MONO percent) %;
- Granulocyte percent (GRAN percent) %;
- Lymphocyte number (LYMPH #) $*10^3$;
- Mononuclear cell number (MONO #) $*10^3$;
- Granulocyte number (GRAN #) $*10^3$;
- Red Blood Cell (RBC) or erythrocyte count $*10^6$;
- Hemoglobin (Hgb) concentration g/dl;
- Hematocrit (relative volume of erythrocytes) (Hct) %;
- Mean Corpuscular (erythrocyte) Volume (MCV) fL;
- Mean Corpuscular (erythrocyte) Hemoglobin (MCH) pg;
- Mean Corpuscular (erythrocyte) Hemoglobin Concentration (MCHC) g/dl;
- Red Cell (erythrocyte volume) Distribution Width (RDW) %;
- Platelet (PLT) or thrombocyte count $*10^3$;
- Platelet distribution width (PDW);
- Relative volume of thrombocytes (PCT); and

- Mean Platelet (thrombocyte) Volume (MPV) fL.

5.2 Equipment and Supplies

5.2.1 General Description of the Coulter S-Plus Jr. and Its Reagent Subsystem

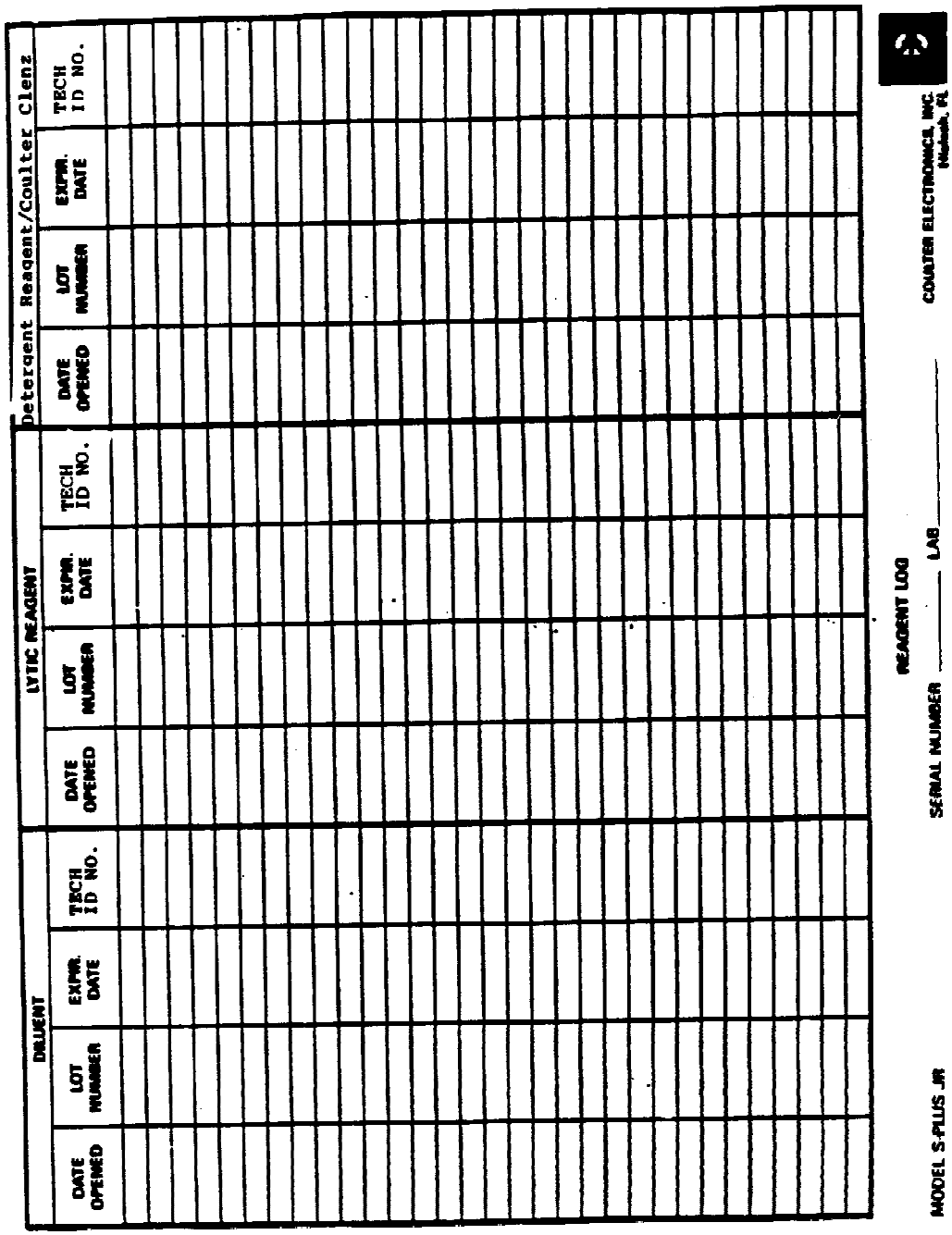
You will use the following equipment and supplies to determine hematological parameters using the S-Plus Jr.:

- Coulter Counter S-Plus Jr.;
- Coulter vials;
- Isoton III diluent;
- Coulter Clenz;
- Lyse S III diff lytic reagent;
- 4C Plus Cell Control (Normal, High, Low);
- S-Cal Calibrator;
- Coulter tool kit;
- Coulter printer/plotter paper; and
- Hematology Worksheet.

Note that these supplies are also listed in the Inventory Sheet for the Laboratory (Exhibit 4-4). Also note that you must use the Reagent Log (Exhibit 5-1) to record the date you open each container of reagent, its lot number, its expiration date, and your tech ID Number. This log must be completed for Isoton III diluent, Lyse S III diff lytic reagent and Coulter Clenz reagent.

The Model S-Plus Jr. is a modular system that consists of a pneumatic power supply, main unit, data terminal, and printer/plotter. The system is available with various power requirements.

Exhibit 5-1. Coulter reagent log



Pneumatic Power Supply:

This unit provides air pressure and vacuum to the system.

Main Unit:

This is the main operating unit of the system. It contains a diluter section, signal processing section, system control section, and the electronic power supply. It aspirates, pipets, dilutes, mixes, lyses, and senses automatically. The operating cycle is controlled electronically and results are analyzed. This unit counts, sizes, and computes the various parameters. This information is sent to the data terminal to be displayed.

Data Terminal (DT):

The DT receives information from the main unit and sends it to the printer. It derives LYMPH, MONO, and GRAN percents, computes LYMPH #, MONO #, GRAN #, provides a comprehensive QC program that incorporates the five different quality control techniques and allows for results management. Extended storage is also available as an option. (For complete information, refer to the Universal Data Terminal Product Reference Manual, PN 4235641).

Printer/Plotter:

This unit provides a printer record of the parameters obtained by the Model S-Plus Jr.

Reagent Subsystem:

The required reagents consist of a diluent, detergent reagent, and lytic reagent introduced into the instrument via tubing. The reagents are drawn from their individual external containers (cubitainers) and dispensed automatically in measured amounts during each operating cycle. Coulter recommends the following reagents for use with the Model S-Plus Jr.: Isoton III diluent, Coulter Clenz detergent reagent and LYSE S III diff lytic reagent. All stated performance characteristics, however, refer to the Model S-Plus Jr. using only the "III" line of reagents. Refer to the cubitainer's label for detailed information before using the reagent.

Function Keys:

These keys, located on the main unit, allow you to communicate with the equipment. See Exhibit 5-2 for a description of their use.

CAUTION

The ISOTON III diluent, Coulter Clenz detergent reagent, and LYSE S III diff lytic reagent system was specially developed for use in this instrument. This reagent system is NOT compatible with the ISOTON II diluent-ISOTERGE II detergent reagent-LYSE S II lytic system. Do not mix them.

The service contract with Coulter Electronics provides a yearly Performance Maintenance Inspection (PMI) which will include a thorough certification inspection on each S-Plus Jr. The chief lab technician is responsible for monitoring the frequency of PMIs and contacting the biomedical engineer if one has not been performed within the year. After the completion of the PMI, the certification should be placed in the quality control notebook and a copy sent to NCHS.

If there are any problems with servicing the S-Plus Jr., contact Al Mishko in the Coulter Electronics Maintenance Service Department (1-800-241-7693) for assistance.

5.2.2 Principles of Operation of the Coulter Method

The Coulter method of cell counting and sizing is based on the detection and measurement of changes in electrical resistance produced by a particle, suspended in a conductive liquid, traversing a small aperture.

When cells are suspended in a conductive liquid (diluent), they function as discrete insulators. When a dilute suspension of cells is drawn through a small cylindrical aperture, the passage of each individual cell momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. An electrical pulse, suitable for counting and sizing, results from the passage of each cell through the aperture.

5.3 Operating Procedures

5.3.1 General

The operating procedures detailed in this section have been developed to provide optimum performance from your Model S-Plus Jr; that is, to obtain reliable results within the instrument's specifications and performance characteristics. These procedures are based on the assumption that the main unit has remained on as recommended.

Exhibit 5-2. Coulter Counter Model S-Plus Jr. <F> key functions

<F> <0> <1>	CLEANING APER.	Activates aperture "burn" circuit; 1 s burn, 6 s cooling period.
<F> <0> <2>	BACKWASH	Backwash pump delivers 1 mL diluent through backwash route to rinse cup.
<F> <0> <3>	SWEEP FLOW PRIME	HI VAC applied to RBC aperture for 10 s to prime sweep-flow line with diluent.
<F> <0> <4>	ASPIRATING	The aspiration pump draws 100 μ L of sample through the aspirator tip.
<F> <0> <5>	BSV:ROTATE CW	Clockwise rotation of the Blood Sampling Valve to the "segment" position.
<F> <0> <6>	BSV:RETURN CCW	Counterclockwise rotation of the Blood Sampling Valve to the "return" position.
<F> <0> <7>	BSV:CYCLE	Alternating CW and CCW rotation of the Blood Sampling Valve.
<F> <0> <8>	BLEACH:CLEAR	Pressure (5 psi) applied to rear of apertures to clear liquid from aperture housings into the aperture baths.
<F> <0> <9>	BLEACH:PRIME	LO VAC applied to apertures to draw liquid from the aperture baths into the aperture housings.
<F> <1> <0>	RINSE CUP OUT	Extends backwash arm to expose rinse cup for cleaning. Press <RES1> and <RES2> simultaneously to end function.
<F> <1> <1>	PRIME	Vacuum is applied to the rear of the aperture for 15 s.
<F> <1> <3>	XMIT CAL FACTORS	Transmits current CAL Factors to the DT's CALIBRATION MENU.
<F> <1> <4>	LATEX CALI-BRATION DATA ENTRY MENU	Entry of MPV assay values.
<F> <1> <5>	LATEX CAL VALUES	Calculates new MPV CAL Factor.

TO ACTIVATE, PRESS <ENTER> AFTER KEYING IN THE FUNCTION

5.3.2 Operator's Responsibility

It is your responsibility to:

- Keep a copy of both the Coulter Counter S-Plus Jr. Products Reference Manual and the Universal Data Terminal Manual in the laboratory at all times.
- Become thoroughly familiar with the information in the Coulter Counter S-Plus Jr. Products Reference Manual before operating the Model S-Plus Jr.
- Perform the recommended procedures as described in the operating iNstructions (Section 3 of the Products Reference Manual) and perform the preventive maintenance (Section 5, Service and Maintenance).
- See Section 5 of the Product Reference Manual when:
  - The instrument does not perform as described in this section;
  - The variations from the performance characteristics and specifications exceed the tolerance established by your laboratory; and
  - The instrument produces unacceptable data.
- Document the performance of preventive maintenance procedures, stand start-up and shutdown procedures, daily startup and shutdown procedures, quality control procedures, reagent preparation, and unscheduled maintenance in the appropriate logs of the Quality Control Manual.

5.3.3 Startup Procedures for the Coulter S-Plus Jr.

The medical technicians are responsible for starting up the Coulter S-Plus Jr. at the beginning of the stand. The local Coulter representative will then perform the instrument verification procedure (see Appendix I). Vera Osidach will call Coulter Electronics (305-822-8250) to obtain the area Coulter representative's name and telephone number. She will then call to schedule the Coulter representative's time of arrival at the MEC.

Make sure all of the necessary equipment, materials and reagents are unpacked, and inventoried as soon as possible so that the technician assigned to hematology may power up the S-Plus

Jr. The technician who is responsible for setting up the phlebotomy room should also collect a sample of normal blood in a 3 ml lavender vacutainer from a MEC staff volunteer approximately 30 minutes before the medical technicians plan to begin the startup of the Coulter S-Plus Jr. The volunteer must:

- Not be receiving drugs;
- Have normal hematologic parameters; and
- Have normal erythrocyte, thrombocyte and leukocyte morphology.

5.3.3.1 Beginning of Stand Power Up of S-Plus Jr.

On arrival at each stand, locate the Coulter reagents, Isoton II diluent, Clenz detergent reagent and the Lyse S III diff lytic reagent. The medical technician is to perform the following procedures to power up the S-Plus Jr.

Connecting Reagents

Perform the following procedures to connect the reagents to the S-Plus Jr.:

- Connect the Waste Container
  - Remove the protective cover from the pickup tube assembly.
  - Place the pickup tube assembly straight into the new waste container, and screw the pickup tube into position.
  - Check that the tubing to and from the new container is properly connected (see Figure 5.4. of the Operations Manual).
- Connect the diluent, detergent reagent, and lytic reagent containers as follows:
  - Verify that the new reagent does not contain precipitate, turbidity, particulate matter, or unusual color. If any of these is evident, do not use the reagent.
  - Verify that the new container has been stored at room temperature and that its contents have not been transferred from the original container.
  - Record in the Coulter Reagent Log (Exhibit 5-1) the new container's lot number, expiration date, today's date, and your ID number.

- Remove the protective cover from the pickup tube assembly.

- Being careful not to touch the pickup tube with your hands or contaminate it in any other way, place the pickup tube assembly straight into the new container and screw the pickup tube into position.

IMPORTANT
Keep reagent lines from contact with electrical lines.
Such contact could cause elevated background counts.

- Check that the tubing to and from the new container is properly connected. (See Figure 5.4 of the Operation Manual.)

- Place another reagent container adjacent to the container that was just connected. This eliminates the possibility of the reagent being shaken prior to connection, thereby avoiding the introduction of bubbles into the Diluter.

- If a reagent or waste alarm locks up the instrument after five consecutive alarms, turn off the power to the Main unit, then turn on to reset the instrument.

- Remove spacers from pinch valves.

Power-Up

Perform the Power-Up procedures as follows:

- Press the POWER button (See Figure 3.1 of the Operations Manual) on the Channelizing module (located on the right side) and then on the Main unit. The POWER buttons illuminate when on. Once the Channelizing module power button is pressed, it is only necessary to use the Main unit power button to power up and down both the Main unit and the Channelizing module. A flashing display accompanied by four beeps indicates that the Pneumatic Power Supply is off. (Do not turn the Pneumatic Power Supply on until performing the Daily Startup Procedures.) After four flashes, the DATE prompt appears.

- Enter the date and test number or press <RES1> and <RES2> simultaneously to reset the unit. The display changes to SELECT FUNCTION.

- Allow the Main unit to warm up for 30 minutes before running SP samples or controls.

- Press the POWER button on the Data Terminal. Wait until the main menu appears on the screen. Check to see if the battery is within tolerance on the Data Terminal.

ON DT press 5 <ENTER>, 9 <ENTER> if the message "BATTERY WITHIN TOLERANCE" appears, continue with the power up. If the message "BATTERY OUT OF TOLERANCE" appears, report this to the Coulter Service Representative. Continue with the Power Up.

- Open the door on front of the Pneumatic Power Supply and turn on the pneumatic power supply by pressing the **power** button.

- Check that the gauges on the front panel of the pneumatic power supply indicate the required values. The correct readings are:

Vacuum:	20" Hg (minimum)
Pressure:	60 ± 2 psi
30 PSI:	30 ± 1 psi
5 PSI:	5 ± 0.25 psi

- Close the door on the pneumatics power supply.

- Open the door of the diluter and

  - Move the Optic Lamp switch to the ON position.

  - Verify the top of the red indicator in the electronic manometer is within the green operating range.

  - Close the diluter door.

- Prime the reagents:

  - Diluent (Isoton III).

    A. Press <**START UP**>

    B. After the startup sequence has been completed, activate the SWEEP FLOW function from the keypad by pressing <**F**>, <**0**>, <**3**>, <**ENTER**>. Wait for the function to end.

    C. Press <**DRAIN**>.

    D. Press <**RINSE**>.

  - Detergent Reagent. It is not necessary to prime at this point. Priming occurs at first shutdown.

  - Lytic Reagent. To facilitate priming, place the lytic reagent container at the same level as the Diluter.

A. Press <**DRAIN**> until the baths are empty.

B. Press and release <**LYSE**> until the lytic reagent supply line and pump are completely filled with lytic reagent and free of bubbles.

C. Press <**DRAIN**>; the baths drain.

D. Press <**RINSE**>.

- Turn on the Printer/Plotter and place on line.

- Access the Startup Menu on the Data Terminal by pressing **3** <**ENTER**>, **5** <**ENTER**>. Enter the lot numbers and the expiration dates of the coulter reagent into the startup log. To enter the lot numbers and expiration dates of the reagents into the DT, from the Main Menu, press <2> and <ENTER>, then <3> and <ENTER>.

Daily Startup Procedures

- Perform the daily startup procedures as described in Section 5.3.3.2, Summary of Daily Startup Procedures for the Coulter S-Plus Jr.

- Plot the **Startup** results.

Beginning of Stand Calibration

Perform the Beginning of Stand Calibration as follows:

- Preliminary procedures (see Section 5.4.2., Preliminary Procedures).

- Reproducibility check (see Section 5.4.3, Reproducibility Check).

- Carryover check (see Section 5.4.4, Carryover Check).

- Electronic subsystem check (see Section 5.4.5, Electronic Subsystem Check).

- Final precise calibration with S-Cal Calibrator (see Section 5.4.6, Calibration with S-Cal Calibrator).

- Quality control checks using 4C Plus control material (see Section 5.3.5, Quality Control Check).

Document your performance of the daily and stand startup procedures in the Scheduled Cleaning Procedures and Operational Checks Log (Exhibit 5-3), recording the date and your ID number.

Keep a copy of the printout from each of the stand startup procedures in the MEC Laboratory files and send the copies to NCHS at the end of the stand.

Exhibit 5-3. Scheduled cleaning procedures and operational checks

SCHEDULED CLEANING PROCEDURES AND OPERATIONAL CHECKS

DAILY				WEEKLY*				MONTHLY*	
STARTUP PROCEDURES*		SHUTDOWN PROCEDURES		CLEAN BSV		BLEACH APERTURES		CLEAN AIR FILTERS	
Date	Tech	Date	Tech	Date	Tech	Date	Tech	Date	Tech

*OR AS REQUIRED

COULTER ELECTRONICS, INC.
Hialeah, FL

PN 4235642 (September 1986)
5-10

5.3.3.2 Summary of Daily Startup Procedures for the Coulter S-Plus Jr.

The following summary is intended for use only after you are thoroughly familiar with all operating procedures in Section 3 of the Product Reference Manual. For reference, each heading includes the number of the heading in that manual which provides detailed instructions. This summary assumes that the main unit and channelizing module have been left on (heading 3.8) since the last shutdown (at least 30 minutes).

Daily Startup Procedures (3.9)

- Set date and test number.

  Press <DIR> to display the first directory option. Press <SEL> and enter the month, day, and year, then press <ADV> and enter the test number. When finished, press <ENTER>.

- Open the Pneumatic Power Supply front door, press the POWER button and check that the gauges indicate the required values. The correct readings are as follows:

Vacuum:	20" Hg (minimum)
Pressure:	60 ± 2 psi
30 PSI:	30 ± 1 psi
5 PSI:	5 ± 0.25 psi

- Close the Pneumatic Power Supply front door and open the Diluter front door.
- Move the OPTIC LAMP switch to the ON position.
- Verify that the top of the red indicator in the electronic manometer is within the green operating range.
- Close the Diluter front door.
- Turn on the Printer/Plotter and place it on-line.
- From the MAIN MENU on the DT, press <2>, <ENTER> and <1>,<ENTER>. Enter your three-digit operator ID number.
- From the MAIN MENU on the DT, press <3>, <ENTER>, <1>, <ENTER>, then again <1>, <ENTER>.

- On the Main Unit, verify that "SELECT FUNCTION" appears on the display.

- On the Main Unit keypad, press <START UP>, observe the automatic startup cycle, and verify that results are acceptable. A system check and background count are automatically run at the end of the STARTUP sequence. Press <PLOT> on the DT keyboard. Save the printout for the MEC files to be sent to NCHS at the end of the stand.

- If the reagent lot information is required from the STARTUP MENU on the DT, press <3> and <ENTER>. Then press <PLOT> to obtain a printed copy. Save the printout for the MEC files to be sent to NCHS at the end of each stand.

- Prime the instrument by cycling a normal, whole-blood sample as follows:

  - On the DT, access PRIME (from the MAIN MENU, press <6> and <ENTER>.

  - Hold the mixed priming sample to the aspirator tip with the tip submerged in the sample.

IMPORTANT
Do not remove the sample until the display reads WIPE TIP.

  - Press the WHOLE BLOOD button and hold the sample in position until the display changes from ASPIRATING to WIPE TIP.

CAUTION
Do not exert force on the aspirator tip; it may cause it to bend.

WARNING
You must remove the sample container and be clear of the area around the aspirator tip before the display indicates BACKWASH.

  - With a vertical motion, wipe the aspirator tip with a clean, lint-free tissue.

- Observe the Diluter during the rest of the cycle.

- Record performance of daily startup procedures in the Scheduled Cleaning Procedures and Operational Checks Log (Exhibit 5-3). Locate the column headed "Startup Procedures." Record the date you performed the procedures and your tech ID number.

5.3.4 Daily Calibration Verification with S-Cal Calibrator

5.3.4.1 Introduction

The verification of the Coulter S-Plus Jr. calibration using S-Cal Calibrator is performed at the beginning of each session after the daily startup procedures. The purpose of this verification is to monitor the accuracy of the Coulter S Plus Jr. and to correct for the variation in the results produced by the three instruments at three different locations over a 6-year period. Results of the daily calibration verification with S-Cal Calibrator are reported to Coulter headquarters via telephone and compared to results obtained by Coulter Electronics instruments in Hialeah. The results from each Coulter S-Plus Jr. in the MEC laboratories must be within specified limits before the laboratory may run SP specimens. Correction factors are derived for each instrument and applied to the SP results to approximate zero bias in the data.

Frank Anderson of Coulter Electronics will supply the S-Cal Calibrator for each stand. It should be refrigerated at 4 degrees Centigrade until it is used or until the expiration date is reached. Expired vials of S-Cal Calibrator should not be used. If a new lot number of S-Cal Calibrator is sent and some of the old lot number is left, discard the vials with the old lot number. You should allow Frank Anderson one week to send new S-Cal material. Inventory your supply daily. If you are running low, contact Versa Osidach; she will order new S-Cal Calibrator for you.

Frank Anderson, Manager of Coulter's Corporate Office of Medical and Regulatory Affairs, will provide the laboratory with limitation values for the following assays for each lot of S-Cal: WBC, RBC, HGB, MCV, PLT.

5.3.4.2 Daily S-Cal Calibration Procedure

S-Cal Calibrator is cycled through the Coulter 10 times, results are plotted and the data are reported to Coulter Electronics in Hialeah, Florida. Results are reported on weekdays only. When performing daily calibration verification on weekends, save the results and report them to Coulter on the next weekday. When the results of the verification of the calibration are within the specified limits, the

startup procedures are continued with the 4 C Plus Quality Control Check. On weekends, the startup procedures are continued automatically.

Follow the steps listed below to perform the daily verification and reporting procedures:

- Remove a vial of S-Cal Calibrator from the refrigerator and allow it to come to room temperature. Label the vial with the date at the time it is opened.
- Select the DT PRIME mode. Cycle one sample of S-Cal Calibrator to prime the instrument.
- From the Coulter DT, select the Main Menu and press <4> and <ENTER>.
- Delete previous values in Control File 9. Return to the Main Menu.
- Access the Control Data File Selection display: press <2> and <ENTER>, then <4> and <ENTER>.
- Select File 9 for daily S-Cal calibration. Set the Batch size equal to one.
- Enter the lot number and the expiration date of the S-Cal Calibrator you are using. Return to the Main Menu.
- Press <4> and <ENTER>, then <1> and <ENTER>. Select the System Ready for Control File 9.
- Mix S-Cal gently and cycle 10 times, remixing between each sample.
- Verify that the values for each parameter are within the limits specified on the assay sheet.
- Print the RBC Profile and the WBC-Platelet Profile tables.
- Refer to the printed copy when reporting the results by phone to Coulter Electronics.
- Using the regular telephone lines, dial 1-800-327-6531. Ask for extension 4244 and ask to speak with Lizette. If she is unavailable, contact Frank Anderson at 1-800-327-6531, ext. 4336.
- Report the service number of the Coulter S-Plus Jr.
- Report the S-Cal lot number.
- Report the day, date, month and year.

- Report the mean and standard deviation and the number of runs for WBC, RBC, HGB, MCV, PLT and MPV.

- If all the reported parameter values are within limits, you will be given the okay to run controls and SP samples. If not, you may be asked by the Coulter representative to repeat the calibration verification or to recalibrate the Coulter.

- When all of the parameters receive an "assurance" response, the daily calibration verification is finished.

- Keep a copy of the RBC Profile and WBC-Platelet Profile Tables in the MEC files to be sent to NCHS at the end of each stand.

5.3.5 Quality Control Check (3.10)

Perform quality control checks using 4 C Plus control material at the beginning of each session to verify that the instrument produces accurate results.

Every time you open new lot number of 4C Plus control material you must plot graphs of the daily values for each level of control of the previous lot numbers, clear the control files of the previous lot number data, and enter the assay and limitation values for the new lot numbers as follows:

- To enter assay and limitation values, access the CONTROL DATA: ASSAY VALUES AND LIMITS displays via <4> <ENTER> from the DATA ENTRY MENU. Select the file number. For each control file, enter the following data. Remember to press <ENTER> or an arrow key after data is entered to store it.

  - FILE # [1] (1 through 9).

  - CONTROL TYPE [9]. Refer to the legend on the display and enter the number corresponding to the control type for the file for which you are entering data. For example, to enter NORMAL as the control type, press <1> <ENTER>; NORMAL appears after CONTROL TYPE. (File 1=Normal, File 2=Low, File 3=High).

    If you press <4>, the space next to CONTROL TYPE is a blank.

  - LOT # [8]. Enter the lot number of the control you are using for this file. If the lot number is less than seven digits, enter leading zeros to fill the extra spaces.

- EXP. DATE [7]. Enter the six-digit expiration date of the control using zero for a blank. The slashes appear automatically when the date is stored in memory via <ENTER> or an arrow key.

- BATCH SIZE [6]. Enter <2> for the number of control samples to be included in a batch. All controls are run in duplicate.

- The HOSP ID, DATE, and OPR [2] number are displayed, but not entered here. HOSP ID appears as it has been entered via DATA ENTRY, option 1. DATE corresponds to the date that any entry in a particular file was last changed. OPR indicates the number of the operator who made that change.

- ASSAY VALUE [5]. The assay value of each parameter found on the assay sheet supplied with the control. For the diff parameters, enter values for both percent and number; change mode via SYSTEM CONFIGURATION, as described in Lab Action Limits.

- SAMPLE LIMIT [4]. The control's sample limits for each parameter. Use the cell control's assay sheet as a guide.

- BATCH LIMIT [3]. Use the same limits used for SAMPLE LIMIT above.

- To plot graphs, access the graph options from MAIN MENU by pressing <4> <ENTER>, <10> <ENTER>. Plot all five graph options for each control level. Store the plots in the MEC laboratory files until the end of the stand and then send them to NCHS.

- To clear control files, access the MAIN MENU and press <4> <ENTER>, then <11> <ENTER>. Select the file number and delete old data.

Prime the S-Plus Jr. with one sample of normal whole blood before running control materials. Label each vial of control with the date at the time it is opened. Use the following procedures to run controls.

- From the DT MAIN MENU, press <4> and <ENTER> to access the control data menu.

- Press <1> and <ENTER> to access the control DATA FILE SELECTION display.

- Follow the directions on the D5 screen to select the file for the lot number of the control you are running.

- Press <ENTER>. The SYSTEM READY FOR CONTROL FILE (#) message will

appear.

- Cycle each control and monitor the results as they appear on the display. Run each control in duplicate. Cycle the controls in this order: low, normal and high. An H or L (high or low) appears to the right of any parameter value that is not within the control sample limits. CB LIMIT (IN, OUT) indicates whether the last control batch was within the batch limits.

- The parameter results are automatically stored in the CONTROL FILE.

- The results will be plotted automatically on the Coulter printer-plotter. Save the histograms in the MEC files to be sent to NCHS at the end of the stand. Also, you must record the results of the **second** run of each control by hand on the Coulter IQAP forms (Exhibits 5-4 to 5-6). Follow the instructions below to record these results.

  - Use the proper form, depending on whether you are running low, normal, or high controls.

  - Record the lot number of the control in the boxes provided in the right margin.

  - Record your five digit Laboratory No. in the box provided.

  - Record the Lab No., System Code, and Shift in the boxes provided.

  - Record the date started in the boxes in the right margin.

  - Record the serial number of the Coulter on the line.

  - Check the box to indicate that we calibrate with S-Cal.

  - Each time you run a control, record the date.

  - Record the values from the second control run on the IQAP forms.

  - Each time you open a control with a new lot number, begin a new IQAP form. Keep one copy of the completed IQAP forms in the Quality Control Notebook. Do not send this form to Coulter Electronics unless there are problems with the printer/plotter copies. At the end of the stand, send a copy of these forms to Dollie Kendrick at NCHS. After all of the data on a particular lot have been gathered, send a plotted copy of the data to Coulter Electronics at the following address. This should be done at all levels of controls:

    Coulter Diagnostics
    740 West 83rd Street
    Hialeah, Florida 33014

INTERLABORATORY QUALITY ASSURANCE PROGRAM

DATA ENTRY FORM

4C./4C.[PLUS] CELL CONTROL ABNORMAL LOW

EXPECTED RESULTS														
DAY OF THE MONTH	LINE NO	WBC	RBC	Hgb	Hct	MCV	MCH	MCHC	RDW	PLT	MPV	LYMPH %	LYMPH x 10³	INITIAL
	1													
	2													
	3													
	4													
	5													
	6													
	7													
	8													
	9													
	10													
	11													
	12													
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	14													
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	18													
	19													
	20													
	21													
	22													
	23													
	24													
	25													
	26													
	27													
	28													
	29													
	30													
	31													

LOT NUMBER

LABORATORY NO.

Participant No.

Lab No. | System Code | Shift

DATE STARTED

MONTH DAY YEAR

DATE COMPLETED

MONTH DAY YEAR

Serial No. _____

Name _____

Address _____

City State Zip

CALIBRATION

S-CAL® Kit ☐

Whole Blood ☐

Other (Specify) _____

® Trademarks of Coulter Electronics, Inc.

7590137C R 5-85

PART 1 - ORIGINAL - RETURN TO COULTER
PART 2 - COPY - KEEP FOR YOUR FILES

PAGE ___ OF ___

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INTERLABORATORY QUALITY ASSURANCE PROGRAM

DATA ENTRY FORM

4C./4C.® PLUS

CELL CONTROL
NORMAL

EXPECTED RESULTS															
DAY OF THE MONTH	LINE NO	WBC	RBC	Hgb	Hct	MCV	MCH	MCHC	RDW	PLT	MPV	LYMPH %	LYMPH # 10³	INITIAL
	1													
	2													
	3													
	4													
	5													
	6													
	7													
	8													
	9													
	10													
	11													
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	23													
	24													
	25													
	26													
	27													
	28													
	29													
	30													
	31													

LOT NUMBER

LABORATORY NO.

Participant No.

Lab No. | System Code | Shift

DATE STARTED

MONTH DAY YEAR

DATE COMPLETED

MONTH DAY YEAR

Serial No. _____

Name _____

Address _____

City State Zip

CALIBRATION

S-CAL® RR ☐

Whole Blood ☐

Other (Specify) _____

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PAGE OF

COULTER DIAGNOSTICS

INTERLABORATORY QUALITY ASSURANCE PROGRAM

DATA ENTRY FORM

4C./4C.* PLUS

CELL CONTROL
ABNORMAL HIGH

EXPECTED RESULTS														
DAY OF THE MONTH	LINE NO	WBC	RBC	Hgb	Hct	MCV	MCH	MCHC	RDW	PLT	MPV	LYMPH %	LYMPH x 10³	INITIAL
	1													
	2													
	3													
	4													
	5													
	6													
	7													
	8													
	9													
	10													
	11													
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	24													
	25													
	26													
	27													
	28													
	29													
	30													
	31													

LOT NUMBER

LABORATORY NO

Participant No

Lab No | System Code | Shift

DATE STARTED

MONTH DAY YEAR

DATE COMPLETED

MONTH DAY YEAR

Serial No. _____

Name _____

Address _____

City State Zip

CALIBRATION

S-CAL® RX ☐

Whole Blood ☐

Other (Specify) _____

* Trademarks of Coulter Electronics, Inc.

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PART 1 - ORIGINAL - RETURN TO COULTER
PART 2 - COPY - KEEP FOR YOUR FILES

PAGE ___ OF ___

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5.3.6 Sample Analysis (3.12)

Run each sample approximately 20 minutes after it is collected. Do not wait until the end of the session to run the samples.

IMPORTANT
If it has been more than one hour since a blood sample was cycled through the instrument, you must prime it by cycling one sample of normal whole blood before resuming sample analysis.

- On the Main unit, check that the proper test number is entered, if necessary:
  - Press <DIR>.
  - Press <SEL>.
  - Press <ADV>.
  - If the test number is not correct, enter a number from the keypad and press <ENTER>.
  - If the number is correct, press <ADV>.
- From the SAMPLE ANALYSIS MENU, access the LOAD LIST via <6> <ENTER>. Use this function to record your laboratory's worklist. This display includes the following:

  DATE [1]. This field displays the date the sample was cycled, as set on the Main unit. To edit, move the cursor to the command line DATE field and press the down arrow (< ú >). Use the left and right arrows to reach the desired position.

  LAB NUMBER [2]. There is space available for six digits.
  - The AUTO-NUMBERING option is enabled and the label number, once set, is automatically generated sequentially. Do not edit a lab number while cycling because that can disrupt the numbering process.
  - As storage limits are approached, a warning message beneath the LO/HI/DATE fields indicates the number of remaining locations when space for less then 30 samples remains. When the storage space is full, the system does not accept additional entries.
  - The lab number can be edited from either the LOAD LIST or REVIEW/EDIT.

- After a lab number and ID number have been entered, you can erase these fields using <CLEAR>. This does not delete the line; a blank field is valid and results are assigned to that line. If you want to delete the line, assign it a fictitious lab number and delete as described in Output Options available via LOAD LIST, heading 2.9, Daily: LOAD LIST of the Operations Manual.

ID NUMBER [3]. There are 11 spaces available for the examinee identification number. A decimal point entered as part of the ID number is displayed as a dash. If no ID number is assigned, the display in the ID NUMBER field is blank. This field can be edited.

IMPORTANT
It is your responsibility to cycle samples in the same sequence as they are assigned on the LOAD LIST.

- The ID number can be entered manually via the DT keyboard.
- Verify that the Printer/Plotter is on and ready to print.
- Verify that the instrument is primed as described in heading 3.9, Daily Startup Procedures of the Operations Manual.
- From the MAIN MENU press <1>, SAMPLE ANALYSIS.
- Verify that SELECT FUNCTION appears on the display.
- From the SAMPLE ANALYSIS MENU, press <1> and <ENTER>.
- Gently remix the sample.
- Hold the sample up to the aspirator tip with the tip submerged toward the bottom of the sample container.

IMPORTANT
Do not remove the container from the aspirator tip until the display changes from ASPIRATION to WIPE.

- Press the WHOLE BLOOD button to begin the operating cycle.

IMPORTANT
You must remove the sample container and be clear of the area around the aspirator tip at the time the display indicates BACKWASH.

- Remove the sample container as soon as WIPE TIP displays. Use a clean, lint-free tissue to wipe the excess sample from the aspirator tip.

- Observe the Diluter and the display during the remainder of the operating cycle.

- Check the display at the end of the final count period for a voting matrix. Its presence indicates a voteout of parameter results from one or more of the count periods. Voteouts are indicated by asterisks.

- Monitor the display for any alarms or warnings at the end of the Diluter cycle. Review the results using the hematology reference ranges provided in Exhibit 5-13. If the results are out of the lab action limits, rerun the specimen. If the results are still outside the action limits, report the results to the physician immediately.

- Review the results to make sure the hemoglobin and hematocrit results are compatible. The hematocrit should be approximately three times the hemoglobin.

- Review the results to make sure that the hemoglobin and hematocrit results are acceptable. The hematocrit should be approximately three times the hemoglobin. If the results are not compatible, rerun the specimen.

- When the results are printed, remove them from the Printer.

- If a voting matrix appears in the display, press <RES1> and <RES2> simultaneously to restore the SELECT FUNCTION display. After 3 s, SELECT FUNCTION display automatically.

- Repeat the entire procedure for each sample. If there is not enough sample for a second run, save the data from the first run. Document that the specimen was QNS for a duplicate run.

- Use the chart below to determine whether or not the duplicate values for RBC, WBC, HGB and PLT are within the stated precision limits. If they are, continue. If not, rerun the sample in duplicate. If the results are still out of limits, rerun the 4-C Plus control before rerunning the sample again.

RBC	0.2×10^6
WBC	0.4×10^3
HGB	0.2 grams %
PLT	±10%

- After the results for one SP have been printed, place the printout in the box located outside the laboratory. Note that the MEC physician is to return the printouts to you at the end of the session. Keep the printouts in a folder beside the Coulter until you ship the corresponding specimens to CDC. The printouts are included in that CDC shipment.

- The X_B analysis is enabled. When 20 samples have accumulated, an alarm will sound, signaling that a batch has been completed. Press any key to stop the alarm. Print the current X_B values for the RBC profile and the WBC - X-PLT profile. Store the printouts in the MEC laboratory files. Ship them to NCHS at the end of the stand.

5.3.7 Shut Down

5.3.7.1 Short-Term Shutdown (3.18)

At the end of each session place the OPTIC LAMP switch in the OFF position and turn off the Pneumatic Power Supply.

5.3.7.2 Daily Shutdown Procedure (3.19)

Perform the daily shutdown procedure at least once every 24 hours.

- Press <SHUT DN>.

- At the end of the SHUTDOWN cycle, open the Diluter front door and verify that the WBC and RBC diluent dispensers and the aperture baths are filled with detergent reagent.

- Turn off the Pneumatic Power Supply.

- Turn off the OPTIC LAMP switch.

- Turn off the Printer/Plotter.

- Leave the Main Unit, Channelizing Module, and Data Terminal on.

- Document the performance of daily shutdown procedures in the Scheduled Cleaning Procedures and Operational Checks Log (Exhibit 5-3). Locate the column headed "Daily Shutdown Procedure." Record the date and your Tech ID Number.

5.3.7.3 Emergency Shutdown (3.20)

In the event of an emergency:

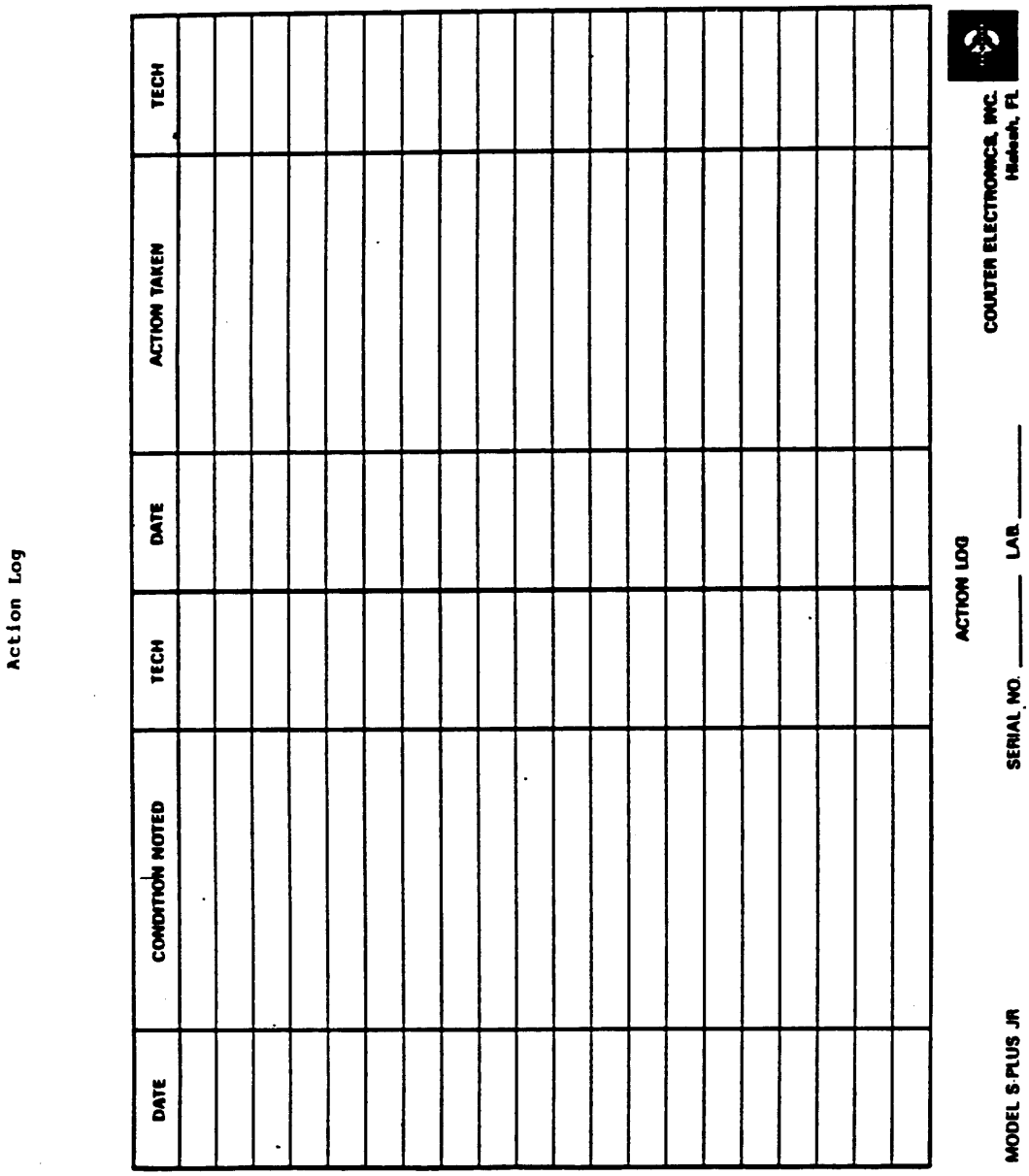
- On the Data Terminal, from the SPECIAL TEST MENU, perform the BATTERY CHECK routine.
- Turn off the Printer/Plotter.
- Turn off the Data Terminal.
- Turn off the Main Unit and Channelizing Module by pressing the POWER button.
- Turn off the Pneumatic Power Supply by pressing its POWER button.
- Unplug the power cords from the wall outlet.
- Perform Daily Shutdown Procedures as soon as practical.
- Document the performance of emergency shutdown procedures in the Coulter Action Log (Exhibit 5-7). Record the following information at the bottom of the page:

  - Serial No: Record the serial number for the Coulter S-Plus Jr.
  - Lab: Record the IQAP Lab Number.

  Record the information listed below in the table:

  - Date: Record the month, day and year that an emergency or unusual incident occurred.
  - Condition: Briefly describe the condition of the Coulter.
  - Tech: Record your four-digit tech ID number.
  - Date: Record the month, day, and year that action was taken to respond to an emergency, investigate an unusual incident or correct a malfunction.
  - Action Taken: Describe, briefly, the action that was taken to respond to an emergency, investigate an unusual incident or correct a malfunction.

Exhibit 5-7. Action Log



Action Log

DATE	CONDITION NOTED	TECH	DATE	ACTION TAKEN	TECH

ACTION LOG

COULTER ELECTRONICS, INC.
Hialeah, FL

MODEL S PLUS JR SERIAL NO. _____ LAB _____

5.3.7.4 Shutdown at the End of the Stand or For Periods of 8 Days or More When the Coulter Will Not Be Used

At the end of each stand or for periods of 8 days or more when the Coulter will not be used, perform the following procedure:

- Place the Isoton, lytic reagent and Isoterge pick-up tubes in a 30% solution of bleach. Perform two startups and two shutdowns to cycle the 30% bleach solution.
- Place the Isoton, lytic reagent and Isoterge pick-up tubes in distilled water and perform two startups and two shutdowns to cycle the distilled water.
- After you have cycled distilled water, remove the pick-up tubes from the distilled water and perform two startups and two shut downs to cycle air through the lines.
- Put all locking levers in up position. Install spacer clips on all pinch valves with levers.
- Carefully place all pick-up tube assemblies in plastic bags and secure them with millipore tape to the Coulter S-Plus Jr. Main Unit.
- Document the performance of the end of stand shutdown procedures in the Scheduled Cleaning Procedures and Operational Checks Log (Exhibit 5-3). Locate the column headed "Daily Shutdown Procedures." Record the month, day, and year. Record your four-digit tech ID number. In the space directly below the date and your tech ID, write "End of Stand."

5.4 Calibration (4)

5.4.1 General

Full calibration procedures should be performed at the beginning of every stand and after replacing any component that involves the dilution characteristics or the primary measurements to maintain your Model S-Plus Jr. within optimum operational tolerances. We will use the S-CAL Kit for calibration. Follow the instructions provided in the kit's package insert.

Perform calibration by following the procedures given in this section:

- Preliminary Procedures;
- Reproducibility Check;
- Carryover Check;
- Electronic Subsystem Check; and
- Calibration with S-CAL Calibrator.

Initial adjustments and the total instrument check are essential for a complete verification of all functions prior to the final, precise calibration.

Your Coulter representative performs the validation procedures at the time your instrument is installed and at the beginning of each stand (see Appendix I, Coulter S-Plus Jr. Instrument Verification Procedure). You are responsible for performing precise calibration with S-Cal calibrator and printing the results. If necessary, your Coulter representative can assist you in performing the final calibration.

Recalibration is necessary **when replacing any component that involves the dilution characteristics** (such as the blood sampling valve) **or the primary measurements** (such as an aperture).

If recalibration appears necessary, but no component affecting calibration has been replaced, do NOT recalibrate the instrument. First check your control sample and then call your Zone Service Center.

Although the Model S-Plus Jr. is relatively insensitive to room temperature changes, the calibration should be performed when the room temperature is within the normal ambient temperature range. If the room temperature varies by more than 10^{o}F, then verification and possible recalibration is necessary.

In the normal process of tracking data for an extended period of time, Coulter or NCHS may make a specific decision to recalibrate a given parameter. Never adjust to a specific value for an individual sample.

If any problems or malfunctions are encountered while performing the procedures in this section, see Section 5 of the Coulter Counter Product Reference Manual. If the corrective procedures fail to eliminate the problem, call your Zone Service Center.

Be sure to document the performance of unscheduled calibration procedures in the Coulter Action Log (Exhibit 5-7). Record the date, the condition of the Coulter and your tech ID number whenever you encounter a situation that requires the unscheduled performance of the calibration procedures. Record the date, the action taken, and your Tech ID whenever you perform the calibration procedures.

Save the following printouts for the MEC files to be sent to NCHS at the end of the stand:

- Background check;
- System check;
- Carryover check;
- Table of Average Factors;
- Histograms; and
- Calibration Batch Table.

5.4.2 Preliminary Procedures

Perform the preliminary procedures to calibrate the Coulter S-Plus Jr. First, clean the blood sampling valve (BSV) and the apertures as described in Section 5 of the Product Reference Manual. Check that you have a sufficient supply of reagents to complete the cleaning procedures. Then perform Daily Startup Procedures as described in Part 2 of Section 3 of the Product Reference Manual. Verify reproducibility and carryover as described below.

5.4.3 Reproducibility Check

Use the STARTUP: REPRODUCIBILITY function to check reproducibility.

- You need 10 samples of one specimen that meets the following requirements:
  - The donor must not be receiving drugs; have normal hematologic parameters; and have normal erythrocyte, thrombocyte, and leukocyte morphology;
  - The specimen must be stored in the proper amount of EDTA anticoagulant; and.
  - The vacuum collection tubes must be filled properly.
- At the DT, access the PRIME mode; prime by cycling two normal whole-blood samples.
- Access the STARTUP: REPRODUCIBILITY mode, delete any previous results, and cycle 10 consecutive samples.
- Review the displayed results. Verify that the average CV (coefficient of variation) does not exceed the following limits for the parameters listed:

WBC	3.0%
RBC	2.0%
Hgb	1.0%
MCV	2.0%
RDW	3.2%
PLT	4.0%
MPV	5.0%
LY #	5.0%
MONO #	10.0%
GRAN #	5.0%

5.4.4 Carryover Check

Use the STARTUP: CARRYOVER, PRIMARY MODE function to check carryover. Follow the instructions on the display and verify that DATA: ACCEPT appears.

5.4.5 Electronic Subsystem Check

Perform the following procedures to verify that the power supply voltages are within their acceptable ranges.

- Press <DIR> to access the Directory.
- Press and release <ADV> until DVM appears.
- Observe the initial voltage displayed and use <ADV> to review the power supply voltages. Verify that the displayed values are within the acceptable ranges given in the table below.

Acceptable power supply voltage ranges

Display	Acceptable Range
HBL	7.00 ± 0.25 Vdc
+5 V supply	5 ± 0.2 Vdc
+15 V supply	15 ± 0.5 Vdc

- Verify that the WBC bath contains clean, bubble-free diluent. If the HGB BLANK reading is not within tolerances, use <DIR> and <ADV> to access the HGB BLANK ADJUST option (refer to heading 3.4, Keypad). Press <SEL> when the option appears on the display.
- Verify that the reading is 7.00±0.25 Vdc. If the reading is out of tolerance, adjust the value by pressing <7>, <0>, <0>, and <ENTER>. Allow 30 s for the adjustment to be made before continuing.
- When SELECT FUNCTION appears on the display, the adjustment has been completed. Reaccess the HGB BLANK ADJUST or DVM option to verify that the reading is 7.00±0.25 Vdc. If it is not, call your Zone Service Center.

5.4.6 Calibration with S-CAL Calibrator

Use S-Cal calibrator to perform the final, precise calibration of the Model S-Plus Jr. After S-CAL calibration, verify calibration as described in the S-CAL Kit package insert.

Calibration is required for WBC, RBC, Hgb, MCV, and PLT. The Coulter representative calibrates MPV (see heading 6.4.7, MPV Calibration with Latex). Hct, MCH, MCHC, RDW, LYMPH #, MONO #, GRAN #, and LYMPH, MONO, and GRAN percents do not require calibration.

Before you begin, familiarize yourself with the procedures on the package insert supplied with your S-CAL Kit. Use the S-CAL Kit, its package insert, and these instructions to calibrate WBC, RBC, Hgb, MCV, and PLT.

When using the DT's calibration program, remember that when entering a value, you must move the cursor past the last digit entered in order to store the value.

1. Select the CALIBRATION MENU option 3, CALIBRATION PARAMETER SELECTION, to select the parameters to be calibrated: WBC, RBC, Hgb, MCV, and PLT.

2. Transfer to the DT the average calibration factors that are now in the main unit's memory as follows:

    a. From the CALIBRATION MENU, select option 1, RESULTS AND HISTOGRAMS.

    b. On the main unit's keypad, press <F>, <1>, <3>, and <ENTER>. XMIT CAL FACTORS displays.

    c. After the DT displays the average CAL factors, press <PLOT> on the DT keyboard. This prints a hard copy of the average CAL factors.

3. From the CALIBRATION MENU, select option 4, OLD CALIBRATION FACTORS. Verify that these factors match the values just printed, if not, enter them at this time. Press <RETURN>.

4. Select the CALIBRATION MENU option 7, REFERENCE TABLE.

    a. If the table displays data from a previous run, go to option 8 and delete it.

    b. Enter the REFERENCE TABLE the assigned values from the package insert supplied with your S-CAL Kit. Remember to move the cursor past the last digit.

5. Select the CALIBRATION MENU option 5, CALIBRATION BATCH TABLE; if the table displays data from a previous run, go to option 6 and delete it.

6. Prepare S-CAL calibrator according to the instructions on the package insert.

7. Select the DT PRIME mode. Cycle two samples of S-CAL calibration to prime the instrument.

8. Select the CALIBRATION MENU option 1, RESULTS AND HISTOGRAMS, and cycle 10 samples of S-CAL calibrator. Between each cycle, mix S-CAL calibrator gently by inversion. Results are accumulated in the CALIBRATION BATCH TABLE. Monitor the display during each cycle.

    a. If any sample is unacceptable (for example, a short sample), use option 2 to delete it. The sample can also be deleted at the end of the 10 runs. Follow the CLEAR directions on the bottom of the CALIBRATION BATCH TABLE.

    b. The backlighted area at the bottom of the histogram display indicates the quantity of samples that have been cycled.

9. Select the CALIBRATION MENU option 5, CALIBRATION BATCH TABLE. Inspect the 10 sets of results for trending and precision. Use the flowchart (Exhibit 5-8) to decide which parameters to calibrate.

IMPORTANT
Do not calibrate MCV if RBC % DIFF is out of range.

10. Use the CALIBRATION MENU option 3, CALIBRATION PARAMETER SELECTION, to eliminate any out-of-range parameters as follows:

    a. Cancel all parameter selections.

    b. Select only parameters with acceptable criteria.

    c. Return to option 5, CALIBRATION BATCH TABLE.

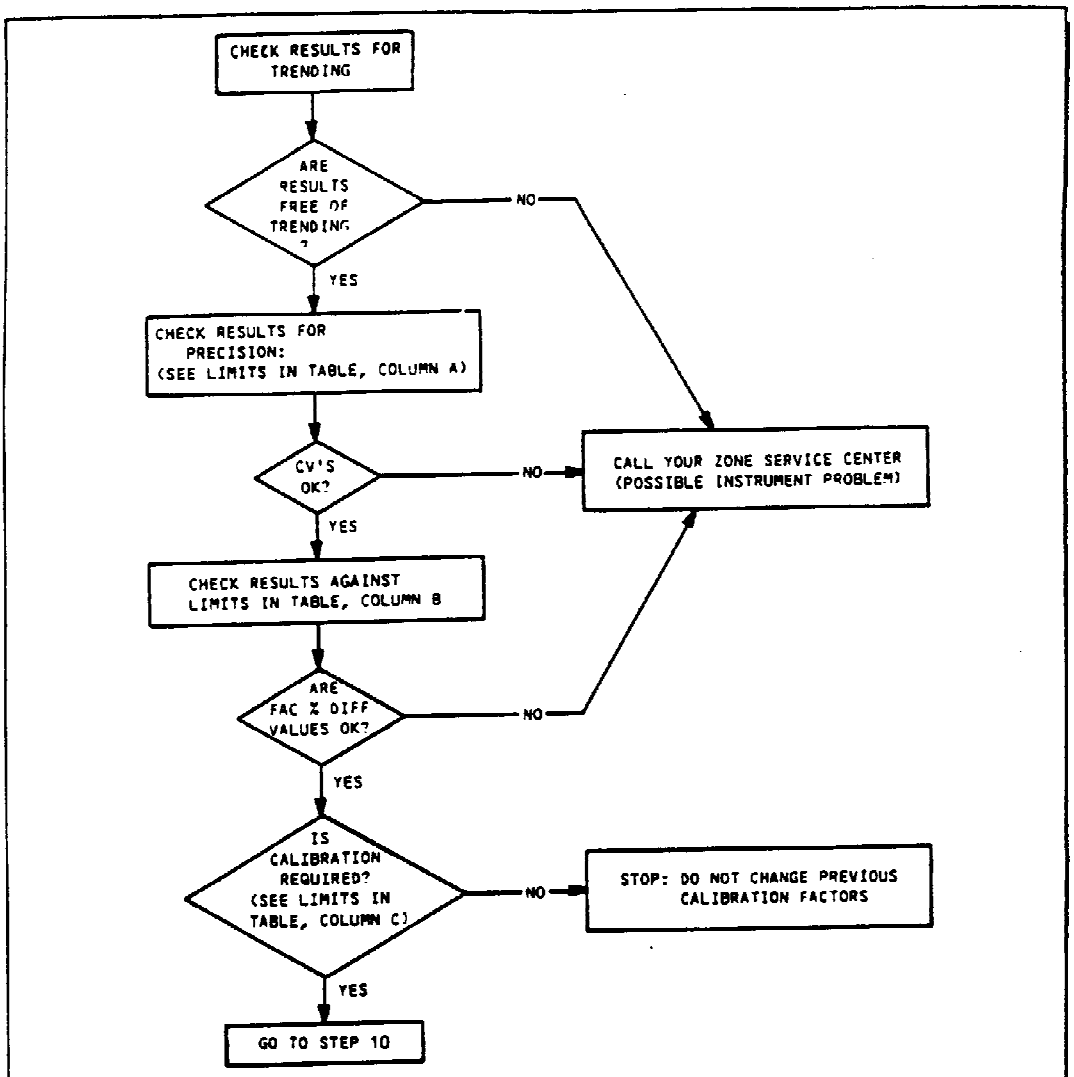
11. If all the percent differences are within limits, plot the display or record the new calibration factors. Transfer the new calibration factors to the Main unit as follows:

    a. On the main unit keypad, press <DIR>.

    b. Press <ADV> until CALIBRATE displays.

    c. Press <SEL> and enter the SUPERVISOR code <8>, <4>, <2>, AND <ENTER>.

Exhibit 5-8. Calibration flow chart



CALIBRATION CRITERIA

PARAMETER	(A) PRECISION (CV%)	(B) ACCEPTABLE FAC % DIFF	(C) CALIBRATE IF FAC % DIFF IS:
WBC	CV ≤ 3.0%	< 5.0%	>1.25%
RBC	CV ≤ 2.0%	< 2.0%	>0.7 %
HGB	CV ≤ 1.0%	< 3.0%	>0.78%
MCV	CV ≤ 2.0%	< 2.5%	>1.18%
PLT	CV ≤ 4.0%	< 9.0%	>2.7 %

d. Use the numeric keypad to enter the new calibration factors. Press <ADV> to advance to the next parameter. When finished, press <ENTER>. Even if no change is necessary, use <ADV> to advance through all parameters; otherwise, the changes are not recorded.

12. Follow the procedure in steps 2 and 3 to transfer the now old calibration factors to the DT for use in the next calibration.

13. To verify calibration:

    a. Repeat steps 5 through 8.

    b. Select the CALIBRATION MENU option 5, CALIBRATION BATCH TABLE. The numbers in the FAC % DIFF row must be:

WBC	$\leq$1.25%
RBC	$\leq$0.7%
HGB	$\leq$0.78%
MCV	$\leq$1.18%
PLT	$\leq$2.7%

If any parameter is not within these limits, call your Zone Service Center.

5.5 Care and Maintenance

5.5.1 General

This section details the cleaning, replacement, and adjustment procedures that are your responsibility.

CAUTION
Do not attempt any procedures that are not included in the Product Reference Manual. You may void our warranty if you make unauthorized repairs. Call your Zone Service Center for service and maintenance beyond the scope of this manual.

5.5.2 Scheduled Cleaning Procedures

Perform the cleaning and bleaching procedures described below, according to the schedule in Exhibit 5-9. Be sure to record your initials and the date the procedure was performed in the Scheduled Cleaning Procedures and Operational Checks Log (Exhibit 5-3).

For optimum performance from your instrument, perform the Daily Startup Procedures after performing any of the following cleaning procedures.

5.5.2.1 Clean Blood Sampling Valve (BSV)

Clean the BSV at the beginning and end of each stand and as necessary. Signs that indicate the BSV needs cleaning include: binding or irregular motion of the BSV, erratic results, imprecision, or failure to recover control values.

CAUTION
Do not attempt to remove any tubing from the BSV. Handle the center section carefully; do not pull on the sample loop. Do not scratch or use abrasive materials on the inside surfaces or passageways.

Follow the instructions below to clean the BSV. The numbers in parenthesis refer to the numbers in Figure 5.1. of the Product Reference Manual.

- If the BSV is stuck, press <F>, <0>, <7>, and <ENTER> to free the valve.
- Open the Pneumatic Power Supply front door and turn off the pneumatics by pressing the POWER button on the Pneumatic Power Supply.
- Open the Diluter front door.
- Unscrew and remove the BSV knob assembly (10).
- Pull out the three sections (4, 7, 8) of the BSV until the rear section (4) clears the mounting post (14).

Exhibit 5-9. Preventive maintenance schedule

Procedure	Weekly	Monthly	Required	Reference Heading (Section 5)
Cleaning: Blood Sample Valve			X	5.2
Bleaching: Apertures			X	5.2
Cleaning: External Surface			X	5.3
Cleaning: Blower Filter		X	X	5.2

- Separate the three sections of the BSV using a sliding, not a pulling, motion.

CAUTION
Never attempt to remove debris by inserting an object in the valve's passageways. Never use bleach on the BSV.

- Clean the inside surfaces of the three sections with ISOTERGE III detergent reagent. Clean the valve's passageways (12) with a stream of detergent reagent from the wash bottle. If debris is lodged in the passageways, use a high air pressure source to dislodge it.

- After cleaning, rinse the inside surfaces and passageways with distilled water.

- Remove the spacer bar (13) and clean the mounting post (14), and guide post (3) with distilled water and dry.

- Before each section of the BSV is returned to the mounting post (14), moisten its inside surfaces with distilled water. Do not use fingertips to spread distilled water on the surfaces.

- Dry the center opening of each section with a lint-free cloth.

- Align the notch (5) in the rear section (4) with the guide post (3). Return the rear section to its original position by pushing it onto the mounting and guide posts.

- Align the key (6) of the center section (7) with the keyway (15) on the mounting post (14). Return the center section to its original position by pushing it onto the mounting post.

- Align the notch (9) in the front section (8) with the guide post (3). Return the front section to its original position by pushing it onto the mounting and guide posts.

- Verify that no tubing is pinched, then screw the knob assembly (10) into the mounting post. Pull on the knob assembly. There should be about a 1/16-in. space between the knob and the front section.

- Turn the Pneumatic Power Supply on.

- Press <DRAIN> then <RINSE>. Verify that the BSV rotates properly and is not leaking.

- Close the Diluter front door.

5.5.2.2 Bleach Apertures

Bleach the apertures at the beginning and end of each stand and as necessary. Bleaching removes the protein buildup at the apertures that restricts proper sample flow. Signs that the apertures require bleaching include: increased voteouts, increased MCV values and decreased cell counts, or failure to recover control values. Before bleaching, check that the apertures are not clogged; if an aperture appears clogged, perform the clogged aperture cleaning procedure (heading 5.5.3.2). (The numbers in parentheses refer to the numbers in Figure 5.2 of the Product Manual.) To bleach the aperture, follow the instructions below.

- Open the Diluter front door.
- Press <DRAIN>.

CAUTION
ISOTON III diluent is not compatible with bleach.

- Put about 30 ml of a fresh solution of one part bleach (5% solution of sodium hypochlorite) and four parts distilled water into a wash bottle; mix.
- Connect a 20-cm (7-in.) piece of tubing to the spout of the wash bottle containing the bleach solution.
- Disconnect the tubing to the inlet port of the check valve (9, 12) for each bath.
- Connect the loose end of the tubing on the wash bottle to the inlet port of the check valve (12) for the RBC bath.
- Put bleach solution into the bath so that the solution is 1/4 in. below the top side ports of the bath.
- Repeat the previous 2 steps for the WBC bath, leaving the wash bottle connected to the inlet port of the check valve (9) for the WBC bath.
- Activate the BLEACH: PRIME function from the keypad by pressing <F>, <0>, <9>, and <ENTER>. Wait 60 s for the function to end.

  It might be necessary to add more bleach solution to the WBC bath to keep the liquid level above the apertures. (The WBC aperture is larger and draws a greater volume of liquid.)

- Disconnect the wash bottle.
- Let the bleach solution remain in the baths for 15 minutes.
- Press <DRAIN>.
- Fill a wash bottle with detergent reagent.
- Connect a 20-cm (7-in.) piece of tubing to the spout of the wash bottle.
- Connect the loose end of the tubing to the inlet port of the check valve (12) for the RBC bath.
- Put detergent reagent into the bath so that it is 1/4 in. below the diluent input port (14) of the bath.
- Repeat the previous 2 steps for the WBC bath (14, diluent input); disconnect the wash bottle.
- Reconnect the tubing to the inlet port of the check valve for each bath.
- Press <DRAIN>.
- Activate the BLEACH: CLEAR function from the keypad by pressing <F>, <0>, <8>, and <ENTER>. Wait 60 s for the function to end.
- Press <DRAIN>.
- Press <RINSE>.
- From the MAIN MENU, select option 6, PRIME.
- Cycle instrument four times.
- Press <SHUT DN>. The color of the liquid in the baths and waste chamber should change to green.
- From the STARTUP MENU press <1>, <ENTER>, and again <1>, <ENTER>.
- Press <START UP> and verify that the keypad displays ACCEPT. If REVIEW displays, press <TEST>, <0>, <1>, and check results. Repeat until results are acceptable.
- Before running a control or patient sample, prime the instrument by cycling one sample of whole blood.
- Close the Diluter front door.

5.5.2.3 Clean Blower Filters

Clean the blower filters at least once every 30 days and at the end of each stand. The foam filter pads are located at the lower right on the rear of the Main unit and on the hinged Channelizing module (rear of Main Unit) on the right side by the Channelizing module button. To clean the filters, do the following:

- Remove the filter holder by prying it outward with a screwdriver;
- Remove the foam filter;
- Wash the filter in tap water and blot it dry with a paper towel; and
- Replace the foam filter and filter holder.

5.5.3 Additional Cleaning Procedures

The following cleaning procedures are not included in the scheduled cleaning procedures. It is your responsibility to decide how often they are to be performed. Document the performance of any unscheduled cleaning procedures in the Coulter Action Log (Exhibit 5-7). You must record the date, condition and your ID whenever you find a problem. You must record the date, the action taken and your ID when you perform the cleaning procedures.

5.5.3.1 External Surfaces

The external surfaces of the Main unit and the Pneumatic Power Supply should be cleaned with warm, soapy water to prevent the buildup of corrosive deposits.

5.5.3.2 Clogged Aperture

If an aperture is clogged, try to dislodge the debris by pressing <CLEAR>. If the aperture remains clogged:

- Activate the burn circuit by pressing <F>, <0>, <1> AND <ENTER>. Repeat. Press <CLEAR> again. If the aperture still remains clogged:
- Bleach the aperture as instructed in heading 7.5.2, Scheduled Cleaning Procedures. If the aperture remains clogged:
- Remove the bath and clean the aperture with a camel hair brush. Remove the bath as instructed in the aperture bath replacement procedure, heading 5.6, of the Product Reference Manual. Using the tip of the camel hair brush supplied with the instrument, gently brush the aperture. Return the bath to its original position. Turn power on, rinse, and prime as instructed in the aperture bath replacement procedure.

5.5.4 Replacement Procedures

Procedures for replacing a variety of components are described in detail in Section 5.4 of the Product Reference Manual. Refer to this section when you need to replace the waste container fuses, check valves, chokes, dispenser pump, pickup tube, tube fittings, tubing, tubing valve, aperture bath, optics lamp or the hemoglobin lamp. In the section which follows we outline the procedures to follow when replacing reagent containers, priming the reagent, and replacing the waste containers.

WARNING
Some operator-replaceable items may have come in contact with residual biological material. Dispose of these in accordance with acceptable laboratory procedures.

The reagent and waste containers are replaceable by the operator. The recommended reagents are listed below:

Reagent	Coulter Part Number
ISOTON III diluent (20 liter)	8546733
ISOTERGE III detergent reagent (10 liter)	8546755
CLENZ detergent reagent (10 liter)	8546931
LYSE S III diff lytic reagent (500 ml)	7546757
LYSE III diff lytic reagent (5 liter)	7546796

5.5.4.1 Replacement of the Reagent Container

Replace the diluent, detergent reagent, and lytic reagent containers as follows:

- Verify that the new reagent does not contain precipitate, turbidity, particulate matter, or unusual color. If any of these is evident, do not use the reagent.
- Verify that the new container has been stored at room temperature and that its contents have not been transferred from the original container.
- Record in your logbook the new container's lot number, expiration date, today's date, and your tech ID number (Exhibit 5-1). Enter this information into the DT under Start Up Lab Reference Values.
- Being careful not to touch the pickup tube with your hands or to contaminate it in any other way, unscrew the pickup tube assembly from the old container and carefully lift the assembly straight up and out.
- Carefully place the pickup tube assembly straight into the new container and screw the pickup tube into position.

IMPORTANT
Keep reagent lines from contact with electrical lines. Such contact could cause elevated background counts.

- Check that the tubing to and from the new container is properly connected. (See Figure 5.4 in the Operating Manual.)

- Place another reagent container adjacent to the container that was just connected. This eliminates the possibility of the reagent being shaken prior to connection, thereby avoiding the introduction of bubbles into the Diluter.

- If a reagent or waste alarm locks up the instrument after five consecutive alarms, turn off the power to the Main unit, then turn on to reset the instrument.

- Prime the instrument for the appropriate reagent as instructed below.

  A. Diluent.

  - Press <START UP>.

  - After the startup sequence has been completed, activate the SWEEP FLOW PRIME function from the keypad by pressing <F>, <0>, <3>, and <ENTER>. Wait for the function to end.

  - Press <DRAIN>.

  - Press <RINSE>.

  B. Detergent Reagent

  It is not necessary to prime with detergent reagent. If the system was in the shutdown cycle when the detergent reagent was replaced, repeat the shutdown sequence. If it was not in the shutdown cycle, priming occurs during the next shutdown.

  C. Lytic Reagent

  To facilitate priming, place the lytic reagent container at the same level as the Diluter.

  - Press <DRAIN> until the baths are empty.

  - Press and release <LYSE> until the instrument is primed with lytic reagent; that is, until the lytic reagent supply line and pump are completely filled with lytic reagent and free of bubbles.

  - Press <DRAIN>; the baths drain.

  - Press <RINSE>.

5.5.4.2 Replacement of the Waste Container

WARNING
The contents of the old waste container and its associated tubing may include residual biological material and must be handled with care. Avoid skin contact and clean up spills immediately. Dispose of the contents of the waste container in accordance with acceptable laboratory procedures.

Replace the waste container as follows:

- Unscrew the pickup tube assembly from the old container.
- Lift the pickup tube assembly straight out of the old container.
- Place the pickup tube assembly straight into new container and screw the pickup tube into position.
- Check that the tubing to and from the new container is connected properly. (See Figure 5.4 in the Operating Manual.)

5.6 Troubleshooting Guide

The troubleshooting guide provided in the Product Reference Manual comprises flowcharts, fault isolation tables, schematic diagrams, and inspection procedures. Use them to diagnose and correct problems that arise as a result of malfunctions in the instrument. Note that you must record the date, condition and your ID on the Action Log (Exhibit 5-7) whenever you find a problem. The date action was taken, the action taken and your ID must be recorded when you take action.

The system comprises electronic, reagent, and mechanical (Pneumatic Power Supply and Diluter) subsystems. A detailed presentation of how to troubleshoot each subsystem is provided in the Troubleshooting Guide in the Product Reference Manual.

Troubleshooting is based on isolating the cause of a problem to a functional subsystem. A functional subsystem consists of those specific components of the reagent, electronic, and mechanical subsystems that are required to perform a distinct instrument function. For example, the lytic-reagent

functional subsystem requires lytic reagent (reagent), pneumatic force, a pinch valve, dispenser pumps (mechanical), and timed, electrical signals (electronic) to deliver 1 ml of lytic reagent to the WBC aperture bath.

The troubleshooting guide can apply to problems that present symptoms that are observed during normal operation of the instrument or indicated by obtaining consistently anomalous results for one or more of the measured parameters.

To troubleshoot instrument problems you must understand the operating principles described in Section 2 of the Product Reference Manual. This understanding includes, but is not limited to, knowledge of the following:

- Principles of measurement;
- Electronic signal flow;
- Components and their functions;
- Proper operation of the instrument; and
- Methods of sample collection, preparation, and storage.

In addition you must familiarize yourself with Part 2 of the Product Reference Manual (pp. 5-29 to 5-83), particularly with Figures 5-16 to 5-22. These figures are flow diagrams which direct you to the specific instructions in the Product Reference Manual.

5.7 Recording the Results of the Coulter S-Plus Jr.

The Coulter S-Plus Jr. data terminal (Coulter DT) is interfaced directly to the MEC automated system (VAX).

Transmit all SP results collected during a session from the Coulter DT to the VAX at the end of the session. When the transmission is complete, review the results from the VAX system to determine the completeness and the accuracy of the transmission. If the results are

inaccurate or incomplete, repeat the transmission procedure. If, after you repeat the procedure, the results are still inaccurate or incomplete, inform your MEC Manager. If the results of the transmission are acceptable, transfer the Coulter results from the VAX system to the Laboratory Database Management System (Oracle). When the Coulter data is in Oracle, access the Hematology Data Entry Screen (Exhibit 5-10) to confirm that duplicate Coulter determinations have been performed for every SP that has given a blood or urine sample. If duplicate determinations were not done, enter a comment to explain the reason. Be sure to use the lower case type when entering comments into the Hematology Data Entry screen.

Refer to the Hematology Section of the Laboratory Automation Manual for detailed instructions on how to transmit Coulter results to the VAX, transfer them into Oracle and how to use the Hematology Data Entry Screen to enter comments about Coulter data.

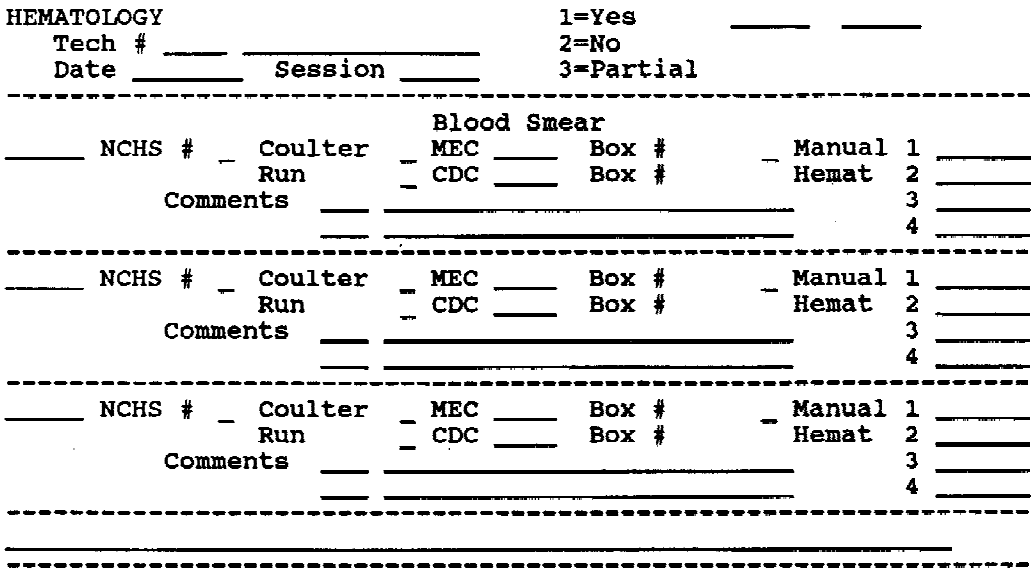
You must also enter the Coulter results on the Hematology Worksheet (Exhibit 5-11). You must account for every SP who has given a blood or urine sample by recording a result or set of results for each procedure or by recording a comment to explain why a procedure was not performed.

To complete the Hematology Worksheet, record the month, day, and year, for the date of collection, using two digits for each value, in the upper right hand corner. Record your four digit tech ID number in box 5.

Then, for each SP, record the following information:

- Sample #: Record the SP's seven-digit ID number in the left most column. Refer to the Daily Appointment Schedule (DAS).
- Age: Record the SP's age in years. Right justify and zero-fill. Refer to the DAS.
- Sex: Check one box to indicate the SP's sex. Refer to the DAS.
- Date of Exam: Record the month, day, and year for the date of the examination.
- Session: Mark one box to indicate whether the examination took place during a morning, afternoon or evening session.

Exhibit 5-10. Hematology data entry screen



SCREEN: Hematology

DESCRIPTION: To record the hematology data, including:

1) Whether the Coulter was run;
2) Whether slides were made for the MEC and CDC, and the box numbers where the slides were put;
3) Whether manual hematocrits were done, and the results of the hematocrits; and
4) Any comments corresponding to any of the hematology data.

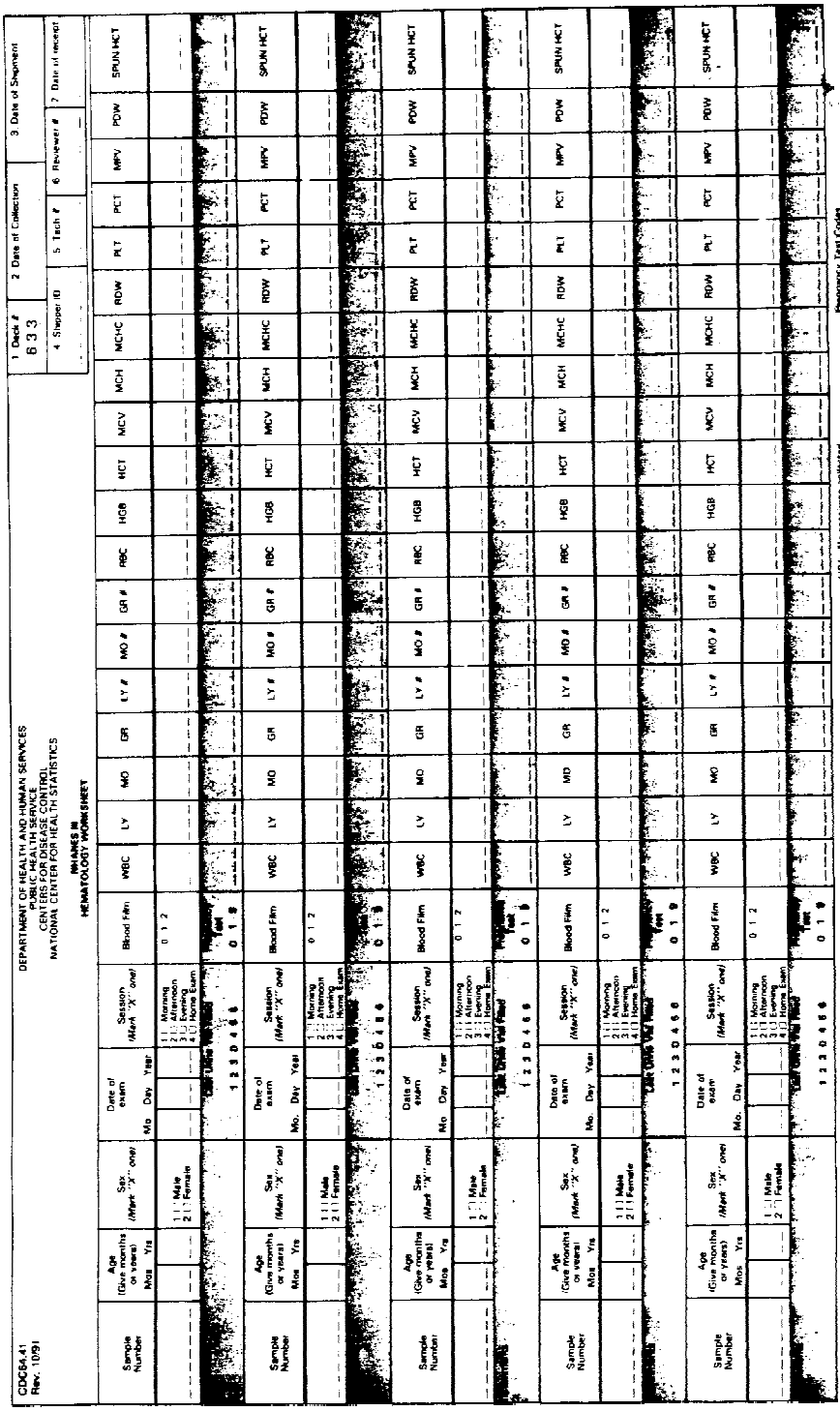
CALLED FROM:

MENU CHOICE: Hematology
ITEM: Hematology Data Entry

WHEN USED: During the session, to record the hematology data.

VALID KEYS: Return, Enter, Select, arrow keys, Prev Screen, Next Screen, Remove, PF4, F9, F12, space bar, number keys

Exhibit 5-11. Hematology worksheet



- Blood film: This is completed when you prepare the slide. Check one box to indicate that you did (yes) or did not (no) prepare two blood slides. If only one blood slide was prepared, check the box for no and make a comment to indicate whether you prepared no slides at all or one slide.

- Coulter parameters: Use the Coulter DT to view the results for each SP. From the Sample Analysis Menu, access the REVIEW/EDIT display via <5> <Enter> <1> <Enter>. This displays the data in sequence by SP ID number. Each sample is run in duplicate.

  Record the first set of results in the first row under each parameter heading. Record the second set of results in the second row.

  Be very careful in recording the results. It is easy to transpose digits when you are recording numeric data. After recording the data, check each entry against the result displayed on the data terminal. Note: Record the results exactly as they are displayed. Thus, use +++ if the result is overrange, --- for a voteout card, ... for an incomplete computation.

  Note: If more than two Coulter runs are performed for an SP, record the results on the rows directly below the results of the first two runs and record the reason for the extra runs in the comments section.

- Spun Hct.: This is completed when you perform the spun hematocrit on a 10 percent systematic sample of lavender top specimens in order to verify the Coulter hematocrit results. Or, if the Coulter is malfunctioning, it is completed when you perform a spun hematocrit on every lavender top specimen. Spun hematocrits are done in duplicate. Record each value to the nearest decimal place. Record the first results in row 1 and the second results in row 2.

- Comments: Record any comments you have regarding the state of the specimens, etc. You must also use this space to indicate why any results are missing or ambiguous in any way. If possible, use the comment codes listed at the bottom of the form. Otherwise write out a brief explanation.

Retain the pink copy of the Hematology Log for the MEC files. Include the white copy with the appropriate blood and urine shipments for CDC. Mail the yellow copy to CDC with a copy of the corresponding CDC blood and urine transmittal under separate cover.

5.8 Reporting Abnormal Results

You are to supply the MEC physician with a copy of each subject's Coulter results as soon as they are available from the Coulter plotter-printer by placing them in an area located just outside the

laboratory. The physician will interpret the SP results and determine whether or not the subject should be referred for treatment.

In addition to the reference ranges, Exhibit 5-12 also displays the hematology lab action limits. If the values for an SP are outside of the lab action limits specific to the SP's age and sex, you are to rerun the specimen in duplicate. SP results that are outside of lab action limits should not be flagged as abnormal values for the physician. The physician will use clinical decision limits not lab action limits to determine whether the values are abnormal.

The MEC physician will return the copies of the SP Coulter results to you at the end of each session. Include them with blood and urine shipments to CDC.

5.9 Verification of the HCT

A manual hematocrit will be run once during each session (twice daily) as a verification of the results obtained with the S-Plus Jr. Manual hematocrits will also be run for all SP's if the S-Plus Jr. is dysfunctional. The hematocrit, sometimes called packed cell volume, is the volume of erythrocytes expressed as a percentage of the volume of the whole blood in a sample. To obtain the hematocrit, a sample of blood is centrifuged at a given speed for a specified length of time for optimal packing of the red blood cells. After centrifugation, the volume of red cells as compared to the total volume of the sample is measured. The venous hematocrit, which is what we will be doing for NHANES III, agrees closely with the hematocrit from a finger stick; both are greater than the total body hematocrit. We will be using samples from the well-mixed EDTA (lavender) tube to make hematocrit determinations for NHANES III.

5.9.1 Equipment and Supplies

Hematocrit determinations will be made at Work Station 3 using samples from the EDTA tubes. You will use the following equipment and supplies to make hematocrit determinations:

- Capillary hematocrit tubes;

Exhibit 5-12. Laboratory Hematology reference ranges and lab action limits

Females

Test	3-14 years old			15-75 years old		
	Reference Range	Lab Action Limits		Reference Range	Lab Action Limits	
WBC ($x10^3uL$)	3.3 - 11.7	< 1.5	> 13.5	3.0 - 11.3	< 1.5	> 13.4
RBC ($x10^6uL$)	3.8 - 5.1	< 3.5	> 5.5	3.7 - 5.2	< 3.3	> 5.6
Hb (g/dL)	10.9 - 14.5	< 10.0	> 15.5	11.3 - 15.7	< 10.5	> 17.0
HCT	32.6 - 41.8	< 30.0	> 44.0	34.0 - 46.0	< 30.9	> 48.9
MCV (fL)	73.5 - 93.1	< 69	> 98	79 - 101	< 75	> 105
MCH (pg)	25.1 - 31.7	< 23.5	> 33.0	26.3 - 34.3	< 24.5	> 35
MCHC (g/dL)	31.6 - 36.5	< 30	> 37	31.2 - 36.0	< 30	> 37
RDW (%)	NA	NA		13.3 $\pm$ 1.5	< 11.5	> 15.5
Plt ($x10^3uL$)	200 - 400	< 50	> 600	200 - 400	< 50	> 600
MPV (fL)	9.5 $\pm$ 3	NA		9.5 $\pm$ 3	NA	
Lymph (%)	NA	NA		20.5 - 51	NA	
Mono (%)	NA	NA		1.5 - 9.5	NA	
Gran (%)	NA	NA		42 - 75	NA	

Exhibit 5-12. Laboratory Hematology reference ranges and lab action limits (continued)

Males

Test	3-14 years old			15-75 years old		
	Reference Range	Lab Action Limits		Reference Range	Lab Action Limits	
WBC ($x10^3uL$)	3.5 - 11.0	< 1.5	> 13	3.3 - 11.3	< 1.5	> 11.5
RBC ($x10^6uL$)	3.75 - 5.2	< 3.4	> 5.5	4.2 - 5.8	< 3.8	> 6.2
Hb (g/dL)	11.1 - 14.7	< 10.0	> 15.7	12.9 - 17.3	< 11.8	> 18.4
HCT	32.5 - 42.5	< 30.0	> 45.0	38.5 - 49.5	< 35.5	> 52.5
MCV (fL)	73 - 91.5	< 68	> 96.5	78.5 - 100.5	< 75	> 105
MCH (pg)	25 - 31.5	< 23.5	> 33.0	27 - 34	< 25	> 36
MCHC (g/dL)	31.5 - 37	< 30.5	> 38	31.8 - 36.5	< 30.5	> 38
RDW (%)	NA	NA		13.3 $\pm$ 1.5	< 11.5	> 15.5
Plt ($x10^3uL$)	200 - 400	< 50	> 600	200 - 400	< 50	> 600
MPV (fL)	9.5 $\pm$ 3	NA		9.5 $\pm$ 3	NA	
Lymph (%)	NA	NA		20.5 - 51	NA	
Mono (%)	NA	NA		1.5 - 9.5	NA	
Gran (%)	NA	NA		42 - 75	NA	

- Clay sealant;
- Microhematocrit centrifuge; and
- Microhematocrit reader.

5.9.2 Calibration and Maintenance of the Microhematocrit Centrifuge

At the beginning of each stand the NCHS Washington engineer will use a tachometer to check the timer and rpm of the hematocrit centrifuge. At the same time, the engineer will check the brushes of this equipment. It is the chief technician's responsibility to verify that the calibration and maintenance procedures are performed by the engineer and that the results are documented in the Laboratory Centrifuge QC Log of the Quality Control Manual (see Exhibit 5-13).

5.9.3 Procedures for Hematocrit Determination

To obtain a systematic sample for Coulter hematocrit verification, select the third lavender top tube sampled for the Coulter during each session and do a manual hematocrit determination. Run each sample in duplicate. Follow the procedures below:

- Mix the contents of the EDTA or tube well by inverting it gently 15 times.
- Fill two capillary tubes by gravity and capillarity.
- Seal one end of each capillary tube with clay sealant.
- Place filled tubes in the numbered radial grooves in the microhematocrit centrifuge head with the sealed end in contact with the peripheral rim of the centrifuge head. **NOTE:** Failure to put the capillary tube in contact with the rim may result in a shattered tube.
- Balance capillary tubes by placing them around the centrifuge head so that they are equally distant from each other.
- Carefully screw the flat centrifuge head cover tightly in place.
- Set the automatic timer for five minutes.

Exhibit 5-13. Laboratory Centrifuge QC Log

NHANES III QUALITY CONTROL:
LABORATORY CENTRIFUGES

MEC _____

STAND # _____

STAND LOCATION _____

YEAR _____

To be done at beginning of Stand by NCHS Biomedical Engineer

Date	Type	RPM	RPM	RPM	RPM	Brushes	Bio Engineer #	Comments	Other Maintenance	Tech ID#
	S#1									
	S#2									
	H									
	Table Top									

Date	H	Determine optimum packing time for whole blood - annually.					
	Spec	3 min	4 min	5 min	6 min	7 min	8 min

- Centrifuge at 10,000 rpm for five minutes.

- Use the microhematocrit reader to determine the hematocrit value.

  - Place each centrifuged capillary tube in the groove of the plastic indicator so that the bottom of the column of red cells coincides with the black line on the plastic indicator.

  - Rotate the bottom plate so that the 100 percent line is directly beneath the red line on the plastic indicator.

  - Using the finger hole, rotate the top plate so that the spiral line intersects the capillary tube at the left edge of the plasma-air interface. Note that the design of the plastic indicator is such that when your eye is in the correct position, the spiral line appears continuous as it passes beneath the plastic indicator. If the spiral line appears broken, readjust your position until the line appears continuous.

  - Rotate both discs together until the spiral line on the top disc intersects the capillary tube at the left edge of the red cell-white cell interface. If there is a pink-tinged layer, read at the point below this layer.

  - Red cell volume in percent is read from the point on the scale of the bottom disc directly beneath the red line of the plastic indicator.

- Enter the results of both runs on the Hematology Data Entry Screen (see Exhibit 5-10). Also enter your tech ID and any comments you have.

- If the results of the two determinations do not match each other within ± 1 or the Coulter Hct results within ± 3, repeat the test, and enter the results of the second two determinations on the Hematology Data Entry Screen.

- Check the chart below for the normal limits of a hematocrit:

Males	47 ± 7
Females	42 ± 5
Children	38 ± 4

- If no Coulter hematocrit was done and if the spun HCT is below 34 or above 55, record the results of the manual HCT on the Hematology Worksheet and immediately give a copy of the results to the physician.

5.9.4 Quality Control for Hematocrit Determination

There are several possible sources of error in hematocrit determination:

- Inadequate centrifugation;
- Failure to thoroughly mix the blood sample;
- Hemolysis of the sample, which gives falsely decreased values;
- High WBC, which may give false high values; and
- An inadequate amount of blood being drawn into the EDTA tube, resulting in an excess of anticoagulant, which may give falsely low values.

To avoid or to control for these errors you must:

- Use a properly calibrated centrifuge;
- Use the automatic timer to set the microhematocrit centrifuge;
- Mix the blood sample thoroughly using the rocker. If the rocker is not operating, completely invert the EDTA (lavender) tube 8 to 10 times before preparing the capillary tube;
- Note any hemolysis of the sample on the Hematology Data Entry Screen or Hematology Log in the space labelled "comments"; and
- Measure from the top of the red cell column and below the buffy coat layer.

5.9.5 Recording the Results of Hematocrit Determination

You use the MEC automated control system and access the Hematology Data Entry Screen (Exhibit 5-10) to enter the results of hematocrit determination. Refer to the Hematology Section of the Laboratory Automation Manual for specific instructions on how to enter the results of hematocrit determinations.

You must also record the results of duplicate determinations on the Hematology Worksheet in the column labeled "Spun HCT" (see Exhibit 5-11). Record each entry to one decimal point. Also record any comments you may have in the comments section of the log.

5.10 Differential Blood Smears

Duplicate blood smears are prepared from the EDTA (lavender top tube) whole blood sample for SPs in each age group. The slides are stored in slide boxes and sent to CDC to be used as a back-up for the automated differential that is determined on the Coulter S-Plus Jr. from the same whole blood samples. Slides are not prepared if automated differentials are not determined because the Coulter is down.

5.10.1 Blood Smear Preparation Procedures

Before you perform the Coulter S-Plus Jr. assays on the EDTA samples, use the following instructions to prepare a differential blood smear:

- Use two 1 x 3 inch glass slides;
- Label one slide with the NCHS number as it appears on the EDTA blood tube;
- Place a drop of blood about 2 to 3 mm in diameter about 1 inch from the end of the labeled, clean, dry slide;
- Use the second glass slide as a "pusher." Place this slide at an angle of 30^{o} to 40^{o} to the specimen slide and then draw back the pusher slide to make contact with the blood;
- Allow the blood to spread toward the sides of the pusher slide and then push it smoothly and lightly toward the opposite end of the specimen slide, drawing the specimen behind it in a thin film;

  A satisfactory smear is narrower than the slide. It is smooth, with no ridges, waves, holes or finger-like projections at the end. When held to the light it has a feathery edge;
- Repeat the above procedure to prepare a duplicate slide; and
- Allow the smears to air dry.

5.10.2 Recording Results of Blood Smear Preparation

Access the Hematology Data Entry Screen (Exhibit 5-10) to enter the results of the blood smear preparation into the automated system. Refer to the Hematology section of the Laboratory Automation Manual for specific instructions.

You must also record the results of the blood smear preparation on the Hematology Worksheet (Exhibit 5-11) in column labeled "Blood Film". Circle the number "1" box next to "Yes" if you prepared both blood slides. Circle the number "2" box next to "No" if you did not prepare two blood slides and use the "Comments" area to indicate whether one slide or no slides was done and to explain why two slides were not prepared.

5.10.3 Storing Blood Smears

Blood smears are stored in numbered slide boxes in numerical ascending ID order by session. One slide is stored in a box which is sent to CDC as soon as it is full. The duplicate slide is stored in second slide box which is kept on the MEC until the end of the stand and then sent to CDC as a backup in the event that the first slide is lost or broken.

Before you store the slides in the slide boxes, you must use the automated system to assign a bar-coded label to each slide box. Refer to the Hematology section of the Laboratory Automation Manual for specific instructions on assigning numbers to slide boxes. The number which the computer assigns to a slide box corresponds to one of the barcoded storage box and shipper labels which are given to the laboratory at the beginning of each stand. Label each slide box with the appropriate designated barcoded label.

You must enter the results of the blood smear preparation into the automated system to assign a blood smear to a numbered slide box. After you have entered the results of the blood smear preparation, place each blood smear in the appropriate numbered slide box.

6. URINE SPECIMEN PROCESSING

6.1 Introduction

The purposes of urine collection and processing are to: (1) perform a pregnancy test for females aged 20 to 59 years, and (2) allocate urine to processing/storage tubes for transport to contract laboratories where samples will be analyzed for urinary cadmium, creatinine/ microalbumin, urinary drugs (for SPs 18 and over), urinary iodine, urinary arsenic and phenols.

A urine specimen will be collected from all SPs 6 years of age or older. At least 25 ml will be needed for SPs aged 6-17, while 40 ml will be needed from every SP age 18 and over. (For women aged 20-59, an additional 5 ml is needed for a pregnancy test.) An additional 40 ml will be needed from the volunteers aged 20-59 who participate in the volatile toxicants study. To collect the urine specimen, the coordinator will ask each SP aged 6 and over to void at the same time that the SP changes clothes or within 45 minutes after arrival at the MEC. This initial urine specimen will be collected and transported to the laboratory by the coordinator as soon as it is available. If the urine specimen is less than is needed for an SP, you must inform the coordinator of this by writing the SP's ID on the Second Specimen Notification Form (Exhibit 6-1). This will alert the coordinator to ask the SP to void at the same time the SP changes back into her/his street clothes. This second urine specimen will be collected and transported to the laboratory by the coordinator.

The following instructions should be explained by the coordinator to the subject prior to urine collection:

- Wash hands with soap and water;
- It is important that the inside of the cup and cap not be touched or come into contact with any parts of the body or clothing or external surfaces; and
- Exposure to air should be minimized.

Exhibit 6-1. Second specimen notification

Date ____ /____ /____
Session ____
Tech No. |__|__|__|__|

SP's for whom we need a second urine specimen

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Date ____ /____ /____
Session ____
Tech No. |__|__|__|__|

SP's for whom we need a second urine specimen

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

6.2 Equipment and Supplies

The following equipment and supplies will be used in collecting and processing urine specimens:

- 4 1/2 oz. plastic cups with lids (urine specimen cups);
- Transfer pipettes;
- Labels;
- 2.0 ml Nalgene vial;
- 4.5 ml vial;
- 15 ml polystyrene conical bottom centrifuge tubes (15 ml Falcon tubes);
- 60 ml Wheaton vials, stoppers and seals;
- Crimper;
- Second Specimen Notification Forms; and
- Pregnancy Test Results Cards.

6.3 Specimen Allocation

The allocation of urine specimens for NHANES III will be done for:

- Pregnancy test;
- Cadmium;
- Creatinine/Microalbumin;
- Urine drug test (anonymous);
- Urinary iodine;
- Urinary arsenic; and
- VOC-Phenols.

The urine processing protocol is summarized in Exhibit 6-2. The procedures for allocating the urine sample for each of these tests are described below:

- For women aged 20-59, aliquot 5 ml of the specimen to perform the pregnancy test (see Chapter 7).

- Aliquot 10 ml of the specimen for the cadmium assay into 15 ml vial, U-1.

- Pour 2.5 ml for creatinine/microalbumin into a 4.5 ml vial, U-2. Do not pipet the urine. Do not overfill this vial. The specimen will expand upon freezing and, if the vial is too full, force the cap off or crack the tube.

- Aliquot 10 ml for urinary iodine into a 15 ml vial, U-3.

- For all SPs aged 18 or over, pour 15 ml of urine into a 15 ml Falcon tube, U-D. **Do not label this tube with an SP ID #.** The tube will be labelled with a Z label when the results of the urine processing are entered in the automation system (see Section 6.4). Refer to Appendix G for instructions on assigning Z numbers.

- Check with the phlebotomist; if SP is not in the volatile toxicants sample, discard the remainder of the initial urine specimen.

- If SP is in the volatile toxicants sample, process the remaining urine for vials U-4, U-5 and U-6 as described below:

  - Aliquot 10 ml of the specimen Urinary Arsenic into a 15 ml vial, U-4.

  - Pour 30 ml of urine for Urine Phenols into a 60 ml Wheaton vial, U-5, as follows: The Wheaton vials, stoppers, and seals are packed four to a ziplock bag to prevent contamination. Remove the vials from the bag one at a time as they are needed and reseal the bag. Label the Wheaton vial with an SP ID number label and a U-5 label. Pour off 30 ml of urine into the labeled vial. Do not pipet the urine. Insert a teflon coated gray stopper snugly and evenly into the vial. Place the aluminum seal over the stopper so that it lies flat. Attach the crimper snugly over the seal and squeeze the handle until a secure seal is achieved. Test the seal by determining that it cannot be easily turned by hand.

  - Aliquot 1-2 ml of urine for Creatinine into a 2 ml Nalgene vial, Vial U-6.

  - Write the **time** you fill vials U-4, U-5, and U-6 on the vials.

  - Record the results of urine specimen allocation (see Section 6.5). Be sure to indicate if the volatile toxicant vials came from a second urine specimen (see Section 6.4) instead of the initial specimen.

Exhibit 6-2. NHANES III urine processing protocol

Tube No.	Assay Group	Age Size	Sample Type	Vial	Laboratory
U-1	Cadmium	C-E	10.0	15 ml	CDC/EHLS
U-2	Creat/ Microalb	C-E	2.5	4.5 ml	U of Minn
U-3	Urinary Iodine	C-E	10.0	15 ml Falcon	U of Mass
U-D	Urine Drug Test	D-E*	15.0	15 ml Falcon	~~Columbia~~ Compuchem Lab
U-4	Urinary Arsenic	E**	10.0	15 ml Falcon	CDC
U-5	Urine Phenols	E**	30.0	60 ml Wheaton	CDC
U-6	Creatinine	E**	1.0	2 ml Nalgene	CDC

*Done on all SPs 18+.

**Done on 45 volunteers each stand ages 20 to 59.

- If you don't know whether or not the SP is in the Volatile Toxicants sample, i.e., the blood draw has not been done yet, refrigerate the remainder of urine until you know. Then process the urine accordingly.

6.4 Requesting Second Urine Specimens

If there is not enough urine remaining in the initial urine specimen to fill all of the urine tubes, fill as many vials as possible and then complete a Second Specimen Notification Form to alert the MEC Coordinator to request a second specimen from the SP. To complete this form:

- Record the date in the upper right hand corner;
- Record the session code number beneath the date, i.e.,
  "01" for morning,
  "02" for afternoon,
  "03" for evening;
- Record your ID number beneath the session code; and
- Record the SP's ID number on the first available blank line.

Note: You should ship any partially filled urine tubes, except U-D, to the contract laboratories. Tube U-D must contain at least 15 ml before it can be shipped to Columbia.

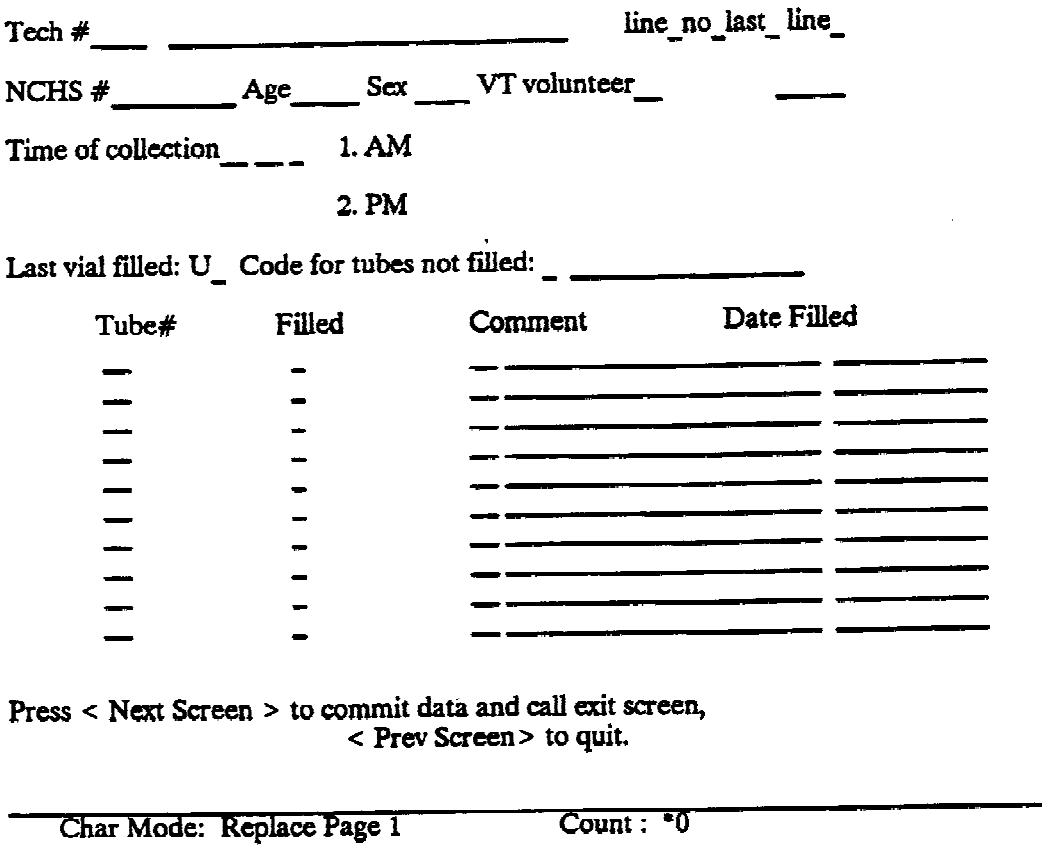
6.5 Recording the Results of Specimen Allocation

Use the Urine Processing Data Entry Screen and the Hematology Worksheet to enter the results of urine specimen allocation (Exhibit 6-3). See Chapter 6, Urinalysis, of the Laboratory Automation Manual for specific procedures to use the Urine Processing Data Entry Screen.

For each person aged 6 and above, complete the Hematology Worksheet as follows:

- Record the date in box number 2 and your tech ID number in box number 5 in the upper right hand corner.
- Then, for each SP, record the sample ID number, age, sex and date of exam from the Daily Appointment Schedule.

Exhibit 6-3. Urine processing data entry screen



- Circle the number of the last urine vial filled. If the specimen was not allocated according to protocol, you must enter the amount aliquoted in ml and comments explaining the reason for departing from the protocol. Comment codes are provided below for your convenience.

  U01 = Unable to collect
  U02 = QNS
  U03 = Old specimen
  U99 = Other (SPECIFY) (You must specify a reason if you use code U99.)

  Please note: If you receive a urine specimen and no blood specimen for an SP, record "99 Urine Only" in the comments section of the Hematology Worksheet and Hematology Data Entry Screen. Be sure to enter all comments on the Hematology Data Entry Screen in lower case letters only.

You must then record the appropriate exit code for the urine collection in the automated system. The list of exit codes for the urine collection is given in Exhibit 6-4. Select the most appropriate result for the procedure.

If a partial urine sample is obtained and a second sample is collected, change the results of urine specimen allocation in the automated system and on the Hematology worksheet.

6.6 Specimen Storage

After you fill the vials and enter the results of the urine specimen allocation, you must prepare to store the vials. Place the vials in the appropriate racks which have been labeled with the contract laboratory destination. Freeze all the specimens, except U-D vials which should be refrigerated, until shipment.

At the end of the session check your work by using the "View Urine by Destination" screen. Then transfer the vials to the appropriate storage bags. Vials are stored in bags according to the site to which they will be shipped. Store the vials as indicated in Exhibit 6-5.

Exhibit 6-4. Urine collection exit codes

Result Codes	Category	Instructions
110	Urine Sample Obtained, Full Cup	Adequate amount of urine specimen obtained, (not including Volatile Toxicants).
111	Partial Urine Sample Obtained	Adequate amount of urine specimen not obtained.
113	Refused/Uncooperative	SP initiated non-response. SP refused to give urine specimen for any reason and no specimen collected (e.g., SP or a family member sick, SP leaves, SP comes late, etc.).
114	Out of Time	No time to collect specimen (should never happen).
115	Physically Unable to Cooperate	SP unable to give urine due to physical handicap.
116	SP Unable to Understand Instruction	SP unable to understand instructions due to language, cognitive impairment or other communication problems.
117	No Container	Out of urine collection kit.
118	Other reasons	Limit use of this code only to reasons that cannot be coded with above categories (e.g., SP sent home or excluded by the physician or inadequate staff to collect specimen, etc.). Explain in comments.
210	Done at Prior Session	SP has been rescheduled and urine specimen was collected at the previous visit.

Exhibit 6-5. Storage protocol for urine

Recipient	Vials	Destination Codes	Storage Arrangements
CDC-EHLS	U-1	U	Place vials in a rack labeled "CDC U-1". Freeze. At the end of the session, transfer the frozen vials to matching SP storage bag with CDC miscellaneous blood vials. Ship frozen to CDC.
University of Minnesota	U-2	W	Place vials in a rack labeled "U-2". Freeze. At the end of the session, transfer the frozen vials to a plastic storage bag labeled with the date, session number and destination. Fill a new bag for each session. Ship frozen to the University of Minnesota.
University of Massachusetts	U-3	V	Place vials in a rack labeled "U. Mass. U-3". Freeze. At the end of the session, transfer the frozen vials to a plastic storage bag labeled with the date, session number, and destination. Fill a new bag for each session. Ship frozen to U. Mass.
Columbia	U-D	Y	Place vials in a rack labelled "Columbia U-D." Refrigerate. At the end of the session, transfer the vials to a plastic storage bag labelled with the destination. Do not label with time and date of session. Fill a new bag for each session. Ship on frozen synthetic ice to EHRT.
CDC-EHLS	U-4, U-5, U-6	E	Place vials in a rack labeled "CDC U-4, U-5, U-6". Freeze. At the end of the session, transfer the frozen vials to a plastic storage bag labeled with the date, session number and destination. Fill a new bag for each session. Ship frozen to CDC.

The "View Urine by Destination" screen will display a list of urines processed during the session by destination. For example, to check your work for all U-1s processed during the session, follow the steps below.

- Enter destination "U" for CDC U-1 urines.
- Type <2>, <Enter>, <1>, <Enter> to view filled urine tubes that have not been shipped.
- The urines will be listed in ascending SP ID order by date and session with the most recent session and the lowest ID numbers at the top of the screen.
- Make sure that the ID numbers of the urines in the rack match exactly the ID numbers for the urines listed on the screen.

6.7 Responding To SP's Concern About Urine Drug Testing

When questions concerning the urine drug test are raised by the SPs, it is important that you are prepared to answer them. Therefore, if you are asked questions about NHANES III and drug testing, we would like you to do the following:

- If the SP has not already read the SP Brochure, have him or her read the question and answer on page six of the brochure that deals with drug testing:

  Q - Will I receive the results of my drug use test?

  A - No. The test for NHANES III is being done to tell us how many people in the United States are currently using marijuana, cocaine, opiates, amphetamines, or phencyclidine for medical or other reasons. To protect your privacy, no information to identify you will be attached to the urine specimens tested for drug use. Therefore, your results will be anonymous.

- If further information or reassurance is needed, read and hand to the respondent the Drug Testing Information Sheet (Exhibit 6-6). This card will be encased in a plastic cover and is not to be left with the respondent but is provided for the respondent to read while he/she is in your room.
- If the respondent has further questions/concerns about the drug testing, provide him or her with your Stand Coordinator's office phone number. If the SP has further questions which cannot be answered by the Stand Coordinator, provide him or her with the following NCHS name and number: Dr. Marsha

Exhibit 6-6. Drug Testing Laboratory Sheet

DRUG TESTING IN NHANES III

NHANES is a survey that looks at the health of the United States population as a whole. The survey studies many important health problems such as diabetes, allergies, arthritis, high blood pressure and high blood cholesterol. Since drug use has a major impact on health, scientists need to know how widespread the drug use is. Therefore, all survey participants who are 18 years old or older will receive this test.

Your drug test sample will be put into a test tube that does not have your name or any information that could identify you attached to it. This means that we cannot tell you or anyone else the results of your test.

This study is not interested in any one person's test results but rather in drug usage in the total population. This means that the results of your tests will be combined with the results of thousands of others and only a total result will be reported.

Davenport, National Center for Health Statistics, 301-436-8267 (SPs may call collect).

- As you do with other potentially sensitive issues, do not attempt to answer questions based on your own knowledge as it may lead to unnecessary concerns on the respondent's part and impede the interview.

- If the respondent has concerns about someone obtaining the results of his or her test, point out that the testing is anonymous and we will not be able to tell anyone, even the respondent, about the results.

- If the respondent insists that he/she will participate in the MEC exam except for the drug testing, accept this and note "No Drug Test" on the top left of the Control Record. Then inform the coordinator and the urine processor.

- Anytime the drug test is brought up we would like you to record it on the NHANES III Question Log Sheet (Exhibit 6-7). Please document your conversation with the SP thoroughly. The completed NHANES III Question log sheet will be sent to the Director, MEC Operations at Westat at the end of the stand.

Exhibit 6-7. NHANES III Question Log Sheet

NHANES III

QUESTION LOG SHEET

Date _____ **Tech ID#** _____

SP Age _____ **SP Sex** _____ **SP Race** _____

What question was asked?

What was your response?

Describe anything you said that persuaded the SP to accept HIV/Urine Drug testing:

Comments:

Please forward completed form to
Director, MEC Operations, at Westat
at end of stand.

7/10/91

7. PREGNANCY TEST

7.1 Introduction

A pregnancy test must be done for each woman aged 20 to 59. This test must be done prior to scheduling the woman for x-rays and bone density testing to ensure that only women who test negative on this pregnancy test receive the x-ray and bone density examination components.

7.2 Equipment and Supplies

7.2.1 General Description

We will be using the TANDEM ICON II hCG Immune Concentration Assay for the pregnancy test. The supplies for this are listed below:

- Urine samples in vial;
- Test cylinder;
- Antibody conjugate (Bottle A);
- Substrate Reagent (Bottle B);
- Wash Concentrate (Bottle C);
- Transfer pipettes;
- Distilled water; and
- Negative and positive urine controls.

ICON II hCG Test Cylinders, liquid reagents and Wash Concentrate should be refrigerated at 2-8^{o}C (36-46^{o}F) until the expiration date of the kit. Remove the reagents from the refrigerator at the beginning of each session to allow them to come to room temperature. Return them to the refrigerator at the end of each session.

Substrate Reagent (Bottle B) is light sensitive and should be stored in the dark. The Substrate Reagent should be colorless. **If it has turned blue, it must be replaced**.

ICON II hCG is intended for *in vitro* diagnostic use. Do **not** mix components from different kit lots.

The Substrate Reagent and the Wash Concentrate contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents, always flush with running water for five minutes to prevent azide build-up.

> NOTE: Any urine specimen is appropriate for hCG testing, but the first morning urine is optimal because it generally contains the highest concentration of hCG.

Urine specimens are collected in clean, plastic containers. The specimens must be assayed immediately.

7.2.2 Principles of Operation

The ICON II hCG Assay for confirming pregnancy is based on detecting elevated levels of human chorionic gonadotropin (hCG), a hormone which the placenta begins to produce in increasing amounts about ten days after fertilization1[2]. It incorporates monoclonal antibody technology, the ICON Immuno-Concentrator testing cartridge, and an internal Positive Reference to allow for rapid, visually interpreted, semi-quantitative hCG test results.

The ICON II hCG Assay detects hCG in urine by using two different monoclonal antibodies which react with two different regions of an hCG molecule. The first of these antibodies is contained in the Test Zone of the ICON II membrane and serves to capture and immobilize any hCG molecules present. The second antibody to hCG is chemically linked to the enzyme alkaline phosphatase and binds

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1 Patents pending.

to another site on the immobilized hCG molecules. The hCG molecules are "sandwiched" at the Test Zone between the membrane-linked antibodies. Alkaline phosphatase linked antibodies which have *not* bound to immobilized hCG molecules are removed, so that the only enzyme remaining at the Test Zone is that which was incorporated in the hCG sandwiches. To detect this remaining enzyme, a color developer is added which becomes blue in the presence of the enzyme. The intensity of blue color is directly proportional to the amount of enzyme that was specifically bound to the membrane, which in turn is proportional to the amount of hCG that was present in the specimen.

Each TANDEM ICON II hCG Assay incorporates a unique feature, the Positive Reference Zone. A test result is interpreted by comparing the color development found at the Test Zone with that observed at the internal Positive Reference Zone. The color development produced at the Positive Reference Zone has been adjusted to a level such that specimens containing 50 mIU hCG/ml yield an equivalent or darker color. Assay variables that cause a darker or lighter color to develop at the Test Zone also produce the same effect at the Positive Reference Zone. Additionally, the Positive Reference Zone serves as an internal assay control since it turns blue only if the reagents were added correctly and were performing properly.

With the Immuno-Concentrator and the internal Positive Reference, the ICON II hCG Assay can be performed quickly and simply without special instrumentation. A matched pair of monoclonal antibodies which, in combination, are specific for the hCG ensures a high degree of sensitivity without cross-reactivity to homologous hormones.

7.3 Procedures for the Test

Follow the procedures below to conduct the urine pregnancy test.

- Pour off 5 ml of the initial urine specimen into a 15 ml Falcon tube.
- Label the Falcon tube with an SP ID label.
- Inspect the **initial** urine specimen:
    - If the specimen is turbid, centrifuge it prior to testing at 2500 RPM for 5 minutes.

- If the specimen contains particulate matter, such as salts which have settled out of solution, do not shake or disturb it. Pipette samples from the clear supernatant.

- Label the test cylinder with an SP ID.

- Use a new transfer pipette with a new, unused, disposable tip to draw up about 2 ml of the initial urine specimen.

- Slowly dispense **5 drops** of urine sample onto the center of the ICON II hCG membrane, allowing each drop to absorb into the membrane before adding the next.

- Dispense **3 drops** from Bottle A (Antibody Conjugate) in rapid succession onto the ICON II membrane so that reagent covers the entire surface of the membrane. (Do not allow the tip of Bottle A to touch the membrane surface.)

- Set timer for one minute.

- After one minute dispense Wash Solution from Bottle C by directing the flow toward the inner well of the test cylinder. (Do **not** dispense Wash Solution directly onto the filter membrane.)

- Fill the cylinder up to the edged fill line.

- Wait for **complete** drainage of Wash Solution before adding the next reagent (approximately 30 seconds).

- Dispense **3 drops** from Bottle B (Substitute Reagent) in rapid succession onto the ICON II membrane so that reagent covers the entire surface of the membrane. (Do not allow the tip of Bottle B to touch the membrane surface.)

- **Wait 2 minutes**.

- Stop the color development by filling the cylinder up to the fill line with Wash Solution (Bottle C).

- With the indicator mark, P, facing you, observe the color development at the Test Zone and the Positive Reference Zone.

- Interpret the results as follows:

  - **Negative Result** - A specimen that does not produce a circular blue spot in the Test Zone is negative for the presence of hCG.

  - **Positive Result** - A specimen that produces a circular blue spot of any intensity in the Test Zone is positive for the presence of hCG and should be reported as "positive."

  - **Invalid Test** - For the test to be valid, the Positive Reference Zone must appear

as a discernible blue spot within two minutes after the addition of the Substrate. The absence of color development at the Positive Reference Zone indicates that the reagents were added incorrectly or were not performing properly. If this occurs, the specimen should be retested using a new cylinder.

NOTE: ICON II hCG is designed to provide for internal quality control of the wash step. If light blue color develops over the entire membrane, inadequate washing has occurred. If this blue background interferes with the interpretation of results, the specimen should be retested using a new cylinder. **Random blue specks on the membrane should not be interpreted as a positive result**.

- Complete a Pregnancy Test Card (Exhibit 7-1) for all SPs who receive a pregnancy test. Give the completed card to the MEC coordinator. Notify the coordinator of all invalid and positive pregnancy test results.

7.4 Quality Control

Good laboratory practices include the use of control specimens to ensure proper kit performance. Test negative and positive urine controls containing hCG at concentrations of 0 and 50 mIU/ml daily, just prior to performing the first examinee pregnancy test of the day.

Record the following information on the ICON QC Log (Exhibit 7-2):

MEC: Record the number of the MEC.

Stand #: Record the number of the current stand.

Stand Location: Record the location of the current stand.

Year: Record the year of the NHANES III survey.

Date: Record the month and day you performed the quality control test.

Tech ID: Record your 4-digit tech ID.

Exhibit 7-1. Pregnancy test card

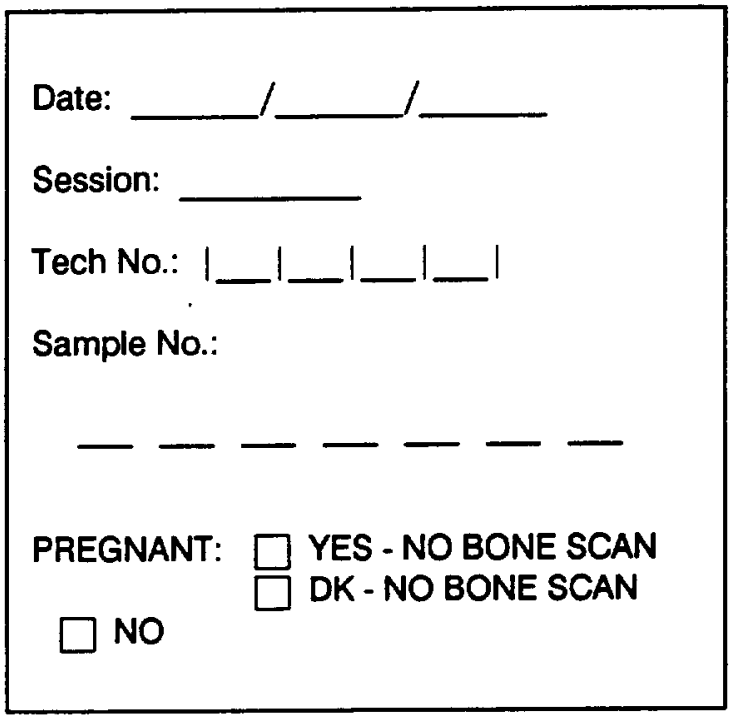

Exhibit 7-2. ICON QC log

NHANES III ICON QC LOG

MEC ____________________

Stand # ____________________

Stand Location ____________________

Year ____________________

Date	Tech ID #	Negative Control O mIU			Positive Control 50 MIU			Eligible SPs? (If no, check.)
		Neg	Positive	Invalid	Neg	Positive	Invalid	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
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		0	1	9	0	1	9	
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		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	
		0	1	9	0	1	9	

Negative Control **Positive Control:**	For each type of control, circle one number to indicate if the result of testing each control is negative (0), positive (1) or invalid (9).
Eligible SPs?:	Check this box if the controls were not run because there were no female SPs aged 20-59 examined that day.

Repeat the control if you do not get the expected result. If you fail to get the expected result, use a different lot of control if available. If you still fail to get the expected result, discard the entire lot of pregnancy test kits and begin testing a different lot of kits.

Document the use of the pregnancy test kit and the urine control kit on a Supply Use Control Log (Exhibit 3-6). Keep a separate log for each type of kit. Record the date a new kit is opened, the lot number of the kit, the expiration date and your tech ID.

7.5 Recording the Results

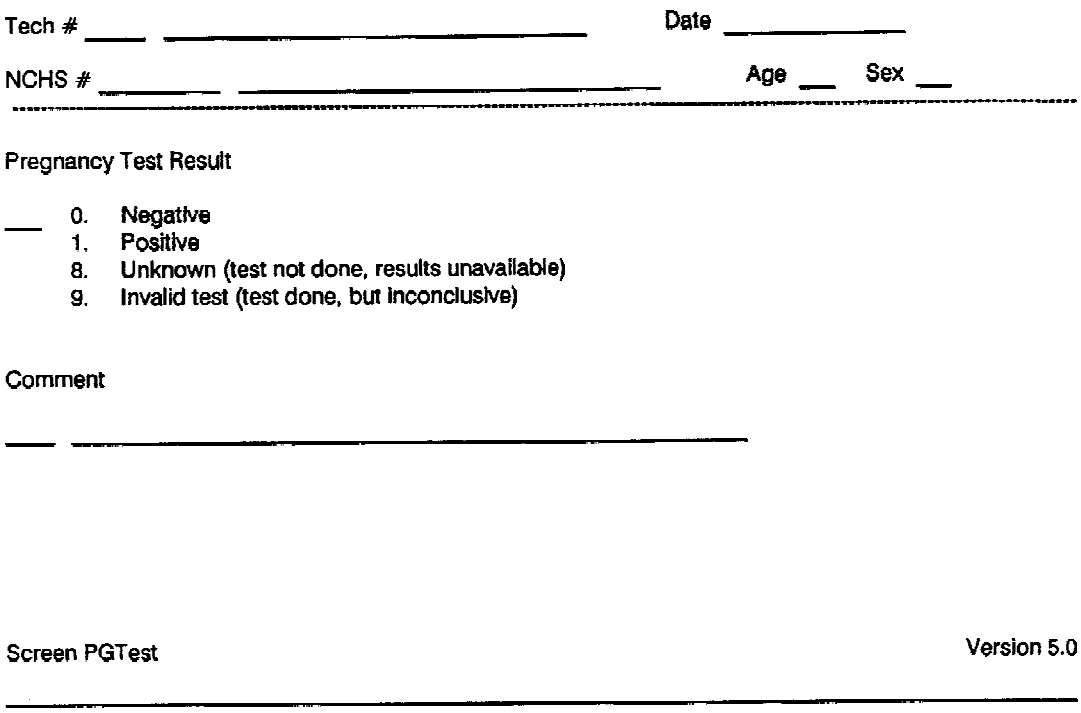
Use the Pregnancy Test Data Entry Screen to enter the results of the ICON II pregnancy test (Exhibit 7-3). Refer to the Urinalysis section of the Laboratory Automation Manual for specific instructions.

You must also record the results of the pregnancy test on the paper version of the Hematology Worksheet (Exhibit 5-12), following the specifications listed below.

- If you have not already done so, enter the date and your tech ID number in the upper right corner.
- Enter the SP's ID number, age, sex, and date of exam from the Daily Appointment Log.
- Enter the appropriate code to indicate whether the test result was:

Negative	=	0
Positive	=	1
Invalid test	=	9

Exhibit 7-3. Pregnancy test data entry screen



If the results of the first test were invalid, document this, repeat the test and enter the results of the second test.

- If the test cannot be performed for any reason, e.g., the ICON II pregnancy test kit is out of control or expired, record the information in the comments section.

- Enter any additional comments.

  NOTE: If the results are positive or invalid or the test cannot be performed, inform the coordinator **immediately**.

8. SPECIMEN SHIPMENT

8.1 Introduction

Blood and urine specimens are shipped to a variety of contract laboratories three or five times a week in double-sided polyfoam and corrugated cardboard shippers with dry ice or synthetic ice (wet ice), a copy of a Shipping Transmittal, and a floppy diskette . The specifications for the shipment of blood and urine specimens to each contract laboratory are given in Exhibit 8-1, the Shipping Protocol.

The MEC Manager determines which express mail service you will use to ship packages and the times to ship them. Packages should be shipped using Federal Express, if possible. If this is not possible, use Express Mail Service, Priority Mail, or Air Mail Special delivery. The MEC Manager also arranges for the delivery of dry ice on shipping days. It is your responsibility to confirm the arrangements for shipping and dry ice delivery with the MEC Manager when you arrive at a stand.

The chief technologist will work with the MEC Manager and the contract laboratories to determine exactly which days specimens will be shipped to the contract laboratories. As a general rule, most specimens should be packed and shipped on split shift days once a week. Exceptions are listed in Exhibit 8-1. All specimens should be received at their respective destinations within 3 days of the time they are packed except vials 28 and 31. Vial 28 should be received at its destination the day after it is packed while Vial 31 should arrive within 2 days after it is packed. The 3 day limitation may conflict with off days, holidays and vacation. If you encounter a conflict with the shipping schedule and your working schedule or the contract laboratory schedule, consult your MEC manager.

8.2 Equipment and Supplies

To ship the specimens you will use a variety of equipment and supplies, which are listed below:

- Barcoded shipping labels;

Vial #	Destination	Destination Code	Assay	Ship Frequency	Instructions
1,2,3,7,8,10,11 14,15,17,18,19 24,25,26,27, TO and Hematology Data	CDC Serum Bank	A G	Misc	1 x per week	Bag, freeze, ship on dry ice. Include transmittal and floppy diskette. Include white copy of the Hematology Worksheet, one copy of the Hematology Log and a copy of each SP histogram. Include U-1 urines, transmittals and diskettes.
4	U of Mo	I	Glycosylated Hgb	2 x per week	Box, refrigerate, ship on wet ice to arrive within 5 days of collection. Include transmittal and floppy diskette.
5,5A,5B	U of Mo	J	Glucose	1 x per week	Box, freeze, ship on dry ice with Vial 6, 6A, and 6B. Include transmittal and floppy diskette.
6,6A,6B	U of Mo	K	Insulin C - peptide	1 x per week	Box, freeze, ship on dry ice with Vials 5, 5A, and 5B. Include transmittal and floppy diskette.
9	Johns Hopkins	H	Lipids	1 x per week	Box, freeze, ship on dry ice. Include transmittal and floppy diskette.
12	U of Wash	L	C-react. prot/RF	1 x per week	Box, freeze, ship on dry ice. Include transmittal and floppy diskette.
13	White Sands	N	SMAC	1 x per week	Box, freeze, ship on dry ice with Vial 23. Include transmittal and floppy diskette.
16	MUSC	M	Tetanus	1 x per week	Box, freeze, ship on dry ice. Include transmittal and floppy diskette.

Exhibit 8-1. Shipping protocol for blood and urine

Exhibit 8-1. Shipping protocol for blood and urine (continued)

Vial #	Destination	Destination Code	Assay	Ship Frequency	Instructions
20	CDC	C	HIV	1 x per week	Box, freeze, ship on dry ice. Include transmittal and floppy diskette.
21	USC	P	Thyroid	1 x per week	Box, freeze, ship on dry ice. Include transmittal and floppy diskette.
22	U Mass	Q	FSH & LH	1 x per week	Box, freeze, ship on dry ice. Include transmittal and floppy diskette.
23	White Sands	R	Fibrinogen	1 x per week	Box, freeze, ship on dry ice with Vial 13. Include transmittal and floppy diskette.
RU	CDC	RU	Rubella	1 x per week	Box and freeze. Ship on dry ice. Include transmittal and floppy diskette.
IE	Bratton	IE	IgE	1 x per week	Box and freeze. Ship on dry ice. Include transmittal and floppy diskette.
28	CDC	D	Volatile Toxicants	2-3 x per week	Bag, refrigerate. Ship on wet ice to arrive the day after packing. *(Include one empty gray top tube per shipment.)* Include transmittal and floppy diskette.
29	CDC	X	Volatile Toxicants	2 x per week	Box and freeze. Ship frozen on dry ice with volatile toxicants urines, Vials U4-U6. Include transmittal and floppy diskette. *(Add one empty non-silicone coated red top tube and one capped, crimped 5ml Wheaton vial per shipment.)*
C1, C2	SRA	C1	DNA/HBG Adducts	1 x per week	Box and freeze. Ship on dry ice. Include transmittal and floppy diskette.

Exhibit 8-1. Shipping protocol for blood and urine (continued)

Vial #	Destination	Destination Code	Assay	Ship Frequency	Instructions
31	CDC	F	Genetics	2-3 x per week	Bag, refrigerate. Ship on wet ice to arrive within 48 hours of collection. Include transmittal and floppy diskette.
Slides-MEC	CDC Serum Bank	T	Differential	As needed	Ship slide box in padded envelope (Fed Ex). Include transmittal and floppy diskette.
Slides-CDC	CDC Serum Bank	B	Differential	End of stand	Ship slide box in padded envelope (Fed Ex). Include transmittal and floppy diskette.
U-1	CDC	U	Cadmium	1 x per week	Freeze. Ship on dry ice in storage bag with other CDC miscellaneous samples. Include transmittal and floppy diskette.
U-2	U of Minn	W	Creatinine	1 x per week	Freeze. Ship on dry ice. Include transmittal and floppy diskette.
U-3	U of Mass	V	Iodine	1 x per week	Freeze. Ship on dry ice. Include transmittal and floppy diskette.
U-D	Columbia	Y	Urine Drug Test	1 x per week	Refrigerate. Ship on wet ice. Include transmittal and floppy diskette.
U-4,U-5,U-6	CDC	E	Volatile Toxicants	1 x per week	Band together. Freeze upright. Ship on dry ice with Vial 29. *(Include Chemical Exposure Questionnaires.)* Include transmittal and floppy diskette.

- Large styrofoam shippers;
- Medium styrofoam shippers;
- Dry ice chips;
- Cryo gloves;
- Eye shields;
- Hammer;
- Unprinted newsprint;
- Packing material;
- Absorbent packets;
- Plastic bags;
- Rubber bands;
- Paper clips;
- Synthetic ice pellets;
- Floppy diskettes;
- Floppy diskette mailers;
- Pens;
- Shipping Transmittal Forms;
- Filament tape;
- Index cards;
- Cards with labels which state:
  Keep Frozen,
  Refrigerate,
  Human Blood, and
  Contains Dry Ice ORM-A UN-1845;
- Contains Blood Samples for Medical Use (stamp or label);
- Pretyped Federal Express Mail address labels for each NCHS contract laboratory;

- Pretyped regular mailing labels for each NCHS contract laboratory;
- Pretyped Field Office return address labels; and
- "Memorandum to NCHS Contract Laboratory" forms.

8.3 General Instructions

Medical technologist 3 is primarily responsible for packing and shipping the specimens to the various laboratories on a given day. He/she is assisted as necessary by the other laboratory technologists in performing each of the steps listed below to complete the shipping procedures.

- At the beginning of each stand, send a list of the anticipated shipping schedule for the stand to each contract laboratory that receives specimens on dry ice.
- On the day before or on the morning of a given shipping day, prepare the Shipping Transmittal (Exhibit 8-2) and floppy diskette for each shipper being sent to a contract laboratory.
- Assemble the Shipping Transmittal, floppy diskette, pretyped Federal Express label, pretyped contract laboratory address label, pretyped return address label, assorted "warning" labels and the "Memorandum to NCHS Contract Laboratory" form (Exhibit 8-3) for each shipper. Include other forms as appropriate. Clip all materials together until you are ready to pack the shippers.
- Collect the shippers from the compartments under the MEC.
- Pack the shippers with the specimens, absorbent material, newsprint (padding), and a sufficient supply of dry ice or synthetic ice as appropriate (see Section 8.5).
- Complete the "Memorandum to NCHS Contract Laboratory" forms (Exhibit 8-3). Write the MEC laboratory phone number in the space provided and underneath write the name of the Chief Medical Technologist.
- Place the appropriate Shipping Transmittal and floppy diskette with a copy of the "Memorandum to NCHS Contract Laboratory" form and any other data collection forms on the polyfoam lid of shipper and place the lid on shipper. Secure the polyfoam lid with tape.
- Place the cardboard lid on the top of the polyfoam lid. Secure the lid to the shipper with strapping tape.
- Weigh each shipper, record the weight of the contents of the shipper and the weight of the dry ice on the Federal Express label.

Exhibit 8-2. Sample shipping transmittals

Blood Vial Transmittal from NHANES MEC

UNIVERSITY OF MISSOURI - Columbia
Department of Child Health
Room M770
One Hospital Drive
Columbia, MO 65212
Attn: Jack England

Shipper No. BA00106
Date of Shipment: 04/14/88
Reviewer No. 9999
Date of Receipt ___/___/___

Glycosylated Hb
Vial No. 4

Box No. BA00102

NCHS #	Age	S	Specimen Collected	Analysis Date	GLYHB %	Tech ID	Notes
9983597	77	F	02/20/88				
9982051	23	F	02/20/88				
9985395	68	F	02/20/88				
9985387	72	F	02/20/88				
9981497	39	F	02/21/88				
9984232	20	F	02/21/88				
9984381	66	F	02/21/88				
9984453	46	F	02/21/88				
9984186	32	F	02/21/88				
9984224	48	F	02/21/88				
9981578	22	M	02/21/88				

- Label each shipper with the appropriate Federal Express label, contract laboratory address label, Field Office return address label and warning labels.

- Retain three copies of the Shipping Transmittal for each shipper. File two copies in the MEC laboratory files and mail one copy separately to each contract laboratory as a backup trace copy in case of lost shipments.

When the NCHS contract laboratory personnel receive the shippers, they will unpack the specimens and send the shippers, synthetic ice and absorbent packets back to the field office. The MEC Manager will return the shippers to the storage compartments under the MEC and return the synthetic ice and absorbent material to you.

8.4 Preparation of Shipping Transmittals and Floppy Diskettes

Each shipper must include a Shipping Transmittal (Exhibit 8-2) and a floppy diskette, both of which list the inventory of the specimens in the storage boxes/bags contained in the shipper. If possible, you should prepare the Shipping Transmittals and floppy diskettes the day or evening before you are going to ship to avoid any last minute confusion on shipping day. It is also helpful to prepare the transmittals when the MEC is not in session. The process will take less time with only one component accessing the Vaxmate. Follow the steps listed below to prepare the Shipping Transmittals and floppy diskettes.

- Use the automated system to select a destination.

  After you enter your selection, the automated system will assign a shipper number to the destination. Locate the corresponding numbered, barcoded shipper label and attach it to an index card. Write the vial number(s) and the contract laboratory on the card. You will use this card (shipper number card) to label the shipper.

  If you are shipping blood vials or blood and urine vials to a contract laboratory, the automated system will display, in numerical order by date and session, a list of the storage containers with vials that have been filled but not shipped.

  If you are shipping only urine specimens to a contract laboratory, the computer will display, in numerical order by date and session, the list of urine vials which have been filled but not shipped.

- Select the specific storage containers or urine vials that you are shipping to the selected destination.

Exhibit 8-3. Memorandum to NCHS contract laboratory

TO: NCHS Contract Laboratory

FROM: NHANES III Chief Medical Technician

SUBJECT: Enclosed Shipping Transmittal

Please check the enclosed Shipping Transmittal against the contents of this NHANES III shipment. If there are any discrepancies, contact me at

(_____) _____-_____.

In addition, please return the foam blood vial storage containers and any unused absorbent packets with the shippers you return to us. Thank you.

Enclosure

- After you enter your selection, the automated system will assign each storage container or vial that you selected to the numbered shipper and create an inventory of the shipper which can be transmitted to paper or floppy diskette.

- Print the Shipping Transmittals. You should have the shipping transmittal in hand before you use the VAXmate to transmit the information to a floppy diskette.

  - When printing Transmittals for CDC miscellaneous blood and urine, always print the U-1 transmittal before printing the CDC miscellaneous blood transmittal.

- Use the Vaxmate to transmit the shipper inventory to a floppy diskette. **Always use double-sided, double-density diskettes**. Do not use high density diskettes. You must finish printing the transmittal and floppy diskette for one shipper before you can begin to print the transmittal for another shipper.

- Label the floppy diskette with the specimen shipment date, the stand number, the shipper number and the contract laboratory destination. Do not write directly on the floppy diskette. Write on the floppy diskette label and then place the label on the diskette.

- Assemble the Shipping Transmittals and the floppy diskettes (in their mailers) and the "Memorandum to NCHS Contract Laboratory" form with the appropriate address labels, return address labels, data collection forms, and Federal Express labels for each contract laboratory destination and set them aside until you are ready to pack and label the shippers.

  Please note: Detailed instructions for using the automated system to assign shipper numbers, select storage boxes or urine vials to be shipped and for printing Shipping Transmittals and floppy diskettes are given in Chapter 8 of the Laboratory Automation Manual.

8.5 Packing the Shippers

Most of the shipments require dry ice to keep the specimens frozen during shipment (see Exhibit 8-1). It is the MEC Manager's responsibility to supply you with dry ice chips for shipping specimens. Well in advance of a scheduled shipment, the third technologist should estimate how much dry ice will be needed for the shipment and tell the MEC Manager. Store the dry ice in an extra shipping container until it is used. When handling dry ice, wear cryo gloves to avoid burning your hands. Also wear an eye shield when filling bags with ice chips.

Federal regulations require that the shippers of all blood, urine and other liquid diagnostic specimens package such items following certain regulations and packaging procedures. The federal regulations include:

- A watertight primary receptacle e.g., sealed cryovial, sealed vacutainer, sealed 15 ml falcon tubes, and sealed Wheaton vials;
- A watertight secondary packaging e.g., a sealed plastic storage bag;
- Absorbent material placed between the primary receptacle and the secondary receptacle;
- If multiple glass primary receptacles are placed in a secondary packaging, they must be wrapped individually to ensure that contact between them is prevented;
- The absorbent material must be sufficient to absorb the entire contents of all primary receptacles;
- It is the responsibility of the shipper to ensure that adequate absorbent material is used; and
- A sturdy outside packaging constructed of corrugated fiberboard, metal or wood must be used.

The federal packaging procedures are provided below.

- To pack the primary and secondary receptacles, do the following:

  - **2 inch or 3 inch storage box(es)**

    Place the vials in the storage boxes, separating them using the grids provided. Secure the top of the box to the bottom with a rubber band. Place the box in a plastic bag, add one absorbent packet and then seal the bag.

  - **Gallon size sealable plastic bags**

    8 ml leukoprep tubes and 10 ml gray top tubes - Separate the vials from each other by placing them in the foam blood vial storage containers. Place the vials, rubber banded together by session, in a plastic bag. Once the primary bag is sealed, place several bags in one gallon-sized bag, add an absorbent packet and then seal the bag.

    CDC Vials - Place the 4 ml SSTs in a foam blood vial storage container before rubber banding it with the other CDC vials for that SP. Put the vials in a plastic bag. Once the primary bag is sealed, place several bags in one gallon-sized bag, add one absorbent packet, and seal the bag.

Volatile Toxicants Urines - Place the 15 ml falcon tube in a foam blood vial storage container. Rewrap the Wheaton vials in the bubblewrap they were packed in. Rubber band the three urine tubes together and place in a plastic bag. Once the primary bag is sealed, place several bags in one gallon-sized bag and add one absorbent packet before sealing.

- To pack a large or medium shipper container with dry ice, follow the steps listed below:

  - Place a layer of chipped dry ice in the bottom of a shipper;

  - Pack the specimen storage bags or boxes tightly in the shipper to prevent them from moving;

  - Use newsprint to fill holes and to even the top to 4-1/2" from the top rim of the shipper;

  - Place chipped dry ice on top so that the shipper is filled with dry ice to 1/4" below the rim;

  - Pack the sides with crumbled newsprint;

  - Place the polyfoam lid on top of the polyfoam bottom and secure it with strapping tape;

  - Place a plastic envelope containing the appropriate Shipping Transmittal, any other paper forms (see below) and a mailer containing the floppy diskette on top of the polyfoam lid. Secure both with scotch tape;

  - When shipping volatile toxicants urines (Vials U4-6), the completed Chemical Exposure Questionnaires should be included with the shipment. An NHANES Record of Transmittal Form should be completed for the Chemical Exposure Questionnaires (see Section 8.8 for instructions). The white copy of the transmittal should be included in the shipment with the Questionnaires. The yellow copy should be sent to Westat at the end of the stand. The pink copy should be given to the MEC Manager who will mail it to NCHS at the end of the stand;

  - When shipping CDC miscellaneous blood samples, the white copy of the Hematology Worksheet, a copy of the Hematology Log and the corresponding SP histograms should be included with the shipment. Also include the U-1 urines and the corresponding transmittals and floppy diskettes;

  - Secure the outer carton lid with strapping tape;

  - Weigh the shipper on the scale in the body measurements room. Assume the specimens weigh approximately 5 lbs. Subtract 5 lbs from the total weight of the shipper to obtain the weight of the dry ice. Each large shipper should contain at least 15 lbs of dry ice;

- Record the total weight of the shipper on the appropriate Federal Express label;

- Record the weight of the dry ice on the Federal Express label and an ORM-A label;

- Send a separate copy of the Shipping Transmittal to the recipient of the shipment. (Include the yellow copy of the Hematology Worksheet and a copy of the Hematology Log with the copy of Shipping Transmittals for CDC bloods and U-1 urines sent under separate cover to the CDC Serum Bank.); and

- Keep two copies of the Shipping Transmittal until the end of the stand, at which time one copy is sent to NCHS and one copy is sent to Westat.

Some shipments require a coolant to keep the specimens cold but not frozen during shipment (see Exhibit 8-1). For these shipments, enough frozen synthetic ice pellets should be added to the shipper to keep specimens cold for the length of time they will remain in the shipper. Keep approximately 30 pounds of synthetic ice pellets in the freezer at all times, replacing it as it is used.

To pack a shipper with frozen synthetic ice follow the steps listed below:

- Place several inches of synthetic ice in the bottom of the shipper;
- Place the specimen storage container in the shipper on top of the synthetic ice;
- Add another layer of synthetic ice;
- Completely surround the storage container with synthetic ice;
- Use packing material to pack the shipper tightly so that the contents cannot move around;
- Place the polyfoam lid on top of the polyfoam bottom and secure it with strapping tape;
- Place a plastic envelope containing the Shipping Transmittal and a mailer containing the appropriate floppy diskette on the top of the polyfoam lid and secure with scotch tape;
- Secure the cardboard carton lid with four 4-inch pieces of strapping tape;
- Weigh the shipper on the scales in the body measurements room;
- Record the total weight of the shipper on the appropriate Federal Express label;
- Send a separate copy of the Shipping Transmittal to the recipient of the shipment; and
- Keep two copies of the Shipping Transmittal until the end of the stand, at which time one

copy is sent to NCHS and one copy is sent to Westat.

8.6 Labeling Shippers

All shippers must be labeled with a barcoded shipper label, a Federal Express label, a contract laboratory address label, a return address label (Westat Business Reply Label for all contract laboratories except SRA Technologies and any CDC destination) and the following notice: "Contains Blood Samples for Medical Use". In addition, all shippers should be labelled with the appropriate warning labels as follows:

- Shippers containing dry ice should be labeled with a "Contains Dry Ice" label, a "Keep Frozen" label and an ORM-A UN 1845 label;
- Shippers containing frozen synthetic ice should be labeled with a "Refrigerate" label; and
- Shippers containing whole blood, serum or plasma specimens should be labeled with a "Human Blood" label.

The Federal Express labels, the contract laboratory address labels and the Field Office return address labels to be used at each stand are prepared in advance by the Field Office staff and given to you by the MEC manager when you arrive at the MEC. It is your responsibility to make sure the labels are correct. Use the list of contract laboratory addresses (Exhibit 8-4) to check the contract laboratory address labels and the recipient addresses and telephone numbers on the Federal Express labels. Verify the accuracy of the Westat Federal Express account numbers, the current Field Office address, and the MEC Manager's telephone number with the MEC Manager.

The contract laboratory address labels, the Field Office labels and the Westat Warehouse address labels will be prepared in advance at Westat and sent directly to the MEC in care of the Chief Technologist.

For shipments with only one shipper per contract laboratory, follow the instructions below to label shippers.

- Complete the section of the Federal Express label which requests the weight of the

contents of the shipper, and if applicable, the section which requests the weight of the dry ice contained in the shipper.

- Place the Federal Express label with the appropriate contract laboratory address in a plastic Federal Express window and attach the window to the cardboard lid of the shipper.

- For all destinations, except SRA or any CDC destination, create a return address card by recording the contract laboratory number (see Exhibit 8-4) as well as the stand number on a Westat business reply label. For example, shipments to Johns Hopkins University during stand 145 would be marked 1-145.

  If you are shipping specimens to SRA Technologies or any CDC destination, do not use a Westat business reply label as the return address card. Attach a current field office label to a 5" x 7" index card for the first half of the stand and attach a Westat warehouse address label to a 5" x 7" index card for the second half of the stand.

- Place the return address card in a second Federal Express plastic window. Attach the second Federal Express plastic window to the cardboard lid of the shipper.

- Place the appropriate shipper number card on top of the return address card.

- Place the appropriate warning label card on top of the shipper number card and attach the plastic Federal Express window to the lid of the shipper.

If for any reason the specifications for the Federal Express forms change during the stand and the forms cannot be retyped by the field office staff, you must prepare the entire form by hand before shipping specimens.

Contractor (Number)	Assays	Contact Persons	Telephone Number	Specimen Shipment Address	Correspondence	Express Airbills per Stand
Centers for Disease Control	Volatile Toxicants Blood Vial 28	Dr. David Ashley	(404) 488-4176	Centers for Disease Control Bldg 17, Rm 1814, F17 4770 Buford Highway Chamblee, GA 30341 Attn: Dr. David Ashley	Centers for Disease Control Bldg. 17, Rm. 1814, F17 1600 Clifton Road Atlanta, GA 30333 Attn: Elaine Gunter	8
Centers for Disease Control	HIV	Charles Schable	(404) 639-3174	Centers for Disease Control Building 1, Room 2367 1600 Clifton Road Atlanta, GA 30333 Attn: Charles Schable	Same	7
Centers for Disease Control	Genetics	Dr. Jack Reidy	(404) 488-4170	Centers for Disease Control Building 32, Room 1502, F24 4770 Buford Highway Chamblee, GA 30341 Attn: Dr. Jack Reidy	Centers for Disease Control Bldg. 32,Rm. 1502, F24 1600 Clifton Road Atlanta, GA 30333 Attn: Dr. Jack Reidy	24
Centers for Disease Control	Volatile Toxicants Urine and Blood Vial 29	Dr. Bob Hill Susan Head	(404) 488-4176	Centers for Disease Control Bldg. 17, Room 1814, F17 4770 Buford Highway Chamblee, GA 30341 Attn: Dr. Bob Hill	Centers for Disease Control Bldg. 17, Rm. 1814, F17 1600 Clifton Road Atlanta, GA 30333 Attn: Dr. Bob Hill	4
Centers for Disease Control	Misc. Blood Urine Vial U-1 MEC and CDC slides	Suzette L. Bartley Dollene Hammerlein John Hall	(404) 339-5917	CDC Serum Bank 602 Webb Ginn House Road Bldg B Lawrenceville, GA 30245-5427 Attn: Serum Bank Branch	Same	9

Exhibit 8-4. NHANES III Contract laboratory addresses (continued)

Contractor (Number)	Assays	Contact Persons	Telephone Number	Specimen Shipment Address	Correspondence	Express Airbills per stand
Bratton Biotech (10)	IgE	Sharon Ved Brat	(301) 762-5301	Bratton Biotech, Inc. 1 Taft Court, Suite 101 Rockville, MD 20850 Attn: Sharon Ved Brat	Same	7
Columbia Biomedical Laboratory (9)	Urine Drug Test	Ayad Muddarris	1 (800) 848-4245	Columbia Biomedical Laboratory 4700 Forest Drive, Suite 200 Columbia, SC 29206 Attn: Ayad Muddarris	Same	7
Johns Hopkins University (1)	Lipids	Terry Cloey	(410) 955-3197	Lipoprotein Analytical Laboratory CMSC 4-125 Johns Hopkins Hospital 600 North Wolfe Street Baltimore, MD 21205 Attn: Terry Cloey	Lipoprotein Analytical Laboratory CMSC 604 Johns Hopkins Hospital 600 North Wolfe Street Baltimore, MD 21205 Attn: Dr. Paul Bachorik	7
University of Massachusetts (2)	Urinary Iodine and FSH-LH	Dr. Lewis Braverman Dr. Christopher Longcope	(508) 856-3115 (508) 856-4251 or 856-6168	Univ. of Mass. Medical Center 55 Lake Avenue North Worcester, MA 01655 Attn: Dr. Lewis Braverman	Same	7
University of Minnesota (3)	Urine Microalbumin/ Creatine	Dr. Blanche Chavers Susan Kupcho Belinda Lewis	(612) 626-2922 (612) 624-6153 (612) 624-6153	University of Minnesota School of Medicine Dept. of Pediatrics Room 13-219 - MOOS Tower 515 Delaware St. S.E. Minneapolis, MN 55455 Attn: Susan Kupcho	Univ. of MN/Pediatrics Box 491 UMHC Minneapolis, MN 55455 Attn: Susan Kupcho	7
University of Missouri (4)	Glucose Insulin/C-Peptide, Glycosylated Hemoglobin	Jack England Kurt Rohlfing Barbara Bingelli Hsiao-Mei-Weidmeyer	(314) 882-2709 (314) 882-2708 (314) 882-2708 (314) 882-2705	University of Missouri-Columbia School of Medicine Department of Child Health Rm M770 One Hospital Drive Columbia, MO 65212 Attn: Jack England	Same	21

Exhibit 8-4. NHANES III Contract laboratory addresses (continued)

Contractor (Number)	Assays	Contact Persons	Telephone Number	Specimen Shipment Address	Correspondence	Express Airbills per stand
White Sands (8)	SMAC and Fibrinogen	Brenda Billhymer Carolyn Ditmen	(505) 434-1725	White Sands Research Center 1300 LaVelle Road Alamogordo, NM 88310 Attn: Brenda Billhymer	Same	7
University of South Carolina (5)	Tetanus Antitoxin	Ms. Barbara Hyman Dr. Gabriel Virella	(803) 792-4347 (803) 792-4339	Medical University of South Carolina Dept. of Microbiology and Immunology - Rm. 216 B.S.B 171 Ashley Avenue Charleston, SC 29425 Attn: Dr. Gabriel Virella	Same	7
University of Southern Calif. (6)	Thyroid Hormones	Stan Patel	(213) 342-2690	Univ. of Southern California Endocrine Services Laboratory McKibben Rm. 245 USC Clinical Laboratories 2025 Zonal Avenue Los Angeles, CA 90033 Attn: Stan Patel	Same	7
University of Washington (7)	C-Reactive Protein/ Rheumatoid Factor	Phyliss Daum	(206) 548-6149	Immunology Division - SB10 Univ. of Washington Dept. of Lab. Medicine, NW 176 1959 Pacific Ave. Seattle, WA 98195 Attn: Phyliss Daum	Same	7
SRA Technologies, Inc.	DNA/HGB Adducts	Juanita Dalzell Charlene Wiggens	(919) 544-0806	SRA Technologies, Inc. Building 2100 2515 Highway 54 Durham, NC 27713 Attn: Juanita Dalzell	Same	12

Follow the steps listed below to prepare a Federal Express form (Exhibit 8-5) for specimen shipment.

1. - Sender's Federal Express Account Number: Each stand location will have an individual account number. Obtain the number from the MEC Manager at the beginning of each stand.

   - Date: Record the month, day, and year that the specimens are shipped.

   - From: Print the MEC Manager's name.

   - Your Phone Number: Print the MEC Manager's office phone number.

   - Company: Print "**Westat NHANES III Field Office**"

   - Street Address: Fill in the Field Office street address. You will be given the Field Office address at the beginning of each stand by the MEC Manager.

   - City, State, Zip: Fill in the city, state, and Zip code for the Field Office location.

2. - Recipient's Name: Fill in the name of the recipient for the appropriate contract lab.

   - Recipient's telephone number: Fill in the recipient's telephone number.

   - Company: Fill in the name of the appropriate contract laboratory.

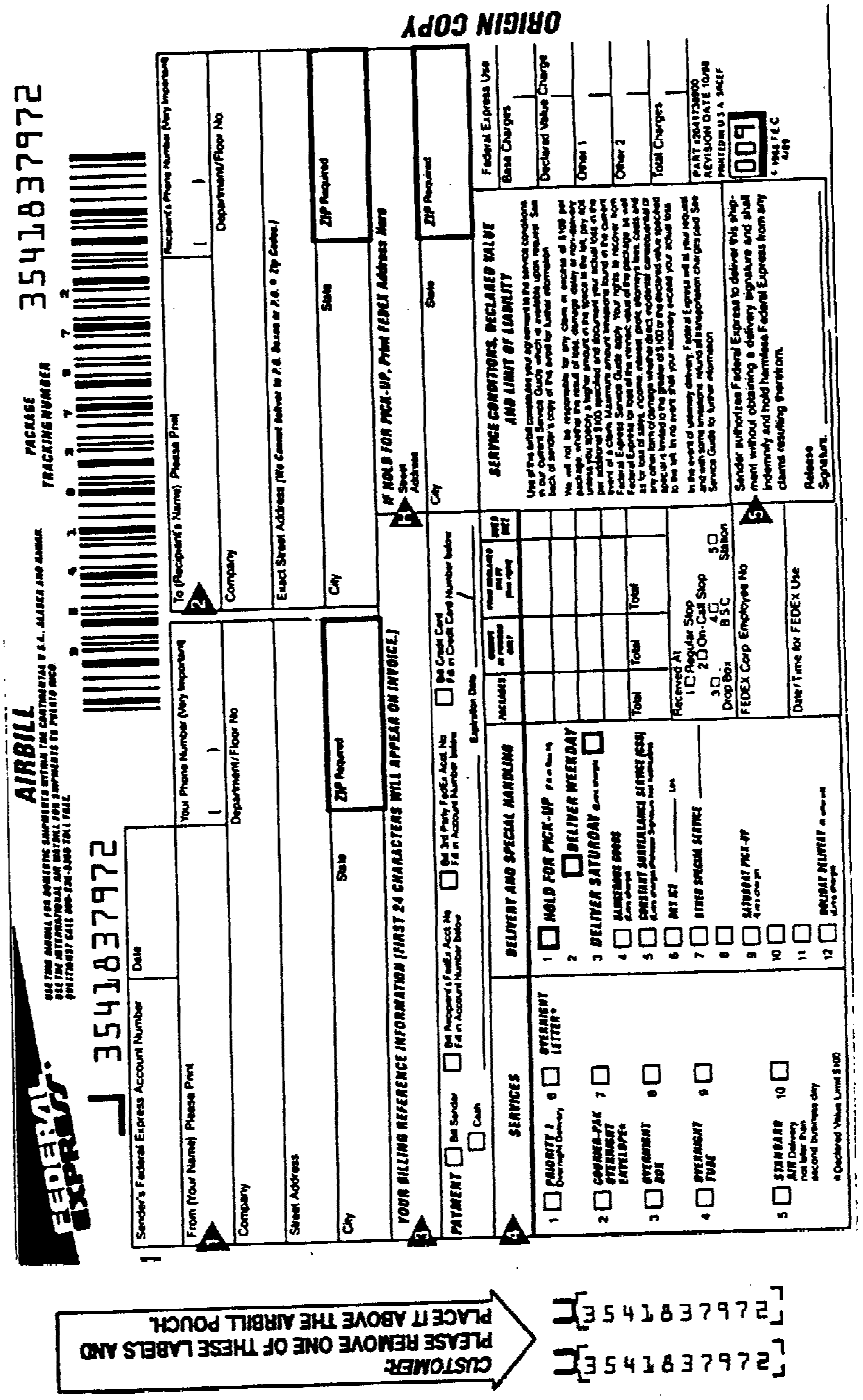
   - Exact street address: Fill in the specimen shipment address of the appropriate contract laboratory.

   - City, State, Zip: Fill in the city, state and Zip code for the appropriate contract laboratory.

3. - Your Billing Reference Information: Print the six character stand project number.

   - Payment: Check the box labeled "Bill 3rd Party Fed. Ex. Acct. No." and print Westat's Federal Express account number as follows in the space provided: 0200-0361-8.

Exhibit 8-5. Federal Express label



4. - Services: Check the box labeled "Priority 1, Overnight Delivery Using Your Packaging."

   - Delivery and Special Handling: If the shipment contains blood or urine to be delivered to a contract laboratory on a Saturday, check Box 3, "Deliver Saturday."

   - If shipment is not to be delivered on Saturday, do not check Box 3.

   - If the shipment contains dry ice, check Box 6, "Dry Ice," and indicate how much the dry ice weighs, in lbs.

   - Packages, Weight, Your Declared Value: Enter "1" for each shipper. Enter the pound weight for each shipper. Round to the nearest pound. Leave the "Declared Value" space blank. Enter the total number of packages and the total weight.

5. - Release Signature: Leave the space blank.

Some shipments contain more than one shipper going to a single contract laboratory. Use the Federal Express Multiple Package Service (MPS) (Exhibit 8-6) to label these shippers as follows:

- Create an address card for each shipper to be mailed to the contract laboratory by placing one of the contract laboratory address labels on an index card for each shipper.

- If necessary, complete one Federal Express form as described above. Place it on one of the shippers. Designate the shipper Number 1 of ____ (total number of shippers).

- Obtain the Federal Express Multiple Package Service labels (see Exhibit 8-6).

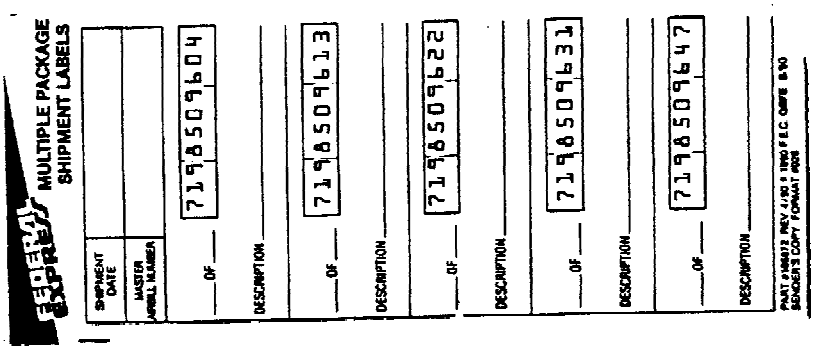
- Enter the shipment date and master Federal Express form number.

- Sequentially label each shipper within the shipment starting with Package Number 2 of ___. (Package Number 1 will have the Federal Express form attached to it.) If all five tracking numbers are not used, those numbers should be destroyed.

- Place an entire seven-inch label that includes the barcode and customer package tracking number on each of the address cards. Place an address card in a plastic Federal Express window and place a window on the lid of each shipper except the shipper which has the Federal Express form attached.

- Destroy any unused MPS labels.

Exhibit 8-6. Federal Express multiple package service label



- After completion attach the MPS Sender copy (pink) to the Shipping Transmittal that lists the contents of Shipper Number 1 of the shipment.

- Attach the self-adhesive MPS trace copy to the trace copy of the Federal Express form.

- Create a return address card and place the card in a plastic Federal Express window.

- Place the appropriate shipper number card on top of the return address card in the plastic window.

- Place the appropriate warning label card on top of the shipper number card and place the plastic Federal Express envelope containing all three cards on the lid of the shipper.

8.7 Shipping Blood Slides

The duplicate blood slides which are prepared as back-ups for the automated differential are stored in slide boxes in numerical ascending SP ID order by session. The first slide is stored in a slide box which is shipped to CDC as soon as it is full. The duplicate slide is stored in a slide box which is kept on the MEC until the end of the stand and then shipped to CDC. Slide boxes are shipped to CDC with a copy of a Blood Slide Transmittal (Exhibit 8-7), which lists the contents of the box. Follow the steps below to prepare Blood Slide Transmittals and to pack and ship slide boxes to CDC during the stand or at the end of the stand:

- Use the automated system to indicate the slide box you are going to ship to a specific destination.

  - Enter the destination CDC or MEC. Enter the type of material being shipped (slides). The automated system will display a list of the numbered slide boxes which contain slides for the specified destination;

  - Select the number of the slide box or boxes you wish to ship. The automated system will assign a shipper number to each box that you select;

- Label each slide box to be shipped with its designated shipper number label;

- Print a Shipping Transmittal for each slide box;

- Tape each slide box closed and wrap it in a bench cover;

Exhibit 8-7. Blood Slide Transmittal

Blood Slide Transmittal from NHANES MEC

CDC Serum Bank
602 Webb Gin House Road
Building B
Lawrenceville, GA 30245-5427
Attn: Serum Bank Branch

Shipper No. BA00106
Date of Shipment: 04/14/88
Reviewer No. 9999
Date of Receipt ___/___/___

CDC Slides

NCHS #	S	Age	Date	Code	Notes

- Place a slide box and the appropriate Shipping Transmittal in a padded envelope and tape the envelope shut;

- Address slide shipments to CDC as follows:

  CDC Serum Bank
  Centers for Disease Control
  602 Webb Gin House Road
  Building B
  Lawrenceville, GA 30245-5427
  Attn: Serum Bank Branch
  Suzette L. Bartley;

- Take the packages to the field office for posting; and

- Send one copy of the Shipping Transmittal to CDC Serum Bank under separate cover and keep one copy in the MEC laboratory files.

8.8 End of Stand Shipments

At the end of each stand you are to empty the MEC laboratory files and separate the copies of all the forms for Westat or NCHS according to the protocol for end of stand shipments (see Exhibit 8-8). If only one copy of a form is available, xerox it and address the original to NCHS and the photocopy to Westat.

Address shipments for Westat to:

Westat, Inc.
1650 Research Blvd.
Rockville, MD 20850
Attention: C. Novak

Exhibit 8-8. End of stand shipments

Laboratory Forms	DECK #	Send to	Frequency
Shipping Transmittals:			
CDC Blood and Urine: Vials 1-3, 7-8, 10-11, 14-15, 17-19, 24-27, TO, U-1	670a.	NCHS/Westat	Stand
CDC Volatile Toxicants Blood: Vials 28	670d.	NCHS/Westat	Stand
CDC Volatile Toxicants Blood: Vials 29	670d.	NCHS/Westat	Stand
CDC Volatile Toxicants Urine: Tubes U-4, U-5, U-6	670d.	NCHS/Westat	Stand
CDC HIV1: Vial 20	670b.	NCHS/Westat	Stand
CDC Genetic Testing: Vial 31	670e.	NCHS/Westat	Stand
Glycosylated Hgb: Vial 4	680	NCHS/Westat	Stand
Glucose Vials 5, 5A, 5B	671	NCHS/Westat	Stand
Insulin/C-peptide: Vial 6, 6A, 6B	672	NCHS/Westat	Stand
NHLBI Lipids: Vial 9	673	NCHS/Westat	Stand
C-reactive protein/Rheumatoid Factor: Vial 12	674	NCHS/Westat	Stand
SMAC Profile: Vial 13	676	NCHS/Westat	Stand
Tetanus: Vial 16	675	NCHS/Westat	Stand
Thyroid: Vial 21	679	NCHS/Westat	Stand
FSH and LH: Vial 22	677	NCHS/Westat	Stand
Fibrinogen: Vial 23	678	NCHS/Westat	Stand
Rubella: Vial RU	686	NCHS/Westat	Stand
IgE: Vial IE	688z	NCHS/Westat	Stand
DNA/HGB Adducts: Vials C1, C2,	687	NCHS/Westat	Stand
Creatinine/Microalbumin: Tube U-2	681	NCHS/Westat	Stand
Urinary Iodine: Tube U-3	682	NCHS/Westat	Stand
Urine Drug: Tube U-D	685z.	NCHS/Westat	Stand
Blood Slides	670c.	NCHS/Westat	Stand

Exhibit 8-8. End of stand shipments (continued)

Laboratory Forms	DECK #	Send to	Frequency
Home Exam Venipuncture Questionnaire	658	NCHS	Stand
Hematology Log	633	NCHS	Stand
Coulter Start-Up Procedures Printout	637	NCHS	Stand
Coulter Daily S-Calibration Printout	637	NCHS	Stand
Coulter 4C plus Quality Control Check Printouts	637	NCHS	Stand
SP Coulter Results/Histogram Printout	637	NCHS	Stand
Coulter Calibration Procedures Printout	637	NCHS	Stand
XB Printouts	637	NCHS	Stand
Daily Appointment Schedules	Not Applicable	NCHS	Stand
Pre-printed "BackUp" Forms:		NCHS	Stand
Blood, Urine and Slide Transmittals	Preprinted on Transmittals	NCHS	Stand
Hematology Worksheet	633	NCHS	Stand
Blood Processing Worksheet	632	NCHS	Stand
Venipuncture Questionnaire	615	NCHS	Stand

Address shipments for NCHS to:

National Center for Health Statistics
Presidential Building Room 900
6535 Belcrest Rd
Hyattsville, MD 20782
Attention: J. Findlay

Use the NHANES III Record of Transmittal Form (Exhibit 8-9) when mailing these forms to NCHS. Use one transmittal for each type of form and complete the transmittal as follows:

- To: Record the appropriate Westat or NCHS address.
- Date: Record the date you are mailing the forms.
- Stand Number: Record the three-digit stand number.
- Total Number of Records: Record the total number of forms you are shipping in the space provided.
- Total Number of Boxes: Record the total number of boxes containing the type of form you are shipping.
- Completed by: Record your four-digit tech ID number.
- Type of Record: Enter the type of form you are mailing in the space provided.
- Deck Number: Record the DECK number, if applicable, of the particular type of form in the space provided (see Exhibit 8-8). If the form has no DECK number, write "NA" (not applicable) in the space provided.
- Stand Location: Record the location of the stand in space provided.
- Examination Dates: Enter in the appropriate spaces the earliest and the latest examination dates recorded on the forms you are mailing.
- Sample Numbers: Complete this section only if you are mailing the Home Exam Venipuncture Questionnaire, the Coulter SP Results/Histogram Printout, the Chemical Exposure Questionnaire, or the Venipuncture Questionnaire. Circle the three-digit number which corresponds to the 4th, 5th and 6th digit of the NCHS number for each form being sent, if applicable.

Exhibit 8-9. NHANES III Record of transmittal

PHS-6184
Rev. 12/87

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Centers for Diseases Control
National Center for Health Statistics

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY III
RECORD OF TRANSMITTAL

TO:

DATE | STAND NUMBER

TOTAL NUMBER OF RECORDS

TOTAL NUMBER OF BOXES

COMPLETED BY

Here are the _____ (Type of Record) _____ (Deck Number) For _____ (Stand Location)

Examinations were conducted from _____ (Date) through _____ (Date)

Sample numbers of records included are circled below:

001	041	081	121	161	201	241	281	321	361	401	441	481	521	561	601	641	681	721	761	801	841	881	921	961
002	042	082	122	162	202	242	282	322	362	402	442	482	522	562	602	642	682	722	762	802	842	882	922	962
003	043	083	123	163	203	243	283	323	363	403	443	483	523	563	603	643	683	723	763	803	843	883	923	963
004	044	084	124	164	204	244	284	324	364	404	444	484	524	564	604	644	684	724	764	804	844	884	924	964
005	045	085	125	165	205	245	285	325	365	405	445	485	525	565	605	645	685	725	765	805	845	885	925	965
006	046	086	126	166	206	246	286	326	366	406	446	486	526	566	606	646	686	726	766	806	846	886	926	966
007	047	087	127	167	207	247	287	327	367	407	447	487	527	567	607	647	687	727	767	807	847	887	927	967
008	048	088	128	168	208	248	288	328	368	408	448	488	528	568	608	648	688	728	768	808	848	888	928	968
009	049	089	129	169	209	249	289	329	369	409	449	489	529	569	609	649	689	729	769	809	849	889	929	969
010	050	090	130	170	210	250	290	330	370	410	450	490	530	570	610	650	690	730	770	810	850	890	930	970
011	051	091	131	171	211	251	291	331	371	411	451	491	531	571	611	651	691	731	771	811	851	891	931	971
012	052	092	132	172	212	252	292	332	372	412	452	492	532	572	612	652	692	732	772	812	852	892	932	972
013	053	093	133	173	213	253	293	333	373	413	453	493	533	573	613	653	693	733	773	813	853	893	933	973
014	054	094	134	174	214	254	294	334	374	414	454	494	534	574	614	654	694	734	774	814	854	894	934	974
015	055	095	135	175	215	255	295	335	375	415	455	495	535	575	615	655	695	735	775	815	855	895	935	975
016	056	096	136	176	216	256	296	336	376	416	456	496	536	576	616	656	696	736	776	816	856	896	936	976
017	057	097	137	177	217	257	297	337	377	417	457	497	537	577	617	657	697	737	777	817	857	897	937	977
018	058	098	138	178	218	258	298	338	378	418	458	498	538	578	618	658	698	738	778	818	858	898	938	978
019	059	099	139	179	219	259	299	339	379	419	459	499	539	579	619	659	699	739	779	819	859	899	939	979
020	060	100	140	180	220	260	300	340	380	420	460	500	540	580	620	660	700	740	780	820	860	900	940	980
021	061	101	141	181	221	261	301	341	381	421	461	501	541	581	621	661	701	741	781	821	861	901	941	981
022	062	102	142	182	222	262	302	342	382	422	462	502	542	582	622	662	702	742	782	822	862	902	942	982
023	063	103	143	183	223	263	303	343	383	423	463	503	543	583	623	663	703	743	783	823	863	903	943	983
024	064	104	144	184	224	264	304	344	384	424	464	504	544	584	624	664	704	744	784	824	864	904	944	984
025	065	105	145	185	225	265	305	345	385	425	465	505	545	585	625	665	705	745	785	825	865	905	945	985
026	066	106	146	186	226	266	306	346	386	426	466	506	546	586	626	666	706	746	786	826	866	906	946	986
027	067	107	147	187	227	267	307	347	387	427	467	507	547	587	627	667	707	747	787	827	867	907	947	987
028	068	108	148	188	228	268	308	348	388	428	468	508	548	588	628	668	708	748	788	828	868	908	948	988
029	069	109	149	189	229	269	309	349	389	429	469	509	549	589	629	669	709	749	789	829	869	909	949	989
030	070	110	150	190	230	270	310	350	390	430	470	510	550	590	630	670	710	750	790	830	870	910	950	990
031	071	111	161	191	231	271	311	351	391	431	471	511	551	591	631	671	711	751	791	831	871	911	951	991
032	072	112	152	192	232	272	312	352	392	432	472	512	552	592	632	672	712	752	792	832	872	912	952	992
033	073	113	153	193	233	273	313	353	393	433	473	513	553	593	633	673	713	753	793	833	873	913	953	993
034	074	114	154	194	234	274	314	354	394	434	474	514	554	594	634	674	714	754	794	834	874	914	954	994
035	075	115	155	195	235	275	315	355	395	435	475	515	555	595	635	675	715	755	795	835	875	915	955	995
036	076	116	156	196	236	276	316	356	396	436	476	516	556	596	636	676	716	756	796	836	876	916	956	996
037	077	117	157	197	237	277	317	357	397	437	477	517	557	597	637	677	717	757	797	837	877	917	957	997
038	078	118	158	198	238	278	318	358	398	438	478	518	558	598	638	678	718	758	798	838	878	918	958	998
039	079	119	159	199	239	279	319	359	399	439	479	519	559	599	639	679	719	759	799	839	879	919	959	999
040	080	120	160	200	240	280	320	360	400	440	480	520	560	600	640	680	720	760	800	840	880	920	960	

Sample numbers of records not included and reasons why are listed below:

Attach the white original of the NCHS transmittal form to the packet of forms for NCHS. Attach the yellow copy with the forms for Westat. Give the pink copy to the MEC Manager who will sent it with all other end of stand transmittal forms to NCHS. Give the packets of forms to the MEC Manager who will take them to the Field Office to be posted.

8.8.1 Quality Control Records for NCHS

NCHS has requested that copies of several quality control records be sent to Dollie Kendrick at the close of each stand. The original records which are normally kept in the workbook in each MEC lab should remain in place, but copies of the pertinent records for the stand should be made and sent to her. The records Dollie should receive are as follows:

- MLA Pipette QC Log;
- LFBSC Log;
- Unusual Occurrence Form;
- Laboratory Centrifuge QC Log;
- Freezer/Refrigerator Log;
- Room Temperature QC Log;
- IQAP Data Collection 4C Control Forms;
- Coulter Electronics Action Log;
- Scheduled Cleaning Procedures and Operational Checks Log; and
- Coulter Reagent Log;
- CDC Water Sample QC Log;
- ICON QC Log; and
- All Supply Use Control Logs.

The forms should be grouped and sent to NCHS Receipt and Control at the end of the stand with all other forms. The NHANES III Record of Transmittal is not required for these copies, but you may want to include a note labelling the forms as "Laboratory Quality Control" and asking that they be sent to Dollie Kendrick for review.

8.9 How to Handle Automated System Failure

If the automated control system on the MEC fails, you must assign a barcoded number to each shipper and complete a preprinted version of the Shipping Transmittal for each shipper that is being sent to a contract laboratory (examples of the preprinted transmittals for each contract laboratory are given in Appendix J). However, because this will be very time consuming, you should postpone packing and shipping for as long as possible and wait for the automated system to be repaired.

To assign shipper numbers, use the barcoded storage container and shipper labels. Assign one number to each shipper that you pack. Use the numbers consecutively in ascending order.

To complete a preprinted Shipping Transmittal (Exhibit 8-10) for a shipper which is to be packed with storage bags/boxes containing one type of vial for multiple SPs, follow the instructions listed below:

- Complete a new Shipping Transmittal for each storage bag or box packed in the shipper;
- Record the vial number of the vials in the storage container in the space provided at the top center of the form;
- Record the seven-digit shipper number in the space provided in the top righthand corner of the form;
- Record the date the specimens are to be shipped in the space provided in the top righthand corner of the form;

Exhibit 8-10. Preprinted shipping transmittal (one vial type)

Blood Vial Transmittal from NHANES MEC

ADDRESS

Shipper No._____
Date of Shipment_____
Reviewer No._____
Date of Receipt ___/___/___
Deck No.

VIAL NUMBER

Box No. _____

NCHS #	Age	Sex	Specimen Collected	Code	Notes

- Record your four-digit tech ID number in the space labeled "Reviewer No;"
- Record the seven-digit storage container number on the line labeled "Box;"
- Record the NCHS number in the column labeled "NCHS" for each vial in the storage container. Follow the serpentine order in which the vials were placed in a box to record the NCHS numbers on the form; and
- Record the Age and Sex for each NCHS number. This information can be obtained from the Daily Appointment Schedules.

To complete a preprinted Shipping Transmittal (Exhibit 8-11) for a shipper which is to be packed with storage bags or boxes containing multiple vial types for one SP or for multiple SPs, follow the instructions below:

- Record the seven-digit shipper number in the space provided in the top righthand corner of the form;
- Record the date the specimens are to be shipped in the space labeled "Date of Shipment;"
- Record your four-digit tech ID number in the space labeled "Reviewer No;" and
- Record the following information for each storage container to be packed in the shipper:
  - Record the number of the storage container in the column labeled "Box,"
  - Record the NCHS number in the column labeled "NCHS" and the vial number in the column labeled "Vial" for each vial in the storage container, and
  - Record the Age and Sex for each NCHS number. This information can be obtained from the Daily Appointment Schedules,

If you are unable to make a shipment on the day for which it is scheduled, the Chief Medical Technologist is to notify the MEC Manager who will telephone the laboratories which are expecting the shipments and make arrangements with them to accept a shipment on the following day or another mutually convenient day. @The contact person for each laboratory is listed in Exhibit 8-4

Exhibit 8-11. Preprinted shipping transmittal (multiple vial type)

Blood Slide Transmittal from NHANES MEC

ADDRESS

Shipper No._____
Date of Shipment_____
Reviewer No._____
Date of Receipt ___/___/___
Deck No.

Box No. _____ VIAL NUMBERS

NCHS #	Age	Sex	Specimen Collected	Vial	Notes

9. QUALITY CONTROL

9.1 Introduction

A quality control program monitors laboratory performance to detect excessive random or systematic error. It is a necessary component of any laboratory. Failure to incorporate a quality control program should cause any value reported by that laboratory to be discredited. Some personnel working in laboratories may institute some degree of quality control intuitively. However, this "intuitive" use of quality control, although well intentioned, can be as disastrous as the lack of quality control. It is, therefore, imperative that every laboratory have a documented program of quality control.

Ideally, a good quality control program includes both internal and external surveillance and monitors the following five parameters:

- **Clerical Error:** This includes properly documented acknowledgement of transmittal and receipt of specimens (i.e., "logging in"), proper labeling of all specimens, correct assignment of laboratory values to the proper SP ID number, and maintenance of proper records from all specimens for future reference;

- **Reagents and Materials:** This includes confirmation of commercial standards and controls before they reach the bench; proper labeling of reagents, particularly those prepared in the laboratory; insuring all reagents in use are not outdated; having an adequate supply of current reliable reagents; proper calibration of equipment, such as pipettes; and proper washing of glassware;

- **Techniques:** This includes continued assurance that all personnel performing an assay understand the principles underlying a particular assay and are cognizant of the proper technique for that assay; that all personnel use the same technique for a particular assay; that there is ready access to a current technique manual; and that periodic review is undertaken to assure use of the most current and reliable techniques;

- **Bench Performance:** This includes the use of controls and standards for each assay performed; a technique based on sound statistical principles, which allows the technologist performing the assay to detect error outside of previously determined limits before reporting data; documentation of daily bench performance for detection of less obvious error (particularly those which tend to accumulate over time, so-called "drift"), and established procedures to be followed wherever error is found to exceed previously determined limits; and

- **Instrumentation:** This includes periodic preventive maintenance of all instruments in use in the laboratory and documentation that each instrument is maintaining a previously determined level of each performance at each check.

Each individual laboratory must determine to what extent each of these parameters is monitored. A laboratory should determine what degree of precision it wishes to attain and be able to reproduce consistently. It then institutes a quality control system to achieve this goal. The particular level of precision a laboratory desires to attain will depend on many considerations. Items to be considered include the expense of the program, work load of the laboratory, time and personnel available to implement the program, the purposes for which data from the laboratory will be used, attainable precision possible with existing techniques, and availability of tools for implementing the various aspects of the program.

For our laboratory in the MEC, we have designed a quality control system which monitors each of the parameters indicated above. Each parameter will be monitored carefully, through a quality program which is reliable, easily understood and implemented, easily documented and surveyed, incorporates periodic surveillance methods and achieves precision and reproducibility.

9.2 Internal Quality Control Procedures

9.2.1 Complete Replicates and Home Replicates

We will conduct several types of replicate examinations as an internal quality control procedure. Some volunteer SPs will be re-examined at the MEC. Other volunteers will be re-examined in their homes. In both cases, when the SP is scheduled for a replicate exam, he/she is assigned a new ID number through the Field Office. Thus, these replicate examinees will be handled just as though they were normal examinees.

9.2.2 The Coulter Counter S-Plus Jr.

The reliability of analytical values obtained with a procedure often depends on the quality of the standards and the calibration procedure employed. The College of American Pathologists

(CAP) suggests that automated instruments be calibrated using multiple analytical whole blood specimens or a certified, stabilized whole-blood type preparation. The International Committee for Standardization of Hematology (ICSH) by its definition requires that a calibrator "be based on or traceable to a reference preparation or material."

Coulter Electronics provides S-Cal calibrator which is used to calibrate the Coulter S-Plus Jr. at the beginning of each stand and to verify calibration daily. The S-Cal calibrator values for WBC, RBC, HGB, MCV and PLT parameters are derived by replicate analysis of fresh whole blood samples on serial S-Plus and S series instruments. These assigned values are traceable to reference methods with an accuracy to within $\pm$ 2%.

Instructions for the performance of calibration procedures using S-Cal calibration are given in Section 5, Hematology.

The 4C Plus Coulter Counter Cell Control is a modified whole blood hematology reference control prepared from fresh human blood. The control has seven stable values. When used with Coulter's blood diluent, Isoton III, it serves as a check on the accuracy of dilution, WBC counts, RBC counts and hemoglobin determinations. Mean assay values include such variables as:

- Day to day variation;
- Different analysts;
- Different instruments;
- Different glassware;
- Different batch numbers of test reagents; and
- A representative sampling, 3% of the production run of 4C.

The allowable limit of variation from the mean value, $\pm$2 standard deviations, represents the precision obtained from routine work.

4C Plus must be run at the beginning of each session to monitor the precision of the instrument, reagents, and technologists. Instructions for the performance of quality control procedures using 4C Plus are given in Section 5.3.5, Quality Control Check.

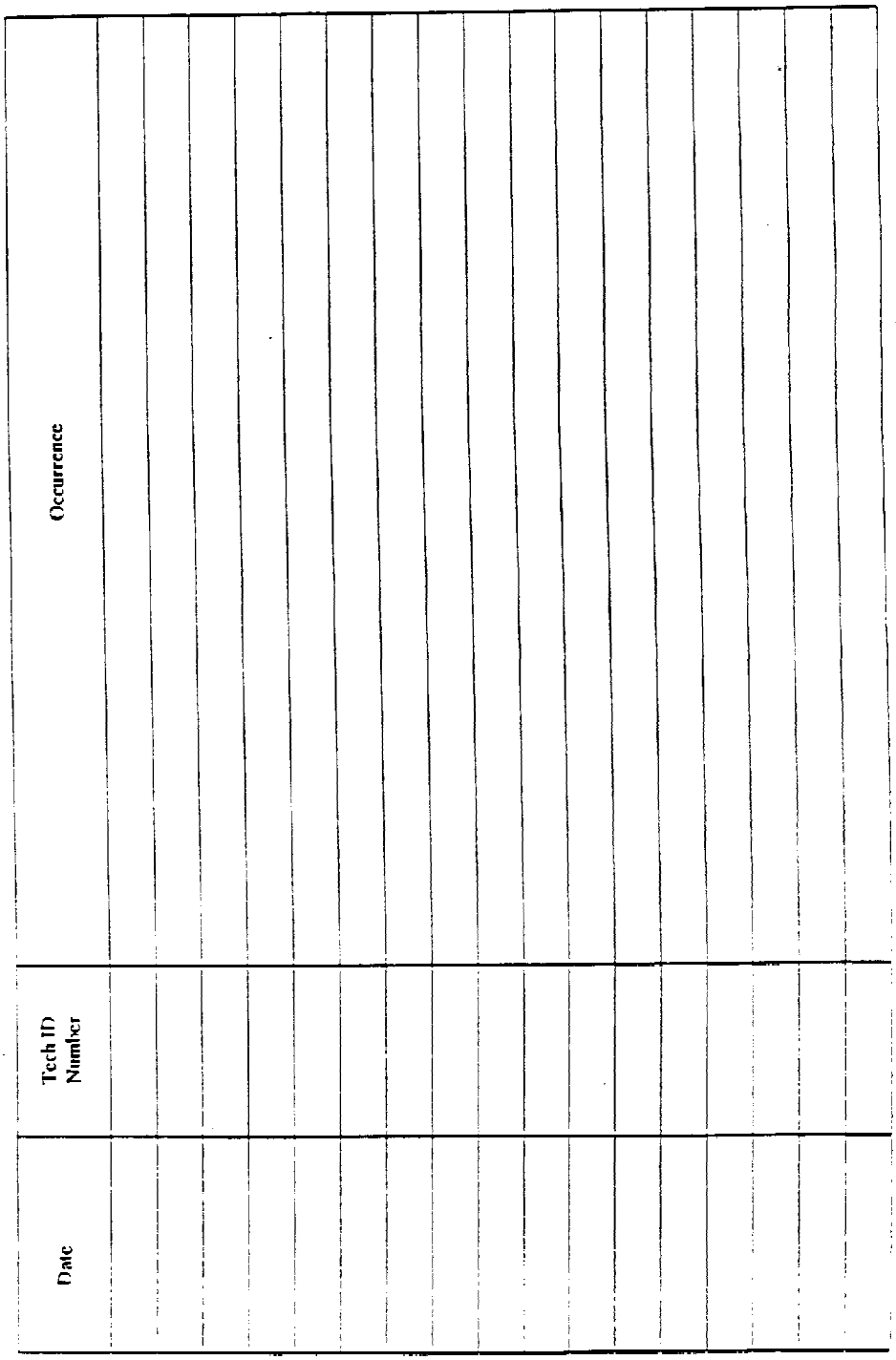
A planned maintenance program for the Coulter S-Plus Jr. includes scheduled cleaning procedures and operation checks which are performed as appropriate on a daily, weekly or monthly basis and documented in the Scheduled Cleaning Procedures and Operations Checks Log (Exhibit 5-3) of the Quality Control Notebook. Use of Coulter reagents is monitored and documented in the Coulter Reagent Log (Exhibit 5-1) of the Quality Control Notebook. Any malfunction or repair of Coulter S-Plus Jr. equipment is documented in the Coulter Action Log (Exhibit 5-7).

9.2.3 Microhematocrit, Sorvall and Table-top Centrifuges

All centrifuges are checked at the beginning of each stand by the NCHS engineer who determines the rpm of the instrument using a strobe light or a tachometer. The Sorvall centrifuge should exceed 3,200 rpm, the table-top centrifuges should exceed 2,500 rpm and the Microhematocrit centrifuge should exceed 8,500 rpm to assure adequate centrifugal force development. Each timer is also checked against a stop watch. Each time an instrument is checked, the values are recorded in the Laboratory Centrifuge QC Log (Exhibit 5-13) in the Quality Control Manual. In the event that a centrifuge malfunctions, the occurrence should be documented in the Unusual Occurrence Log (Exhibit 9-1) and the NCHS engineer should be notified. Record the date, your Tech ID number and an explanation of the incident and what steps were taken to resolve it. Be sure to record the model and the serial number of the centrifuge.

You will be responsible for cleaning the centrifuges periodically as needed. You will also be responsible for replacing the gasket on the Hematocrit Centrifuge when it becomes worn. Document maintenance procedures in the Other Maintenance section of the Laboratory Centrifuge QC Log (see Exhibit 5-13).

Exhibit 9-1. Unusual occurrence form



9.2.4 Refrigerators and Freezers

Quality control procedures for the refrigerators and freezers involve cleaning them at the beginning and the end of the stand and whenever necessary, monitoring their temperatures on a daily basis using a Dickson Recording Instrument, and documenting any necessary unscheduled maintenance. Each of these procedures is described below.

9.2.4.1 Cleaning

The refrigerators and freezers should be cleaned and defrosted at the end of each stand and whenever it is necessary. Wear rubber gloves to clean each unit. Clean and defrost the unit as you would clean any refrigerator or freezer, avoiding the use of abrasive cleansers. After you have finished cleaning the unit, disinfect the interior and exterior by cleaning it with a 1:100 solution of bleach and water.

Use the Freezer/Refrigerator Log (Exhibit 9-2) to document that you have cleaned each unit. Complete this form as follows:

- Check one box in the upper left hand corner of the form to indicate whether the form is being completed for a refrigerator or a freezer.
- Record the serial number of the refrigerator or freezer on the line provided in the upper left corner of the form.
- Record the MEC ID on the line provided in the upper right corner of the form.
- Record the number of the stand on the line provided.
- Record the stand location on the line provided.
- Record the year on the line provided in the upper right corner of the form.
- Each time you clean the unit, complete one line of the chart as follows:
  - Record the number of the month and day in the column labeled "Date."
  - Record your tech ID number in the column labeled "Tech ID Number."
  - Place a check on the line in the column labeled "Cleaned today?" to indicate that you cleaned the unit.

Exhibit 9-2. NHANES III freezer/refrigerator log

NHANES III Freezer/Refrigerator Log

Equipment: Freezer ☐

Allowable Temp: ≤ 1°F (≤-17°C)

Refrigerator ☐

Allowable Temp: 39°F - 46°F (4°C - 7.8°C)

Serial Number ____________

MEC ____________________

Stand # ____________________

Stand Location ______________

Year ____________________

Date	Time	Tech. ID Number	Temperature	Cleaned today? (If yes, check)
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
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			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	
			°F °C	

Note that you are to use the same line in the chart for recording the time that you took the daily temperature reading and the daily temperature on the same day that you cleaned the unit.

9.2.4.2 Use of the Dickson Recording Instrument

The DT4 model of the Dickson Recording Instrument is a battery operated temperature recording device which automatically monitors the interior temperature of the refrigerator and freezer units in which it is installed. The device continuously graphs this record on a circular paper chart so that a week's worth of temperature data can be inspected easily.

Exhibit 9-3 depicts the components of Model DT4. Refer to this exhibit when reading the operating and maintenance instructions for the DT4.

Dickson DT4 Temperature Recorders use a filled system consisting of a sensitive bulb, a length of flexible capillary tubing with a protective armor of 1-or 2-ply stainless steel braid, and the Dickson spiral Bourdon tube. Systems are filled with either gas (linear chart scale) or liquid-vapor (non-linear chart scale).

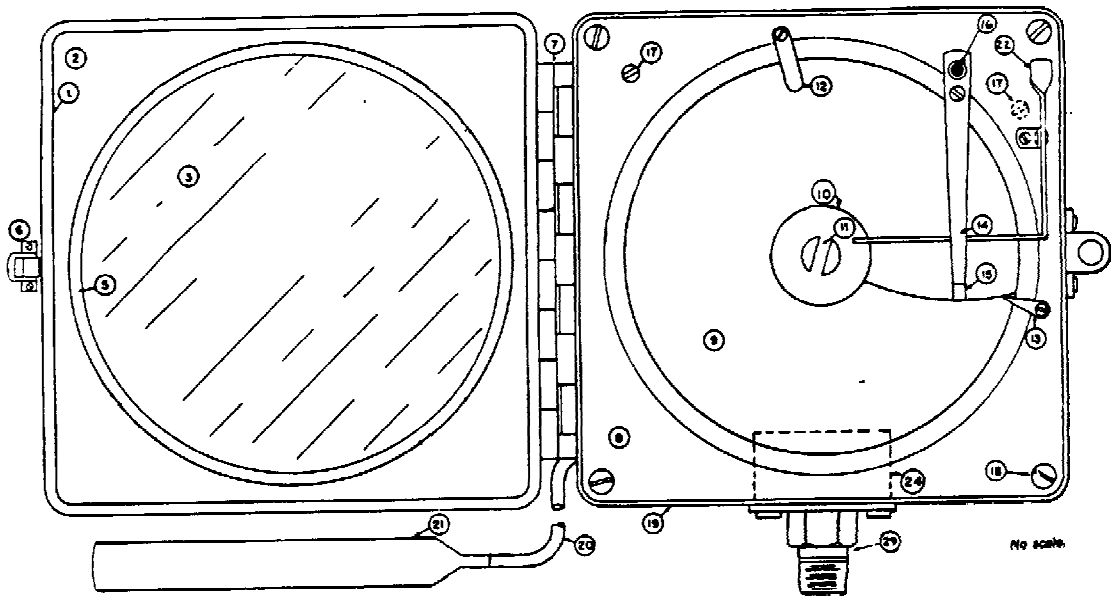
The NHANES III engineer is responsible for mounting, installing, and calibrating the DT4 recorder as specified in the manufacturer's Operating Manual. You are responsible for monitoring the results of the recorder at the beginning of each day, for replacing charts on a weekly basis, and for replacing batteries and pens, as needed.

To monitor the results of the recorder, look at the chart for each refrigerator and freezer at the beginning of each day, read the temperature indicated on the chart, and record it on the appropriate Freezer/Refrigerator Log (Exhibit 9-2). Use the specifications outlined below to complete this log.

To record the daily temperature reading complete one line of the form for each day that the MEC is in operation.

- Record the number of the month and day in the column labeled "Date" to indicate the date;

Exhibit 9-3. Components of the Dickson Recording Instrument



1. **DOOR GASKET RUBBER. 700-0541**
2. **DOOR ASSEMBLY.** Includes casting, glass, hasp and hinge. **700-0542**
3. **WINDOW GLASS. 700-0543**
5. **GLASS GASKET. 700-0545**
6. **HASP ASSEMBLY.** Includes hasp and strike, **700-0556** (Panel hasp assem. **700-0506**)
7. **DOOR HINGE. 700-0507,** (Panel **700-0508**)
8. **INSTRUMENT DIAL ASSEMBLY.** All operating parts are mounted on this dial. Parts are replaceable.
9. **CHART.** All charts are identified by number. Proper chart must be as originally specified.
10. **CHART HUB.** Integral with the clock. **700-0510**
11. **CHART HUB SLOT.** Holds and rotates chart. Use small coin and rotate to set chart for time.
12. **CHART GUIDE CLIP. 700-0512**
13. **TIME INDEX CLIP.** Indicates pen record time set. **700-0513**
14. **PEN ARM. 700-0570**
15. **CARTRIDGE PEN. 700-0120**
16. **PEN ARM MOUNTING PLATE & SHAFT ASSEM. 700-0579**
17. **ADJUSTMENT SCREW.** Use coin and turn to set pen for exact position on chart scale. Use also to set pen on Multi-range Recorders. **700-0517**
18. **DIAL ASSEMBLY SCREWS. 700-0518**
19. **CASE ASSEMBLY.** Includes gasket & hasp loop. **700-0549**
20. **CONNECTING TUBE.** Braid armored copper capillary. Cannot be cut nor changed after assembly. Broken tubes require factory repair or replacement.
21. **SENSITIVE BULB.** Plain copper bulb No. 10 illustrated. Other types and metal on original order only. Bulb must be fully immersed in temperature to be measured.
22. **PEN LIFTER.** Lift pen from surface when changing chart. **700-0534**
23. **CHART CLOCK MOVEMENT.** Screwed to back of dial. All electric clocks are interchangeable for any voltage or speed. 24 hour and 7 day battery clocks are interchangeable with their own kind.
24. **NAME PLATE.** Has identifying Serial Number. (See *)
29. **TYPE 3 GAUGE CONNECTION.** ¼" N.P.T. **700-0621**

- Record the time when you took the temperature reading;
- Record your four digit tech ID number; and
- Record the highest temperature shown on the chart since the last time the chart was read. Remember to circle the appropriate unit.

The allowable temperature range for the refrigerators is 39°F to 46°F (4°C-7.8°)C; the allowable temperature range for the freezers is not to exceed 1°F (-17°C). Note that if the temperature for a refrigerator or freezer has exceeded the allowable temperature range since the last time that you read the chart, you are to document this in the Unusual Occurrence Log (Exhibit 9-1) and inform the MEC Manager immediately. Transfer contents of the refrigerator or freezer.

To complete the Unusual Occurrence Log (Exhibit 9-1), record the date, your tech ID number, and a complete description of the occurrence, e.g., "Freezer (SERIAL NUMBER) in MEC (ID NO.) had a temperature of 10°F recorded at 9:00 p.m. on October 3, 1988. MEC manager was informed and asked to arrange for repairs."

Maintenance of the Dickson DT4 Temperature Recorder involves chart installation on a weekly basis, replacement of the cartridge pen as needed, and replacement of the batteries as needed (approximately once a year).

To install the chart, refer to the dial plate located on the instrument to obtain the proper chart number. (We expect to use chart number 17 in our recorders, but you should double check this.) Obtain a new chart of the correct size.

1. To install the new chart:
    - Lift the pen using the pen lifter;
    - Slip a chart under the raised pen arm and locate the chart hole hub;
    - Slip the edge of the chart under the chart guides and index clip;
    - Push the chart flat against the dial plate; and

- Using a coin or a screwdriver, rotate the chart hub clockwise 15 minutes to one hour past the time scale line or the time index clip. Turn back to the correct time to take up the slack in the gears.

2. To remove a chart once it has expired follow these instructions:

   - Lift the pen using the pen lifter;
   - Slip the edge of the chart out from under the chart clips; and
   - Remove the threaded knob and lift the chart off of the hub.

The DT4 uses a standard cartridge pen which requires no filling. It consists of a porous fiber tip and a self-contained ink supply housed together in a replaceable cartridge. When the ink runs out, you are to dispose of the spent cartridge and install a new one. To install a cartridge, follow the steps listed below:

- Lift the pen using the pen lifter;
- Lay the cartridge on the pen arm with the tip boss centered in the radius cut; and
- With your forefinger and thumb (see Exhibit 9-4) deflect the hinged retainer and snap it into engagement around the pen arm. Be careful not to distort the pen arm.

1. To start the ink flow, follow these steps:

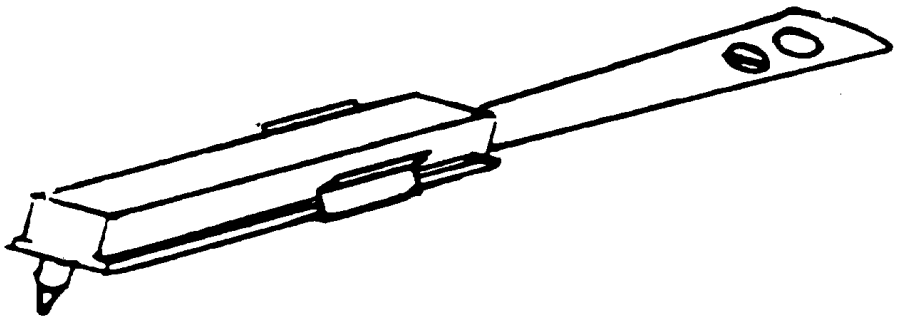
   - Lift the pen using the pen lifter;
   - Remove the cap from the fiber tip of the pen;
   - Place a scrap of paper under the tip and move the paper against the tip to start the ink flowing;
   - If necessary, slightly moisten the tip of the pen with water; and
   - If the line is too fine, sand the tip of the pen lightly to flatten the point and broaden the line.

2. Removal of the cartridge pen is straightforward:

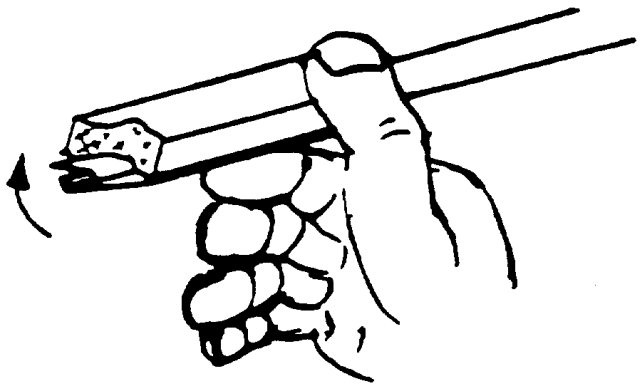
   - Lift the pen using the pen lifter;
   - Grasp the cartridge (see Exhibit 9-4) between the thumb and forefinger of your right hand; and
   - Pry down the hinge clip using your left thumbnail.

The only other maintenance required by the DT4 is battery replacement. The recorder is designed to run for approximately one year between battery changes using a cylindrical

Exhibit 9-4. DT4 cartridge pen



Removal of the DT4 cartridge pen



AA alkaline battery. Note that the manufacturer recommends that the drive be left running continuously even if the recorder is used only intermittently. (To do this, simply lift and cap the pen cartridge.) Access to the battery varies with recorder model. If a cylindrical battery holder is present, place a coin in the cap slot and turn it one quarter turn counterclockwise to obtain access to the battery. If no cylindrical battery holder is present, you will need to remove the dial plate or back plate of the recorder, depending on which is more convenient, in order to gain access to the battery.

Occasionally, a recorder may malfunction. The manufacturer offers the following troubleshooting guide:

SYMPTOM	POSSIBLE CAUSES	CHECK/REMEDY
Pen line too fine or missing.	Tip too sharp; cartridge dried out; pen not contacting paper.	Sand pen tip; deflect pen arm with thumb and forefinger until point just contacts paper.
Chart speed incorrect.	Chart clips or pen lifter interfering with paper; faulty chart drive.	Provide clearance from lifter or clip; replace battery or drive.
Recorder shows no response.	Capillary blocked, crimped or system leak.	Document in Unusual Occurrence Log; notify MEC manager.

9.2.4.3 Documentation of Unscheduled Maintenance

Aside from regular cleaning, the refrigerator and freezers require no regular maintenance. However, if they require any unscheduled maintenance for any reason, it is your responsibility to document this using the Unusual Occurrence Log (Exhibit 9-1). You are also to notify the MEC manager immediately so that service can be arranged as soon as possible.

9.2.5 MLA Pipettes

The MLA pipettes will be calibrated at CDC twice a year. You are to pack and ship all of the used MLA pipettes via Federal Express, Standard Air, to CDC every 6 months, that is at the end

of the stand in January and July. Also, if at any time during a stand, one or more of the MLA pipettes malfunctions, you are to send it to the CDC for repair immediately.

Document scheduled and unscheduled maintenance of the MLA pipettes in the MLA Pipette QC Log (Exhibit 9-5). Record the following information:

- The size and serial number of each MLA pipette to be recalibrated or repaired;
- The date of shipment;
- Your tech ID number;
- The date of receipt of the pipettes from CDC;
- Your tech ID number, and;
- A comment to describe the situation as a recalibration or malfunction repair.

Follow the specifications listed below to ship MLA pipettes:

- Complete a shipping transmittal for each shipment (see Exhibit 9-6). Record the date of shipment, your tech ID number, the stand number, and the size and serial number for each pipette included in the shipment. At the bottom of the transmittal complete the MEC number and MEC manager items.
- Place each pipette in its original case. If necessary pack the case with crumpled paper to prevent the pipette from moving.
- Place the cases in an appropriate sized box. If necessary pack the box with crumpled paper to keep the cases from moving.
- Place the MLA Pipette Transmittal inside an envelope in the box.
- Close and secure the box with strapping tape.
- Label the box with a mailing label addressed to:

  Elaine Gunter
  Building C-17, Room 2814F18
  Centers for Disease Control
  Atlanta, GA 30333

- Label the box with the return address of the Field Office.

Exhibit 9-5. MLA pipette QC log

MEC # _____

MLA Pipette Size	MLA Pipette Serial No.	Date of Shipment	Tech ID #	Date of Receipt	Tech ID #	Comment

Exhibit 9-6. MLA pipette transmittal

MLA Pipettes
Transmittal from NHANES MEC

Date of Shipment: ___/___/___
Tech No. ____ ____ ____ ____
Stand No. ____ ____ ____

Elaine Gunter
Building 17, Room 1814E17
Centers for Disease Control
Atlanta, GA 30333

Pipette Size	Serial Number
100 ul	
100 ul	
400 ul	
400 ul	
1,000 ul	
1,000 ul	

PLEASE RETURN PIPETTES TO: MEC # _____
MEC MANAGER _____

- Take the box to the Field Office for mailing.
- Send a separate copy of the MLA Pipette Transmittal to Elaine Gunter.
- Keep one copy of the MLA Pipette Transmittal in the MEC files.

9.2.6 Reagents

You will also maintain logs for all reagents. As each new reagent is procured, enter the reagent's name, concentration (if applicable), date of arrival and expiration date in the appropriate log (see Exhibit 5-1). At the same time, label each reagent with a gummed label. Record the name of the reagent, strength or concentration (if applicable), expiration date and your ID number on the label.

9.2.7 Use of the Class II Type A Biological Safety Cabinet

9.2.7.1 Introduction

The Class II Laminar Flow Biological Safety Cabinet (LFBSC), when used with proper technique, provides an effective partial containment system for safe manipulation of moderate and high-risk microorganisms. The vertical laminar airflow barrier prevents contaminated air from entering or escaping from the open-front work chamber, protecting the cabinet contents and you. A high-efficiency filter system decontaminates both the incoming air and the exhaust.

9.2.7.2 Installation, Certification, and Maintenance

The NCHS biomedical engineer will install the LFBSC in the MEC and arrange for CDC technologists to perform the required annual certification which includes replacement of HEPA filters as necessary.

The basic concept of the LFBSC is to take air through a blower system, pressurize a plenum, and force air through a filter. Built-in supply and exhaust blowers are equipped with separate HEPA filters. The recirculating airflow pattern directs a portion of the HEPA filtered air straight down over the central work area driving the airborne contaminants into the surrounding grills, allowing

a pollution free environment for particular specifications. If a filter is defective, the work station filtration system no longer filters and becomes a vacuum cleaner, taking in gross contamination and exploding it through the defective filter onto and around the critical work area. The filter of the LFBSC is permanently installed into a disposable plenum. A magnehelic gauge which is calibrated in "inches of water gauge" pressure (w.g.) indicates when the supply HEPA filter is clogged. As the filter loads with particulate matter, the amount of pressure registered on the gauge will increase. The initial pressure reading is approximately 0.4 w.g. $\pm$ 0.05 w.g. depending on the altitude from sea level. You must check the reading on the gauge every day. If the gauge registers an increase in pressure of more than 0.1 w.g., you are to notify the NCHS engineer. The NCHS engineer will check the airflow pressure and the HEPA filter system. If the HEPA filter is contaminated to the point where it is no longer effective, the entire filter and plenum are discarded and a new replacement unit is substituted.

Document all scheduled maintenance for the LFBSC, including daily pressure readings, and certification procedures in the Biological Safety Cabinet Log (Exhibit 9-7) as follows:

- Write the serial number of the LFBSC in the space provided in the upper left-hand corner of the form.
- Record the MEC number in the space provided in the upper right-hand corner of the form.
- Record the stand number in the space provided.
- Record the stand location on the line provided.
- Record the month and year on the lines provided in the upper right-hand corner of the form.
- Each time you check the pressure, record the following information:
  - Record the month and day in the column labeled "Date."
  - Record the time of day in the column labeled "Time."
  - Record your four-digit tech ID number.
  - Record the pressure gauge reading.
- If the CDC technologists have performed certification procedures, complete the form as instructed above and place a check in the column labelled "CDC certification".

Exhibit 9-7. NHANES III biological safety cabinet log

Serial Number ____________

Allowable Range: Less than 0.1 w.g. increase per day

MEC ____________

Stand # ____________

Stand Location ____________

Year ____________

Date	Time	Tech. ID Number	Magnehelic Gauge Pressure Reading	CDC Certification? (If yes, check)

Document all unscheduled maintenance for the LFBSC in the Unusual Occurrence Log (Exhibit 9-1). Record the date, your tech ID number and description of the malfunction and the steps taken to repair it.

9.2.7.3 Operating Sequence

- Turn on the cabinet blower and lights, check the air intake and exhaust portals of the cabinet to make sure they are unobstructed.
- Check the pressure on the magnehelic gauge. If the pressure has increased more than 0.1 w.g. since the previous reading, notify the NCHS engineer. Record the pressure reading and any comments you may have in the Biological Safety Cabinet Log (Exhibit 9-7).
- Allow the blowers to operate for a minimum of 15 minutes before beginning work in the cabinet.
- Disinfect the interior of the work space by wiping it down with a solution of bleach and water (1:100).
- Set up the equipment for processing. Do not place any equipment or supplies over the front intake grills.
- Arrange materials so that clean and contaminated materials are well separated.
- Wait 2-3 minutes after placing the materials and supplies in the cabinet before beginning work. This will rid the area of all "loose" contamination that may have been introduced with the items.
- Wear a long sleeved lab coat and gloves. This will minimize the shedding of skin flora into the work area and concurrently protect your hands and arms from viable agent contamination. Wash your hands with soap and water before and after work in the cabinet.
- After you have completed your work, leave the blower on for 2-3 minutes to purge the unit.
- Decontaminate interior surfaces after removal of all specimens and biohazardous waste by wiping them with a solution of bleach and water (1:100).
- Check the grills and diffuser vents for spills or splashes. In the event that there are spills or splashes of biological materials, follow the procedures given in Section 10.3 to decontaminate and clean the area.
- Turn off the blowers and lights.

9.2.8 Ambient Air Temperature

Quality control procedures for ambient air temperatures for the laboratory involve checking the thermometer for damage, monitoring the temperature each session and documenting any unusual occurrences.

Check the wall thermometer for damage at the beginning of each stand. Notify the MEC manager of any damage.

At the end of each session use the Ambient Air QC Log to record the room temperature (see Exhibit 9-8). Complete as follows:

- Record the location of the wall thermometer in the space provided in the upper left-hand corner;
- Record MEC ID on the line provided in the upper right corner of the form;
- Record the stand # on the line provided;
- Record the location of the stand;
- Record the year on the line provided;
- Each time you record the temperature, complete one line of chart as follows:
  - Record the month and day in the column labeled "Date";
  - Record the temperature; and
  - Record your tech ID number.

The allowable temperature range for the room is 60°F to 70°F (15.5°C-21°C). NOTE: <u>if the room temperature is out of allowable range since the last time you read the thermometer you are to document this in the Unusual Occurrence Log (Exhibit 9-1) and inform the MEC manager immediately</u>. Complete a separate form for each wall thermometer in the laboratory. Remember to indicate the location of the wall thermometer on the Ambient Air Temperature Quality Control Log.

Exhibit 9-8. Ambient air temperature log

NHANES III

LABORATORY QUALITY CONTROL LOG
AMBIENT AIR TEMPERATURE RECORDING

Lab Location: ____________________
Allowable Temp: 60°F - 70°F (15.5°C - 21°C)

MEC ____________________
Stand # ____________________
Stand Location ____________________
Year ____________________

Date	END OF SESSION - TEMPERATURE (°F)			COMMENTS
	AM (1)	PM (2)	EVENING (3)	

9.3 External Quality Control for Hematology

Four times a year, February 29, May 23, August 29 and November 28, NCHS will send you CAP samples for hematology proficiency testing. Each quarterly shipment will include two 3 ml whole blood specimens. Perform duplicate Coulter determinations on each whole blood sample and record the results on the CAP forms provided. Send the completed forms to the address specified by CAP Surveys Program Support or to NCHS at the following address:

Geraldine McQuillan, Ph.D
National Center for Health Statistics
Room 900
6525 Belcrest Rd.
Hyattsville, MD 20782

9.4 Quality Control for the Contract Laboratories

NHANES III uses several methods to monitor the quality of the analyses performed by the contract laboratories.

During the dry run session for each location and whenever "guest" SPs are examined, you will prepare laboratory replicates. To do this, you split the blood drawn from each examinee and send pairs of tubes to the various laboratories performing the NHANES III analyses. Each split duplicate is sent to the laboratory in the same shipment with the original sample but with a different identifying number (see Section 11.4, Dry Run).

In addition to the laboratory replicates (split duplicates), the various laboratories participating in NHANES III routinely perform their own replicate and quality control determinations. Whenever differences larger than predetermined tolerances occur, the analyses are repeated.

9.5 Quality Control Protocol for Medical Technologists

In order to assure equal workloads of the laboratory procedures, calibration and maintenance of equipment, quality control and other duties in the laboratory, responsibilities are rotated among the medical technologists utilizing the system described below.

The technologist responsible for set-up day is also the technologist responsible for pack-up at the last stand. He/she begins rotation as Technologist 1, the blood processing tech, and has the following responsibilities:

- Ensure that the laboratory is fully set up;
- Start the begin stand inventory;
- Check to see if annual certification of the Laminar Flow Biological Safety Cabinet is required at the stand. If certification is required, contact the MEC Manager who will arrange for certification;
- Check to see if annual performance maintenance inspection of the Coulter is required at the stand. If PMI is required, contact Vera Osidach, who will arrange for PMI;
- Twice a year, at the end of the stand, ship the used MLA pipettes to CDC for calibration;
- Once a year, replace the battery in the temperature recorders; and
- Start the end stand inventory.

9.5.1 Dry Run and Examination Sessions

Routine responsibilities for quality control are outlined below for each work station.

9.5.1.1 Phlebotomist - Phlebotomy Room

- Perform venipuncture and complete data entry using the Automated Venipuncture Questionnaire.
- Record receipt of venipuncture supplies on the Mobile Exam Center Inventory sheets.

- Check expiration dates of vacutainer tubes and needles.
- Document use of each type of vacutainer tube on the appropriate Supply Use Control Logs (Exhibit 3-6) in the Quality Control Notebook.
- Rotate supplies.
- Assist the laboratory technologists as needed (refer to Section 2.3 for specific tasks).
- Document in the Unusual Occurrence Log (Exhibit 9-1) any unusual occurrence or malfunction of equipment that occurs when you are performing and recording results of phlebotomy procedures.

9.5.1.2 Technologist 1 at Work Station 1

- Perform serum separation procedures.
- Perform blood specimen processing and enter results.
- Record receipt of blood processing supplies on the Mobile Exam Center Inventory Sheets.
- Check biological safety cabinet pressure gauge and record the pressure in the NHANES III Biological Safety Cabinet Log (Exhibit 9-8).
- Document in the Unusual Occurrence Log (Exhibit 9-1) any unusual occurrence or malfunction of equipment that occurs when you are processing blood specimens.

9.5.1.3 Technologist 2 at Work Station 2

- Check refrigerators and freezers for proper temperatures. Record the temperatures in the appropriate Temperature Log (Exhibit 9-2).
- Perform the hematology, urine pregnancy test and urine processing procedures.
- Perform Coulter calibration procedures.
- Record receipt of hematology and urine processing supplies on the Mobile Exam Center Inventory Sheets.
- Record receipt of Coulter Reagents on the Coulter Reagent Log (Exhibit 5-1).
- Complete data entry for hematology, urine processing and urine pregnancy testing.

- Run pregnancy test controls daily and record results in the ICON II QC Log (Exhibit 7-1).

- Run 4C Plus and inspect and record results.

- Document the use of the ICON II pregnancy test kit, the urine control kit, the urine specimen cups and the 15 ml Falcon tubes in the appropriate Supply Use Control Logs of the Quality Control Notebook.

- Perform daily, weekly, and monthly requirements of scheduled maintenance on the Coulter S Plus Jr. and record the results in the Scheduled Cleaning Procedures and Operational Checks Log (Exhibit 5-3).

- Document in the Unusual Occurrence Log (Exhibit 9-1) any data entry problems or other unusual occurrences you incur as you perform the hematology and urine processing procedures.

9.5.1.4 Technologist 3 at Work Stations 1 and 2

- Perform shipping procedures and document the results.

- Record receipt of shipping supplies on the Mobile Exam Center Inventory Sheets.

- Assist Technologists 1 and 2 and the phlebotomist, as necessary.

- Document unusual occurrences and computer malfunctions in the Unusual Occurrence Log (Exhibit 9-1).

9.5.2 Evaluation Criteria

9.5.2.1 Laboratory Evaluation Criteria

Use the following criteria to evaluate the quality of the work you do in the laboratory:

- Document the collection and receipt of incomplete blood samples in the Comments section of Venipuncture Questionnaire;

- Document all Venipuncture refusals on the Venipuncture Questionnaire;

- Make two determinations for each hematology test. If only one determination is done, an explanation must be recorded in the comments section of the appropriate log;

- Check to see that duplicate hematology test results are within the established allowable range. If not within the allowable range, explain the reason in the comments section of the appropriate form;

- Check to see that Hgb and Hct are compatible. The hematocrit should be three times the hemoglobin within $\pm$3 units. Repeat the determinations and record the results in the comments section of the appropriate log if Hgb and Hct are incompatible;

- Check to see that the manual and automated Hct are within +3 units;

- Enter all of the appropriate log data correctly. Check the screen or worksheet for omissions and incorrectly entered data, i.e., age, indices, 4C Plus lot no., control limits;

- Note under the comments section of the Hematology Log or the Blood Processing Log if and when you report abnormal values to the physician; and

- Note all tests that were omitted because of equipment defects in the Comments section of the Hematology Data Entry Screen or Blood Processing Screen.

9.5.2.2 Quality Control (QC) Documentation

- Print the Coulter background counts daily and store them in the MEC files. Explain any unusual occurrences in the Coulter Action Log of the QC Notebook.

- Print results of Coulter calibration/verification procedures daily and store them in the MEC files. If the calibration values are out of range, explain the situation and describe measures taken to correct the problem in the Coulter Action Log of the Quality Control Notebook.

- Print the 4C control values (High, Low, Normal) for each Coulter test daily and store them in the MEC files. Record the second of the duplicate control runs on the IQAP forms. When the values are out of range, explain the situation and describe the measures taken to correct the problem in the Coulter Action Log of the Quality Control Notebook.

- Print 4C control batch tables. Send one copy to IQAP. Store the second copy in the MEC files.

- Print results of all calibration procedures. Store results in the MEC files.

- Print X B batch tables as necessary. Store them in the MEC files.

- Perform instrument and equipment maintenance at the specified times and record the results in the appropriate logs of QC Workbook.

- Document receipt of all supplies in the Mobile Exam Center Inventory Sheets.

- Document the use of all types of vacutainer tubes, needles and butterflies, the Trutol, the 15 ml Falcon tubes, the urine specimen cups, the ICON II pregnancy test kit and the urine control kit in the appropriate Supply Use Control Logs of the QC Notebook.

- Keep the Unusual Occurrence Form (Exhibit 9-1) up to date each day. For each examinee, record any deviation from a usual procedure. Record unscheduled instrument and equipment maintenance (except for the Coulter S-Plus Jr.) and any malfunctions or unusual occurrences. Record any accident or injury to technologists working in the laboratory or phlebotomy room. Record start and end any experiments conducted in the lab to test new procedures.

9.6 Observation

The CDC's supervisory laboratory technologist will make surprise visits to the field to evaluate the quality of the laboratory work and the quality control procedures. He/she will make a structured evaluation of the quality of your work, including the procedures you use in operating the equipment, collecting and preparing samples, and following all test procedures. You will be given feedback about any problems which are identified.

10. BIOSAFETY

10.1 Venipuncture Procedures

Many serious diseases are communicable through blood, including hepatitis B and HIV. You must be extremely careful in handling needles and biological specimens and assume that every specimen is potentially hazardous. We recommend that you:

- Obtain the HBV, measles, mumps, and rubella vaccines if you have not already done so;
- Obtain up-to-date tetanus immunization;
- Have a tuberculin skin test before starting work;
- Wear gloves and a lab coat when handling biological specimens;
- Wash your hands before and after completing each venipuncture;
- When performing venipuncture, change the gloves you wear between SPs;
- Wear gloves when handling vacutainers, i.e., transporting to the laboratory;
- Handle needles with extraordinary care to prevent occurrence of injuries;
- Place used needles in the needle box provided; and
- Do not recap, bend, break, or otherwise manipulate used needles.

10.2 Laboratory Procedures

Safety is an intrinsic part of the laboratory operations. Certain precautions and procedures must be followed in order to eliminate accidents and to provide a better working environment.

- Do not allow SPs or casual visitors into the laboratory area. Closely supervise non-laboratory personnel to see that they use appropriate protective measures (wear gloves when working with laboratory equipment) and to ensure that they do not cause a hazard to themselves or to any of the laboratory personnel.

- The bench space between the hematology and blood processing stations has been reserved for setting up blood processing racks and assembling shipping materials. Do not work with hazardous or biohazardous materials in this area.

- Do not eat, drink, smoke, or apply make-up in the laboratory. Do not keep food or drinks in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or potentially infectious materials are present.

- Wear gloves and a lab coat when handling biological specimens and commercial controls and when working with laboratory equipment. Masks and eyewear (e.g., safety glasses) should be worn together or a faceshield should be worn by lab staff when in situations where spashes of blood are likely, such as blood processing and hematology.

- Change your gloves when they become visibly contaminated with blood or urine.

- Change your lab coat if it becomes visibly contaminated with blood or urine.

- Remove you lab coat and gloves before leaving the laboratory. Wash your hands.

- Wash your hands with soap and water after removing gloves contaminated with biological specimens or commercial controls, upon accidental skin contact with biological specimens or commercial controls and before leaving the laboratory.

- Protect any skin abrasions or wounds on hands, arms, face or neck from hazardous material by wearing water impermeable bandaids or bandages.

- Do not mouth pipette material containing etiological agents or sera, corrosive chemicals or any other known hazardous material. Effective hand-pipetting devices are available and must be used.

- Use non-absorbent paper to cover environmental surfaces in the phlebotomy and laboratory areas. Discard used paper in biohazard containers.

- Blood specimen tubes should be placed in a closeable, leakproof container when transported from the phlebotomy room to the laboratory.

- Open all blood specimen tubes in the biological safety cabinet. Minimize spattering of blood, plasma or serum by covering the tube with a gauze square while removing the stopper.

- Clean up any spills of biological materials immediately, using a (1:100) solution of bleach and water.

- At the end of a session, decontaminate laboratory work surfaces with a (1:100) solution of bleach and water.

- Dispose of potentially infectious waste in biohazard bags. If the outside of the bag is

contaminated, put it inside a second biohazard bag.

- Should an accident occur, refer to the safety manual for specific instructions.

10.3 Decontamination of Spills

All spills or spatters of biological materials should be cleaned up and the area decontaminated immediately. The following procedure is recommended for cleaning and decontaminating spills:

- Wear gloves and a lab coat. Heavy-weight puncture-resistant gloves such as those used for house cleaning and dishwashing are recommended;
- If a glass tube or vial has broken, use a hemostat to remove the broken glass from the area;
- Absorb blood or urine with disposable towels;
- Using a detergent solution, clean the spill site of all visible biological material;
- Wipe down the spill site with disposable towels soaked in a (1:100) solution of bleach and water; and
- Place all disposable materials used to clean and decontaminated the spill into a biohazard container.

10.4 Disposal of Hazardous Waste

Follow these rules in disposing of biohazardous waste:

- Place all needles in needle boxes;
- Dispose of all other used blood drawing and blood and urine processing supplies in rigid containers lined with leakproof, plastic biohazard bags;
- Keep needle boxes and biohazard bags in a secure site so that they are not accessible to SPs, particularly children;
- Seal all biohazard bags and boxes before removing them from the laboratory and phlebotomy areas; and

- Decontaminate biohazard containers with 1:100 bleach solution each time you remove the biohazard bag for disposal.

Disposal of biohazardous waste is the responsibility of the MEC Manager. At each stand the MEC Manager will make arrangements with a local hospital, clinic or laboratory for the disposal of our hazardous waste. It is your responsibility to meet with the MEC Manager and to comply with the arrangements that have been made.

10.5 Procedures for Accidents

If an accident occurs and you are stuck by a dirty needle, cut by contaminated glass or exposed to biological material in some other way, notify the MEC manager and immediately see the MEC physician for treatment.

If you have skin contact with biological materials, wash the area immediately with soap and water.

If you have eye contact with Lyse, Clenz or Isoton, flush your eyes immediately with plenty of cold water.

If you have skin contact with Lyse, Clenz or Isoton, flush the area immediately with large amounts of cold water.

If Lyse, Clenz or Isoton is ingested, refer to the safety manual for specific instructions and notify the physician immediately.

For your protection, document each accident on the Unusual Occurrence Form. Record the date, your tech ID, and the nature of the accident.

10.6 Fire Safety

If a fire breaks out in the laboratory, evacuate all SPs and notify the coordinator

immediately. He/She will phone the appropriate local authorities. If possible, use the fire extinguisher to put out the fire. If this is impossible, leave the MEC yourself, turn out the lights, shut the windows and leave.

11. OPERATIONAL ISSUES

11.1 Setting Up at the Beginning of a Stand

11.1.1 Introduction

Before you begin work in the field the MEC will be loaded with all of the equipment and supplies you need for the first stand. For later stands Westat, CDC, NCHS and other suppliers will ship supplies to you in the field.

Most of the laboratory supplies will be located in the belly compartments of trailers 1 and 2 of the MEC. The ICON II pregnancy test kit, pregnancy test controls, Coulter 4 C Controls, and S-Cal Calibrator will be located in a refrigerator in the laboratory. The vacutainers, ascorbic acid, and MPA will be located at the Field Office, in the Phlebotomy Room or in the laboratory.

On the day the examination staff sets up the MEC, you are to unpack the belly compartments, retrieve the supplies from the Field Office, inventory the supplies and set up each work area. Setting up a work area involves stocking the area with the appropriate supplies, performing scheduled maintenance on all instruments and equipment, and testing each instrument and piece of equipment to see that it functions properly. Notify the MEC Manager as soon as possible if you need additional supplies. Also, notify the MEC Manager if any of the equipment is malfunctioning. If necessary, call your Coulter service representative or the NCHS biomedical engineer to report malfunctioning instruments or equipment. Document all instrument and equipment malfunctions in the Unusual Occurrence Log of the Quality Control Notebook (Exhibit 9-1).

11.1.2 Setting Up the Phlebotomy Room

- Check the sink to see that the hot and cold water is running and that the drain is not clogged.
- Clean all work surfaces and storage areas.
- Use Exhibit 3-2 to determine which equipment and supplies should be used to stock the Phlebotomy Room. Place the frequently used supplies in areas of the room where they will be most accessible.

- Perform all scheduled maintenance on the refrigerator in the Phlebotomy Room before you stock it with Trutol, water, and juice.

  - Clean the refrigerator.

  - Confirm that the refrigerator temperature is maintained in the range of 39 to 46° F (4 to 7.8°C).

  - Document all maintenance in the appropriate Refrigerator/Freezer QC Log (Exhibit 9-2) in the QC Notebook.

- Check your computer terminal. Log on and access the laboratory automation system. Log off.

- Keep a small supply of Venipuncture Questionnaires on hand in the Phlebotomy Room in case of automation system failure.

11.1.3 Setting Up the Laboratory

- Check the sink to make sure the hot and cold water is running and the drain is not clogged.

- Clean the counters, cabinet surfaces, equipment surfaces and storage areas.

- Use Exhibit 4-4 to determine which supplies should be used to stock WorkStation 1 (Blood Processing and Shipping).

- Keep frequently used blood processing supplies in the storage areas close to the bench and the Laminar Flow Biological Safety Cabinet.

- Store floppy diskettes in an area where they will not be exposed to extreme heat.

- Store shippers in the belly compartment of trailers 2 and 3 until the days specimens are to be shipped.

- Store the blood processing/storage vials, vial labels, SP labels and blood processing racks in the blood processing area.

- Keep all cleaning materials in the area under the laboratory sink.

- Clean the interior and exterior of the refrigerator and the freezers. Confirm that the NCHS engineer has calibrated every Tempscribe and documented his/her activity on the appropriate Refrigerator/Freezer QC Log (Exhibit 9-2). Contact the MEC Manager if the engineer has not performed the calibration. See that the refrigerator maintains a temperature in the range of 39 to 46°F (4 to 7.8°C) and that the freezers maintain a temperature not to exceed 1°F (-17°C). Set the internal dial of the freezers to 7. Document this in the Refrigerator and Freezer QC Logs in the QC Notebook.

- Check the wall thermometers for damage. See that the room maintains a temperature in the range of 60 to 70°F (15.5 to 21°C). Document in the QC notebook.

- Perform scheduled maintenance on the Laminar Flow Biological Safety Cabinet. Clean the interior and exterior of the cabinet. Turn on the light and the blower. Check the pressure on the magnehelic pressure gauge. Document your activity in the Biological Safety Cabinet Log (Exhibit 9-8). Once a year a CDC engineer should certify the LFBSC. Also document this in the Biological Safety Cabinet Log.

- Confirm that the NCHS engineer has calibrated every centrifuge and checked the centrifuge timers, and that he/she has documented the activity in the Centrifuge QC Log (Exhibit 5-13). If the engineer has not performed and documented the centrifuge calibration, contact the MEC Manager and explain the situation.

- Check to see that the telephone in the laboratory is working properly.

- Obtain a list of the MEC, Field Office, Westat, NCHS, and Coulter Electronics telephone numbers from the MEC Manager and post it by the phone.

- Obtain the pretyped Federal Express labels, contract laboratory address labels, and return address labels to be used for labeling shippers from the Field Office Manager. Verify the Federal Express account numbers, Field Office addresses and MEC Manager's telephone number with the MEC Manager.

- Use Exhibit 4-4 to determine which supplies should be used to stock Work Station 2 (Hematology and Urine Processing, Pregnancy Testing).

- Store the hematology and Coulter supplies in the vicinity of the Coulter S Plus Jr. Store the urine processing and pregnancy test supplies in the storage areas above the sink.

- Refrigerate the ICON II pregnancy test kit, the 4 C Plus, the S-Cal calibrator and urine pregnancy test quality control materials in the laboratory refrigerator as soon as possible.

- Your Coulter representative is responsible for starting up the Coulter at the beginning of the stand (Section 5.3.3.1 Starting Up the Coulter at the Beginning of a Stand). Call the Coulter representative to confirm the time of his/her arrival at the MEC. Thirty minutes before the Coulter representative is scheduled to arrive, collect a blood sample in a 3 ml lavender tube from a MEC staff volunteer.

- Check your VAXmate and VT320 computer terminals. Log on to each terminal, access the laboratory automation system, and Log off.

- Store a supply of the pre-printed Hematology Worksheets, Blood Processing Worksheets and the Blood and Urine Shipping Transmittals in the blood processing area.

- After you have completed the set up for each area, mentally step through each procedure, blood processing, urine processing, specimen storage, urine pregnancy test, blood smear preparation, spun hematocrit determination, Coulter determinations, and shipping. Answer the following questions:

  - Is all of the necessary equipment in place and functioning properly?

  - Are all supplies readily available in the laboratory area?

11.1.4 Setting Up the MEC Laboratory Files

Two file cabinets are available for laboratory use. They should contain the following labeled expandable manila folders to be used for filing all completed laboratory documents and forms:

- Daily Appointment Schedules;

- Coulter Daily Startup Printouts;

- Coulter 4C Plus Daily Quality Control Printouts;

- Coulter 4C Plus Batch Table Quality Control Printouts

- Coulter Daily S-Cal Calibration/Verification Printouts;

- Coulter Calibration Printouts;

- Coulter SP Result Printouts;

- Hematology Log;

- Venipuncture Questionnaires;

- Hematology Worksheet;

- X B Bath Table Printouts;

- Master Log of Shipping Transmittals
  - CDC Miscellaneous Blood Transmittals;
  - CDC U-1 Urine Transmittals;
  - Blood Smear Transmittals;
  - Volatile Toxicants Blood Transmittals - Vial 28;
  - Volatile Toxicants Blood Transmittals - Vial 29;
  - Volatile Toxicants Urine Transmittals;
  - HIV Transmittals;
  - Glycosylated HGB Transmittals;
  - Glucose Transmittals;
  - Insulin/C-peptide Transmittals;
  - NHLBI lipids Transmittals;
  - C-Reactive Protein/RF Transmittals;
  - SMAC Profile Transmittals;
  - Tetanus Transmittals;
  - Thyroid Transmittals;
  - FSH & LH Hormones Transmittals;
  - Fibrinogen Transmittals;
  - Toxoplasmosis Transmittals;
  - Rubella TransmittAls;
  - IgE Transmittals;
  - DNA/HgB Adducts Transmittals;
  - Genetic Testing Transmittals;
  - Creatinine/Microalbumin (U-2) Transmittals;
  - Urinary Iodine (U-3) Transmittals;
  - Urinary Drugs (U-D) Transmittals; and

- Federal Express Receipts.

11.2 Taking Inventory

At the beginning of each stand, you will receive a Mobile Exam Center Inventory Sheet (Appendix F-1) to inventory all your consumable supplies, including those that have been carried over from a previous stand and the new supplies sent from Westat at the beginning of the stand.

The Inventory Sheet is a multipage computer generated form which is organized by component. Laboratory supplies are listed with the following component codes:

- LAB: (Laboratory Supplies). Inventory all items with a LAB code in the component column.

- ALL: (Supplies Shared by All Components). Inventory items with an ALL code in the component column only if they also have a LAB code in the Item Description column.

- OFC: (Office Supplies). Inventory items with an OFC code in the component column only if they are used in the laboratory or phlebotomy room.

To complete the Inventory Sheet, count lab supplies found in the laboratory belly compartments, the phlebotomy room, and the laboratory and record the quantity of each item in the appropriate space on the inventory sheet. When the inventory is complete, the chief lab tech should sign his/her name to the first page of the list and give the complete form to the MEC Manager.

Notify the MEC Manager immediately if you anticipate a shortage of supplies during a stand. The shipment of supplies will be coordinated with your travel schedule and a pickup date and location will be arranged. Some items, such as pencils or facial tissues, may be purchased in the field, as necessary. Submit requests for these items to the MEC Manager.

After the last examination has been given at a stand, use the Mobile Exam Center Inventory Sheet to inventory all consumable supplies remaining and enter this information on the form. Enter the amount of each type of supply remaining. Give the completed inventory form to the MEC Manager.

Every 6 months you will also inventory the non-consumable items used for the laboratory using the Mobile Exam Center Inventory Sheet Non-Consumable Items form. See Appendix F-2 for a copy of this form. For each item (equipment or supply) enter the number of each type of equipment and the amount of each non-consumable supply. Give the completed inventory form to the MEC Manager.

CDC ships several of the laboratory supplies directly to the MECs at the stand locations, rather than shipping them to Westat first. These items will not be listed on the Mobile Exam Center Inventory Sheets for laboratory supplies; however, they must be inventoried at the end of each stand and a count of each supply sent to Elaine Gunter at CDC. Elaine has provided an inventory list for the supplies she ships directly to the MECs. An example copy of the NHANES III End of Stand Inventory

for CDC-Supplied Items is given in Appendix F-3. Complete this inventory form at the end of the stand when you are counting the rest of the laboratory supplies and send it to Elaine Gunter at the following address:

Centers for Disease Control
Building 17, Room 1814, F17
1600 Clifton Road
Atlanta, GA 30333
Attn: Elaine Gunter

11.3 Ordering Additional Supplies

The Chief Medical Technologist is responsible for notifying the MEC Manager of any supplies that are needed during the stand. However, each laboratory technologist is responsible for noting any potential shortage of supplies at each work station.

11.4 The Dry Run

11.4.1 Introduction

After you set up each work station at a new stand, you will do a "dry run" session of the data collection and specimen processing procedures using volunteers. One purpose of the dry run is to help you identify any problem areas, particularly with equipment, so that they can be resolved before the stand begins. Another purpose is to provide the contract laboratories with blind duplicate samples for quality control determinations. Document the results of the dry run just as you would document the results of an actual session.

11.4.2 Preparation of Blind Split Duplicate Samples

11.4.2.1 Introduction

During the dry run you will prepare split samples for each volunteer subject, all of which will be sent to the contract laboratories. Protocols for venipuncture, blood processing, and urine

processing have been established so that split duplicate samples can be prepared for each contract laboratory without substantially increasing the amount of blood or urine to be collected from a subject. (See Exhibits 11-1, 11-2 and 11-3 for the "Dry Run" Venipuncture, Blood Processing and Urine Processing Protocols.) The results of several assays are included in both protocols and are reported to the examinee. The other assays included in Protocol 1 or in Protocol 2 are not reported to the examinee.

On the day before the dry run, the Chief Medical Technologist obtains the Daily Appointment Schedule for the dry run session and the series of ten ID numbers that have been designated for quality control purposes. The Chief Technologist uses them to assign a second set of ID numbers (duplicate ID numbers) to each scheduled subject aged 20 and over. He/she then uses the automated system to link the original NCHS number and the duplicate ID number thereby creating a "full" blood draw record, a hematology record, a "full" processing record and the appropriate storage containers for the duplicate ID number.

Also, the Chief Technologist assembles the blood processing racks for each dry run subject using the Daily Appointment Schedule and the Dry Run Blood Processing Protocol (Exhibit 11-2). Subjects with an original NCHS number ending in an odd digit are assigned to Protocol Group 1 and subjects with an original NCHS number ending in an even digit are assigned to Protocol Group 2. The Chief Technologist labels two vials for each assay, one with the appropriate vial label and the subject's original NCHS number and the other with the appropriate vial label and the subject's duplicate ID number.

11.4.2.2 Phlebotomy Procedures

On dry run day the phlebotomist at Station 1 refers to the following instructions to conduct the phlebotomy procedures:

- Access the Venipuncture Questionnaire using the subject's original ID number.
- Administer the Venipuncture Questionnaire.
- Perform the venipuncture. The tubes required for each subject are specified by the

Dry Run Venipuncture Protocol (Exhibit 11-1) which will be posted in the Phlebotomy room.

Exhibit 11-1. "Dry run" venipuncture protocol for SPs aged 20 and over

Vacutainer	Group 1 (Odd IDs)	Group 2 (Even IDs)
4 ml SST	2	0
2 ml lavender	1	1
3 ml lavender	2	2
3 ml gray	2	2
15 ml red	5	5
2 ml light blue	1*	1*
8 ml leukoprep	2	2

*Two vials are to be prepared from this vacutainer (only for SPs 40+)

Exhibit 11-2. "Dry run" blood processing protocol for SPs aged 20 and over

NOTE: Prepare two vials for each assay, one for each ID assigned to the SP

Vial ID #	Test Name	Groups 1 (odd IDs)	Group 2 (even IDs)
01	Lead	0.5	0.5
02	Erythrocyte Protoporphyrin	-	1.0
03	RBC Folate	0.1 plus 1 ml 1% ascorbic acid	-
04	Glycosylated Hemoglobin	-	remainder of 3 ml Lav
05A	Glucose	1.0	1.0
06A	Insulin/C peptide	-	1.5
07	Iron/TIBC	1.25	-
08	Ferritin/Folate	-	1.5
09	NHLBI Lipids	2.5/5.5	2.5/5.5
10	Vitamins A/E/Carotene	-	1.25
11	Cotinine	2.0	-
12	C-Reactive Protein/RF	-	0.5<60/1.0≥60
13	SMAC	1.0	-
14	Vitamin C	-	0.1 plus 0.4 ml MPA
15	Vitamin D/Calcium	All	-
16	Tetanus	0.5	1.0
17	Hepatitis	-	1.0
18	Herpes	1.0	-
19	Selenium	-	0.5
21	Thyroid	1.0	-
22	FSH & LH	0.75 (Women 35-60)	-
23	Fibrinogen	Half (40+ only)	Half (40+ only)
TO	Toxoplasmosis	0.5	-
RU	Rubella	-	0.5
IE	IgE	1.0	-
31	Genetics	All (leukoprep tube)	All (leukoprep tube)
*	Coulter CBC, bloodsmear, HCT	0.10	0.10

*Hematology Protocol

Exhibit 11-3. "Dry run" urine processing protocol for SPs aged 20 and over

NOTE: Prepare two vials for each assay, one for each ID assigned to the SP

Test ID	Group 1	Group 2
U-1	10 ml	
U-2		2.5 ml
U-3	10 ml	

- Enter the results of the venipuncture using the Dry Run Venipuncture Data Entry Screen. The automated system will present the Dry Run venipuncture protocol.

- Label the vacutainer tubes for each subject as follows:

  - Place an original NCHS number and a duplicate ID number on the 2 ml lavender tube, the 15 ml red tubes and the 2 ml blue tube.

  - Place an original NCHS number on one tube of the pair of 3 ml lavender tubes and a duplicate ID number on the other tube of the pair. Follow the same procedure for the pair of 3 ml gray tubes, the pair of 4 ml SST tubes, and the pair of 8 ml leukoprep tubes.

- Do not attempt to enter the results of the venipuncture for a subject by using the subject's duplicate ID number.

- Do not administer any glucose tolerance tests during the dry run session.

11.4.2.3 Blood Processing and Storage

The technologist at Station 1 processes blood for the dry run using the Dry Run Blood Processing Protocol (Exhibit 11-2) and the instructions given below:

- Use the same techniques for spinning and separating the blood as described in Chapter 4.

- Fill two vials for each assay filling both of the higher priority vials before going on to the next set of vials (i.e., fill both Vial 1s before going on to Vial 2). Check the vials before you fill them making sure that one vial is labeled with the appropriate vial number and the subject's original NCHS number and that the other vial is labeled with the appropriate vial number and the subject's duplicate ID number.

- Enter the results of blood processing twice--first using the subject's original ID number and then using the subject's duplicate ID number.

- Store the split duplicate sample vials in the same way you store vials from a regular session.

11.4.2.4 Hematology

The technologist at Station 2 conducts the hematology procedures for each dry run subject as indicated by the Dry Run Blood Processing Protocol (Exhibit 11-2) and the following instructions:

- Obtain the 2 ml lavender tube labeled with the subject's original NCHS number and duplicate ID number from the processing technologist.
- Perform duplicate Coulter runs using the subject's original NCHS number. If any of the parameters are outside of the lab action limits, repeat the test.
- Perform duplicate Coulter runs using the subject's duplicate ID number. If any of the parameters are outside of the lab action limits, repeat the test.
- Prepare four blood smears. Label two slides with the subject's original NCHS number and two slides with the subject's duplicate ID number.
- Select the third 2 ml lavender tube that you receive for Coulter determinations and perform a spun hematocrit in the same way as you would for a regular session. Enter the results of the spun hematocrit using the subject's original NCHS number.
- Enter the results for the Coulter, blood smears, and spun hematocrit as you would enter the hematology results from a regular session.

11.4.2.5 Urine Processing and Pregnancy Testing

The technologist at Station 2 completes the urine processing and pregnancy test procedures for each dry run subject by following the specifications given below.

- Check the Daily Appointment Schedule; if the subject is a female, aged 20 to 59 years, perform a pregnancy test.
- Refer to the Dry Run Urine Processing Protocol (Exhibit 11-3) to determine which urine tubes to prepare. Subjects with an original NCHS number that ends in an odd digit are assigned to the Protocol Group 1. Subjects with an original NCHS number that ends in an even digit are assigned to the Protocol Group 2.
- Label two 15 ml Falcon tubes for each test. Label one tube with the test number and the subject's regular NCHS number. Label the other tube with the test number and the subject's duplicate ID number.

- Fill the tubes in priority order as indicated by the Dry Run Urine Processing Protocol. Remember to fill both tubes of the higher priority assay before filling the next set of tubes.

- Enter the results of urine processing for the original ID number and again for the duplicate ID number. The Urine Processing Data Entry Screen will display the tubes to be collected for the regular urine processing protocol so you must enter the results for each individual tube.

- Store the urine tubes just as you would store urine tubes processed from a regular session.

11.4.2.6 Shipping Blood and Urine Specimens

Ship the blind split-duplicate blood and urine samples with samples from the regular sessions.

11.4.2.7 Dry Run Quality Control

Elaine Gunter (CDC) will send bottles of purified water to the MEC at the beginning of every stand. This water should be used on dry run day to check the EDTA tubes, lead free Nalgene vials, and blue cap Falcon tubes for trace metal and other contamination that may occur during regular use on the MEC. Follow the steps below to perform the quality control check with the purified water.

- Obtain a 2 ml or 3 ml EDTA tube from the blood collection tray in the phlebotomy room.

- Obtain a 2 ml lead free Nalgene vial from an open bag of vials.

- Carry the EDTA tube and the 2.0 ml lead free Nalgene vial to the laminar flow biosafety hood. (The blower should be on.)

- Open the EDTA tube under the hood. Fill the EDTA tube with purified water. Put the cap back on the EDTA tube.

- Remove the cap from the EDTA tube. Remove the cap from the 2.0 ml lead free Nalgene vial. Pour the purified water from the EDTA tube into the 2.0 ml lead free Nalgene vial. Recap the 2.0 ml lead free Nalgene vial.

- Write the date and "QC Water" on the 2.0 ml lead free Nalgene vial.

- Place the 2.0 ml lead free Nalgene vial in a plastic bag. Write the date and "QC Water" on the plastic bag.

- Take a 15.0 ml Falcon tube from an open container of Falcon tubes.

- Work in the urine processing area. Take the cap off of the 15.0 ml Falcon tube and fill the tube with 10 ml of purified water. Replace the cap on the tube.

- Label the tube with "QC Water" and the date.

- Place the 15.0 ml Falcon tube in the labeled plastic bag with the 2.0 ml Nalgene tube QC Water sample.

- Refrigerate both samples for 30 minutes.

- Freeze the QC samples with the CDC blood and urine samples collected during the same session.

- Ship the samples to CDC with the blood and urine specimens for CDC. These samples will not appear on the CDC Shipping Transmittal.

- Document the preparation and shipment of the CDC water samples in the CDC Water Sample QC Log (see Exhibit 11-4) following the instructions given below.

    - Sample Processed: Complete for EDTA Tube, 2.0 ml lead-free Nalgene vial, and 15.0 ml Falcon tube. In each column, circle "1" if you processed the tube and "2" if you did not.

    - Date Nalgene Vial and Falcon Tube Processed: Write the date you processed the Nalgene vial and Falcon tube water samples in the space provided.

    - Tech ID #: Record your tech ID number.

    - Date Nalgene Vial and Falcon Tube Shipped: Write the date you shipped the Nalgene vial and Falcon tube water samples in the space provided. If you did not ship water samples, record the reason in the Comment section of the log.

    - Tech ID #: Record your tech ID number.

    - Comment: If a water sample was not processed or shipped, write an explanation in the space provided.

Exhibit 11-4. CDC Water Sample QC Log

NHANES III
CDC WATER SAMPLE QC LOG

Sample Processed: 1 = Yes 2 = No			Date Nalgene Vial and Falcon Tube Processed	Tech ID #	Date Nalgene Vial and Falcon Tube Shipped	Tech ID #	Comment
EDTA Tube	2.0 ml Lead-Free Nalgene Vial	15 ml Falcon Tube					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
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1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					
1 2	1 2	1 2					

11.5 Packing Equipment and Supplies at the End of a Stand

11.5.1 Introduction

For security reasons, equipment and supplies must be packed away in the MEC each day after examinations are completed. You must lock up all needles and turn off all designated electrical equipment.

When preparing for a long distance move, shut down all equipment, inventory all supplies, pack all breakable and loose supplies and equipment in boxes and store them in designated areas on or under the MEC. Carefully wrap all breakable supplies before packing for the move. Place all heavy pieces of equipment which are not bolted to a counter in a customized packing box and place them on the floor in a corner of the laboratory area or in a corner in a compartment beneath the MEC. Lock all cabinet and drawers. See that all biohazardous and other waste is removed from the phlebotomy and laboratory areas.

11.5.2 Packing Up the Phlebotomy Room

- Inventory all supplies and equipment in the phlebotomy area.
- Turn off, empty, unplug and clean the refrigerator. Leave the door propped open. Secure it with tape.
- Turn off and unplug the computer terminal.
- Pack the water and juice in labeled boxes and store them under the MEC.
- Remove all loose supplies and equipment from the counter tops; pack them in boxes and label the boxes "Phlebotomy Room." If possible place the boxes in the cupboards above the counter, underneath the couch, or in corners on the floor of the phlebotomy room. If these areas are full, place the boxes, except those containing vacutainers, in the designated areas underneath the MEC.
- Pack the supplies securely in the cupboards so that they will not move around during the trip.
- Close the cupboards and lock them.
- Lock all needles in the cupboards or under the MEC.

11.5.3 Packing up the Laboratory

- Shut down the Coulter S-Plus Jr. (Section 5.3.7.4).
- Turn off and unplug all of the Coulter equipment.
- Check the expiration dates on the 4 C Plus, the S-Cal Calibrator, the urine pregnancy test controls and the ICON II pregnancy test kits. If they have not expired and will not expire before the beginning of the next stand, pack them in shippers with cool packs and ask the MEC manager to ship them back to Westat. If they have expired or will expire before the beginning of the next stand, discard the supplies and document on the NHANES III Supply Discard Log.
- Turn off, unplug, and clean the freezers and the refrigerators. If you have shipments to make to contract laboratories on the last day of the stand, pack shippers in the morning so that you can defrost and clean freezers later in the day.
- Remove the hematocrit centrifuge and the table-top centrifuge from the counter. Pack them securely in customized packing boxes and store them on the floor in the corners of the laboratory or underneath the MEC.
- Remove all supplies and small equipment from the counters and from the Laminar Flow Biological Safety Cabinet (LFBSC). Pack them in boxes and place the boxes in cupboards or drawers or in the corners on the floor in the laboratory area.
- Any supplies except the MPA and ascorbic acid that do not fit in the cupboards or cannot be secured against movement and possible breakage should be carefully packed in labeled boxes and stored in designated compartments under the MEC. Always store the MPA and ascorbic acid reagents inside the MEC where they will not be exposed to extreme heat.
- Close and lock all of the cupboards and drawers.
- Clean all counters, the LFBSC and all equipment.
- Turn off and unplug the computer terminals.
- Photocopy the pages of the Unusual Occurrence Log and Coulter Action Log that were completed during the stand and give the photocopy to the MEC manager. Return the original pages to the Quality Control Notebook.
- Photocopy <u>all</u> of the pages of the quality Control Notebook that were completed during a stand. The copies will be sent to Dolly Kendrick at NCHS. Return the original pages to the Quality Control Notebook.

11.5.4 Packing up the Laboratory Files

Empty the files and send the forms to the appropriate destinations (Section 8-8, End of Stand Shipments).

11.6 How to Deal with System Failure

If the computer is down for an extended period of time and hand written transmittals are sent out, all venipuncture questionnaire, blood processing, urine processing, hematology and shipping data must be entered into the computer later and regular shipping transmittals and diskettes must be made according to the procedure listed below. All of these steps can be completed by the laboratory tech using the Laboratory Automation Menu.

- Enter all information from paper forms for all SPs. Enter the Phlebotomy questionnaire and venipuncture data using the "Enter Phlebotomy from Paper Form" procedure (Section 10.2 of the Laboratory Automation System Manual). Enter the Urine Processing information using the regular urine processing screen (Section 6.2 of the Laboratory Automation System Manual), making sure to enter the correct date, time and session for each SP's records.

- Create any boxes which were used but not initialized during the down time, including any which were shipped. Use the "Initialize Box" screen to perform this task. To see whether a box is initialized in the computer, use the " View Boxes" screen (Section 7.4 of the Laboratory Automation System Manual).

- Enter the Blood Processing information using the regular screens (Section 7.2 of the Laboratory Automation System Manual). If new boxes with higher numbers have been "opened" for any of the destinations, the higher box number will come up automatically. Overwrite the box numbers that come up with the correct box number for each of the vials.

- Use the "Check Boxes" procedure to make sure all of the data has been entered correctly (Section 7.4 of the Laboratory Automation System Manual). This should be checked against the processing records and the hand written transmittals.

- Use the regular shipping procedure to ship to each of the destinations that specimens were sent to while the system was down. Type in the shipper number that was used, even though it is lower than the number that comes up automatically (Sections 8.2 and 8.3 of the Laboratory Automation System Manual).

- After a transmittal is printed, check the computer transmittal against the hand written transmittal. If there are any inconsistencies, correct them and then rerun and reprint the transmittal (Section 8.5 of the Laboratory Automation System Manual).

- When the transmittal is correct, make a diskette (Section 8.4 of the Laboratory Automation System Manual). Then repeat the shipping procedure to create the computer transmittals and diskettes for each of the hand written transmittals.

12. PROBLEM SITUATIONS

12.1 Laboratory Team Illness

If you are ill, notify the Chief Medical Technologist and the MEC Manager as soon as possible. The MEC Manager will attempt to secure a replacement. In the meantime, the other staff will allocate their time to venipuncture in the phlebotomy room, blood specimen processing at Work Station 1, and urine pregnancy testing, urine processing, spun hematocrit determinations and blood smear preparations at Work Station 2. In addition, as time allows, all staff will share shipping duty, operation of the Coulter-S Plus Jr. and specimen collection and processing for the volatile toxicants study.

The blood processing protocol has priority over the hematology protocol. The lavender vacutainer to be used for hematology can be refrigerated and the Coulter run as soon as possible in the next 24 hours.

12.2 Upset Sample Persons

Some children and adults may become frightened at the prospect of having venipuncture. In general, the handling of each situation should be based on your own good judgment. If an SP is just mildly nervous, let him/her watch while another family member is having venipuncture if the latter agrees to this. Apprehensive SPs, especially young children, may feel less apprehensive if they see others brave the exam. Remember that, in general, an SP should not watch while another SP is having venipuncture because each examinee has a right to privacy. If a child (or adult) has apparently decided not to participate and is demonstrating this in a disruptive manner (e.g., a tantrum), it is best not to persist. Return the SP to the coordinator's station.

12.3 Sample Person Illness

A common cold does not preclude an SP from being examined. Venipuncture should not be done if the SP has a fever or, in the physician's opinion, is too ill to be examined.

12.4 Handicapped Sample Persons

Some of the SPs will be handicapped. As a rule, this should not pose a problem. If an SP is in a wheelchair, you can perform venipuncture while the SP is sitting in the wheelchair after first locking the wheelchair wheels. If the SP is emotionally disturbed and is extremely frightened by the prospect of venipuncture, do not be too persistent in persuading him/her to participate.

12.5 Medical Emergencies

Although venipuncture is simple, some SPs may have post-examination complaints such as faintness, weakness, or hematomas. Minimize these complaints by following the venipuncture protocol. When complaints occur, follow the guidelines presented in Section 3.12 and in Appendix C.

APPENDIX A
ANSWERS TO FREQUENTLY ASKED QUESTIONS REGARDING VENIPUNCTURE

APPENDIX A

ANSWERS TO FREQUENTLY ASKED QUESTIONS
REGARDING VENIPUNCTURE

- WHY DO YOU NEED TO DRAW MY BLOOD?

  By examining a small sample of blood, researchers can obtain much useful information regarding a person's health. Over 30 tests will be done on your blood sample, and they will provide information which can't be obtained in any other way.

- HOW MUCH BLOOD WILL YOU DRAW?

  We need to draw about eight tablespoons of blood. This is much less than the amount drawn when you donate blood.

- IT SEEMS LIKE THAT'S A LOT OF BLOOD!

  Although I am drawing a little less than four ounces of blood, it may seem like more because I am using several different tubes to collect the blood. This is necessary because we need to have separate containers in order to perform different tests.

- WILL IT HURT?

  You may feel a slight pinch. The discomfort should be slight and last only a few seconds.

- CAN I GET AIDS FROM GIVING BLOOD?

  There is absolutely no chance for you to get AIDS from giving us blood. All needles are sterile and are used only once. You will be the only person to come into contact with the needle used to draw your blood.

- I JUST ANSWERED ALL THOSE QUESTIONS DURING THE INTERVIEW. HOW MUCH MORE INFORMATION DO YOU NEED?

  The questions you answered during the interview provided us with information about habits over much of your life. By testing a small sample of your blood, researchers will be able to add current information, such as level of vitamins in your blood, to the information you have already provided.

- ARE YOU A DOCTOR?

  I am a trained and certified medical technologist/phlebotomist, and I am well experienced in drawing blood. I have been specially trained for this research.

- WHAT ARE YOU LOOKING FOR IN MY BLOOD?

  A variety of tests will be done on your blood sample. These tests are not designed to detect any specific illness, but they do provide an overall picture of certain aspects of the health of people of the U.S.

APPENDIX B

CHEMICAL EXPOSURE QUESTIONNAIRE

ENGLISH AND SPANISH VERSIONS

OMB NO 09200237
APPROVAL EXPIRES

Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Center for Health Statistics

Third National Health and Nutrition Examination Survey

NHANES III

CHEMICAL EXPOSURE QUESTIONNAIRE
(Ages 20-59 Years)

NOTICE - Information contained on this form which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated for this study, and will not be disclosed or released to others without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m)

Public reporting burden for complete participation in the NHANES III is estimated to average five hours. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to PHS Reports Clearance Office; Room 721-H, Humphrey Building; 200 Independence Avenue, SW, Washington, DC 20201; ATTN: PRA, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503

SAMPLE NO.	AGE	SEX
___ ___ ___ ___ ___ ___ ___	_____	☐ Male ☐ Female

Please answer the following questions about different chemical products that you may have been exposed to by checking the appropriate box. If you answer yes in column 1, please answer the questions in columns 2 and 3.

		COLUMN 1: In the last 3 days: today or yesterday or the day before yesterday, have you either breathed or had on your skin, any of the following?				COLUMN 2: During these 3 days: Altogether, have you either breathed fumes from this product or had it on your skin?		COLUMN 3
		No	Don't Know	Yes	→	30 minutes or less	More than 30 minutes	Check here if this happened while you were working at your job?
(1)	Diesel fuel or Kerosene	☐	☐	☐	→	☐	☐	☐
(2)	Gasoline	☐	☐	☐	→	☐	☐	☐
(3)	Pain thinner, brush cleaner or furniture stripper	☐	☐	☐	→	☐	☐	☐
(4)	Varnish, lacquer, wood stain, or wet paint	☐	☐	☐	→	☐	☐	☐
(5)	Bug or insect spray	☐	☐	☐	→	☐	☐	☐
(6)	Weed killer	☐	☐	☐	→	☐	☐	☐
(7)	Solid toilet bowl deodorants	☐	☐	☐	→	☐	☐	☐
(8)	Air freshener or room deodorizer	☐	☐	☐	→	☐	☐	☐
(9)	Moth balls or crystals	☐	☐	☐	→	☐	☐	☐
(10)	PRESSURE-TREATED lumber/wood products	☐	☐	☐	→	☐	☐	☐
(11)	Fingernail polish or fingernail polish remover	☐	☐	☐	→	☐	☐	☐
(12)	Drycleaning fluid or spot remover	☐	☐	☐	→	☐	☐	☐

PHS
Rev. 10/88

(13)	Have you eaten seafood or any fish (including tuna) in the last 48 hours?	☐ Yes	☐ No
(14)	Did you drink any red wine in the last 48 hours?	☐ Yes	☐ No

09200237

Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Center for Health Statistics

Third National Health and Nutrition Examination Survey

NHANES III

CHEMICAL EXPOSURE QUESTIONNAIRE
(Ages 20-59 Years)

NOTICE - La información contenida en este formulario que permitiría identificar a cualquier individuo o establecimiento ha sido recolectada con la garantía que será mantenida en la más estricta confidencialidad, será usada solo para los propósitos establecidos para este estudio y no será divulgada o entregada a otros sin el consentimiento del individuo o del establecimiento de acuerdo con las sección 308(d) de la Ley del Servicio de Salúd Publica - Public Health Service Act (42 USC 242 m)

Carga al publico de reportaje para participación completa en el NHANES III se estima que, en promedio, sea cinco horas. Envie comentarios respetó a esta carga o cualquier otro aspecto de esta colección de información, incluyendo sugerencias para reducir esta carga al PHS Reports Clearance Officer; Room 721-H, Humphrey Building; 200 Independence Avenue, SW, Washington, DC 20201. ATTN: PRA y a Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503

SAMPLE NO.	AGE	SEX
____ ____ ____ ____ ____ ____	____	☐ Male ☐ Female

Por favor responda a las siguientes preguntas acerca de diferentes químicos a los cuales usted puede haber estado expuesto marcando el encasillado correspondiente. Si responde si en la columna 1, por favor responda a las preguntas de las columnas 2 y 3.

		COLUMNA 1: En los últimos 3 días: hoy o ayer o anteayer, ¿ha respirado o ha tenido sobre la piel algo de lo siguiente?				COLUMNA 2: Durante estos 3 días: En total, ¿ha respirado los vapores de estos productos o los ha tenido sobre la piel?		COLUMNA 3: Indique aquí si esto sucedió mientras estaba trabajando en su empleo
			No	No Sabe	Si	30 minutos o menos	Más de 30 minutos	
(1)	Combustible diesel o kerosen		☐	☐	☐	☐	☐	☐
(2)	Gasolina		☐	☐	☐	☐	☐	☐
(3)	(Diluyente/tiner) para pintura, limpiadores de brocha, o removedor de pintura para muebles		☐	☐	☐	☐	☐	☐
(4)	Barniz, laca, tinte para madera, o pintura húmeda		☐	☐	☐	☐	☐	☐
(5)	(Aerosol/"spray") para insectos		☐	☐	☐	☐	☐	☐
(6)	Producto para matar hierba mala		☐	☐	☐	☐	☐	☐
(7)	Desodorante sólido para la taza del (servicio/excusado/inodoro)		☐	☐	☐	☐	☐	☐
(8)	Purificadores de aire odorizador ambiental o de cuartos		☐	☐	☐	☐	☐	☐
(9)	Bolas de naftalina para las polillas		☐	☐	☐	☐	☐	☐
(10)	Productos de madera TRATADOS A PRESION		☐	☐	☐	☐	☐	☐
(11)	(Esmalte/pintura) para las uñas o (removedor/acetona) de (esmalte/pintura) para las uñas		☐	☐	☐	☐	☐	☐
(12)	Líquidos para limpieza en seco o quitamanchas para la ropa		☐	☐	☐	☐	☐	☐

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(13)	¿Ha comido marisco o pescado (incluyendo atún durante las últimas 48 horas?	☐ Si	☐ No
(14)	¿Ha tomado vino rojo durante las últimas 48 horas?	☐ Si	☐ No

APPENDIX C

QUESTION-BY-QUESTION SPECIFICATIONS FOR THE PHLEBOTOMY QUESTIONS

OMB NO. 0920-0237

VENIPUNCTURE QUESTIONNAIRE
AGES 1+ YEARS

a. STAFF NO. ____	b. Language of Interview 1 ☐ English 2 ☐ Spanish	c. SAMPLE NO. ____

d. GTT Half-Sample (MORNING ONLY) 1 ☐ Yes-Priority 1 2 ☐ No-Priority 2	e. 1 ☐ First Visit 2 ☐ Rescheduled Visit	f. Date __/__/__ Time __:__

1. Do you have hemophilia? This is a hereditary blood-clotting disorder.	1 ☐ Yes (13) 2 ☐ No
2. Within the past four weeks have you received any cancer chemotherapy treatment?	1 ☐ Yes (13) 2 ☐ No
3. Are you currently taking insulin?	1 ☐ Yes 2 ☐ No
4. Including your last meal and any snacks, at what time did you last have anything at all to eat?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Noon, 4 ☐ Midnight } { 1 ☐ Yesterday, 2 ☐ Today, 3 ☐ Before Yesterday }
5. Have you had anything to drink, other than water after (TIME IN ITEM 4)?	1 ☐ Yes 2 ☐ No (7)
6. At what time did you last have anything at all to drink, besides water?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Noon, 4 ☐ Midnight } { 1 ☐ Yesterday, 2 ☐ Today, 3 ☐ Before Yesterday }
7. COMPUTE NUMBER OF HOURS SINCE LATEST TIME IN ITEM 4 OR 6	_____ hours ago (number)

CDC 64.17
REV. 10/91

APPENDIX C

QUESTION-BY-QUESTION SPECIFICATIONS FOR THE PHLEBOTOMY QUESTIONS

Administer this questionnaire for all SPs age 1 and over. For SPs under age 12, you administer the questionnaire to the SPs parent or guardian. For SPs aged 12 and over, administer the questionnaire directly to the SP.

Note that questions 1-6 are to be asked directly of the respondent. The remainder of the items, a-f, Check Items A, B, and C and Items 7-15 are to be completed by you and not asked of the respondent.

Item a: Record your four digit Tech ID on the lines provided here.

Item b: Note that you cannot answer this item until after you interview the SP. Check one box to indicate whether the interview was done in English or Spanish. If the interview was done in both English and Spanish, switching back and forth between the two languages, write this in the margin, leaving both boxes blank.

Item c: Record the SPs seven digit NCHS ID number on the lines provided, using one line for each digit of the number. Obtain the SPs NCHS ID number from the SPs Control Record (Exhibit 3-4).

Item d: Check one box to indicate whether or not the SP is in the GTT half-sample. This information is available from the Control Record. Remember that all SPs who are selected for the GTT half-sample must be scheduled for morning appointments. If the Control Record indicates that the SP is in the GTT half-sample, but he/she is scheduled for an afternoon session, check the box for "Yes" and inform the Coordinator immediately. You will still administer the GTT, but the Coordinator should try to reschedule the GTT for a morning session.

OMB NO. 0920-0237

VENIPUNCTURE QUESTIONNAIRE
AGES 1 + YEARS

a. STAFF NO. ____	b. Language of Interview 1 ☐ English 2 ☐ Spanish	c. SAMPLE NO. ________

d. GTT Half-Sample (MORNING ONLY) 1 ☐ Yes-Priority 1 2 ☐ No-Priority 2	e. 1 ☐ First Visit 2 ☐ Rescheduled Visit	f. Date __/__/__ Time __:__

1. Do you have hemophilia? This is a hereditary blood-clotting disorder.	1 ☐ Yes (13) 2 ☐ No
2. Within the past four weeks have you received any cancer chemotherapy treatment?	1 ☐ Yes (13) 2 ☐ No
3. Are you currently taking insulin?	1 ☐ Yes 2 ☐ No
4. Including your last meal and any snacks, at what time did you last have anything at all to eat?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Noon, 4 ☐ Midnight } { 1 ☐ Yesterday, 2 ☐ Today, 3 ☐ Before Yesterday }
5. Have you had anything to drink, other than water after (TIME IN ITEM 4)?	1 ☐ Yes 2 ☐ No (7)
6. At what time did you last have anything at all to drink, besides water?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Noon, 4 ☐ Midnight } { 1 ☐ Yesterday, 2 ☐ Today, 3 ☐ Before Yesterday }
7. COMPUTE NUMBER OF HOURS SINCE LATEST TIME IN ITEM 4 OR 6	_____ hours ago (number)

CDC 64.17
REV. 10/91

Item e: Check the Control Record to determine whether that is the SP's first visit or a rescheduled visit. (If it is a rescheduled visit, the Control Record will indicate that on the first visit the GTT could not be done for some reason.) Check one answer code box to indicate the appropriate response.

Item f: Record the date and time that the interview began.

Item 1. This is an extremely important question since it identifies those SPs who have hemophilia. These SPs are to be excluded from venipuncture since the procedure would pose a threat to their health. Ask the question exactly as it is worded and check one answer box. If the response is "Yes," follow the skip instruction and go to the end (Item 13). Tell the respondent that he/she is not eligible for venipuncture because he/she has hemophilia. Thank the respondent for answering your questions and for cooperating in the survey. If the response is "No," proceed to Item 2.

Item 2. Determine whether or not the SP has received chemotherapy in the last four weeks as treatment for cancer. Check one answer code box for this item. Note, if the response is "Yes," the SP is ineligible for phlebotomy; follow the skip instructions and go to Item 13. Thank the respondent for participating in the survey and for answering your questions. If the response is "No," go to Item 3.

NOTE: You should continue with Item 3 if 28 days or more have elapsed since the SP's last cancer chemotherapy treatment.

Item 3. Check one box to indicate whether or not the SP is currently taking insulin.

Item 4. Record the time that the SP last had anything at all to eat. Note that this is meant to include **anything at all**, including such items as breath mints and chewing gum as well as other foods. Record the time at which the SP last ate, writing one digit of the time on each line. Determine whether the time was in

OMB NO. 0920-0237

VENIPUNCTURE QUESTIONNAIRE
AGES 1 + YEARS

a. STAFF NO. ____	b. Language of Interview 1 ☐ English 2 ☐ Spanish	c. SAMPLE NO. ____

d. GTT Half-Sample (MORNING ONLY) 1 ☐ Yes-Priority 1 2 ☐ No-Priority 2	e. 1 ☐ First Visit 2 ☐ Rescheduled Visit	f. Date __/__/__ Time __:__

1. Do you have hemophilia? This is a hereditary blood-clotting disorder.	1 ☐ Yes (13) 2 ☐ No
2. Within the past four weeks have you received any cancer chemotherapy treatment?	1 ☐ Yes (13) 2 ☐ No
3. Are you currently taking insulin?	1 ☐ Yes 2 ☐ No
4. Including your last meal and any snacks, at what time did you last have anything at all to eat?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Noon, 4 ☐ Midnight } { 1 ☐ Yesterday, 2 ☐ Today, 3 ☐ Before Yesterday }
5. Have you had anything to drink, other than water after (TIME IN ITEM 4)?	1 ☐ Yes 2 ☐ No (7)
6. At what time did you last have anything at all to drink, besides water?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Noon, 4 ☐ Midnight } { 1 ☐ Yesterday, 2 ☐ Today, 3 ☐ Before Yesterday }
7. COMPUTE NUMBER OF HOURS SINCE LATEST TIME IN ITEM 4 OR 6	_____ hours ago (number)

CDC 64.17
REV. 10/91

the a.m. or p.m., at noon or at midnight, and check one box to indicate the appropriate response. Finally, determine whether the last time the SP ate anything was today, yesterday, or before yesterday and check the appropriate box.

Item 5. Check one box to indicate whether the SP drank anything other than water after the time he/she last had something to eat, i.e., the time recorded in Item 4. As in Item 4, probe for a complete and accurate response. Check the box and follow the appropriate skip pattern.

Item 6. This item asks for the last time the SP had anything to drink besides water after the time indicated in response to Item 4. By "anything" we mean any beverage at all, even if it is noncaloric. Thus, the SP should include beverages such as tea, coffee, diet soda, club soda, etc. Record the time on the lines provided, check one box to indicate a.m./p.m./noon/midnight, and check one box to indicate the day.

Item 7. Carefully compute the number of hours since the SP last ate or drank anything other than water, using whichever time was latest. (Please note: If Item 6 has been completed, the time in Item 6 should be later than the time in Item 4. If it is not, probe to clarify.) On the basis of your computation you will determine whether or not the SP has fasted properly. Perhaps the easiest way to computer the number of hours since the SP last ate is to count forward from the time the SP last ate, using your fingers if necessary. Count only the number of complete hours that the SP fasted. For example, if the SP fasted for 9 hours and 59 minutes, you would compute this as 9 hours.

CHECK ITEM A: IS SP TAKING INSULIN OR NOT	1 ☐ Yes, taking insulin - Do venipuncture 1 only 2 ☐ No - Do venipuncture 1 and 2
8a. SP 20-59?	1 ☐ Yes (Recruit for VOL TOX) 2 ☐ No (9)
8b. SP agrees to VOL TOX	1 ☐ Yes (Draw VOL TOX Tubes) 2 ☐ No (9)
9. HIV Test (18+)	1 ☐ Not Refused 2 ☐ Refused

10. Time __ __:__ __

BLOOD TUBES FILLED (In Priority Order)	Age of SP In Years 1-3	4-5	6-11	12-19	20+
4 ml SST	0	0	0	1__	1__
2 ml lavender	0	0	0	1__	1__
3 ml lavender	1__	1__	1__	1__	1__
3 ml gray	0	0	0	0	* 1__/1__
4 ml SST	1__	0	0	0	* 0/1__
10 ml red		1__	1__	1__	0
15 ml red		1__	2__	3__	5__
2 ml light blue				0	** 1__
8 ml leukoprep				1__	1__
10 ml gray					*** 1__ Time __ __:__ __
10 ml non silicone coated red					*** 1__ Time __ __:__ __

* The 3 ml gray and 4 ml SST are the only tubes drawn for a rescheduled GTT.
** Drawn if SP is 40+
*** Drawn if SP is 20-59, and volunteers for this component for which he/she will be paid extra.

CHECK ITEM B: AGE	1 ☐ SP between ages 40 and 74 2 ☐ SP not between 40 and 74 (13)

Check Item A:

Refer to Item 3. Check box 1 if the SP is currently taking insulin. Do not administer Trutol to anyone who is currently taking insulin for any reason. Tell the respondent that he/she is not eligible for the GTT because he/she is taking insulin. Go to item 8a and perform venipuncture one only. If the SP is not currently taking insulin, check box 2. Proceed to item 8a.

Item 8a.

Do not ask this question of the SP. Obtain the SP's age from the Control Record and check one box to indicate whether or not the SP is 20-59 years old. If the SP is between the ages of 20 and 59, he/she is eligible to participate in CDC's volatile toxicant study. You should recruit any eligible SPs for the volatile toxicant study at this time. If the SP is ineligible to participate in this study, check box 2. Perform the venipuncture before proceeding with Item 9. If the SP is eligible to participate, check box 1 and go to Item 8b.

Item 8b.

If the SP agrees to participate in the volatile toxicant study, check box 1. Perform the venipuncture and draw the 10 ml gray top and 10 ml non-silicone coated red top tube **after** you have filled the other eleven tubes listed on the venipuncture protocol. Go to Item 9.

If the SP does not agree to participate in the volatile toxicant study, check box 2. Perform the venipuncture. Do **not** collect the 10 ml gray top and 10 ml non-silicone red top tubes. Go to Item 9.

Item 9.

Complete this item only if the SP is 18 years of age or older. This item asks whether or not the SP refused the HIV test. If the SP tells you at any time during the examination that he/she does not want an HIV or "AIDS" test check the box for "refused." **Do not** ask the SP if he/she wants an HIV test. If the SP does not refuse the HIV test during the examination, check the box for "Not Refused." Go to Item 10.

CHECK ITEM A: IS SP TAKING INSULIN OR NOT	1 ☐ Yes, taking insulin - Do venipuncture 1 only 2 ☐ No - Do venipuncture 1 and 2
8a. SP 20-59?	1 ☐ Yes (Recruit for VOL TOX) 2 ☐ No (9)
8b. SP agrees to VOL TOX	1 ☐ Yes (Draw VOL TOX Tubes) 2 ☐ No (9)
9. HIV Test (18+)	1 ☐ Not Refused 2 ☐ Refused

10. Time __ __:__ __

BLOOD TUBES FILLED (In Priority Order)	Age of SP in Years 1-3	4-5	6-11	12-19	20+
4 ml SST	0	0	0	1__	1__
2 ml lavender	0	0	0	1__	1__
3 ml lavender	1__	1__	1__	1__	1__
3 ml gray	0	0	0	0	* 1__/1__
4 ml SST	1__	0	0	0	* 0/1__
10 ml red		1__	1__	1__	0
15 ml red		1__	2__	3__	5__
2 ml light blue				0	** 1__
8 ml leukoprep				1__	1__
10 ml gray					*** 1__ Time __ __:__ __
10 ml non silicone coated red					*** 1__ Time __ __:__ __

* The 3 ml gray and 4 ml SST are the only tubes drawn for a rescheduled GTT.
** Drawn if SP is 40+
*** Drawn if SP is 20-59, and volunteers for this component for which he/she will be paid extra.

CHECK ITEM B: AGE	1 ☐ SP between ages 40 and 74 2 ☐ SP not between 40 and 74 (13)

Item 10.

This is the Venipuncture Log. The blood tubes to be collected for each age group are listed in priority order by age group. After you complete the venipuncture, indicate the blood tubes you filled by locating the column representing the age of the SP and writing the number of tubes of each type on the appropriate line. Go on to Check Item B.

Remember to record the time you started the venipuncture as well as the time you drew the volatile toxicant tubes.

Check Item B:

Do not ask this question of the SP. If the SP is between ages 40 and 74, he/she is eligible for the GTT. Proceed to Check Item C. If the SP is less than 40 or more than 74 years of age, he/she is ineligible for the GTT. Thank the SP for cooperating. Go to Item 13.

CHECK ITEM C	1 ☐ 3 ml gray top tube filled 2 ☐ 3 ml gray top tube not filled (13)
11. Trutol given (Do not give Trutol to persons taking insulin)	1 ☐ Yes__ __:__ __{ 1 ☐ AM 2 ☐ PM 2 ☐ No (13)
12. 2-hour blood specimen	1__3 ml gray__ __:__ __ 1__4 ml SST { 1 ☐ AM 2 ☐ PM 3 ☐ Noon
RESULTS OF EXAMINATION 13. Venipuncture 1	_____ Result Code _____ Comment Code
14. Venipuncture 2 -2 hour specimen	_____ Result Code _____ Comment Code

Result Codes

110 Blood drawn, all tubes (VP I).

Drew 2 hour 3 ml gray top and 4 ml SST tubes and completed incomplete first draw protocol (VP II).

111 Blood drawn, some tubes (VP I).

Drew one or both 2 hour tubes and did not complete the first draw protocol (VPII).

112 Safety exclusion (e.g., hemophilia, SP on cancer chemotherapy)

113 Refused - uncooperative.

114 Out of time.

115 Unable to puncture vein, phlebotomy attempted but unsuccessful.

116 SP unable to understand instructions (due to language or cognitive impairment).

117 Equipment/supply problems.

118 Other reason (limit this to: SP sent home by physician or inadequate staff to draw blood - explain).

210 Done at prior session. SP rescheduled and 1st blood draw was completed at the previous visit SP (VP I).

SP rescheduled and second blood draw was completed at the previous visit (VP II).

Check Item C:	Refer to Item 10 and check one box to indicate whether or not an initial blood specimen for the 3 ml gray top tube was drawn. If the tube was not drawn at the first venipuncture, the SP is not eligible to receive Trutol. If the 3 ml gray top tube has been collected and the SP is not taking insulin, give the Trutol to the SP and go to Item 11. If the 3 ml gray top was not collected, **do not** give the Trutol to the SP. Thank the SP for participating and go to Item 13.
Item 11.	Check one box to indicate whether or not you administered Trutol to the SP. NOTE: <u>You are never to administer Trutol to persons taking insulin</u>. If you did administer Trutol, record the time that you administered it on the line provided and check the box to indicate whether the time was in the a.m. or p.m. Then go to Item 12. If you did not administer Trutol, check the box for "No" and go to Item 13.
Item 12.	Complete this item at the time of the 2-hour blood draw. Indicate the blood tubes you filled by writing the number of tubes of each type on the appropriate line. You are also to record the time the specimen was collected. Check the box to indicate whether the specimen was collected in the a.m., p.m., or at noon. If the 2 ml light blue, 8 ml leukoprep or 10 ml gray top tubes were collected at the time of the 2-hour draw, indicate this by writing "collected at 2-hour draw" on the Venipuncture Log (Item 10) next to the result spaces for each of the tubes. Go to Item 13.
Items 13 and 14.	Select one phlebotomy result code from V110-V118 to indicate the results of the first venipuncture. Refer to the result codes on page 3 of the Venipuncture Questionnaire. If the 2-hour specimen was drawn in addition to all the tubes from the first venipuncture, use code V110. If one but not both tubes were drawn on the 2-hour draw and the first venipuncture protocol was not completed, use code 111. If the venipuncture was incomplete or unsuccessful, use the comment codes

to best explain the reason. Refer to page 4 of the Venipuncture Questionnaire for descriptions of the various venipuncture comment codes.

VENIPUNCTURE COMMENT CODE

CODE	CATEGORY	INSTRUCTIONS
01	SP refusal	SP or parent/guardian of SP refuses venipuncture/trutol
02	SP ill/faints	SP becomes ill or faint in reaction to the procedures
03	SP in prone position	SP reclining during venipuncture
04	Multistick required	Two attempts: venipuncture procedure unsuccessful (no blood)
05	SP uncontrollable	Unable to control SP; venipuncture procedure unsuccessful (no blood)
06	Veins not palpable	Unable to palpate veins; venipuncture procedure unsuccessful (no blood)
07	Condition of veins	Venipuncture unsuccessful (some or no blood) due to condition of SP's veins, e.g., too small, fragile, too deep, rolling, etc.
08	Medical exclusion	Physician excluded SP from venipuncture/trutol
09	Glove deterrent	Venipuncture unsuccessful (some or no blood) because appropriate gloves are not available
10	Dry run	Subject examined during dry run session; not a regular SP
11	Problems with needle	Venipuncture incomplete (some or no blood) due to problems with the needle, e.g., improper selection - wrong size or type; improper handling - pushed needle through vein or needle slipped out of vein; malfunction - defective sheath, etc.
12	Problems with vacutainer	Venipuncture incomplete (some or no blood) due to problems with the vacutainer, e.g., no vacuum or cracked
99	Other reasons	Limit use of this code only to reasons that cannot be coded with one of the above categories

OMB NO. 0920-0237

VENIPUNCTURE QUESTIONNAIRE
AGES 1+ YEARS

a. STAFF NO.	b. Language of Interview	c. SAMPLE NO.
____	1 ☐ English 2 ☐ Spanish	____

d. GTT Half-Sample (MORNING ONLY)	e.	f.
1 ☐ Yes–Priority 1 2 ☐ No–Priority 2	1 ☐ First Visit 2 ☐ Rescheduled Visit	Date __/__/__ Time __:__

1. ?Usted tiene hemofilia? Esto es un problema hereditario de coagulacion de la sangre.	1 ☐ Yes (13) 2 ☐ No
2. En las cuatro semanas pasadas, ?ha recibido algun tratamiento de quimioterapia para cancer?	1 ☐ Yes (13) 2 ☐ No
3. ?Esta actualmente tomando insulina?	1 ☐ Yes 2 ☐ No
4. Incluyendo su ultima comida y cualquier (merienda/"snack"), ?a que hora fue la ultima vez que comio?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Mediodia, 4 ☐ Medianoche { 1 ☐ Ayer, 2 ☐ Hoy, 3 ☐ Antes de ayer
5. ?Ha tomada alguna bebida, aparte de agua despues de la(s) (TIME IN ITEM 4)?	1 ☐ Yes 2 ☐ No (7)
6. ?A que hora tomo cualquier bebida, ademas de agua, por ultima vez?	__:__ { 1 ☐ AM, 2 ☐ PM, 3 ☐ Mediodia, 4 ☐ Medianoche { 1 ☐ Ayer, 2 ☐ Hoy, 3 ☐ Antes de ayer
7. COMPUTE NUMBER OF HOURS SINCE LATEST TIME IN ITEM 4 OR 6	_____ hours ago number

CDC 64.18
REV. 07/90

CHECK ITEM A: IS SP TAKING INSULIN OR NOT	1 ☐ Yes, taking insulin - Do venipuncture 1 only 2 ☐ No - Do venipuncture 1 and 2
8a. SP 20-59?	1 ☐ Yes (Recruit for VOL TOX) 2 ☐ No (9)
8b. SP agrees to VOL TOX	1 ☐ Yes (Draw VOL TOX Tubes) 2 ☐ No (9)
9. HIV Test (18+)	1 ☐ Not Refused 2 ☐ Refused

10. Time __ __:__ __

BLOOD TUBES FILLED (In Priority Order)	Age of SP in Years 1-3	4-5	6-11	12-19	20+
4 ml SST	0	0	0	1__	1__
2 ml lavender	0	0	0	1__	1__
3 ml lavender	1__	1__	1__	1__	1__
3 ml gray	0	0	0	0	* 1__/1__
4 ml SST	1__	0	0	0	* 0/1__
10 ml red		1__	1__	1__	0
15 ml red		1__	2__	3__	5__
2 ml light blue				0	** 1__
8 ml leukoprep				1__	1__
10 ml gray					*** 1__ Time __ __:__ __
10 ml non silicone coated red					*** 1__ Time __ __:__ __

* The 3 ml gray and 4 ml SST are the only tubes drawn for a rescheduled GTT.
** Drawn if SP is 40+
*** Drawn if SP is 20-59, and volunteers for this component for which he/she will be paid extra.

CHECK ITEM B: AGE

1 ☐ SP between ages 40 and 74
2 ☐ SP not between 40 and 74 (13)

CHECK ITEM C	1 ☐ 3 ml gray top tube filled 2 ☐ 3 ml gray top tube not filled (13)
11. Trutol given (Do not give Trutol to persons taking insulin)	1 ☐ Yes__ __:__ __{ 1 ☐ AM 2 ☐ PM 2 ☐ No (13)
12. 2-hour blood specimen	1__3 ml gray__ __:__ __ 1__4 ml SST { 1 ☐ AM 2 ☐ PM 3 ☐ Noon
RESULTS OF EXAMINATION 13. Venipuncture 1	_____ Result Code _____ Comment Code
14. Venipuncture 2 -2 hour specimen	_____ Result Code _____ Comment Code

Result Codes

110 Blood drawn, all tubes (VP I).

Drew 2 hour 3 ml gray top and 4 ml SST tubes and completed incomplete first draw protocol (VP II).

111 Blood drawn, some tubes (VP I).

Drew one or both 2 hour tubes and did not complete the first draw protocol (VPII).

112 Safety exclusion (e.g., hemophilia, SP on cancer chemotherapy)

113 Refused - uncooperative.

114 Out of time.

115 Unable to puncture vein, phlebotomy attempted but unsuccessful.

116 SP unable to understand instructions (due to language or cognitive impairment).

117 Equipment/supply problems.

118 Other reason (limit this to: SP sent home by physician or inadequate staff to draw blood - explain).

210 Done at prior session. SP rescheduled and 1st blood draw was completed at the previous visit SP (VP I).

SP rescheduled and second blood draw was completed at the previous visit (VP II).

VENIPUNCTURE COMMENT CODE

CODE	CATEGORY	INSTRUCTIONS
01	SP refusal	SP or parent/guardian of SP refuses venipuncture/trutol
02	SP ill/faints	SP becomes ill or faint in reaction to the procedures
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05	SP uncontrollable	Unable to control SP; venipuncture procedure unsuccessful (no blood)
06	Veins not palpable	Unable to palpate veins; venipuncture procedure unsuccessful (no blood)
07	Condition of veins	Venipuncture unsuccessful (some or no blood) due to condition of SP's veins, e.g., too small, fragile, too deep, rolling, etc.
08	Medical exclusion	Physician excluded SP from venipuncture/trutol
09	Glove deterrent	Venipuncture unsuccessful (some or no blood) because appropriate gloves are not available
10	Dry run	Subject examined during dry run session; not a regular SP
11	Problems with needle	Venipuncture incomplete (some or no blood) due to problems with the needle, e.g., improper selection - wrong size or type; improper handling - pushed needle through vein or needle slipped out of vein; malfunction - defective sheath, etc.
12	Problems with vacutainer	Venipuncture incomplete (some or no blood) due to problems with the vacutainer, e.g., no vacuum or cracked
99	Other reasons	Limit use of this code only to reasons that cannot be coded with one of the above categories

APPENDIX D

EMERGENCY PROCEDURES MANUAL FOR LABORATORY TEAM

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY III

EMERGENCY PROCEDURES MANUAL
FOR
LABORATORY TEAM

Prepared by:

Westat, Inc.
1650 Research Boulevard
Rockville, MD 2050

January, 1990

TABLE OF CONTENTS

Exhibits

1. EMERGENCY PROCEDURES

1.1 Safety in the Mobile Exam Center (MEC)

The best approach to emergency situations in the MEC is to prevent problems from developing into emergencies whenever possible and to be well prepared for those emergencies that cannot be avoided. It is the responsibility of all examination staff members to participate in maintaining safety in the MEC by staying alert for potentially unsafe conditions or unusual sample person (SP) behavior and by being thoroughly familiar with the current NHANES III procedures for emergencies.

Promotion of safety and prevention of accidents and emergencies in the MEC is of particular concern in NHANES III in view of the proportion of elderly sample persons that will be participating in the survey. The number of elderly respondents will be higher than on previous surveys as a result of an intentional oversampling and removal of the upper age limit on the examination. Consequently, a higher number of more elderly sample persons, including those over 75 years of age, can be expected to receive the NHANES III examination.

1.1.1 Elderly Sample Persons

Care should be taken with an elderly sample person to minimize confusion and ensure the safe completion of the examination. Elderly SPs should be escorted when moving between exam procedures and the coordinator's area and should not be left alone for more than a few minutes, such as when changing clothes.

Instructions to elderly SPs should be provided in a clear, clam manner and repeated as needed. It should not be assumed that the directions are understood until the SP offers an appropriate response. It may be necessary to guide SPs through each step required, such as providing a urine specimen or changing into a gown, to successfully complete a task. If the SP is experiencing difficulty in understanding or performing tasks, try to offer one instruction or direction at a time and wait until it is understood by the SP before proceeding.

Exam staff should be alert to complaints or reports of feeling ill from elderly SPs as occasionally the SPs do not clearly communicate the extent of their discomfort or concern. Staff members should be prepared to explore complaints and to refer potential problems to the MEC physician.

1.1.2 Sample Persons in Wheelchairs

Some SPs may arrive for the examination in wheelchairs and the exam staff should be prepared to facilitate the SPs' entry into the MEC and their progress through the examination. The field office will alert the MEC manager and coordinator that an examinee is wheelchair bound so that the lift at the end of the physician's exam room can be assembled in advance.

SPs in wheelchairs should enter the MEC through the physician's exam room where the coordinator will check them in and initiate the exam. The first procedure should logically be the physician's examination, as the SP is already in the room and should be assessed by the physician for any problems that may require exclusion or special consideration from other exam components.

If the SP can bear sufficient weight on at least one leg or can otherwise support him/herself during the transfer, the physician and another exam staff member should assist him/her into the MEC wheelchair, which is kept in the handicapped bathroom, to facilitate movement throughout the MEC. Most other wheelchairs are too large to move easily in the exam center.

Sample persons who cannot bear most of their weight on one leg and assist in transferring to the MEC chair should not be physically lifted or moved out of their wheelchairs. Lifting or moving sample persons without their assistance could result in injury to the SP or staff member and is unwarranted. SPs should remain in their wheelchair and receive the exams that can be conducted in that position. When the transfer of an SP raises questions, the physician should make the decision to transfer or not transfer an SP.

A modified examination is available for SPs who must remain in a wheelchair for the examination and is described in the coordinator's manual, Section 2.0, Standardized Procedures.

1.1.3 Children in the MEC

Children in the MEC should be monitored at all times when not participating in an exam component. Young children should not be permitted to walk through the MEC unescorted and should not interfere with the performance of any examinations.

When waiting for an exam, young or unruly children should remain in the reception area under the supervision of the MEC coordinator and assistant coordinator. Other staff members, when available, may be asked to assist the MEC coordinator and assistant coordinator during particularly busy sessions. Toys are available to entertain young children.

Staff members should be alert to the presence of children in the MEC and always investigate the behavior of young children walking unattended through the exam center.

1.2 Safety Precautions

A number of precautions have been taken to promote safety in the exam center.

Facility Preparations

- Fire extinguishers have been placed throughout the MEC to allow rapid response to fire.
- An entrance or exit door is present in every trailer.
- Emergency equipment consisting of a drug box, portable ECG machine, portable oxygen tank, and portable blood pressure equipment is kept in the same location, the physician's exam room, in each caravan.
- The MEC is a "NO SMOKING" facility. Neither staff nor SPs may smoke in the exam center. Should a staff member or SP have the need to smoke, he/she should step outside the MEC.

Mobile Examination Staff Preparation

- All examination staff members are certified in cardiopulmonary resuscitation, Course Level C, and recertified annually.

- MEC physicians are required to attend an Advanced Life Support Course.

- A physician is required to be present in the MEC when sample persons are in the center.

- At least six staff members are required to be in the trailer to assist in the event of emergencies whenever sample persons are in the exam center.

- Procedures for emergencies in the MEC have been developed and taught to examination staff members.

- Mock emergency drills are being held periodically in the Mobile Exam Center to simulate a medical emergency and permit practice of emergency procedures.

On-Site Preparations at Each Stand

- MEC managers will contact and meet with local fire and rescue representatives to orient them to the location and structure of the MEC.

- The phone number "911" is to be used if applicable for the MEC location. However, the telephone number and address of the local fire and rescue squad will be posted at the coordinator's station and in the staff room by the telephone.

- The address of the MEC will also be posted in the coordinator's station and staff room so that the location can be reported correctly.

- The field office will provide advance notice to the MEC coordinator for any sample person who will require assistance entering or moving through the exam center. The coordinator will inform the MEC managers so that appropriate preparations can be made.

- The physician will review the vitamin and medicine usage pages of the household interview for each SP prior to the examination session in which the SP's appointment is scheduled. These pages described the SP's medications, if any, that are taken for specific conditions. The household interview containing these pages will be sent over to the MEC from the field office at least one session in advance and will be kept in the MEC interview room.

- Portable ECG machine, oxygen tank, blood pressure equipment and emergency drug kit are available in the MEC and will be kept in the physician's exam room. All staff members should be able to recognize and locate this equipment without delay.

- Oxygen face masks for CPR are in 12 different locations int he MEC:

    - Body Measurement Room;
    - Audiometry Room;
    - X-ray Room;
    - Bone Densitometry Room;

- Ultrasound Room;
- Spirometry Room;
- The two Dietary Interview Rooms;
- Physician's Exam Room;
- Venipuncture Room; and
- Coordinator's Area

1.3 Reporting SP Problems and Emergencies

Sample persons who report feeling ill or who appear to feel ill should be reported to the MEC physician at the earliest opportunity. It is expected that persons fasting for long time periods may feel faint during venipuncture and in subsequent procedures or may become ill after drinking the Trutol for the GTT test. If these individuals do not recover completely in a short time, their status should be reported to the MEC physician.

At times, sample persons may have specific complaints, such as viral illnesses, joint pain or fatigue, that do not appear to warrant an emergency response. Exam staff members should offer to have the physician speak with an SP who has a particular complaint. If the SP is reluctant or refuses and there is any question about the health or safety of the SP, staff members should consult the physicians themselves for recommendations on how to proceed through the exam.

1.4 Emergency Procedures

1.4.1 Medical Emergencies

The physician will direct the response to SP's complaints, unusual behavior or obvious medical emergencies, such as loss of consciousness. The appropriate response of the physician will be to stabilize the SP in distress and facilitate a safe and expedited transfer to the nearest medical facility. The response of the physician is limited by a number of factors. The NHANES III's mission is data collection and therefore the MEC is <u>not</u> set up to treat or manage medical problems. There is no trained medical staff in the MEC to assist the physician in case of an emergency (i.e., registered nurses, physician assistants, etc.) which is necessary in a more sophisticated response. This limits what the physician can and should do in the MEC. The MEC is not a diagnostic or treatment center,

nor are the physicians necessarily licensed in the states in which the examinations are being conducted. The liability insurance obtained for Westat physicians does not cover any type of treatment procedure (except emergency stabilization).

1.4.2 Reporting Emergencies

- SP complaints, unusual behavior, or obvious emergencies such as loss of consciousness should be reported to the MEC physician immediately. Any questionable situation should be considered an emergency and evaluated by the physician.

- If you find an SP unconscious or unable to be alone, stay with the SP, call another staff person to help immediately, and start CPR if needed.

- The physician will assume command of the situation and make staff assignments as appropriate.

1.4.3 Staff Assignments

The physician will direct the emergency response. In order to facilitate the response, MEC staff members may be asked to function in one of several roles:

- **Assistants** - Two assistants will stay with the physician and the SP to help with CPR or any other task required and allow the physician to devote full attention to the SP.

- **Runner** - The runner will be directed to place calls for emergency assistance. If possible, calls should be placed from the phone in the staff room to avoid alarming the other SPs. The runner will also help keep other MEC staff members informed of the situation and will be available to obtain emergency equipment or other needed items and perform tasks directed by the physician.

- **Recorder** - The recorder will be responsible for documenting the time of the emergency and the sequence of events that follow the initiation of emergency care on the MEC Emergency Recording Form (Exhibit D-1). The order of the events and time sequence are the critical elements in documentation. MEC Emergency Recording Forms will be kept in the emergency drug kit.

  Instructions for completing this form will be found in Section 1.4.5 of this manual.

- **Supervisor** - The supervisor will assist in clearing the halls and staff room, assist in notifying the emergency squad, and keep the rest of the MEC under control while the emergency is in progress. In most instances, the MEC manager will fill this role.

However, another staff member will be designated by the physician in the manager's absence.

- **Guides for Rescue Squads** - Two staff members will be posted at the entrances to trailers 1 and 4 to guide the rescue squad into the MEC. The MEC Manager will designate staff members for these assignments.

Other staff members should remain clear of the site and assist in keeping order in the MEC unless asked to help. Staff members should remain in exam rooms with other SPs until the emergency is over.

The MEC Emergency Procedure Checklist (Exhibit D-2) and the Guidelines or Documentation of MEC Emergency form (Exhibit D-3) are located in all the major hallways.

1.4.4 Documentation

After the SP has left the MEC, the MEC manager should make sure that the incident and outcome are documented in the automated system. The physician will also complete a full report on a separate form, the Incident/Emergency Report Form. The recorder's notes of the event will be especially important in the completion of the physician's report and should be kept with the physician's documentation of the incident.

All documentation of the emergency should be forwarded to Catherine Novak, Director of MEC Operations, as soon as possible after the incident.

Exhibit D-1. MEC Emergency Recording Form

NHANES III

MEC EMERGENCY RECORDING FORM

DATE _____

TIME STARTED _____

TIME ENDED _____

LOCATION OF EMERGENCY _____

SP NAME _____

SP SAMPLE NUMBER _____

PHYSICIAN NUMBER _____

SP FOUND BY _____

SP STATUS POST EMERGENCY _____

Time	Heart Rate/ Rhythm	Blood Pressue	Respiratory Rate	Pulse (describe)	Other Observations	Medications Treatments/IVs

Exhibit D-1. MEC Emergency Recording Form (continued)

Time	Heart Rate/ Rhythm	Blood Pressue	Respiratory Rate	Pulse (describe)	Other Observations	Medications Treatments/IVs

Exhibit D-2. NHANES III MEC Emergency Procedure Checklist

NHANES III
MEC EMERGENCY PROCEDURE CHECKLIST

- Stay with the SP. Institute CPR if necessary.
- Have someone else call physician.
- Physician to designate 2 assistants, runner, reporter, someone to call emergency/rescue team, supervisor, guides for rescue squad.
- Emergency kit, portable ECG, medication pages from Household Questionnaire should be brought to emergency location.
- Staff not involved in emergency should clear area of emergency.

Exhibit D-3. NHANES III Guidelines for Documentation of MEC Emergency

NHANES III
GUIDELINES FOR DOCUMENTATION OF MEC EMERGENCY

1. Time incident began
2. Where subject found and by whom
3. Description of characteristics of subject (age, sex, race)
4. Clinical symptoms observed
5. Time physician was notified and by whom
6. Names of designated recorder, runner and 2 assistants, and the person told to call emergency squad.
7. Were emergency kit, portable ECG, and medication sheets obtained? If not, why not?
8. Treatment/procedures which were initiated and at what times
9. Time ambulance arrived/left
10. Did physician accompany subject in ambulance?
11. Did family member accompany subject in ambulance?
12. Was SP's physician notified?

1.4.5 MEC Emergency Recording Form

A hard copy form entitled "MEC Emergency Recording Form" will be utilized for recording the sequence of events or actions that are taken during the emergency response. An example of the form is shown in Exhibit D-1. The form is completed by the staff member designated by the physician for recording purposes. Copies of the form will be kept in the Emergency Kit. To complete the form, the staff member includes the following information:

- Date of the emergency response;
- Time that the emergency response started;
- Time that the emergency response ended;
- Location of the emergency in the MEC;
- Examinee's name;
- Examinee's sample number;
- Physician's name;
- Staff member that fund the SP and initiated the emergency response; and
- SP post-emergency status including whether or not the SP was transported by ambulance to emergency room.

The second part of the form is for the specific measurements (including the time done) during the emergency response such as:

- Heart rate and rhythm;
- Blood pressure;
- Respiratory rate;
- Pulse measurement;
- Other observations; and
- Medications/treatments/IVs administered.

1.4.6 Medical Referrals

Based only on the MEC examination, the physician will place the examinee in one of three levels:

Level I	Major medical findings that warrant **immediate** attention by a health care provider; emergencies.
Level II	Major medical findings that warrant attention by a health care provider in the **next 2 weeks** because they are expected to cause adverse effects within this time period.
Level III	No medical findings; minor, medical findings that an examine already knows about, is under care for, or does not require prompt attention by a medical provider.

1.4.7 Report of Findings

Generally it is not necessary to discuss findings with the examinees unless referrals are needed. A single examination often does not allow an adequate interpretation of findings nor provides a solid foundation for giving specific advice to an examinee. Furthermore, providing the examinee wit the findings may be contrary to what his/her personal or clinic physician has decided to so. Only the examinee's personal physician or community clinic physician who has the individual's long-term records available should interpret the findings and decide what to tell the person. For these reasons, SPs are encouraged to discuss the results with their physician. Reports of findings include a physical findings report summary, a Centers for Disease Control (CDC) laboratory report, and if done, an ECG tracing.

1.5 Psychiatric/Behavioral Problem Procedures

1.5.1 Psychiatric/Behavioral Problem SPs

There are situations which may arise regarding SP behavior which will require special handling. They include:

- Psychological injuries; deteriorations and/or deprivations - Due to changes in mental status, the SP may seem confused or may actually have dementia. MEC staff should accept these examinees as they are, without judgment or criticism, and encourage maximum participation;

- Inebriation due to intoxication with alcohol and/or drugs - the SP will be less able to grasp ideas, reason, problem-solve, calculate and attend to the tasks at hand. Therefore, the potential for injury, trauma and violence is present; and

- Belligerence - This will include SPs with non-complaint or abusive behavior.

If the SP is so demented, confused, intoxicated or belligerent that it is impossible to continue the examination, the MEC Manager should calmly terminate the MEC Examination and have the examinee leave the center without delay. For those examinees who require assistance going home, have a family member escort them home or call a cab. An incident form should be completed and the incident reported by telephone of the Director of MEC Operations as soon as possible.

1.6 Natural Disaster Procedures

In the event of an unforeseeable occurrence (i.e., hurricane, tornado, fire, etc.), certain procedures should be followed depending on whether an examination session is taking place in the MEC or an examination session is scheduled for the MEC.

1.6.1 Scheduled Examination Session

(a) Predicated Event - The stand manager should contact the home office for instructions regarding whether to cancel the session. If so, the stand manager will notify the MEC manager, who in turn will notify the MEC staff.

(b) If mobile homes and trailers have been notified to be evacuated, the stand manager should make the decision to cancel the session. He/she should then call the home office to report the occurrence and the canceled session and notify the MEC manager. The MEC manager should notify the MEC staff.

c) The MEC manager may place the staff on stand-by procedures, with instructions to be ready to work but accessible by phone at home awaiting orders from the MEC manager regarding status of operations.

1.6.2 Examination Session Being Conducted

In the event that an examination session is being conducted and SPs are in the MEC when you are notified of a pending natural event, the following procedures should be followed:

- The MEC manager and the physician should make a joint decision regarding closing the MEC and/or canceling the session. The first priority should be the safety of the SPs and staff;

- The MEC staff and SPs should evacuate the MEC as soon as possible and go directly to a safe haven, perhaps a building close by or the hotel the staff are staying in. The staff and SPs should remain at this site until the impending event is over and it is safe to proceed outside;

  A decision should be made once the event is over, by the MEC manager and physician, as to whether or not to continue this session, if the SPs are willing to stay;

- If either the decision is made to cancel the session or the SPs decline to remain, the appointments for those SPs will need to be rescheduled using the usual procedure;

- It is essential for the MEC manager to notify the stand manager of the outcome of events. The stand manager should then notify the home office immediately;

- Examiners who were conducting an exam or interview at the time evacuation of the MEC was ordered should be sure to accurately document the reason for interruption of the exam in the automated system and in room logs as soon as possible after the MEC is reopened; and

- The MEC coordinator should be sure to document the reason for exam components omitted because of the closure of the MEC.

APPENDIX E
DUTIES OF THE CHIEF MEDICAL TECHNOLOGIST

Appendix E

Duties of the Chief Medical Technologist

The Chief Medical Technologist is the most senior member of the laboratory team. The Chief Medical Technologist is responsible for overseeing the activities of the laboratory team, quality control, inventory of supplies, and communication with the MEC Manager. Each of these activities is discussed in more detail in the sections which follow.

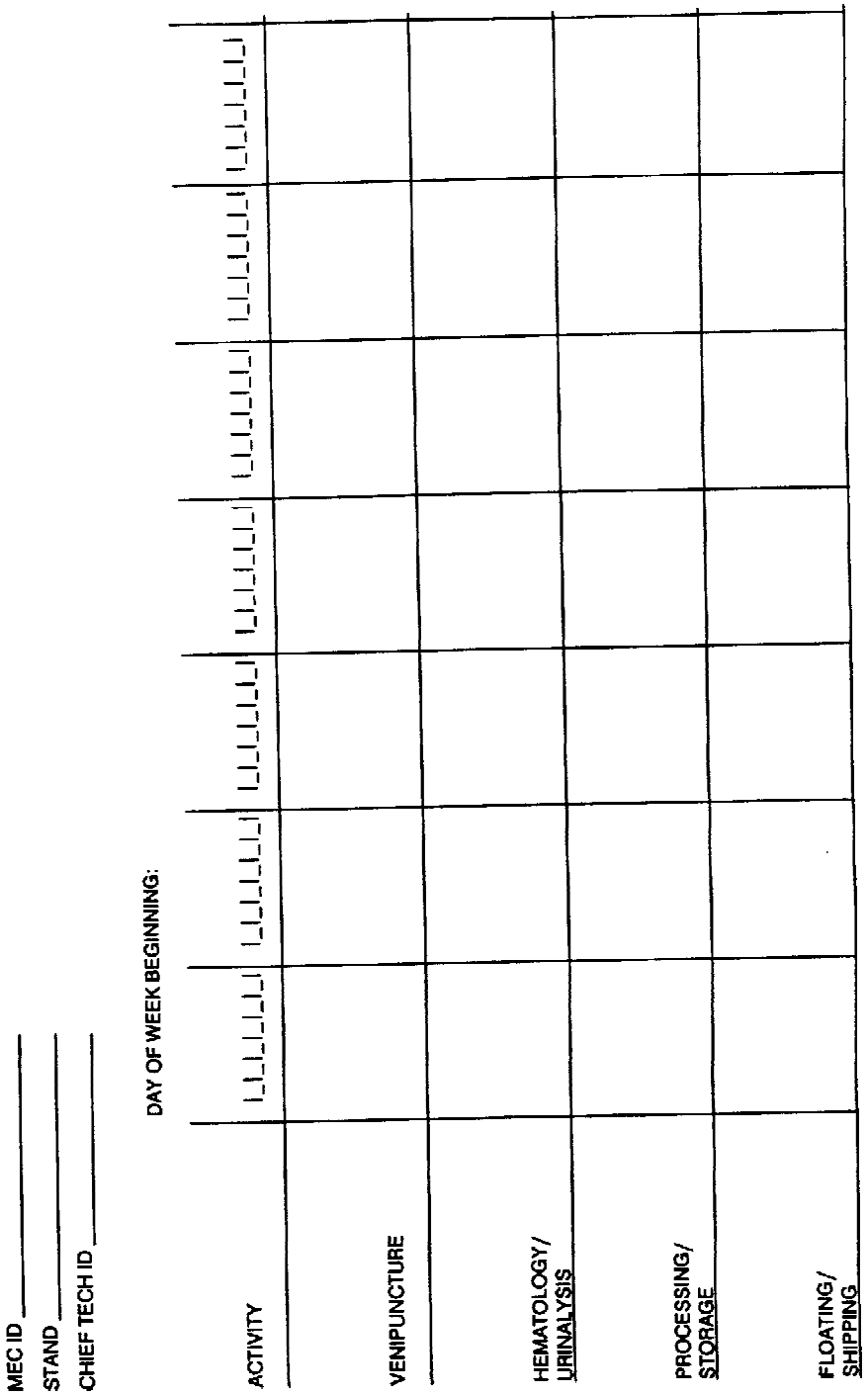
E.1 Overseeing the Activities of the Laboratory Team

The Chief Medical Technologist is responsible for assigning the staff to each of the work stations in the MEC. These assignments are made for one week so that one technologist is responsible for one work station for one week before rotating to the next work station. It is very important that all of the medical technologists rotate through all of the work stations at each stand and that on the average each technologist works at each work station for about the same amount of time over the course of each year of the survey. The work schedule (Exhibit E-1) is to be completed and posted in a prominent place in the main laboratory area.

In addition to making work assignments, the Chief Medical Technologist is to monitor the work of each person in the lab. This is accomplished informally through observation and formally through the systematic review of all of the quality control documentation produced in the lab (see Quality Control).

We do not require that the Chief Medical Technologist review all of the venipuncture and processing results. These results are reviewed by the NCHS staff who are responsible for quality control. However, if it becomes apparent that there is a problem either with venipuncture or processing, the Chief Medical Technologist will be required to begin a systematic daily review of these components of the laboratory.

Exhibit E-1: Work Schedule



E.2 Quality Control

It is the Chief Medical Technologist's responsibility to ensure that all of the equipment used by the staff are properly calibrated and properly maintained. To do this the Chief Medical Technologist reviews the calibration data or QC log for each piece of equipment or supply on a regular basis. The following documentation is to be reviewed and initialed by the Chief Medical Technologist weekly:

- Coulter Scheduled Cleaning Procedures and Operational Checks;
- Coulter IQAP Forms;
- Coulter Action Log;
- ICON QC Log;
- Unusual Occurrence Form;
- Ambient Air Temperature QC Logs;
- Refrigerator/Freezer QC Logs; and
- Biological Safety Cabinet Log.

On a monthly basis the Chief Medical Technologist is to review and initial:

- Coulter Reagent Log; and
- Supply Use Control Logs.

Finally, once each stand the Chief Medical Technologist is to review and initial:

- Laboratory Centrifuge QC Log; and
- MLA Pipette QC Log.

E.3 Inventory and Ordering of Supplies

The Chief Medical Technologist is responsible for making inventory assignments at the beginning and end of each stand and for reviewing and initialing the final Laboratory Supply/Inventory Order Log at the beginning and end of each stand. As with all assignments, staff are rotated through different inventory stations.

The Chief Medical Technologist is also responsible for informing the MEC Manager if it is necessary to order supplies while the MEC is in the field. This is done by completing the appropriate Laboratory Supply/Inventory Order Log and/or reviewing and initialing any Logs prepared by other staff.

E.4 Communication with the MEC Manager

To simplify communication in the field, the laboratory team communicates with the MEC Manager through the Chief Medical Technologist. Thus, when it is necessary to arrange for an equipment repair, additional supplies, dry ice for shipping, or any other matter which is the responsibility of the MEC Manager, the staff is to communicate this to the Chief Medical Technologist and the Chief Medical Technologist is to communicate this to the MEC Manager.

APPENDIX F

INVENTORY SHEETS - EXAMPLES

APPENDIX F-1

MOBILE EXAM CENTER STAND INVENTORY

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
0010	LAB	ACCUVETTES, COULTER DILUTION VIALS	EA	_____	0010	LAB
0260	LAB	APPLICATOR, WOOD, NON-STERILE	BX	_____	0260	LAB
0270	LAB	APRON, LAB, PLASTIC, DISP, 28 X 45	EA	_____	0270	LAB
0290	LAB	BAG, PLASTIC, WHIRL, 6 X 8	EA	_____	0290	LAB
0320	LAB	BAND AID, 3/4"	EA	_____	0320	LAB
0321	LAB	BAND AID, CHILD, SNOOPY OR TURTLES	EA	_____	0321	LAB
0420	LAB	BAG, BIOHAZARD, LRG, 24 X 36"	EA	_____	0420	LAB
0430	LAB	BAG, BIOHAZARD, SM, 8.5" X 11"	EA	_____	0430	LAB
0450	LAB	CONTAINER, BIOHAZARD, 2 GL, SHARPES 897	EA	_____	0450	LAB
0462	LAB	CONTAINER, BIOHAZARD, 5 GL, X-LARGE	EA	_____	0462	LAB
0463	LAB	CONTAINER, BIOHAZARD, YELLOW, SM	EA	_____	0463	LAB
0600	LAB	BOX, CRYO, 2" VIAL BOX, WITH 9 X 9 DIVIDER	BX	_____	0600	LAB
0610	LAB	BOX, CRYO, 3" VIAL BOX, WITH 5 X 5 DIVIDER	BX	_____	0610	LAB
0840	LAB	BLEACH, CLOROX, NO SCENT, GL (HAZ GOOD)	BT	_____	0840	LAB
1000	LAB	CRACKER, GRAHAM, INDIVIDUALLY PACKED	PG	_____	1000	LAB
1080	LAB	CUP, DRINKING, 6 OZ, PLASTIC (FOR TRUTOL)	EA	_____	1080	LAB
1100	LAB	CUP, URINE, PLASTIC, STERILE	EA	_____	1100	LAB
1180	LAB	GLUCOSE TOLERANCE BEVERAGE (TRUTOL)	EA	_____	1180	LAB
1220	LAB	WATER, DISTILLED, 1 GL	EA	_____	1220	LAB
1221	LAB	WATER, DEIONIZED, GLASS BOTTLES	EA	_____	1221	LAB
1575	LAB	FACE SHIELD, DISP	EA	_____	1575	LAB
1805	LAB	GASKET, FOR CENTRIFUGE	EA	_____	1805	LAB
1872	LAB	COLD SPOR, SURFACE DISINFECTANT	BT	_____	1872	LAB
1890	LAB	GLOVE, LATEX, SM, MEDIPAK, 100'S (LAB ONLY)	EA	_____	1890	LAB
1895	LAB	GLOVE, INFANT, SM, 100'S	BX	_____	1895	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
1900	LAB	GLOVE, LATEX, MED, MEDIPAK (LAB ONLY)	EA	_____	1900	LAB
1905	LAB	GLOVE, INFANT, MED, 100'S	BX	_____	1905	LAB
1910	LAB	GLOVE, LATEX, LRG, MEDIPAK (LAB ONLY)	EA	_____	1910	LAB
1915	LAB	GLOVE, INFANT, LRG, 100'S	BX	_____	1915	LAB
1981	LAB	HAND CREAM, VASELINE, LRG DISPENSER	EA	_____	1981	LAB
2070	LAB	ICE PELLET, 1620/BX	BX	_____	2070	LAB
2081	LAB	PREGNCY KIT, ICON, 24 TEST, REFER, DTD	EA	_____	2081	LAB
2082	LAB	URINE CONTROL, ICON PREG-KIT, DTD/REFER	BX	_____	2082	LAB
2090	LAB	HEEL WARMER, INFANT, DISP	EA	_____	2090	LAB
2112	LAB	INSIDE TO BOX, 5 X 5, FOR CRYO BOX	EA	_____	2112	LAB
2120	LAB	CARDS, INDEX, 5 X 7	EA	_____	2120	LAB
.30	LAB	FILTER, ISO, 16MM X 6"	EA	_____	2130	LAB
2150	LAB	ISOTON III, COULTER, CLTR-8546733	EA	_____	2150	LAB
2170	LAB	JUICE, ORANGE, 6 OZ	EA	_____	2170	LAB
2175	LAB	JUICE, APPLE, 6 OZ	EA	_____	2175	LAB
2190	LAB	KIM WIPES, LINT FREE, KIMBERLY CLARK	BX	_____	2190	LAB
2230	LAB	LAB COAT, PAPER, WHITE	EA	_____	2230	LAB
2240	LAB	LABEL, KEEP FROM HEAT	EA	_____	2240	LAB
2241	LAB	LABEL, KEEP FROZEN	EA	_____	2241	LAB
2242	LAB	LABEL, REFRIDGERATE	EA	_____	2242	LAB
2243	LAB	LABEL, CONTAINS DRY ICE	EA	_____	2243	LAB
2244	LAB	LABEL, HUMAN BLOOD	EA	_____	2244	LAB
2245	LAB	LABEL, DO NOT FREEZE	EA	_____	2245	LAB
2246	LAB	LABEL, PRIORITY MAIL	EA	_____	2246	LAB
.260	LAB	LABEL, TEDDY BEAR	EA	_____	2260	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
2261	LAB	LABEL, BLOOD SAMPLE FOR MEDICAL USE	EA	_____	2261	LAB
2480	LAB	MARKER, LAB, BLACK, WATER RESISTANT	EA	_____	2480	LAB
2490	LAB	MARKER, LAB, RED, WATER RESISTANT	EA	_____	2490	LAB
2880	LAB	PAPER, PRINTER, 2 PLY, COULTER ELEC	BX	_____	2880	LAB
2905	LAB	PARAFILM (USED IN HEMOTOLGY)	RL	_____	2905	LAB
3210	LAB	PIPET TIP, LRG, NON-STER, 3 3/8", 200-1K UL	EA	_____	3210	LAB
3220	LAB	PIPET, TRANFER, STERILE, SAMCO PLASTIC	EA	_____	3220	LAB
3230	LAB	PIPET TIP, SM, NON-STER, 1 7/8", 10-200 UL	EA	_____	3230	LAB
3400	LAB	RIBBON, PRINTER, COULTER	EA	_____	3400	LAB
3515	LAB	VIAL, SARDSTEDT, 3.5 ML W/LIDS	EA	_____	3515	LAB
3520	LAB	VIAL, SARDSTEDT, 6.0 ML W/LIDS	EA	_____	3520	LAB
3670	LAB	SHIPPER, INSULATED, LARGE	EA	_____	3670	LAB
3671	LAB	SHIPPER, INSULATED, MEDIUM	EA	_____	3671	LAB
3690	LAB	PAPER, SHIPPING, LARGE SHEETS	EA	_____	3690	LAB
3710	LAB	BOX, SLIDE, 100'S	EA	_____	3710	LAB
3723	LAB	SLIDE, MICRO, GOLD, CLAY ADAMS, 72'S	BX	_____	3723	LAB
3730	LAB	SOAP, DERMA-CIDOL, GL	EA	_____	3730	LAB
4065	LAB	SYRINGE, 3 CC (FOR LAB COULTER USE)	EA	_____	4065	LAB
4110	LAB	TAPE, SURGICAL, TRANSPORE, 1"	RL	_____	4110	LAB
4175	LAB	CHART, TEMP SCRIBE, FOR REFRIGERATOR	EA	_____	4175	LAB
4176	LAB	PEN AND IKN, TEMP SCRIBE	EA	_____	4176	LAB
4280	LAB	TOURNIQUET, LATEX, ADULT	EA	_____	4280	LAB
4290	LAB	TOWELETTE, WET NAPS	EA	_____	4290	LAB
4305	LAB	TOWEL, PLAST, 3 PLY, 13 X 19", BLUE OR WHITE	EA	_____	4305	LAB
4330	LAB	SEALANT, TUBE, HEMATOCRIT DETERMINATION	EA	_____	4330	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
4390	LAB	TUBE, FALCON, 50 ML ED 2098	EA	_____	4390	LAB
4400	LAB	TUBE, FALCON, 15 ML	EA	_____	4400	LAB
4405	LAB	TUBE, CRYO, STERILE, 5 ML, URINE SAMPLE	EA	_____	4405	LAB
4410	LAB	TUBE, HEMATOCRIT, BLUE TOP, MS-MICRO VIAL	EA	_____	4410	LAB
4430	LAB	TIE, TWIST, FOR BIOHAZARD BAGS	RL	_____	4430	LAB
4440	LAB	VACUTAINER, #6383, GRAY 3 ML	EA	_____	4440	LAB
4450	LAB	VACUTAINER, #6384, LAVENDER, 2 ML	EA	_____	4450	LAB
4460	LAB	VACUTAINER, #6385, LAVENDER, 3 ML	EA	_____	4460	LAB
4470	LAB	VACUTAINER, #6394, LT BLUE, 1.8 ML	EA	_____	4470	LAB
4480	LAB	VACUTAINER, #6430, RED, 10 ML	EA	_____	4480	LAB
4485	LAB	VACUTAINER, LEUCO PREP, SPECIAL RED/GREEN	EA	_____	4485	LAB
190	LAB	VACUTAINER, #6428, GRAY, 10 ML	EA	_____	4490	LAB
4500	LAB	VACUTAINER, #6432, RED, 15 ML	EA	_____	4500	LAB
4510	LAB	VACUTAINER, #6381, RED, 3 ML	EA	_____	4510	LAB
4530	LAB	VACUTAINER, #6514, RED/GRAY, SST	EA	_____	4530	LAB
4540	LAB	VACUTAINER, #4597, PEDIATRIC TUBE ADAPTER	EA	_____	4540	LAB
4550	LAB	VACUTAINER, #4893, LARGE GREEN	EA	_____	4550	LAB
4560	LAB	VACUTAINER, #7292, PEDIATRIC, SMALL	EA	_____	4560	LAB
4570	LAB	VACUTAINER, #7215, 20 GA, 1 1/2", MULTI-SAMPLE	EA	_____	4570	LAB
4575	LAB	VACUTAINER, #7213, 21 GA, MULTISAMPLE	EA	_____	4575	LAB
4580	LAB	VACUTAINER, #7251, 21 GA, 3/4",BUTTERFLY	EA	_____	4580	LAB
4591	LAB	VACUTAINER, #7253, 23 GA, 3/4", BUTTERFLY	EA	_____	4591	LAB
4593	LAB	VACUTAINER, #4919, 19 GA, 7/8" BUTTERFLY	EA	_____	4593	LAB
4615	LAB	WADDING, SHIPPING, BROWN PADDING 50'S	BX	_____	4615	LAB
760	LAB	4C TRI PAC, COULTER (DTD,REFER)	PG	_____	4760	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
4762	LAB	CLENZ, COULTER 10 L, CUBE	EA	_____	4762	LAB
4770	LAB	LYSES III, COUNTER, COL#854-6757	EA	_____	4770	LAB
5000	LAB	FORM, HEMATOLOGY WORKSHEET, NCHS	EA	_____	5000	LAB
5001	LAB	FORM, LIPID, NCHS	EA	_____	5001	LAB
5002	LAB	FORM, CDC BLOOD AND URINE TRANMITTAL	EA	_____	5002	LAB
5003	LAB	FORM, CDC VOLATILE TOXICANTS BLOOD FORM	EA	_____	5003	LAB
5004	LAB	FORM, CDC VOLATILE TOXICANTS URINE FORM	EA	_____	5004	LAB
5005	LAB	FORM, CDC HIV I FORM	EA	_____	5005	LAB
5006	LAB	FORM, COC GENETIC TESTING FORM	EA	_____	5006	LAB
5007	LAB	FORM, GLYCOSYLATED HGB FORM	EA	_____	5007	LAB
5008	LAB	FORM, GLUCOSE (GTT) FORM	EA	_____	5008	LAB
5009	LAB	FORM, INSULIN/C-PEPTIDE FORM	EA	_____	5009	LAB
5010	LAB	FORM, C-REACTIVE PROTEIN/RHEUMATOID FORM	EA	_____	5010	LAB
5011	LAB	FORM, SMAC PROFILE FORM	EA	_____	5011	LAB
5012	LAB	FORM, TETANUS FORM	EA	_____	5012	LAB
5013	LAB	FORM, THYROID FORM	EA	_____	5013	LAB
5014	LAB	FORM, FSH AND LH FORM	EA	_____	5014	LAB
5015	LAB	FORM, FIBRINOGEN FORM	EA	_____	5015	LAB
5016	LAB	FORM, CREATININE/MICORALBUMIN FORM	EA	_____	5016	LAB
5017	LAB	FORM, URINARY IODINE FORM	EA	_____	5017	LAB
5018	LAB	FORM, CDC SLIDE FORM	EA	_____	5018	LAB
5019	LAB	FORM, MLA PIPETTLE TRANSMITTAL	EA	_____	5019	LAB
5020	LAB	FORM, MEMO TO NCHS CONTRACT LABS	EA	_____	5020	LAB
5021	LAB	FORM, CDC INVENTORY FORM, 3/90	EA	_____	5021	LAB
5022	LAB	FORM, PREGNANCY TEST NOTIFICATION FORM	EA	_____	5022	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
5023	LAB	FORM, BLOOD PROCESSING WORKSHEET, NCHS	EA	_____	5023	LAB
5024	LAB	FORM, VENIPUNCTURE QUEX, ENG, NCHS, 7/90	EA	_____	5024	LAB
5025	LAB	FORM, VENIPUNCTURE QUEX, SPANISH, NCHS, 7/90	EA	_____	5025	LAB
5028	LAB	FORM, SECOND URINE SPECIMEN NOTIFICATION	EA	_____	5028	LAB
5029	LAB	FORM, CHEMICAL EXPOSURE QUEX, ENG, 10/88	EA	_____	5029	LAB
5030	LAB	FORM, CHEMICAL EXPOSURE QUEX, SPAN, 10/88	EA	_____	5030	LAB
5049	LAB	LOG, AIR TEMPERATURE RECORDER LOG	EA	_____	5049	LAB
5050	LAB	LOG, SCHEDULED CLEAN/PROCED/OPS CHK LOG, 9/86	EA	_____	5050	LAB
5051	LAB	LOG, 4C/4C PLUS CELL CONT-ABNORM LOW LOG, 5/85	EA	_____	5051	LAB
5052	LAB	LOG, 4C/4C PLUS CELL CONT/NORMAL LOG, 5/85	EA	_____	5052	LAB
5053	LAB	LOG, 4C/4C PLUS CELL CONT-ABNOR HIGH LOG, 5/85	EA	_____	5053	LAB
)54	LAB	LOG, COULTER ACTION LOG	EA	_____	5054	LAB
5055	LAB	LOG, COULTER REAGENT LOG	EA	_____	5055	LAB
5056	LAB	LOG, MLA PIPETTE QC LOG	EA	_____	5056	LAB
5057	LAB	LOG, UNUSUAL OCCURRENCE LOG	EA	_____	5057	LAB
5058	LAB	LOG, SUPPLY USE CONTROL LOG	EA	_____	5058	LAB
5059	LAB	LOG, CENTRIFUGE LOG	EA	_____	5059	LAB
5060	LAB	LOG, FREEZER/REFRIGERATOR QC LOG	EA	_____	5060	LAB
5061	LAB	LOG, NHANES III ICON QC LOG	EA	_____	5061	LAB
5062	LAB	LOG, NHANES III BIOLOGICAL SAFETY CABINET LOG	EA	_____	5062	LAB
5063	LAB	LOG, CDC WATER SAMPLE QC LOG	EA	_____	5063	LAB
5100	LAB	LABEL, FIELD OFFICE (CHANGES BY STAND)	EA	_____	5100	LAB
5101	LAB	LABEL, GAITHER ROAD, LEONARD MILLER	EA	_____	5101	LAB
5102	LAB	LABEL, CATHY NOVAK (WESTAT)"	EA	_____	5102	LAB
,103	LAB	LABEL, RECIEPT AND CONTROL GROUP, NCHS	EA	_____	5103	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
5104	LAB	LABEL, MED UNIV S CAROLINA, DR. G. VIRELLA	EA	_____	5104	LAB
5105	LAB	LABEL, UNIV S CALIF, STAN PATEL	EA	_____	5105	LAB
5106	LAB	LABEL, IMMUNOL DIV UNIV WASH, K. HUTCHINSON	EA	_____	5106	LAB
5107	LAB	LABEL, PRIMATE RESEARCH NEW MEX U, B BILLHYMER	EA	_____	5107	LAB
5109	LAB	LABEL, CDC - ELAINE GUNTER OFFICE	EA	_____	5109	LAB
5110	LAB	LABEL, CDC SERUM BANK, LANDER STODDARD	EA	_____	5110	LAB
5111	LAB	LABEL, LIPID JOHNS HOPKINS, TERRY CLOKEY	EA	_____	5111	LAB
5112	LAB	LABEL, U MASS MED CEN, DR. L BRAVERMAN	EA	_____	5112	LAB
5113	LAB	LABEL, UNIV MINN PED DEPT, SANDY SPIER	EA	_____	5113	LAB
5114	LAB	LABEL, U MISSOURI CHILD HEALTH, J ENGLAND	EA	_____	5114	LAB
5115	LAB	LABEL, CDC, BUILDING 1 RM 2367, CHAS SCHABEL	EA	_____	5115	LAB
5116	LAB	LABEL, UNIV OF MINN, BOX 491, SANDY SPIER	EA	_____	5116	LAB
5118	LAB	LABEL, CDC (SPECIMENS) DR. DAVID ASHLEY	EA	_____	5118	LAB
5119	LAB	LABEL, CDC (TRANSMITTALS) DR. DAVID ASHLEY	EA	_____	5119	LAB
5120	LAB	LABEL, CDC URINE QUEX, BOB HILL, 4770 BUFORD	EA	_____	5120	LAB
5121	LAB	LABEL, CDC TRANSMITTALS BOB HILL, 1600 CLIFTON	EA	_____	5121	LAB
5122	LAB	LABEL, DR JACK REIDY, ATLANTA, GA	EA	_____	5122	LAB
5123	LAB	LABEL, DR JACK REIDY, CHAMBLEE, GA	EA	_____	5123	LAB
5124	LAB	LABEL, USC ENDOCRINE LABS STAN PATEL CORR ADD	EA	_____	5124	LAB
5125	LAB	LABEL, LIPID, JOHNS HOPKINS, P. BACHORICK	EA	_____	5125	LAB
5126	LAB	LABEL, BUSINESS REPLY, PERMIT 368	EA	_____	5126	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
0621	OFC	BINDER, 3"	EA	_____	0621	OFC
1411	OFC	ENVELOPE, BROWN, MAILING, 250'S	BX	_____	1411	OFC
1490	OFC	ENVELOPE, PADDED, BUBBLE, #7	EA	_____	1490	OFC
1491	OFC	ENVELOPE, PADDED, BUBBLE, #6	EA	_____	1491	OFC
1492	OFC	ENVELOPE, PADDED, BUBBLE, #5	EA	_____	1492	OFC
1510	OFC	ERASER, GUM	EA	_____	1510	OFC
2701	OFC	PAD, POST IT NOTE, 3 X 5, LARGE	PD	_____	2701	OFC
2710	OFC	PAD, SCRATCH, 3" X 5"	PD	_____	2710	OFC
2760	OFC	PAPER CLIP, JUMBO, NO. 1 STYLE	BX	_____	2760	OFC
2770	OFC	PAPER CLIP, SMALL, NO. 1 STYLE	BX	_____	2770	OFC
2775	OFC	PAPER CLIP, PLASTIC, LARGE, KLIPS	BX	_____	2775	OFC
780	OFC	BINDER CLIP, LARGE, BLACK	EA	_____	2780	OFC
2790	OFC	BINDER CLIP, MEDIUM, BLACK	EA	_____	2790	OFC
2800	OFC	BINDER CLIP, SMALL, BLACK	EA	_____	2800	OFC
2830	OFC	PAPER, CALCULATOR	RL	_____	2830	OFC
2900	OFC	PAPER, PAD, WRITING, 8 1/2" X 11", WHITE	PD	_____	2900	OFC
2902	OFC	PAPER, PAD, WRITING, LEGAL	PD	_____	2902	OFC
2940	OFC	PENCIL, BLACK LEAD, #2	EA	_____	2940	OFC
3000	OFC	PEN, FELT, BLACK, EXPRESSO FINE/MEDIUM TIP	EA	_____	3000	OFC
3002	OFC	PEN, FELT, BLUE, EXPRESSO FINE/MEDIUM TIP	EA	_____	3002	OFC
3004	OFC	PEN, FELT, RED, EXPRESSO FINE/MEDIUM TIP	EA	_____	3004	OFC
3006	OFC	PEN, FELT, GREEN, EXPRESSO FINE/MEDIUM TIP	EA	_____	3006	OFC
3020	OFC	PEN, BLACK INK, BIC	EA	_____	3020	OFC
3030	OFC	PEN, RED INK, BIC	EA	_____	3030	OFC
031	OFC	PEN, BLUE INK, BIC	EA	_____	3031	OFC

COMPONENT: OFC INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
3050	OFC	MARKER, BLACK, MAGIC MARKER	EA	_____	3050	OFC
3440	OFC	RUBBERBAND, SIZE 19	BX	_____	3440	OFC
3450	OFC	RUBBERBAND, SIZE 33	BX	_____	3450	OFC
3590	OFC	TAPE, SCOTCH, 3/4"	EA	_____	3590	OFC
3910	OFC	STAMP PAD, BLACK	EA	_____	3910	OFC
3915	OFC	STAMP PAD, RED	EA	_____	3915	OFC
3920	OFC	STAMP PAD INKER, BLACK	EA	_____	3920	OFC
3925	OFC	STAMP PAD INKER, RED	EA	_____	3925	OFC
3950	OFC	STAPLE, STANDARD, 5000'S, BOSTITCH	BX	_____	3950	OFC
4085	OFC	TAPE, PACKING, 2"	RL	_____	4085	OFC
4415	OFC	PAPER, TYPING, GILBERT BOND	SH	_____	4415	OFC
4650	OFC	WHITE OUT, OPAQUE	BT	_____	4650	OFC
5250	OFC	FORM, TRIP EXPENSE REPORT	EA	_____	5250	OFC
5251	OFC	FORM, TIMESHEET, INTERVIEWER	EA	_____	5251	OFC
5252	OFC	FORM, TIMESHEET, SUPERVISOR	EA	_____	5252	OFC

COMPONENT: OFC INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
0070	ALL	ALCOHOL, PT (HAZ GOOD)	EA	_____	0070	ALL
0080	ALL	ALCOHOL PREPS, MEDI-PAK	EA	_____	0080	ALL
0220	ALL	ALUMINUM FOIL, 150 SQ FT	BX	_____	0220	ALL
0230	ALL	AMMONIA INHALER, IND. WRAP	EA	_____	0230	ALL
0240	ALL	APPLICATOR, COTTON TIP	EA	_____	0240	ALL
0300	ALL	BAG, TRASH CAN LINER	EA	_____	0300	ALL
0305	ALL	BAG, TRASH, LRG	EA	_____	0305	ALL
0310	ALL	BAG, ZIPLOC, 1 GL	EA	_____	0310	ALL
0352	ALL	BATTERY, D CELL	EA	_____	0352	ALL
0370	ALL	BATTERY, AA, 8 PKG	EA	_____	0370	ALL
0381	ALL	BATTERY, AAA, PEN LIGHT	EA	_____	0381	ALL
(	ALL	CLEANER, 409, 22 OZ	BT	_____	0760	ALL
0850	ALL	WIPES, CLOTH, REUSABLE	EA	_____	0850	ALL
1211	ALL	DISKETTE, DS, HD, 5 1/4", NOT FORMATTED	EA	_____	1211	ALL
1213	ALL	DISKETTE, DS, DD, 5 1/4", FORMATTED	EA	_____	1213	ALL
1440	ALL	ENVELOPE, DISK MAILING, 8" DISK	EA	_____	1440	ALL
1810	ALL	GAUZE, 2 X 2, STERILE	PG	_____	1810	ALL
1821	ALL	GAUZE, 4 X 4, NON-STERILE, 200'S	PG	_____	1821	ALL
1841	ALL	GAUZE, 2 X 2, NON-STERILE, 200'S	PG	_____	1841	ALL
1871	ALL	MERTICIDE, STERI AND DISINFECT SOL	BT	_____	1871	ALL
1891	ALL	GLOVE, VINYL, SM	EA	_____	1891	ALL
1901	ALL	GLOVE, VINYL, MED	EA	_____	1901	ALL
1911	ALL	GLOVE, VINYL, LRG	EA	_____	1911	ALL
1980	ALL	LOTION, HAND	BT	_____	1980	ALL
2195	ALL	TONER CARTRIDGE KIT	EA	_____	2195	ALL

COMPONENT: ALL INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
2196	ALL	KIT, LASER COPIER, USER MAINTENANCE	EA	_____	2196	ALL
2197	ALL	COMPACTAPE (FIELD OFC)	EA	_____	2197	ALL
2200	ALL	KLEENEX	BX	_____	2200	ALL
2342	ALL	BULB, PENLIGHT	EA	_____	2342	ALL
2344	ALL	BULB, LIGHT, 60 W	EA	_____	2344	ALL
2500	ALL	MASK, TIE, NON-FIBERGLASS	EA	_____	2500	ALL
2560	ALL	MERCURY SPONGE	EA	_____	2560	ALL
2810	ALL	TOWEL, PAPER, BROWN, SINGLE FOLD	PG	_____	2810	ALL
2815	ALL	TOWEL, BROWN, SPEC CFOLD, FOR 3 SM DISP	PG	_____	2815	ALL
2820	ALL	TOWEL, PAPER, WHITE, CFOLD, BLEACHED	PG	_____	2820	ALL
2850	ALL	PAPER, EXAM TABLE, 18"	RL	_____	2850	ALL
2910	ALL	FLASHLIGHT, PEN	EA	_____	2910	ALL
2970	ALL	PENCIL, BLUE EYELINER, MAYBELLINE	EA	_____	2970	ALL
2980	ALL	PENCIL, BROWN EYELINER, MAYBELLINE	EA	_____	2980	ALL
3150	ALL	PILLOW CASE, PAPER, MEDI-PAK 20 X 29	EA	_____	3150	ALL
3750	ALL	SOAP, HAND, REFILL, IVORY LIQUID, 22 OZ	BT	_____	3750	ALL
3760	ALL	SOAP, DISH LIQUID, IVORY, 32 OZ	EA	_____	3760	ALL
3780	ALL	HAND CREAM, SOFT GUARD, 3 OZ	TU	_____	3780	ALL
3790	ALL	CLEANSER, SOFT SCRUB, NON-ABRASIVE, 26 OZ	EA	_____	3790	ALL
3800	ALL	GREASE, STOP COCK	EA	_____	3800	ALL
3840	ALL	SPONGE, CELLU, 3 X 5"	EA	_____	3840	ALL
3860	ALL	LYSOL SPRAY, INSTITUTIONAL, LARGE	EA	_____	3860	ALL
3980	ALL	SPRAY, ANTI-STATIC, 6 OZ.	EA	_____	3980	ALL
4080	ALL	TAPE, SHIPPING, STRAPPING 1" X 60 YD	EA	_____	4080	ALL
4140	ALL	TAPE, PAPER, SURGICAL W/DISPENSER	RL	_____	4140	ALL

COMPONENT: ALL INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES CIRCLE ONE: BEGIN END

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
4260	ALL	TONGUE BLADE, WOOD	EA	_____	4260	ALL
4606	ALL	VINYL JACKET, 9 X 12", HEAVY GAUGE	EA	_____	4606	ALL
4660	ALL	WINDOW CLEANER, SPRAY DISPENSER, 22 OZ	EA	_____	4660	ALL
4913	ALL	FORM, FACT SHEET	EA	_____	4913	ALL
4921	ALL	FORM, ADULT BLOOD PRESSURE RPT, ENGLISH, 5/90	EA	_____	4921	ALL
4922	ALL	FORM, ADULT BLOOD PRESSURE RPT, SPANISH, 5/90	EA	_____	4922	ALL
5558	ALL	FORM, PROXY QUEX, ALG-AUD-SPR, 10/90	EA	_____	5558	ALL
5606	ALL	FORM, NHANES TRANSMITTAL FORM, 7/88	EA	_____	5606	ALL

COMPONENT: ALL INVENTORIED BY _____

APPENDIX F-2

MOBILE EXAM CENTER INVENTORY SHEET

NON-CONSUMABLE ITEMS

STAND INVENTORY - MEC SUPPLIES, NON-CONSUMABLE

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
0400	LAB	BELL, EMERGENCY	EA	_____	0400	LAB
0440	LAB	TRASH CAN, BIOHAZARD W/LID, LARGE	EA	_____	0440	LAB
0480	LAB	STAND, BIOHAZARD, GREEN WIRE	EA	_____	0480	LAB
0560	LAB	BOTTLE, WASH, 500 ML, NALGENE	EA	_____	0560	LAB
0580	LAB	BOTTLE, WASH, 250 ML, NALGENE	EA	_____	0580	LAB
0860	LAB	CAN, COFFEE, COVERED WITH CONTACT PAPER	EA	_____	0860	LAB
1270	LAB	DUST PAN, WITH BRUSH	EA	_____	1270	LAB
1360	LAB	BASIN, EMESIS, SMALL	EA	_____	1360	LAB
1790	LAB	PAD, FOAM RUBBER, 1/2 YD X 1 IN THICK	EA	_____	1790	LAB
1885	LAB	GLOVE, CRYO (FOR HANDLING DRY ICE)	PR	_____	1885	LAB
1940	LAB	CYLINDER, GRADUATED, 100 ML	EA	_____	1940	LAB
1950	LAB	CYLINDER, GRADUATED, 50 ML	EA	_____	1950	LAB
1970	LAB	HAMMER, CARPENTERS	EA	_____	1970	LAB
2010	LAB	FORCEPS, HEMOSTATIC, 8", LG	EA	_____	2010	LAB
2020	LAB	FORCEPS, HEMOSTATIC, 6 1/4", SM	EA	_____	2020	LAB
2060	LAB	ICE CHOPPER, LONG HANDLE	EA	_____	2060	LAB
2840	LAB	KNIFE, UTILITY, RETRACTABLE, X-ACTO	EA	_____	2840	LAB
3250	LAB	PIPETTE, 100 UL, MLA #6C426 CDC	EA	_____	3250	LAB
3251	LAB	PIPETTE, 400 UL, MLA CDC	EA	_____	3251	LAB
3260	LAB	PIPETTE, 1000 UL, MLA #6G435 CDC	EA	_____	3260	LAB
3370	LAB	RACK, PIPETTE HOLDER, MLA #338-210	EA	_____	3370	LAB
3390	LAB	RACK, STYRO, LARGE SARSTEDT	EA	_____	3390	LAB
3391	LAB	RACK, STYRO, SMALL SARSTEDT	EA	_____	3391	LAB
3410	LAB	CART, ROLLING, W/SLIDING TRAYS	EA	_____	3410	LAB
3470	LAB	RULER, PLASTIC, 12"	EA	_____	3470	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES, NON-CONSUMABLE

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
3575	LAB	SCOOP, DRY ICE	EA	_____	3575	LAB
3610	LAB	SCREWDRIVER, PHILLIPS	EA	_____	3610	LAB
3620	LAB	SCREWDRIVER, FLAT TIP	EA	_____	3620	LAB
3665	LAB	SHEET, BED, SINGLE, FLAT	EA	_____	3665	LAB
3731	LAB	DISPENSER, SOAP, DERMA CIDOL/SOFT SCRUB	EA	_____	3731	LAB
3905	LAB	BIN, STACK (FOR LAB ONLY)	EA	_____	3905	LAB
4180	LAB	RACK, TEST TUBE, BLUE, LARGE	EA	_____	4180	LAB
4181	LAB	RACK, TEST TUBE, 10 X 13 MM, WHITE NALGENE	EA	_____	4181	LAB
4190	LAB	RACK, TUBE, CRYOS, FOR 5 ML CRYOS	EA	_____	4190	LAB
4220	LAB	TIMER, LARGE, SQUARE	EA	_____	4220	LAB
4225	LAB	BRUSH, CLEANING, TUBE RACK	EA	_____	4225	LAB
?40	LAB	TIMER, SMALL, SQUARE, PGC	EA	_____	4240	LAB
4281	LAB	TOURNIQUET, VELCRO, PEDIATRIC	EA	_____	4281	LAB
4320	LAB	TRAY, BLOOD DRAW, COMPARTMENTED	EA	_____	4320	LAB
4340	LAB	TUBE, PICK UP, LYSE, SMALL	EA	_____	4340	LAB
4350	LAB	TUBE, PICK UP, WASTE, SHORT	EA	_____	4350	LAB
4370	LAB	TUBE, PICK UP, DETERGENT	EA	_____	4370	LAB
4380	LAB	TUBE, PICK UP, DILUENT	EA	_____	4380	LAB
4420	LAB	TUBING, W/PICK UP TUBE, 25 FT	EA	_____	4420	LAB

COMPONENT: LAB INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES, NON-CONSUMABLE

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
0500	OFC	BOOK END, MEC	EA	_____	0500	OFC
0650	OFC	BOARD, BULLETIN	EA	_____	0650	OFC
0660	OFC	CALCULATOR, SMALL, SOLAR	EA	_____	0660	OFC
0810	OFC	CLIPBOARD, LETTER OR LARGE	EA	_____	0810	OFC
1580	OFC	GUIDE, FILE, LEGAL	EA	_____	1580	OFC
1590	OFC	TRAY, DESK, FILE, LG, PLASTIC, COMPUTER SIZE	EA	_____	1590	OFC
1600	OFC	TRAY, DESK, FILE, LEGAL, PLASTIC	EA	_____	1600	OFC
1610	OFC	TRAY, DESK, FILE, LETTER, PLASTIC	EA	_____	1610	OFC
2771	OFC	HOLDER, PAPER CLIP	EA	_____	2771	OFC
2930	OFC	HOLDER, PENCIL, SMALL	EA	_____	2930	OFC
3405	OFC	ROLADEX FILE (TO HOLD TELEPHONE NUMBERS)	EA	_____	3405	OFC
3460	OFC	RULER, METAL, 12"	EA	_____	3460	OFC
3560	OFC	SCISSORS, REGULAR, LONG HANDLE	EA	_____	3560	OFC
3640	OFC	SHARPENER, PENCIL, VACUUM MOUNT, HUNT BOSTON	EA	_____	3640	OFC
3930	OFC	REMOVER, STAPLE	EA	_____	3930	OFC
3940	OFC	STAPLER, STANDARD	EA	_____	3940	OFC
4081	OFC	DISPENSER, SHIPPING TAPE	EA	_____	4081	OFC

COMPONENT: OFC INVENTORIED BY _____

STAND INVENTORY - MEC SUPPLIES, NON-CONSUMABLE

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
0030	ALL	ADAPTER, 3 PRONG TO 2 PRONG	EA	_____	0030	ALL
0540	ALL	BOTTLE, SPRAY, SMALL	EA	_____	0540	ALL
0570	ALL	BOTTLE, DROPPER, 15 ML	EA	_____	0570	ALL
0830	ALL	CLOCK, WALL	EA	_____	0830	ALL
0930	ALL	CONTAINER, ROUND, 1 CUP, W/LID	EA	_____	0930	ALL
0940	ALL	CONTAINER, ROUND 2 CUP, W/LID	EA	_____	0940	ALL
0950	ALL	CONTAINER, 7-CUP, W/LID	EA	_____	0950	ALL
0960	ALL	CONTAINER, RECT, 4 CUP, W/LID	EA	_____	0960	ALL
0990	ALL	MASK, CPR, SEAL EASY	EA	_____	0990	ALL
1780	ALL	FLASHLIGHT	EA	_____	1780	ALL
1880	ALL	GLASSES, SAFETY	EA	_____	1880	ALL
2292	ALL	LAMP, DESK, CLIP ON	EA	_____	2292	ALL
3140	ALL	PILLOW, BED, HYPOALLERGENIC	EA	_____	3140	ALL
3141	ALL	PILLOW, SMALL	EA	_____	3141	ALL
3300	ALL	PLIERS, NEEDLE NOSE	EA	_____	3300	ALL
3380	ALL	RACK, EXAM TABLE PAPER	EA	_____	3380	ALL
3570	ALL	SCISSORS, SURGICAL	EA	_____	3570	ALL
3630	ALL	SCREWDRIVER SET, JEWELERS, ASST	EA	_____	3630	ALL
3650	ALL	SHARPENER, LINER PENCIL, MAYBELLINE	EA	_____	3650	ALL
3740	ALL	DISPENSER, HAND SOAP, IVORY LIQUID, 9 OZ	EA	_____	3740	ALL
4040	ALL	STOOL, DENTAL, DELTUB	EA	_____	4040	ALL
4051	ALL	STOPWATCH, DIGITAL	EA	_____	4051	ALL
4100	ALL	TAPE, MEASURING, LUFKIN	EA	_____	4100	ALL
160	ALL	TELEPHONE	EA	_____	4160	ALL
4210	ALL	THERMOMETER, WALL MOUNT, TAYLOR	EA	_____	4210	ALL

STAND INVENTORY - MEC SUPPLIES, NON-CONSUMABLE

STAND _____ INVENTORY DATE _____

CODE	COMP	DESCRIPTION	U/I	ON-HAND	CODE	COMP
4620	ALL	WASTEBASKET, COLORFUL, MED, 5-6 GL	EA	_____	4620	ALL
4630	ALL	WASTEBASKET, LARGE, W/LID	EA	_____	4630	ALL

COMPONENT: ALL INVENTORIED BY _____

APPENDIX F-3

MOBILE EXAM CENTER INVENTORY SHEET

CDC-SUPPLIED ITEMS

NHANES III END OF STAND INVENTORY FOR CDC-SUPPLIES ITEMS

THIS STAND #: _____ LOCATION: _____ CARAVAN: _____

NEXT LOCATION THIS MEC WILL TRAVEL TO: _____

PLEASE ENTER THE AMOUNT OF CDC-SUPPLIED ITEMS YOU HAVE REMAINING AT THE END OF THIS STAND, SO THAT THIS MEC WILL BE PROPERLY SUPPLIED AT ITS NEXT LOCATION. ALWAYS USE OLDER SUPPLIES FIRST.

1.	UNCAPPED VIALS (NALGE)	large boxes/5000 (1000 vials = 2.5 bags + bag caps)	_____
2.	CAPPED VIALS (NALGE - for lead only)	small boxes/1000	_____
3.	MPA vials (3g/vial)	1/operating day (can be used for several days/ make fresh weekly)	_____
4.	ASCORBIC ACID (0.5 g/vial)	1/operating day (make fresh daily)	_____
5.	60-ML WHEATON VIALS (& caps & stoppers)	50/stand	_____
6.	5-ML WHEATON VIALS (& caps & Teflon stoppers)	50/stand	_____
7.	10-ML NON-SILICONE COATED RED-TOP VACUTAINERS	50/stand	_____
8.	10-ML GREY TOP VACUTAINERS CDC-PREPARED FOR VOLATILES	50/stand	_____

NOTE: MAKE SURE THAT ALL NEW LOTS OF URINE COLLECTION CONTAINERS, 15-ML POLYSTYRENE CENTRIFUGE TUBES, EDTA (PURPLE TOP), AND RED-TOP VACUTAINERS HAVE BEEN PRESCREENED BY CDC BEFORE USE. DO NOT USE THE REGULAR SILICONE-COATED 10-ML RED-TOP TUBES FOR THE PRIORITY TOXICANTS BLOOD DRAW.

DATE PREPARED: _____ TECH NAME: _____

******** PLEASE MAIL THIS LIST TO:

ELAINE GUNTER 2914
BUILDING 17, ROOM ~~1819~~, ~~F17~~ F18
CENTERS FOR DISEASE CONTROL
ATLANTA, GA 30333

Revised 12/91

APPENDIX G
ASSIGNING Z NUMBERS

Appendix G

Assigning Z Numbers

In order to keep the HIV test and the urine drug test anonymous, the SP's serum and urine samples will be labelled with a Z number. The procedures below were designed to label the SP's serum sample for the HIV test and the urine sample for the drug test with the same Z number.

On the day an SP is scheduled to be examined, the chief technician or the technician who is setting up blood processing racks will use the Daily Appointment Schedule, the Z labels, and the automated system to assign a Z number to all SPs over 18 years. Follow the procedures below to assign the random Z number:

- Access the Assign Z Number screen in the automation system. Refer to the Laboratory Automation System Manual for instructions.
- Enter the SP ID # from the Daily Appointment Schedule (DAS).
- Randomly select one sheet of Z labels, printed six duplicates to a strip, from the box of Z labels located near the automation system terminal.
- Randomly select one of the six Z numbers on the strip and enter it into the automation system. The Z number has now been "linked" to that SP ID number.
- Continue to randomly select Z numbers from the strip for the remaining SP ID #s listed on the DAS. If you run out of Z numbers, select another strip of Z labels from the box.
- Post the Z labels in a central location in the laboratory so that both the blood processor and urine processor has access to them.
- The blood processor will label Vial 20 and urine processor will label Tube U-D with the appropriate Z label when entering the results of their processing into the automation system. Refer to Chapter 6, Urinalysis, and Chapter 7, Blood Processing and Storage, in the Laboratory Automation Manual.

7

APPENDIX H

PROCESSING OF BLOODS FOR AGE GROUPS A-E

Exhibit H-1. Processing of bloods, ages 1-3 (A)

Process 3 ml lavender tube (under hood) and 4 ml SST.

1. Using the tube rocker, mix lavender tube for 2 minutes.
2. Decant 0.50 ml for lead assay into 2.0 ml Nalgene vial (Vial 1).
3. Decant 0.50 ml for erythrocyte protoporphyrin into a 2.0 ml Nalgene vial (Vial 2).
4. Restopper the lavender tube and remix contents.
5. Give 3 ml lavender to hematologist. The hematologist is to:
    a. Check the tube for microclots. **If microclots are present, don't use the specimen.**
    b. Sample 0.20 ml for the CBC/RDW/Plat. Automat. Diff.
    c. Prepare two differential smears.
    d. Restopper the tube and discard.
6. Allow 4 ml SST to clot for 30 to 40 minutes. Centrifuge at **2900 rpm** for 15 minutes and pool sera.
7. Using plastic transfer pipette, carefully remove all the serum from the SST for iron/TIBC and ferritin and put it into a 2.0 ml Nalgene vial (Vial 7).
8. Discard all contaminated supplies in a biohazard bag.

Exhibit H-2. Processing of bloods, ages 4-5 (B)

Process 3 ml lavender tube (under hood), one 10 ml red top, and one 15 ml red top tube.

1. Using the tube rocker, mix lavender tube for two minutes.
2. Decant 0.50 ml for lead assay and put in 2.0 ml Nalgene vial (Vial 1).
3. Decant 1.0 ml for erythrocyte protoporphyrin and place in 2.0 ml Nalgene vial (Vial 2).
4. Aliquot 0.1 ml from the 3 ml lavender tube for RBC folate and place in a 2.0 ml Nalgene vial containing 1 ml of 1% ascorbic acid (Vial 3). Mix gently.
5. Restopper lavender tube and remix contents.
6. Give 3 ml lavender tube to hematologist. The hematologist is to:
    a. Check the tube for microclots. **If microclots are present, don't use the specimen.**
    b. Sample .20 ml for CBC/RDW/Plat. Automat. Diff.
    c. Prepare two differential smears.
    d. Restopper the tube and return it to the processor.
7. If at least 0.5 ml of blood is left in the lavender tube, process it for glycoslyated hemoglobin. Label the tube with a Vial 4 label and refrigerate (Vial 4). If less than 0.5 ml of blood remains in the tube, discard it. If it is necessary to keep the lavender top tube at room temperature for more than one hour, it should be refrigerated. If for some reason Vial 4 is left at room temperature for more than one hour or if the temperature of the MEC is too high, a comment should be made to this effect when entering the results of blood processing into the automated system.
8. Allow red tops to clot for 30 to 40 minutes. Centrifuge at **2900 rpm** for 15 minutes and pool sera.
9. Aliquot 1.25 ml for iron/TIBC into 2.0 ml Nalgene vial (Vial 7).
10. Aliquot 1.5 ml for ferritin/folate into 2.0 ml Nalgene vial(Vial 8).
11. Aliquot 2.5 ml into 6.0 ml Sarstedt vial for NHLBI lipids (Vial 9). Use blood processing comment code #11 to indicate that the SP was lying down during venipuncture.
12. Aliquot 1.5 ml for Vitamins A/E/carotene into 2.0 ml Nalgene vial (Vial 10).
13. Aliquot 2.0 ml for cotinine into 2.0 ml Nalgene vial (Vial 11).
14. Aliquot 0.5 ml for C-reactive protein into 2.0 ml Nalgene vial (Vial 12).
15. Aliquot 0.5 ml for tetanus into 2.0 ml Nalgene vial (Vial 16).
16. Aliquot the remainder of the serum into the 6.0 ml Sarstedt vial for NHLBI lipids (Vial 9).
17. Discard all contaminated supplies in a biohazard bag.

Exhibit H-3. Processing of bloods, ages 6-11 (C)

Process 3 ml lavender tube (under hood), one 10 ml red top tube, and two 15 ml red top tubes.

1. Using the tube rocker, mix lavender tube for two minutes.

2. Decant 0.50 ml for lead assay and put in 2.0 ml Nalgene Vial (Vial 1).

3. Decant 1.0 ml for erythrocyte protoporphyrin and place it in 2.0 ml Nalgene Vial (Vial 2).

4. Aliquot 0.1 ml from the 3 ml lavender tube for RBC folate and place in a 2.0 ml Nalgene Vial containing 1.0 ml of 1% ascorbic acid and then mix gently (Vial 3).

5. Restopper lavender tube and remix contents.

6. Give 3 ml lavender tube to hematologist. The hematologist is to:

    a. Check tube for microclots. **If microclots are present, don't use the specimen.**

    b. Sample 0.20 ml for CBC/RDW/Plat. Automat. Diff.

    c. Prepare two differential smears.

    d. Restopper the tube and return it to the processor.

7. If at least 0.5 ml of blood is left in the lavender tube, process it for glycoslyated hemoglobin. Label with a Vial 4 label, and refrigerate (Vial 4). Discard the 3 ml lavender tube if less than 0.5 ml of blood is left in the tube. If it is necessary to keep the lavender top tube at room temperature for more than one hour, it should be refrigerated. If for some reason Vial 4 is left at room temperature for more than one hour, or if the temperature in the MEC is too high, a comment should be made when entering the results of blood processing into the automated system.

8. Allow the red tops to clot for 30 to 40 minutes. **Centrifuge at 2900 rpm for 15 minutes** and pool sera.

9. Aliquot 1.25 ml for iron/TIBC into 2.0 ml Nalgene Vial (Vial 7).

10. Aliquot 1.5 ml for ferritin/folate into 2.0 ml Nalgene Vial (Vial 8).

11. Aliquot 2.5 ml into a 6 ml Sarstedt Vial for NHLBI lipids (Vial 9). Use blood processing comment code #11 to indicate that the SP was lying down during venipuncture.

12. Aliquot 1.25 ml for Vitamins A/E/carotene into 2.0 ml Nalgene Vial (Vial 10).

13. Aliquot 2.0 ml for cotinine into a 2.0 ml Nalgene Vial (Vial 11).

14. Aliquot 0.5 ml for C-reactive protein into 2.0 ml Nalgene Vial (Vial 12).

15. Aliquot 0.1 ml for Vitamin C into 2.0 ml Nalgene Vial containing 0.4 ml of 6% metaphosphoric acid. Note that this solution becomes milky. Mix well. (Vial 14)

16. Aliquot 0.5 ml for tetanus into 2.0 ml Nalgene Vial (Vial 16).

17. Aliquot 1.0 ml for hepatitis into 2.0 ml Nalgene Vial (Vial 17).

18. Aliquot 0.5 ml for rubella into 2.0 ml Nalgene Vial (Vial RU).

19. Aliquot 0.5 ml for IgE into 2.0 ml Nalgene Vial (Vial IE).

20. Aliquot 1.0 ml for storage into one 2.0 ml Nalgene vial; aliquot 2.0 ml for storage into three 2.0 ml Nalgene vials (Vials 24-27).

21. Aliquot any remaining serum up to 1.0 ml into the 2.0 ml Nalgene vial for IgE (Vial IE).

22. Aliquot any remaining serum up to 5.5 ml into the 6.0 Sarstedt Vial for NHLBI lipids (Vial 9).

23. After Vial 9 is filled, dispense residual serum into 2.0 ml Nalgene vials labeled with SP ID #s.

24. Decant loosened clot from the 15 ml red top tubes into separate 8.0 ml Sarstedt vials (Vials C1 and C2).

25. Discard all contaminated materials into biohazard bags.

Process one 2 ml lavender, one 3 ml lavender (under hood), one 10 ml red, three 15 ml reds, one 4 ml SST, and one 4 ml leukoprep tube.

1. Using the tube rocker, mix the 3 ml lavender tube for two minutes.

2. Decant 0.5 ml from the 3 ml lavender tube for lead assay into a 2.0 Nalgene vial (Vial 1).

3. Decant 1.0 ml for erythrocyte protoporphyrin and place in 2.0 ml Nalgene vial (Vial 2).

4. Aliquot 0.1 ml from the 3 ml lavender tube for red cell folate and put in 2.0 ml Nalgene vial. Add 1.0 ml of 1% ascorbic acid and mix gently (Vial 3).

5. If at least 0.5 ml of blood remains in the 3 ml lavender tube, restopper the tube and label with a Vial 4 label; refrigerate the remainder of the 3 ml lavender for glycosylated hemoglobin (Vial 4). If less than 0.5 ml of blood remains, discard the tube. If it is necessary to keep the 3 ml lavender top tube at room temperature for more than one hour, it should be refrigerated. If for some reason Vial 4 is left at room temperature for more than one hour, or if the temperature of the MEC is too high, a comment should be made to this effect when entering the results of blood processing into the automated system.

6. Give 2 ml lavender tube to hematologist. The hematologist is to:

    a. Check the tube for microclots. **If microclots are present, don't use the specimen.** (Use residual sample of 3 ml lavender.)

    b. Sample 0.20 ml for CBC/RDW/Plat. Automat. Diff.

    c. Prepare 2 differential slides.

    d. Restopper and discard tube.

7. Allow the red tops to clot for 30 to 40 minutes. Centrifuge at **2900 rpm** for 15 minutes and pool sera.

8. Aliquot 1.25 ml for iron/TIBC into 2.0 ml Nalgene vial (Vial 7).

9. Aliquot 1.5 ml for ferritin/folate into 2.0 ml Nalgene vial (Vial 8).

10. Aliquot 2.5 ml for NHLBI lipids into a 6.0 ml Sarstedt vial (Vial 9). Use blood processing comment code #11 to indicate that the SP was lying down during venipuncture.

11. Aliquot 1.25 ml for Vitamin A/E/carotene into 2.0 ml Nalgene vial (Vial 10).

12. Aliquot 2.0 ml for cotinine into a 2.0 ml Nalgene vial (Vial 11).

13. Aliquot 0.5 ml for C-reactive protein into 2.0 ml Nalgene vial (Vial 12).

14. Aliquot 1.0 ml for SMAC profile into 2.0 ml Nalgene vial (Vial 13).

15. Aliquot 0.1 ml for Vitamin C into 2.0 ml Nalgene vial. Add 0.4 ml of 6% MPA. Note that this solution becomes milky. Mix well (Vial 14).

16. Allow the 4 ml SST to clot for 30-40 minutes. **Cool 3-5 minutes.** Centrifuge at **2900 rpm** for 15 minutes. Do not open the tube. Refrigerate it in a upright position between **30 minutes - 2 hours.** Place the SST tube on its side with a 2 ml Nalgene vial (labeled with the SP's ID number) in the SP's CDC bag and freeze by close of business. (Vial 15)

17. Aliquot 0.5 ml for tetanus into 2.0 ml Nalgene vial (Vial 16).

18. Aliquot 1.0 ml for hepatitis into 2.0 ml Nalgene vial (Vial 17).

19. Aliquot 1.0 ml for herpes into 2.0 ml Nalgene vial (Vial 18).

20. Aliquot 0.5 ml for selenium into 2.0 ml Nalgene vial (Vial 19).

21. Check the Daily Appointment Schedule for SP's age. For SPs 18 and older, aliquot 0.5 ml for HIV I into a randomly labeled 2.0 ml Nalgene vial (Vial 20).

22. Aliquot 1.0 ml for thyroid studies into 3.5 ml Sarstedt vial (Vial 21).

23. Aliquot 0.5 ml for toxoplasmosis into 2.0 ml Nalgene vial (Vial TO).

24. Aliquot 0.5 ml for rubella into 2.0 ml Nalgene vial (Vial RU).

25. Aliquot 1.0 ml for IgE into 2.0 ml Nalgene vial (Vial IE).

26. Aliquot 1.0 ml for storage into one 2.0 ml Nalgene vial; aliquot 2.0 ml for storage into three 2.0 ml Nalgene vials (Vials 24-27).

27. Aliquot any remaining serum into the 6.0 Sarstedt vial for NHLBI Lipids (Vial 9).

28. After Vial 9 is filled, dispense residual serum into 2.0 ml Nalgene vials labeled with SP ID #s.

29. Decant the loosened clots from 2 of the 15 ml red top tubes into two separate 8.0 ml Sarstedt vials (Vials C1 and C2).

30. Label the 8 ml leukoprep tube with a Vial 31 label. Make sure it is labelled with the SP's ID label. Centrifuge leukoprep tube at **2,900 RPM** for 20 minutes. If the red cells do not completely spin through the gel, centrifuge the tube for an additional 25 minutes. Refrigerate the tube until shipped to arrive at destination within 48 hours of collection (Vial 31).

31. Discard all contaminated materials in biohazard bags.

Exhibit H-5. Processing of bloods, ages 20 + (E)

Process as follows:

First draw: Process one 2 ml lavender, one 3 ml lavender tube, five 15 ml red top tubes, one 4 ml SST tube, one 3 ml gray top tube (for glucose-Vial 5 or 5A), one 2 ml light blue top tube for SPs 40+, one 8 ml leukoprep top. If the SP is a volatile toxicant volunteer, process one 10 ml gray top tube and one 10 ml non-silicone coated red top tube .

Second draw: Process one 3 ml gray top (glucose 5B) and one 4 ml SST (6B). (If necessary, also process the 10 ml gray top tube, the 10 ml non-silicone coated red top, the 2 ml light blue and the 4 ml leukoprep.)

1. Using the tube rocker, mix the 3 ml lavender tube for two minutes.

2. Decant 0.5 ml whole blood for lead into 2 ml Nalgene (Vial 1).

3. Decant 1.0 ml whole blood for erythrocyte protoporphyrin (Vial 2).

4. Aliquot 0.10 ml (100 ul) from 3 ml lavender tube for RBC folate into 2.0 ml Nalgene vial containing 1.0 ml of 1% ascorbic acid and mix gently (Vial 3).

5. If at least 0.5 ml of blood remains in the 3 ml lavender process is for glycosylated hemoglobin. Restopper the tube; label with a Vial 4 label and refrigerate (Vial 4). If less than 0.5 ml of blood is left in the tube, discard it. If it is necessary to keep the 3 ml lavender at room temperature for more than one hour, it should be refrigerated. If for some reason Vial 4 is left at room temperature for more than one hour or if the temperature of the MEC is too high, a comment should be made to this effect when entering the results of blood processing into the automated system.

6. The 2 ml lavender is given to the hematologist. The hematologist is to:

    a. Check the tube for microclots. **If microclots are present, don't use the specimen.** (Use residual sample of 3 ml lavender.)

    b. Sample 0.20 ml CBC/RDW/Plat. Automat. Diff.

    c. Prepare 2 differential slides

    d. Restopper and discard tube.

7. Centrifuge grey top tube as soon as possible for glucose and transfer all plasma to 2 ml Nalgene vial (Vial 5A).

8. Allow red tops to clot for 30 to 40 minutes. Centrifuge at **2,900 RPM** for 15 minutes and pool sera.

9. Aliquot 1.5 ml for insulin/C peptide into 2.0 ml Nalgene vial (Vial 6A).

10. Aliquot 1.25 ml for iron/TIBC into 2.0 ml Nalgene vial (Vial 7).

11. Aliquot 1.5 ml for ferritin/folate into 2.0 ml Nalgene vial (Vial 8).

12. Aliquot 2.5 ml for lipids into a 6.0 ml Sarstedt vial (Vial 9). Use blood processing comment code #11 to indicate that the SP was lying down during venipuncture.

13. Aliquot 1.25 ml for Vitamins A/E/carotene into 2.0 ml Nalgene vial (Vial 10).

14. Aliquot 2.0 ml for cotinine into a 2.0 ml Nalgene vial (Vial 11).

15. For SPs age 20-59: Aliquot 0.5 ml for C-reactive protein (Vial 12). For SPs age 60+: Aliquot 1.0 ml for C-reactive protein/RF into 2.0 ml Nalgene vial (Vial 12).

16. Aliquot 1.0 ml for SMAC profile into 2.0 ml Nalgene vial (Vial 13).

17. Aliquot 0.1 ml for Vitamin C into 2.0 ml Nalgene vial containing 0.4 ml of 6% MPA. Note that this solution becomes milky. Mix well (Vial 14).

18. Allow the 4 ml SST tube to clot for 30-40 minutes. **Cool 3-5 minutes. Centrifuge at 2900 rpm** for 15 minutes. Do not open the tube. Refrigerate it in an upright position between **30 minutes-2 hours**. Place the SST on its side with a 2 ml Nalgene vial (labeled with the SP ID number) into the SP's CDC bag and freeze by end of day (Vial 15).

19. Aliquot 0.5 ml for tetanus into 2.0 ml Nalgene vial (Vial 16).

20. Aliquot 1.0 ml for hepatitis into 2.0 ml Nalgene vial (Vial 17).

21. Aliquot 1.0 for herpes into 2.0 ml Nalgene vial (Vial 18).

22. Aliquot 0.5 ml for selenium into 2.0 ml Nalgene vial (Vial 19).

23. Aliquot 0.5 ml for HIV into a randomly labeled 2.0 ml Nalgene vial (Vial 20).

24. Aliquot 1.0 ml for thyroid studies into 3.5 ml Sarstedt vial (Vial 21).

25. For female SPs 35-60, aliquot 0.75 ml for FSH & LH hormones into a 2.0 ml Nalgene vial (Vial 22).

26. For SPs 40+, centrifuge light blue tube as soon as possible for fibrinogen. Aliquot all plasma into 2.0 ml Nalgene vial (Vial 23).

27. Aliquot 0.5 ml for toxoplasmosis into 2.0 ml Nalgene vial (Vial TO).

28 Aliquot 0.5 ml for rubella into 2.0 ml Nalgene vial (Vial RU).

29. Aliquot 1.0 ml for IgE into 2.0 ml Nalgene vial (Vial IE).

30. Aliquot 1.0 ml serum for storage into one 2.0 ml Nalgene vial; aliquot 2.0 ml serum for storage into three 2.0 ml Nalgene vials (Vial 24-27).

31. Aliquot any remaining serum into the 6.0 Sarstedt vial for NHLBI Lipids (Vial 9).

32. After filling Vial 9, dispense residual serum into 2.0 ml Nalgene vials labeled with SP ID #s.

33. Label the unopened 10 ml gray top tube for volatile toxicants with Vial 28 label and refrigerate (Vial 28).

34. Allow the 10 ml non-silicone coated red top tube to clot upright for 30 minutes. Centrifuge at **2,900 RPM** for 15 minutes. Remove a 5.0 ml Wheaton vial from its storage bag, label it with an SP ID number and a Vial 29 label. Use a clean transfer pipette to remove the serum from the cells. Transfer the serum directly into the 5.0 ml Wheaton vial. Insert a teflon coated gray stopper snugly and evenly into the vial. Place the aluminum seal over the stopper so that it lies flat. Attach the crimper snugly over the seal and squeeze the handle until a secure seal is achieved. Test the seal by determining that it cannot be easily turned by hand. Freeze the sample immediately.

35. Decant the loosened clots from the 2 of 15 ml red tops into two separate 8.0 ml Sarstedt (Vials C1 and C2).

36. Label the 8 ml leukoprep top tube with a Vial 31 label. Make sure it is labeled with an SP ID label. Centrifuge the tube at **2900 RPM** for 15 minutes. If the red cells do not completely spin through the gel, centrifuge the tube for an additional 25 minutes. Refrigerate the tube until shipped to arrive at destination with 48 hours of collection (Vial 31).

37. Discard all contaminated material into biohazard bags.

APPENDIX I

COULTER S-PLUS JR. INSTRUMENT VERIFICATION PROCEDURE

Appendix I. Coulter S-Plus Jr. instrument verification procedure

Institution Name_____Model/SN_____Date FSR#_____

Problem Reported_____

_____

_____

Corrective Action_____

_____

_____

Preventive Maint._____

_____

A. Pre-cycle State (clean, adjust, repair, or replace components as necessary)

1. Measure and record the following electronic reference voltages and pneumatic supply gauge readings.

PNEUMATIC SUPPLY GAUGES

5 PSI ± 0	_____
30 PSI ± 1	_____
60 PSI ± 5	_____
VACUUM ≥ 21" Bg	_____

ELECTRONIC REFERENCE VOLTAGES

WBC Aperture Current	_____	(107.7v to 129.6v)
RBC Aperture Current	_____	(141.5v to 169.1v)
HGB Blank (7.0 V ± .35)	_____	

Perform start-up and attach printout.

2. Verify that instrument responds to front keys.
3. Clean and check BSV and actuator mechanism for proper tension and for any unusual wear.
4. Verify that the aperture modules are free of bubbles and electrodes are not coated.
5. Check the lyse tubing for crimps.
6. Inspect tubing, baths, pneumatic and mechanical components for leaks or wear.
7. During count tap on vac regulator to check for stability.
8. Check that the pneumatic power supply is not making any unusual noise.
9. Check vacuum trap bottle, air/water separator, and overflow cup for fluid.
10. Press DRAIN button and ensure vacuum gauge drops at least 2", but no more than 4" of vacuum.
11. Verify analyzer fans, power supply, data terminal, and printer operate properly and air filters are clean.
12. Ensure all CRT displays are clear and free of debris and severe burn marks.

13. Clean printer, matrix printer plotter, and data terminal.
14. Verify proper operation of level sense system.
15. Review control data, XB data, and start-up log to ensure proper system performance.
16. Ensure all Service Memos are installed.
17. Ensure "CAL" factors are logged and update if necessary.

B. Cycle State

1. Verify that the aspiration volume is correct.
2. Verify that the baths drain completely.
3. Verify that the BSV rotates smoothly and completely. Ensure aspirate probe is exactly 3" long.
4. Verify that the diluent dispensers activate and fill baths to proper levels.
5. Verify mixing bubbles and rate.
6A. Verify that pumps and dispensers have no leaks, bubbles, or fluid in vacuum/pressure lines.
6B. Verify that the unit backwashes properly and no bubbles are introduced into aspirate lines.
7. Verify proper manometer adjustment and stability while unit is in COUNT cycle.
8. Verify that the burn circuit works properly.
9. Verify that the printer accepts, advances, and properly prints results on ticket.
10. Verify the keyboard, battery and transmission output in the data terminal.
11. Run patient sample and compare to previously run results.
12. Verify with customer that all problems have been addressed.

C. Instrument Performance

1. Perform the following checks, attach tickets or plots and verify that all results are within limits. Ten samples are required for testing reproducibility.

a. Background Limits (verify again using whole blood cycle).

WBC	RBC	HGB	PLT
.4	.04	.1	3

b. Reproducibility (10 samples)

	WBC	RBC	HGB	MCV	RDW	PLT	HPV
CV Limits	2.0%	2.0%	1.0%	2.0%	3.2%	4.0%	5.0%

c. Carryover Limits (run after reproducibility check)

	WBC	RBC	HGB	PLT
Limits	2.0%	1.0%	2.0%	2.0%

$$CV = \frac{\text{Avg. Deviation from Mean} \times 1.25}{\text{Sample Mean}} \times 100$$

$$\text{Carryover} = \frac{\text{Dil. \#1} - \text{Dil. \#3}}{\text{Last Sample}} \times 100$$

2. Verify Histogram Differential operation with at least 5 different normal patient samples and insure all results are obtained on at least 4 out of 5 samples.

3. Have customer run one or more samples and/or controls and verify that the instrument is operational and that all concerns have been addressed.

Customer Signature _____

F.S.E. Signature _____

APPENDIX J

PREPRINTED SHIPPING TRANSMITTALS

Blood Vial Transmittal from NHANES MEC

CDC SERUM BANK
ATTN: Serum Bank Branch
Building B
602 Webb Gin House Road
Lawrenceville, GA 30245-5427

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__

Deck No. 670A

NCHS #	Age	Sex	Vial	Specimen Collected Date	Ses	Code	Notes

Blood Vial Transmittal from NHANES MEC

UNIVERSITY OF MISSOURI-COLUMBIA
ATTN: Jack England
School of Medicine
Dept. of Child Health - Room M770
One Hospital Drive
Columbia, MO 65212

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__
Deck No. 680

Box No. _____

Glycosylated Hb
Vial No. 4

NCHS #	Age	Sex	Vial	Specimen Collected Date	Ses	Analysis Date	GLYHB %	Tech ID	Notes

Blood Vial Transmittal from NHANES MEC

UNIVERSITY OF MISSOURI-COLUMBIA
ATTN: Jack England
School of Medicine
Dept. of Child Health - Room M770
One Hospital Drive
Columbia, MO 65212

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___

Deck No. 671

Box No. _____

Glucose (GTT)
Vial No. 5, 5A, 5B

NCHS #	Age	Sex	Vial	Specimen Collected Date	Specimen Collected Ses	Analysis Date	mg%/dl	Tech ID	Notes

Blood Vial Transmittal from NHANES MEC

UNIVERSITY OF MISSOURI-COLUMBIA
ATTN: Jack England
School of Medicine
Dept. of Child Health - Room M770
One Hospital Drive
Columbia, MO 65212

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 672

Box No. _____

Insulin/C-Peptide
Vial No. 6, 6A, 6B

NCHS #	Age	Sex	Vial	Specimen Collected Date	Ses	Analysis Date	INS ng/ml	C-PEP Pl/ml	Tech ID	Notes

Blood Vial Transmittal from NHANES MEC

UNIVERSITY OF WASHINGTON
ATTN: Phyllis Daum
Immunology Division, SB10
Dept. of Laboratory Medicine, NW 176
1959 Pacific Ave.
Seattle, WA 98195

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 674

Box No. _____

C-Reactive Protein/Rheumatoid Factor
Vial No. 12

NCHS #	Specimen Collected Date	Ses	Analysis Date	C-r. prot. mg/dL	Age 60+ Rh. factor N P	Tech ID	Notes
					0 1:		
					0 1:		
					0 1:		
					0 1:		
					0 1:		
					0 1:		
					0 1:		

Blood Vial Transmittal from NHANES MEC

WHITE SANDS RESEARCH CENTER
ATTN: Brenda Billhymer
1300 LaVelle Road
Alamogordo, NM 88310

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__
Deck No. 676

SMAC profile
Vial No. 13

Box No. _____

NCHS #	Specimen Collected Date	Ses	Code	Notes

Blood Vial Transmittal from NHANES MEC

MEDICAL UNIVERSITY OF SOUTH CAROLINA
ATTN: Dr. Gabriel Virella
Dept. of Microbiology and Immunology
Room 216 B.S.B.
171 Ashley Ave.
Charleston, SC 29425

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 675

Box No. _____

Tetanus
Vial No. 16

NCHS #	Specimen Collected Date	Ses	Analysis Date	Tet. U/ml	Tech ID	Notes

Blood Vial Transmittal from NHANES MEC

CENTERS FOR DISEASE CONTROL
ATTN: Charles Schable
Building 1 Room 2367
1600 Clifton Road
Atlanta, GA 30333

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 67

Box No. _____

HIV I
Vial No. 20

Z number	Age Group	R	E	S	Education Category	Base Weight	Region	Notes

Blood Vial Transmittal from NHANES MEC

UNIVERSITY OF SOUTHERN CALIFORNIA
ATTN: Dr. Stan Patel
JSC Clinical Laboratories
Endocrine Serv. Lab-McKibben Rm. 245
2025 Zonal Ave.
Los Angeles, CA 90033

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 679

Box No. _____

Thyroid
Vial No. 21

NCHS #	Specimen Collected Date	Ses	Analysis Date	TT4 µg/dL	S-TSH µU/ml	AMA U/L	ATA U/L	Tech ID	Notes
				.	.				
				.	.				
				.	.				
				.	.				
				.	.				
				.	.				
				.	.				
				.	.				

Blood Vial Transmittal from NHANES MEC

UNIV. OF MASS. MEDICAL CENTER
ATTN: Dr. Lewis Braverman
55 Lake Avenue North
Worcester, MA 01655

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 677

FSH and LH Hormones
Vial No. 22

Box No. _____

NCHS #	Age	Sex	Specimen Collected Date	Ses	Analysis Date	FSH mIU/ml	LH mIU/ml	Tech ID	
						.	.		
						.	.		
						.	.		
						.	.		
						.	.		
						.	.		
						.	.		
						.	.		
						.	.		

Blood Vial Transmittal from NHANES MEC

WHITE SANDS RESEARCH CENTER
ATTN: Brenda Billhymer
1300 LaVelle Road
Alamogordo, NM 88310

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 678

Box No. _____

Fibrinogen
Vial No. 23

NCHS #	Specimen Collected Date	Ses	Analysis Date	Fibrin mg/dL	Tech ID	Notes

Blood Vial Transmittal from NHANES MEC

CDC Serum Bank
ATTN: Serum Bank Branch
Building B
602 Webb Gin House Road
Lawrenceville, GA 30245-5427

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. ___

Box No. _____

Toxoplasmosis
Vial No. TO

NCHS #	Age	Sex	Specimen Collected Date	Specimen Collected Ses	Proc. Tech ID	Specimen Processed	Shipping Tech ID	Comments*
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		

B01 = No specimen drawn
B02 = QNS
B03 = Broken tube
B04 = Hemolysis
B05 = Icteric
B06 = Lipemia
B07 = Pippetor malfunction
B08 = No MPA
B09 = No ascorbic acid
B10 = Tube or vial thawed
B11 = Prone position
B99 = Other (Specify)

Blood Vial Transmittal from NHANES MEC

CDC Serum Bank
ATTN: Serum Bank Branch
Building B
602 Webb Gin House Road
Lawrenceville, GA 30245-5427

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___

Deck No. 686

Box No. _____

Rubella
Vial RU

NCHS #	Age	Sex	Specimen Collected Date	Specimen Collected Ses	Proc. Tech ID	Specimen Processed	Shipping Tech ID	Comments*
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		
						Y N		

B01 = No specimen drawn
B02 = QNS
B03 = Broken tube
B04 = Hemolysis
B05 = Icteric
B06 = Lipemia
B07 = Pippetor malfunction
B08 = No MPA
B09 = No ascorbic acid
B10 = Tube or vial thawed
B11 = Prone position
B99 = Other (Specify)

Blood Vial Transmittal from NHANES MEC

BRATTON BIOTECH, INC.
ATTN: Sharon Ved Brat
Suite 101
1 Taft Court
Rockville, MD 20850

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 688Z

Box No. _____

IgE
Vial No. IE

NCHS #	Age	Sex	Specimen Collected Date	Ses	Code	Notes

Blood Vial Transmittal from NHANES MEC

CENTERS FOR DISEASE CONTROL
ATTN: Dr. David Ashley
Building 17, Room 1814F17
4770 Buford Highway
Chamblee, GA 30341

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 670D

Box No. _____

Volatile Toxicants - Blood
Vial No. 28

NCHS #	Age	Sex	Vial	Specimen Collected Date	Ses	Time	Code	Notes

Blood Vial Transmittal from NHANES MEC

CENTERS FOR DISEASE CONTROL
ATTN: Dr. Bob Hill
Building 17, Room 1814, F17
4770 Buford Highway
Chamblee, GA 30341

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__
Deck No. 670D

Box No. _____

Volatile Toxicants - Blood
Vial No. 29

NCHS #	Age	Sex	Vial	Specimen Collected Date	Ses	Time	Code	Notes

Blood Vial Transmittal from NHANES MEC

SRA Technologies, Inc.
ATTN: Juanita Dalzell
2515 Hwy. 54, Bldg. 2100
Durham, NC 27713

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__
Deck No. 687

Box No. _____

DNA/HgB Adducts
Vial C1 and C2

NCHS #	Age	Sex	Proc. Tech ID	Specimen Collected Date	Ses	C1 Specimen Processed	C2 Specimen Processed	Shipping Tech ID	Comments*
						Y N	Y N		
						Y N	Y N		
						Y N	Y N		
						Y N	Y N		
						Y N	Y N		
						Y N	Y N		
						Y N	Y N		
						Y N	Y N		

B01 = No specimen drawn
B02 = QNS
B03 = Broken tube
B04 = Hemolysis
B05 = Icteric
B06 = Lipemia
B07 = Pippetor malfunction
B08 = No MPA
B09 = No ascorbic acid
B10 = Tube or vial thawed
B11 = Prone position
B99 = Other (Specify)

Blood Vial Transmittal from NHANES MEC

CENTERS FOR DISEASE CONTROL
ATTN: Dr. Jack Reidy
Building 32, Room 1502, F24
4770 Buford Highway
Chamblee, GA 30341

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 670E

Box No. _____

Genetic Testing
Vial No. 31

NCHS #	Age	Sex	Specimen Collected Date	Ses	Code	Notes

Blood Slide Transmittal from NHANES MEC

MOBILE EXAM CENTER SLIDES

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___

Deck No. 682

MEC Slides

Box No. _____

NCHS #	Age	Sex	Specimen Collected Date	Session	Notes

Blood Slide Transmittal from NHANES MEC
CDC SERUM BANK
ATTN: Serum Bank Branch
Building B
602 Webb Gin House Road
Lawrenceville, GA 30245-5427

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__
Deck No. 670C

Box No. _____

CDC Slides

NCHS #	Age	Sex	Specimen Collected Date	Ses	Code	Notes

Urine Transmittal from NHANES MEC

CDC SERUM BANK
ATTN: Serum Bank Branch
Building B
602 Webb Gin House Road
Lawrenceville, GA 30245-5427

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__
Deck No. 682

Cadmium
Tube No. U1

NCHS #	Age	Sex	Specimen Collected Date	Ses	Code	Notes	Blood

Urine Transmittal from NHANES MEC

UNIVERSITY OF MINNESOTA
ATTN: Susan Kupcho
Pediatrics Dept.
Room 13-219 - MOOS Tower
515 Delaware St., S.E.
Minneapolis, MN 55455

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 681

Box No. _____

Creatinine/Microalbumin
Vial No. U2

NCHS #	Specimen Collected Date	Ses	Analysis Date	Creatinine mmoles/L	Micro-albumin ng/L	Tech ID	Notes

Urine Transmittal from NHANES MEC

UNIV. OF MASS. MEDICAL CENTER
ATTN: Dr. Lewis Braverman
55 Lake Avenue North
Worcester, MA 01655

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___

Deck No. 682

Urinary Iodine
Tube No. U3

Box No. _____

NCHS #	Specimen Collected Date	Ses	Date of Analysis	U. Iodine mcgI/dL	Tech ID	Notes

Urine Transmittal from NHANES MEC

COLUMBIA BIOMEDICAL LABORATORY
ATTN: Ayad Muddarris
4700 Forest Drive, Suite 200
Columbia, SC 29206

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt ___/___/___
Deck No. 685Z

Box No. _____

Drug
Tube No. UD

Z number	Age	R	E	S	Education Category	Base Weight	Region	Notes

Urine Transmittal from NHANES MEC

CENTERS FOR DISEASE CONTROL
ATTN: Dr. Bob Hill
Building 17, Room 1814, F17
4770 Buford Highway
Chamblee, GA 30341

Shipper No. _____
Date of Shipment _____
Reviewer No. _____
Date of Receipt __/__/__
Deck No. 670D

Volatile Toxicants - Urine

NCHS #	Age	Sex	Tube	Specimen Collected Date	Ses	Time	Code	Notes