

National Health  
and Nutrition  
Examination Survey

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TUBERCULOSIS  
SKIN TEST  
PROCEDURES  
MANUAL



January 2001



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## 1. TUBERCULOSIS SKIN TESTING IN NHANES

The Centers for Disease Control and Prevention, Division of Tuberculosis (TB) Elimination, is responsible for the TB skin testing component of NHANES. The objective of this effort is to determine the prevalence of TB infection in the U.S. population. All sample persons (SPs) aged 1 year and older will be tested for infection with the bacterium that causes TB.

### 1.1 Overview of TB and TB Skin Testing

TB is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*. TB is spread by tiny airborne particles expelled by a person who has infectious TB when that person coughs, speaks, or sings. If another person inhales air containing these particles that person may become infected. Infection begins with the multiplication of TB bacteria in the lung, some of which pass into the bloodstream.

If a person becomes infected, the body's immune system usually prevents development of the disease. Ninety percent of people who are infected with TB bacteria never develop active disease. Infected people who do not have active disease probably carry a small number of TB bacteria in their bodies for life but they are not infectious to other people. About 10 percent of infected people do go on to develop active TB disease. About 5 percent develop disease within a year or two after infection but the remaining 5 percent may develop the disease many years later.

TB disease can be found in any part of the body, but most people with active TB have lung disease, with persistent cough, fever, fatigue, and weight loss. People with active disease who have a lot of TB bacteria in their lungs are infectious to others. However, TB disease is curable in almost every case if it is diagnosed quickly and the correct drugs are taken for a long enough period. People on appropriate treatment plans are no longer infectious to others within a few weeks after treatment begins.

People who are exposed to someone with active untreated infectious TB for weeks to months are those to whom TB is most likely to be spread. Transmission is most likely to someone who lives or works regularly with a person ill with TB. Casual brief contact is unlikely to result in TB transmission. TB bacteria are killed by UV light (sunlight). If the bacteria are diluted by air currents outdoors, or by

regular air changes indoors, it is less likely that an uninfected person will inhale enough to become infected. TB is not spread to the mucous membranes like the common cold, which makes it more difficult to transmit. Many bacteria must reach the small deep areas of the lungs for infection to happen .

Tuberculin skin testing, discussed in more detail in later sections, is generally used to allow clinicians to look for infection in household or workplace contacts of people with active disease. Contacts whose skin test and clinical evaluation indicate infection, but who do not have active disease, are sometimes given treatment to prevent active disease. Preventive treatment is not appropriate for some infected people and is only prescribed after careful evaluation by a doctor.

## **1.2 TB Epidemiology**

TB kills more people in the world than any other infectious disease. The majority of TB cases are found in developing countries. After a steady fall in the number of cases in the U.S. between 1953 and 1984, TB reemerged as a serious national problem in the later 1980s. The major factors contributing to the increase were the higher risk of TB associated with human immunodeficiency virus (HIV), immigration from countries where TB is common, outbreaks of TB in congregate settings (health care facilities, prisons, homeless shelters), and a deterioration of the public health infrastructure. Appropriate treatment was less available to many people who therefore remained infectious for longer periods. Many others were given treatment but not followed to see that they completed treatment. Few staff were available to test household contacts and prescribe preventive treatment for those who were infected. Lack of resources resulted in a rise in TB cases.

The rise in case rates took place mostly in a few geographic areas centered in large cities. In most of those areas, including New York City, more money was devoted to TB prevention and control in the 1990s and the numbers of cases have begun to decline again. However, some groups remain at higher risk than others. These groups can be divided into two categories: persons more likely to be exposed to TB, and people more likely to develop TB disease once infected.

People more likely to be exposed to TB include close contacts of a person with infectious TB, foreign-born persons from areas of the world where TB is common, medically underserved, low income populations, and other groups identified locally as having an increased prevalence of TB. Persons who are at high risk of developing TB disease once infected include people whose immune systems are

compromised (including people with HIV), the elderly, and people with other medical conditions that damage the immune system (such as some cancers).

Because of inadequate treatment, some cases of TB have developed resistance to one or more of the drugs routinely used to treat TB. People with active disease carrying drug-resistant TB bacteria remain infectious if they are not treated appropriately. Drug-resistant TB is more difficult to treat, requiring larger numbers of drugs and longer treatment periods. Drug-resistant TB has made TB control more difficult in parts of the country.

Reporting of persons with active TB disease helps public health personnel understand how well TB programs are working, but active disease is only the tip of the iceberg. The much larger group of infected people without active disease are all at risk of developing active disease some time in the future. For public health purposes it is very useful to know the proportion of the population infected with TB, and also which groups have higher rates of infection. The tuberculin skin test is available to detect TB infection, but population-based studies of infection are rare because large numbers of people must be tested for reliable figures to be obtained.

Tuberculin skin testing is used in surveys in order to estimate what percentage of a population is infected with TB. Surveys also look at whether a higher proportion of people are infected in certain geographic or ethnic groups. Studies estimate the overall number of TB-infected people in an area and the groups most at risk of infection, help to evaluate the effectiveness of TB prevention and control programs, and target areas where more work is needed.

NHANES I, conducted in 1971-72, included a tuberculin skin testing component. The results allowed CDC to estimate that, at that time, 21.5 percent of the U.S. population between the ages of 25 and 74 was infected with TB. The current NHANES will be the first population-based survey of infection in the U.S. population since NHANES I. Although cases of active disease are reported yearly, this does not represent the whole picture since most infected people never get active disease and others develop disease many years after infection. In order to work towards TB elimination, we need the information NHANES will provide on infection to supplement the reports on active TB disease regularly received from TB control programs in health departments all over the country.

### **1.3 Overview of TB Skin Testing**

Robert Koch, who discovered the bacterium that causes TB, also thought he had discovered a cure for TB in 1890. He injected doses of tuberculin, a liquid that was filtered from killed TB bacteria, just under the skin of patients. It turned out that this process did not cure TB, but it led to the test that allows us to diagnose TB infection. By the 1930s tuberculin skin testing had become a widespread method for screening for TB infection.

To detect TB infection, a small drop of filtered tuberculin liquid containing some components of heat-killed TB bacteria is injected just under the top layer of the forearm skin. The best test currently available uses purified protein derivative (PPD), a sterile fluid that contains killed, purified standardized mycobacteria components that rarely give problems with side effects. If the person being tested has been previously infected with TB, the immune system recognizes the bacterial components and produces a local immune response on the skin in the area of the test. This reaction is usually a small hard raised area of skin, which can be felt with the fingertips 48-72 hours after the test is placed. The reaction is measured in millimeters and different reaction sizes, depending on the person being tested and the purpose of the test, are defined as positive, indicating that TB infection may have occurred at some time in the person's life. The reaction usually disappears within a week.

If the person being tested has not been previously infected with TB, the test usually produces no reaction at all, or sometime a little redness or some soft swelling. These mild reaction represent irritation and do not indicate TB infection. A red area that is not raised or hard is not considered a positive reaction.

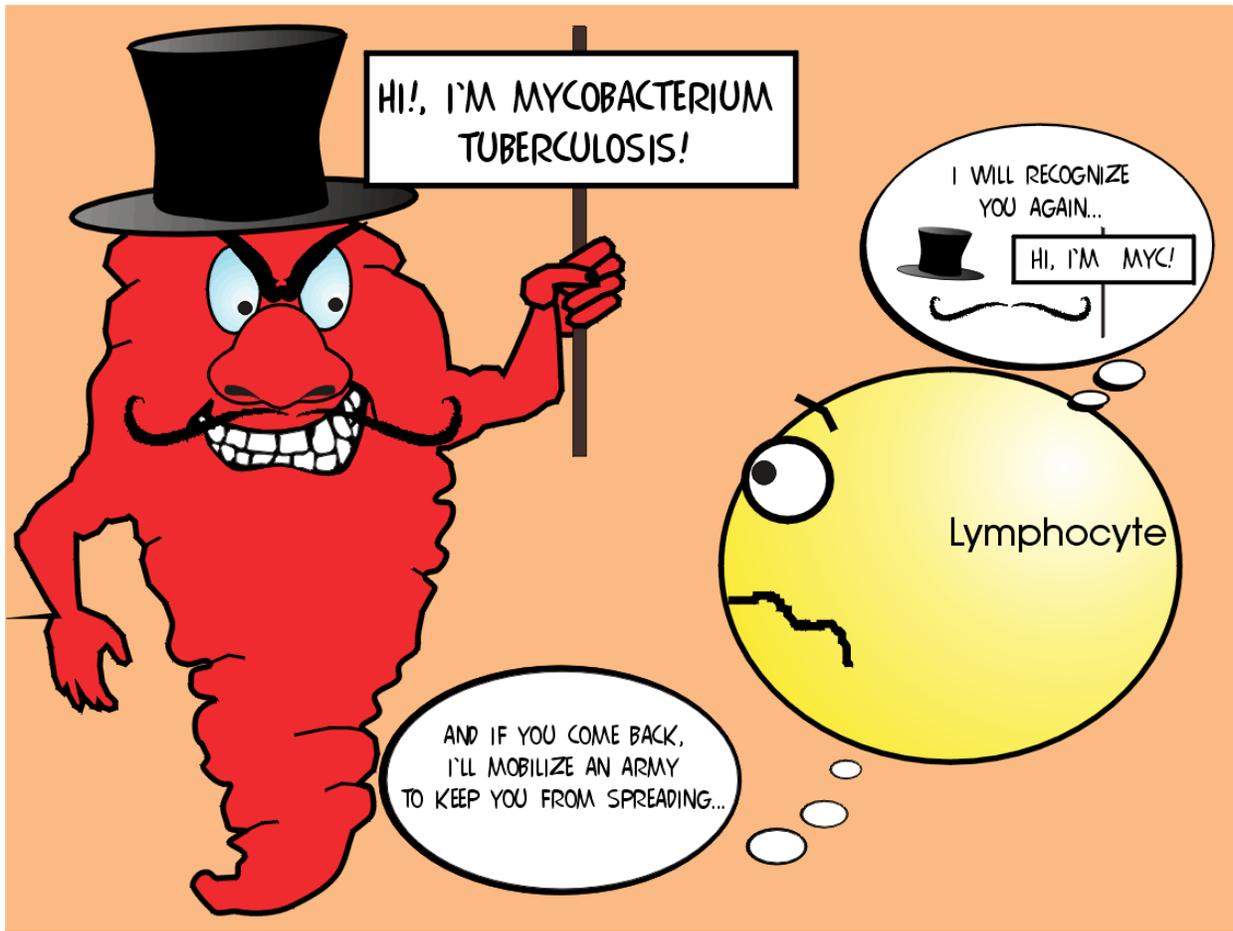


Figure 1-1. *Mycobacterium tuberculosis*

When someone is infected with tuberculosis, the immune system remembers some identifying signs in order to get ready to fight the germ quickly if reinfection occurs. The hard, raised local reaction under the skin when PPD is injected usually happens when the immune system remembers TB and reacts.

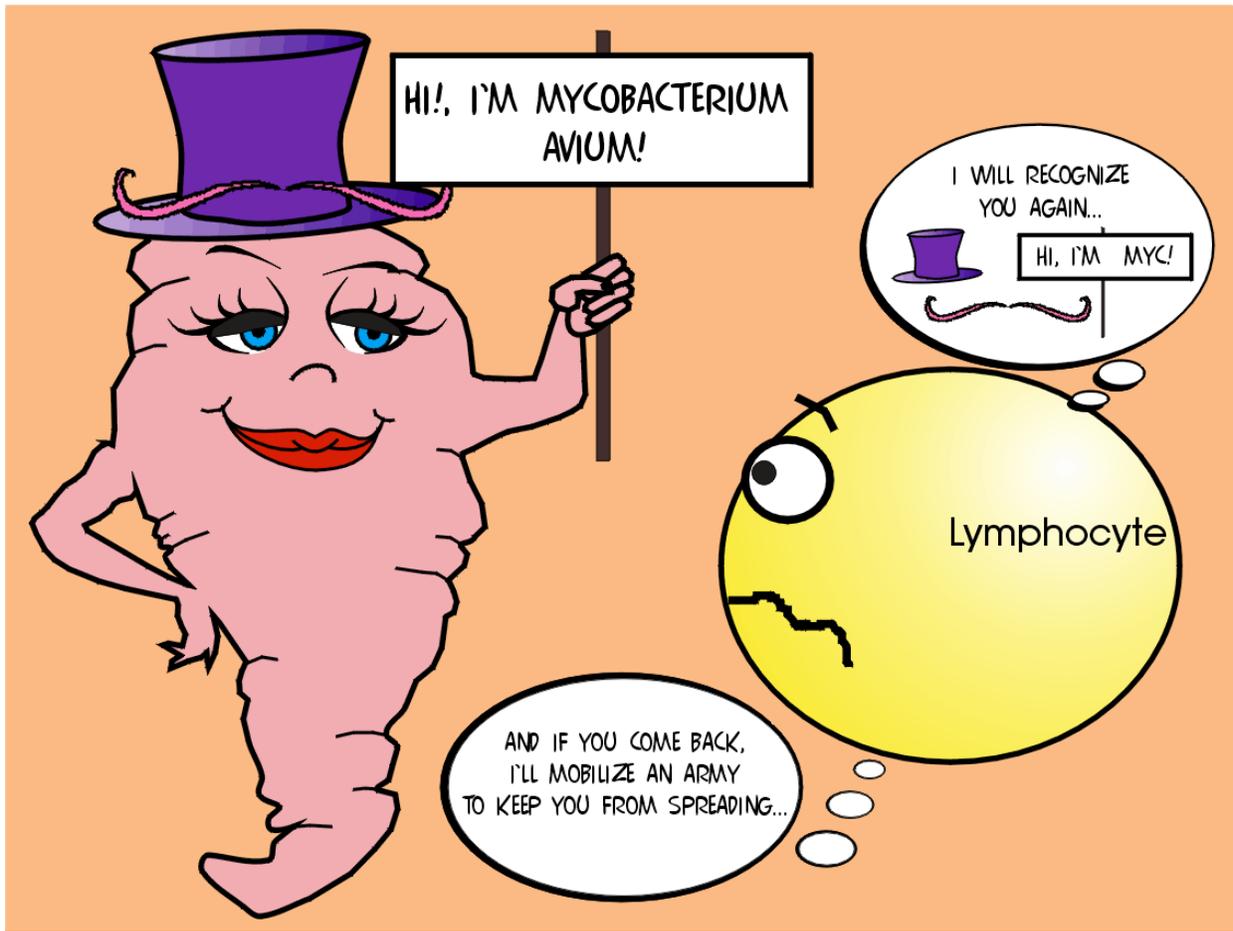


Figure 1-2. *Mycobacterium avium*

When someone is infected with nontuberculous mycobacteria, which are widespread in the soil and water in the U.S. and elsewhere, the immune system remembers some identifying signs. These look enough like similar signs on the TB germ that the immune system may react later to a TB skin test. The reaction is a "false positive" reaction in this case, because the person has not been infected with TB but with a similar harmless germ.

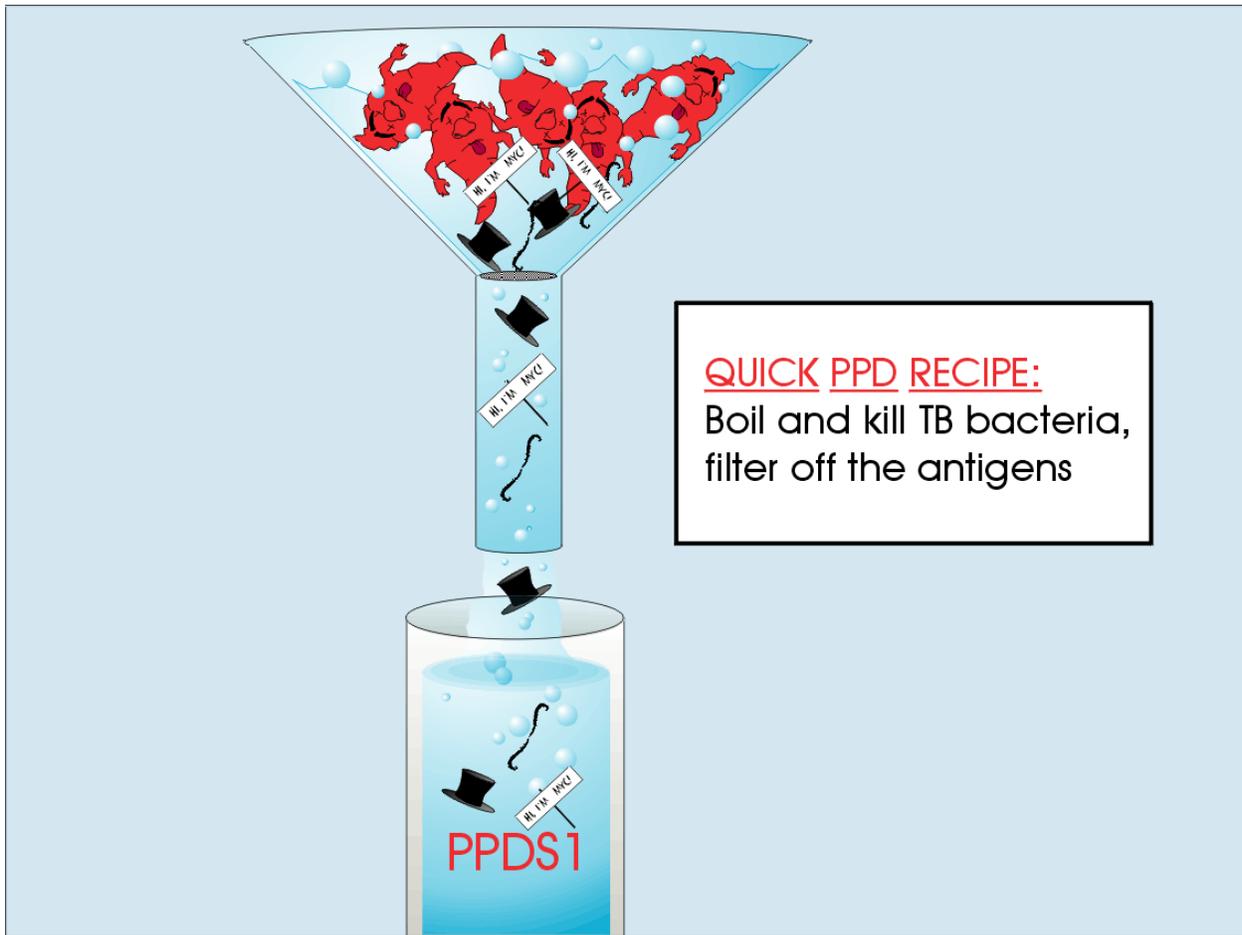


Figure 1-3. Quick PPD Recipe

PPD-S1 is used to test whether the body's immune system "remembers" TB. PPD-S1 contains no TB germs, but only the antigens, or recognizable signs, filtered off after the germs are heat-killed.

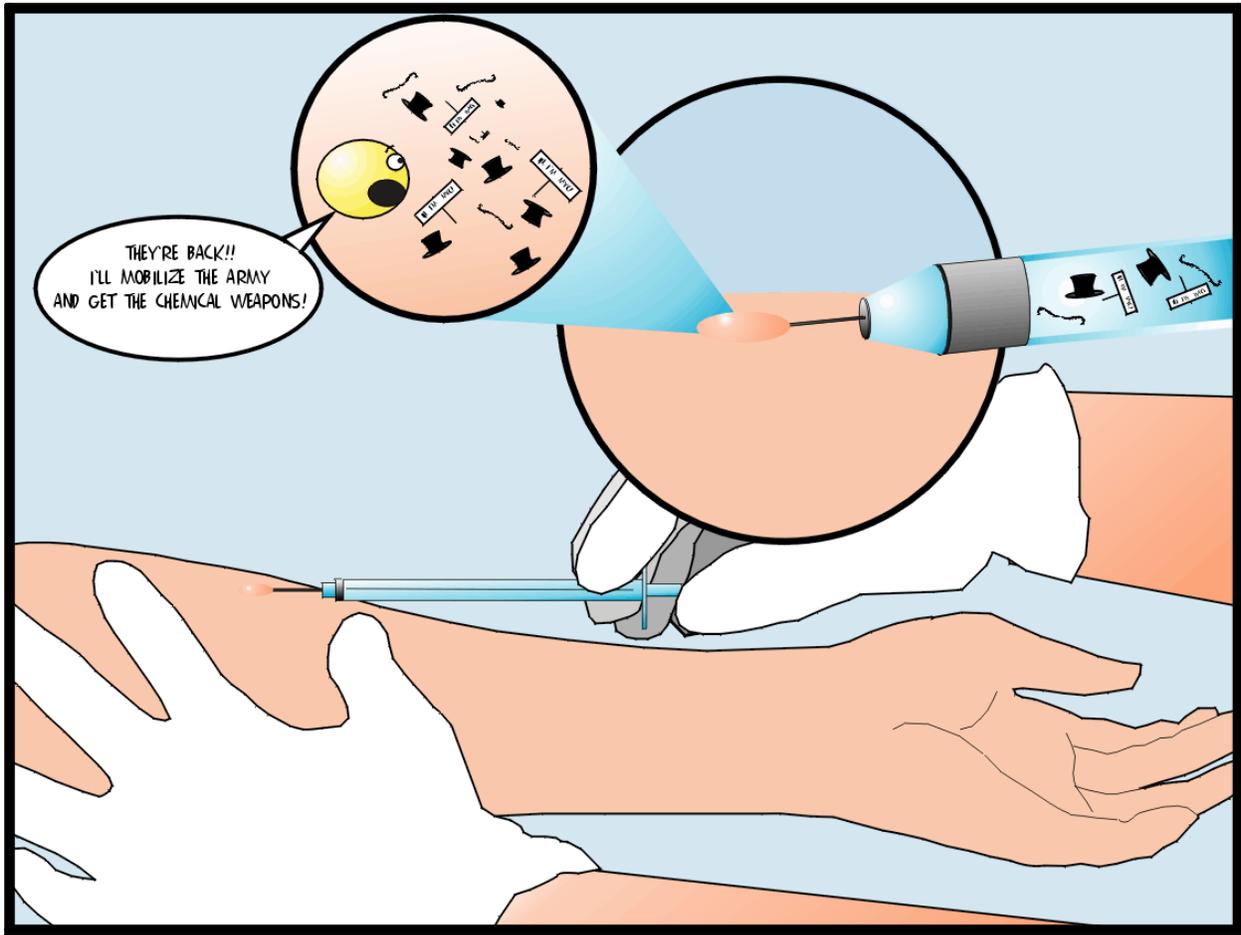


Figure 1-4. PPD test

The PPD test injects a small amount of antigen just under the skin. The immune system reacts within 48-72 hours if it has "seen" similar material before.

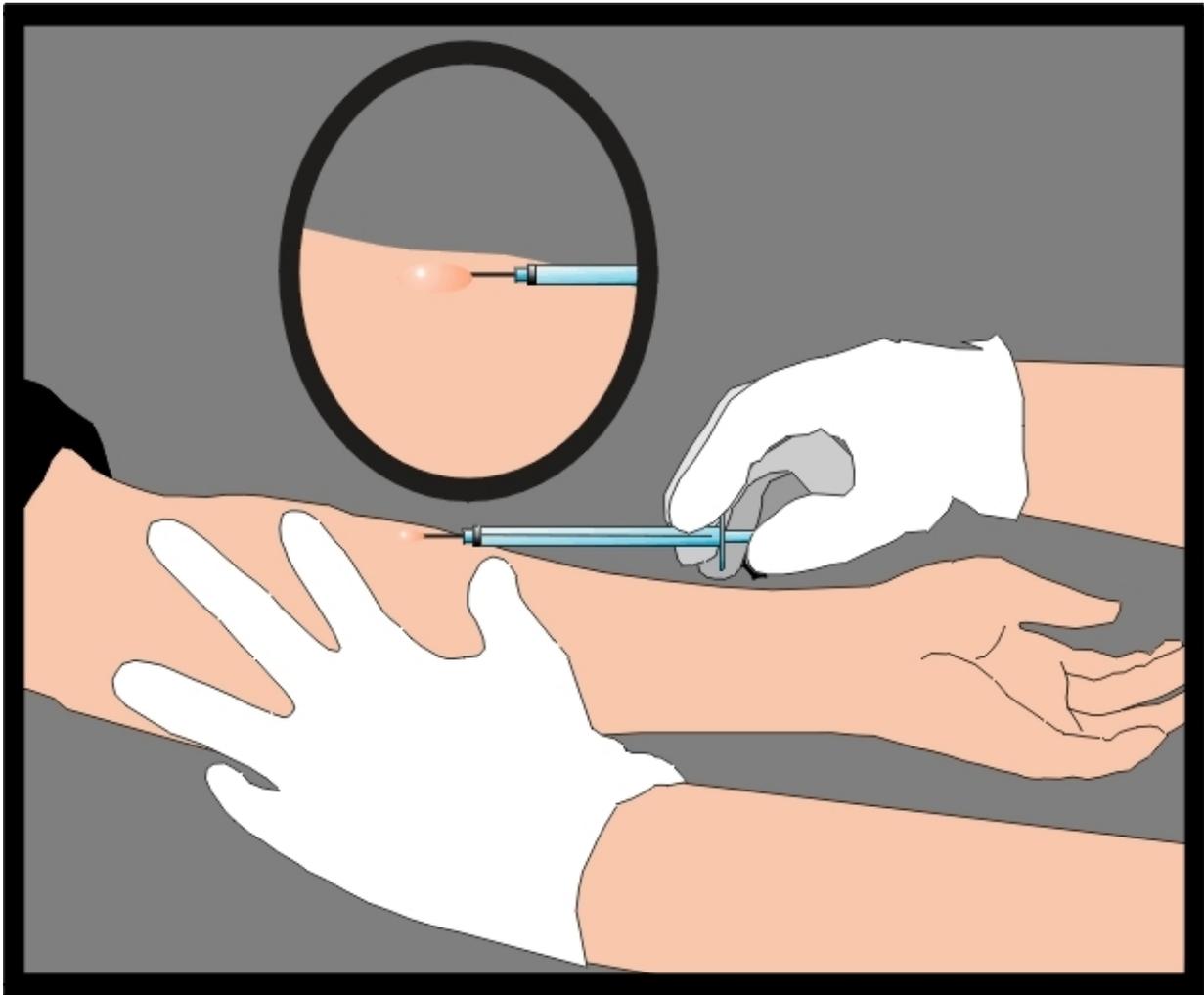


Figure 1-5. The Mantoux Test

The PPD test leaves a small amount of killed, purified mycobacteria material just under the skin, but no significant amount gets into the bloodstream or the system. Pregnant women, young children, people with immune system deficiencies, people who have recently had immunizations and people who have had a positive TB test in the past, can all safely have a PPD test. The test is only contraindicated for the few people who have previously had a severe allergic reaction, including an anaphylactic reaction (an allergic response involving the whole body) and/or ulceration at the test site. A severe allergic reaction is uncommon and usually subsides within a few days. Many clinical workers who apply PPD tests for many years never see such a reaction, and no such reactions were recorded during NHANES I. Previous itching, redness, or mild swelling after a previous test are not considered severe reactions and do not make a person ineligible for NHANES PPD tests.

An early widely used version of the tuberculin test was the Tine test, which used a small circular device with four metal tuberculin-coated prongs. The prongs were pushed into the skin of the forearm to deliver the tuberculin just under the skin. Results were less reliable than with the newer Mantoux test, in which a small needle and syringe are used to inject the tuberculin under the skin (Figure 1-1). The Mantoux version of the test was used in NHANES I. It is being used in the current NHANES both because of its greater reliability, and so that the results can be compared directly to NHANES I.

As noted earlier, a positive reaction to the PPD test indicating infection does not mean the person has active TB disease. It is impossible for an infected person who does not have active disease to spread TB.

#### **1.4 Limitations of Tuberculosis Skin Testing and Implications for NHANES**

Although it is the best test for TB infection that we have, tuberculin skin testing with PPD is imperfect. Some TB-infected people who have other health problems, especially diseases affecting the immune system, may have a negative result. These cases are termed false negatives. False positive results are also possible and they become relatively more common when there is not much TB infection in a population. In some areas of the U.S. where there are few active cases of TB, this could lead to an overestimate of the proportion of people infected with TB.

One common cause of false positive tuberculin tests is infection with harmless germs related to TB called "nontuberculous mycobacteria." These germs are widespread in soil and water in many places, and many people are infected with these germs. They do not cause disease in healthy people and there is no need to treat the infection. However, they can cause a false positive tuberculin PPD test. To minimize the number of false positive tuberculin tests, an additional PPD skin test for nontuberculous mycobacteria was used in NHANES I and will be used again in the current NHANES. This test, called PPD-Batthey, is applied in the same way as the tuberculin skin test. Measuring the reaction to PPD-Batthey will help in the interpretation of the tuberculin skin tests and reduce the number of false positive results in NHANES.

## **1.5 Skin Test Results for NHANES Participants**

SPs over the age of one year in NHANES will receive two (2) injections each: the tuberculin skin test (PPD-S1) and PPD-Batthey. Both of these PPDs are research tools. They have been used safely in many surveys in the U.S. and elsewhere, and will provide a useful estimate of how widespread TB infection is in the United States. PPD-S1 is also the standard against which clinical products used in doctor's offices are compared in the U.S., according to FDA requirements, but it is not used in doctors offices.. Neither PPD-S1 nor PPD-B are licensed for clinical use in the U.S.. Because they are kept for research purposes, no company has ever applied for a clinical license for either one. This means they cannot be used as part of a clinical evaluation to decide whether an individual has TB infection or needs preventive treatment. NHANES SPs whose PPD-S1 tuberculin skin test result is above a minimum cutoff are given a Report of Findings that states that they may have been infected with TB at some time during the past. They are instructed to contact their primary source of medical care or the TB control program at the local health department or for a clinical evaluation. SPs whose PPD-Batthey skin test is above a minimum cut off are given a Report of Findings that states that they may have been infected with germs related to TB, also called nontuberculous mycobacteria. However, since these harmless germs do not cause disease in healthy people and are not spread from person to person, there is no need to see a doctor or have additional tests performed unless the PPD-S1 test is positive.

In research studies using two or more skin tests, results are considered less subject to scientific bias if people who measure and record skin test results do not know which test has been applied to which arm. The two different PPDs used in NHANES will be labeled so that placers who apply the tests (who may also read reactions) will not know which PPD is being injected into which arm. The PPD vials will be labeled PPD-A and PPD-C. The ISIS computer program will randomly generate the directions, for each subject, to indicate to the placer the arm to which each antigen is to be applied.

The reader will not have access to the screen that has directed the application of the tests. The reader reads and records the results for the right and left arms. After the results are recorded, ISIS retrieves the information to match each result to the appropriate PPD, and generates the Report of Findings for the SP. A separate report of findings is generated for each test.

## 2. TUBERCULOSIS SKIN TESTING

### 2.1 Overview of TB and TB Skin Testing

The Centers for Disease Control and Prevention, Division of Tuberculosis (TB) Elimination, is responsible for the TB skin testing component of NHANES. The objective is to determine the prevalence of TB infection in the U.S. population. All sample persons (SPs) aged 1 year and older are tested for infection with the bacterium that causes tuberculosis (TB).

TB is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*. TB is carried from person to person on tiny airborne particles expelled by a person who has infectious TB and coughs, speaks, or sings. If another person inhales air containing these infectious particles, that person may become infected. Infection begins with the multiplication of TB bacteria in the lung. Some of the bacteria pass into the bloodstream.

If a person becomes infected, the immune system of the body usually prevents development of the disease. Ninety percent of infected people never develop active disease. Infected people who do not have active disease probably carry a small number of TB bacteria in their bodies for life but they are not infectious. About 10 percent of infected people eventually develop active TB disease. About 5 percent develop disease within a year or two after infection while the remaining 5 percent may develop the disease many years later.

TB disease may develop in any part of the body, but most people with active TB have lung disease with persistent cough, fever, fatigue, and weight loss. People with active disease who have a significant amount of TB bacteria in their lungs are infectious to others. However, TB disease is usually curable if diagnosed quickly and appropriate drugs are taken for a sufficient period of time. People on appropriate treatment are no longer infectious to others within a few weeks after beginning treatment.

People exposed to someone with active untreated infectious TB for weeks to months are most likely to acquire the disease. TB bacteria are most likely to be transmitted to someone who regularly lives or works with a person ill with TB. Casual brief contact is unlikely to result in TB transmission. Sufficient exposure to UV light (sunlight) can kill the TB bacteria. If outdoor air currents or regular air changes indoors dilute the bacteria, it is less likely that an uninfected person will inhale enough bacteria

to become infected. Since TB is not spread to the mucous membranes like the common cold, it is more difficult to transmit. Infection occurs when many bacteria reach the small deep areas of the lungs.

Tuberculin skin testing allows clinicians to look for infection in household or workplace contacts of people with active disease. Treatment to prevent active disease is provided to some contacts whose skin test and clinical evaluation indicate infection, but who do not have active disease. Preventive treatment is not appropriate for some infected people and is only prescribed after careful evaluation by a doctor.

## **2.2 TB Epidemiology**

TB kills more people in the world than any other infectious disease. The majority of TB cases occur in developing countries, but high rates may be found in some areas of developed countries. After a steady fall in the number of cases in the U.S. between 1953 and 1984, TB reemerged as a serious national problem in the late 1980s. The major factors contributing to the increase were the higher risk of TB associated with human immunodeficiency virus (HIV), immigration from countries where TB is common, outbreaks of TB in congregate settings (health care facilities, prisons, homeless shelters), and a deterioration of the public health infrastructure. Appropriate treatment was less available to many people with active disease who therefore remained infectious for longer periods. Many others began treatment but were not followed to see if they had completed treatment. Few staff were available to test household contacts and prescribe preventive treatment for those who were infected. Lack of public health resources resulted in a rise in TB cases.

A few geographic areas centered in large cities accounted for a large proportion of the rise in case rates. In most of those areas, including New York City, more money was devoted to TB prevention and control in the early 1990s and the numbers of cases began to decline in 1993. However, some groups remain at higher risk than other groups. These groups can be divided into two categories, persons more likely to be exposed to TB, and people more likely to develop TB disease once infected.

People more likely to be exposed to TB include close contacts of a person with infectious TB, foreign-born persons from areas of the world where TB is common, medically underserved populations, low-income populations, and other groups identified locally as having an increased prevalence of TB. Persons who are at high risk of developing TB disease, once infected, include people

whose immune systems are compromised (including people with HIV), the elderly, and people with other medical conditions that damage the immune system (such as some cancers).

Because of inadequate treatment, the bacteria in some individuals with active TB developed resistance to one or more of the drugs routinely used to treat TB. People with active disease carrying drug-resistant TB bacteria remain infectious if they are not treated appropriately. Drug-resistant TB is more difficult to treat and requires larger numbers of drugs and longer treatment periods. Drug-resistant TB has made TB control more difficult in parts of the country.

Reporting cases of active TB helps public health personnel understand how well TB programs are working, but active disease represents only the tip of the iceberg. The much larger group of infected people without active disease are at risk of developing active disease some time in the future. For public health purposes, it would be useful to know the proportion of the population infected with TB, and which groups have higher rates of infection. The tuberculin skin test is available to detect TB infection, but population-based studies of infection are rare because these studies require testing large numbers of people in order to obtain reliable figures.

Surveys use tuberculin skin testing to estimate the percentage of a population infected with TB. Surveys also look at whether higher proportions of infected people are in certain geographic or ethnic groups. Studies estimate the overall number of TB-infected people in an area and the groups most at risk of infection, help evaluate the effectiveness of TB prevention and control programs, and target areas for additional efforts.

The NHANES I conducted in 1971-72 included a tuberculin skin testing component. The results allowed CDC to estimate that, at that time, TB infection occurred in 21.5 percent of the U.S. population between the ages of 25 and 74. The current NHANES is the first population-based survey of infection in the U.S. population since NHANES I. Although cases of active disease are reported yearly, they do not represent the whole picture, since most infected people never get active disease and others develop disease many years after infection. The current NHANES data will provide information on infection to supplement the active TB reports regularly received from TB control programs in health departments across the country, to enable the CDC to work towards TB elimination.

## **2.3 Overview of TB Skin Testing**

Robert Koch, who discovered the bacterium that causes TB, also thought he had discovered a cure for TB in 1890. He injected doses of tuberculin, a liquid filtered from killed TB bacteria, just under the skin of patients. While this process did not cure TB, it did lead to the test that allows diagnosis of TB infection. By the 1930s tuberculin skin testing had become a widespread screening method for TB infection.

To detect TB infection, a small drop of filtered tuberculin liquid containing some components of heat-killed TB bacteria is injected just under the top layer of the forearm skin. The best test currently available uses purified protein derivative (PPD), a sterile fluid that contains killed purified, standardized mycobacteria components that rarely produce problematic side effects. If the person has been previously infected with TB, the immune system recognizes the bacterial components and produces a local immune response on the skin in the area of the test. This reaction is usually a small hard raised area of skin, which can be felt with the fingertips 48-72 hours after placing the test. TB skin test readers measure the reaction in millimeters. Different reaction sizes, depending on the person being tested and the purpose of the test, are defined as positive, indicating that TB infection may have occurred at some time in the person's life. The reaction usually disappears within a week.

In persons not previously infected with TB, the test usually produces no reaction, or sometimes produces a little redness or some soft swelling. These mild reactions represent irritation and do not indicate TB infection. Health care workers evaluating a skin test reaction do not consider a red area that is not raised or hard as a measurable reaction.

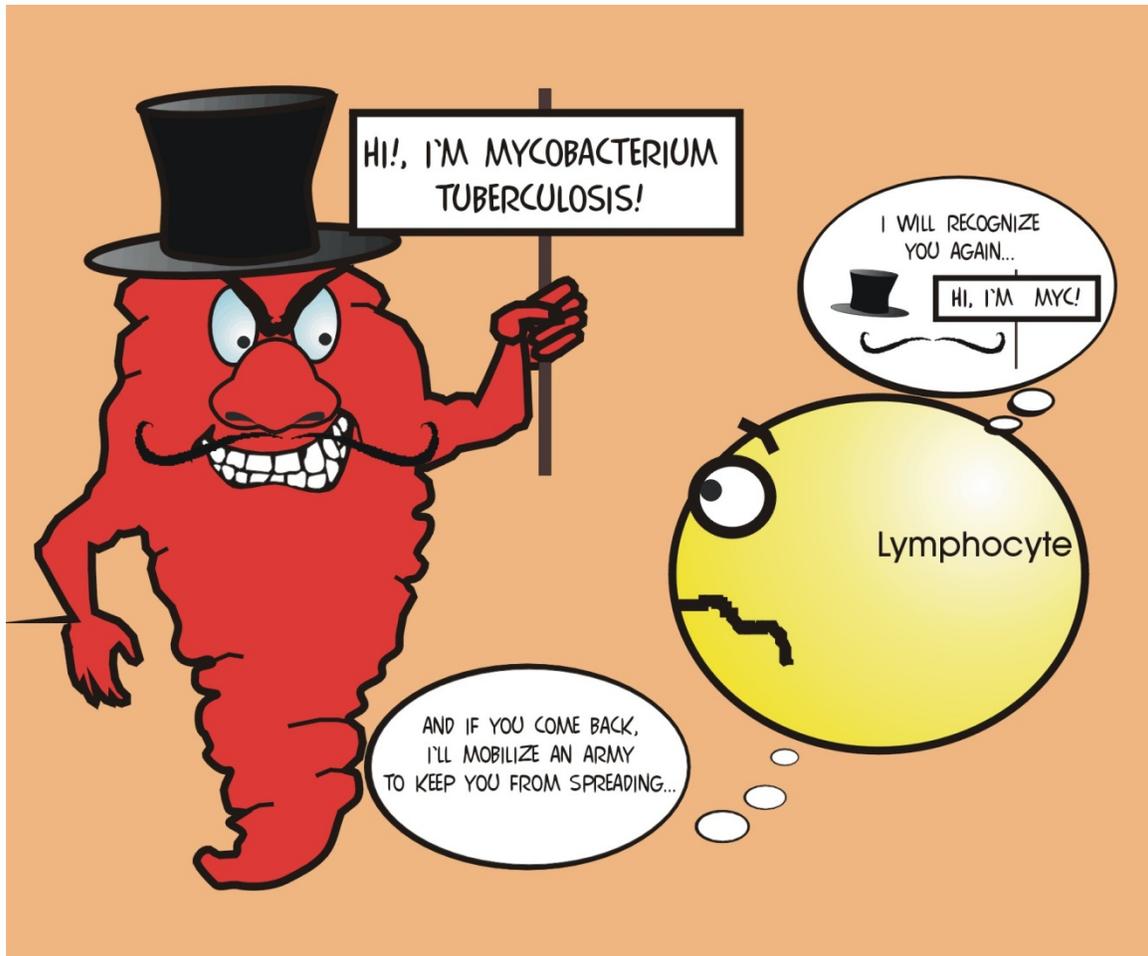


Figure 2-1. *Mycobacterium tuberculosis*

In persons infected with tuberculosis, the immune system prepares to fight the germ quickly if reinfection occurs by “remembering” some identifying signs. The hard, raised local reaction under the PPD injection site on the skin usually occurs because the immune system remembers TB and reacts (Figure 2-1).

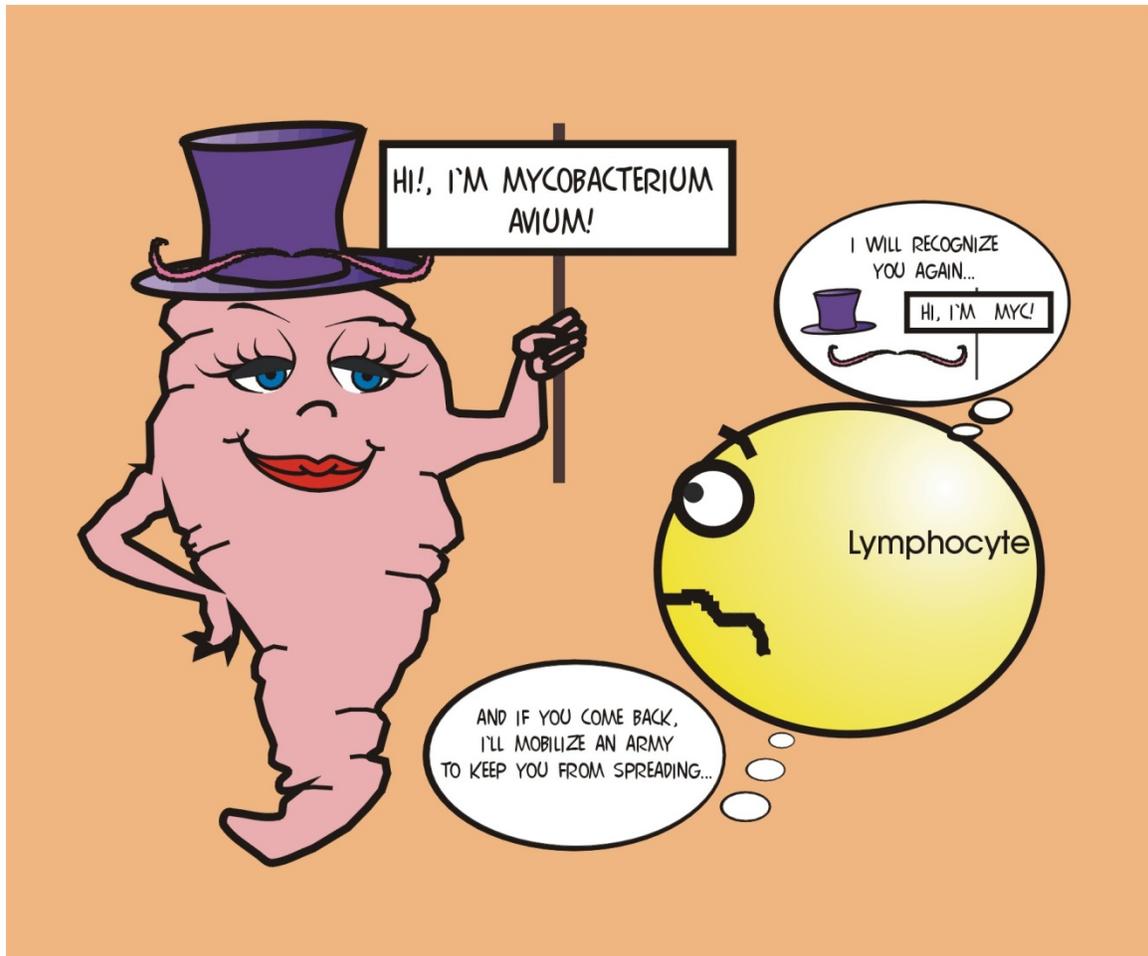


Figure 2-2. *Mycobacterium avium*

Nontuberculous mycobacteria are widespread in the soil and water in the U.S. and elsewhere. The immune system remembers some identifying signs in persons infected with nontuberculous mycobacteria. People infected with nontuberculous mycobacteria may produce a positive reaction to a TB skin test because identifying signs on the two germs are similar. The reaction is a “false positive” reaction, because the person has not been infected with TB but rather with a similar harmless germ (Figure 2-2).

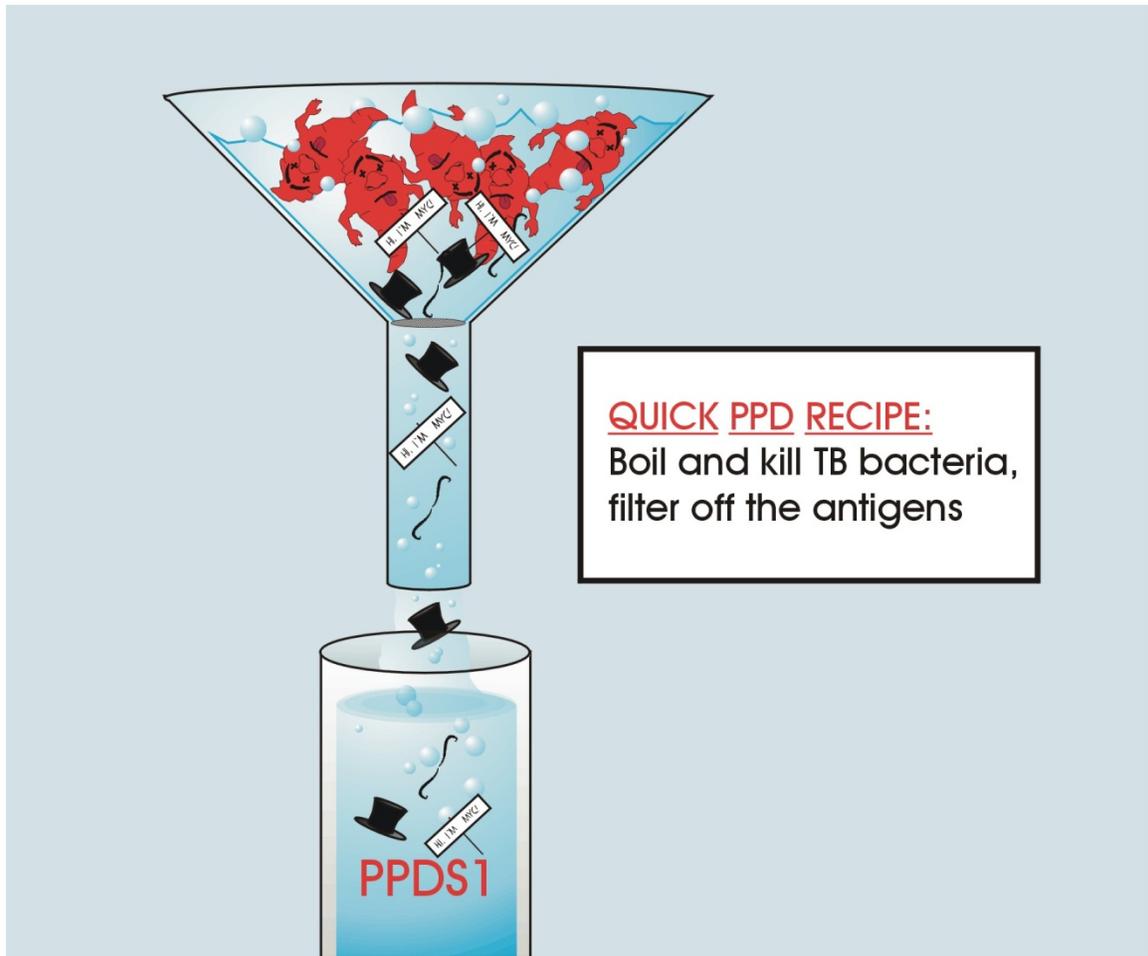


Figure 2-3. Quick PPD Recipe

PPD-S1 tests whether the immune system of the body “remembers” TB. PPD-S1 contains no TB germs, but only the antigens, or recognizable signs, removed by filtration after the germs are heat-killed.

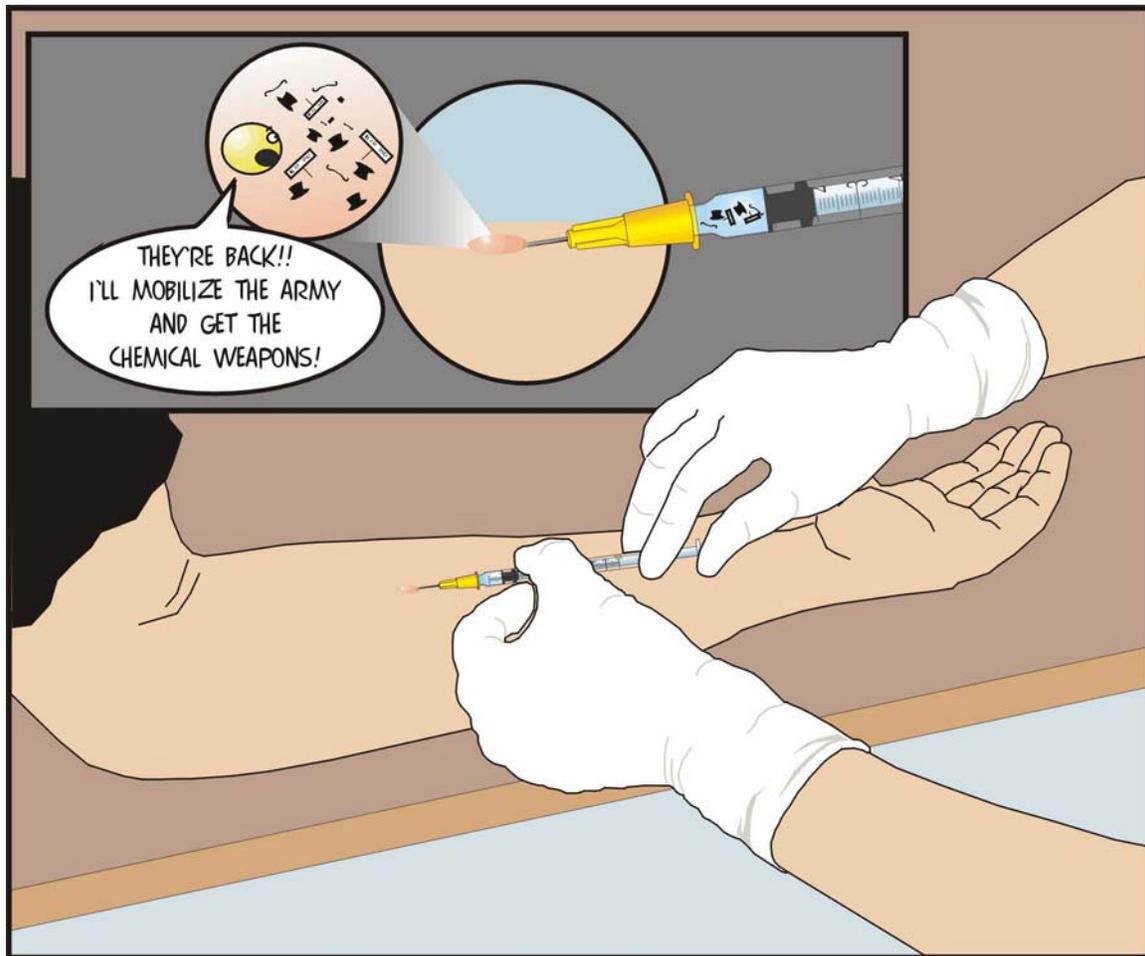


Figure 2-4. The Mantoux Test

The PPD test involves injecting a small amount of antigen just under the skin. The immune system reacts within 48-72 hours indicating that it has “seen” similar material before (Figure 2-4).

The PPD test places a small amount of killed, purified mycobacteria material just under the skin, but the test does not allow a significant amount into the bloodstream. Pregnant women, young children, people with immune system deficiencies, people who have recently had immunizations, and people who have had a positive TB test in the past, can all safely have a PPD test. The test is contraindicated for the few people who have previously had a severe allergic reaction, including an anaphylactic reaction (an allergic response involving the whole body) and/or ulceration(s) at the test site. A severe allergic reaction is uncommon and usually subsides within a few days. Many clinical workers who apply PPD tests for many years never see such a reaction, and no such reactions were recorded

during NHANES I. Trained individuals applying TB skin tests do not consider previous itching, redness, or mild swelling after a previous test as severe reactions; a history of these conditions does not disqualify a person for the NHANES PPD tests.

An early widely used version of the tuberculin test was the Tine test, which used a small circular device with four metal tuberculin-coated prongs. The prongs were pushed into the skin of the forearm to deliver the tuberculin just under the skin. Results were less reliable than with the newer Mantoux test, in which a small needle and syringe are used to inject the tuberculin under the skin (see Figure 2-4). The NHANES I used the Mantoux version of the test. The Mantoux test is being used in the current NHANES both because of its greater reliability, and because the results can be compared directly to NHANES I.

As noted earlier, a positive reaction to the PPD test indicates infection and does not mean the person has active TB disease. It is impossible for an infected person who does not have active disease to spread TB.

## **2.4 Limitations of Tuberculosis Skin Testing and Implications**

Although tuberculin skin testing with PPD is currently the best test for TB infection, it is imperfect. Some TB-infected people who have other health problems, especially diseases affecting the immune system, may have a negative result. These cases are false negatives. False positive results are also possible and they become relatively more common when the proportion of TB infection in a population is low. In some areas of the U.S. where there are few active cases of TB, this could lead to an overestimate of the proportion of people infected with TB.

One common cause of false positive tuberculin tests is infection with harmless germs related to TB called “nontuberculous mycobacteria.” These germs are widespread in soil and water in many places and these germs have infected many people. They seldom cause disease in healthy people and there is no need to treat the infection. However, they can cause a false positive tuberculin PPD test. To minimize the number of false positive tuberculin tests, an additional PPD skin test for nontuberculous mycobacteria was used in NHANES I and is used again in the current NHANES. The Mantoux technique is used to inject a small amount of this antigen, called PPD-Batthey, under the skin in the same way PPD

S1 is injected. Measuring the reaction to PPD-Batthey assists in the interpretation of the tuberculin skin tests and reduces the number of false positive results in NHANES.

## **2.5 Skin Test Results**

SPs over the age of 1 year receive two (2) injections each: the tuberculin skin test (PPD-S1) and PPD-Batthey. Both of these PPDs are research tools. Both PPDs have been used safely in many surveys in the U.S. and elsewhere, and will provide a useful estimate of how widespread TB infection is in the United States. PPD-S1 is also the standard against which clinical products used in doctor's offices are compared in the U.S., according to FDA requirements, but it is not used in doctor's offices. Neither PPD-S1 nor PPD-B is licensed for clinical use in the U.S. Because they are for research purposes, no company has ever applied for a clinical license for either one. This means that clinicians cannot use them as part of a clinical evaluation to decide whether an individual has TB infection or needs preventive treatment. SPs whose PPD-S1 tuberculin skin test result is above a minimum cutoff value are given a Report of Findings that states that they may have been infected with TB at some time during the past. They are instructed to contact their primary source of medical care or the TB control program at the local health department for a clinical evaluation. SPs whose PPD-Batthey skin test is above a minimum cut off value are given a Report of Findings that states that they may have been infected with germs related to TB also called nontuberculous mycobacteria. However, since these harmless germs seldom cause disease in healthy people and are not spread from person to person, there is no need to see a doctor or have additional tests performed unless the PPD-S1 test is positive.

In research studies using two or more skin tests, results are considered less subject to scientific bias if people who measure and record skin test results do not know which test has been applied to which arm. The two different PPDs used in NHANES are labeled so that placers who apply the tests (who may also read reactions) do not know which PPD is being injected into which arm. The PPD vials are labeled PPD-A and PPD-C. The ISIS computer program randomly assigns the PPDs. The ISIS screen displays the placer's instruction for each subject to indicate which antigen to apply to each arm.

The reader does have access to the screen that has directed the application of the tests. The reader reads and records the results for the right and left arms or the upper and lower sites on one arm. After recording the results, ISIS retrieves the information to match each result to the appropriate PPD, and generates the SP's Report of Findings.

### **3. FIELD OFFICE PROCEDURES**

#### **3.1 Overview**

Conduct TB skin testing in the MEC on all SPs aged 1 year and older. The MEC phlebotomist administers the TB skin test and makes an appointment for the SP to return to the field office to have the results of the test read. Schedule reading appointments preferably 46 hours after administering the PPD antigens. TB skin test results must be read between 46 and 76 hours after administration of the PPD antigens. If the SP misses the field office reading appointment, contact the SP so that the skin test reading can be completed in the home before the 76-hour time limit is reached. Do not read skin tests if the time since the administration of the PPD antigens exceeds 76 hours. The phlebotomist also gives each SP important written instructions about not scratching or putting any lotions or ointments on the skin test area.

A subsample of 1,000 SPs also participate in a substudy of exposure to volatile organic compounds (VOCs). These SPs return to the MEC 46 hours after their initial examination to return an air monitoring badge and water sample from their homes, and to answer a brief questionnaire. These SPs, and any family members who are also SPs and were examined at the same time, are eligible to have the results of the TB skin test read in the MEC by the phlebotomist. If a SP misses their MEC appointment, contact the SP so that the skin test reading can be completed in the home before the 76-hour time limit is reached.

Occasionally a VOC SP is only eligible for their return MEC visit on a day when the MEC is closed. Schedule these SPs and any family members to return to the field office. At the field office, the VOC SP has the results of the TB test read and turns in the air monitoring badge and water sample. The TB reader administers the VOC questionnaire. No blood is collected.

Trained TB field readers conduct most TB readings at the field office. Readings are done at the MEC only for VOC participants and their family members who are also SPs. The TB field readers conduct the remaining readings in SP homes. These home readings are primarily part of the nonresponse strategy.

The TB field readers make reminder telephone calls to all SPs that had PPD antigens applied in the MEC or in their homes as part of the home exam. The purpose of the reminder telephone call is to confirm the date, time, and location of the reading appointment, arrange for transportation, and confirm driving directions for SPs who drive themselves to the field office. The field readers also contact SPs who miss scheduled appointments to schedule a home reading within the 76-hour time limit. Contact those who refused to make appointments in the MEC and attempt to schedule a field office or home reading within 76 hours of administration of the PPD antigens.

### **3.2 Scheduling Appointments for Reading TB Skin Tests**

After the phlebotomist administers the two TB PPD antigens, s/he asks the SP to make an appointment to have the TB skin test read. Appointments are made for 2-hour sessions in the field office beginning with the first available session 46 hours after administration of the PPD antigens. The phlebotomist attempts to schedule appointments between 46 and 54 hours after administration of the PPD antigens. The SP is given an appointment reminder before leaving the MEC. The appointment reminder lists the date and time of the appointment, address and telephone number of the field office, and directions. If the SP refuses to make an appointment to have the TB skin test read, or requests that the reading take place in their home or in the MEC, this information is noted in ISIS. ISIS conveys the results of the appointment scheduling process to the field office and the information is viewable in the TB scheduling reports and on the TB appointment calendar in the Appointment Management subsystem. Each of these reports is described below. Please refer to Chapter 4 for detailed field office Appointment Management System instructions.

#### **3.2.1 Report of SPs With Scheduled Appointments**

The report of SPs with scheduled appointments allows the TB field readers to view all currently scheduled TB appointments. The report lists the SPs name, SP ID, address, telephone number, date, time that the antigens were administered, and a time range for reading TB skin test results. The report also indicates the type of transportation arrangements made for the MEC appointment (self or taxi), and includes any comments entered by the MEC phlebotomist indicating where the SP requested that the TB skin tests be read (home or MEC). Filters built into the report system allow the field readers to select a range of dates and reading locations (MEC, field office, and home.) The TB field readers use the Report

of SPs with Scheduled Appointments when making reminder telephone calls and as a schedule of the day's appointments. The MEC manager generates the same report to notify the examination team of any TB/VOC participants scheduled to return to the MEC.

### **3.2.2 Report of SP Without Scheduled Appointments**

This report lists all SPs who had one or both PPD antigens administered but for whom no reading appointment exists. The report lists the SPs name, SP ID, address, telephone number, date and time antigens were administered, and a time range for reading TB skin test results. The report also indicates the type of transportation arrangements made for the MEC appointment (self or taxi), and includes any comments entered by the MEC phlebotomist indicating where the SP requested that the TB skin tests be read (home or MEC).

### **3.3 Refusal Conversion Phone Calls**

If a SP does not show up for a MEC or field office scheduled appointment, attempt to reschedule the TB reading. TB skin test readings must occur between 46 and 76 hours after administration of the PPD antigens for this survey. The TB field readers attempt to reschedule missed appointments for the earliest available appointment slot acceptable to the SP in the SP's home, but the reading must occur no later than 76 hours after administration of the PPD antigens. The field reader should prioritize missed appointments and attempt first to reschedule those SPs with the shortest time period left before the 76-hour cutoff ends. If the SP is offered a TB reading in the home or place of work and refuses, attempt an unannounced home visit if time permits before finally coding the SP as "Refused."

### **3.4 Nonresponse Follow-up of SPs Who Miss a Scheduled TB Reading**

Field readers conduct unannounced home visits as time permits. These visits are primarily designed to increase the response rate for this component. Field readers attempt to make one unannounced home visit for each SP who fails to show for a scheduled appointment; however, conduct home readings less than 76 hours after administering the PPD antigens. Prioritize unannounced home visits so that visits are made first to SPs with the shortest time left before the 76-hour cutoff ends. If a home visit is

attempted and no one is contacted, leave a reminder card at the home requesting that the SP call the Field office to reschedule the appointment. Use the field interviewer's "Call Back" card for this purpose. Refer to Exhibit 3-1 for an example of the Call Back card modified for use by the TB readers.

Exhibit 3-1. Home Visit Reminder Card

## **National Health and Nutrition Examination Survey**

I stopped by your home today to talk with you about the National Health and Nutrition Examination Survey. You were recently contacted about the study and the importance of your participation in it.

I am sorry that I did not find you at home today. I will return within the next several days. Thank you for your cooperation.

1-800-210-3413



DEPARTMENT OF HEALTH & HUMAN SERVICES

## **4. PROTOCOL FOR PLACING SKIN TEST ANTIGENS**

### **4.1 Overview**

Place or administer purified protein derivative (PPD) antigens on all SPs aged 1 year and older. There is one safety exclusion. Ask SPs if they have had a previous severe reaction to the tuberculin antigen. Exclude only those who report a previous severe allergic reaction involving the whole body and/or ulceration at the site of a previous TB skin test from the TB component. There are two inclusion criteria. First, ask the SP if they are available 46-76 hours after the placement to measure skin reactions. Second, examine the SP to make sure that they have a forearm available for placement. SPs who are available 46-76 hours later and who have a forearm available for placement then have their forearms and shoulders examined for BCG scars. Following the examination, each SP receives two skin tests: the tuberculin skin test (PPD-S1 antigen) and a skin test for nontuberculous mycobacteria (PPD-Bathey antigen). The vials are color-coded and labeled “PPD-A” and “PPD-C” to blind the phlebotomists to the antigen identity. ISIS randomly assigns an antigen to each forearm. The phlebotomist places or administers one antigen on each forearm according to directions on the ISIS screen for the individual SP, beginning with the antigen labeled “PPD-A” and following with the antigen labeled “PPD-C.” After administering the antigens, the phlebotomist schedules an appointment for the SP to return to the field office to have the skin reaction measured. The phlebotomist provides instructions informing the SP not to scratch or put lotions or ointment on the skin test areas. The coordinator gives the SP an appointment reminder card when the SP checks out of the MEC. Although TB skin tests can be measured 46 - 76 hours after placing the antigens, make initial appointments for the period 46 - 54 hours, if possible. This allows the TB readers time to contact the SPs if they miss their scheduled appointment.

### **4.2 The Phlebotomy Component**

The phlebotomy component consists of blood collection, TB skin testing, and the Volatile Organic Compounds (VOC) study. Conduct the blood collection first, followed by the TB skin tests and VOC protocol. If the blood collection is delayed so that the SPs can meet their fasting requirement, place the TB skin tests while the SP is in the phlebotomy room. Conduct the blood collection when the SP returns to phlebotomy after meeting the fasting requirement.

### **4.3 Equipment and Supplies**

The equipment and supplies required to place skin test antigens are listed below:

- Needle: sterile ½ inch., 27 gauge, short bevel
- Alcohol wipes
- 2 x 2 gauze pads
- Latex gloves
- Puncture-resistant sharps disposal container
- Permanent marking pen for labeling
- Millimeter ruler for measuring questionable wheal size
- Two color-coded and labeled antigen vial trays for one opened antigen vial each on top shelf of phlebotomy refrigerator (Figure 4-1)
- Stock multidose antigen vials with color-coded labels [PPD-A (white) and PPD-C (pink)] stored in appropriately labeled box in separate laboratory refrigerator
- Laboratory refrigerator with automatically monitored temperature recorder
- Phlebotomy refrigerator and thermometer with manually monitored temperature recording (Figure 4-1)
- Temperature control equipment (e.g., thermos) to transport antigens for home placement
- Adverse Reaction Forms

#### **4.3.1 General Principles for Handling and Storing the PPD Antigens**

The principles for appropriate handling of the skin test antigens include controlling temperature, light, time in the syringe, labeling, and antigen vial tray selection.

Store skin test antigens in a monitored-temperature refrigerator or in temperature-controlled transport equipment except when removing the antigens to fill the syringes. Do not allow filled syringes to stand for more than 20 minutes before use, and discard unused filled syringes after 20 minutes. More

than a brief exposure to room temperature or light can make the skin test antigens less effective. If syringes are prefilled and the liquid containing the antigen is left in the syringe for more than a very brief period, the antigens attach to the walls of the syringe and will not be injected into the SP's forearm, making the test ineffective. Antigens in vials also become less effective if exposed to heat or light for more than a brief period.

When a new vial is needed, retrieve it from the appropriately labeled stock antigen box in the laboratory refrigerator. Label it with the initials of the phlebotomist who opened it and the date. Discard open vials 30 days after opening. When a vial is taken from the phlebotomy refrigerator to fill a syringe, check its identifying label ("PPD-A" or "PPD-C") against the ISIS computer screen to assure that the correct vial has been obtained for the forearm about to be injected. Enter the FDA lot number and expiration date into the computer system. Label the syringe with the identifier and the time. If the wrong tray is removed or syringes are mislabeled so that the incorrect antigen is placed in the forearm directed by ISIS, survey data will be incorrectly recorded.

Store one opened vial of each antigen, labeled respectively PPD-A and PPD-C, in its separate antigen tray in the phlebotomy refrigerator. Label the antigen vial trays clearly and always keep the "A" antigen vial tray to the left of the "C" antigen vial tray. The "A" antigen has a white label and the "C" antigen has a pink label. (See Figure 4-1.)



Figure 4-1. Color-coded and Labeled Antigen Vial Trays in Phlebotomy Refrigerator

Phlebotomy refrigerator contains two color-coded, labeled vial and tray sets (PPD-A and PPD-C) and a thermometer for temperature monitoring. One opened vial of each antigen, labeled PPD-A and PPD-C, is stored in its respective tray. Trays are labeled and color-coded: “A” vial and tray set has a white label and “C” a pink label. Trays are kept in the correct position, “A” tray always to the left of the “C” tray. The thermometer unit measures the temperature of the liquid in the bottle.

Check the vial label against the antigen tray label when taking a vial from the phlebotomy refrigerator or returning it to the refrigerator. Remove only one antigen vial tray at a time from the phlebotomy refrigerator, and replace that tray in the phlebotomy refrigerator before removing the other antigen vial. Always remove the “A” antigen vial tray first; use the “A” antigen to fill the first syringe, and always inject the “A” antigen first. Unless a (prefilled) syringe is used immediately, place the labeled syringe in the antigen vial tray with the corresponding label, which also holds the vial with the corresponding label. (See Figure 4-2.) Placement of vials or syringes in the wrong antigen trays, or placement of antigen vial trays in the wrong location, could lead to placing the incorrect antigens and recording incorrect data.



Figure 4-2. Prefilled Syringe in Antigen Tray with Matching Vial

The syringe may be filled before phlebotomy (prefilled) and kept with the vial used to fill the syringe in the color-coded tray in the refrigerator. Mark syringe with time filled and discard if not used in 20 minutes.

#### **4.4 Procedures Preceding Skin Testing**

Check that at least one forearm is available for administration of tuberculin tests. Place the skin test antigens in the volar surface (palm up side) of each forearm. A forearm is considered unavailable only if (1) the forearm has been amputated, (2) the forearm is completely covered with a cast, (3) the entire surface of the forearm is severely scarred or covered with a rash or burn, or (4) there is a medical order not to place injections in the forearm.

After determining that the SP is eligible for testing (see Section 4.4.1), place one skin test on each forearm if both of the SP's forearms are available. If only one forearm is available, place both skin tests on the available forearm – one skin test on the upper forearm and one skin test on the lower forearm. If neither forearm is available, exclude the SP from participating in the skin testing component.

##### **4.4.1 Screening SPs for Skin Test Eligibility**

Ask each SP whether the SP has experienced a previous severe reaction to a skin test antigen. Read the exclusion question exactly as it is displayed on the computer screen: "Have you ever had a severe reaction to a tuberculosis (TB) skin test?" Do not consider a history of a previously positive reaction, a large induration, swelling, or redness at the skin test site severe reactions and do not exclude the SP from the skin testing component. Exclude SPs who report a previous severe skin test reaction from the TB skin testing component. A previous severe reaction to tuberculin antigen is an anaphylactic response (severe allergic reaction involving the whole body) and/or ulceration at the skin test site. Persons, who are not available 46 to 76 hours later, during the reaction measurement period, are also excluded from skin testing. Refer SPs with questions to the NHANES physician.

##### **4.4.2 Examination for Bacille Calmette-Guerin (BCG) Vaccine Scar**

Examine both forearms and shoulders for a BCG scar. Record the result of the examination in ISIS.

#### **4.4.2.1 BCG: Background**

In many world regions, the BCG vaccine is given to prevent active TB or limit its spread within the body. The BCG vaccine is most often given to children soon after birth, but in some countries, the BCG vaccine is also given to schoolchildren and adults such as health care workers. The BCG vaccine is thought to be effective in limiting some of the most dangerous kinds of TB disease, particularly in young children in some areas of the world. It is not considered useful for TB control in the United States because TB case rates are low and studies have shown that it is ineffective in many geographic areas.

BCG vaccinations are usually given in the lower deltoid area – the area of the upper arm where many immunizations such as measles vaccines are given in the U.S.

A previous BCG vaccine can sometimes cause a positive PPD antigen skin test reaction, particularly if the skin test is placed soon after the BCG vaccine has been given or if the person has been vaccinated with the BCG vaccine many times. However, many people who have had the BCG vaccine do not have a positive reaction to a PPD antigen skin test. Also, many people who have been vaccinated with BCG may still have a positive skin test because of a TB infection, rather than because of the previous vaccination.

#### **4.4.2.2 BCG Scarring**

Most BCG injection sites heal within 6 to 12 weeks, leaving a scar. Typically, the scar is round and 4-7 millimeters wide, but it may be up to 10 mm. It is most often slightly depressed with slightly irregular edges and smooth surface texture, more smooth than smallpox scars (Figure 4-3). Occasionally it may be raised a few millimeters above the skin surface and hard to the touch. Hard fibrous scarring that resembles the scar from a wound with a round object can also be seen. Rarely, the scar tissue balloons upward to become a mushroom-like growth with overhanging margin (keloid scar); this reaction is more common in individuals with African ancestry. Some persons who have been vaccinated with the BCG vaccine do not develop a scar. In many individuals, the scar becomes less obvious with age.

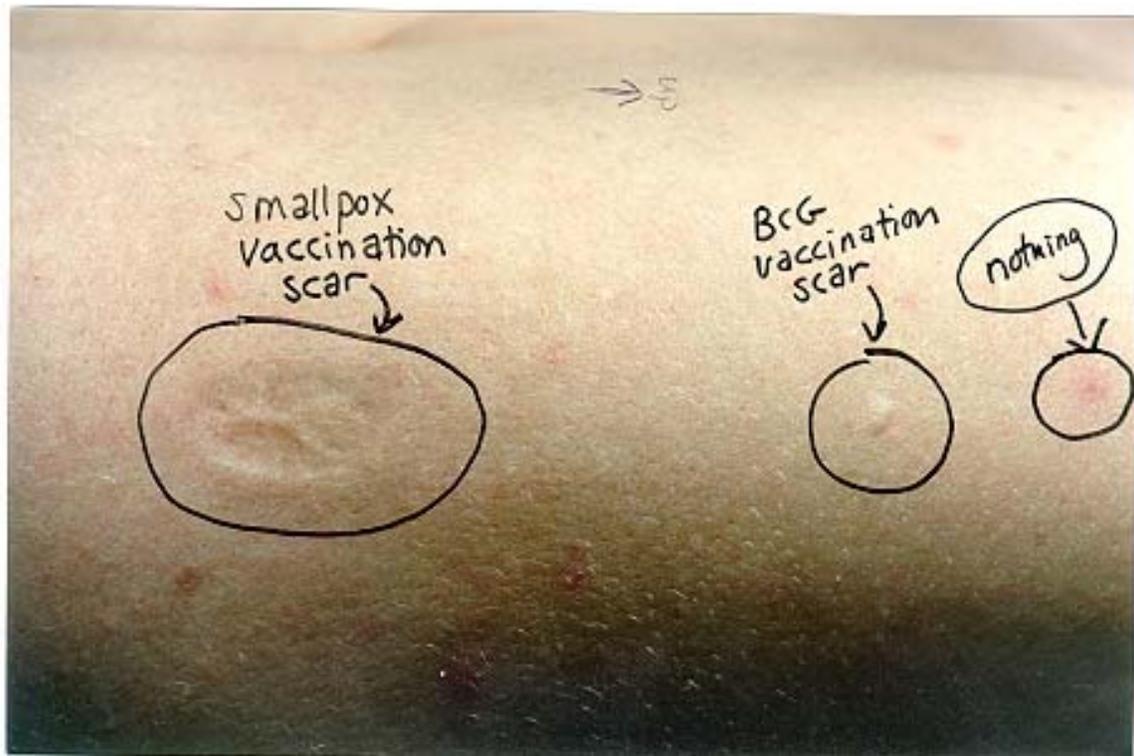


Figure 4-3. BCG and Smallpox Scars

Identify BCG and smallpox scars. The BCG scar has a round shape with defined edges, is about 4-7 mm wide, has a slightly depressed or raised level, and is smooth and hard to the touch. The smallpox scar has little or no visible edges, is frequently at least 15 mm wide, has a depressed level, and has a rough and pitting texture.

#### 4.4.2.3 Examining the SP for a BCG Scar

Examine both upper arms and shoulders for BCG scars. In many countries, BCG is given more than once, so more than one scar may be seen. Record only the presence or absence of a BCG scar in the ISIS. Do not record the number of BCG scars present if more than one scar is observed.

Phlebotomists must be able to distinguish between BCG and smallpox scars. In older adults, a smallpox vaccination scar may also be present. A smallpox vaccination scar may resemble a BCG scar, but it is often much larger than a BCG scar with less well-defined edges or no visible edges at all. In smallpox scars, pitting is usually seen (Figure 4-3). Do not record the presence of a smallpox scar.

Studies have shown that asking people if they have had a BCG vaccine is not a useful exercise. People who have been given other vaccinations but not BCG may mistakenly report that they have had the BCG vaccine. People who have had BCG in infancy may not be aware of it. People who have had a previous skin test may have assumed that it was a “TB vaccination” and mistakenly report that they have had the BCG vaccine. Because individual self-reports are not reliable, it is important not to ask SPs any questions about scarring or BCG vaccination history. If a SP volunteers information, do not record these reports or change the observation based on the self-report.

## **4.5 PPD Antigen Skin Testing**

### **4.5.1 Background: How PPD Antigen Skin Tests Work**

Purified protein derivative (PPD) is extracted from killed bacteria, which have been purified and filtered so that only harmless protein fragments, called antigens, remain. Antigens cannot infect people or cause disease. However, if a person has been infected with the bacteria at some time in the past, the body can recognize the antigens and mount an immune response. After a previously infected person has had the appropriate antigen placed just under the skin, a small local reaction in that area, signaling that the body has recognized the skin test antigen is usually seen 2 to 3 days later. Testing requires two visits, one to place the antigens, and one to measure the skin reactions.

### **4.5.2 Skin Test Preparation Steps: Filling Syringes (May be done before venipuncture)**

Locate two separate antigen vial trays on the top shelf of the phlebotomy refrigerator, one antigen vial in each antigen vial tray, labeled respectively “PPD-A” and “PPD-C.” The “A” antigen vial tray should be to the left of the “C” antigen vial tray (Figure 4-1).

- Remove the “A” antigen vial tray from the phlebotomy refrigerator and fill the syringe immediately.

Fill the syringe using the technique described below:

- If needed, open a new antigen vial. Remove the metal cap from the vial. Mark the label with date opened and phlebotomist's initials.
- For a previously opened vial, verify that today's date is earlier than the expiration date recorded on the vial when it was opened. (If today's date is later than the expiration date, discard the vial and obtain a new vial.)
- Rotate or roll the vial back and forth gently to mix the antigen. Do not shake the vial or place it on the tube rocker.
- For each use, cleanse the top of the vial with an alcohol wipe.
- Remove the needle guard.
- Draw 0.1 milliliter of air into syringe (not more).
- Inject air into the vial airspace (*not* the solution). With the vial resting on the table, hold the vial between the thumb and fingers of the nondominant hand and insert the needle through the rubber stopper into the air space. Injection of air into the air space in the vial prevents creation of negative pressure within the vial, allowing antigen to be withdrawn easily. Injecting air into the solution creates bubbles and may interfere with withdrawing the correct amount of antigen (Figure 4-4).
- Fill the syringe. Draw slightly more than 0.1 ml of antigen into the syringe by pulling back on the plunger with the vial inverted (Figure 4-4).
- Remove the needle from the vial.
- Remove excess volume/air bubbles from the syringe. Leave exactly 0.1 ml antigen solution in the syringe. Hold the syringe in an upright position and tap the barrel lightly to break up air bubbles. Draw back slightly on the plunger and push forward. Expel all air and excess fluid from the syringe and needle. Replace the needle guard unless the antigen is to be placed immediately. (See Figure 4-4.)

Return the "A" antigen vial tray to the phlebotomy refrigerator.

If the syringe is not to be used immediately, use a waterproof marker to label the syringe "PPD-A" and the time the syringe was filled. Place it in the matched refrigerated tray. (See Figure 4-2.)

Repeat steps 1-4 as above for the "C" antigen (Figure 4-4).

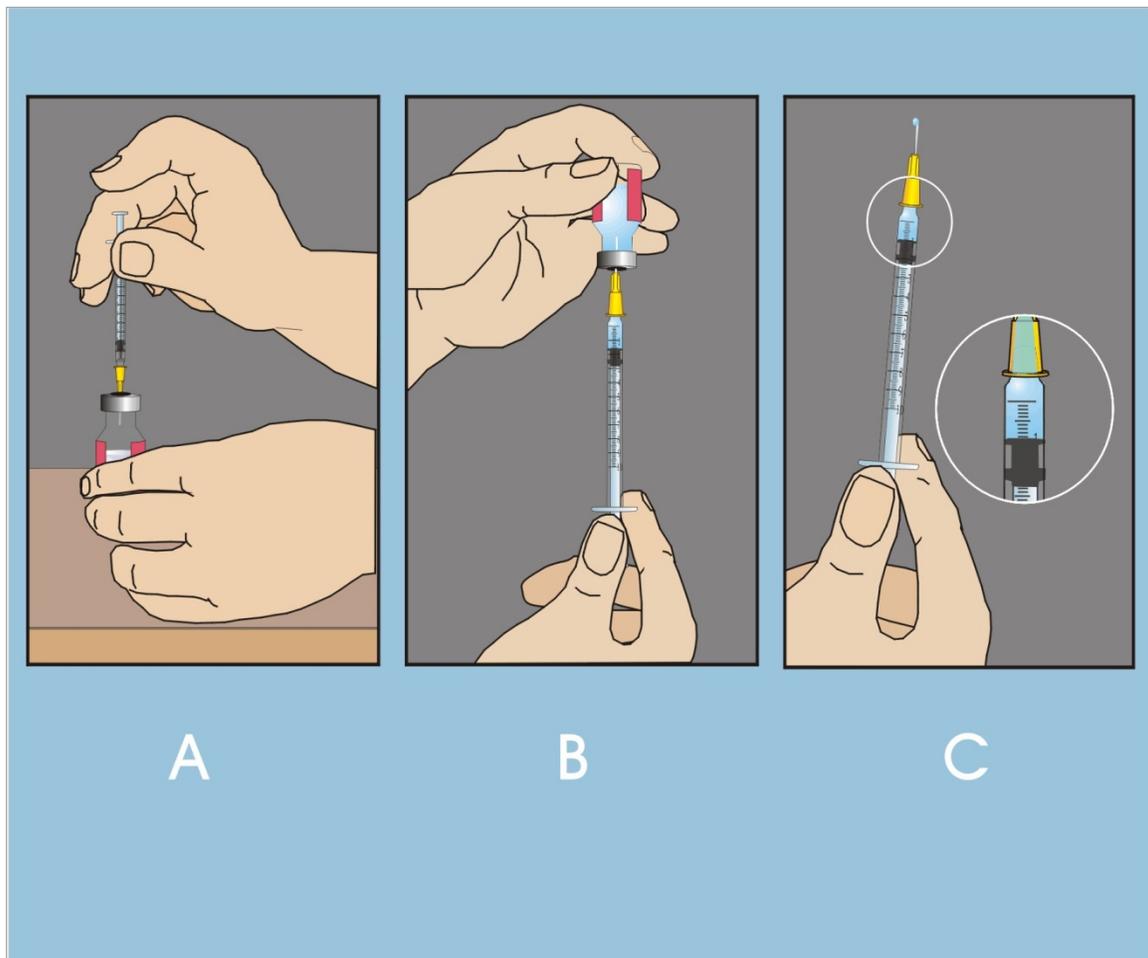


Figure 4-4. Syringe Filled with Exactly 0.1 ml Antigen

Fill the syringe with antigen. (A) Inject a small amount of air (less than 0.1 ml) into the vial air space. (B) Invert the vial and withdraw slightly more than the 0.1 ml dose by pulling back on the plunger. Separate the syringe from the vial and remove air bubbles. Push plunger to the 0.1 ml line, completely filling the syringe and needle with the antigen. The filled syringe should contain exactly 0.1 ml of PPD antigen.

### 4.5.3 Skin Test Administration Steps

Following the examination for available arms and eligibility, each SP receives two skin tests. Always place the “A” antigen first.

Procedures for administering the skin test antigens follow:

1. After phlebotomy, remove “A” antigen vial tray with syringe from phlebotomy refrigerator. Remove the filled syringe from the tray and replace the antigen vial tray in the phlebotomy refrigerator. Check that no more than 20 minutes have elapsed since the syringe was filled. (If more than 20 minutes have elapsed, discard the syringe in the puncture-resistant container and fill a new syringe according to the steps in 4.5.2. Apply skin tests using the fresh antigen). Check the label on the syringe to confirm that it is labeled “PPD-A” and check the computer screen to confirm the correct forearm placement for the “A” antigen.
2. Immobilize the forearm of young children. Have a medical technologist hold the child securely while the phlebotomist gently but firmly immobilizes the forearm. Place the “A” antigen skin test as described below.
  - Selecting and Cleaning the Injection Site
    - Consult the ISIS computer screen for the identity of the appropriate forearm in which to inject the “A” antigen.
    - Select injection site on the inner forearm with the palm up, at least 2” from the elbow, wrist, or other injection site as shown in Figure 4-5.
    - Avoid areas over veins; avoid sites that have lesions, heavy hair, bruises, scars, or a muscle ridge.
    - Clean the injection site with an alcohol wipe using a circular motion beginning in the center and working toward the outside. Allow the area to dry thoroughly.
    - Put on gloves.

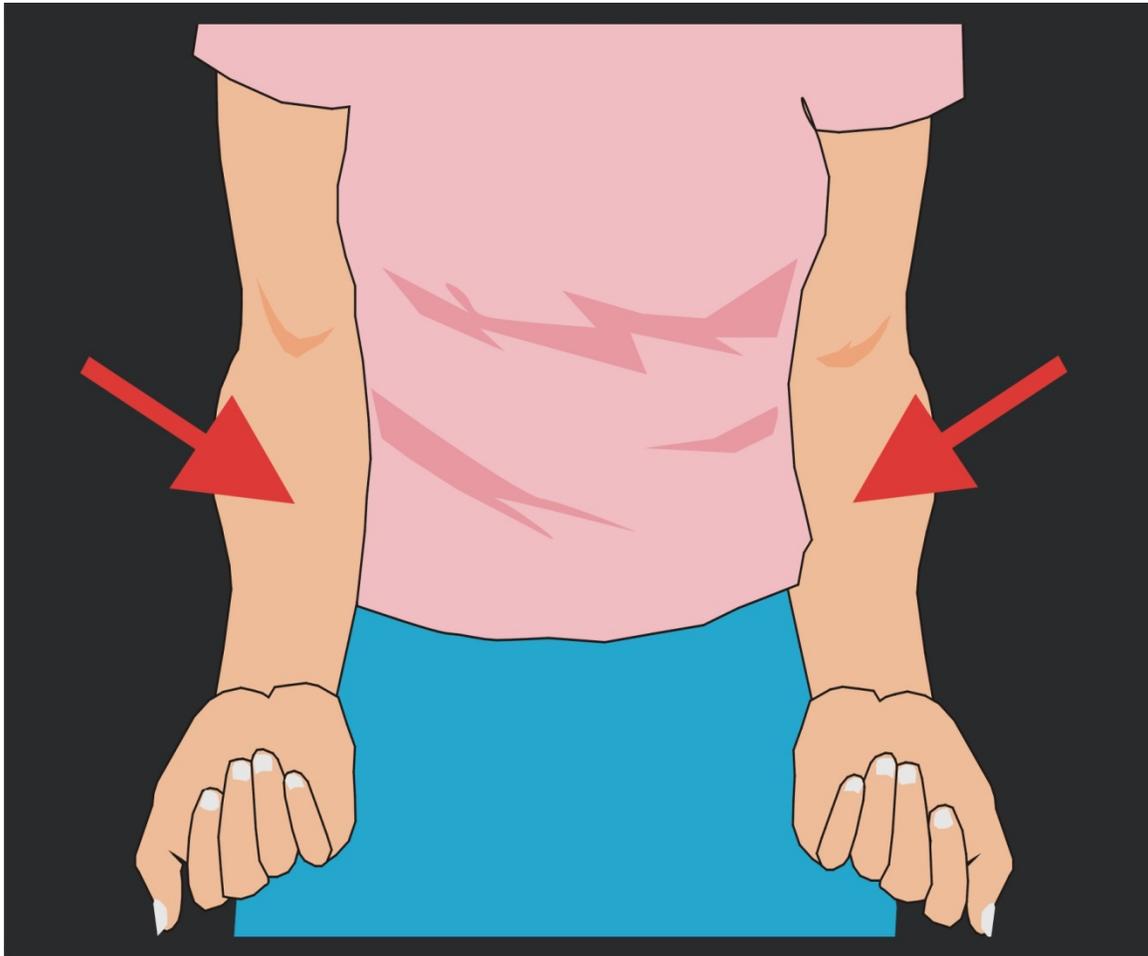


Figure 4-5. TB Skin Test Placement Sites

Administer antigens in the standard site: Inner forearm with the palm up, at least 2” from the elbow, wrist, or other injection site. Avoid areas over veins; avoid sites that have lesions, heavy hair, bruises, scars, or a muscle ridge.

- Inserting the needle and injecting the antigen
  - Intradermally inject 0.1 ml of PPD antigen on the volar surface of the forearm with the 1/2", 27-gauge short-beveled needle just beneath the skin surface with needle bevel up to form a small round bleb wheal (at least 6 mm in diameter) at the injection site (Figure 4-6).
    - Rest the SP's forearm on a firm, well-lit surface.
    - Stretch the skin slightly over the site. This creates a firmer surface for needle insertion.
    - Hold the needle with the bevel up, 1° to 5° angle to the skin.
    - Insert the needle into the superficial layer of skin so that needle tip is visible beneath the skin surface.
    - Advance the needle until entire bevel lies just under the skin.
    - Release the stretched skin. Refer to Figures 4-7 and 4-8 for incorrect needle insertion positions.
    - Slowly inject the entire dose (0.1 ml antigen) forming a tense skin elevation (wheal) at least 6 mm in diameter (See Figure 4-8.).
    - If an adequate wheal does not appear, re-administer the test at least 2 inches from the original site.
    - Remove the needle without pressing or massaging the area.
    - Engage the shielding needle guard and discard the used syringe immediately in the designated puncture-resistant container.
    - Lightly blot injection site with a 2x2-gauze pad if a drop of blood appears.
    - Discard contaminated gauze and used gloves according to NHANES procedures.
    - Remove antigen vial tray labeled the "PPD-C" antigen.
    - Repeat all steps in 4.5.3 to place "C" antigen.
    - Wash hands.
    - Follow appropriate NHANES emergency procedures if unexpected reactions occur as skin tests are being placed.

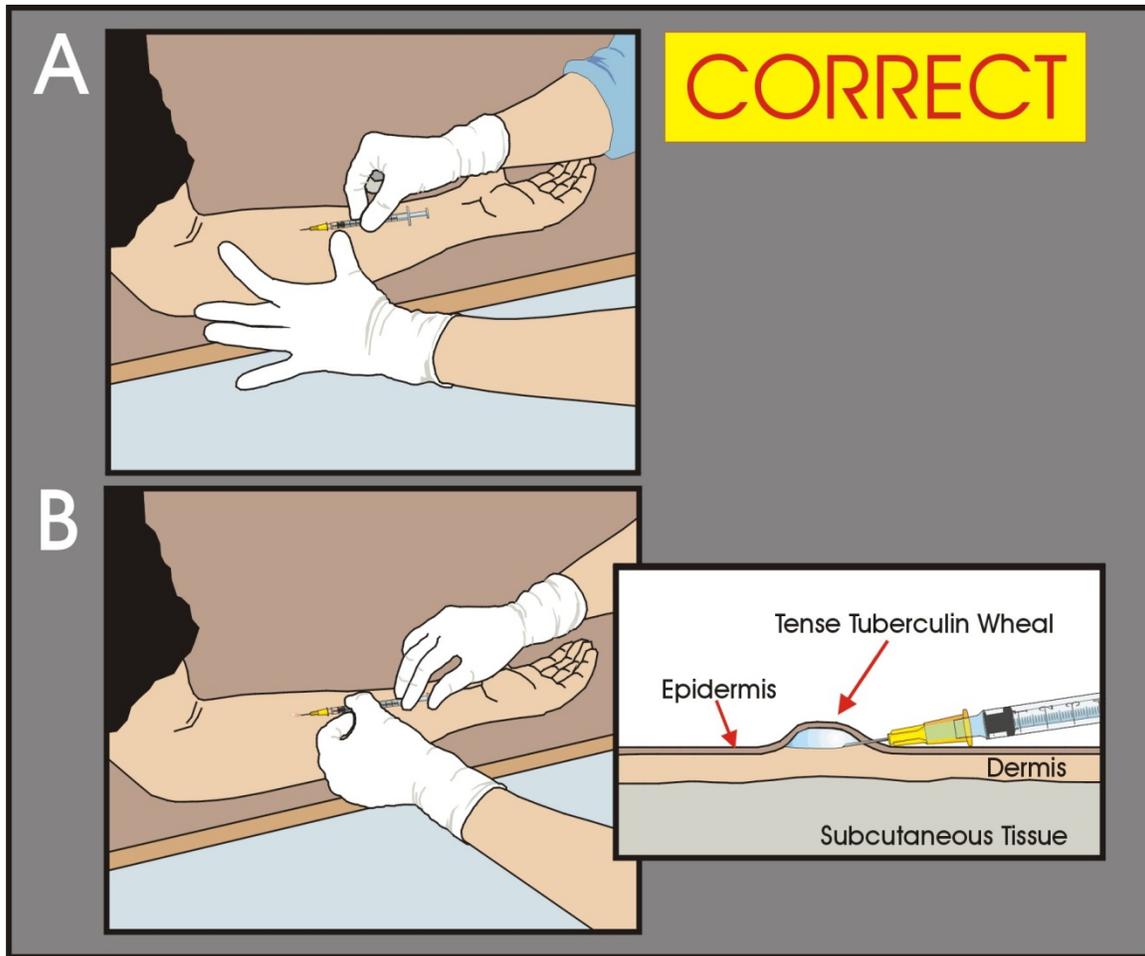


Figure 4-6. Correct Skin Test Placement

Correct insertion: (A) Stretch the skin to make it taut at the site of injection. Hold the needle with the bevel up at a  $1^{\circ}$  -  $5^{\circ}$  angle to the skin. Insert the needle into the dermis layer beneath the skin surface so that the needle tip is visible beneath the skin surface. Advance the needle until the entire bevel lies just under the skin. (B) Release the stretched skin. Support the needle and inject exactly 0.1 ml PPD antigen just beneath the skin surface - forming a small flat, anemic bleb or wheal (at least 6 mm in diameter with steep border line).

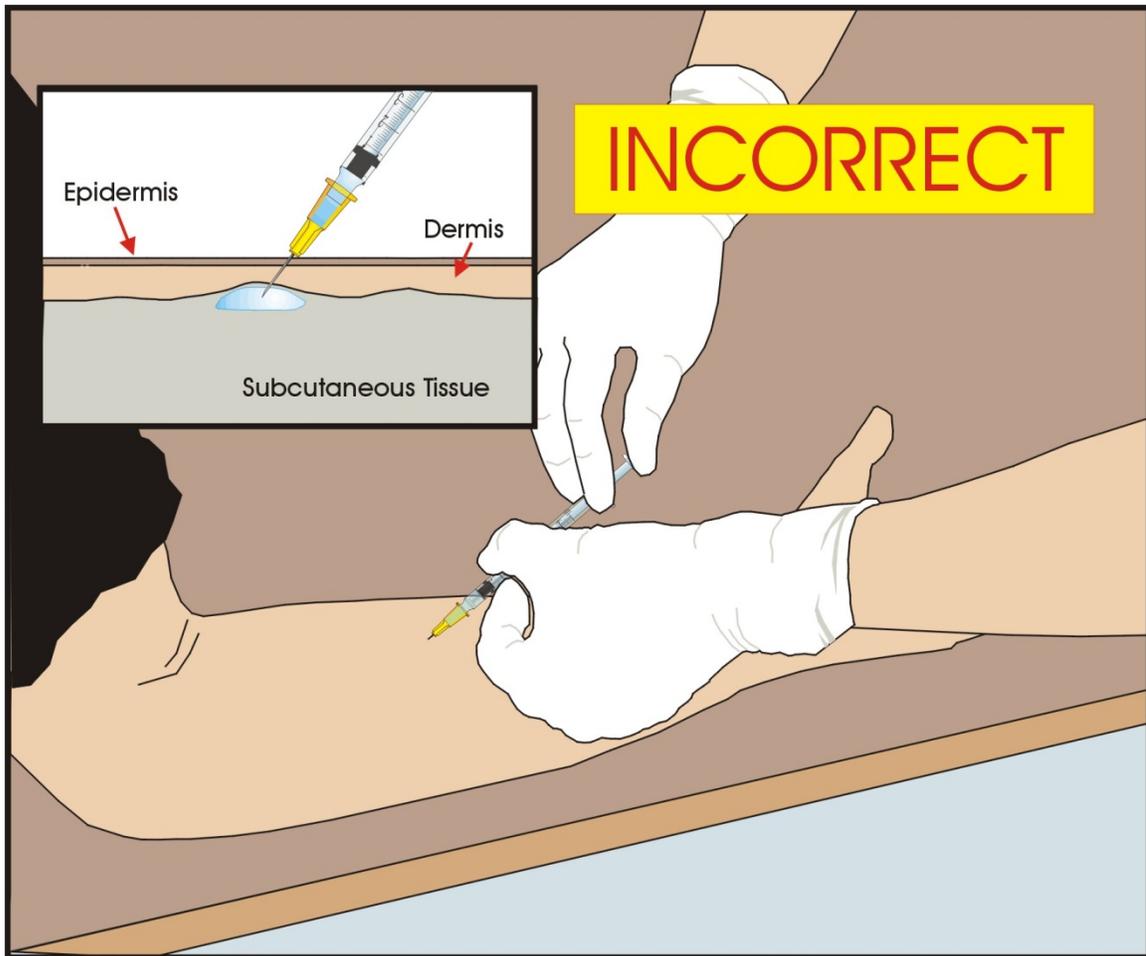


Figure 4-7. Incorrect Skin Test Placement

Incorrect insertion into subcutaneous tissue occurs with an injection angle of greater than ( $>$ )  $5^{\circ}$ . No wheal will form because the antigen is administered too deeply.

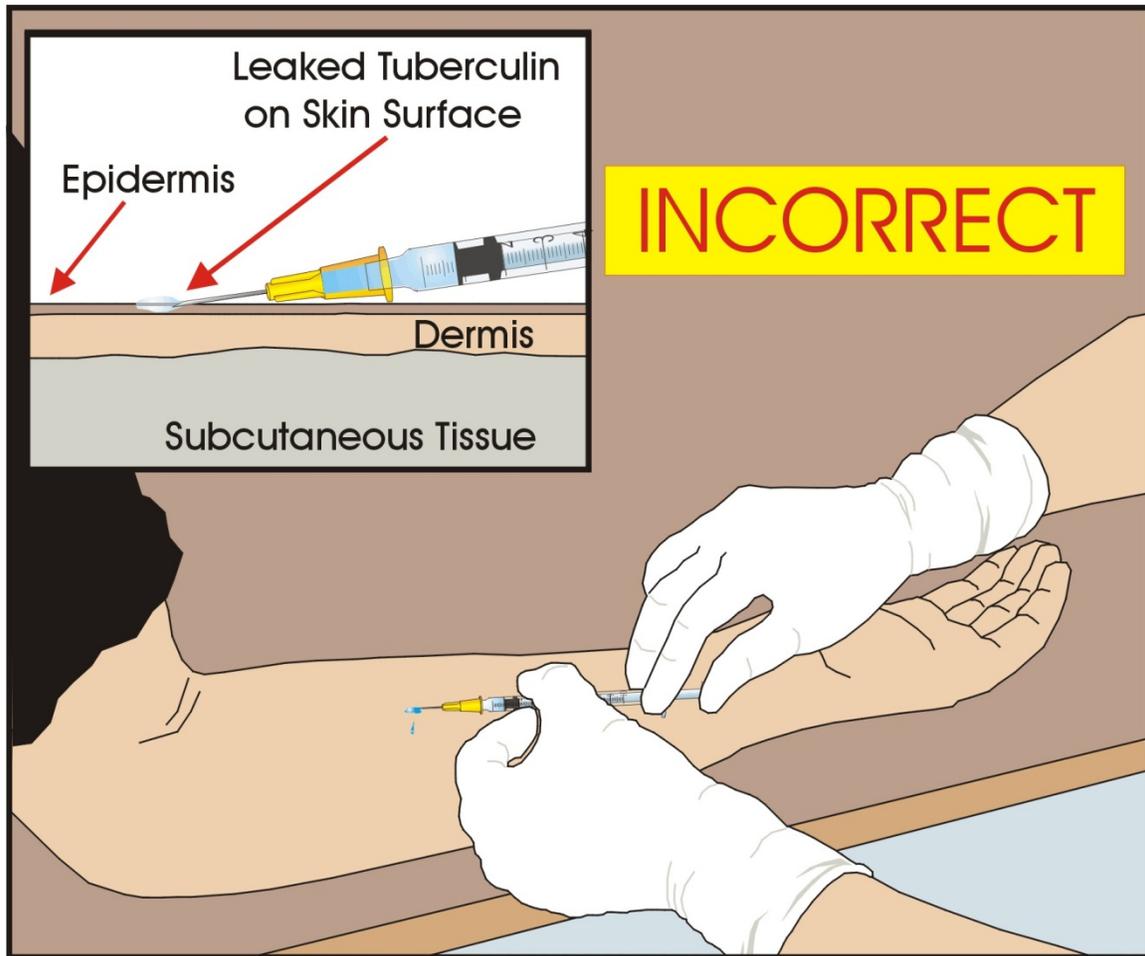


Figure 4-8. Incorrect Skin Test Placement

Incorrect insertion occurs when the needle bevel is not completely inserted into the layer beneath the skin surface (dermis). This incorrect needle insertion position can cause leakage of antigen preventing the formation of a proper wheal.

#### **4.6 Appointments for Measurement of Skin Reactions**

Make an appointment for the measurement of the skin reaction to the tests 46–76 hours after placing the skin tests. Skin test readers may not conduct measurements outside this 30-hour window. Attempt to schedule the SP for the first appointment available 46 hours after administration of the skin tests. Make every effort to schedule appointments between 46 and 54 hours after administration of the skin tests. This allows the TB field readers approximately 24 hours to contact and obtain results on SPs who do not show up for their scheduled appointment. SPs who are participants in the Volatile Organic Compounds (VOC) substudy have the skin tests measured in the MEC when they return 46-76 hours later to turn in the air-monitoring badge and water sample, have additional blood samples collected, and answer a brief questionnaire.

The phlebotomist makes an appointment for the SP to return to the field office or MEC, as appropriate, after placing the skin test antigens. The MEC coordinator gives SPs reading appointment reminders and maps to the field office when they check out of the MEC session. Information on all scheduled appointments is sent and received electronically at the field office. The TB field readers are responsible for contacting each SP to confirm the appointment date and time. The TB readers attempt to reschedule the appointment in the SP's home when the SP does not show up at the field office or MEC for a scheduled appointment.

The phlebotomist is only able to schedule non-VOC study SPs to field office appointments and VOC study SPs to MEC appointments. The phlebotomist can schedule field office appointments for VOC study SPs and their family members only if some portion of the 46-76 hour reading period falls on a day the MEC is closed. ISIS captures specific requests such as when a SP requests an appointment in his/her home, office, or the MEC (for non-VOC study SPs). However, the phlebotomist cannot schedule these appointments; the TB field readers contact the SP to arrange to measure the SP's skin test reactions. The phlebotomist makes every effort to encourage SPs to have their skin tests measured in the field office. SPs are paid \$30 if they return to the field office (or MEC for VOC study SPs) and \$10 if the measurement of skin reactions is conducted in the SP's home, office, or MEC for non-VOC participants. SPs are also paid transportation costs (taxicab or mileage) for travel to and from the field office or MEC.

The appointment card includes information about what to expect in the period between the test and the measurement. Explain that mild itching, swelling, or irritation may occur and that these are normal reactions, which do not require any treatment. These normal reactions usually subside within a

week or earlier. The phlebotomist reads aloud the instructions that are displayed on the phlebotomist's computer screen. These instructions also appear on the appointment card. These remind SPs that they should avoid scratching their forearms and avoid placing anything (e.g., adhesive bandages, cream, ointment, lotion, liquids, or medication) on the sites. SPs may wash their forearms lightly with mild soap and water without pressure. Immediately after placement, they should not touch or cover the wheal until it absorbs naturally; this occurs in about 10 minutes.

No immediate adverse reactions were recorded when skin tests using the same antigens were injected into the forearms of thousands of participants in NHANES I, and no such reactions are expected during the present survey. However, there is a theoretical possibility that anaphylactic shock can occur when any foreign substance is injected or ingested. If anaphylactic shock should occur after the injection of a skin test antigen, follow the procedures in the Emergency Procedures Manual and report the occurrence to Dr. Kathryn Porter using the Adverse Reaction Form.

## 4.7 Entering Results in ISIS

The TB introduction screen displays after the Venipuncture Status screen.

The screenshot displays a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "Venipuncture Status" and contains a form with the following elements:

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

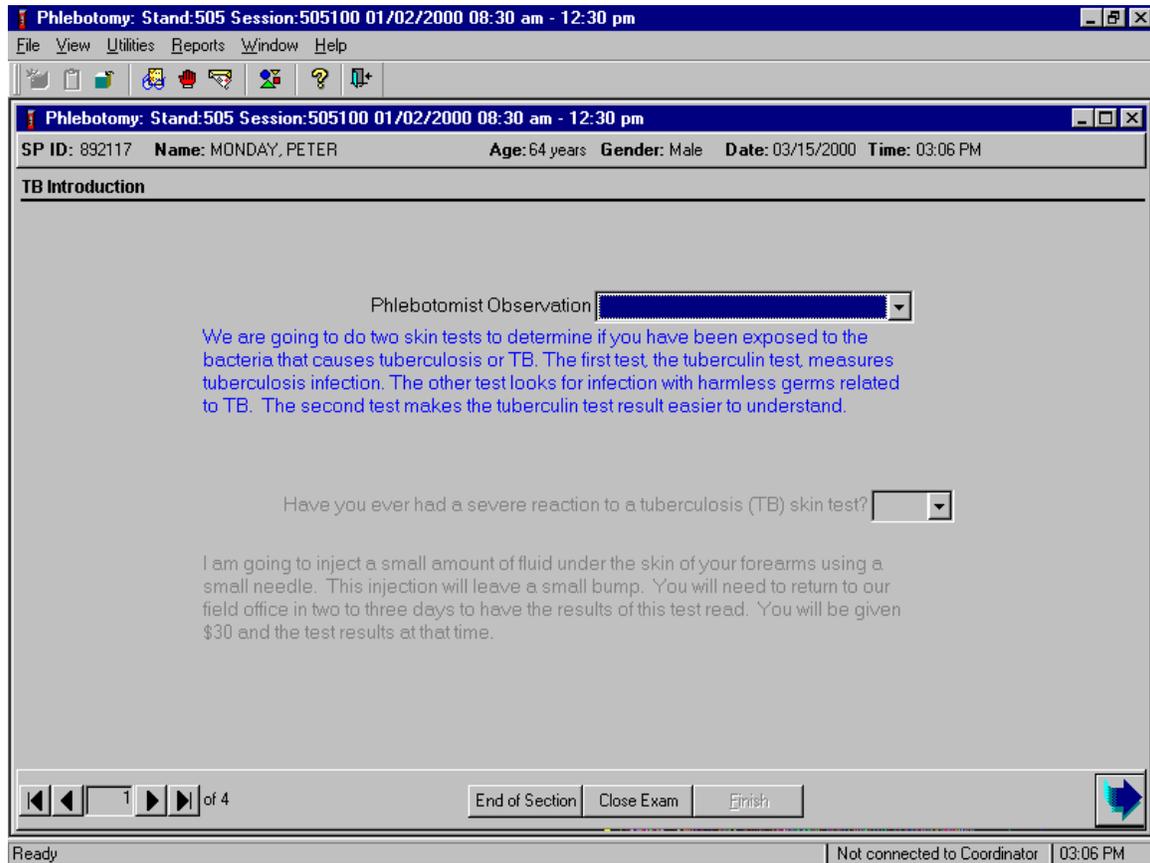
At the bottom of the window, there is a navigation bar with the following elements:

- Navigation icons: back, forward, and a page indicator showing "4 of 4".
- Buttons: "End of Section", "Close Exam", and "Finish".
- A large blue arrow icon in the bottom right corner.

The Windows taskbar at the bottom shows "Ready" on the left and "Not connected to Coordinator | 03:06 PM" on the right.

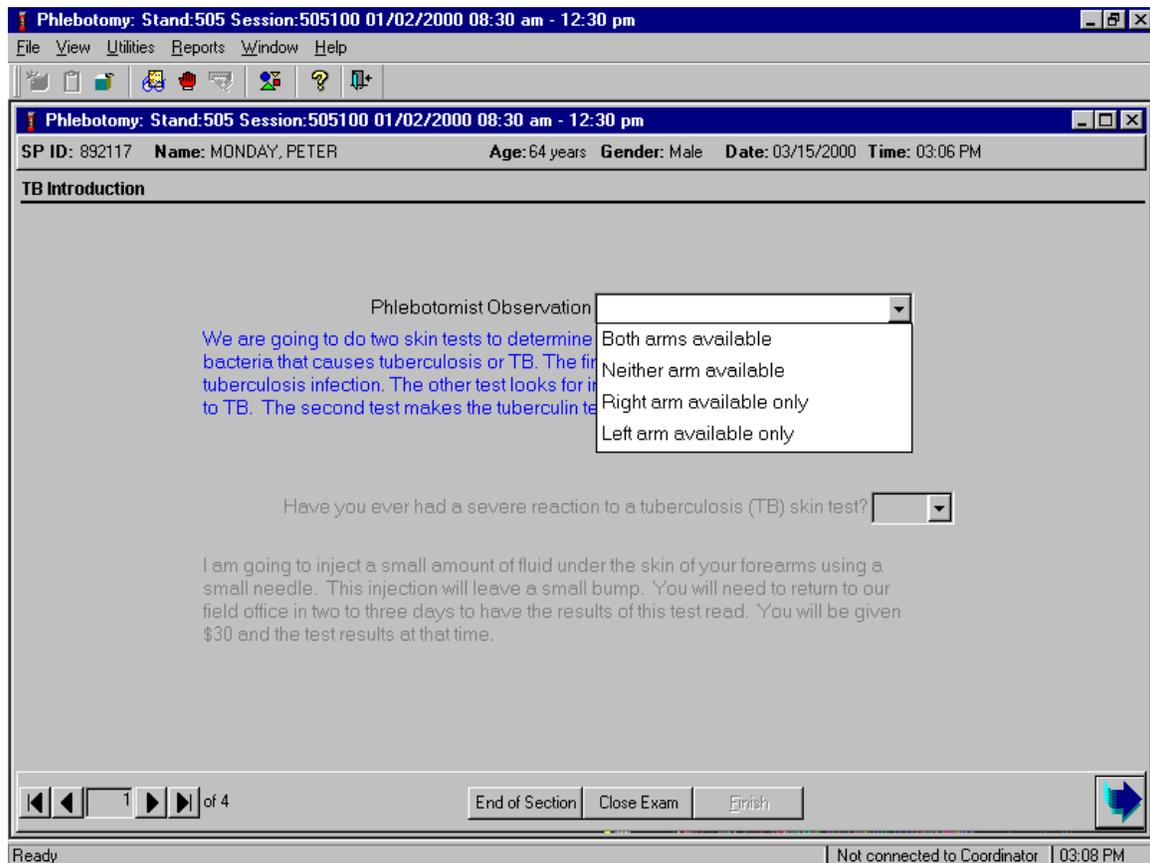
When finished reviewing the Venipuncture Status screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click to progress to the next section (TB) or select [Enter] when this blue arrow is highlighted.

The TB Introduction Screen displays.



Complete the forearm examination as described in Section 4.4. Proceed to record the observation.

Record the forearm observation.



To record the observation, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click.

If neither forearm is available, the remaining parts of the introduction screen remain disabled. To move to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click or select [Enter] when this blue arrow is highlighted.

Ask the safety exclusion question.

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM

**TB Introduction**

Phlebotomist Observation: Both arms available

We are going to do two skin tests to determine if you have been exposed to the bacteria that causes tuberculosis or TB. The first test, the tuberculin test, measures tuberculosis infection. The other test looks for infection with harmless germs related to TB. The second test makes the tuberculin test result easier to understand.

Have you ever had a severe reaction to a tuberculosis (TB) skin test?

I am going to inject a small amount of fluid under the skin of your forearms using a small needle. This injection will leave a small bump. You will need to return to our field office in two to three days to have the results of this test read. You will be given \$30 and the test results at that time.

1 of 4

End of Section Close Exam Finish

Ready | Not connected to Coordinator | 03:09 PM

After recording “Both arms available,” “Right arm available only,” or “Left arm available only,” the safety exclusion question is enabled.

Read the safety exclusion question and record the response.

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM

**TB Introduction**

Phlebotomist Observation: Both arms available

We are going to do two skin tests to determine if you have been exposed to the bacteria that causes tuberculosis or TB. The first test, the tuberculin test, measures tuberculosis infection. The other test looks for infection with harmless germs related to TB. The second test makes the tuberculin test result easier to understand.

Have you ever had a severe reaction to a tuberculosis (TB) skin test?

I am going to inject a small amount of fluid under the skin of your forearms using a small needle. This injection will leave a small bump. You will need to return to our field office in two to three days to have the results of this test read. You will be given \$30 and the test results at that time.

End of Section Close Exam Finish

Ready | Not connected to Coordinator | 03:09 PM

Record whether or not the SP has had a previous severe reaction; this is defined as ulceration at the site or an anaphylactic reaction (allergic reaction involving the whole body). Read the exclusion question exactly as it is displayed on the computer screen: “Have you ever had a severe reaction to a tuberculosis (TB) skin test?” Do not consider a history of a previously positive reaction, a large induration, swelling, or redness at the skin test site severe reactions and do not exclude the SP from the skin testing component

To record the response, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, to record the response, type the first letter of the correct choice and [Tab.] For example, type [Y/y] for “Yes” or [N/n] for “No.”

After recording a positive response, the remaining part of the introduction screen remains disabled. To move to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click or select [Enter] when this blue arrow is highlighted.

Read the script to all SPs who report a negative response.

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM

**TB Introduction**

Phlebotomist Observation: Both arms available

We are going to do two skin tests to determine if you have been exposed to the bacteria that causes tuberculosis or TB. The first test, the tuberculin test, measures tuberculosis infection. The other test looks for infection with harmless germs related to TB. The second test makes the tuberculin test result easier to understand.

Have you ever had a severe reaction to a tuberculosis (TB) skin test? No

I am going to inject a small amount of fluid under the skin of your forearms using a small needle. This injection will leave a small bump. You will need to return to our field office in two to three days to have the results of this test read. You will be given \$30 and the test results at that time.

1 of 4

End of Section Close Exam Finish

Ready | Not connected to Coordinator | 03:10 PM

If the SP has not had a previous severe reaction to a skin test antigen, read the test description script. To move to the next screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click or select [Enter] when this blue arrow is highlighted.

The TB Application screen displays.

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM

**TB Application**

BCG Scar

TB Application:

PPD-S Applied Right Arm

PPD-B Applied Left Arm

Antigen Information	
Lot #	Expiration Date
PPD-A <input type="text"/>	<input type="text"/>
PPD-C <input type="text"/>	<input type="text"/>

2 of 4

End of Section Close Exam Finish

Ready | Not connected to Coordinator | 03:10 PM

Examine the forearms and shoulders for a BCG scar as described in Section 4.4.2.

Enter the BCG scar examination result.

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM

**TB Application**

BCG Scar

TB Application:

PPD-S Applied

PPD-B Applied

Antigen Information

	Lot #	Expiration Date
PPD-A	<input type="text" value=""/>	<input type="text" value="//"/>
PPD-C	<input type="text" value=""/>	<input type="text" value="//"/>

2 of 4

End of Section Close Exam Finish

Close the exam | Not connected to Coordinator | 03:11 PM

The presence or absence of a BCG scar does not have an impact on the skin test administration. If uncertain as to whether a scar is a BCG scar or not, assume it is and select “Present.” Record whether or not the SP has a BCG scar or if they refuse to allow an examination.

To record the response, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, to record the response, type the first letter of the correct choice. For example, type [P/p] for “Present,” [A/a] for “Absent, or [R/r] for “Refused.”

Apply the “PPD-A” antigen and record the application results.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar displays patient information: "SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM". The main area is titled "TB Application" and contains the following fields and controls:

- BCG Scar: Absent (dropdown menu)
- TB Application: (label)
- PPD-S Applied: Right Arm (dropdown menu)
- PPD-B Applied: Left Arm (dropdown menu)
- Antigen Information table:

	Lot #	Expiration Date
PPD-A		//
PPD-C		//

At the bottom of the window, there is a navigation bar with a page indicator "2 of 4", buttons for "End of Section", "Close Exam", and "Finish", and a status bar showing "Close the exam", "Not connected to Coordinator", and "03:11 PM".

Store skin test antigens in a monitored-temperature refrigerator or in temperature-controlled transport equipment except when removing the antigens to fill the syringes. Do not allow filled syringes to stand for more than 20 minutes before use. ISIS randomizes the forearm that receives each skin test and indicates this on the screen. If only one forearm is available, placement of antigens is randomized to the upper and lower forearms of the available forearm. This displays on the screen. Always place the “A” antigen first. Follow procedures described in Section 4.5.

To record the results of the PPD-A antigen application, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, to record the response, type the first letter of the correct choice and [Tab]. For example, type [Y/y] for “Yes” or [N/n] for “No.” As soon as [Y/y] is recorded, the Lot # and Expiration Date text boxes enable.

Record the Lot # and Expiration Date for PPD-A antigen.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The patient information is as follows:

SP ID:	892117	Name:	MONDAY, PETER	Age:	64 years	Gender:	Male	Date:	03/15/2000	Time:	03:06 PM
--------	--------	-------	---------------	------	----------	---------	------	-------	------------	-------	----------

The "TB Application" section contains the following fields:

BCG Scar	Absent	
PPD-S Applied	Right Arm	Yes
PPD-B Applied	Left Arm	

The "Antigen Information" section contains the following fields:

	Lot #	Expiration Date
PPD-A	555555	12/15/2000
PPD-C		//

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom indicates "Close the exam", "Not connected to Coordinator", and "03:11 PM".

Verify the existing Antigen Information. The lot # and expiration date defaults to the last entry. To change either the lot # or the expiration date, use the numeric keyboard keys to type the correct information when the box is highlighted. Select [Tab] to move to the next box. Enter the date format as mm/dd/yyyy. Select [Tab] to move to the PPD-B text box.

If the “No” or “No antigens available” option is selected for the PPD-A antigen, then the PPD-C antigen is not placed and this section of the screen remains disabled.

If the “A” antigen placement is successful and “yes” is recorded, the “C” antigen application section enables.

The screenshot displays a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar shows patient information: "SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM". The main area is titled "TB Application" and contains the following fields:

- BCG Scar: Absent (dropdown menu)
- TB Application: (label)
- PPD-S Applied: Right Arm Yes (dropdown menu)
- PPD-B Applied: Left Arm (dropdown menu with options: Yes, No, No antigens available)
- Antigen Information table:

	Lot #	Expiration Date
PPD-A	555555	12/15/2000
PPD-C		//

At the bottom of the window, there is a navigation bar with a progress indicator (2 of 4), buttons for "End of Section", "Close Exam", and "Finish", and a status bar showing "Close the exam", "Not connected to Coordinator", and "03:13 PM".

Administer the PPD-C antigen. Follow procedures described in Section 4.5. Record the results of the PPD-C application.

To record the results of the PPD-C antigen application, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, to record the response, type the first letter of the correct choice and [Tab]. For example, type [Y/y] for “Yes” or [N/n] for “No.” As soon as [Y/y] is recorded, the Lot # and Expiration Date text boxes enable.

Record the Lot # and Expiration Date for PPD-C antigen.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar, patient information is displayed: "SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM". The main section is titled "TB Application".

Under "TB Application", there are several input fields:

- BCG Scar: Absent (dropdown menu)
- TB Application: (label)
- PPD-S Applied: Right Arm Yes (dropdown menu)
- PPD-B Applied: Left Arm Yes (dropdown menu)

An "Antigen Information" table is also present:

	Lot #	Expiration Date
PPD-A	555555	12/15/2000
PPD-C	5555555	12/15/2000

At the bottom of the window, there is a navigation bar with buttons: "End of Section", "Close Exam", "Finish", and a blue arrow button. The status bar at the very bottom shows "Close the exam", "Not connected to Coordinator", and "03:13 PM".

Verify the existing Antigen Information. The lot # and expiration date defaults to the last entry. To change either the lot # or the expiration date, use the numeric keyboard keys to type the correct information when the box is highlighted. Select [Tab] to move to the next box. Enter the date format as mm/dd/yyyy. Select [Enter] to move to the next screen or use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click or select [Enter] when this blue arrow is highlighted.

Schedule the SPs reading (measurement) appointment.

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

File View Utilities Reports Window Help

Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm

SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM

**Appointments**

I now need to make an appointment for you two days from now to have the results of this test read.

Household Members in This Session:

SP Name	Age	VOC	Session Date	Start Time	Reason
PETER MONDAY	64 y N				
DOROTHY MONDAY	80 y N				

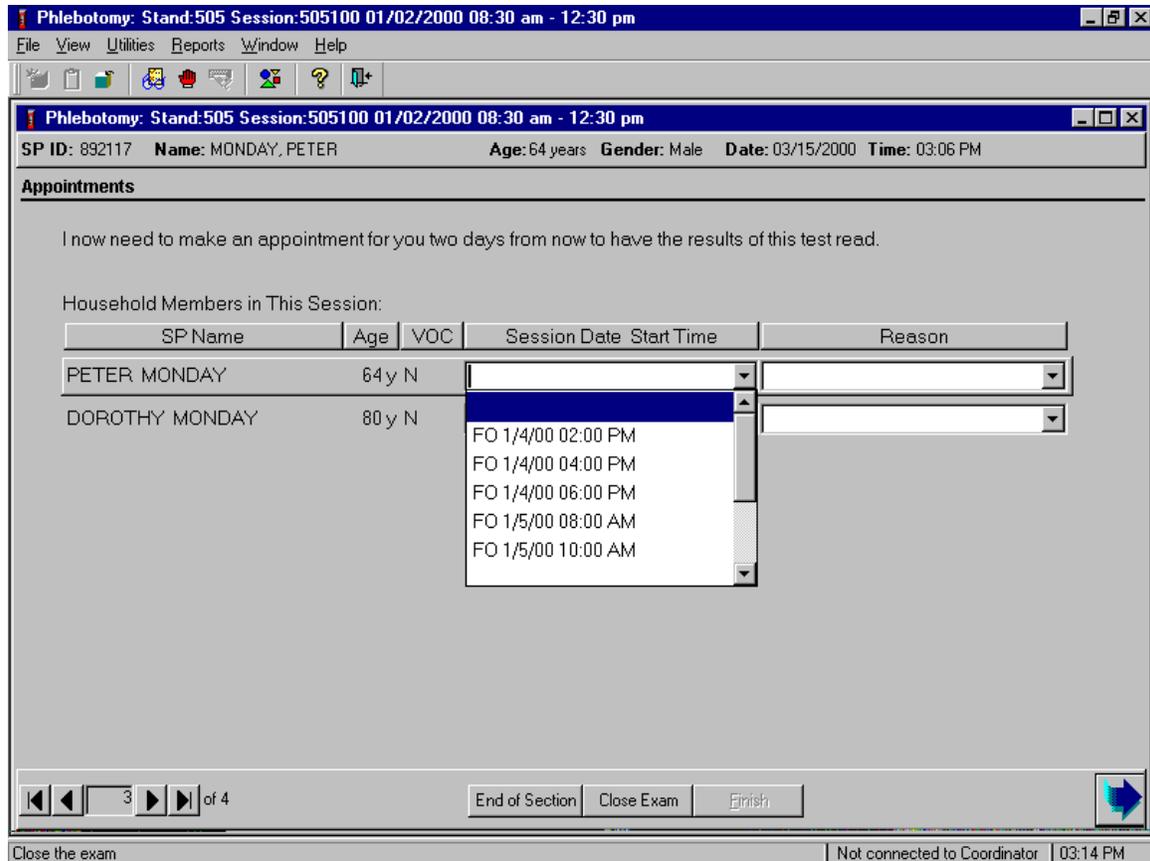
3 of 4

End of Section Close Exam Finish

Ready | Not connected to Coordinator | 03:14 PM

The appointment screen displays a list of SPs including the SP who just received the skin test(s) and any other family members who are also SPs in the same MEC session. The SP may make an appointment for him/herself and for any or all other family members. If appointments already exist for any SP on the list, this information displays. The SP may change appointments for any or all of the SPs on the displayed list.

Read the text to the SP – “I now need to make an appointment for you two days from now to have the results of this test read.”



Display the appointment sessions for which the SP is eligible. To display the available sessions, use the mouse to direct the mouse arrow to the drop down arrow and left click. Only field office sessions are listed for non-VOC study SPs; only MEC sessions are listed for VOC study SPs unless the MEC is closed during the 46- to 76-hour reading period. Attempt to schedule SPs for sessions 46 – 54 hours from the current time.

Select the session.

The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar displays "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". A status bar below the header shows "SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM".

The main area is titled "Appointments" and contains the text: "I now need to make an appointment for you two days from now to have the results of this test read." Below this, it says "Household Members in This Session:".

SPName	Age	VOC	Session Date Start Time	Reason
PETER MONDAY	64 y	N	FO 1/4/00 04:00 PM	
DOROTHY MONDAY	80 y	N		

A dropdown menu is open for the "Session Date Start Time" column of the DOROTHY MONDAY row, showing the following options:

- FO 1/4/00 02:00 PM
- FO 1/4/00 04:00 PM
- FO 1/4/00 06:00 PM
- FO 1/5/00 08:00 AM
- FO 1/5/00 10:00 AM

At the bottom of the window, there is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons. A status bar at the very bottom shows "Close the exam", "Not connected to Coordinator", and "03:15 PM".

To select and insert the session into the Session Date Start Time text box, drag the mouse arrow to the selected appointment time and left-click. The session date and time is inserted into the Session Date Start Time text box.

Attach a reason for SPs who refuse to make an appointment.

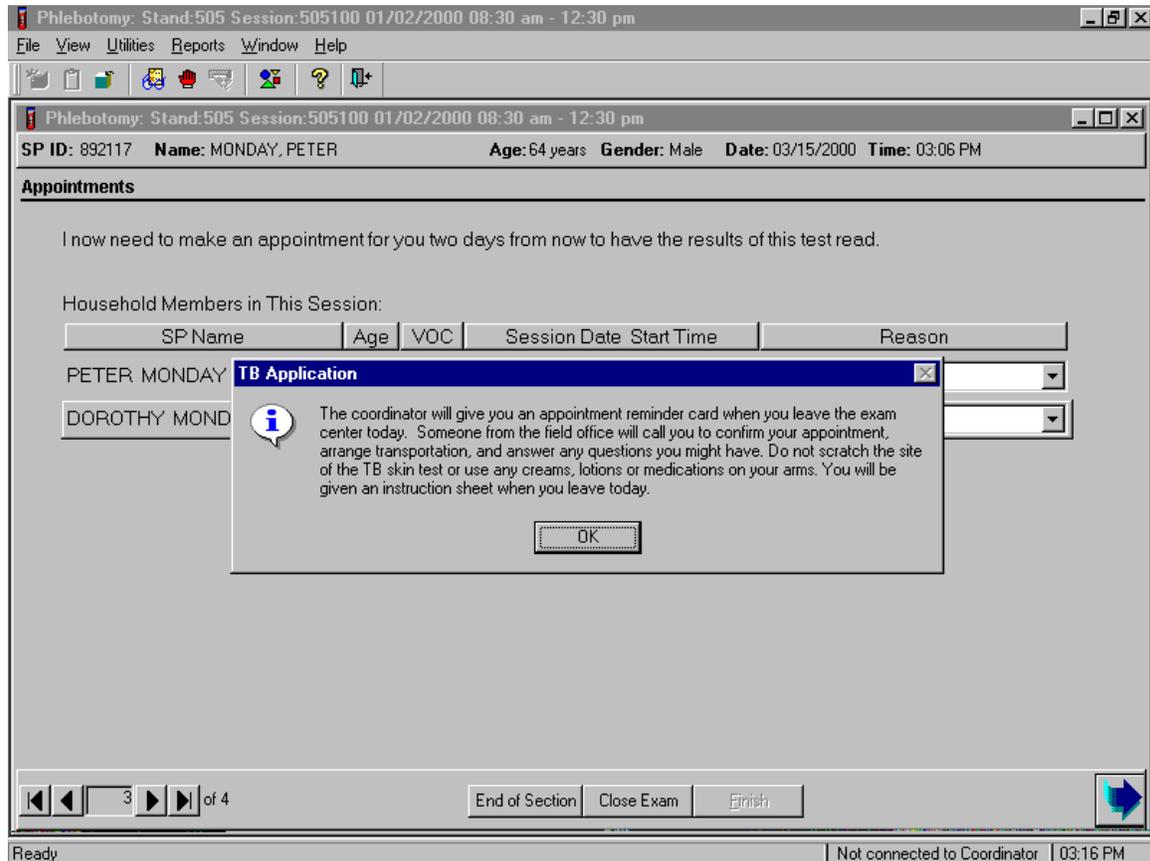
The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The window contains a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the toolbar, a header bar displays "SP ID: 892117 Name: MONDAY, PETER Age: 64 years Gender: Male Date: 03/15/2000 Time: 03:06 PM". The main area is titled "Appointments" and contains the text: "I now need to make an appointment for you two days from now to have the results of this test read." Below this, it says "Household Members in This Session:" and lists two members in a table:

SP Name	Age	VOC	Session Date	Start Time	Reason
PETER MONDAY	64 y	N			
DOROTHY MONDAY	80 y	N			

The "Reason" dropdown menu for Peter Monday is open, showing the following options: "SP refused", "SP requested home", "SP requested MEC", and "SP requested FO". At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom indicates "Close the exam", "Not connected to Coordinator", and "03:15 PM".

If the SP refuses to schedule an appointment or requests an appointment in their home or a location other than the field office (for non-VOC study SPs) or MEC (for VOC study SPs), indicate the SP's request by leaving the Session Date Start Time text box empty and selecting the appropriate comment. To select the appropriate comment, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. ISIS transmits all scheduling information to the field office. The TB field readers contact the SP to schedule the appointment. To move to the next screen select [Enter], use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click, or select [Enter] when this blue arrow is highlighted.

Review the instructions with the SP.



The TB Application informational message window displays. Read these instructions to the SP. Answer any questions or concerns. To progress to the TB section status screen, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter.]

Review the TB section status.

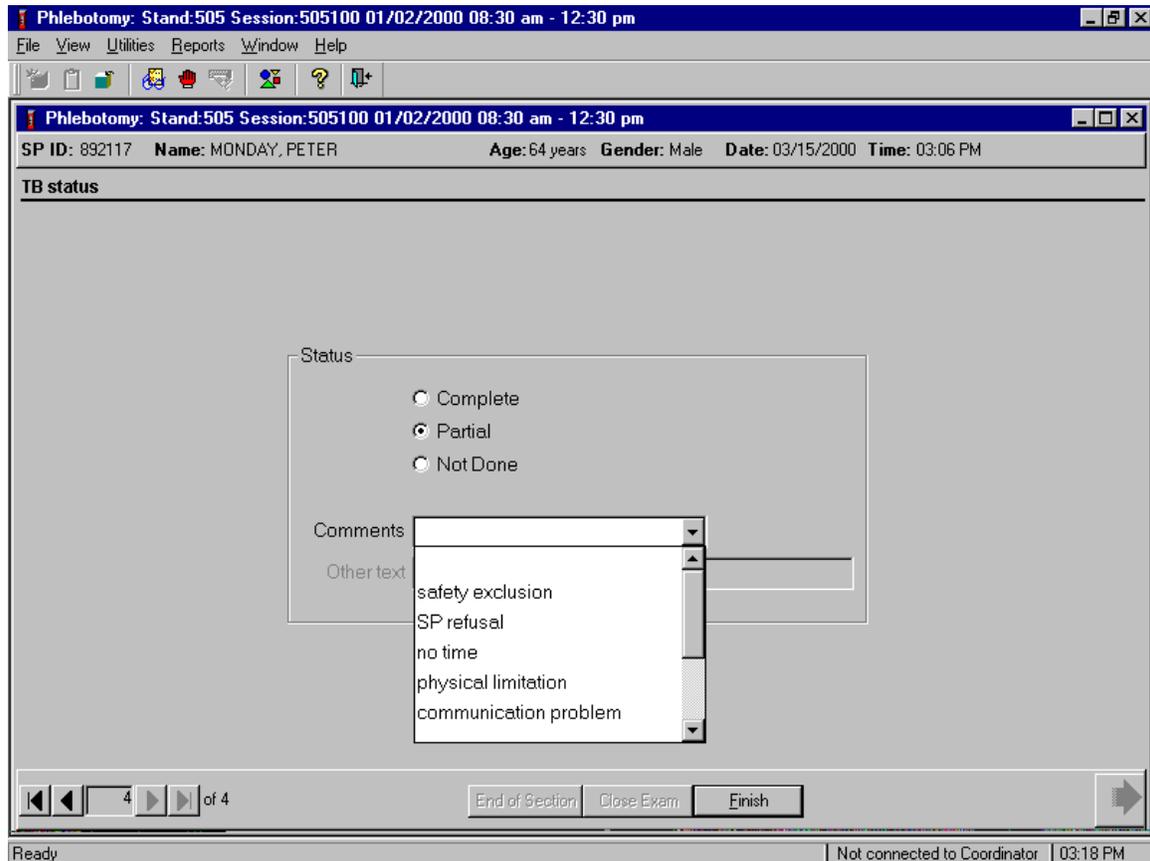
The screenshot shows a software window titled "Phlebotomy: Stand:505 Session:505100 01/02/2000 08:30 am - 12:30 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "TB status" and contains a form with the following elements:

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

At the bottom of the window, there is a navigation bar with buttons for "End of Section", "Close Exam", and "Finish". The status bar at the very bottom shows "Ready", "Not connected to Coordinator", and "03:17 PM".

The TB status is complete if both antigens were applied, partial if only one of the antigens was applied and not done if the SP was excluded or neither antigen was placed. If the SP was excluded as a result of a "Yes" response to the question, "Have you ever had a severe reaction to a tuberculosis (TB) skin test?" enter the "Safety Exclusion" comment in the Comments text box.

Use comment codes to explain Partial and Not Done status codes.



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

Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	The SP refuses to have the antigen administered. This is SP initiated nonresponse due to refusal. The SP refuses the component or a part of the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam.
no time	Not applicable
physical limitation	SP is unable to have the test due to a physical problem.
communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
equipment failure	Not applicable.
SP ill/emergency	The SP became ill or an emergency occurred and the test could not be performed on the SP.
interrupted	The exam is interrupted, usually for a MEC-wide emergency, and cannot be completed by the SP.
SP did not meet fast	Not applicable
other, text	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, text and record a comment in the text field.

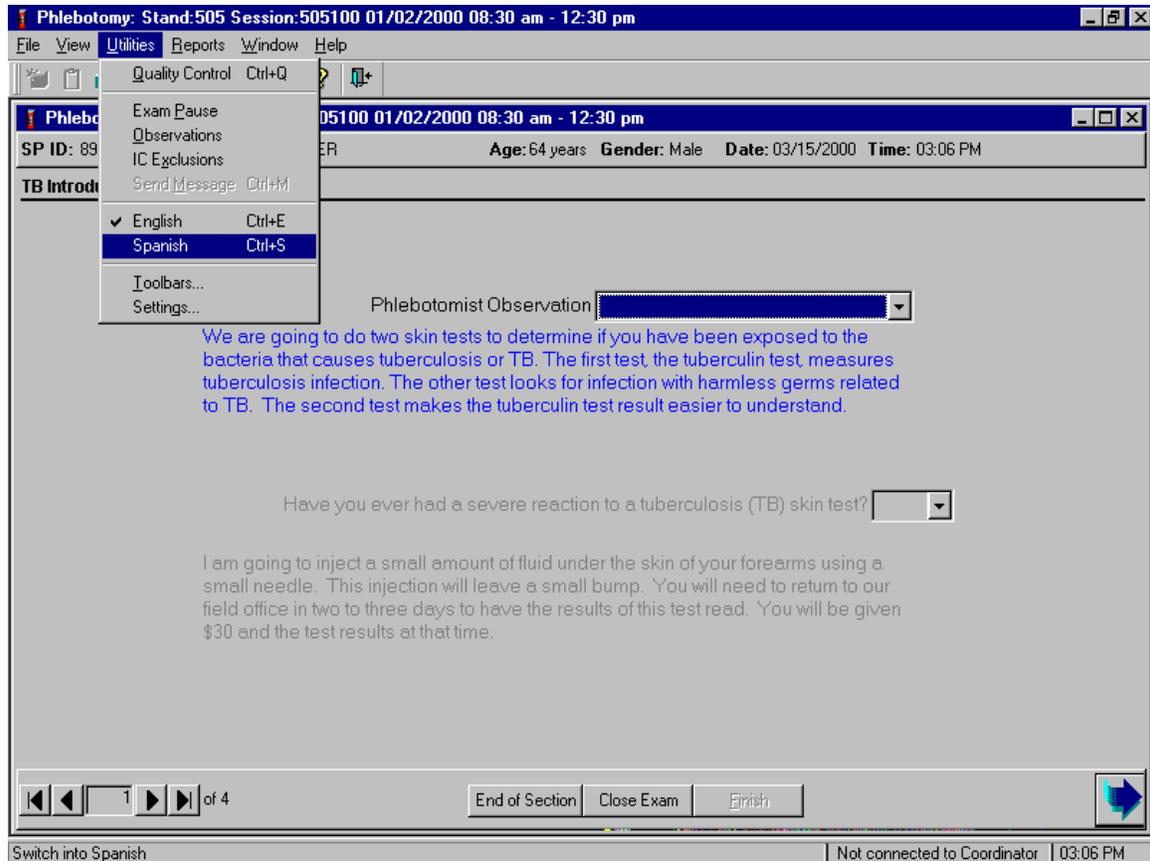
When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right hand corner and left click to progress to the end of the exam or next section (VOC) or select [Enter] when this blue arrow is highlighted.

#### **4.8 Conducting the TB Exam in Spanish**

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

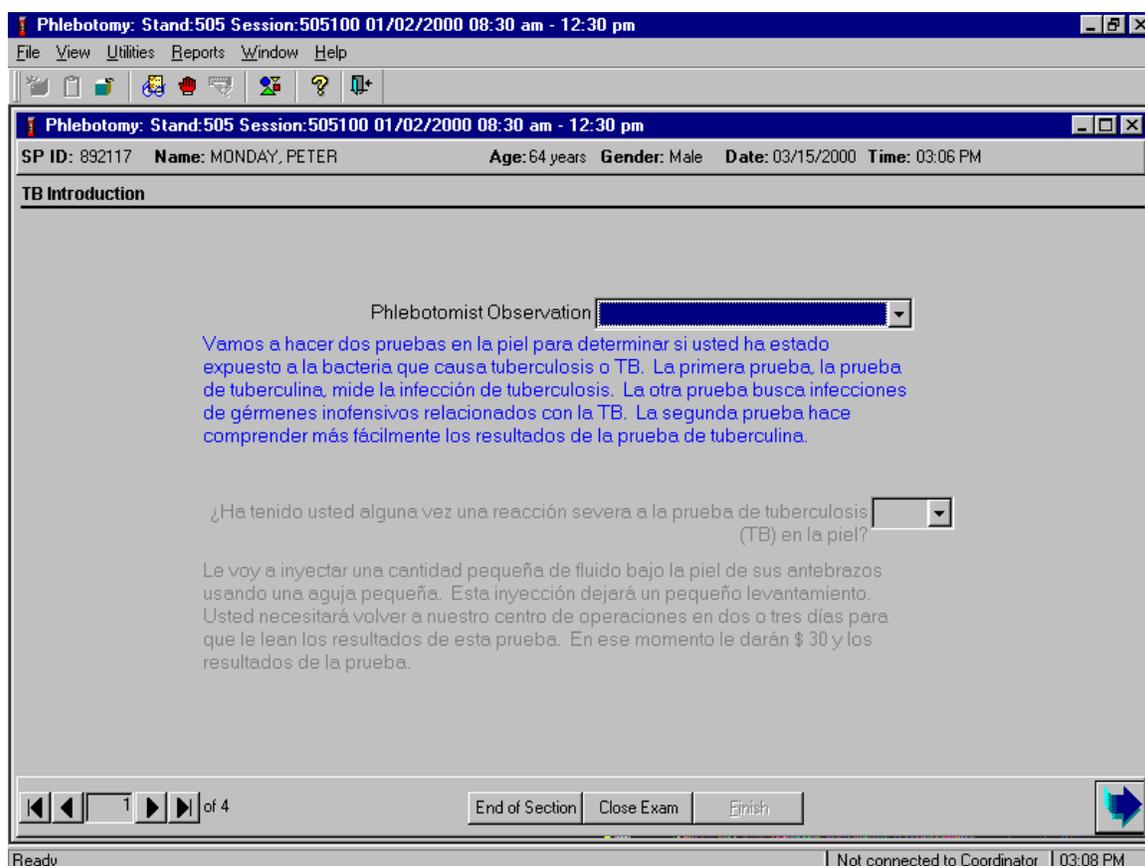
The translator stays with the phlebotomist and the SP for the entire procedure. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the examination.

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



To view the scripts in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S].

All scripts display in Spanish.



To return the scripts to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E].

#### 4.9 Severe Adverse Reactions during Antigen Administration

No immediate adverse reactions were recorded when skin tests using the same antigens were injected into the forearms of thousands of participants in NHANES I and no such reactions are expected during the present survey. However, there is a theoretical possibility that anaphylactic shock can occur when any foreign substance is injected or ingested. If anaphylactic shock should occur after the injection of a skin test antigen, complete an incident/emergency form for severe placement reactions (see Exhibit 4-1). Follow the procedures in the Emergency Procedures Manual. The occurrence must also be reported on the Adverse Reaction form to Dr. Kathryn Porter. Email to Dr. Porter immediately.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Centers for Disease Control and Prevention

National Center for Health Statistics  
6525 Belcrest Road  
Hyattsville, Maryland 20782

## MEC INCIDENT/EMERGENCY REPORT

### Incident/Emergency

Incident     Emergency

### Person Type

SP     Tech     Other

### General Information

Physician Name:	Recorder Name:
Emergency Date:	Runner Name(s):
Start Time:                      End Time:	Who Called 911:
Location:	Who Found:
Description:	

### Personal Information

Person ID:	Age:	Gender:
Last Name:	First Name:	Middle Name

### Vitals

Exhibit 4-1. MEC Incident/Emergency Report (continued)

Time	Heart Rate	Systolic BP	Diastolic BP	Respiratory Rate	Comments

**Treatment**

Time	Medication/Equipment	Comment
	Exhibit 4-1. MEC Incident/Emergency Report (continued)	

**Symptoms**

**Observation**

**Assessment**

**Plan**

**Urgent Care**

Exhibit 4-1. MEC Incident/Emergency Report (continued)

<input type="checkbox"/> Transported to Hospital	Hospital Name:
Ambulance Arrival Time:	Ambulance Departure Time:
Emergency Service Name:	
<input type="checkbox"/> Physician Accompanied SP to Hospital	

<b>Notification</b>		
<input type="checkbox"/> Family Member Notified	Name:	Date/time:
Relation:		
<input type="checkbox"/> Family Physician Notified	Family Phys Named:	Date/time:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_





**Chapter 5**  
**Appointment Manager Guide**  
**for TB Readers**

**National Health and Nutrition Examination Survey**

## Appointment Manager Overview

The Appointment Manager (AM) program enables the Field Office to schedule SPs into sessions for the MEC exam, Home exam, and TB and Dietary interviews. The system provides the ability to schedule, reschedule, and cancel appointments. Basic information required to schedule SPs is entered as well as transportation arrangements, interpreter information, and special considerations.

The TB Reader module of the AM program permits the Readers to focus on their specific tasks involved in managing the TB reading requirements without engaging the complexity of the full AM program.

## Opening the Program

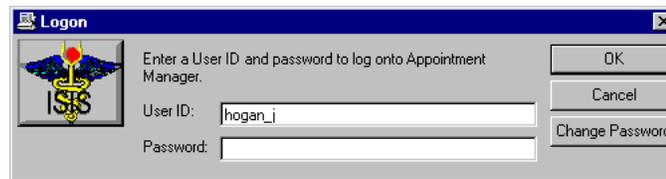
- Locate and double-click the Appointment Manager desktop icon. 

Or,

- Click on the **Start** button.
- Click on **Programs**.
- Click on the **Appointment Manager** folder on the Program menu.
- Click on the **Appointment Manager** icon.
- The current stand initializes information and displays.

## Logon

Upon opening the Appointment Manager program, the Logon dialog box displays prompting you to enter your User ID and Password.



Type in the information in the appropriate fields and press **OK**. Access rights to the Appointment Manager are limited to designated staff members. **TB Reader** and **Dietary Interviewer** User IDs and Passwords will activate the appropriate AM mode tailored to their requirements.

After entering your password and before pressing **OK**, you can change your password by clicking on the **Change Password** button. The Change Password dialog box appears.



Enter your current password for access verification, followed by your new password.

Confirm your new password and press **OK**.

## Toolbar and Menu Options

A toolbar with icon buttons displays for most actions available through the menu bar. The toolbar buttons provide a rapid means for accessing information with a single mouse click. Dim buttons are disabled and their actions are not available for the window or pane currently active.

Each menu option has an associated shortcut key that enables you to access the menu from the keyboard instead of using the mouse. The underlined letter in the option name indicates the shortcut key for an option. The shortcut key activates when pressing the **Alt** key in combination with the shortcut key, such as **Alt+F** to access the **F**ile menu options. Holding the **ALT** key while pressing **F**, then **C** keys will close the currently opened Stand. Additionally, actions indicated with a **Ctrl+letter** key on the menu can be accessed immediately anywhere in the application. Pressing the **Ctrl+S** keys, for example, will save all changes immediately.

**Note:** Not all menu or toolbar options are available all the time. Each menu option or toolbar action is associated with specific actions within appropriate panes. Unavailable menu options are dimmed or not shown. Toolbar buttons are dim when their action is not executable.

### File

	Open	Available when no current stand is open. Opens the Stand List to select a stand for management.
	Close	Closes the open stand.
	Print <i>Ctrl+P</i>	Prints the active pane or window.
	Print Pre <u>view</u>	Previews the active pane or window as it will appear when printed.
	Page Setup...	Opens the Page Setup dialog box for print settings.
	Print Immediate	Immediately prints the active pane, bypassing the printer dialog box.
	Call Log	Opens the Call Log window to record SP contacts.
	Ex <u>it</u>	Exits the Appointment Manager program and returns to the operating system.

### View

	Search ▶	
	SP's	Displays Search for All Persons pane.
	<i>Ctrl+S</i>	
	SP Query	Executes the search based on the query constructed in the Search for Sample Persons window.
	Switch Query ▶	Search for Persons that need to be scheduled for a TB an/or VOC Appointment. Search for All Persons Given TB Antigens or with a TB and/or VOC Appointment.
	Execute Search	Executes the search based on the query constructed in the Search for Sample Persons window.
	ReFresh	Retrieves Calendar information and refreshes the display.

<i>Ctrl+R</i>	Calendar Comments View	Displays the session and stand comments in calendar form.
<i>Ctrl+Alt+C</i>	Stand Calendar View	Displays session statuses for all stand sessions in calendar form.
<i>Ctrl+Alt+S</i>	Appointment Location ▶	<b>MEC</b> – Displays MEC Appointment Calendar. <b>FO</b> – Displays FO Appointment Calendar. <b>Home</b> – Displays Home Appointment Calendar. <b>All</b> – Displays All locations Appointment Calendar. <b>FO and Home</b> – Displays both FO and Home locations Appointment Calendar.
	Appt Type ▶	<b>Non-TB</b> - Displays Non-TB appointment types in the Session Appointment Detail pane. <b>TB</b> - Displays TB appointment types in the Session Appointment Detail pane. <b>All</b> - Displays TB and 2 <sup>nd</sup> Day Dietary.
	First	Displays first screen display page of selected window/pane.
	Next	Displays next screen display page of selected window/pane.
	Prior	Displays prior screen display page of selected window/pane.
	Last	Displays last screen display page of selected window/pane.
	Sort...	When active, resorts selected window/pane by user-defined sort order.
	Filter...	When active, filters selected window/pane by user-defined filter.
	Zoom...	When active, enlarges or reduces view in print preview window.

## Admin

	Appointment Administration	<i>F4</i>	Opens Appointment Detail window for SP selected in the Session Appointment window.
	Session Status Changes	<i>F5</i>	Enables Session Status Change drop-down boxes to change status of sessions. Also displays all sessions including inactive sessions.
	Edit Session Comment	<i>F6</i>	Opens Session Comment box for session comments.
	Current Session	<i>F9</i>	Monitors the arrival of scheduled SPs for the current session.
	Appointment Status Changes		Changes the Appointment Statuses of selected SP records.
	Delete SP		Opens the Delete SP window to delete SPs added before the Interviewer uploads SP files.
	2 <sup>nd</sup> Exam/Diet Response	<i>F10</i>	Opens the 2 <sup>nd</sup> Exam/Diet Response window displaying the recruited SPs affirmative response for the 2 <sup>nd</sup> Day and Dietary exams.

## Reports

Appt Schedule	Generates a MEC Appointment Schedule for the selected session.
TB Appt Schedule with Time Constraints	Generates a TB Reading Appointment Schedule for the selected session with Earliest and Latest Reading times.
SP's Needing TB Appt	Generates a list of SPs who need a TB appointment.
IM Appt Schedule Reconciliation	Generates a list of scheduling discrepancies detected between the interviewer pentop and the FO server's appointment information.
Call Reminder	Produces the Appointment Call Reminder Report for the session selected in the <i>Calendar</i> . All information needed to confirm key dates, times, address, transportation, consents, and appointment type are listed for each SP.
2 <sup>nd</sup> Day Dietary In-Take	Produces the Appointment Schedule – Day 2 Dietary In-Takes for the selected session in the Calendar. Information includes SP information, Mode of Original Exam, and Interviewer.
Second Exam Recruitment ▶	<b>All</b> – Displays report for all SPs recruited for the 2 <sup>nd</sup> Exam and 2 <sup>nd</sup> Dietary examinations. <b>2<sup>nd</sup> Dietary</b> – Report displays only SPs recruited for the 2 <sup>nd</sup> Day Dietary. <b>2<sup>nd</sup> Exam</b> – Report displays only SPs recruited for the 2 <sup>nd</sup> Day MEC exam.
Home Exam Appt. Schedule	Lists all scheduled SPs for Home exams along with appointment time, SP address and language, consents, and assigned HE interviewer.

## Window

<u>C</u> ascade	Displays multiple windows overlapped and slightly offset as to show the title bar of each open window.
Tile <u>H</u> orizontal	Displays open windows on top of each other and sized to fit all in the main program window.
Tile <u>V</u> ertical	Displays open windows next to each and sized to fit in the main program window.
<u>L</u> ayer	Displays open windows stacked over each other.
M <u>i</u> nimize All Windows	Reduces all windows to a button in the lower portion of the main program window.
<u>U</u> ndo	Returns the window configuration to its previous display before the last window command.
✓ <u>1</u> (Open window or view name)	

## Help



Help  
F1  
About

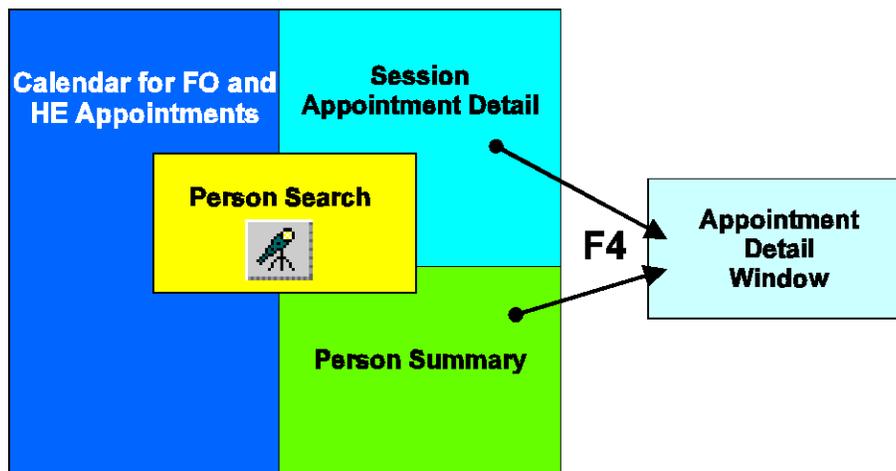
Topics Opens Help topics focused on Appointment Manager “How-to”.  
Displays the version and date of the Appointment Manager program.

## Important Navigational Keystrokes

Keystrokes are a rapid navigational tool in the Appointment Manager. Although all navigation could be accomplished through the menu bar options, special keys have the ability to rapidly display desired windows and data panes. The right mouse button menus, double-clicking the left mouse button, coupled with these special keys enable quick and easy access to all management tools.

It is very important to be aware of which window or pane has “focus” whenever you are using any function in the Appointment Management System. The window/pane with *focus* will always have a light blue highlighted title bar, and reacts to the keyboard or menu commands. Only one window or pane can be active to receive commands, although multiple windows and panes are open.

Every window/pane in the AM system are printable. Therefore, be sure focus is on the window/pane you want before printing or taking other actions.



**F12 key** The Calendar window cycles through different information each time the **F12 key** is pressed.

The *Calendar* pane displays the FO and HE Appointments by default, and cycles through the various session types each time the **F12** key is pressed. Subsequent presses of the **F12** key will display the MEC sessions, FO sessions, Home sessions, and All sessions, and back to the FO and HE Appointments.

<**Enter**> Performs the same action as double-clicking the primary mouse button. This feature is helpful to users who are keyboard oriented.

<**Arrow**> Highlights the next row of information in a table in the direction of the arrow (up or down).

Double-click a session in the Calendar window to open the *Session Appointment Detail* pane.

Double-click an SP appointment in the Session Appointment Detail pane to open the *Person Summary* pane.

To access an SP's *Appointment Detail* window, select one or more SP appointments, then

- Click the  **Appointment Administration** icon

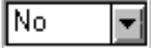
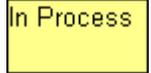
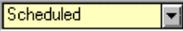
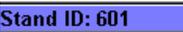
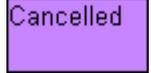
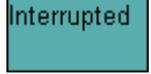
Or

- Right click on the selected appointments and select Appointment Administration from the popup menu.



## Colors

Colors are used to differentiate areas of a table, key information fields, editable fields, and identifies the window that has focus (receives system commands). These colors and their descriptions are:

<b>Grays</b>		Used in two tones in table windows to provide a visual separation of data columns and <i>display information only</i> (non-editable).
<b>White</b>		Optional data field that is editable.
<b>Yellow</b>		In Process session status.
<b>Light Yellow</b>		Essential data field that requires completion.
<b>Light Blue</b>		Title bar color on data window that has the system "focus" and is active.
<b>Light Green</b>		Available session status.
<b>Purple</b>		Cancelled session status.
<b>Teal</b>		Interrupted session status.

<b>Orange</b>		Booked session status.
<b>Dark Blue</b>		Selected row, records, or fields. Also used for the Comment indicator flag.
<b>Rose</b>		Dry run session status.
<b>Red</b>		Overbooked session status and response to consent.

SP Response to Future Research Question

## The Stand List

Appointments are managed by one stand at a time. The Stand List displays only the current stand level for review or management at the FO. The Appointment Manager automatically displays the current stand upon opening the program.

### To Reopen the Current Stand:

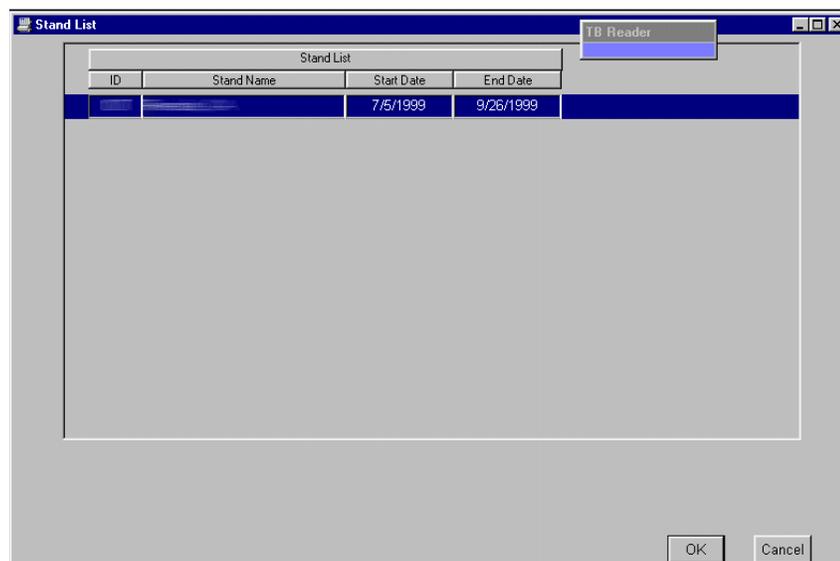
- Select *File / Open* from the menu bar.
- The *Stand List* appears.
- Either double-click the desired stand,

*Or,*

- Select the desired stand and click the **OK** button,

*Or,*

- Select the desired stand and press **<Enter>**.



The **Stand List** shows:

- ID (Stand). Numeric identification for the stand.

- Stand Name. Name assigned to the stand, usually by location.
- Start Date. The date the Field Office is established and operational.
- End Date. The date the Field Office is officially closed.

## Appointments Calendar

### Calendar

The *Calendar for FO and HE Appointments* is the first window to display upon opening a stand. The *Calendar* is structured in a spreadsheet-like table to display session summary and detail information. Sessions are shown in rows with session statistics in columns.

**TB Reader**

Tailored **TB Readers** views display calendar information specific to their needs. The TB Reader indicator appears when a user logs into the AM program with a TB Reader ID and password. This alerts the user that the TB Reader mode is active. You can move the indicator by clicking and dragging it to a new location.

Additional calendars are shown by repetitively pressing the **F12** key:

- FO and HE Appointments
- MEC Appointments
- FO Appointments
- Home Appointments
- All Appointments

A sample FO and HE Appointments Calendar is shown below:

The screenshot shows a window titled "Calendar for FO and HE Appointments, Stand ID: [redacted]". The window contains a menu bar (File, View, Admin, Reports, Window, Help), a toolbar with various icons, and a "TB Reader" indicator. Below the menu bar is a "Calendar Title Bar" with the text "Calendar for FO and Home Appointments, Stand ID: [redacted]". The main content is a table with columns for Date, Day, Type, Status, Read TB, Diet Day 2, and Comment. The table is divided into sections for different dates. The first section is for "08/04 Wed" and the second for "08/04 Wed". The "Status" column is highlighted in green for "Available" sessions. The "Read TB" and "Diet Day 2" columns show numerical values. The "Comment" column contains the text "Session Comments are recorded here." for the selected row. Annotations on the left side of the image point to the "Menu Bar", "Tool Bar", "Calendar Title Bar", "Session Type", "Session Date/Day (Row Selected)", and "Session Status". An annotation on the right side points to the "Session Comments" column.

Session						Comment
Date	Day	Type	Status	Read TB	Diet Day 2	
08/04	Wed	FO-Early Afternoon	Available	0	0	Session Comments are recorded here.
		FO-Late Afternoon	Available	3	0	
		FO-Early Evening	Available	1	0	
		FO-Late Evening	Available	7	0	
		Home All Day	Available	1	0	
08/04	Wed	FO-Early Morning	Available	1	0	
		FO-Late Morning	Available	4	0	
		FO-Early Afternoon	Available	0	0	
		FO-Late Afternoon	Available	1	0	
		FO-Early Evening	Available	0	0	

Note that the **Title Bar** of the Appointment Manager reads:

**[Calendar Detail for FO and HE Appointments, Stand ID: ###]**

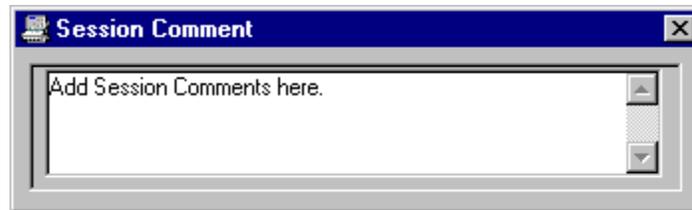
As you navigate to various data windows and panes, the Title Bar will help you track where you are until you become familiar with the program.

Session rows are arranged by **Date/Day** with several sessions **Type(s)** per day:

- { Home All Day
- { FO – Early Morning
- { FO – Late Morning
- { FO – Early Afternoon
- { FO – Late Afternoon
- { FO – Early Evening
- { FO – Late Evening

The columns are headed by **Appointment Categories** defined by *Read TB and Diet Day 2*.

To add, edit, or view **Session Comments**, click on the **Edit Session Comments** button . Both the MEC and Field Office can read these comments. The **Comment** box can remain open while switching between sessions. To close the **Comment** box, press the **Edit Sessions Comment** button again.

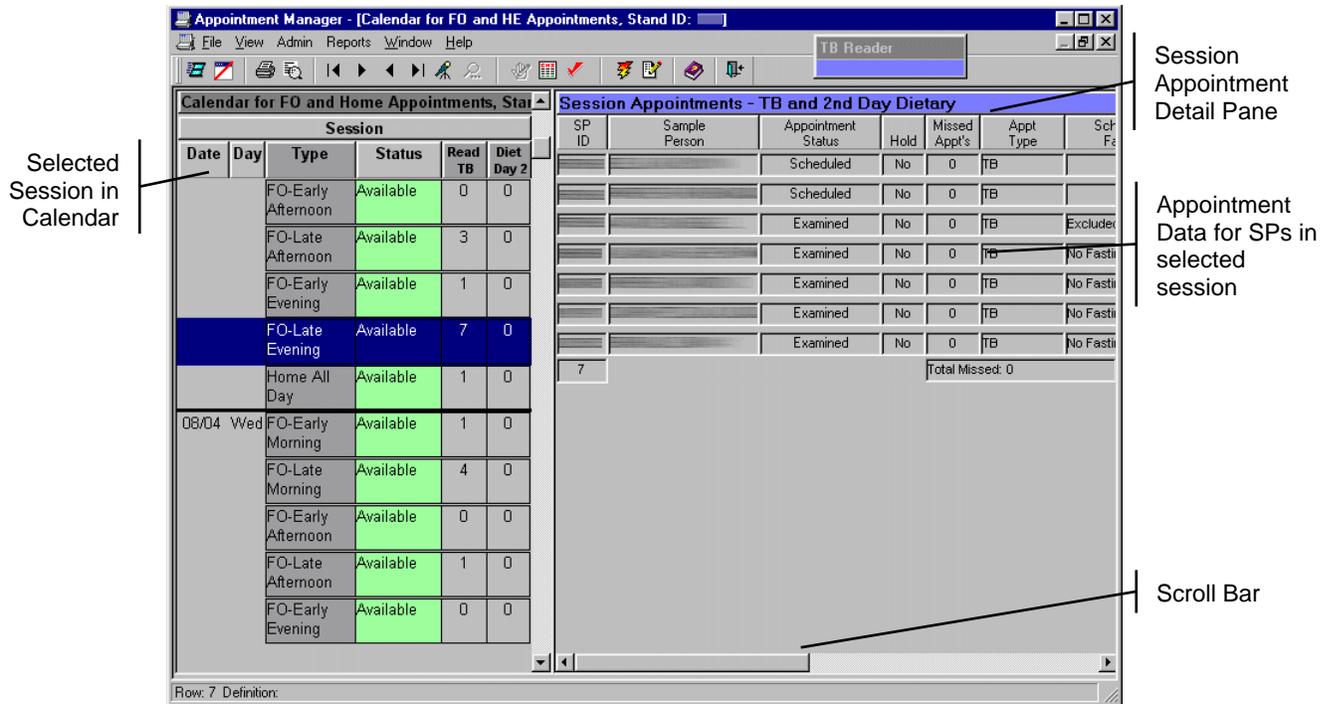


### Session Appointment Detail

The *Session Appointment Detail* pane displays appointment details for SPs scheduled for the selected session in the *Calendar* window.

#### To View the Session Appointment Details:

- Double-click or press <Enter> on a selected row in the *Calendar*.



The *Session Appointment Detail* pane overlays the right portion of the *Calendar*. Note that the light-blue **Title Bar** indicates the pane has focus (active pane). This is important to remember since any actions apply only to the active window or pane.

Using the scroll bar in the lower frame of the right pane will reveal the details for all scheduled SPs.

All information fields are grayed, indicating the information is read only and cannot be edited in this pane.

Only *TB and 2<sup>nd</sup> Day Dietary* information is displayed.

Double-click a *Session Appointment Detail* row to display the *Person Summary* pane.

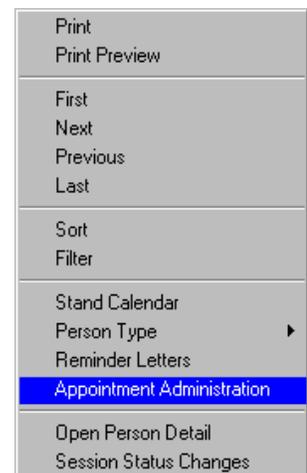
Double-click anywhere on the *Calendar* to close the *Session Appointment Detail* and return to the full calendar view.

Additional actions are available through the right mouse button.

Right-click (click with the right mouse button) anywhere on the *Session Appointment Detail* pane to reveal these menu options.

Once the menu appears, select an action with the left mouse button.

To close the menu, left-click anywhere away from the menu or press the <Esc> key.



## Person Summary

The Person Summary pane is viewed from the Session Appointment Detail pane that displays the SP's basic information and Special Considerations. This pane is read-only.

### To View Person Summary:

- Select SP in *Session Appointment Detail* pane.
- Double-click or press <Enter> on a selected *Session Appointment Detail* row, or right-click on a selected row and choose *Open Person Summary* on the displayed menu.

The screenshot displays the Appointment Manager software interface. The main window is titled "Appointment Manager - [Calendar for FO and HE Appointments, Stand ID: ]". The interface is divided into several panes:

- Calendar for FO and Home Appointments, Stand ID:** A table showing session appointments. The selected row is "FO-Late Evening" with a status of "Available", 7 reads, and 0 diet days.
- Session Appointments - TB and 2nd Day Dietary:** A table showing appointment details for the selected session, including SP ID, Sample Person, Appointment Status, Hold, Missed App'ts, and Appt Type.
- Person Summary:** A pane in the lower right corner displaying personal information for the selected session. Fields include Participant#, Name, Address, Age (13), DOB, Grade (7th Grade), Gender (Male), Language (English), Race (Other), and Ethnicity (Mexican-American or M). This pane is labeled "Person Summary pane" with an arrow.
- Special Considerations:** A field associated with the selected SP, labeled "Special Considerations" with an arrow.

The Person Summary pane and Special Considerations field are grayed out, indicating they are read-only.

The *Person Summary* pane appears in the lower right corner of the Calendar. All fields are grayed, indicating read-only. The *Special Considerations* field is associated with the selected SP and lists special factors peculiar to the SP.

- Selecting another SP in the *Session Appointment Detail* pane will automatically update the *Person Summary* pane.
- Selecting another session in the *Calendar* pane (single mouse click) refreshes the *Session Appointment Detail* pane and the *Person Summary* pane, displaying the first SP record.
- Double-click on the *Session Appointment Details* pane to **close** the *Person Summary* pane, or

## Appointment Detail Window



The *Appointment Detail* window opens when an SP is scheduled, rescheduled for an appointment, or when an SP(s) is selected in the *Session Appointment Detail* pane and the **Appointment Administration** button is clicked. This window keeps detailed SP information that is required to schedule, plan, transport, and plan for examinations.

**Appointment Detail**

SP: [ ] Participant ID: [ ] Session: FO-Late Evening - 08/03/1999 - Start Time: 18:00 Appointment: 1 of 1

Address: [ ]

Type: TB Status: Examined Status Date: 8/2/1999 Scheduled By: [ ]

Arrival Time: 17:00 Field Reminder: [ ] Child/Adult Care: No Interviewer: [ ]

Assigned Fast: Morning Sched Fasting: No Fasting Required Language: English

**Detail Tabs:** Transportation | Interpreter | Considerations/Incentives | History | SP Addresses | Comments | SP Info | Consents

**Trips for this Appointment**

To Appointment: [ ] Authorization: No 1 Edit Appointment

Trip Detail: Taxi - O'hare Taxi Service - Pick-up Time: 18:00

**Other Occupants**

Occupant Type	Occupant Name

Previous Transportation Information:  
No Transportation Info Available

**Button Bar:** Previous Appointment | Next Appointment | Insert Detail | Delete Detail | Ok | Cancel

Information fields that are gray are generated by the system and are read only fields. White colored fields are optional information. The light yellow or cream color fields are *required* fields and must be completed before the record can be generated. Pressing the **<Tab>** key will advance the cursor to the next editable field; **<Shift>+<Tab>** reverses direction.

### Button Bar – Appointment Detail

The button bar is used to add new persons, move between multiple Appointment Detail windows, add or delete selected information, and save.

Buttons that are disabled are not available for the current action. For example, if only one SP is currently being added or edited, the **Previous** and **Next** buttons are dimmed.

Previous Appointment

Next Appointment

**Previous Appointment:** Displays the previous added appointment.

**Next Appointment:** Displays the next newly added appointment in sequence, if not the last appointment.

Insert Detail	<b>Insert Detail.</b> Inserts a blank detail entry in the selected (active) detail tab, if allowed.
Delete Detail	<b>Delete Detail.</b> Deletes the selected SP detail entry, if allowed.
Cancel Current Change	<b>Cancel Current Change.</b> Cancels changes made to current record.
Ok	<b>OK.</b> Saves the newly added records and exits to the Newly Added Persons data window.
Cancel	<b>Cancel.</b> Cancels all Appointment changes for all records since window was opened.

### General Information – Appointment Detail Window

The screenshot shows the 'Appointment Detail' window with the following fields and values:

- SP:** [Empty]
- Participant ID:** [Empty]
- Session:** FO-Late Evening - [Empty] - Start Time: 18:00
- Address:** [Empty]
- Type:** TB (dropdown)
- Status:** Examined
- Status Date:** 8/4/1999
- Scheduled By:** 000: Not Applicable, (dropdown)
- Arrival Time:** 08:30
- Language:** English
- Interviewer:** [Empty]
- Assigned Fast:** Afternoon/Evening
- Sched Fasting:** Excluded, Diabetic taking Insulin
- Field Reminder:**

**SP.** Automatically filled-in upon display and is read only.

**Participant ID.** Read only.

**Session.** Session, date, and start time. Read only.

**Address.** SP address, read only.

**SP Initiated.** Radio button indicated the SP rescheduled the appointment.

**FO Initiated.** Indicates the FO rescheduled the appointment.

**Type.** Select from the drop down or type the first letter of the Type name:

- { TB
- { TB & VOC
- { VOC

**Status.** The display only field defaults to *Scheduled*. Read only.

**Status Date.** Date Status is assigned and is read only.

**Scheduled By.** *Required.* Default is *Not Applicable*, except for Primary appointments (automatically displayed base on case assignment). Select from the drop-down list the interviewer responsible for scheduling the appointment.

**Arrival Time.** Expected time of arrival to appointment location. Default is beginning of session.

**Field Reminder.** Checkbox. Reminder telephone call from field staff requested.

**Interviewer.** Field staff that conducted the interview. Read only.

**Assigned Fast.** Fasting requirement assigned to the household for the primary appointment. Read only.

**Sched Fasting.** Read only. Type of fasting assigned by the system based on:

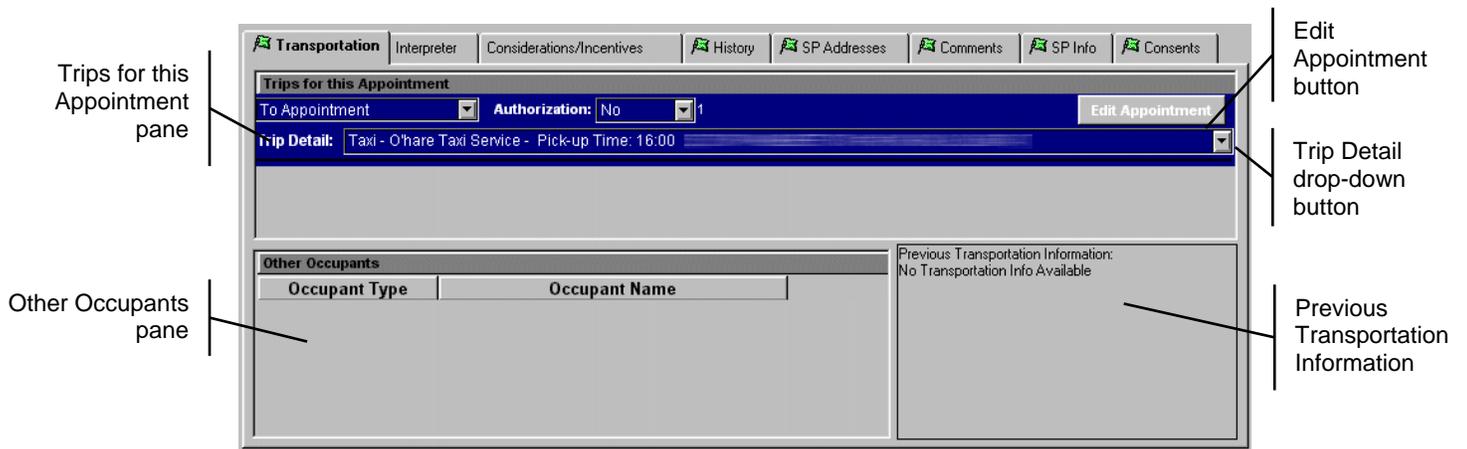
- SP age
- Type of session
- Scheduling information (morning/afternoon/evening)
- If SP is taking insulin (as indicated in the SP Questionnaire).

**Language.** SP's primary language. Read only.

**Hold.** Yes/No. Appointment not confirmed.

### Transportation Tab– Appointment Detail Window

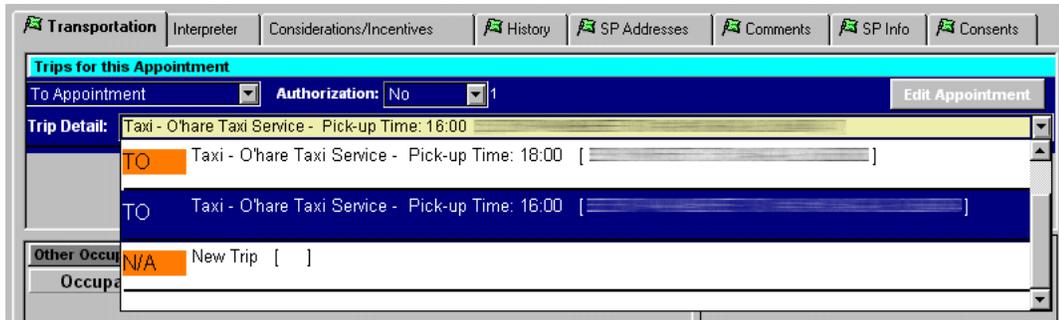
The Transportation tab maintains detailed information for transporting the SP to and from appointments. Information includes when and where the SP will be picked up, who will accompany the SP, transportation type, and staff member will pick-up the SP if a Field Staff Pick-up is required.



**Note:** The Previous Transportation Information pane lists the type of transportation the SP used in their previous appointments.

#### To Add/Edit a Trip:

- Click the *Transportation* tab.
- Click **Insert Detail** button on the button bar.
- Select **To Appointment** or **From Appointment** from the drop-down list, if necessary to override the default.
- If the SP is a minor, select **Authorization** (Yes or No).
- For new trips, click on the blank row to open the Trip Detail drop-down list and select **New Trip** [ ] (bottom of list).

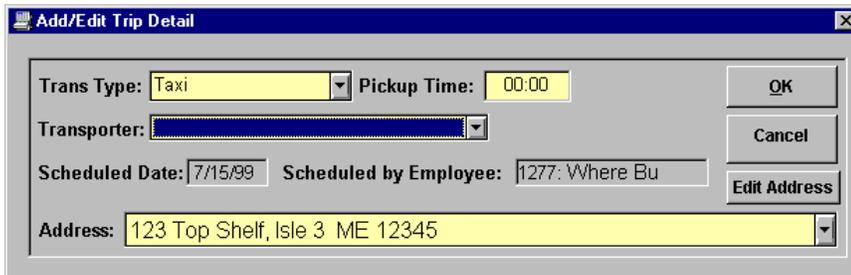


Or,

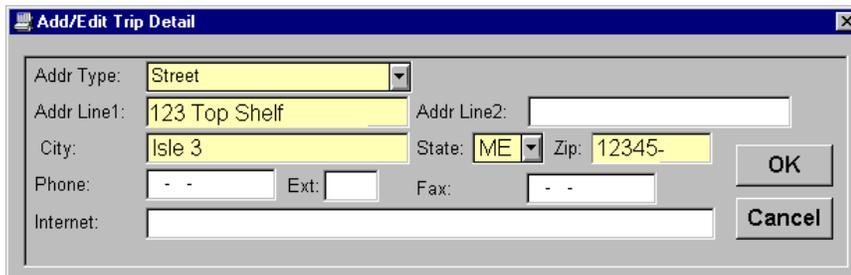
- Select a trip from the Trip list.
- The *Add/Edit Trip Detail* window appears.



- Select **Trans Type** from the drop-down list. Choices are Taxi, Public, or Field Staff Pick-up.



- Enter **Pickup Time**.
- For *Taxis*, select provider from the **Transporter** drop-down list.
- For *Field Staff Pick-up*, select staff member from the **Trans By** drop-down list.
- Select the **Address** for pick-up from the Address drop-down list. If the pick-up address is different from addresses shown on the list, choose *Add New Address* from the drop-down list. The address edit window appears.



- Enter address information and click **OK**.
- Click **OK** to exit the *Add/Edit Trip Detail* window.
- If another person will accompany the SP, click in the **Other Occupants** pane.

Other Occupants	
Occupant Type	Occupant Name
<div style="border: 1px solid black; padding: 2px;"> <span style="background-color: #cccccc; display: inline-block; width: 100%; height: 15px;"></span> </div> <ul style="list-style-type: none"> <li>Escort/Guardian</li> <li>Interpreter</li> <li>Other</li> </ul>	

- If the SP is a child, a row for an escort is automatically added.
- Click the **Insert Detail** button.
- Select the **Occupant Type** from the drop-down list.
- Enter the other occupant's name in the **Occupant Name** field.

#### **To Add a Return Trip (Auto-create):**

- Click the Transportation tab.
- Click **Insert Detail** button on the button bar.
- A popup message appears asking; “Do you want to auto-create the return trip?”
- Click **Yes** to auto-create the return trip. This action will reverse the To and From locations of the first trip created, and schedule the pickup time to the closing of the appointed session.
- Click **No** to manually enter the transportation requirements as required.
- If an escort was added for the “**To**” trip, this information is copied too the “**From**” trip.

#### **Important Transportation Considerations**

- { Every SP can have one and only one appointment of a given type (e.g., one Primary, one TB Appointment).
- { Every appointment can be linked to zero, one, or two trips
- { A person transporting himself has zero trips.
- { If a person transports himself to the MEC and then provided with transportation for the return trip, this makes one trip.
- { A person may be transported in both directions, in that way having two trips
- { Trips describe a carrier, time, place and direction. (Yellow Cab, at 10 a.m. to Elm Street to the MEC, or Metro-bus, at 1 p.m. to Maple Lane from the MEC)

- { Trips are independent of appointments.
- { Trips exist as an independent pool. It is possible, but rare, for a trip to exist without any connection to any appointment. A trip can be linked to one or many appointments. If a family of 5 all have appointments at the same MEC session and one taxi is dispatched to take them all, that one taxi trip is linked to 5 separate appointments.
- { When you link a trip to an appointment, you are first offered a list of all trips currently scheduled to the MEC session of that appointment.

*It is important that you choose a preexisting trip from the list, rather than creating a new trip if a preexisting trip already describes the trip.*

**For instance**, in the case described above, a family of 5 is traveling in the same cab ride. Once the appointment is made for the first member of that family, a new trip will need to be created because it will not preexist in the trip pool. However, the next 4 appointments for that family should not have new trips made because the trip made for the first member *may be linked* to the remaining four family members. The remaining four family members may use the newly created trip information from the first family member.

**Note:** **Auto-create** *should not* be used to create the return trips for members linked to another trip record. Auto-create will insert new records for each member although they will be traveling under the original linked record. When adding trip information to linked members, select “**No**” when prompted for Auto-creation of return trip.

- { Editing a trip affects all the appointments to which that trip is linked.

**For instance**, if one of the five family members needs to change his trip’s pickup time, *it is important to create a new trip for him, rather than editing his currently linked trip*. A new trip is required because his currently linked trip is also linked to four other appointments. *If you do change the time for his trip, it will mean all five family members will be picked up at the new time.*

- { Just as trips exist independently of appointments, addresses exist independently of trips. *Every trip must be linked to an address*. Whenever you create a trip, you must select an address from the address pool.

The address pool contains every address any trip has ever had at that stand. Unlike trips lists, addresses are not restricted to those already linked to a particular session. Consequently, if a husband and wife have appointments to the MEC on different days and they need transportation, you must create four different trips for them:

1. Husband to MEC March 1 evening from Elm Street.
2. Husband from MEC March 1 evening to Elm Street.
3. Wife to MEC March 2 morning from Elm Street.
4. Wife from MEC March 2 morning to Elm Street.

Although four separate trips were needed, the same address applies to all four trips. In this case, *it is very important not to create new addresses for each trip but select the preexisting address after creating it one time for the first trip.*

- { Just as with trips, if you edit an address, remember you are changing it for all the trips to which it is linked, not just the one you are looking at currently.

### Interpreter Tab– Appointment Detail Window

The Interpreter tab displays SP interpreter requirements.

#### To Add an Interpreter:

- Click on the Interpreter tab.
- Click the **Inset Detail** button on the button bar.
- Select **Type** from drop-down list. Choices are **NHANES**, **None**, or **Personal**.
- If an **NHANES** interpreter is requested, select **Employee Name** from drop-down list.
- If the SP has a **Personal** interpreter, complete the interpreter information in the labeled fields.

### Considerations/Incentives Tab– Appointment Detail Window

**Considerations** tab indicates the type of special considerations needed for preparations, handling, or special attention the SP requires during transportation and examinations. Select the allowed incentives for transportation and childcare payments in the **Incentives** pane. Allowing incentives in this tab authorizes the MEC Coordinator to pay the SP for the selected incentives. Select the appropriate incentives for FO or HO sessions if the incentives apply, although the TB program does not calculate the incentive payment. Validated incentives for the SP’s primary appointment are indicated on the right side of the Incentives tab.

**Incentive Allowance Considerations:**

- Allow only one incentive flag for multiple SPs coming from the same household location (identical transportation arrangements) and are travelling to the MEC.
- Allow appropriate incentives for each SP of the same household if they are travelling to the MEC separately. This allowance should coincide with the separate transportation arrangements.

Type	Incentive Allowed
Transportation	No
Child/Adult Care	Yes
Non-SP Payment	Yes

Household Incentive: \$50 - \$125

**To Add a Special Consideration Code:**

- Click on the Special Consideration tab.
- Click the **Insert Detail** button on the button bar.
- Choose the appropriate code in the drop-down list. (Note: You cannot select the same code twice.)

- BL** – Blind
- CN** -- Cane
- CR** – Crutches
- DF** – Deaf
- HB** – Home Bound
- HI** – Hearing Impaired
- LN** – Lift Needed
- MI** – Mental Impairment
- OB** – Obese
- OP** – Other physical impairment
- SA** – Substance Abuse
- WC** – Wheel chair
- WL** – Walker

Special Considerations

- BL
- CN
- CR
- DF
- HB
- HI

- To add more than one code, select the **Insert Detail** button for each code to enter.
- Click **OK** when complete.

**To Add Incentives Allowed:**

- All incentives are defaulted to No.
- Click on the appropriate incentive to activate a drop down menu.
- Select Yes.
- Click OK when complete.

Type	Incentive Allowed
Transportation	No
Child/Adult Care	No
Non-SP Payment	No

**History Tab– Appointment Detail Window**

The History tab lists the appointment rescheduling history for the SP. The history information is read-only.

Sample Person Name	Status	Type	Session	Rescheduled By	Status Date	History Date
	Examined	TB	08/03/1999 - FD-Late Ever		8/2/1999	11/8/1999 08:19:48
	Examined	Primary	08/01/1999 - Morning		7/29/1999	11/8/1999 08:19:48

Nbr of Rows: 2

**SP Addresses Tab– Appointment Detail Window**

SP Addresses tab lists all address information by type. Address types include Street, Mailing, Office, or Other.

**To Add an SP Address:**

- Click on the SP Addresses tab.
- Click the **Insert Detail** button on the button bar.
- For each type of address, complete the information in the labeled fields. For most SPs, the mailing and street address is defaulted to the information provided at the time of interview. (Note: You cannot select the same **Type** twice.)
- Click **OK** when completed.

**Comments Tab– Appointment Detail Window**

The Comments tab captures observations made during the conduct of managing the appointment. Each comment is categorized by type. Only General and Transportation Types are currently reflected in reports.

Type	Appointment Comments
General	call back @ 6pm

**To Add a Comment:**

- Click on the Comment tab.
- Click the **Insert Detail** button on the button bar.
- Select **Type** from the drop-down window.

- Enter comments in the **Comments** text field.
- Click **OK** when complete.

**Note:** You cannot select the same **Type** twice.

### SP Info Tab– Appointment Detail Window

The SP Info tab displays key person details and is primarily read-only, except name, ROF, and telephone numbers.

Phone Type	Phone No	Ext.
Home	[redacted]	00000

#### To Edit Name:

- Click the **Add/Edit Name** button.

- Edit the name in the Add/Edit Person Name window.
- Click **OK** when complete.

#### To Edit Ethnicity or Race:

- Press the **F8** keyboard key.
- Select the appropriate entry from the drop-down list.
- Press the **F8** key to deactivate the lists.

### To Add Telephone Numbers:

- Click in the Telephone Numbers window.
- Edit existing numbers or click the **Insert Detail** button.
- Enter new telephone information.
- Duplicate phone types are not accepted.

### Consents Tab– Appointment Detail Window

The Consents tab lists Type, Consent Date, Consent (Obtained), and Comments. Consents Types with a red background indicate that the Consent was obtained with a signature, versus an oral consent.

Type	Consent Dt	Consent	Consent Comment
MEC Consent/Assent Signed By SP?	12/15/1999	No	
Future Research Consent Signed By SP or REF?	12/15/1999	No	
Future Research Box Checked By SP?	12/15/1999	No	
Genetic Research Box Checked By SP?	12/15/1999	No	

Inserts are not allowed.

### Change or Cancel Appointment Status



This action allows you to change the status of a TB, VOC, TB and VOC, or Dietary appointment status. Canceling an appointment does not delete the SP record.

### To Change Appointment Status:

- Select the SP record from the *Session Appointment Detail* pane.

Either:

- Click the **Change Appt Status Changes** button on the toolbar to display the *Appointment Status* popup.

Appointment Status

Select the type of status change

Cancel

Examined

No Show

OK Cancel

- Select the type of status change.

- Click **OK**.

*Or:*

- Select *Admin / Appointment Status Changes* from the menu bar.
- Select *Cancel, Examined, or No Show*.

*Then:*

- Confirm change of status action.
- The system notifies you when action is complete.

## Search

 The Appointment Manager provides the capability to quickly search for SPs in a Stand by multiple search criteria. SPs selected from the search result pane can be scheduled or rescheduled for an appointment directly from the search pane.

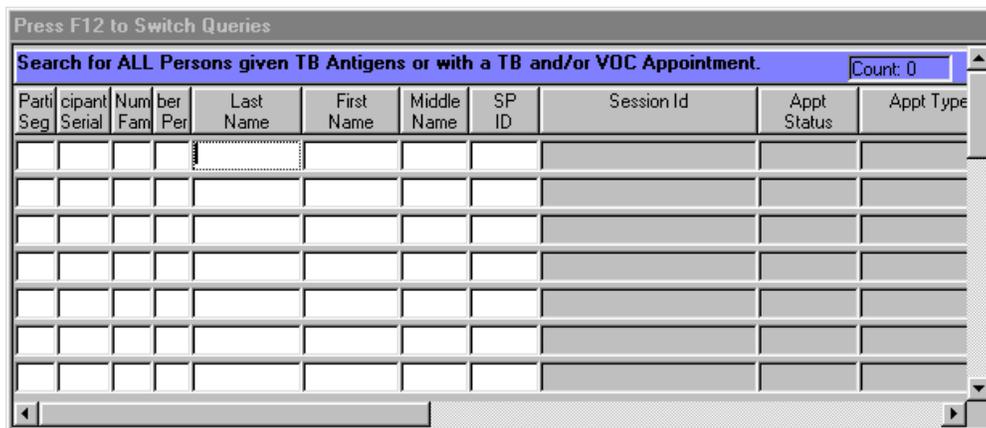
You can switch **Search For** options by pressing **F12** (options vary depending on type of user).

- Search for Persons that need to be Scheduled for TB and/or VOC Appointments.
- Search for All Persons given TB Antigens or with a TB and/or VOC Appointment.

### Search for All Persons Given Antigens or with a TB and/or VOC Appointment

#### To Conduct a Search for All Persons Given Antigens or with a TB and/or VOC Appointment:

- Click the **Search Persons** button on the Tool bar. 
- The *Search Persons* pane appears and overlays the Calendar.



Participant Seg	Serial	Number	Last Name	First Name	Middle Name	SP ID	Session Id	Appt Status	Appt Type

The pane scrolls to display the multiple columns available to build your search criteria. The white color fields are used to type in the column-related information. The gray fields are read only.

Information entered in any column establishes the search criteria. The search engine will select and display SP records that match the information you provide.

Multiple search criteria entered on the *same row* searches the stand records with an “**AND**” condition. For example, when entering both a Last Name AND First Name the search will look for both matching Last Name *and* matching First Name.

Multiple search criteria entered on *separate rows* searches the stand records with an “**OR**” condition. Typing in a Last Name in row one and another Last Name in row two will specify a search for Last Names which match either the row one Last Name OR the

row two Last Name. Last Names matches of both row names will display in the data window if found. This search technique is useful if the spelling of a name is uncertain. The <Enter> key can be used to execute the search based on your criteria, clears the pane of displayed information, or displays all stand SP records if pressed on an empty pane.

- Click the **Execute Search** button . The button both executes a search action and clears the pane, just like the <Enter> key.

Press F12 to Switch Queries

Search for ALL Persons given TB Antigens or with a TB and/or VOC Appointment. Count: 4

Parti Seg	cipant Serial	Num Fam	ber Per	Last Name	First Name	Middle Name	SP ID	Session Id	Appt Status	Appt Type
1	6	1		MARVIS	Starven		123456	09/25/1999 - Home All Day	Scheduled	TB
1	1	1		MARVIS	Carven		123456	07/22/1999 - Morning	Examined	Primary
7	1	1		BELL	Maw		123456	08/14/1999 - FO-Early Ever	Examined	TB
10	1	1		BELL	Ringmi		123456	08/03/1999 - FO-Late Ever	Scheduled	TB

- You can drag and drop SPs to schedule or reschedule. See *Scheduling Appointments from Search Results* on page 29.
- Click the **Search for All Persons** button  to close the pane.

### Search by Last Name

- Simple searches for a SP by Last Name involves typing the name in the Last Name column:

Press F12 to Switch Queries

Search for ALL Persons given TB Antigens or with a TB and/or VOC Appointment. Count: 0

Parti Seg	cipant Serial	Num Fam	ber Per	Last Name	First Name	Middle Name	SP ID	Session Id	Appt Status	Appt Type
				One						

- Then click the **Execute Search** button  or press <Enter> to initiate the search.
- The search results will display the SP record in the pane.

Press F12 to Switch Queries

Search for ALL Persons given TB Antigens or with a TB and/or VOC Appointment. Count: 1

Participant Seg	Serial	Number Fam	Number Per	Last Name	First Name	Middle Name	SP ID	Session Id	Appt Status	Appt Type
1	13	65	2	ONE	TEST		465450	08/09/1999 - Home All Day	Scheduled	TB

- Note that only the record rows that match are displayed.

### Search with Multiple Criteria

Searches for SPs by multiple criteria involve typing the criteria in multiple rows.

Example:

- Enter a Last Name in row one.
- Enter another Last Name in row two.
- You can also use Boolean techniques of comparison (<, >, <>, etc.).

Press F12 to Switch Queries

Search for ALL Persons given TB Antigens or with a TB and/or VOC Appointment. Count: 0

Participant Seg	Serial	Number Fam	Number Per	Last Name	First Name	Middle Name	SP ID	Session Id	Appt Status	Appt Type
				Marvis						
				Bell						

- Then click the **Execute Search** button or press <Enter> to initiate the search.
- The search results will display the SP record in the data window.

Press F12 to Switch Queries

Search for ALL Persons given TB Antigens or with a TB and/or VOC Appointment. Count: 4

Participant Seg	Serial	Number	Family	Last Name	First Name	Middle Name	SP ID	Session Id	Appt Status	Appt Type
1	6	1		MARVIS	Starven		123456	09/25/1999 - Home All Day	Scheduled	TB
1	1	1		MARVIS	Carven		123456	07/22/1999 - Morning	Examined	Primary
7	1	1		BELL	Maw		123456	08/14/1999 - FO-Early Ever	Examined	TB
10	1	1		BELL	Ringmi		123456	08/03/1999 - FO-Late Ever	Scheduled	TB

- Note the results display all occurrences of matching Last Names in alphabetical order.
- You can also sort and filter this screen.

### Scheduling Appointments from Search Results

After locating single or multiple SPs from a search, you can schedule and reschedule individually selected SPs or several selected SPs as a group. An SP(s) with an existing scheduled appointment will be rescheduled.

#### To Schedule or Reschedule SPs from Search:

- Click on the SP record to select one record
- Or,
- Using <Shift>+click or <Ctrl>+click techniques select multiple records (up to 15 records).
  - While holding down the left mouse button on the last clicked record, **drag** the selection to the session for scheduling or rescheduling the SP(s) selected, then release the mouse button.
  - Confirm the action in the dialog box.
  - In a moment, the *Appointment Detail* pane displays.

Calendar for FO and Home Appointments, Starven

Date	Day	Type	Status	Participant Seg	Serial	Number	Family	Per	Dist
		FO-Late Morning	Avail						
		FO-Early Afternoon	Avail						
		FO-Late Afternoon	Avail	1	6	1	20	MA	
		FO-Early Evening	Avail	7	13	1	2	BE	
		FO-Late Evening	Avail	10	9	1	3	BE	
		Home All Day	Avail						
08/04	Wed	FO-Early Morning	Available						

Update both the **Type** and **Scheduled by** data fields. See *Appointment Detail Screen*.

## Current Session Appointments Status (Check-in Window)



F9

The *Current Session Appointment Status* monitors the arrival of scheduled SPs to their MEC appointment. Monitoring SP arrivals in the **Exam Status** column allows the FO staff to determine if any SPs missed their appointment. They can then contact the SPs to resolve any problems or take other appropriate actions.

When logged on AM as a TB reader, you can use the check-in monitor window ( button) to see the status of all SPs coming back to the MEC, including TB, VOC, and TB/VOC appointments. You need to make sure that they are displaying the **MEC** calendar when you attempt to open the check-in window.



The screenshot shows a window titled "Current Session" with the subtitle "Current Session / Appointments: 01:57 PM". Below the subtitle, it displays the date and time: "12/14/1999 Morning 08:30 AM - 12:30 PM". The main content is a table with the following columns: Sp Id, Name, Exam Status, Appt Type, Arrival Time, and Hold. The table contains several rows of data, including one row with "checked out" status and another with "being examin" status.

Sp Id	Name	Exam Status	Appt Type	Arrival Time	Hold
		checked out	2nd Dietary	09:30 AM	No
		being examin	Primary	08:30 AM	No
		being examin	Primary	08:30 AM	No
		checked out	2nd Dietary	08:30 AM	No

If you are on the FO or HOME calendar when you click the button, you will receive a message indicating that there is no "In Process" session.

You can leave this window open and it will refresh itself every minute. It also includes the "Arrival Time" so you will need to make sure that you don't start calling the SP until they have passed their designated arrival time. Some SPs will be told to arrive at some point later in the session.

## Session Status Changes



Selecting Session Status Changes displays the Calendar with all sessions for the MEC, Field Office, and Home Office.

### To Change a Session Status:

- Select *Admin / Session Status Changes* from the menu bar, click the **Session Status Changes** button , or press **F5**.

- Locate the session for editing.
- Click in the **Status** column of the session row.
- Select the new status from the drop-down list.
- Making a Status selection will close the drop-down list.
- To cancel, press **F5** or click the **Session Status Changes** button again.



## Edit Session Comment



F6

Session comments are used to record notes for a selected session, and are read by both the MEC and Home Office.

### To Add and Edit a Session Comment:

- Select a session for comment.

*Either:*

- Right-click to display the mouse menu.
- Select **Edit Session Comment**.

*Or,*

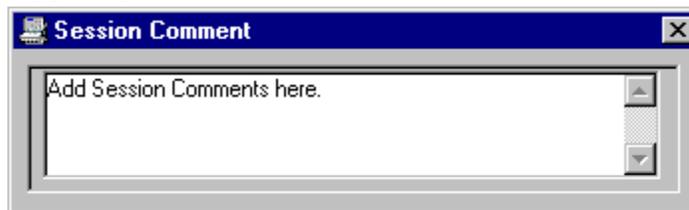
- Select *Admin / Edit Session Comment* from the main menu.

*Or,*

- Press **F6**.

*Then,*

- Type in your comments.



- Press **F6** or click the **Edit Session Comment** button again to close the window.
- Confirm changes when queried.

## Stand Calendar View

The Stand Calendar is established automatically when the Session Schedule and Sessions are created in the Advance Arrangements program. The Stand Calendar

displays the scheduled sessions in a familiar block-calendar style. Morning, afternoon, and evening session statuses are color-coded as indicated in the Session Status legend.

Appointment Manager - [Calendar for MEC Appointments, Stand ID: 700]

Calendar for MEC Appointments, Stand ID: 700

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				3/4/99	3/5/99	3/6/99
				Stand Start Date	Stand Interview Start	MEC Dryrun Date
				Morning 08:45	Morning 08:30	Morning 08:30
				Afternoon 13:30	Afternoon 13:30	Afternoon 13:30
				Evening 17:30	Evening 17:30	Evening 17:30
3/7/99	3/8/99	3/9/99	3/10/99	3/11/99	3/12/99	3/13/99
-	Stand exam start date	-	-	-	-	-
Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30
Afternoon 13:30	Afternoon 13:30	Afternoon 13:30	Afternoon 13:45	Afternoon 13:30	Afternoon 13:30	Afternoon 13:30
Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30
3/14/99	3/15/99	3/16/99	3/17/99	3/18/99	3/19/99	3/20/99
-	-	-	-	-	-	-
Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30	Morning 08:30
Afternoon 13:30	Afternoon 13:30	Afternoon 13:30	Afternoon 13:30	Afternoon 01:22	Afternoon 20:30	Afternoon 13:30
Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30	Evening 17:30

Session Status Legend

Session Status

Available:  Complete:  In Process:  Unavailable:

Booked:  Cancelled:  Interrupted:

Number of Selected Sessions: 0

Button Bar

Edit Status Clear Selected Edit Time Print Close

Row: 0 Definition: Detail data on sample person for selected appointment

#### **To Open the Stand Calendar View:**

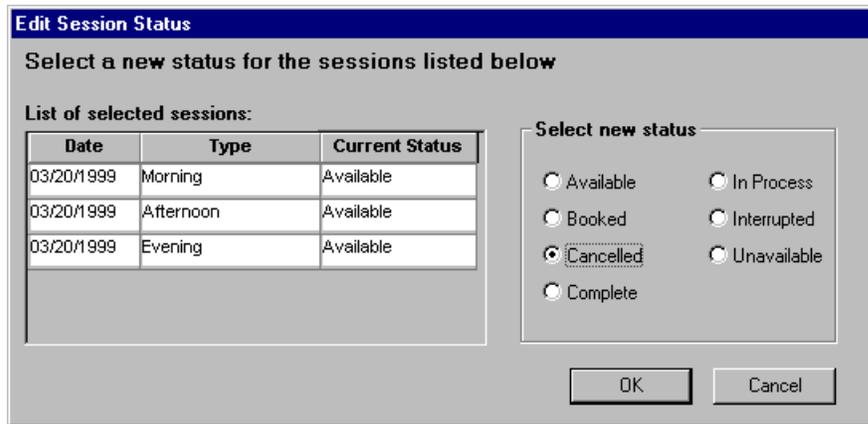
- Select *File / View / Stand Calendar View* from the menu bar

Or,

- Press **Ctrl+Alt+S** key combination.

#### **To Edit a Session's Status:**

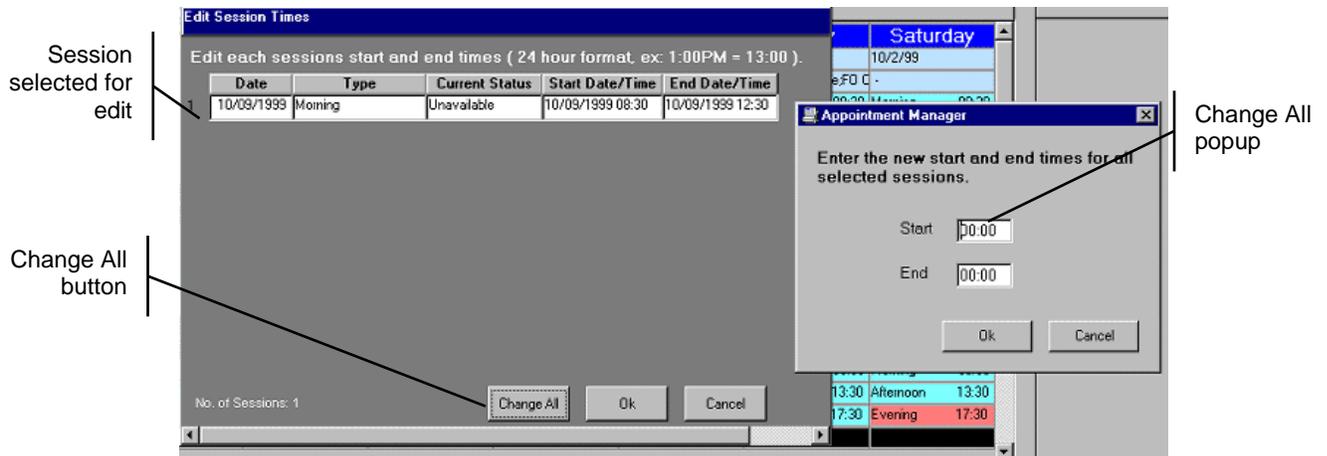
- In the *Stand Calendar View*, locate and select the desired session or multiple sessions if all selected sessions will be assigned the same status.
- Click on a session to select the session. Selected session cells will turn yellow. Clicking on a selected session will deselect the session, returning the session cell color to white.
- Click the **Edit Status** button.
- The *Edit Session Status* window appears and displays all selected sessions.



- Select a new status and click **OK**.
- A confirmation window appears to notify you of the total number of sessions affected.

**To Edit a Session's Time:**

- In the *Stand Calendar View*, locate and select the desired session or *multiple* sessions if all selected sessions will be assigned the same period.
  - Click **Edit Time** button.
  - Edit the Start Date/Time and/or End Date/Time directly in the date/time field(s)
- Or*
- Click the **Change All** button to edit both start and end times in a popup window.
  - Times are entered using the 24-hour clock system.
  - Click **OK** in both windows.



## Call Log

The Call Log maintains contact records with scheduled SPs for several types of appointment related calls or personal contact. Each contact record in the Call Log is maintained and listed by the type of call: **TB, Dietary, Validation, Appointment Reminder, and Other.**

**TB Type** calls display time-sensitive information regarding the date/time the TB antigen was administered, and the date/time period the results must be read.

**Dietary** contacts are conducted for follow-up telephone or in person dietary interviewing.

**Validation** contacts are conducted as a quality control measure to ensure scheduled or assigned interviews were conducted in accordance with established protocols.

**Appointment Reminders** are contacts with SPs to remind them of scheduled appointments for MEC examinations. SPs with a history of missing appointments are key candidates for this type of call.

**Other** SP contacts are recorded for reasons not addressed in the above contact types.

To open the Call Log, select *File / Call Log* from the Appointment Manager menu bar.

The screenshot shows the 'Field Office Call Log' application window. On the left, several call log records are listed in a table. The selected record is for SP ID 464097, DIANE KOHL. Below this, a 'Contact Details' pane shows a log of three telephone calls made by employee 1002: Hogan, Jacquie on 02/10/1999 at 14:37. The results of these calls are 'Did Not Leave Message', 'Did Not Leave Message', and 'Completed Assignment'.

SP ID	Name and Participant Number	Call Type	Final Result
801370	Brian Participant# 805-05-0001-11-01	TB Call	
624402	Camilla Denise Thornton Participant# 806-02-0008-01-01	TB Call	
673566	Tim Coleman Participant# 807-04-0008-08-01	TB Call	Complete
464097	DIANE KOHL Participant# 400-01-0006-02-01	TB Call	

#	Employee	Call Date and Time	Contact Type	Contact Result	Comment Text
1	1002: Hogan, Jacquie	02/10/1999 14:37	Telephone	Did Not Leave Message	
2	1002: Hogan, Jacquie	02/10/1999 14:37	Telephone	Did Not Leave Message	
3	1002: Hogan, Jacquie	02/10/1999 14:37	Telephone	Completed Assignment	

The **Call Log Type** drop-down list displays the type of contact calls made for the selected type of call. TB Calls display contacts made for TB, while Dietary contacts, when

selected, display Dietary related calls, etc. Contacts selected under the Call Log type are displayed in the Master Record pane.

The **Add and Delete Record** buttons are used to Add or Delete Master or Detail Records on the Call Log.

The **TB Antigen Key Information** pane shows the date/time the TB antigen was administered, and the 46 to 76 hour window the results must be read.

The **Master Record** pane displays SPs previously contacted under the selected Call Log type. This pane shows the *SP ID*, *Name* and *Participant Number*, *Call Type* (as shown in the Call Log Type drop-down window) and *Final Result*. The Final Result field is completed when the action is complete or no further contact is required or possible.

The **Contact Details** pane lists previous contacts with the SP selected in the Master pane. When a new contact record is added, the *Employee* and *Call Date and Time* fields are automatically filled in. The *Contact Type*, *Contact Result*, and optional *Comment Text* are completed when the contact is attempted or completed.

#### **To Add a New Master Record Call Log:**

- Select **Call Log Type** (*TB Call*, *Dietary*, *Validation*, *Appt Reminder*, or *Other*)
- Verify that an existing record for the SP is not recorded by scanning the *Master Record* pane.
- Click the **Add Record** button.
- A blank SP contact entry is added to the *Master Record* pane.
- Click on the **SP ID** drop-down list and select the **SP ID**. This list shows all SPs in the stand.
- The SP *Master Record* information is automatically completed, except for the **Final Result** field.
- Click the *Detail Record* pane. You must click on this pane first to have the computer focus on the pane for adding a Detail record.
- Click the **Add Record** button.
- A *Contact Detail* record is added to the pane with Employee and Call Date and Time automatically filled in.
- Click on and select the **Contact Type** from the drop-down list (*Telephone* or *In Person*).
- After the contact is made or attempted, click on and select the appropriate **Contact Result** from the drop-down list:
- Left Message, Did Not Leave Message, No Contact, Completed Assignment (*Scheduled*), *SP Refused*, *Other* (Specify).
- Enter **Comment Text**, if appropriate, by clicking on the *Comment Text* field and typing any comments.

In the **Master Record** pane, indicate the **Final Result** from the drop-down list if the contact action(s) is completed or terminated (*Complete (Scheduled)*, *SP Refused*, or *Unable to Contact*).

**To Add a New Call to Existing Master Record:**

- Select **Call Log Type** (*TB Call, Dietary, Validation, Appt Reminder, or Other*).
- Select the **SP ID** record in the *Master Record* pane.
- Click on the *Detail Record* pane. You must click on this pane first to have the computer focus on the pane for adding a Detail record.
- Click the **Add Record** button.
- Employee and date/time information is automatically filled-in.
- Indicate **Contact Type** from the drop-down list (*Telephone or In Person*).
- Indicate **Contact Result** from the drop-down list (*Left Message, Did Not Leave Message, No Contact, Completed Assignment (Scheduled), SP Refused, or Other (Specify)*).
- Enter **Comment Text** if appropriate.
- In the *Master Record* pane, indicate the **Final Result** from the drop-down list if the contact action is completed or terminated (*Complete (Scheduled)*, *SP Refused*, or *Unable to Contact*).

**To Delete a Master Call Log or Detail Record:**

- Locate and select the Call Log or Detail Record for deletion.
- Selecting the SP Master Record will display all previous calls in the Contact Detail pane.
- Deleting a *Master Record* removes *all Detail Records*.
- Deleting a *Detail Record* removes only the selected Detail Record.
- Select either the Master Record or a Contact Detail record.
- Click the **Delete Record** button.
- Confirm deletion action when prompted.

## Reports

Reports are automatically displayed in the **Print Preview** mode. All Reports can be printed, sorted, filtered, and zoom applied for each displayed report. You can change the view of some reports to display All, MEC, or Field Office records under the *View* menu bar option of the report window.

## TB Appt Schedule with Time Constraints

**TB Appointment Schedule with Time Constraints** generates the TB Reading Appointment Schedule and displays detailed TB appointment information for each SP. The report shows an *Earliest* and *Latest* possible TB reading dates for the selected session.

Appointment Schedule - TB and TB / VOC Appointments with TB Reading Time Constraints										
Stand #:		Stand Name:								
From:										
Page 1 of 9		Sorted by Session Date/Time and Participant Number								
Participant No.	Arrival Time	Name	SP ID	Age	Gender	Language	Date/Time Antigens Given	Earliest Possible TB Reading	Latest Possible TB Reading	App Type
Session: -- FD - Late Morning: (10:00 AM - 12:00 PM) -- Session ID - Session Comments: None										
	10:00 AM				Female	English	10:07 AM	08:07 AM	02:07 PM	TB
<u>Appointment Comment</u> confirmed			Child /Adult Care : No		<u>Transportation</u> To Appointment: Taxi					
<u>Address</u>										
<u>Phone</u>										
	10:00 AM				Female	English	09:54 AM	07:54 AM	01:54 PM	TB
<u>Appointment Comment</u> confirmed			Child /Adult Care : No		<u>Transportation</u> To Appointment: Taxi					
<u>Address</u>										
<u>Phone</u>										

Additional Appointment Schedule information is not shown on the right side of this report.

## Appt Schedule

**Appointment Schedule** generates a MEC Appointment Schedule and displays all key SP appointment information for the selected session.

Appointment Schedule - MEC Appointments										
Stand #:		Stand Name:								
From:										
Page 1 of 1		Sorted by Session Date/Time and Participant Number							0	
Participant No.	Arrival Time	Name	SP ID	Age	Gender	Fasting Incentive	Language	Interviewer	Appointment Type	
Session: -- Afternoon: (1:30 PM - 5:30 PM) -- Session ID -										
Session Comments: None										
	01:30 PM					\$125 - Yes				Primary
			Child /Adult Care : No			<u>Transportation</u> To Appointment: Taxi From Appointment: Taxi		<u>Consents</u> Yes - MEC Consent/Assent Signed By SP? No - Future Research Consent Signed By SP or REF? No - Future Research Box Checked By SP? No - Genetic Research Box Checked By SP?		
	01:30 PM									2nd Exam
			Child /Adult Care : No			<u>Transportation</u> To and From Appt: Self		<u>Consents</u> Yes - MEC Consent/Assent Signed By SP? Yes - Future Research Consent Signed By SP or REF? No - Future Research Box Checked By SP? No - Genetic Research Box Checked By SP?		
Afternoon Session Total: 2										
Total Number of MEC Appointments on : 2										

Additional Appointment Schedule information is not shown on the right side of this report.

## SP's Needing TB Appt

Generates a list of SPs given a TB antigen during the MEC examination and needs a scheduled TB appointment.

SPs Needing TB Appointment								
Stand #:		Stand Name:						
Click on Column Header to Sort by Desired Column								
Page 1 of 1								
Participant No.	Name	SP ID	Age	Gender	Phone Number	Language	Date/Time Antigens Given	E T
			54	Female	( )	-	11/18/1999 11:11 AM	17
			34	Female		English	08/08/1999 02:34 PM	08
Count: 2								
NHANES - Report #70								

Additional Appointment Schedule information is not shown on the right side of this report.

## Sort a Report

The Sort command allows you to re-sort a selected list, most panes, and reports based on the name of the displayed column headings.

### To Sort a Report:

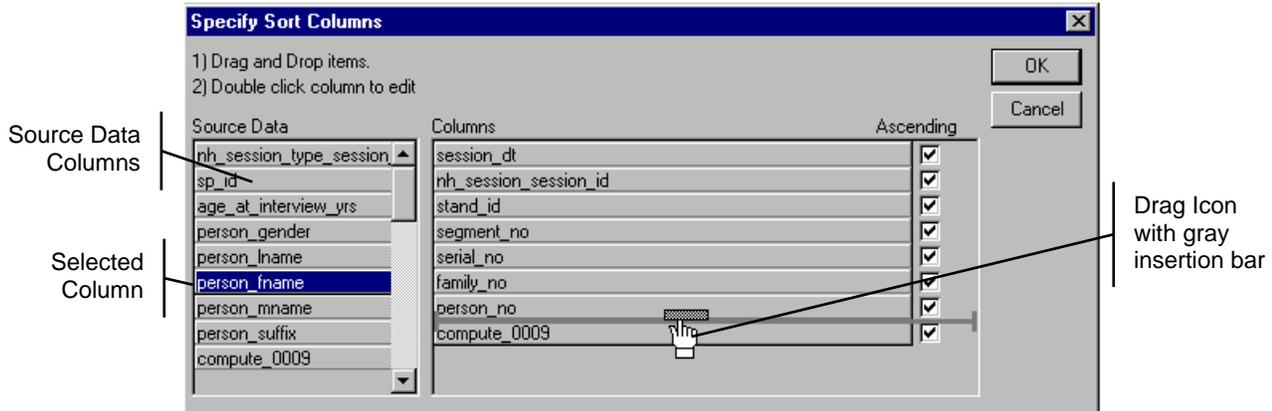
- With the list you wish to re-sort displayed,
- Select *View / Sort* from the menu bar.
- The Specify Sort Columns dialog box appears.
- The example below illustrates the sorting of the Appointment Schedule Report.

### Appointment Schedule - MEC Appointments

Stand #:123 Stand Name: Anywhere US

From 7/5/1999 To 7/5/1999

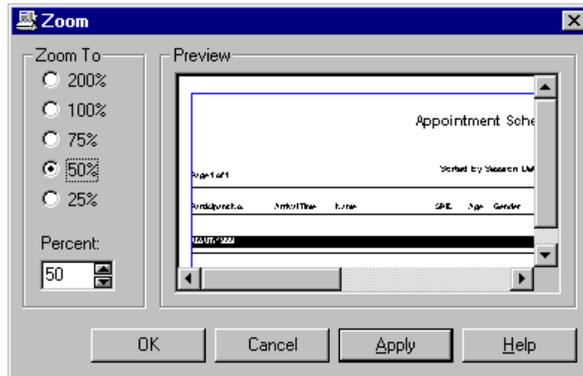
Sorted by Session Date/Time and Participant Number



- Note that the report header shows the default columns sorted by Session Date/Time and Participant Number. The actual column names used to sort the report include additional columns not specified in the report header. Most column names used in the various lists and reports can be easily deciphered. Others are more cryptic and may require assistance.
- Click on and drag a column heading from the **Source Data** window on the left into the **Columns** window on the right. Position the drag icon with the gray insertion bar where you want the new column placed.
- Release the mouse button when you have the insertion bar in place.
- Continue to drag other headings to refine the sort. Each additional column heading will sort after the column heading above it.
- Check or uncheck the Ascending checkbox. A checked **Ascending** box will sort A – Z, while an unchecked box will sort Z-A.
- Click **OK** to execute the new sort based on your new column headings and column order.
- *The sort will remain in effect until modified or the AM program is rebooted.*

## Zoom

The Zoom function allows you to increase or decrease the size of the print previewed report. You can select the percentage of resizing by preset radio button, or use the spin box located under the title “Percent” to fine-tune.

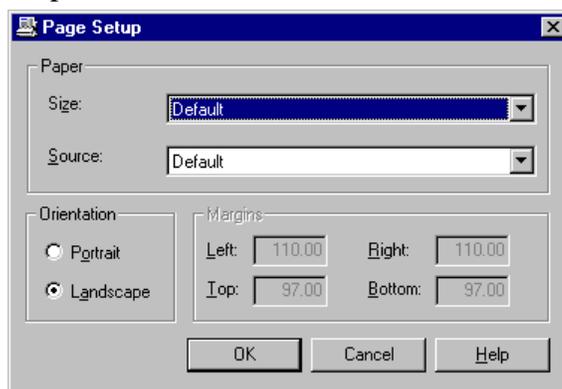


Click **Apply** to apply the resizing selected without closing the window. Click **OK** to accept the resizing and close the window. Click **Cancel** to close the window without resizing.

Resizing the previewed report also resizes the printed version.

## Page Setup

The Page Setup menu option displays the Page Setup dialog box where you can specify the paper size and source and orientation. Changing the paper size in this dialog box does not add the appropriate size paper to the printer. You must do this before sending the print command.



The Page Setup establishes the default printing settings, and is the only method available to change printer settings before printing. The Print and Print Immediate is essentially the same command in the AM program; neither display the Print dialog box before sending the print object to the printer specified in the Page Setup.

## Printing a Report

Open reports, and windows or panes with focus can be printed by:

- Selecting *File / Print* from the menu bar,

*Or,*

- Clicking on the **Print** toolbar button .

## **6. PROTOCOL FOR MEASUREMENT OF SKIN REACTIONS**

### **6.1 Overview**

Perform measurement of the skin reactions to the PPD antigens between 46 and 76 hours after the antigens were placed. Conduct SPs measurements in the field office (FO), the MEC phlebotomy room, and in the SP's homes and offices. At least one reader should read both skin test reactions for each SP. Two to three readers may read SP's reactions for Quality Assurance (QA) purposes. Generally when two or three readers measure the same reactions, they perform blinded independent duplicate readings (BIDRs), in which the readers neither consult nor observe one another's readings. When a BIDR is performed, record results independently. Results may be discussed after both readers have recorded their results, but results cannot be changed. Readers may also perform consultative readings, in which more than one reader reads but the process and results are discussed. In a consultative reading, both readers agree on the definitive result and record this one result. Supervised readings may also take place, in which one or more readers read and the process and results are observed and discussed with a gold standard reader (GSR). Discussion and coaching may take place during the reading but only one result is recorded. Chapter 7 describes specific quality assurance requirements.

One or both of the two primary field readers (PFRs) conduct most measurements in the field office. The PFRs are also responsible for traveling to SP's homes and offices to measure the skin test reactions of SPs who cannot or will not return to the MEC or field office. The field office supervisors are trained to measure skin reactions and act as back-up field readers (BFR) to the PFR. The field office supervisors measure skin reactions only in the field office and perform skin test readings alone only if neither of the PFRs is available. The phlebotomist acts as the Primary MEC Reader (PMR), measuring skin test reactions in the MEC. The Back-up MEC Reader (BMR) reads in the MEC when the PMR is unavailable. GSR are designated by the Centers for Disease Control and Prevention, Division of TB Elimination, and visit NHANES sites for quality assurance purposes.

Enter TB reading measurements directly into ISIS at the time of the reading. ISIS generates a Report of Findings (ROF) for the reading measurement. The ROF lists separate "positive" or "negative" results for PPD-S1 and PPD-B antigens. Print and give the ROF to the SP at the time of the reading. Enter measurements into the notebook PC when conducting readings in SP homes and other locations away

from the field office or MEC. Findings are listed on the screen. The PFR completes a hard-copy report and gives the report to the SP.

The possibility that a SP was infected with TB at some time during the past will be determined by the size of the tuberculin test (PPD-S1) measurement. The reader does not know which forearm received the tuberculin test and which forearm received the test for nontuberculous mycobacteria, but records the measurement for both forearms into ISIS. Never discuss findings while measuring and recording results. If the SP asks for findings before readings are completed, explain that no results can be discussed until the computer-generated ROF reveals which forearm received which test. ISIS matches each reading measurement to the antigen assigned to that arm and generates the ROF accordingly. Referrals for further evaluation are based on the measurement of the skin reaction to the tuberculin skin test, PPD-S1. Inform SPs whose reaction to PPD-S1 is above the minimum cut-off size that they may have been infected with TB in the past. Because PPD-S1 is a research and survey antigen not licensed for clinical use in the United States and clinical evaluation is needed to interpret a skin test, instruct these SPs to see their regular source of medical care or the local TB control program at the health department for clinical evaluation. The ROF for a SP who may be infected with TB includes referral information providing a contact address, telephone number, and directions to the local health department TB control program.

## **6.2 Equipment and Supplies**

The equipment and supplies required to measure skin reactions are listed below:

- Ruler, small (6”), flexible, clear plastic with millimeter increments
- Black marking eyeliner pencil
- Incandescent goose-neck lamp (MEC and FO)
- Portable, rechargeable lamp (for SPs’ homes and offices)
- Baby oil and dispenser or eye-make-up remover and dispenser or oil free make-up remover pads
- 2 x 2 gauze pads
- Report of Findings (ROF) forms (for SPs’ homes and offices)

## **6.3 Procedures for Measurement of Skin Reaction**

### **6.3.1 Overview**

Careful accurate measurement of the reactions to PPD tests is important because it is used to estimate TB infection in the U.S. population. Procedures assure the accurate measurement and recording of results, the referral of SPs who may be infected with TB, and the recording of adverse reactions.

The reader makes sure that the area for reading is suitable and that equipment and supplies are at hand before the reading begins. The readers introduce themselves and explain that the skin test measurement consists of examining each arm to locate, mark, and measure any reaction. Inform the SP that the results are recorded in the computer and that the computer generates a report of the results after the examination. Assure the SP that the results will be explained at that time, but not before. Comfortably position the reader and the SP in a well-lit area with arm support.

Verify the identity of the SP before beginning the examination of the arms. Some SPs may bring their bar coded MEC SP ID bracelet. All SPs were given an appointment reminder when they exited the MEC. This document lists the SP's age and gender. Use this information to help confirm the identity of the SP. Most SPs over the age of 16 carry a driver's license or other form of identification. If in doubt about the SP's identify, ask to see some form of identification. Most children under 16 years of age do not have any form of identification. TB readers must rely on the person escorting the SP to the reading site to correctly identify younger SPs. Confirm the SPs identify and verify that the information contained on the ISIS results screen is identical.

Begin the examination with the right arm (or with the upper arm if two antigens were injected on the same arm.) Use visual examination only to locate the site at which the antigen was injected. After locating the site, rely on palpation (touch) with the fingertips to discover whether there is induration (a hard dense raised reaction) at the site. Keep fingernails sufficiently short so that they do not protrude beyond the finger in order to palpate properly. (Figure 6-1).

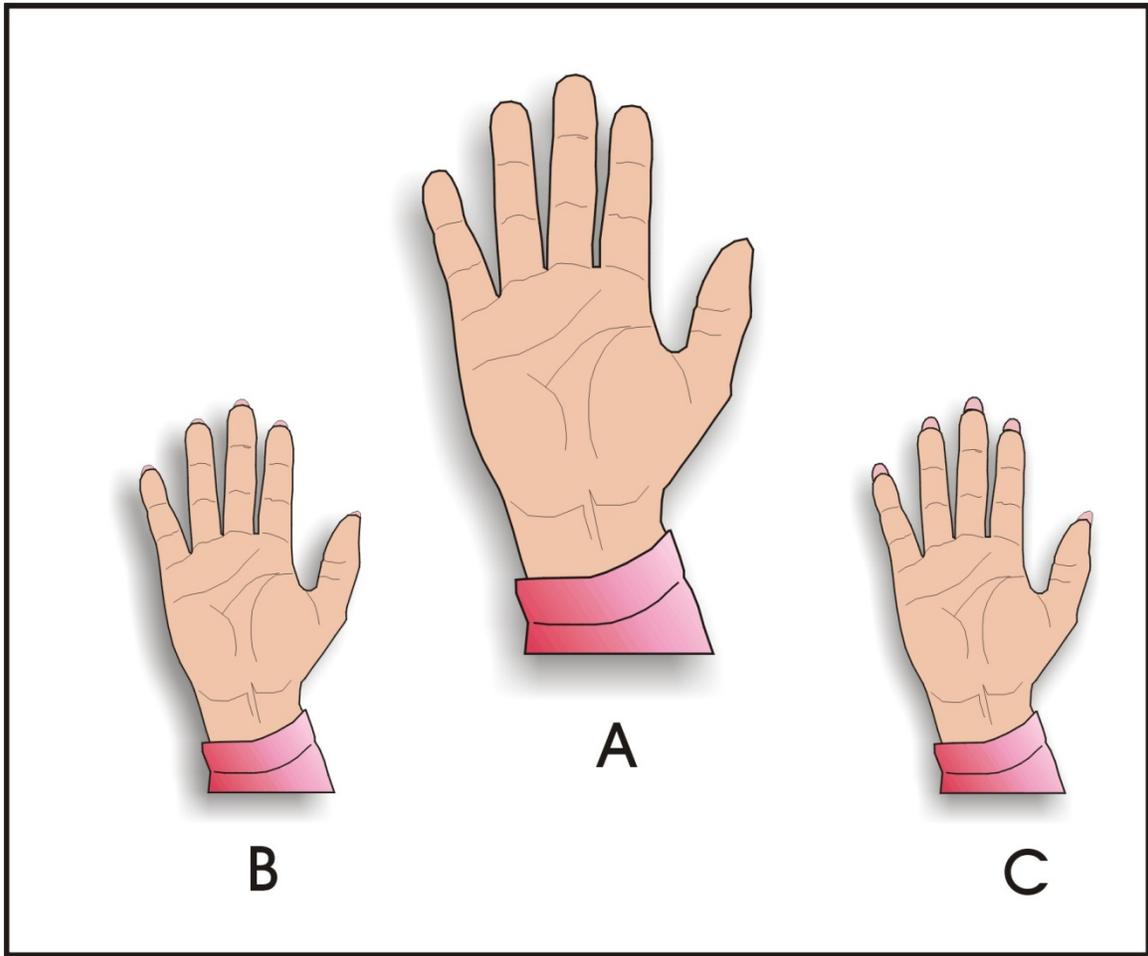


Figure 6-1. Correct and Incorrect Fingernail Length for Palpation Method

(A) Maintain fingernails sufficiently short so that they do not protrude beyond the fingertip in order to palpate properly. (B) Nails should not be visible above the tips of the fingers. (C) Nails should not be long and sharp.

Reactions to the PPD tests at the injection site range from no induration to a large well-circumscribed hard density in the skin. Only measure induration; if no induration is present, do not measure. Never measure redness (also called erythema) and soft swelling. If induration is present, further palpate to locate the margins of induration transverse to the long axis of the forearm.

Use the light palpation method to locate margins of induration. Touch the area lightly with the pads of the fingertips with fingers together, using a light gentle motion (Figure 6-2). It is important to avoid short quick jabs, pressure, or friction, all of which may make the reaction area more difficult to examine.

When palpating for margins, take care not to confuse a margin of induration with a margin of muscle on the forearm. If there is no hard density, record a 0 (zero) result even if other skin changes such as redness or soft swelling are noted. If one margin of induration is definitely palpable, it is necessary to mark the margins on either side of the induration, even if the margin is not equally clear all the way around the area of hard denseness (Figure 6-3). Even if the area of induration is small, mark the margins and measure the small area of hard density transverse to the long axis of the arm. Lightly mark each of the two sides of the induration with a dot (Figure 6-4). If the margins of induration are irregular, mark and measure the largest diameter transverse to the long axis of the arm (Figures 6-6).

Repeat the process for the second measurement on the left arm (or, if both injections were performed on one arm, then repeat the process on the lower arm). Document adverse reactions (either or both arms), on the adverse reaction form and email immediately to Dr. Kathryn Porter. (See Section 6.5.)

If performing BIDRs, complete recording and remove marks from the arms before the additional reader enters the area for their reading. Previous readers should not remain in the reading area during a BIDR.

During consultative reading, more than one reader reads the arm before recording a reading. Discuss the result until there is agreement. Record only one agreed reading and do not use the QA screen. If a supervised reading takes place in which coaching is carried out by a GSR during the reading, then record only one reading. The GSR does not use the QC screen for a supervised reading.

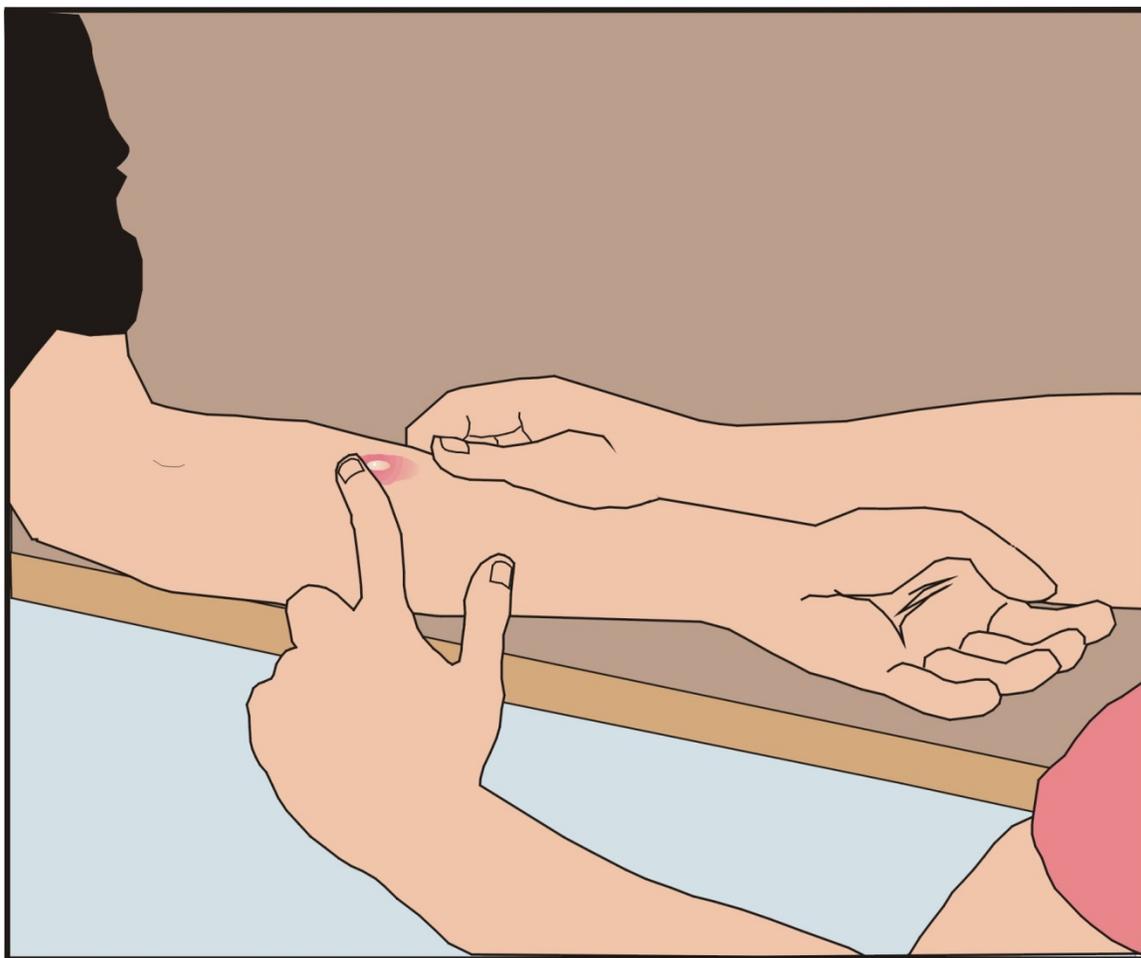


Figure 6-2. Palpating to Find the Borders of the Induration

Palpate to find the margins (borders) of induration transverse to the long axis of the forearm. With the SP's forearm bent 90° at the elbow, supported on a hard surface, lightly sweep the fingertips over the volar surface of the forearm, and outline the margins of induration.

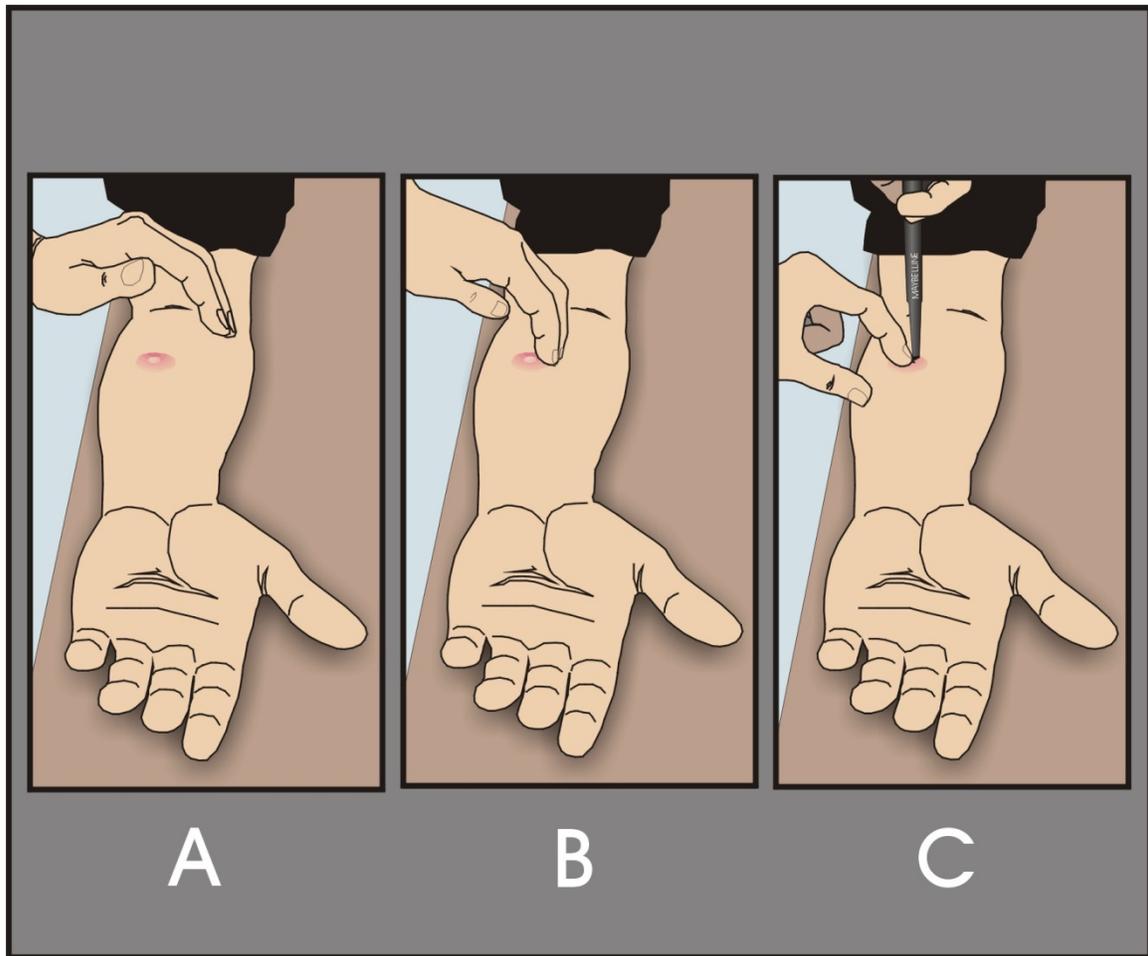


Figure 6-3. Marking the Margin Points at Either Side of the Widest Area of Induration Transverse to the Long Axis of the Forearm

(A) Hold palm over the injection site with fingertips at the outer edge of the arm. (B) Without lifting, move the fingertip from the outer edge of the arm towards the induration. Rest the finger firmly against the induration margin border on one side before marking (fingertip remains in contact with skin at all times). (C) Mark lightly with a fine dot at the widest edge of the induration, using the fingertip as a guide. Repeat procedure to place second mark on margin of induration.

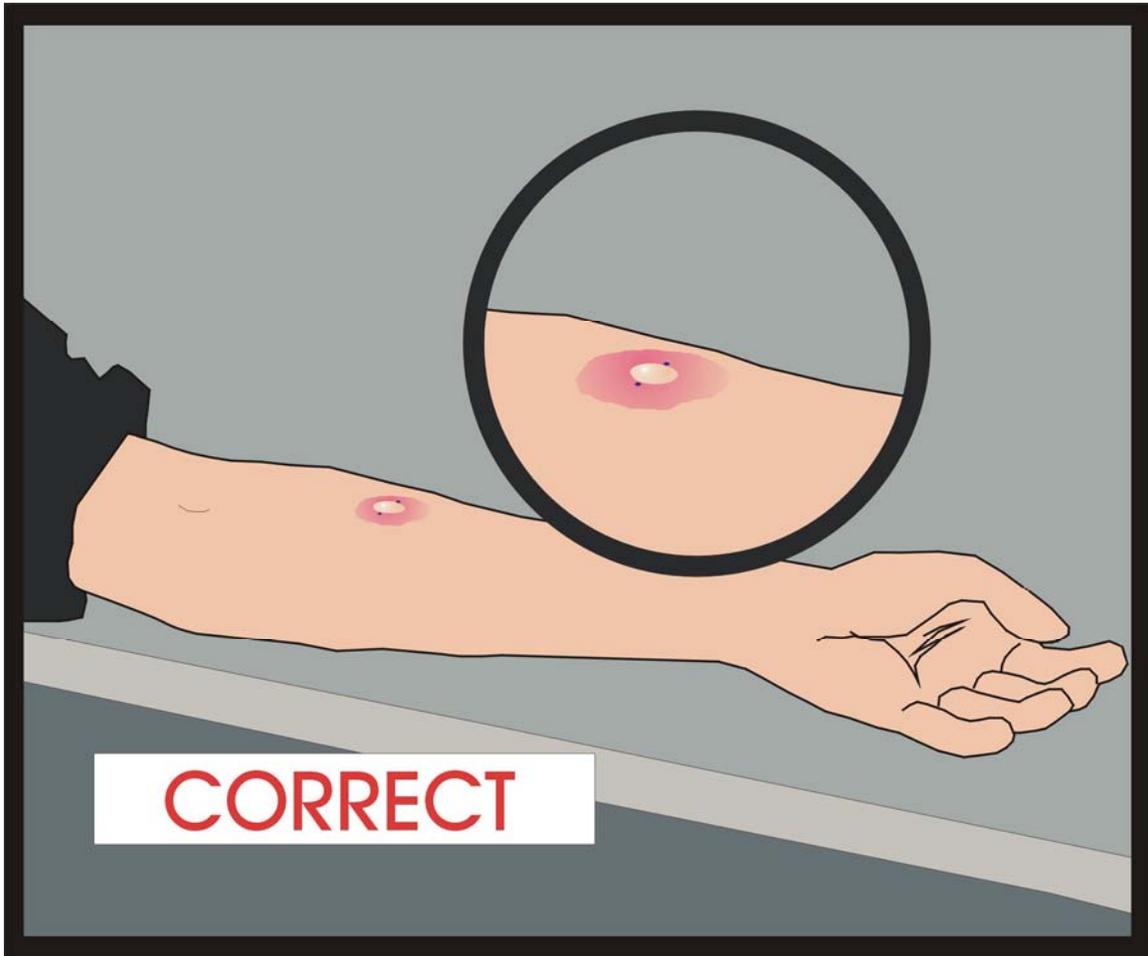


Figure 6-4. Correct Marking of the Points on the Margins of Induration

A correct marking - shows fine dot marks on two sides of the induration transverse to the long axis of the forearm.

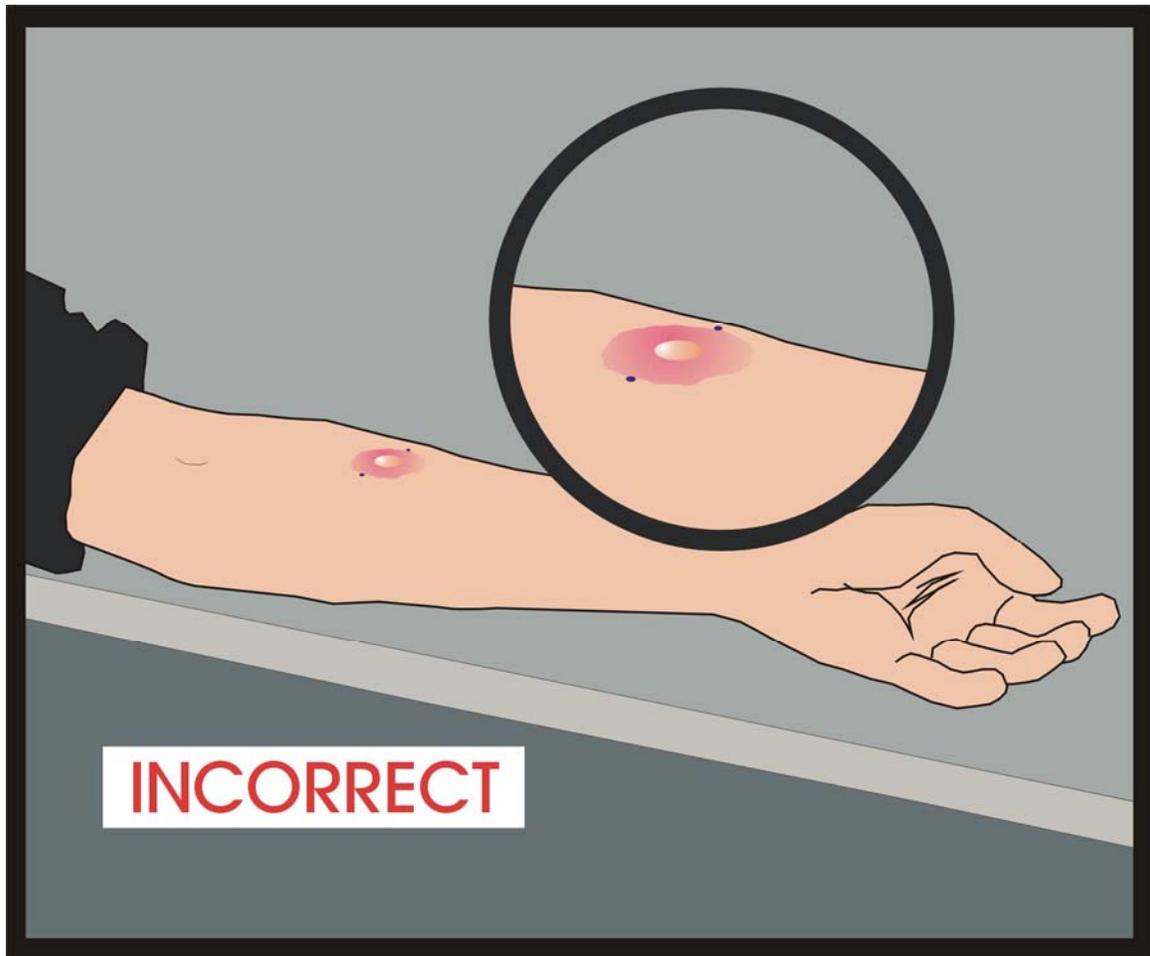


Figure 6-5. Incorrect Marking

An incorrect marking - shows fine dot marks on two sides of the redness or soft swelling transverse to the long axis of the forearm. Only mark hard density (induration). Do not mark other skin changes such as redness or soft swelling.

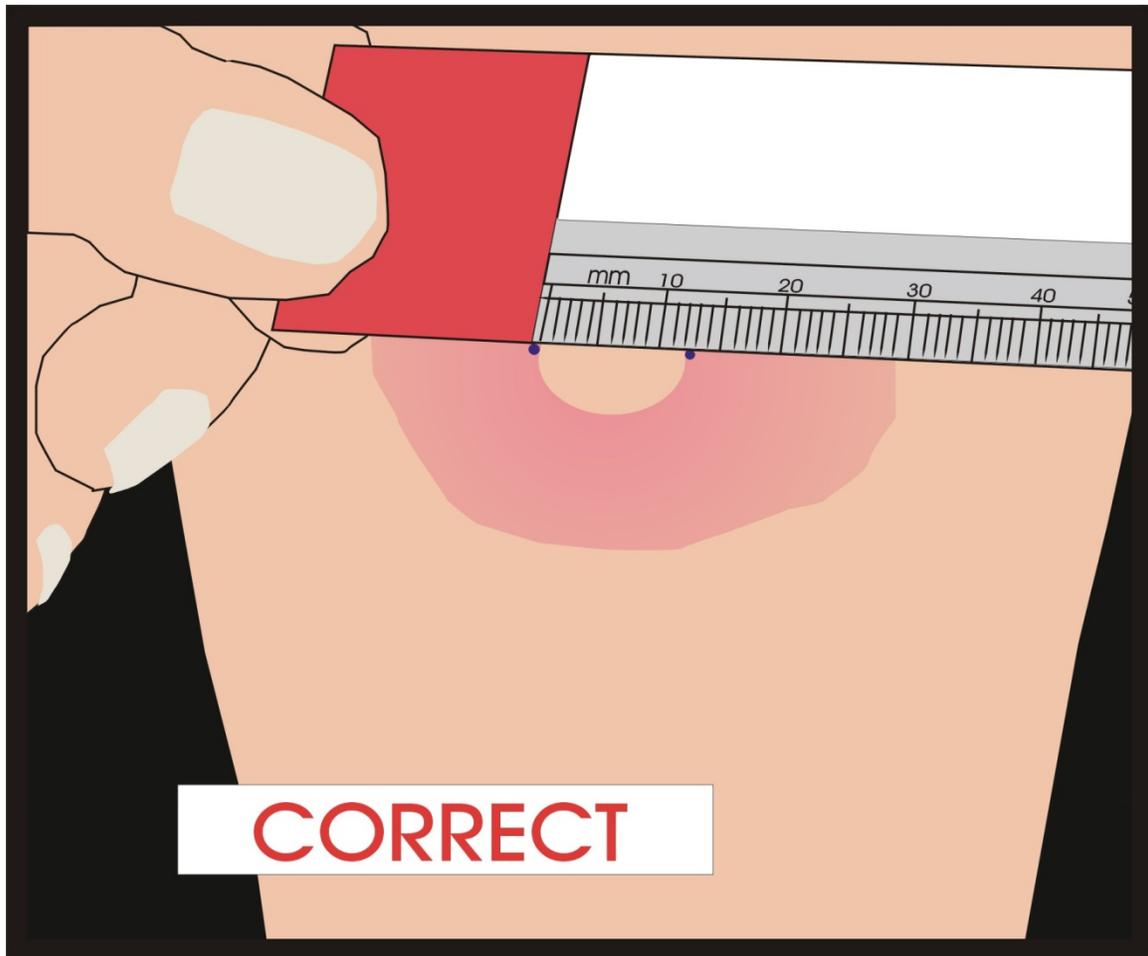


Figure 6-6. Correct Placement of the Millimeter Ruler to Measure the Points on the Margins of Induration

Correct ruler placement. Measure skin reactions with the millimeter ruler. Place the zero millimeter ruler line inside the left dot edge. Read the ruler line inside the right dot edge. If the measurement falls between two divisions on the millimeter scale, record the lower mark.

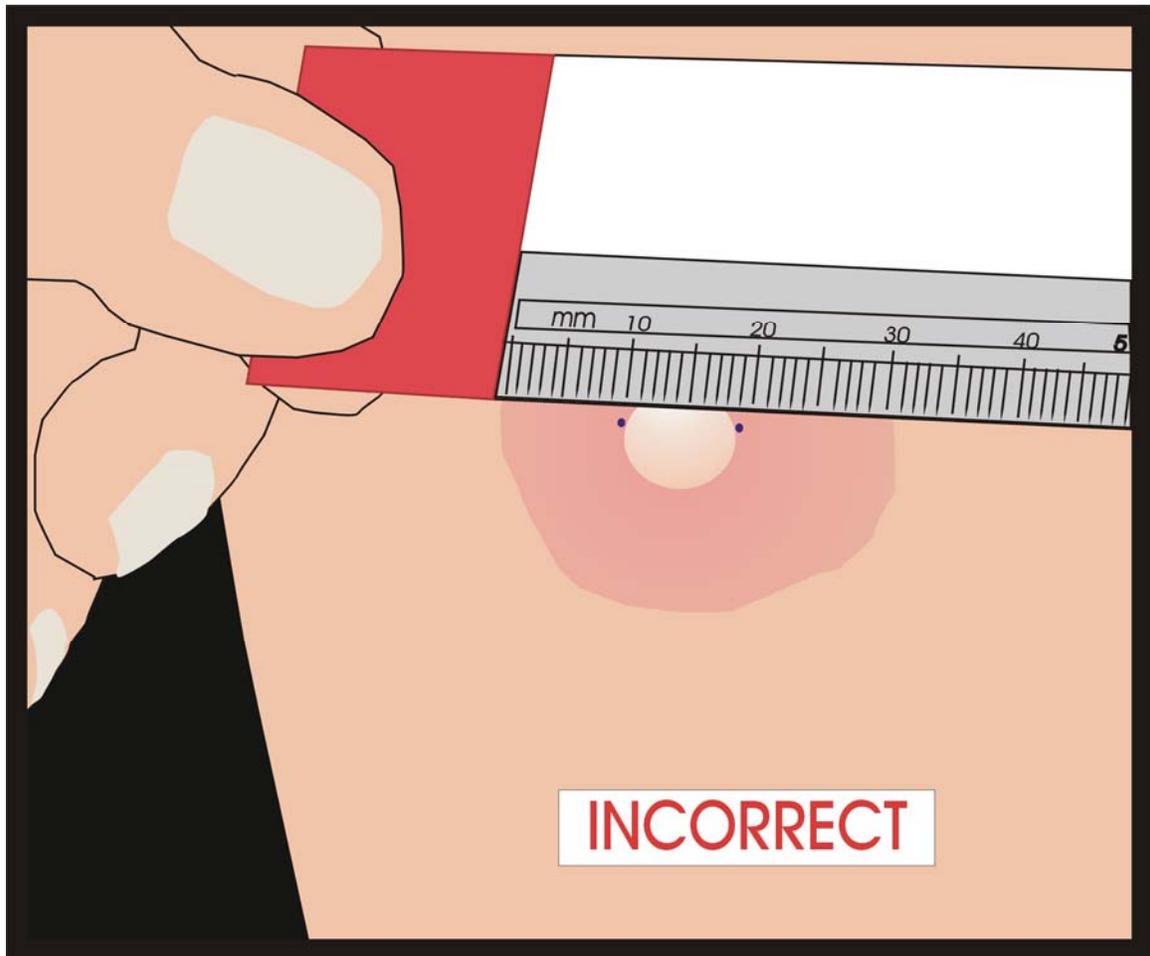


Figure 6-7. Incorrect Placement of the Millimeter Ruler to Measure the Points on the Margins of Induration

This is an incorrect ruler placement. The zero ruler line is incorrectly placed on the edge of redness instead of on the mark.

If a SP asks about their test findings during the examination of the arms, explain again that the findings must wait until the computer generates the ROF. After recording all results, the Report of Findings (ROF) prints; read the text to the SP. Answer questions using of the language in the ROF. Refer questions that cannot be answered by repeating the information printed on the ROF to Dr. Kathryn Porter.

## **6.3.2 Procedures for Measuring the Skin Reaction**

### **6.3.2.1 Preliminary**

- Keep fingernails sufficiently short so that they do not protrude beyond the finger.
- Set up the computer and supplies in a well-lighted area, turn on the lamp, and support the arm being examined.
- Sharpen marking instrument (eyeliner pencil) to make a small, fine dot so that the dot is easily removed without friction.
- Introduce yourself to the SP and briefly explain the procedure.
- Confirm the identity of the SP and match it against the information on the computer screen.
- **Read the right forearm first (or read the upper forearm first if both antigens were applied to one arm).** ISIS randomly assigned the PPD antigens. Antigens were placed on the right and left forearms of the SP as designated by ISIS, one antigen on each forearm. In rare cases in which the SP does not have both forearms available for injection of the antigens, both antigens were assigned to the one available forearm. In these cases, the two antigens are randomly assigned to the upper and lower part of the available forearm. The ISIS data entry screen indicates whether antigens were placed on both forearms (read the right forearm first, then the left) or on only one forearm (read the upper forearm first, then the lower forearm).

### **6.3.2.2 Inspect the Injection Site**

Using good light, carefully inspect the volar (palm up) surface of the forearm to locate the site of injection. Focus the palpation in this area.

### **6.3.2.3 Palpate to Find the Margins (borders) of Induration**

- Palpate with forearm bent 90° at elbow.
- Lightly sweep the fingertips over the entire volar surface of the forearm to confirm the position of the injection site.
- Lightly sweep 2" diameter from injection site (four directions) to locate any area of induration (hard raised density) and to differentiate induration from muscular soft swelling.
- Use zigzag feather-like touch over the area of induration to outline the margins of induration. If the injection site is near a muscle margin, do not confuse the muscle margin with a margin of induration. Mentally note the provisional location of the margin points at either side of the widest area of induration transverse to the long axis of the forearm (Figure 6-2).
- Repeat the palpation method with forearm bent 45° at elbow to determine effect of position on the margin points (Figure 6-2).
- Maintain the arm in the position at which the margins are most clearly palpable in order to mark them. Once more, locate the position of margin points at either side of the widest area of induration transverse to the long axis of the forearm and proceed to marking.

### **6.3.2.4 Mark the Margin Points at Either Side of the Widest Area of Induration Transverse to the Long Axis of the Forearm (Figures 6-4 and 6-5)**

- If the palpation revealed that the margin bordering one side of the induration was more definite than that on the other side, begin the marking procedure on that side.
- Hold palm over injection site with fingers transverse to the long axis of the forearm (Figure 6-3).
- Move fingertips lightly on skin toward injection site.
- Without lifting finger, pull fingertip tight against the margin bordering the area of induration on one side before marking (fingertip remains in contact with skin at all times) (Figure 6-3).
- Place single dot on skin at margin point (Figure 6-3).
- Repeat the procedure on the other side of the induration.

- If margin is indefinite on one side, follow the margin of induration around from the side on which it is more definite and place the second dot at the point across from the first dot located by this procedure.
- Inspect dots, repeat finger movement toward margins, and verify dot placement under adequate light by confirming that each dot is at the point where the fingertip meets the margin.
- Verification should confirm that dots are located where the distance between the points is the widest diameter between the margins of induration that is perpendicular to the arm length (Figure 6-4). This means that the two dots are across from one another and that an imaginary line drawn between the two dots would be at 90 degrees relative to the long axis of the forearm.
- Figures 6-4 and 6-5 show the correct and incorrect placement of dots defining the margins of induration.

#### **6.3.2.5 Measure: Placing and Measuring Skin Reactions with the Millimeter Ruler**

- Place the zero ruler line inside the left dot edge.
- Read ruler line inside right dot edge.
- If the measurement falls between two divisions on the millimeter scale, record the lower mark.
- Refer to Figures 6-6 and 6-7 for the correct and incorrect placement of the ruler for measuring hard density in the skin.

#### **6.3.2.6 Record Measurement on the ISIS Screen**

- Record right (or upper) forearm results before reading left (or lower) forearm.
- Record millimeter measurement of skin reactions correctly.
- Record measurements between 0 and 86 millimeters as measured. Record measurements greater than 86 millimeters as 87+ millimeters. No reaction >86 millimeters is expected; if such a reaction is recorded, confirm that this is correct and complete an Adverse Reaction Form and email the form to Dr. Kathryn Porter on the same day.

### **6.3.2.7 Inspect the Volar Surface of Each Forearm for Adverse Reactions**

- Note the presence or absence of other skin reactions such as vesiculation and bullae or ulceration and necrosis anywhere on the volar surface of the arm being examined. If any of these skin reactions are present anywhere on the volar surface, do not make a judgement about whether these are related to the skin test, but record their presence. If two antigens have been placed on the same forearm, record any skin reaction present on the screens for both tests—upper and lower.
- Identify and record the presence or absence of vesiculations and/or bullae correctly. Vesiculation refers to small, fluid-filled, blister-like lesions. Bullae are similar to vesiculations but they are larger.
- Identify and record the presence or absence of ulceration and/or necrosis correctly. Ulceration refers to sloughing of damaged skin or a raw, open sore. Necrosis is the death of cells because of damage or disease.

Repeat the measurements and skin reaction recordings for the second antigen. Gently remove dots from forearm after measuring using baby oil and gauze or cotton pad, or using eye makeup remover pad.

If any skin reactions are present, complete an Adverse Reaction Form while the SP is present.

Repeat steps 6.3.2.1 through 6.3.2.7 on the left or lower forearm.

### **6.4 Quality Control Measurement of Skin Reactions: (BIDRs)**

- Enter measurements and then select “Yes” to the QC question in order to obtain the blank QC screen before second reader comes into the area.
- Gently remove dots from forearm after measuring using baby oil and gauze or cotton pad, or using eye makeup remover pad before the second reader comes into the area.
- Leave the area while the QC measurement of skin reactions takes place. Do not watch the second reader because nonverbal involuntary movements or facial expressions may bias the reading of the second reader.
- The second reader follows the procedure for reading noted above. A QC question also appears at the end of the second reader’s readings. If there are no further readings, the second reader should select “No” to the QC question. If a third reader is to perform a BIDR, the second reader should select “Yes.”

#### **6.4.1 BIDR by a Third Reader**

- A third reader may also record readings. This will allow BIDR comparisons between three pairs of readers (the first and second reader, the second and third reader, and the first and third reader).
- If an additional third reading is to take place, the second reader should complete his or her readings.
- The second reader gently removes dots from forearm after measuring using baby oil and gauze or cotton pad, or using eye makeup remover pad before the third reader comes into the area.
- Leave the area while the QC measurement of skin reactions takes place. Neither the first nor the second reader should watch the third reader because nonverbal involuntary movements or facial expressions may bias the reading of the third reader.
- The third reader should follow the procedure for reading noted above. No QC question will appear after the third reader completes his or her readings. The report of findings prints.

#### **6.5 Adverse Reaction Form**

Expect a small percentage of minor adverse reactions with all TB skin tests, including those used in NHANES. These usually resolve within a few days. Record ulcerations, necrosis, vesiculations, or bullae on the ISIS computer screen. Although minor expected adverse reactions are unlikely to be a problem for the individual, report all adverse reactions quickly so that Dr. Kathryn Porter has the necessary information if a SP with such a reaction calls her with a question. Reporting is also important because an unusual number of adverse reactions may indicate that investigation of antigen formulation or administration is needed. In the past the rare adverse reactions to PPDs have generally been in the form of vesiculations or bullae. Record these reactions or any other questionable reactions possibly related to the antigen(s) on the Adverse Reaction Form (Exhibit 6-1) and email the form to Dr. Kathryn Porter on the same day. The Adverse Reaction Form is available in the Blank Forms directory in the MEC and the Shared Directory in the field office. Contact the data manager with questions about accessing, and saving the form. Telephone to Dr. Porter to let her know to expect the email. Record the SP's ID, the date and time, the nature of the reaction, and the arm or arms on which the adverse reaction was noted. Record any other adverse reaction the SP reports and believes to be associated with the skin test on the adverse reaction form. Dr. Porter may seek additional information from the SP.

# National Health and Nutrition Examination Survey

## TUBERCULOSIS (TB) SKIN TESTING ADVERSE REACTION REPORT

### SP Information

SP ID:	Age:	Gender:
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### TB Skin Test Information

Date and Time of Administration:	_ _ _ - _ _ _ - _ _ _ _ _ _ _      _ _ _ : _ _ _  <b>M M D D Y Y Y Y    H H M M</b>	<input type="checkbox"/> <b>AM</b> <input type="checkbox"/> <b>PM</b>
Date and Time of Reading:	_ _ _ - _ _ _ - _ _ _ _ _ _ _      _ _ _ : _ _ _  <b>M M D D Y Y Y Y    H H M M</b>	<input type="checkbox"/> <b>AM</b> <input type="checkbox"/> <b>PM</b>

### Test Results

Right/Upper Arm	Induration: _____mm	Vesiculation/Bullae: <input type="checkbox"/> Present <input type="checkbox"/> Absent	Ulceration/Necrosis: <input type="checkbox"/> Present <input type="checkbox"/> Absent	Antigen (if known): <input type="checkbox"/> PPD-S1 <input type="checkbox"/> PPD-Batthey
Left/Lower Arm	Induration: _____mm	Vesiculation/Bullae: <input type="checkbox"/> Present <input type="checkbox"/> Absent	Ulceration/Necrosis: <input type="checkbox"/> Present <input type="checkbox"/> Absent	Antigen (if known): <input type="checkbox"/> PPD-S1 <input type="checkbox"/> PPD-Batthey

### Report of Findings

Tuberculosis (PPD-S1) result:	<input type="checkbox"/> Positive <input type="checkbox"/> Negative
Nontuberculosis (PPD-B) result:	<input type="checkbox"/> Positive <input type="checkbox"/> Negative

### Comments or description of other adverse reactions:

### TB Reader

Name:	Tech ID:	Stand No./Location:
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**Instructions:** Print and review the Report of Findings. Complete this form and send electronically to Dr. Kathryn Porter, M.D. at kzs4@cdc.gov. Destroy (shred) the Report of Findings.



The definition of “adverse reaction” is not the same as that of “severe reaction” which makes a SP ineligible for skin testing. A SP with vesiculation, for instance, has an adverse reaction, but a history of vesiculation does not constitute a “severe” reaction that would make the SP ineligible for skin testing. Reader/placers should review the definitions of “adverse” and “severe” reactions and make sure they understand the difference. Guidance should be sought from trainers if there is any confusion.

## **6.6 Report of Findings (ROF)**

After all readings are completed, provide the SP with the ROF. ISIS generates this report automatically when the last measurement of the skin reaction is entered into the computer system in the field office and MEC. For measurement of skin reactions conducted outside of these sites, ISIS indicates whether the result for each antigen is positive or negative. The TB reader records this information on the ROF form manually. Read the ROF to the SP. If the SP has questions about the measurement of the skin reaction or the ROF, attempt to answer the question by repeating the language of the ROF. If the SP is not satisfied, or if the SP has questions that cannot be answered by using the language of the ROF, refer the SP to Dr. Kathryn Porter at NCHS. Dr. Porter’s telephone number is listed on the ROF.

If the measurement of the skin reaction to the tuberculin antigen is less than the minimum cut-off, the SP receives a report indicating that he or she is not likely to have been infected with TB in the past. If the induration measurement for the tuberculin antigen is equal to or greater than the minimum cut-off for a possible TB infection in the past, the SP receives a report indicating that he or she may have been infected with TB at some time during the past, but that clinical evaluation is needed.

If the measurement of the skin reaction to the PPD-Batney test is less than the minimum cut-off, the SP receives a report indicating that he or she is not likely to have been infected with harmless germs related to TB in the past. If the induration measurement for the PPD-B reaction is equal to or greater than the minimum cut-off for an infection with harmless germs related to TB, the SP receives a report indicating that he or she may have been infected with harmless germs related to TB at some time during the past, but that no clinical action is necessary because these germs do not cause illness in healthy people.

If any reader or more than one reader records a result greater than or equal to the minimum cutoff for the tuberculin test, the printed ROF will report the result as “positive.” If the positive result is

for TB infection, the ROF will include the referral to the local source of health care or the TB control program at the health department for further evaluation.

Verify the hard copy TB ROF against the computer generated ROF at the start of each stand. There are two versions of the TB ROF, one for children between the ages of 1 and 17 and one for adults, aged 18 years and older. The TB ROFs are shown in the following exhibits:

- Exhibit 6-2a and b. Child's ROF: PPD-S1 is negative; PPD-Batthey is negative
- Exhibit 6-3a and b. Child's ROF: PPD-S1 is positive; PPD-Batthey is negative
- Exhibit 6-4a and b. Child's ROF: PPD-S1 is negative; PPD-Batthey is positive
- Exhibit 6-5a and b. Child's ROF: PPD-S1 is positive; PPD-Batthey is positive
- Exhibit 6-6a and b. Adult's ROF: PPD-S1 is negative; PPD-Batthey is negative
- Exhibit 6-7a and b. Adult's ROF: PPD-S1 is positive; PPD-Batthey is negative
- Exhibit 6-8a and b. Adult's ROF: PPD-S1 is negative; PPD-Batthey is positive
- Exhibit 6-9a and b. Adult's ROF: PPD-S1 is positive; PPD-Batthey is positive

In the field office and in SP homes, the TB reader provides the SP with the ROF. In the MEC the ROF prints at the coordinator's desk and is given to the SP at the time the SP checks out of the MEC. The PMR explains the skin test findings to the SP.

Exhibit 6-2a. Child's ROF: PPD-S1 is negative; PPD-Batthey is negative



## National Health and Nutrition Examination Survey

### TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis

**Date of Examination:**

**Date of Application:**

**Participant Name:**

**Participant Age:**

**Participant Gender:**

**Attention:**

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### **Tuberculosis Results**

Based on the skin readings, your child's test for TB (PPD-S1) was negative. This means your child probably has not been infected with tuberculosis.

### **Nontuberculous Mycobacteria Results**

Your child's skin test for the germs related to TB (PPD-B) was negative. This means that your child probably has not been infected with the germs related to tuberculosis. The scientific term for these germs is nontuberculous mycobacteria.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.

Exhibit 6-2b. Child's ROF: PPD-S1 is negative; PPD-Batthey is negative (Spanish)



National Health and Nutrition Examination Survey

Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico

Fecha de Expiración:

Fecha de Aplicación:

Nombre del Participante:

Edad del Participante:

Género del Participante:

Atención:

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A su niño le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, la prueba de su niño de TB (PPD-S1) fue negativa. Esto significa que su niño probablemente no ha estado infectado con tuberculosis.

### Resultados de Micobacteria No Tuberculosa

La prueba para los gérmenes relacionados con la TB (PPD-B) aplicada en la piel de su niño, fue negativa. Esto significa que su niño probablemente no ha estado infectado con los gérmenes relacionados con la tuberculosis. El término científico de estos gérmenes es micobacteria no tuberculosa.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.

Exhibit 6-3a. Child's ROF: PPD-S1 is positive; PPD-Batney is negative



## National Health and Nutrition Examination Survey

### TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis

**Date of Examination:**

**Date of Application:**

**Participant Name:**

**Participant Age:**

**Participant Gender:**

**Attention:**

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### Tuberculosis Results

Based on the skin readings, your child's test for TB (PPD-S1) was positive. This means that it is possible your child was infected with tuberculosis at some time in his/her life. Most people infected with tuberculosis never get the disease. People who are infected but do not have active disease cannot spread tuberculosis to anyone else. If no one has told you before that your child may have been infected with TB, we strongly recommend you take this report to your child's doctor or local health department as soon as you can. Your doctor or the health department may want to do another skin test and an examination to see if your child needs medicine to prevent TB disease. The address and phone number for further evaluation at your local health department are:

### Nontuberculous Mycobacteria Results

Your child's skin test for the germs related to TB (PPD-B) was negative. This means that your child probably has not been infected with the germs related to tuberculosis. The scientific term for these germs is nontuberculous mycobacteria.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.

Exhibit 6-3b. Child's ROF: PPD-S1 is positive; PPD-Batney is negative (Spanish)



## National Health and Nutrition Examination Survey

### Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico

**Fecha de Expiración:**

**Fecha de Aplicación:**

**Nombre del Participante:**

**Edad del Participante:**

**Género del Participante:**

**Atención:**

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A su niño le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, la prueba de su niño de TB (PPD-S1) fue positiva. Esto significa que es posible que su niño haya estado infectado con tuberculosis en algún momento durante su vida. La mayoría de las personas infectadas con tuberculosis nunca contraen la enfermedad. Las personas que están infectadas pero que no tienen la enfermedad activa, no pueden propagar la tuberculosis a ninguna otra persona. Si nadie le ha dicho antes que su niño puede estar infectado con TB, le recomendamos enfáticamente que le lleve este informe al médico de su niño o al departamento de salud local tan pronto como pueda. Su médico o departamento de salud puede que le quiera hacer otra prueba en la piel y un examen para ver si su niño necesita medicinas para prevenir la enfermedad de TB. La dirección y número de teléfono para evaluación adicional en su departamento de salud local son:

### Resultados de Micobacteria No Tuberculosa

La prueba para los gérmenes relacionados con la TB (PPD-B) aplicada en la piel de su niño, fue negativa. Esto significa que su niño probablemente no ha estado infectado con los gérmenes relacionados con la tuberculosis. El término científico de estos gérmenes es micobacteria no tuberculosa.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.



Exhibit 6-4a. Child's ROF: PPD-S1 is negative; PPD-Batney is positive



## National Health and Nutrition Examination Survey

### TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis

**Date of Examination:**

**Date of Application:**

**Participant Name:**

**Participant Age:**

**Participant Gender:**

**Attention:**

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### Tuberculosis Results

Based on the skin readings, your child's test for TB (PPD-S1) was negative. This means your child probably has not been infected with tuberculosis.

### Nontuberculous Mycobacteria Results

Your child's skin test for the germs related to TB (PPD-B) was positive. This means that at some time in your child's life it is possible that he/she was infected with the germs related to tuberculosis that usually do not cause disease in healthy people. These germs are widespread in the water and soil in many parts of the U.S., and surveys have indicated that in some parts of the country from one-fifth to one-half of the population has these germs. The scientific term for these germs is nontuberculous mycobacteria. Healthy people infected with these germs usually do not get sick and no treatment is needed. Nontuberculous mycobacteria do not cause tuberculosis and are not spread from person to person. There is no need to have any more tests or to see a doctor.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.



National Center For Health Statistics, 6525 Belcrest Road, Room 900, Hyattsville, Maryland 20782.

Exhibit 6-4b. Child's ROF: PPD-S1 is negative; PPD-Batthey is positive (Spanish)



## National Health and Nutrition Examination Survey

### Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico

Fecha de Expiración:

Fecha de Aplicación:

Nombre del Participante:

Edad del Participante:

Género del Participante:

Atención:

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A su niño le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, la prueba de su niño de TB (PPD-S1) fue negativa. Esto significa que su niño probablemente no ha estado infectado con tuberculosis.

### Resultados de Micobacteria No Tuberculosa

La prueba para los gérmenes relacionados con la TB (PPD-B) aplicada en la piel de su niño, fue positiva. Esto significa que en algún momento en su vida es posible que su niño haya estado infectado con los gérmenes relacionados con la tuberculosis que usualmente no causan la enfermedad a personas saludables. Estos gérmenes están propagados en el agua y en la tierra en muchas partes en Estados Unidos, y las encuestas han indicado que en algunas partes del país de un quinto a la mitad de la población tiene los gérmenes. El nombre científico de estos gérmenes es micobacteria no tuberculosa. Las personas saludables que están infectadas con estos gérmenes normalmente no se enferman y no necesitan tratamiento. La micobacteria no tuberculosa no causa tuberculosis y no se propaga de persona a persona. No hay necesidad de hacer más pruebas o de ver a un médico.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.



National Center For Health Statistics, 6525 Belcrest Road, Room 900, Hyattsville, Maryland 20782.

Exhibit 6-5a. Child's ROF: PPD-S1 is positive; PPD-Batney is positive



National Health and Nutrition Examination Survey

TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis

Date of Examination:

Date of Application:

Participant Name:

Participant Age:

Participant Gender:

Attention:

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### Tuberculosis Results

Based on the skin readings, your child's test for TB (PPD-S1) was positive. This means that it is possible your child was infected with tuberculosis at some time in his/her life. Most people infected with tuberculosis never get the disease. People who are infected but do not have active disease cannot spread tuberculosis to anyone else. If no one has told you before that your child may have been infected with TB, we strongly recommend you take this report to your child's doctor or local health department as soon as you can. Your doctor or the health department may want to do another skin test and an examination to see if your child needs medicine to prevent TB disease. The address and phone number for further evaluation at your local health department are:

### Nontuberculous Mycobacteria Results

Your child's skin test for the germs related to TB (PPD-B) was positive. This means that at some time in your child's life it is possible that he/she was infected with the germs related to tuberculosis that usually do not cause disease in healthy people. These germs are widespread in the water and soil in many parts of the U.S., and surveys have indicated that in some parts of the country from one-fifth to one-half of the population has these germs. The scientific term for these germs is nontuberculous mycobacteria. Healthy people infected with these germs usually do not get sick and no treatment is needed. Nontuberculous mycobacteria do not cause tuberculosis and are not spread from person to person.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.



National Center For Health Statistics, 6525 Belcrest Road, Room 900, Hyattsville, Maryland 20782.

Exhibit 6-5b. Child's ROF: PPD-S1 is positive; PPD-Batthey is positive (Spanish)



National Health and Nutrition Examination Survey

Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico

Fecha de Expiración:

Fecha de Aplicación:

Nombre del Participante:

Edad del Participante:

Género del Participante:

Atención:

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A su niño le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, la prueba de su niño de TB (PPD-S1) fue positiva. Esto significa que es posible que su niño haya estado infectado con tuberculosis en algún momento durante su vida. La mayoría de las personas infectadas con tuberculosis nunca contraen la enfermedad. Las personas que están infectadas pero que no tienen la enfermedad activa, no pueden propagar la tuberculosis a ninguna otra persona. Si nadie le ha dicho antes que su niño puede estar infectado con TB, le recomendamos enfáticamente que le lleve este informe al médico de su niño o al departamento de salud local tan pronto como pueda. Su médico o departamento de salud puede que le quiera hacer otra prueba en la piel y un examen para ver si su niño necesita medicinas para prevenir la enfermedad de TB. La dirección y número de teléfono para evaluación adicional en su departamento de salud local son:

### Resultados de Micobacteria No Tuberculosa

La prueba para los gérmenes relacionados con la TB (PPD-B) aplicada en la piel de su niño, fue positiva. Esto significa que en algún momento en su vida es posible que su niño haya estado infectado con los gérmenes relacionados con la tuberculosis que usualmente no causan la enfermedad a personas saludables. Estos gérmenes están propagados en el agua y en la tierra en muchas partes en Estados Unidos, y las encuestas han indicado que en algunas partes del país de un quinto a la mitad de la población tiene los gérmenes. El nombre científico de estos gérmenes es micobacteria no tuberculosa. Las personas saludables que están infectadas con estos gérmenes normalmente no se enferman y no necesitan tratamiento. La micobacteria no tuberculosa no causa tuberculosis y no se propaga de persona a persona.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.



Exhibit 6-6a. Adult's ROF: PPD-S1 is negative; PPD-Bathey is negative



## National Health and Nutrition Examination Survey

### TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis.

Date of Examination:

Date of Application:

Participant Name:

Participant Age:

Participant Gender:

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### Tuberculosis Results

Based on the skin readings, your test for TB was negative. This means that you probably have not been infected with tuberculosis.

### Nontuberculous Mycobacteria Results

Your skin test for the germs related to TB was negative. This means you probably have not been infected with germs related to tuberculosis. The scientific term for these germs is nontuberculous mycobacteria.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.



National Center For Health Statistics, 6525 Belcrest Road, Room 900, Hyattsville, Maryland 20782.

Exhibit 6-6b. Adult's ROF: PPD-S1 is negative; PPD-Batthey is negative (Spanish)



National Health and Nutrition Examination Survey

Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico.

Fecha de Expiración:

Fecha de Aplicación:

Nombre del Participante:

Edad del Participante:

Género del Participante:

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A usted le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, su prueba de TB (PPD-S1) fue negativa. Esto significa que usted probablemente no ha estado infectado con tuberculosis.

### Resultados de Micobacteria No Tuberculosa

Su prueba en la piel para los gérmenes relacionados con la TB (PPD-B) fue negativa. Esto significa que probablemente no ha estado infectado con los gérmenes relacionados con la tuberculosis. El término científico de estos gérmenes es micobacteria no tuberculosa.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.

Exhibit 6-7a. Adult's ROF: PPD-S1 is positive; PPD-Batney is negative



## National Health and Nutrition Examination Survey

### TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis

Date of Examination:

Date of Application:

Participant Name:

Participant Age:

Participant Gender:

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### Tuberculosis Results

Based on the skin readings, your test for TB was positive. This means that it is possible you were infected with tuberculosis at some time during your life. Most people infected with tuberculosis never get the disease. People who are infected but do not have active disease cannot spread tuberculosis to anyone else. If no one has told you before that you may have been infected with TB, we strongly recommend you take this report to your doctor or to the local health department as soon as you can. Your doctor or the health department may want to do another skin test and an examination to see if you need medicine to prevent TB disease. The address and contact phone number for further evaluation at your local health department are:

### Nontuberculous Mycobacteria Results

Your skin test for the germs related to TB was negative. This means you probably have not been infected with germs related to tuberculosis. The scientific term for these germs is nontuberculous mycobacteria.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.

Exhibit 6-7b. Adult's ROF: PPD-S1 is positive; PPD-Batthey is negative (Spanish)



National Health and Nutrition Examination Survey

Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico

Fecha de Expiración:

Fecha de Aplicación:

Nombre del Participante:

Edad del Participante:

Género del Participante:

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A usted le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, su prueba de TB (PPD-S1) fue positiva. Esto significa que es posible que usted haya estado infectado con tuberculosis en algún momento durante su vida. La mayoría de las personas infectadas con tuberculosis nunca contraen la enfermedad. Las personas que están infectadas pero que no tienen la enfermedad activa, no pueden propagar la tuberculosis a ninguna otra persona. Si nadie le ha dicho antes que usted puede estar infectado con TB, le recomendamos enfáticamente que le lleve este informe a su médico o al departamento de salud local tan pronto como pueda. Su médico o departamento de salud puede que le quieran hacer otra prueba en la piel y un examen para ver si usted necesita medicinas para prevenir la enfermedad de TB. La dirección y el número de teléfono para evaluación adicional en su departamento de salud local son:

### Resultados de Micobacteria No Tuberculosa

Su prueba en la piel para los gérmenes relacionados con la TB (PPD-B) fue negativa. Esto significa que probablemente no ha estado infectado con los gérmenes relacionados con la tuberculosis. El término científico de estos gérmenes es micobacteria no tuberculosa.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.

Exhibit 6-8a. Adult's ROF: PPD-S1 is negative; PPD-Batthey is positive



## National Health and Nutrition Examination Survey

### TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis

Date of Examination:

Date of Application:

Participant Name:

Participant Age:

Participant Gender:

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### Tuberculosis Results

Based on the skin readings, your test for TB was negative. This means that you probably have not been infected with tuberculosis.

### Nontuberculous Mycobacteria Results

Your skin test for the germs related to TB was positive. This means that at some time in your life it is possible you were infected with germs related to tuberculosis that usually do not cause disease in healthy people. These germs are widespread in the water and soil in many parts of the U.S., and surveys have indicated that some parts of the country from one-fifth to one half of the population has these germs. The scientific term for these germs is nontuberculous mycobacteria. Healthy people infected with these germs usually do not get sick and no treatment is needed. Nontuberculous mycobacteria do not cause tuberculosis and they are not spread from person to person. There is no need to have any more tests or to see a doctor.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.

Exhibit 6-8b. Adult's ROF: PPD-S1 is negative; PPD-Batthey is positive (Spanish)



National Health and Nutrition Examination Survey

Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico

Fecha de Expiración:

Fecha de Aplicación:

Nombre del Participante:

Edad del Participante:

Género del Participante:

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A usted le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, su prueba de TB (PPD-S1) fue negativa. Esto significa que usted probablemente no ha estado infectado con tuberculosis.

### Resultados de Micobacteria No Tuberculosa

Su prueba en la piel para los gérmenes relacionados con la TB (PPD-B) fue positiva. Esto significa que en algún momento en su vida es posible que haya estado infectado con los gérmenes relacionados con la tuberculosis que usualmente no causan la enfermedad a personas saludables. Estos gérmenes están propagados en el agua y en la tierra en muchas partes en Estados Unidos, y las encuestas han indicado que en algunas partes del país de un quinto a la mitad de la población tiene los gérmenes. El nombre científico de estos gérmenes es micobacteria no tuberculosa. Las personas saludables que están infectadas con estos gérmenes normalmente no se enferman y no necesitan tratamiento. La micobacteria no tuberculosa no causa tuberculosis y no se propaga de persona a persona. No hay necesidad de hacer más pruebas o de ver a un médico.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.

Exhibit 6-9a. Adult's ROF: PPD-S1 is positive; PPD-Batney is positive



## National Health and Nutrition Examination Survey

### TB Skin Test Report of Findings

These measurements were obtained as part of a survey and do not represent a medical diagnosis

**Date of Examination:**

**Date of Application:**

**Participant Name:**

**Participant Age:**

**Participant Gender:**

The tuberculin skin test can show if a person has ever been 'infected' by tuberculosis (TB) germs. There are several kinds of tuberculin skin tests. The test used in the NHANES survey is the national standard for TB skin tests used at clinics and doctors offices.

You had two skin tests applied at the time of your exam. One was to test for TB (PPD-S1) and the other was to test for germs that are related to TB which usually do not cause illness in healthy people (PPD-B). The latter test helps investigators understand the results of the TB test.

### Tuberculosis Results

Based on the skin readings, your test for TB was positive. This means that it is possible you were infected with tuberculosis at some time during your life. Most people infected with tuberculosis never get the disease. People who are infected but do not have active disease cannot spread tuberculosis to anyone else. If no one has told you before that you may have been infected with TB, we strongly recommend you take this report to your doctor or to the local health department as soon as you can. Your doctor or the health department may want to do another skin test and an examination to see if you need medicine to prevent TB disease. The address and contact phone number for further evaluation at your local health department are:

### Nontuberculous Mycobacteria Results

Your skin test for the germs related to TB was positive. This means that at some time in your life it is possible you were infected with germs related to tuberculosis that usually do not cause disease in healthy people. These germs are widespread in the water and soil in many parts of the U.S., and surveys have indicated that some parts of the country from one-fifth to one half of the population has these germs. The scientific term for these germs is nontuberculous mycobacteria. Healthy people infected with these germs usually do not get sick and no treatment is needed. Nontuberculous mycobacteria do not cause tuberculosis and they are not spread from person to person.

If you have questions about your results, please contact Dr. Kathryn Porter at 800-452-6115.

Exhibit 6-9b. Adult's ROF: PPD-S1 is positive; PPD-Batthey is positive (Spanish)



## National Health and Nutrition Examination Survey

### Informe de los Resultados de la Prueba de TB en la Piel

Estos resultados fueron obtenidos como parte de una encuesta y no representan un diagnóstico médico.

**Fecha de Expiración:**

**Fecha de Aplicación:**

**Nombre del Participante:**

**Edad del Participante:**

**Género del Participante:**

La prueba de tuberculina en la piel puede mostrar si una persona ha estado 'infectada' alguna vez con los gérmenes de la tuberculosis (TB). Hay varios tipos de pruebas de tuberculina en la piel. La prueba usada en la encuesta de NHANES es el patrón nacional de la prueba de tuberculina en la piel que se usa en clínicas y en consultorios médicos.

A usted le hicieron dos pruebas en la piel en el momento de su examen. Una fue la prueba para la TB (PPD-S1) y la otra fue una prueba para los gérmenes que están relacionados con la TB los cuales usualmente no causan enfermedades a personas saludables (PPD-B). La última prueba ayuda a los investigadores a comprender los resultados de la prueba de TB.

### Resultados de la Prueba de Tuberculosis

Basado en las lecturas en la piel, su prueba de TB (PPD-S1) fue positiva. Esto significa que es posible que usted haya estado infectado con tuberculosis en algún momento durante su vida. La mayoría de las personas infectadas con tuberculosis nunca contraen la enfermedad. Las personas que están infectadas pero que no tienen la enfermedad activa, no pueden propagar la tuberculosis a ninguna otra persona. Si nadie le ha dicho antes que usted puede estar infectado con TB, le recomendamos enfáticamente que le lleve este informe a su médico o al departamento de salud local tan pronto como pueda. Su médico o departamento de salud puede que le quieran hacer otra prueba en la piel y un examen para ver si usted necesita medicinas para prevenir la enfermedad de TB. La dirección y el número de teléfono para evaluación adicional en su departamento de salud local son:

### Resultados de Micobacteria No Tuberculosa

Su prueba en la piel para los gérmenes relacionados con la TB (PPD-B) fue positiva. Esto significa que en algún momento en su vida es posible que haya estado infectado con los gérmenes relacionados con la tuberculosis que usualmente no causan la enfermedad a personas saludables. Estos gérmenes están propagados en el agua y en la tierra en muchas partes en Estados Unidos, y las encuestas han indicado que en algunas partes del país de un quinto a la mitad de la población tiene los gérmenes. El nombre científico de estos gérmenes es micobacteria no tuberculosa. Las personas saludables que están infectadas con estos gérmenes normalmente no se enferman y no necesitan tratamiento. La micobacteria no tuberculosa no causa tuberculosis y no se propaga de persona a persona.

Si desea hacer alguna pregunta acerca de sus resultados, puede llamar a la doctora Kathryn Porter a nuestro número gratis, 1-800-452-6115.

If the ROF indicates that the test result is negative, explain that the person has probably not been infected with the bacteria (germs) that cause TB. If the test result is positive, explain that it is possible the person was infected with the bacteria that cause TB but that clinical evaluation is needed. The ROF recommends that if the person has not previously had a positive skin test, he or she should report these findings indicating possible infection to their physician so that a clinical evaluation can be performed. The ROF also provides the name, address, and telephone number of the local health department where evaluation can be performed in case the SP does not have or does not wish to use a private source of medical care. Reassure the SP that infected individuals without active TB are not infectious to others, and that infection with TB bacteria does not mean the SP “has TB.” However, some infected people need treatment to prevent TB and that is why a clinical evaluation is important. Remind the SP to take the ROF with them. If the SP wishes to discuss the findings further, refer them to Dr. Kathryn Porter at the telephone number on the ROF.

If the ROF indicates that the test result for the germs related to TB is negative, explain that the person has probably not been infected with the bacteria (germs) related to TB, called nontuberculous mycobacteria. If the test result is positive, explain that it is possible the SP was infected with these bacteria at some time in his or her life. These bacteria are widespread in the soil and water and 1/3 of the U.S. population is thought to be infected. Healthy people who become infected with nontuberculous mycobacteria usually do not get sick. Nontuberculous mycobacteria do not cause TB and they do not spread from person to person. There is no need for the SP to have any more skin tests done or see a doctor.

Again, if the SP has questions about the TB skin test that was performed or about the ROF, repeat the language of the ROF and refer the SP to Dr. Kathryn Porter at NCHS if the language of the ROF does not answer the question. Dr. Porter’s telephone number is listed on the ROF.

## **6.7 Remuneration**

SPs who return to the field office or MEC within the 46- to 76-hour window to have the test measurement taken are given a remuneration of \$30.00. SPs who have the test measurement taken someplace other than the field office or MEC are given \$10.00. In the MEC the coordinator handles the

remuneration when the SP checks out. In the field office and in SP homes, the PFR prepares two copies of a receipt using a standard receipt book. The following information is included on the blank receipt:

- SP's name
- SP ID
- Date
- "TB skin test"
- Amount of remuneration (\$30 or \$10)

Ask the SP to sign the receipt indicating they have received the cash payment. If the SP is between the ages of 1 and 17, the parent or adult accompanying the child to the field office signs the receipt. If an unaccompanied child arrives at the field office, the child can sign the receipt but another field office staff member also signs as a witness.

SPs are also paid mileage to and from the reading site.

### **6.7.1 Petty Cash**

The field office manager (FOM) provides the TB PFRs with the amount of cash required for the day's scheduled appointments and additional funds for unscheduled readings and readings performed in the field. The TB readers reconcile the petty cash account with the FOM daily or when requested by the FOM. The cash remaining in the TB petty cash fund plus the value of the signed receipts must equal the amount of cash advanced by the FOM.

### **6.8 Measurement of the Skin Reactions after the Stand Closes**

Place TB skin test antigens through the last MEC exam day at all stands. PFRs remain at each stand up to 3 days after the last examination session to measure skin reactions. Neither the MEC nor field office are available during this period, therefore the measurement of tests placed the last 2 to 3 days of the stand are read only in SP's homes.

### **6.8.1 End of Stand Procedures**

In most stands the field office closes immediately following the last MEC examination session. Confirm this date with the field office manager. Complete the following tasks after the last MEC examination session and before the field office computer system is shut down:

1. Generate reports of reading appointments made by the phlebotomist, and SPs who received the skin test antigens but do not have scheduled appointments.
2. Using the Appointment Management System (AMS), transfer the SPs listed on the reports to “home” appointments for readings.
3. Undock the TB readers’ laptop PCs. Verify that the appointment information in the AMS is correct and that the SPs appear in the TB reader application on both laptops.
4. Obtain cash for SP remuneration from the field office manager. SPs are paid \$30 for TB readings conducted at the end of stand. The FOM provides \$30 for each SP who received the test antigens and has not yet had the test measurements taken. The FOM also provides a petty cash reconciliation form that is completed before the PFRs leave the stand.
5. Conduct an end of stand inventory.

Each PFR verifies that they have sufficient supplies, including hard copy ROF forms. The TB readers also prepare one TB Reader’s Call Record for each SP listed on the reports of scheduled and unscheduled SP appointments. Any call records in the Call Record Log Book for readings that have not been completed should be removed and added to the new call records. Shred the remaining call records (completed appointments). Pack the empty Call Record Log Book with the TB supplies for transport to the next stand with the other FO supplies.

### **6.8.2 Measurement of Skin Reaction after the Field Office Closes**

Once the field office closes, PFRs make reminder telephone calls from their hotel rooms and measure skin reaction in SP homes and offices. TB readings are not conducted in the hotel. It is anticipated that the number of readings scheduled during this period will be relatively small. The TB readers should accompany each other whenever possible when conducting these end-of-stand readings.

The home office supervisor provides the PFRs with the date and time they may leave the stand to travel to the next stand. If all work is completed before this time, the TB readers may leave the stand after notifying their Home Office supervisor.

### **6.8.3 Tasks Completed before Leaving a Stand**

Before leaving a stand the TB readers complete the following tasks:

1. Complete all TB readings.
  - Obtain a Cashier's Check for any unspent remuneration funds. Attach the check to the petty cash reconciliation form. Copies of any signed receipts are also attached to the form. The value of the Cashier's Check added to the value of the signed receipts should equal the petty cash advanced to the TB readers. The reconciliation form is placed in a Federal Express envelope and returned to the WESTAT Home Office before leaving the stand.
  - Give the inventory sheet to the MEC manager before the MEC closes. Contact the Home Office supervisor and notify them that TB readings at the stand have been completed.
2. Transfer the data using the TB Data Transfer with Dial-Up Networking Instructions that follow.

## Final TB Data Transfer with Dial-Up Networking

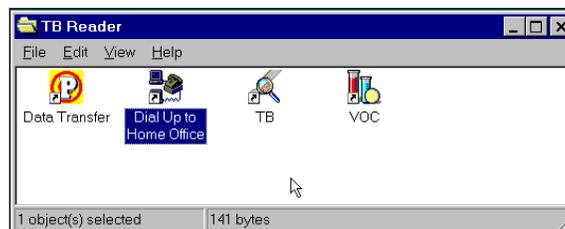
*Note – you will need the current password for the Home Office dial-up account. If you discover you don't have it, CALL any data manager or Taylor Cooper at 1-800-WESTAT1, ext 72-5480.*

### Step 1 –

Connect telephone line from hotel telephone jack to laptop and boot computer.

### Step 2 –

Double-click the “Dial-up to home office” icon in the TB Reader folder.



### Step 3 –

Make sure the user name = nh4ppp and type in the password.

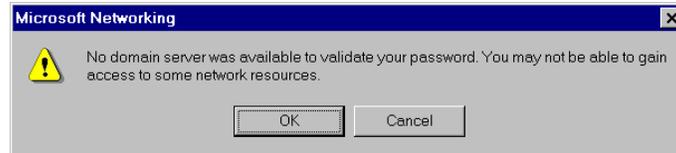
The telephone number for dial up = 1-800-823-6720. If you need to dial a “9” to get out of the office or hotel telephone system, type the “9” into the “Phone number” box before the telephone number.

Click “Connect.”



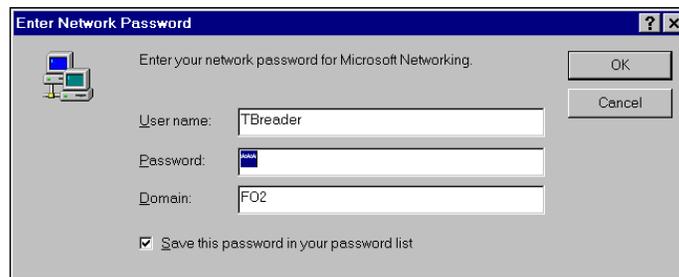
#### Step 4 -

A message box will appear “No domain server was available...”. Click “OK.”



#### Step 5 -

A network sign-in box will appear. Click “Cancel”



#### Step 6 -

A message will appear “You are connected to Isis”. It is good to be connected to Isis. Click “Close.”



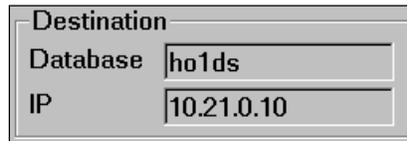
#### Step 7 -

Look in the bottom right corner of the screen. You will see a tiny picture of two computers that appear to be connected. This is also a good thing.



**Step 8 –**

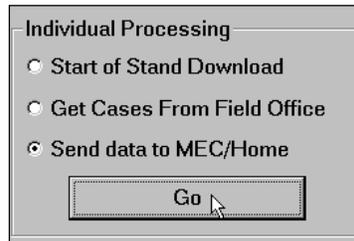
Double-click the “Data Transfer” icon in the TB Reader folder. Look at the section under “Destination” on the right side of the screen. It should show the database = “ho1ds” and the IP = “10.21.0.10”. If it doesn’t – give up and call a data manager.



Destination  
Database ho1ds  
IP 10.21.0.10

**Step 9 –**

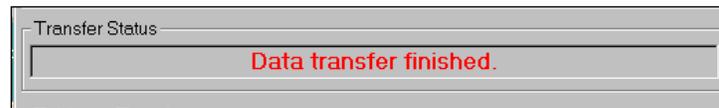
Do not click “Transfer Cases.” In the top right corner, click “Send data to MEC/Home” and click “Go.”



Individual Processing  
 Start of Stand Download  
 Get Cases From Field Office  
 Send data to MEC/Home  
Go

**Step 10 –**

After the data has successfully transferred, click “Close.”



Transfer Status  
Data transfer finished.

**NOTE – If you get an error message at any time during the data transfer process outlined above or if you do NOT get the “Data transfer finished” message – CALL a Data Manager immediately.**

**Step 11 –**

After you have closed the “Data Transfer” application, open your CCMail and send an email to the following recipients to let them know that the data transfer was successful:

Barb Lindstrom	LindstB1
Stephen Bernas	BernasS1
Helen Marie Graves	GravesH1
Greg Binzer	BinzerG1
Taylor Cooper	CooperT1
Terri Jones	JonesT2
Steve Reser	ReserS1
Mike Hooten	HootenM1

The Office Manager at the departing stand:

Kim Gibson	Gibsonk
Gayle Veum	VeumG1
Shannon McNeil	McNeilS

### Step 12 –

Right click on the little computers in the very lower right corner of the screen. Select “Disconnect.”



1. Call Barbara Lindstrom at 1-800-WESTAT1, ext 8324 (or 301-738-8324) and leave a voice mail indicating:
  - The stand number and location;
  - The number of SPs uploaded;
  - The SP ID of each uploaded SP; and
  - The final examination status for each SP.

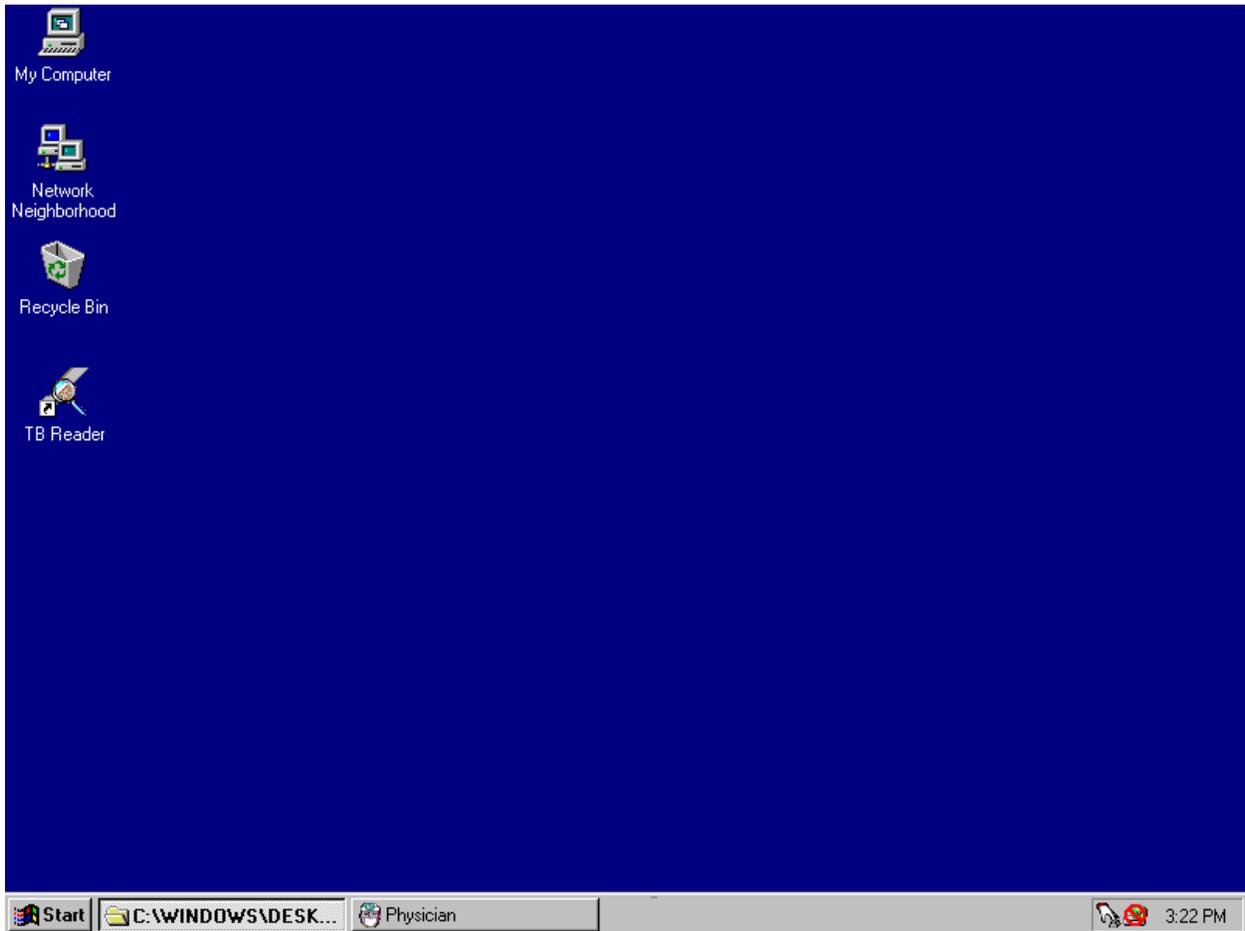
Once the information is recorded on the voice mail, there is no need to send the “SPs who need to have their TB appointment status changed (end of stand)” form back to the Home Office. Keep it with the laptop and destroy it once you get to the next field office.

## 6.9 Entering Results in ISIS

ISIS provides data entry screens for entering the measurement of the two skin tests. As stated previously, ISIS randomly assigns the PPD antigens. ISIS provides the phlebotomist with instructions as to which test to place on which forearm. This information is not available to the skin test readers until after the measurement of the skin reactions has been recorded and the ROF generated.

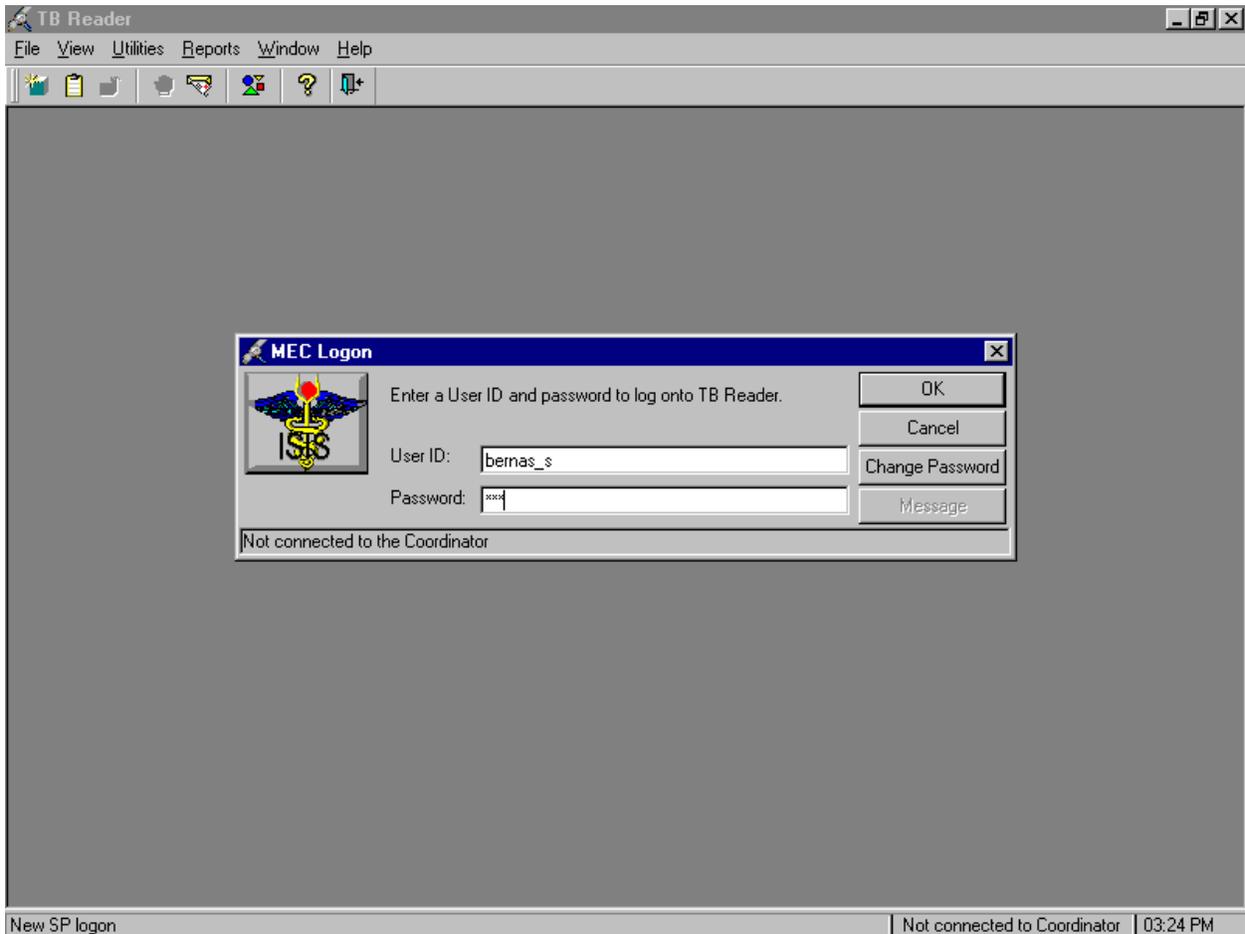
## 6.9.1 Begin the Exam and Logon

Open the TB Reader application.



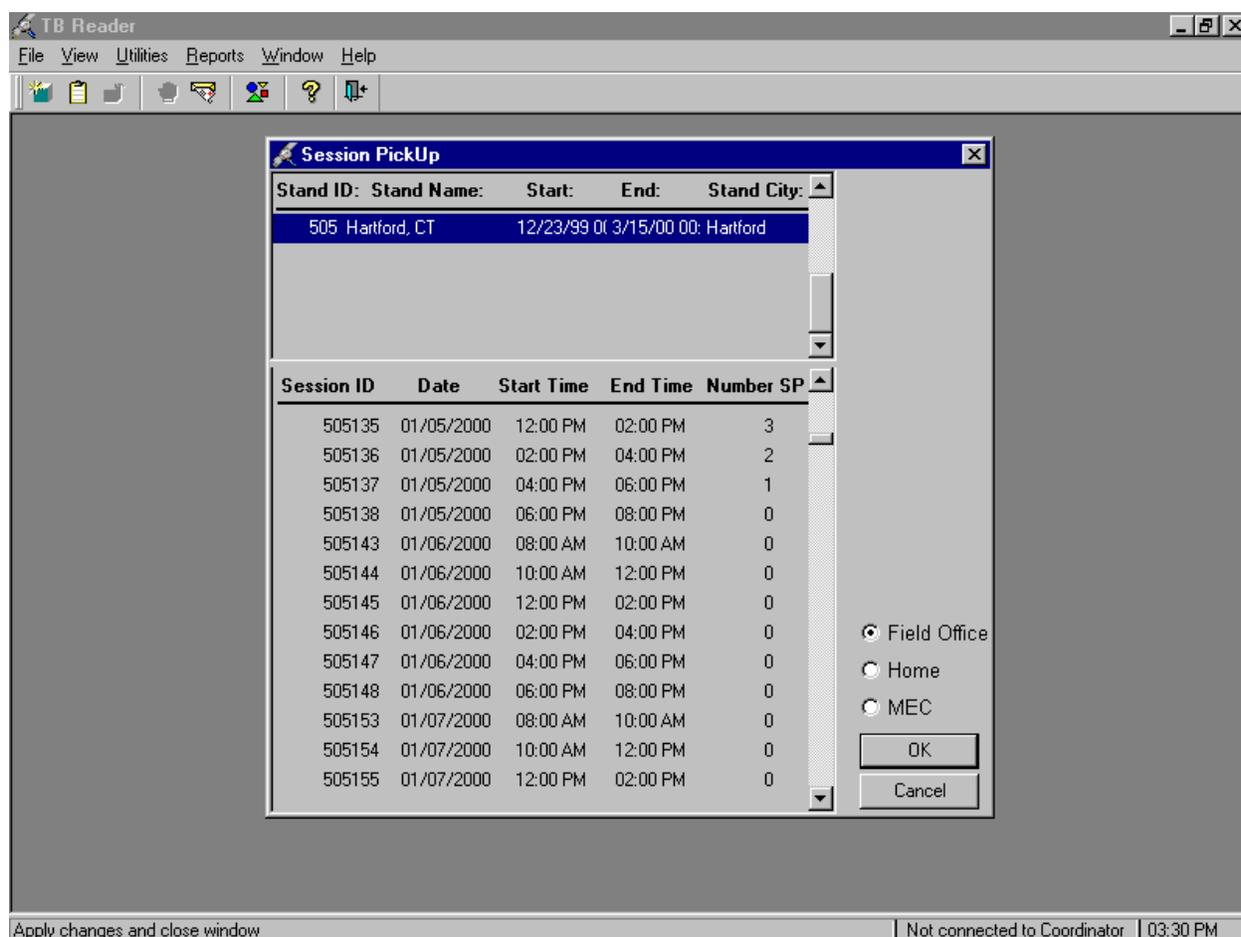
To access the TB Reader application, use the mouse to direct the mouse arrow to the TB Reader icon on the desktop and double left click.

Open an exam and log onto the TB Reader application.



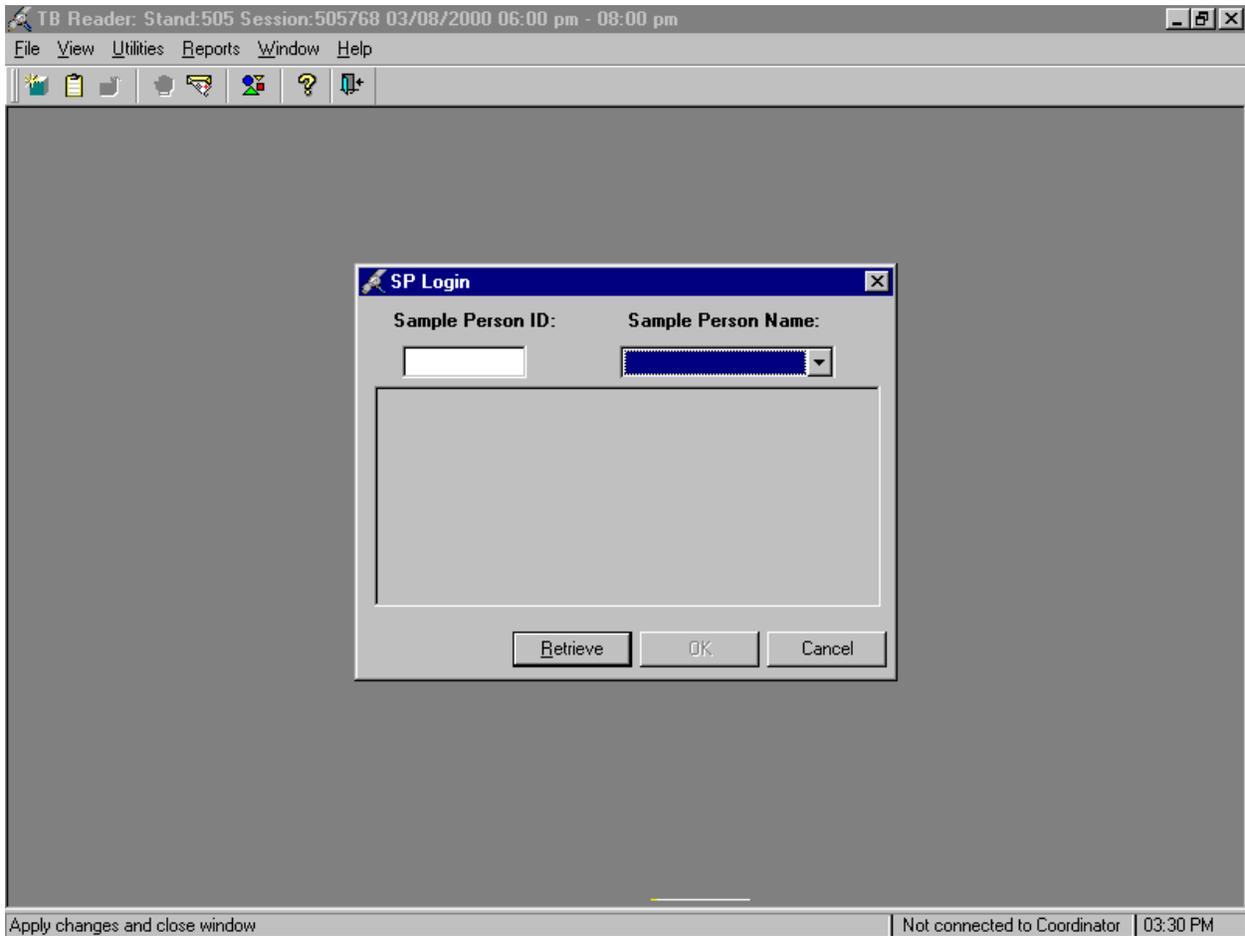
To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F], [O], or [Ctrl] [O]. The MEC Logon window displays. Type the password using the keyboard's numeric keys, select [Enter], or use the mouse to direct the mouse arrow to the [OK] button and left click. To exit this screen without entering a password, use the mouse to direct the mouse arrow to the [Cancel] button and left click.

The Session Pickup window displays.



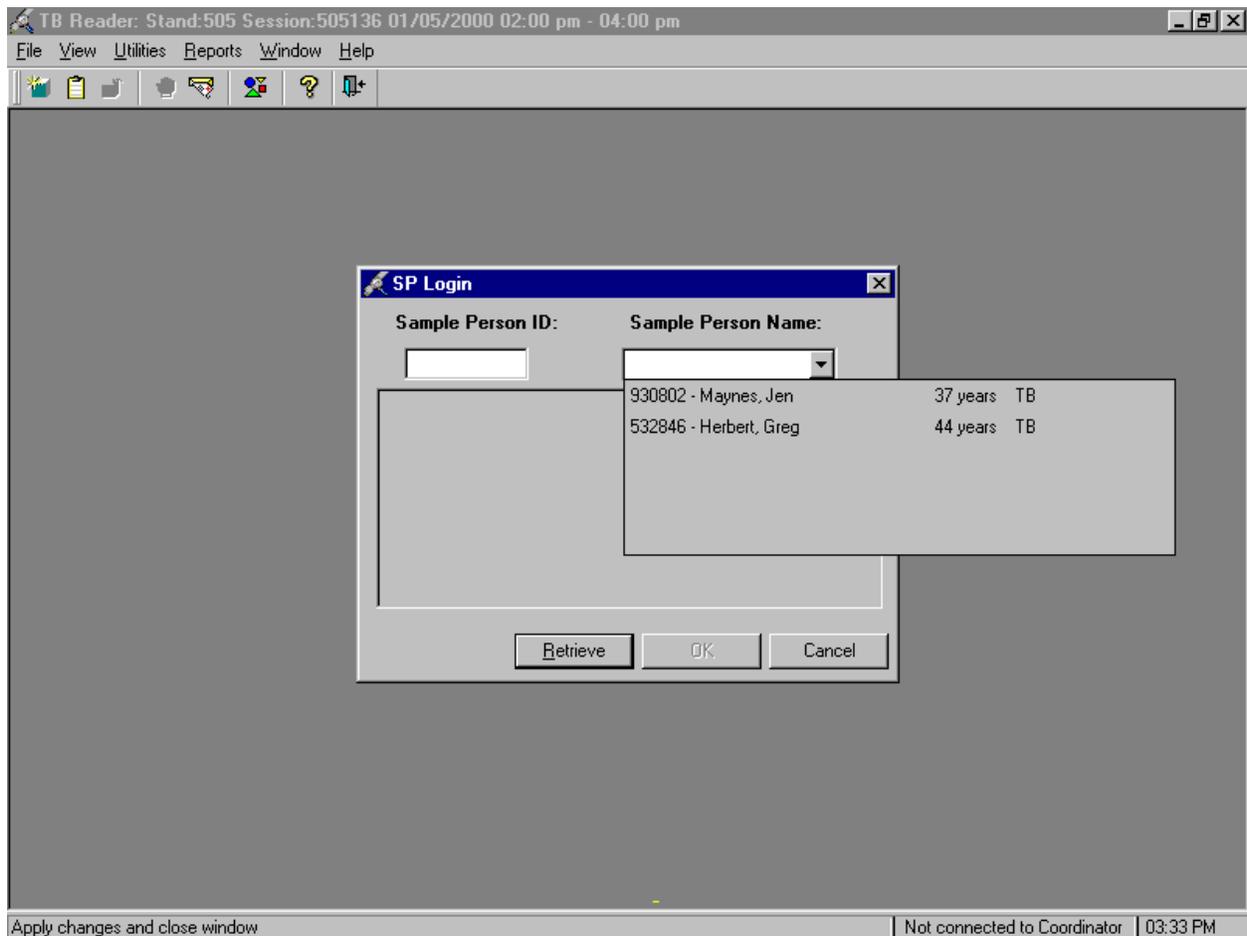
Select the correct filter (Field Office, Home, or MEC) and session from the Session Pickup list. To select a filter, use the mouse to direct the mouse arrow to the desired radio button and left click. To select a session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Log the SP into the session.



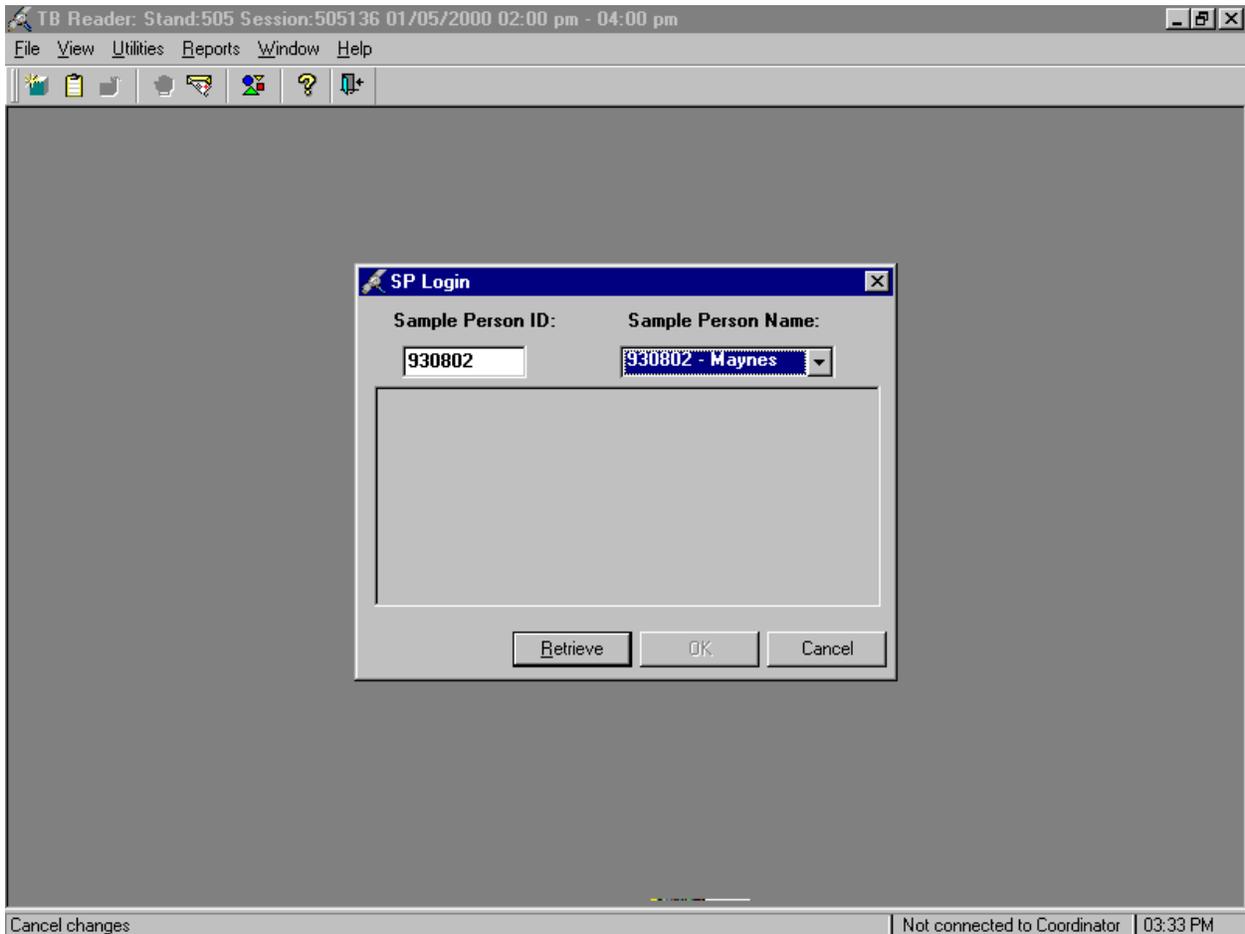
The SP Login window displays.

Continue to log the SP into the session.



To view a list of SPs scheduled into the session, use the mouse to direct the mouse arrow to the drop-down arrow on the Sample Person Name text box and left click. To select or identify a specific SP, drag the mouse arrow to the correct SP and left click.

Continue to select the SP.



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

Continue to select the SP.

TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm

File View Utilities Reports Window Help

**SP Login**

Sample Person ID:  Sample Person Name:

Last Name:  First Name:  Middle Name:

Date of Birth:  Gender:  Age at Interview:

Special Considerations:

Retrieve data | Not connected to Coordinator | 03:33 PM

Once the **Retrieve** button is selected, the remaining data in the SP Login window fills in. To move forward and to begin the exam, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter].

## 6.9.2 Record TB Readings

The TB Reader exam screen displays.

The screenshot shows the TB Reader software interface. The title bar reads "TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and help. The main window displays patient information: "SP ID: 930802", "Name: MAYNES, JEN", "Age: 37 years", "Gender: Female", "Date: 03/15/2000", and "Time: 03:43 PM". The section is titled "TB Skin Testing - Reader's Screen". It shows "Date of Application: Dec. 28, 1999", "Time of Application: 01:35 PM", and "Time from Application: 51 hrs 8 min". There are two columns for "Right Arm" and "Left Arm". Each column has fields for "Induration" (with a text input and "mm" label), "Vesiculation or Bullae", and "Ulceration or Necrosis", each with a dropdown menu. A "Technician ID" field and a "Tech Name:" label are also present. A "QC - No" button is located at the bottom right. The bottom status bar shows "Ready", "Not connected to Coordinator", and "03:42 PM". Navigation buttons include "End of Section", "Close Exam", "Finish", and a blue arrow button.

The TB Reader screen includes:

- SP ID, Name (last, first), Age, Gender, Current Date and Current Time
- Date of Application
- Time of Application
- Time from Application (The number of hours and minutes since the antigens were placed)

The number of hours since the antigen application must be between 46 hours 0 minutes and 76 hours 0 minutes to be valid. If the elapsed time is less than 46 hours, ask the SP to return when the 46-hour minimum requirement is met. If the elapsed time is greater than 76 hours, inform the SP that the skin reaction cannot be measured. If the SP is interested in receiving test findings, refer them to the local health department or their regular source of medical care for another TB skin test.

Enter the Technician ID.

The screenshot shows the 'TB Reader' software interface. The title bar reads 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window displays patient information: 'SP ID: 930802', 'Name: MAYNES, JEN', 'Age: 37 years', 'Gender: Female', 'Date: 03/15/2000', and 'Time: 03:43 PM'. Below this is the 'TB Skin Testing - Reader's Screen' section. It shows 'Date of Application: Dec. 28, 1999', 'Time of Application: 01:35 PM', and 'Time from Application: 51 hrs 8 min'. There are two columns for 'Right Arm' and 'Left Arm'. The 'Right Arm' column has fields for 'Induration' (with a text box and 'mm'), 'Vesiculation or Bullae', and 'Ulceration or Necrosis'. The 'Left Arm' column has similar fields. A 'Technician ID' field contains '1119' and a 'Tech Name' field is empty. A 'QC - No' button is located at the bottom right. The status bar at the bottom shows 'Ready', 'Not connected to Coordinator', and '03:43 PM'.

Enter the four-digit technician ID by typing the four digits using the keyboard numeric keys. To move to the induration measurement text box, select [Tab].

ISIS checks the technician ID against the database and the technician's name fills in automatically. If the ID is incorrect, use the mouse to direct the mouse arrow to the technician ID field and type or reenter the correct ID.

### 6.9.2.1 Induration – Right Arm

Enter the measurement of the diameter of the induration in millimeters in the data entry field.

The screenshot shows the TB Reader software interface. The title bar reads "TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window displays patient information: "SP ID: 930802", "Name: MAYNES, JEN", "Age: 37 years", "Gender: Female", "Date: 03/15/2000", and "Time: 03:43 PM". The section is titled "TB Skin Testing". It shows "Date of Application: Dec. 28, 1999", "Time of Application: 01:35 PM", and "Time from Application: 51 hrs 8 min". For the "Right Arm", the "Technician ID" is "1119" and the "Tech Name" is "Brian Dolan". The "Induration" field is empty with "mm" next to it. A drop-down menu is open, showing options: "87+ mm", "Refused", and "Could not obtain". The "Vesiculation or Bullae" and "Ulceration or Necrosis" fields are also empty with drop-down menus. A "QC - No" button is present. At the bottom, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the bottom shows "Ready", "Not connected to Coordinator", and "03:48 PM".

If the measurement is 87 millimeters or greater, select "87+ mm" from the drop-down menu. Do not enter a value greater than 86 millimeters in the data entry field. If the SP refuses to allow measurement of the skin reaction, select "Refused" from the drop-down menu. If the measurement could

not be obtained for any reason other than SP refusal, select “Could not obtain” from the drop-down menu. If selecting either the “Refused” or “Could not obtain” option, indicate the exact reason using the “comments” field on the final TB Skin Testing Status screen.

To record either “87+mm,” or “Refused,” or “Could not obtain,” use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, type the first letter of the correct choice and select [Tab] to move to the next field. For example, type [8] for “87+mm,” [R/r] for “Refused,” or [C/c] for “Could not obtain.” The Ulceration or Necrosis text box enables as soon as a choice is recorded.

Enter the induration measurement for the right arm.

The screenshot shows the 'TB Reader' software interface. The title bar reads 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The toolbar contains icons for file operations and help. The main window title is 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. Below the title bar, patient information is displayed: 'SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM'. The main area is titled 'TB Skin Testing - Reader's Screen'. It contains the following fields and controls:

- Date of Application:** Dec. 28, 1999
- Time of Application:** 01:35 PM
- Time from Application:** 51 hrs 8 min
- Right Arm:**
  - Induration:  mm
  - Vesiculation or Bullae:
  - Ulceration or Necrosis:
- Left Arm:**
  - Induration:  mm
  - Vesiculation or Bullae:
  - Ulceration or Necrosis:
- Technician ID:**
- Tech Name:** Brian Dolan
- QC - No** button

At the bottom, there are navigation controls: 'End of Section', 'Close Exam', 'Finish', and a blue arrow button. The status bar at the very bottom shows 'Ready' on the left and 'Not connected to Coordinator | 03:44 PM' on the right.

Read the right forearm first. Enter the measurement of the diameter of the induration in millimeters is entered in this text box. Enter the induration measurement using the keyboard numeric keys. Select [Tab] to move to the vesiculation/bullae text box.

### 6.9.2.2 Vesiculation or Bullae – Right Arm

Vesiculation and bullae are fluid-filled, blister-like lesions in the area of the TB antigen injection site.

TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm

File View Utilities Reports Window Help

TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm

SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM

TB Skin Testing - Reader's Screen

Date of Application: Dec. 28, 1999 Time of Application: 01:35 PM Time from Application: 1874 hrs 8 min

Right Arm Left Arm Technician ID 1119

Tech Name: Brian Dolan

Induration 6 mm Induration mm

Vesiculation or Bullae Absent Vesiculation or Bullae

Ulceration or Necrosis Present Absent Could not obtain Ulceration or Necrosis

QC - No

1 of 2 End of Section Close Exam Finish

Ready Not connected to Coordinator 03:45 PM

Indicate the presence or absence of vesiculation and/or bullae by selecting “present” or “absent” from the drop-down menu. If the reader selects “present”, a pop-up confirmation box appears with the statement, “Please confirm that the vesiculation/bullae are indeed present.” Use the mouse to

direct the mouse arrow to the  button and left click if vesiculation or bullae are present. If neither is present but “present” was selected in error, change the result to “absent” at this time. If either vesiculation or bullae are present, complete the Adverse Reaction Form.

To record either “Present,” or “Absent,” or “Could not obtain,” use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, type the first letter of the correct choice and select [Tab] to move to the next field. For example, type [P/p] for “Present,” [A/a] for “Absent,” or [C/c] for “Could not obtain.” As soon as a choice is recorded, the Ulceration or Necrosis text box enables.

### 6.9.2.3 Ulceration or Necrosis – Right Arm

Ulceration and necrosis are terms that describe skin damage, usually raw, open sores.

The screenshot shows the 'TB Reader' software interface. The title bar reads 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The toolbar contains icons for file operations and help. The main window title is 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. Below the title bar, patient information is displayed: 'SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM'. The main area is titled 'TB Skin Testing - Reader's Screen'. It shows 'Date of Application: Dec. 28, 1999', 'Time of Application: 01:35 PM', and 'Time from Application: 51 hrs 8 min'. There are two columns for 'Right Arm' and 'Left Arm'. The 'Right Arm' column has 'Induration' set to '6 mm', 'Vesiculation or Bullae' set to 'Absent', and 'Ulceration or Necrosis' set to 'Present'. The 'Left Arm' column has 'Induration' set to an empty field, 'Vesiculation or Bullae' set to an empty field, and 'Ulceration or Necrosis' set to an empty field. A 'QC - No' button is located to the right of the 'Ulceration or Necrosis' dropdown. At the bottom, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. The status bar at the bottom shows 'Ready' and 'Not connected to Coordinator | 03:45 PM'.

Indicate the presence or absence of ulceration and/or necrosis by selecting “present” or “absent” from the drop-down menu. If the reader selects “present”, a pop-up confirmation box appears with the statement, “Please confirm that the ulceration/necrosis are indeed present.” Use the mouse to direct the mouse arrow to the **OK** button and left click if vesiculation or bullae are present. If neither is present but “present” has been selected in error, change the result to “absent” at this time. If either ulceration or necrosis is present, complete the Adverse Reaction Form.

To record either “Present,” or “Absent,” or “Could not obtain,” use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice,

and left click. Alternatively, type the first letter of the correct choice and select [Tab] to move to the next field. For example, type [P/p] for “Present,” [A/a] for “Absent,” or [C/c] for “Could not obtain.” As soon as a choice is recorded, the left arm induration text box enables.

After skin reaction measurements are entered for induration, vesiculation/bullae and ulceration/necrosis for the right forearm, the data entry fields for the left forearm become enabled. If both skin tests were placed on a single forearm, ISIS indicates “Upper Forearm” rather than “Right Forearm” and “Lower Forearm” rather than “Left Forearm.”

### 6.9.2.4 Induration – Left Arm

Enter the induration measurement for the left arm.

The screenshot shows the 'TB Reader' software interface. The title bar reads 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The toolbar contains icons for file operations and help. The main window title is 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. Below the title bar, patient information is displayed: 'SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM'. The main area is titled 'TB Skin Testing - Reader's Screen'. It shows 'Date of Application: Dec. 28, 1999', 'Time of Application: 01:35 PM', and 'Time from Application: 51 hrs 8 min'. There are two columns for 'Right Arm' and 'Left Arm'. The 'Right Arm' column has 'Induration' (6 mm), 'Vesiculation or Bullae' (Absent), and 'Ulceration or Necrosis' (Absent). The 'Left Arm' column has 'Induration' (empty), 'Vesiculation or Bullae' (empty), and 'Ulceration or Necrosis' (empty). A 'Technician ID' field contains '1119' and 'Tech Name: Brian Dolan'. A 'QC - No' button is at the bottom right. The status bar at the bottom shows 'Ready', 'Not connected to Coordinator', and '03:45 PM'. Navigation buttons include 'End of Section', 'Close Exam', 'Finish', and a blue arrow button.

Read the left forearm second. Enter the measurement of the diameter of the induration in millimeters is entered in this text box. Enter the induration measurement using the keyboard numeric keys. Select [Tab] to move to the vesiculation/bullae text box.

### 6.9.2.5 Vesication or Bullae – Left Arm

Vesication and bullae are fluid-filled, blister-like lesions in the area of the TB antigen injection site.

**TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm**

File View Utilities Reports Window Help

**TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm**

SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM

**TB Skin Testing - Reader's Screen**

Date of Application: Dec. 28, 1999 Time of Application: 01:35 PM Time from Application: 51 hrs 8 min

Right Arm Left Arm Technician ID 1119  
Tech Name: Brian Dolan

Induration 6 mm Induration 6 mm

Vesication or Bullae Absent Vesication or Bullae Present  
Absent  
Could not obtain

Ulceration or Necrosis Absent Ulceration or Necrosis

QC - No

1 of 2 End of Section Close Exam Finish

Ready Not connected to Coordinator 03:46 PM

Indicate the presence or absence of vesication and/or bullae by selecting “present” or “absent” from the drop-down menu. If the reader selects “present”, a pop-up confirmation box appears with the statement, “Please confirm that the vesication/bullae are indeed present.” Use the mouse to direct the mouse arrow to the **OK** button and left click if vesication or bullae are present. If neither is present but “present” has been selected in error, change the result to “absent” at this time. If either vesication or bullae are present, complete the Adverse Reaction Form.

To record either “Present,” or “Absent,” or “Could not obtain,” use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, type the first letter of the correct choice and select [Tab] to move to the next field. For example, type [P/p] for “Present,” [A/a] for “Absent,” or [C/c] for “Could not obtain.” As soon as a choice is recorded, the Ulceration or Necrosis text box enables.

### 6.9.2.6 Ulceration or Necrosis – Left Arm

Ulceration and necrosis are terms that describe skin damage, usually raw, open sores.

**TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm**

File View Utilities Reports Window Help

**TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm**

SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM

**TB Skin Testing - Reader's Screen**

Date of Application: Dec. 28, 1999 Time of Application: 01:35 PM Time from Application: 51 hrs 8 min

Right Arm Left Arm Technician ID 1119  
Tech Name: Brian Dolan

Induration	6 mm	Induration	6 mm
Vesiculation or Bullae	Absent	Vesiculation or Bullae	Absent
Ulceration or Necrosis	Absent	Ulceration or Necrosis	Absent

QC - No

1 of 2 End of Section Close Exam Finish

Ready Not connected to Coordinator 03:47 PM

Indicate the presence or absence of ulceration and/or necrosis by selecting “present” or “absent” from the drop-down menu. If the reader selects “present”, a pop-up confirmation box appears

with the statement, “Please confirm that the ulceration/necrosis are indeed present.” Use the mouse to direct the mouse arrow to the  button and left click if vesiculation or bullae are present. If neither is present but “present” has been selected in error, change the result to “absent” at this time. If either ulceration or necrosis is present, complete the Adverse Reaction Form.

To record either “Present,” or “Absent,” or “Could not obtain, use the mouse to direct the mouse arrow to the arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Alternatively, type the first letter of the correct choice and select [Tab] to move to the next field. For example, type [P/p] for “Present,” [A/a] for “Absent,” or [C/c] for “Could not obtain.”

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

### **6.9.3 QC Readings**

If quality control measurement of skin reactions is not going to be completed on the SP, progress to the next screen. The TB Skin Testing Status screen displays.

The TB Reader’s QC screen and TB Reader’s Second QC screen are identical to the Reader’s screen used for recording the initial measurement of the skin reaction. Each QC reader enters his or her ID in the space provided in the upper right corner of the screen. Record the skin test measurements. The second and third readers do not see the measurement obtained by any previous reader. After the final set of readings is completed, selecting the “next screen” arrow brings up the TB component status screen.

If a second TB reader is available and if the SP is willing to undergo a second set of measurements for quality control purposes, select the “QC” button. To allow another reader to record their readings, use the mouse to direct the mouse arrow to the  button and left click. The “No” changes to “Yes.” When the “next screen” bright blue arrow is selected the TB Reader’s QC screen displays.

The TB Skin Testing Reader's QC Screen displays.

TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm

File View Utilities Reports Window Help

SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM

TB Skin Testing - Reader's QC Screen

Date of Application: Dec. 28, 1999 Time of Application: 01:35 PM Time from Application: 51 hrs 8 min

Right Arm Left Arm Technician ID

Tech Name:

Induration  mm Induration  mm

Vesication or Bullae  Vesication or Bullae

Ulceration or Necrosis  Ulceration or Necrosis

QC - No

2 of 3 End of Section Close Exam Finish

Ready Not connected to Coordinator 03:47 PM

Enter the technician's ID in the text box.

Complete all readings and enter results.

TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm

File View Utilities Reports Window Help

TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm

SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 03:43 PM

TB Skin Testing - Reader's QC Screen

Date of Application: Dec. 28, 1999 Time of Application: 01:35 PM Time from Application: 51 hrs 8 min

Right Arm Left Arm Technician ID 1000

Tech Name: Terri Jones

Induration 0 mm Induration 6 mm

Vesiculation or Bullae Absent Vesiculation or Bullae Absent

Ulceration or Necrosis Absent Ulceration or Necrosis Absent

QC - No

2 of 3 End of Section Close Exam Finish

Ready Not connected to Coordinator 03:51 PM

Enter a third set of QC readings by selecting the “QC” button at the bottom of the TB Reader’s QC Screen. The “No” will change to “Yes” on this screen as it did on the previous screen when this button was selected. When the “next screen” arrow is selected the TB Reader’s Second QC Screen is displayed.

## 6.9.4 TB Section Status

ISIS assigns the component status for measurement of the skin reaction based on the following criteria:

- Complete - measurements of the skin reaction for both skin tests are recorded
- Partial - measurement of the skin reaction for only one skin test is recorded
- Not done - no measurement of the skin reaction is recorded

Review the TB status screen.

The screenshot displays the TB Reader software interface. The title bar reads "TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains icons for file operations and help. The main window title is "TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm". The patient information bar shows "SP ID: 930802", "Name: MAYNES, JEN", "Age: 37 years", "Gender: Female", "Date: 03/15/2000", and "Time: 03:43 PM". The main content area is titled "TB Skin Testing - Status". It features a "Status" section with three radio buttons: "Complete" (selected), "Partial", and "Not Done". Below this are a "Comments" dropdown menu and an "Other text" text input field. The bottom navigation bar includes "End of Section", "Close Exam", and "Finish" buttons, along with a "3 of 3" indicator and a right arrow. The system tray at the bottom shows "Ready", "Not connected to Coordinator", and "03:52 PM".

Enter a required comment if the component status is “partial” or “not done.”

Choose and enter the appropriate comment code when the TB Skin Testing status is partial or not done. To record a comment in the Comments text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

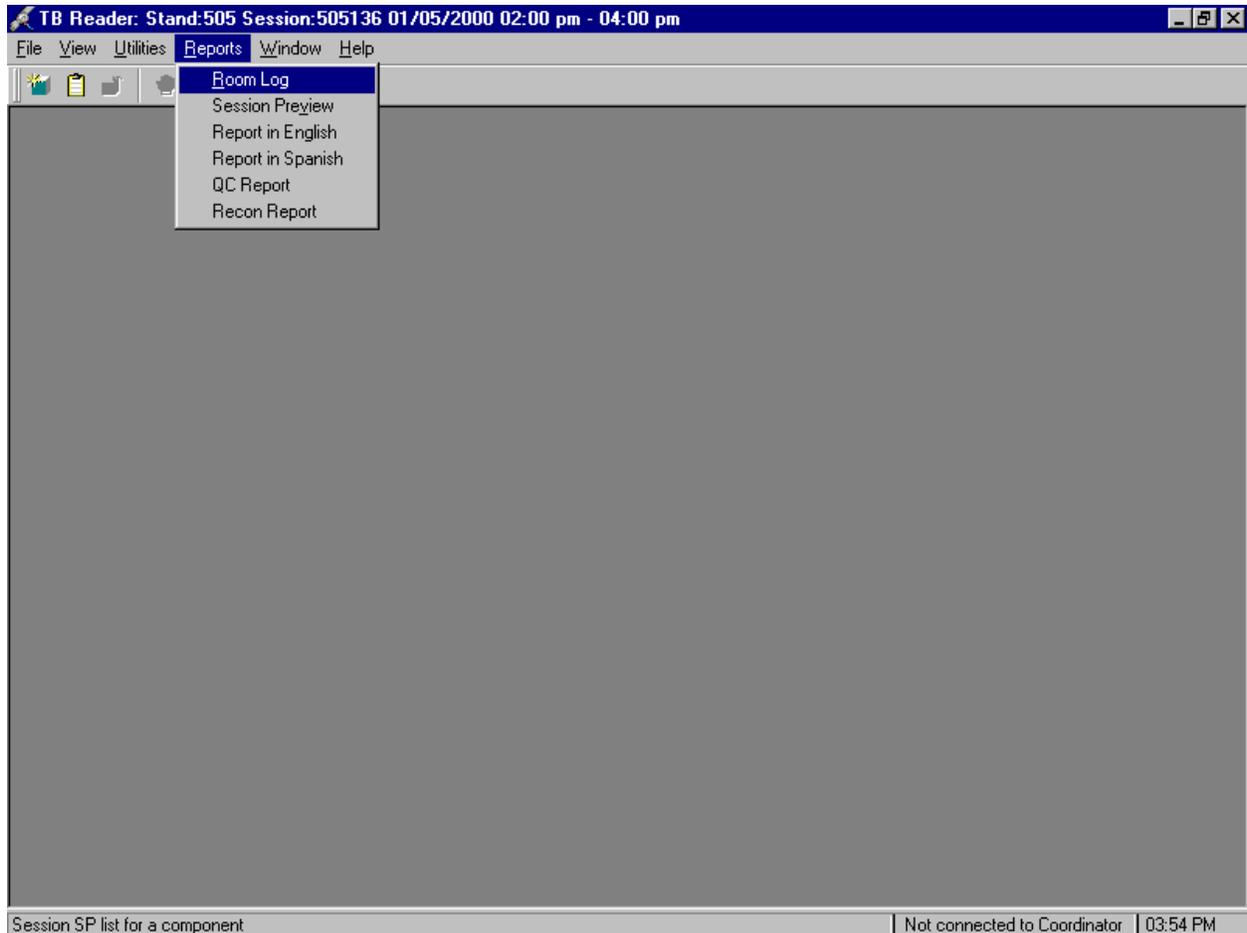
Comment Code	Use when:
safety exclusion	Not applicable
SP refusal	The SP refuses to have the skin test read. This is SP initiated nonresponse due to refusal. The SP refuses the component or a part of the component for any reason other than an illness or emergency.
no time	Not applicable
physical limitation	SP is unable to have the test due to a physical problem.
communication problem	SP is unable to understand and follow instructions for the component due to language, cognitive impairment, or other problem, and is unable to complete the test.
equipment failure	Not applicable.
SP ill/emergency	The SP became ill or an emergency occurred and the test could not be performed on the SP.
interrupted	The exam is interrupted, usually for a field office-wide emergency, and cannot be completed by the SP.
SP did not meet fast	Not applicable
other, text	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, text and record a comment in the text field.

When finished, use the mouse to direct the mouse arrow to the  button in the bottom navigation bar and left click to end the exam or select [Enter] when this  button is highlighted.

## 6.10 Room Log

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

Access the Room Log.



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

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

**TB Skin Test Reader Room Log** 03/15/2000 03:53 PM  
Stand: 505

Session: 5051531 01/05/2000 02:00 PM - 04:00 PM Total: 1 SPs

SP ID	SP Name	Gender	Age	Component Status
930802	Jen Maynes	Female	37	complete

Page 1 of 1

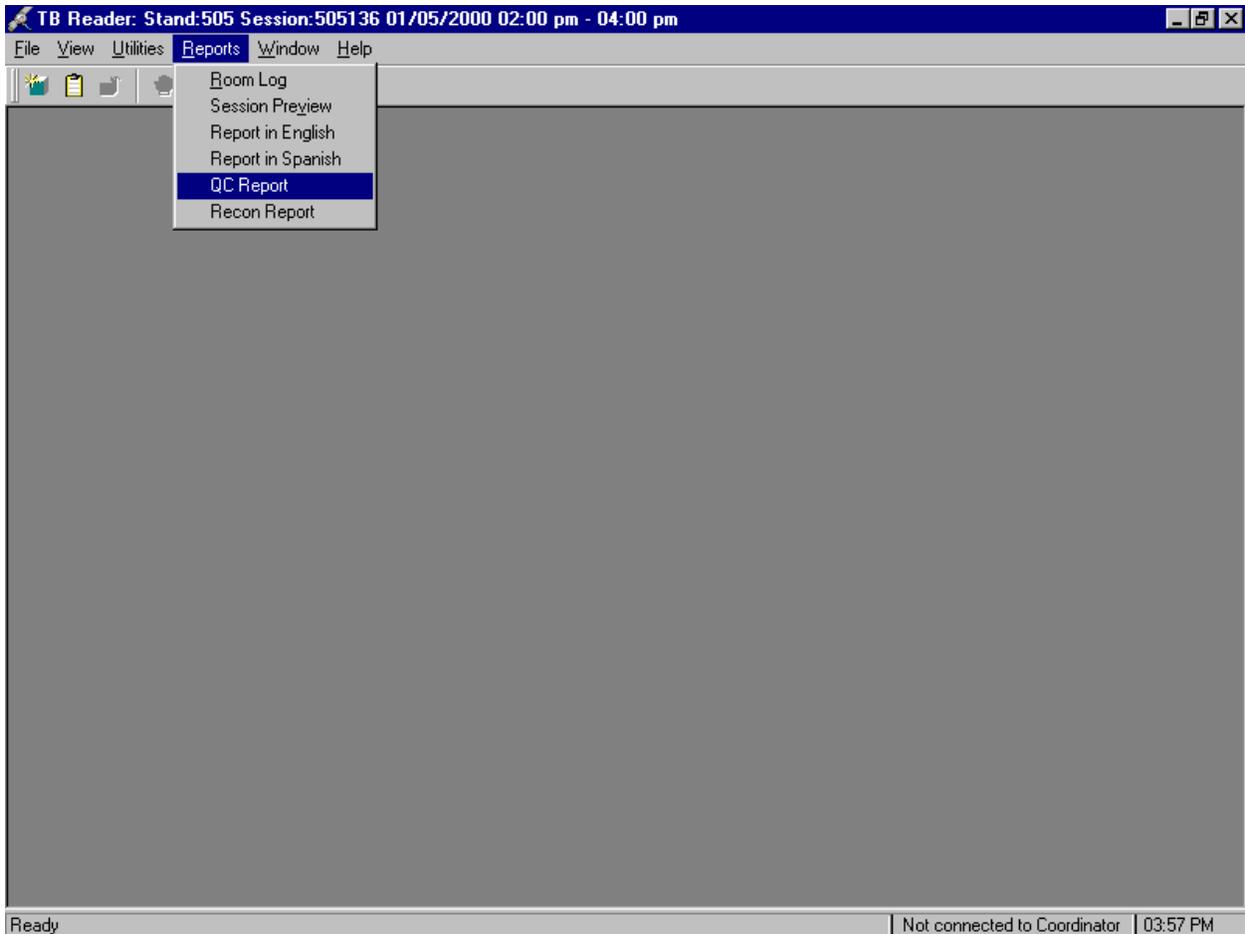
Ready | Not connected to Coordinator | 03:52 PM

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

## 6.11 QC Report

The QC Report is available in ISIS.

Access the QC Report.



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

The QC report displays.

**TB Reader Quality Control Report**  
 Stand #: 107 Stand Name: Poolside, CA  
 TB Exam Dates From: 09/07/1999 To: 03/07/2000  
 Page 1 of 4 Sorted by Date of Reading 03/15/2000 03:58 PM

Read Date	Tech 1	PPD-S	PPD-B	Tech 2	PPD-S	PPD-B	Tech 3	PPD-S	PPD-B
09/07/1999	Timothy Quinlan	5	5						
09/13/1999	Stephen Bernas	0	0						
09/13/1999	Denise Schaar	0	0						
09/20/1999	Judy Gibson	0	0						
10/07/1999	Lauren Lambert	5	5						
10/11/1999	Judy Gibson	0	0						
10/11/1999	Judy Gibson	0	0						
10/14/1999	Terri Jones	10	10						
10/14/1999	Judy Gibson	0	0						
10/18/1999	Stephen Bernas	0	0						
10/18/1999	Stephen Bernas	0	0	Michelle Sells	0	0	Taylor Cooper	0	0
10/18/1999	Stephen Bernas	0	0	Taylor Cooper	0	0			
11/02/1999	Charlotte Stroman	0	0						
11/02/1999	Charlotte Stroman	0	0	Judy Gibson	0	0			

NHANES

Ready | Not connected to Coordinator | 03:58 PM

The QC report includes stand number, Stand Name, From and To Exam Dates, the date of each TB reading, the technician associated with the reading, the results associated with the technician, the second technician's name and readings and the third technician's name and readings.

Print the TB Reader Quality Control Report.

**TB Reader Quality Control Report**  
 Stand #: 107 Stand Name: Poolside, CA  
 TB Exam Dates From: 09/07/1999 To: 03/07/2000

Page 1 of 4 Sorted by Date of Reading 03/15/2000 03:58 PM

Read Date	Tech 1	PPD-S	PPD-B	Tech 2	PPD-S	PPD-B	Tech 3	PPD-S	PPD-B
09/07/1999	Timothy Quinlan	5	5						
09/13/1999	Stephen Bernas	0	0						
09/13/1999	Denise Schaar	0	0						
09/20/1999	Judy Gibson	0	0						
10/07/1999	Lauren Lambert	5	5						
10/11/1999	Judy Gibson	0	0						
10/11/1999	Judy Gibson	0	0						
10/14/1999	Terri Jones	10	10						
10/14/1999	Judy Gibson	0	0						
10/18/1999	Stephen Bernas	0	0						
10/18/1999	Stephen Bernas	0	0	Michelle Sells	0	0	Taylor Cooper	0	0
10/18/1999	Stephen Bernas	0	0	Taylor Cooper	0	0			
11/02/1999	Charlotte Stroman	0	0						
11/02/1999	Charlotte Stroman	0	0	Judy Gibson	0	0			

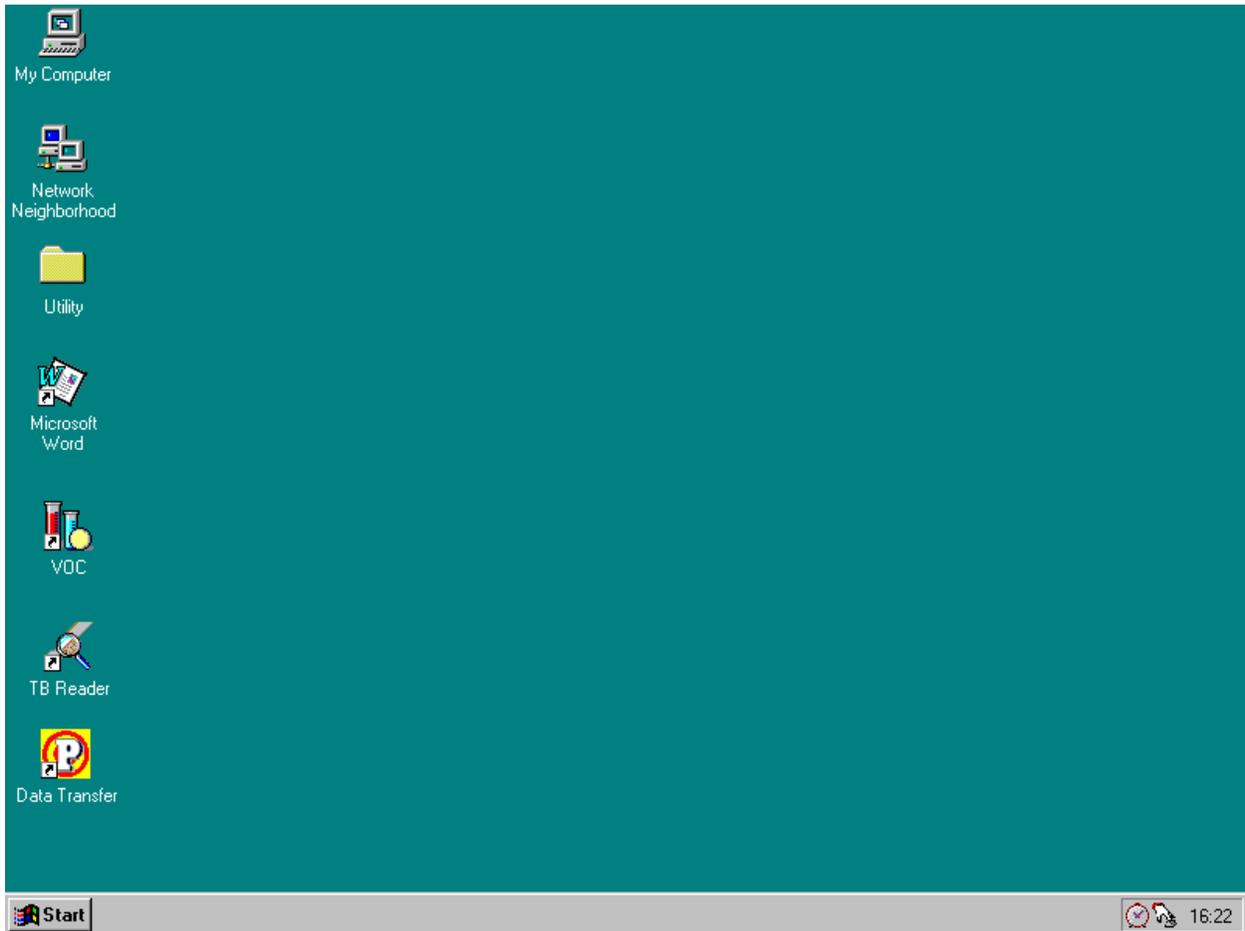
NHANES

Prints the item | Not connected to Coordinator | 03:58 PM

To print the TB Reader Quality Control Report, use the mouse to direct the mouse arrow to {File} in the menu bar, drag the mouse arrow to {Print} and left click or type [Alt] [F] [P].

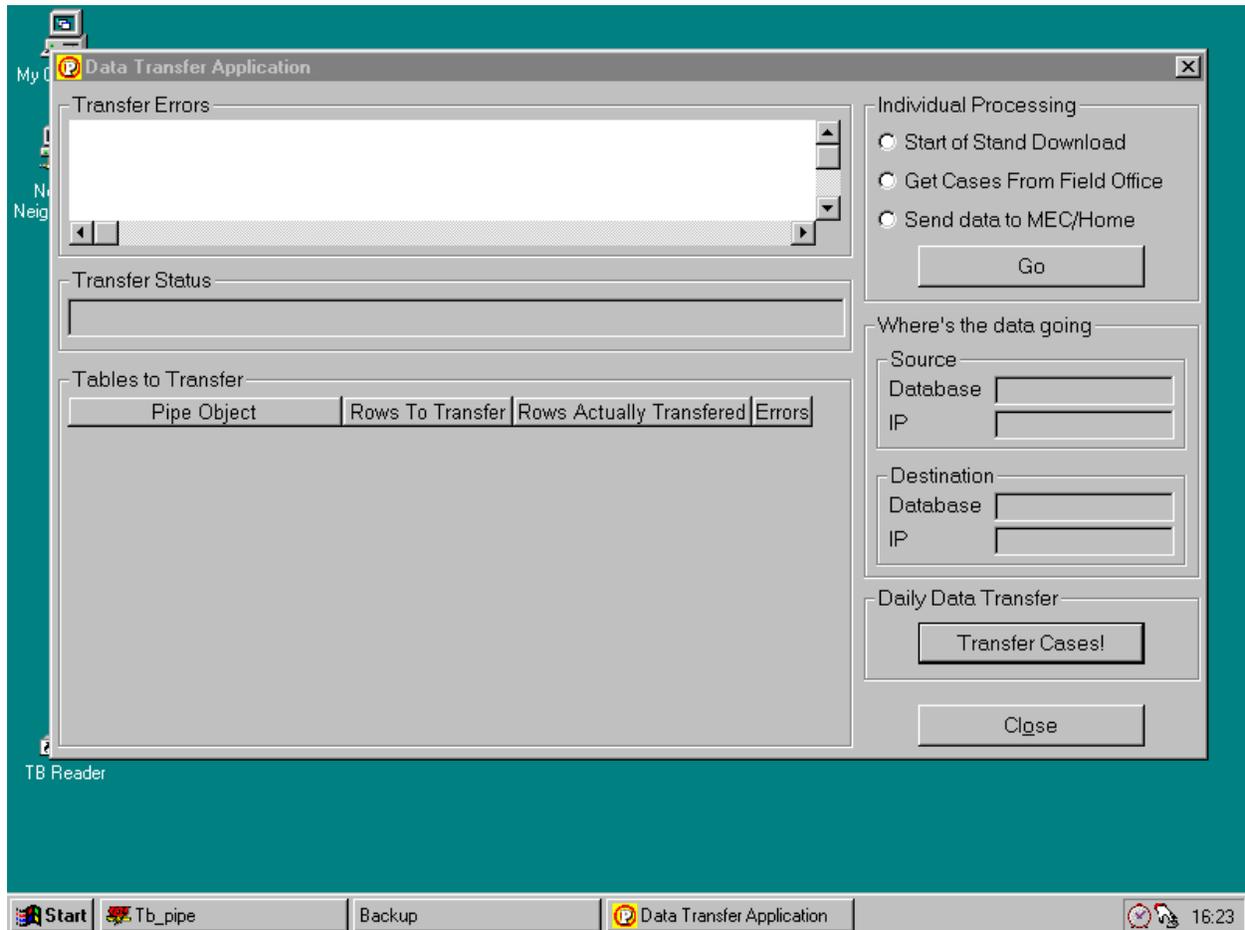
## 6.12 Data Transfer

Access the Data Transfer application.



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

The data transfer application window displays.



The data transfer application includes three functions:

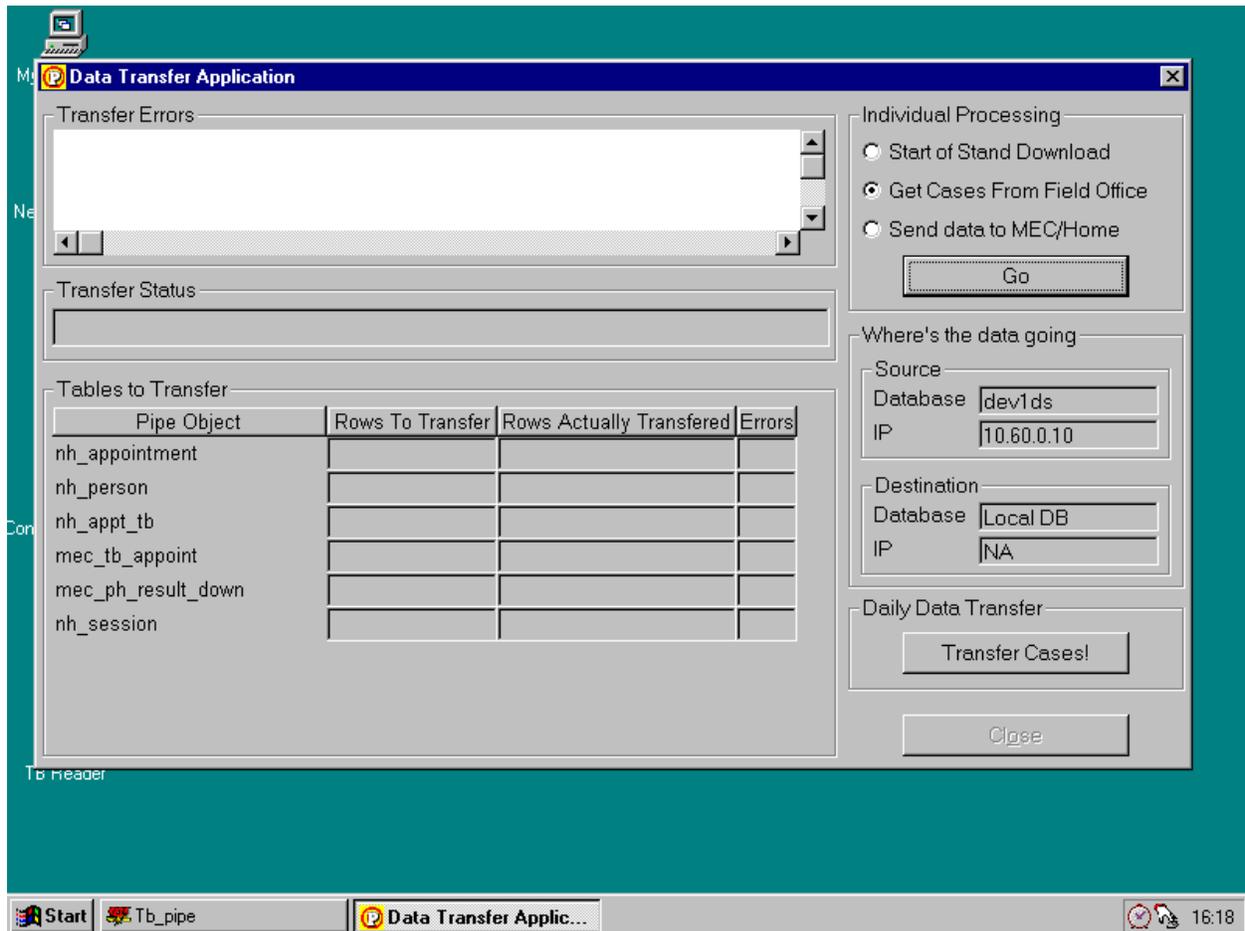
- Start of Stand Download
- Get Cases from Field Office
- Send Data to MEC/Home

The data manager performs the start of stand download as part of their start of stand activities.

- Use the Daily Data Transfer button routinely to transmit data between the MEC, field office and home office at the start and end of each workday.
- Use the “Get Cases from the Field Office” whenever the MEC server is not accessible.

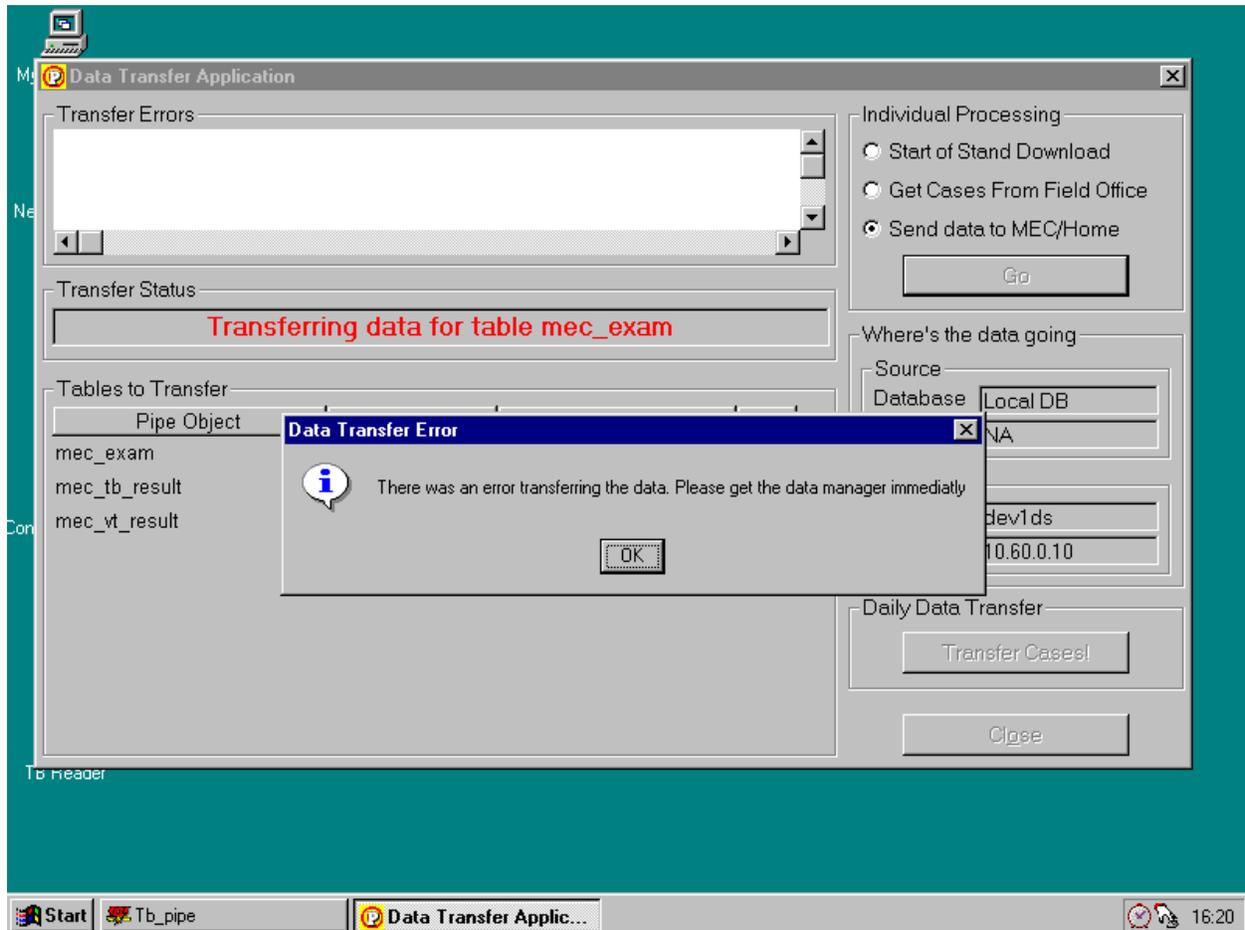
- Use the “Send Data to MEC/Home” download at the end of the final end-of-stand home readings.

Perform the various downloads.



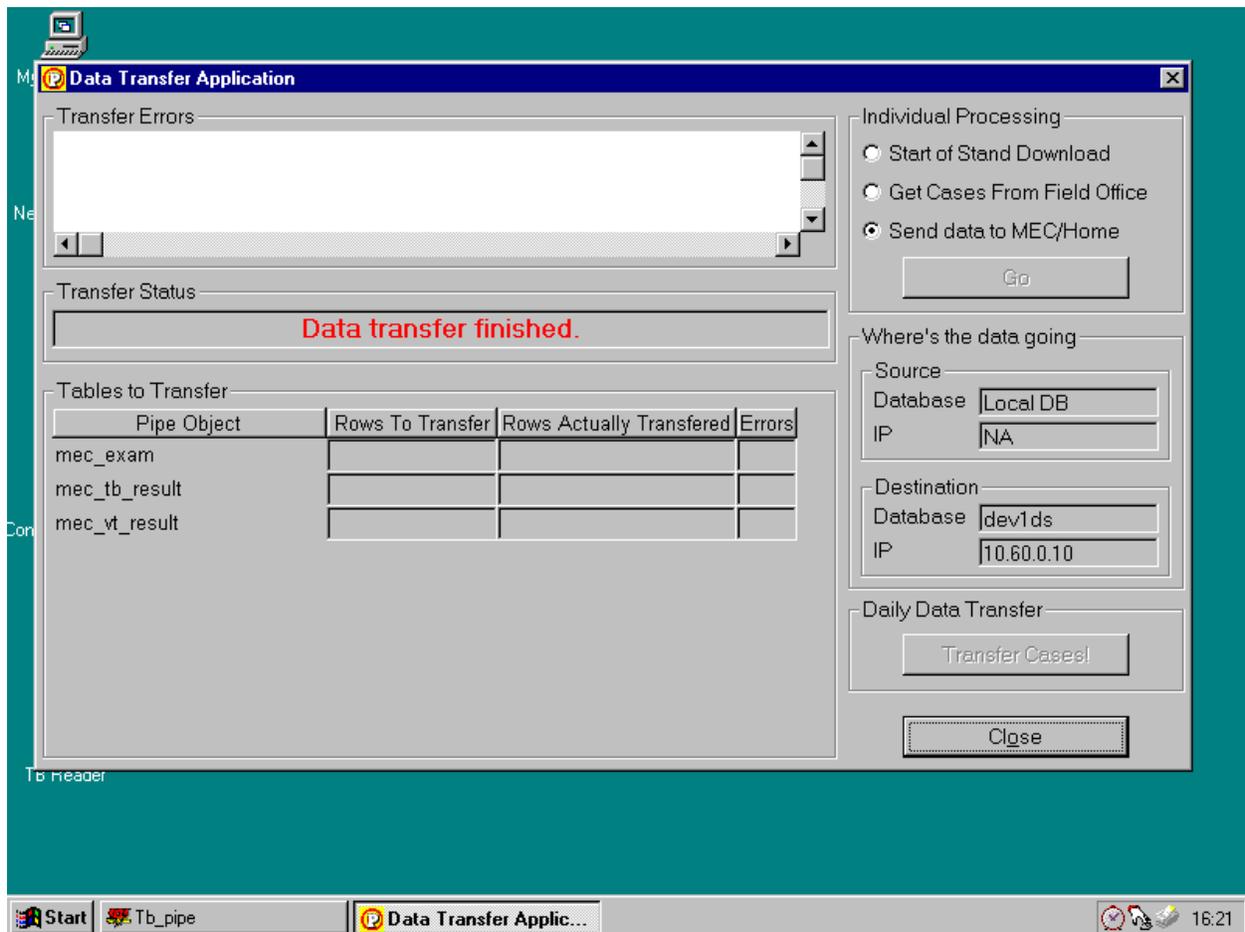
To begin a download, use the mouse to direct the mouse arrow to the Transfer Cases button and left click. To select one of the individual processing alternatives, use the mouse to direct the mouse arrow to the correct radio button and left click. To continue, use the mouse to direct the mouse arrow to the **Go** button and left click or select [Enter].

Review any data transfer error messages.



If an error is detected during the transfer process, a Data Transfer Error information message box displays. Review the data transfer message and contact the data manager. To remove the message box, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter].

The Transfer Status bar provides an update when the status is complete.

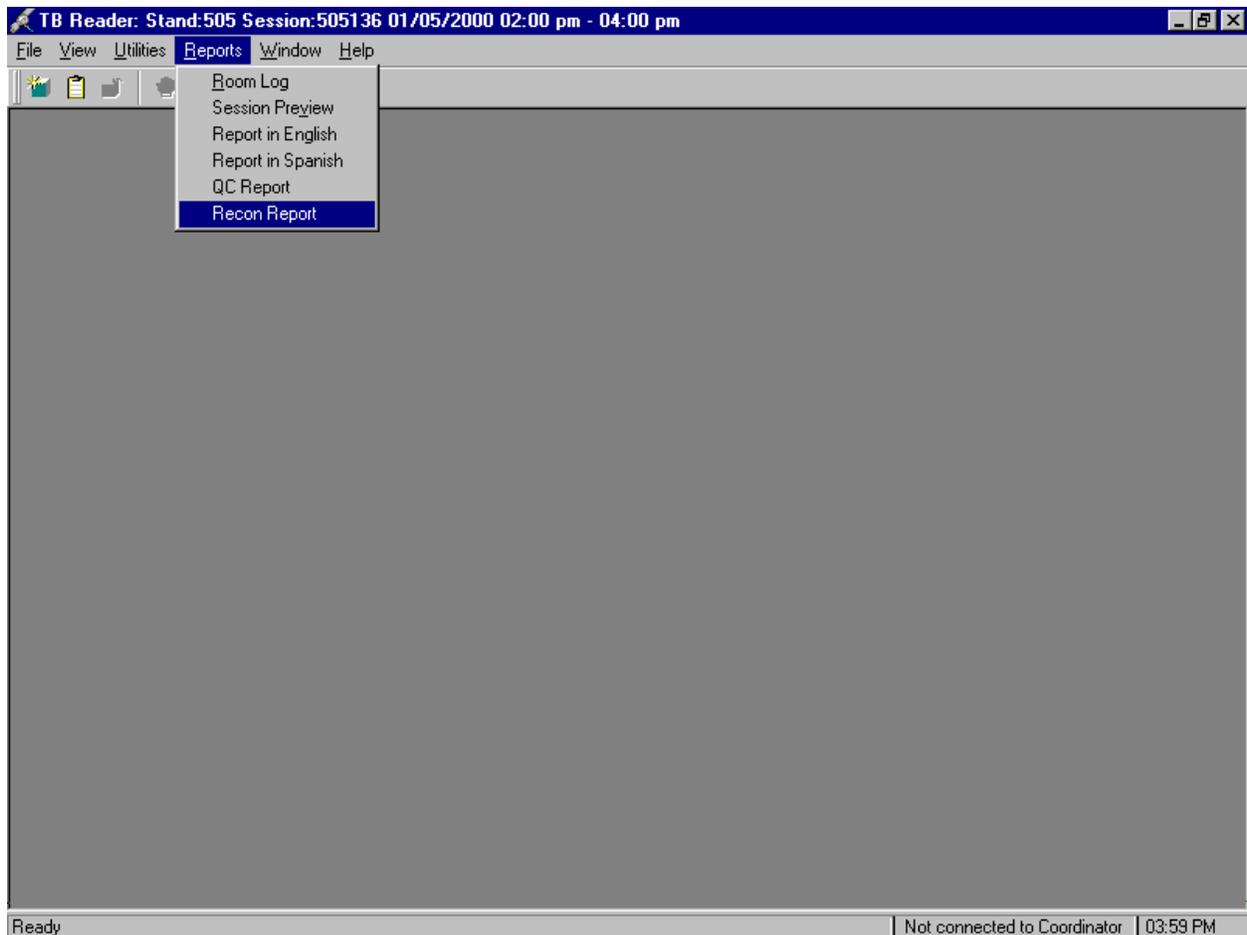


To close the Data Transfer application, use the mouse to direct the mouse arrow to the Close button and left click, type [O], or select [Enter] when the **C**lose button is highlighted.

## 6.13 TB/VOC Reconciliation Report

Access, print, and review the TB/VOC Reconciliation Report daily after completing the data transfer to review the status of all TB and VOC examinations and appointments.

Access the Recon Report.



To access the Recon (Reconciliation) report, use the mouse to direct the mouse arrow to {Reports} in the menu bar, drag the mouse arrow to {Recon Report} and left click.

The TB/VOC Reconciliation Report displays.

**TB/VOC Reconciliation Report**  
 Stand 107 Stand Name: Poolside, CA  
 Exam Dates From: 07/09/1999 To: 09/25/1999  
 Sorted by Exam Type, Tech ID, TB Exam Date/Time and Appointment Status  
 Page 1 of 23 03/15/2000 04:00 PM

SP Name	Application Date		Exam Status		Appointment Status	
	SP ID	App Dt	Status	Exam Date/Time	Session	Status
<b>TB Not done/In progress</b>						
ALVAREZ, YULIANA	287187	8/7/99			107356	Examined
ANGEL, MARIA	710763	8/9/99			107374	Examined
ANGEL, JOSE	751817	8/9/99			107374	Examined
ARELLANO, MARIA	654551	8/8/99			107368	Examined
ARROYO, RUFINA	459020	2/15/00			107332	Scheduled
ARROYO, JULIAN	897468	8/2/99			107316	Examined
ARROYO, ELVIA	716829	8/2/99			107316	Examined
BASIC, FIKRET	377212	2/25/00			107042	Scheduled
BATHANI, ATRI	824405	8/2/99			107308	Examined
BAXTER, KRISTA	864210	8/12/99			107413	Examined
BELL, KARL	766629	8/1/99			107298	Scheduled
BELL, EBONI	937631	8/12/99			107407	Examined
BENITEZ, JESSICA	218051	8/14/99			107428	Examined

**NHANES - Report #128**

Ready | Not connected to Coordinator | 04:00 PM

The TB/VOC Reconciliation report includes the Stand Number, Stand Name, From and To Exam Dates, and a line for each TB or VOC SP. The line for each SP includes the SP's Name (last, first), SP ID, Appointment Date, Exam Status, Exam Date/Time, Appointment Session Number and Appointment Status.

Use this report to reconcile appointments and exam statuses from all SPs. ISIS captures and updates each SP's examination status after each data transfer. Exams should have a complete, partial or not done status, depending on the exam's final disposition. Each SP should have either a "Scheduled" or "Examined" appointment status. If the appointment status is blank, the SP should show up on the SPs Needing TB Appointment Report. After completing an exam the TB readers mark the scheduled appointment status as either "Complete" or "No Show," depending on the disposition of the exam.

Print the TB/VOC Reconciliation Report daily.

**TB/VOC Reconciliation Report**  
 Stand 107 Stand Name: Poolside, CA  
 Exam Dates From: 07/09/1999 To: 09/25/1999  
 Sorted by Exam Type, Tech ID, TB Exam Date/Time and Appointment Status

Page 1 of 23 03/15/2000 04:00 PM

SP Name	Application Date		Exam Status		Appointment Status	
	SP ID	App Dt	Status	Exam Date/Time	Session	Status
<b>TB Not done/In progress</b>						
ALVAREZ, YULIANA	287187	8/7/99			107356	Examined
ANGEL, MARIA	710763	8/9/99			107374	Examined
ANGEL, JOSE	751817	8/9/99			107374	Examined
ARELLANO, MARIA	654551	8/8/99			107368	Examined
ARROYO, RUFINA	459020	2/15/00			107332	Scheduled
ARROYO, JULIAN	897468	8/2/99			107316	Examined
ARROYO, ELVIA	716829	8/2/99			107316	Examined
BASIC, FIKRET	377212	2/25/00			107042	Scheduled
BATHANI, ATRI	824405	8/2/99			107308	Examined
BAXTER, KRISTA	864210	8/12/99			107413	Examined
BELL, KARL	766629	8/1/99			107298	Scheduled
BELL, EBONI	937631	8/12/99			107407	Examined
BENITEZ, JESSICA	218051	8/14/99			107428	Examined

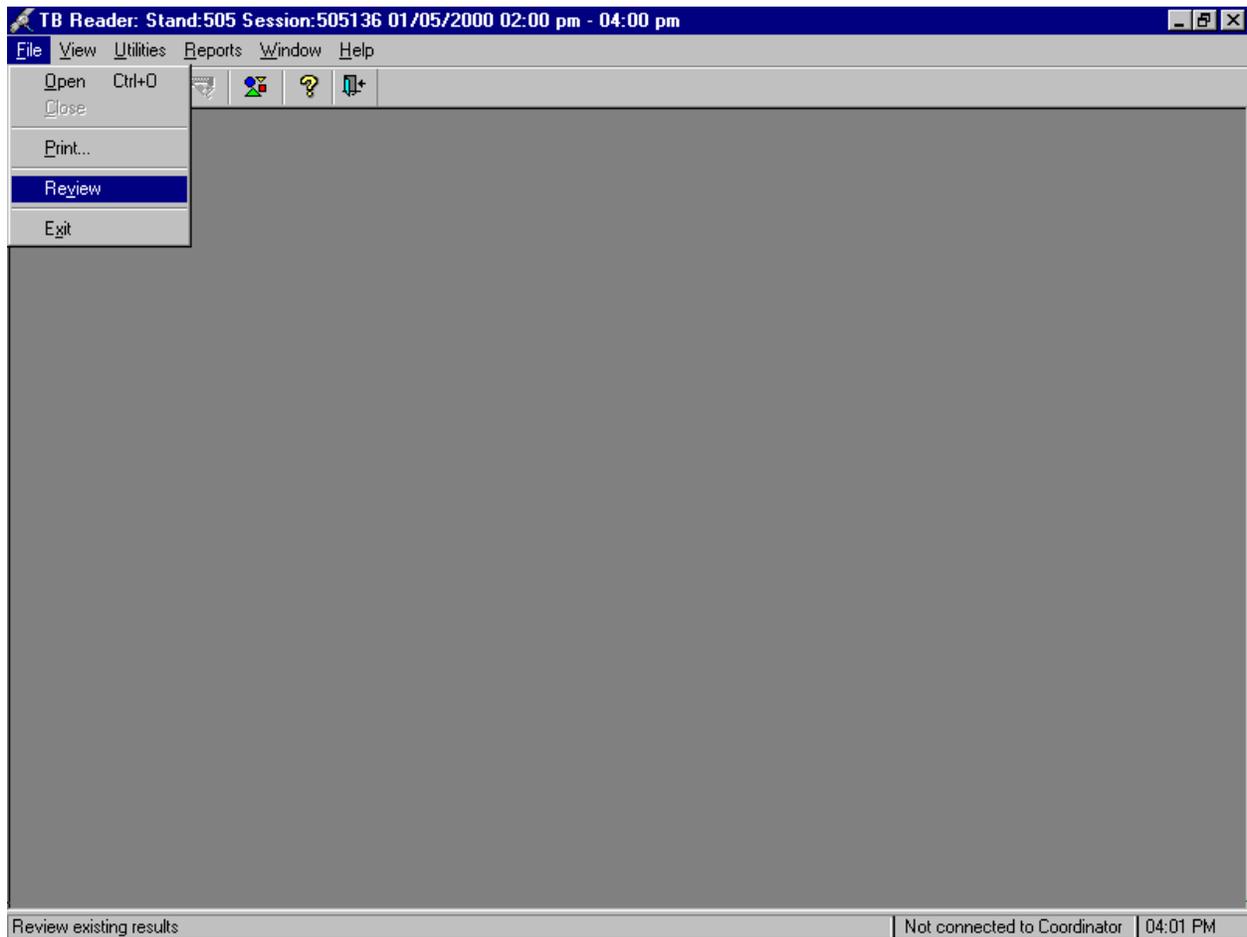
**NHANES - Report #128**

Prints the item Not connected to Coordinator | 04:00 PM

To print the TB/VOC Reconciliation Report, use the mouse to direct the mouse arrow to {File} in the menu bar, drag the mouse arrow to {Print} and left click or type [Alt] [F] [P].

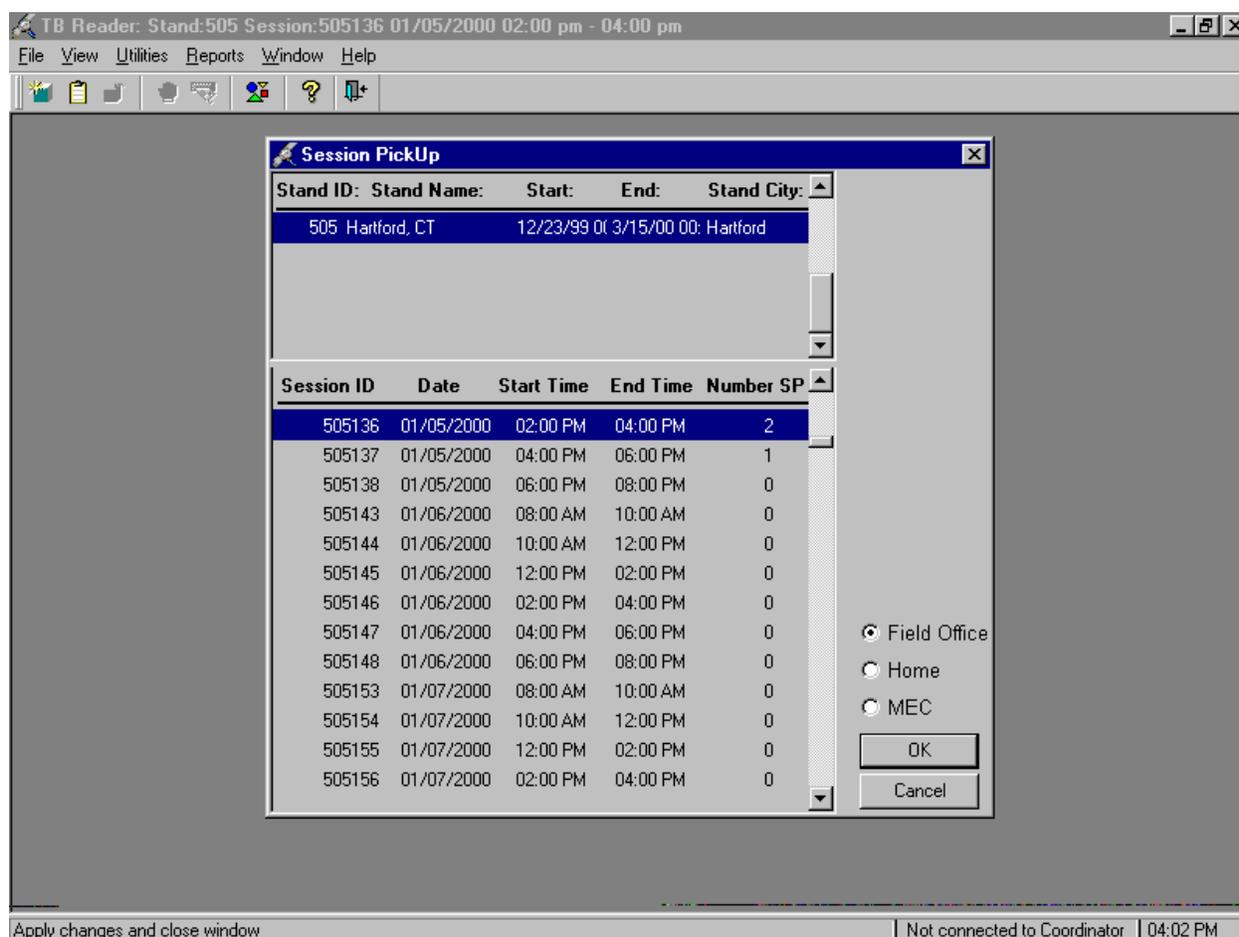
## 6.14 Review an Exam

Review a completed exam. Access the Review module.



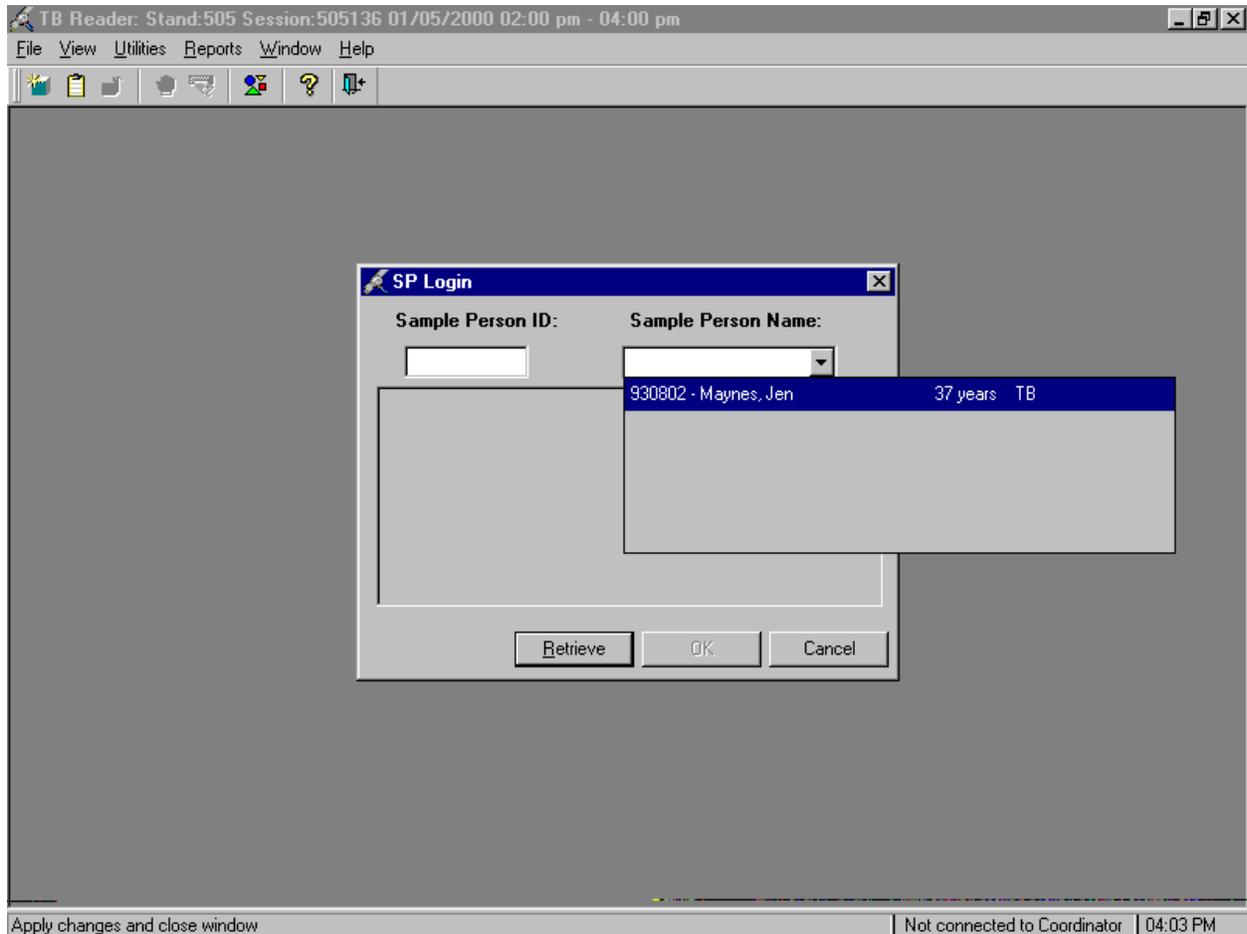
To access the Review module, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the mouse arrow to {Review} and left click, or type [Alt] [F], [V]. The Session Pickup list displays.

Select the session.



Select the correct filter (Field Office, Home, or MEC) and session from the Session Pickup list. To select a filter, use the mouse to direct the mouse arrow to the desired radio button and left click. To select a session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Select the SP.



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

Continue to select the SP.

The screenshot shows a window titled "TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm". Inside the window is a dialog box titled "SP Login". The dialog box has two main sections: "Sample Person ID:" with a text box containing "930802", and "Sample Person Name:" with a dropdown menu showing "930802 - Maynes". Below these are several input fields: "Last Name:" with "MAYNES", "First Name:" with "JEN", "Middle Name:" (empty), "Date of Birth:" with "05/15/1962", "Gender:" with "Female", and "Age at Interview:" with "37 years". There is also a "Special Considerations:" field which is empty. At the bottom of the dialog box are three buttons: "Retrieve", "OK", and "Cancel". The "OK" button is highlighted with a dashed border. The status bar at the bottom of the window shows "Apply changes and close window" on the left, "Not connected to Coordinator" in the middle, and "04:03 PM" on the right.

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

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

The TB Skin Testing Readers Screen displays.

The screenshot shows the 'TB Reader' software interface. The title bar indicates the session details: 'TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm'. The menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The patient information section displays: 'SP ID: 930802', 'Name: MAYNES, JEN', 'Age: 37 years', 'Gender: Female', 'Date: 03/15/2000', and 'Time: 04:04 PM'. The main section is titled 'TB Skin Testing - Reader's Screen'. It shows the 'Date of Application' as 'Dec. 28, 1999' and 'Time of Application' as '01:35 PM', with a 'Time from Application' of '51 hrs 8 min'. The interface is divided into two columns for 'Right Arm' and 'Left Arm'. For each arm, there are three rows of data: 'Induration' (with a text input field containing '6' and a unit 'mm'), 'Vesiculation or Bullae' (with a dropdown menu set to 'Absent'), and 'Ulceration or Necrosis' (with a dropdown menu set to 'Absent'). A 'Technician ID' field contains '1119' and the 'Tech Name' is 'Brian Dolan'. A 'QC - Yes' button is located at the bottom right of the main area. The bottom status bar shows 'Ready', 'Not connected to Coordinator', and '04:04 PM'. Navigation controls at the bottom include a page indicator '1 of 2', buttons for 'End of Section', 'Close Exam', and 'Finish', and a large blue arrow button in the bottom right corner.

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

If there are second and third TB QC readings, these screens display.

The screenshot shows a software window titled "TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm". The interface includes a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar with various icons. The main content area is titled "TB Skin Testing - Reader's QC Screen" and displays patient information: "SP ID: 930802 Name: MAYNES, JEN Age: 37 years Gender: Female Date: 03/15/2000 Time: 04:04 PM".

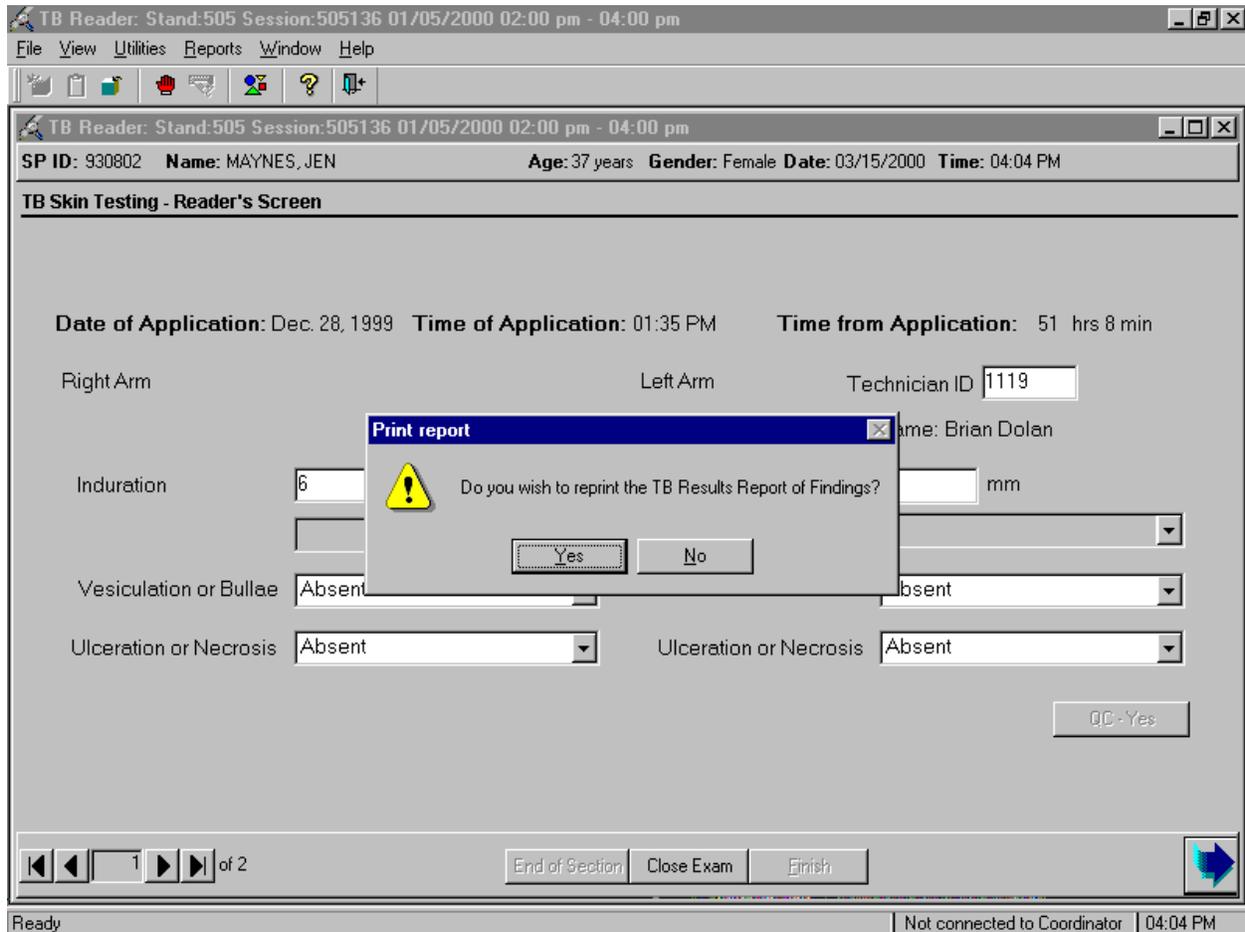
Key data points from the form:

- Date of Application: Dec. 28, 1999
- Time of Application: 01:35 PM
- Time from Application: 51 hrs 8 min
- Right Arm Induration: 0 mm
- Left Arm Induration: 6 mm
- Right Arm Vesication or Bullae: Absent
- Left Arm Vesication or Bullae: Absent
- Right Arm Ulceration or Necrosis: Absent
- Left Arm Ulceration or Necrosis: Absent
- Technician ID: 1000
- Tech Name: Terri Jones

Navigation and control elements include a "QC - No" button, a page indicator "2 of 3", and buttons for "End of Section", "Close Exam", and "Finish". A status bar at the bottom shows "Ready", "Not connected to Coordinator", and "04:08 PM".

Once the bright blue button is selected, a Print report message text box displays.

Respond to the Print Report message.



The Print report informational message text box displays the following message; “Do you wish to reprint the TB Results Report of Findings?” To reprint the ROF, use the mouse to direct the mouse arrow to the **Yes** button and left click, or select [Enter]. To decline the opportunity to reprint ROF, use the mouse to direct the mouse arrow to the **No** button and left click.

The TB Skin Test status window displays.

The screenshot shows a software window titled "TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "TB Skin Testing - Status" and contains a form with the following elements:

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

At the bottom of the window, there is a navigation bar with the following elements:

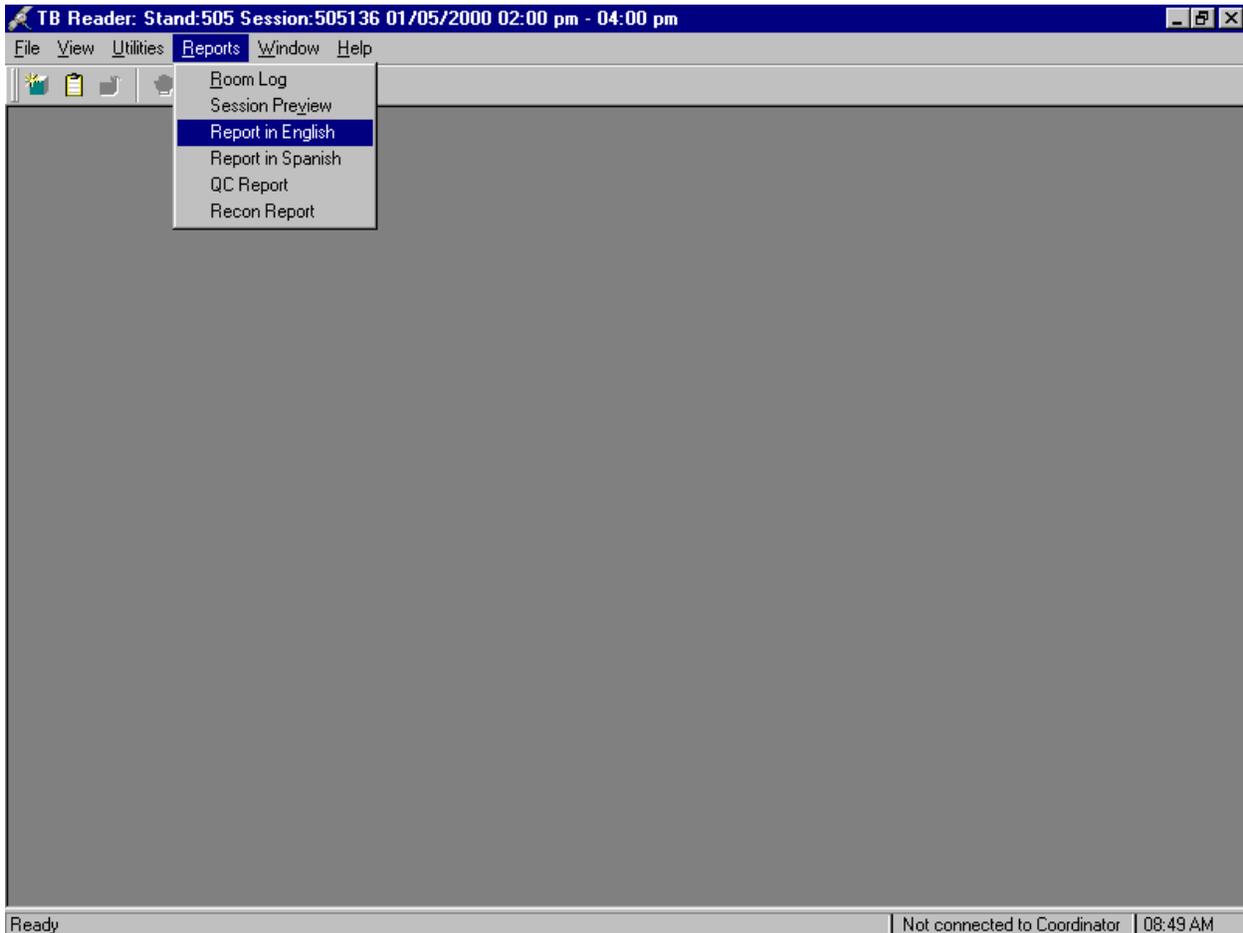
- Navigation buttons: Left arrow, double left arrow, a box containing the number "3", double right arrow, right arrow.
- Buttons: "End of Section", "Close Exam", "Finish".
- A right-pointing arrow button.

The status bar at the very bottom of the window displays "Ready" on the left, "Not connected to Coordinator" in the middle, and "04:08 PM" on the right.

To finish, select [Enter].

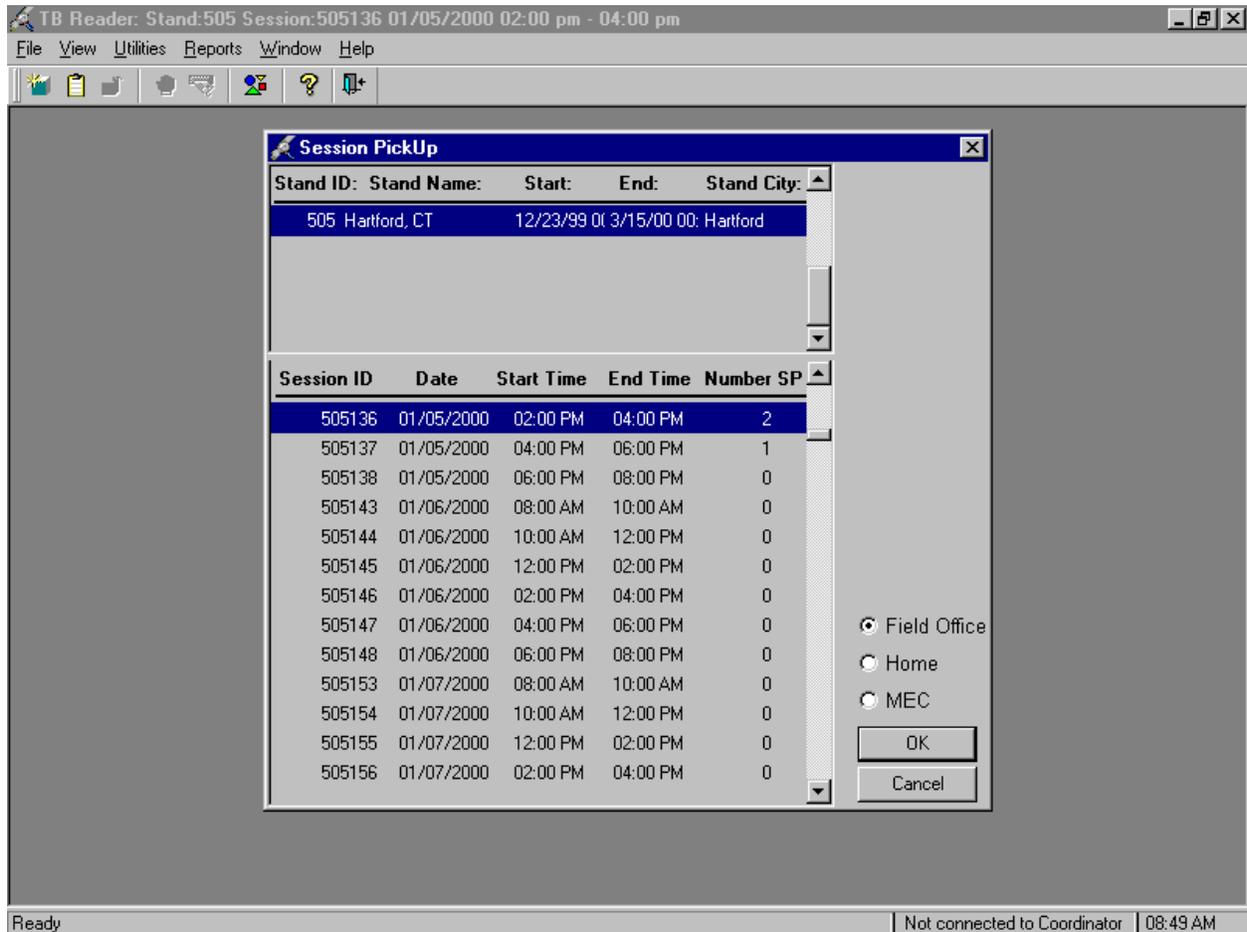
## 6.15 Reprinting Report of Findings

Reprint ad-hoc Report of Findings for individual SPs either in English or Spanish.



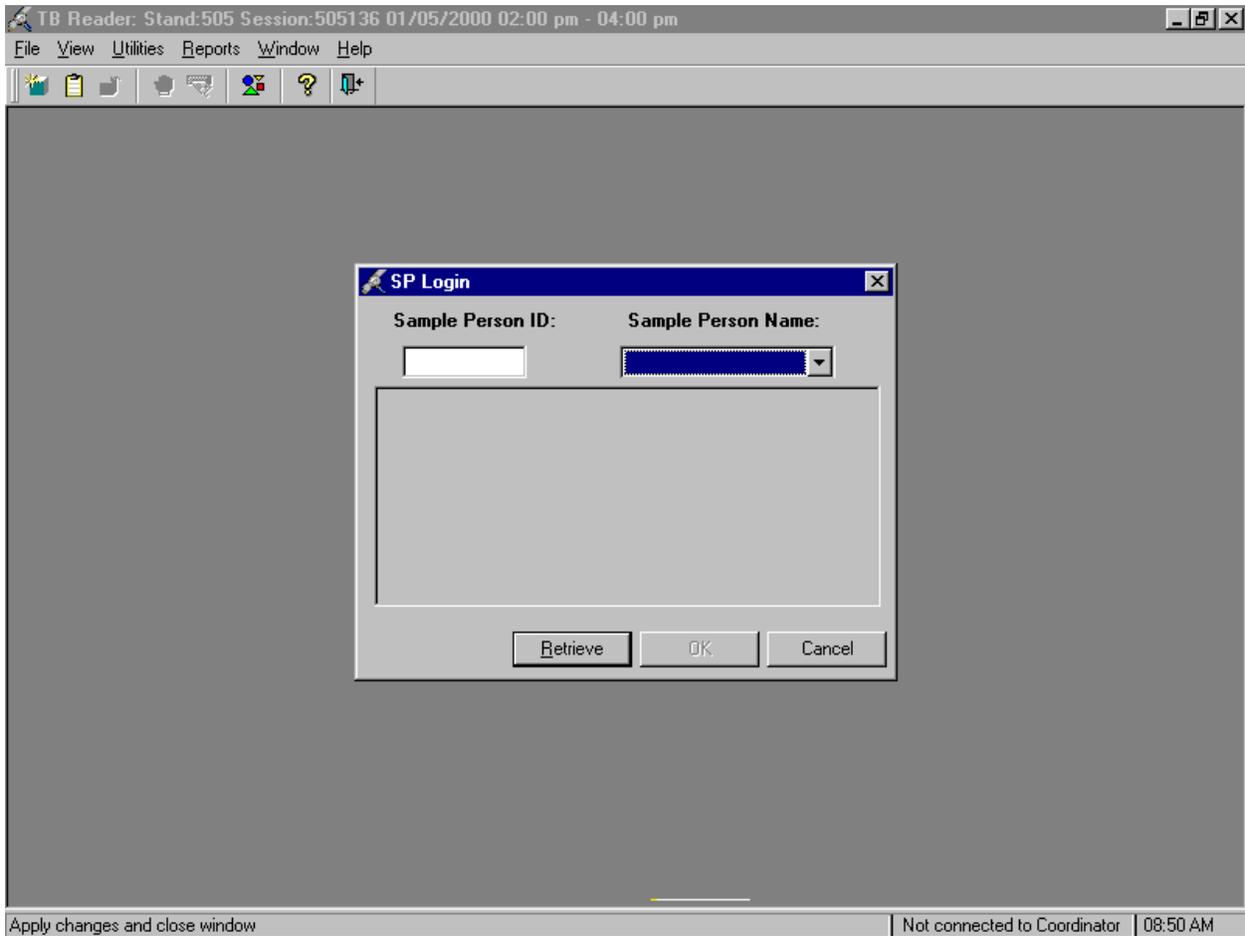
To access the Report in English or Report on Spanish reprint functionality, use the mouse to direct the mouse arrow to {Reports} in the menu bar, left click, drag the mouse arrow to either {Report in English} or {Report in Spanish} and left click.

The Session Pickup window displays.



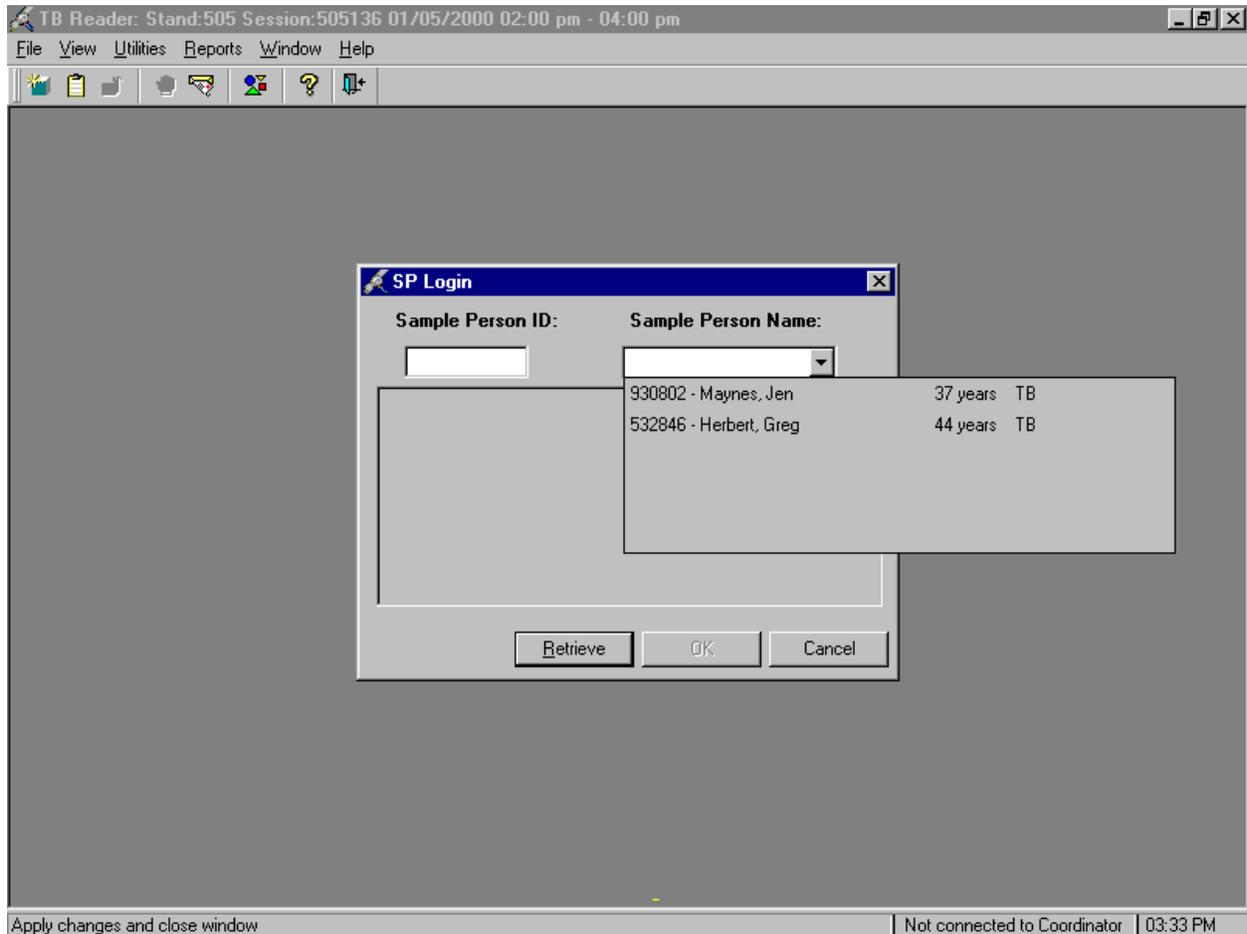
Select the correct filter (Field Office, Home, or MEC) and session from the Session Pickup list. To select a filter, use the mouse to direct the mouse arrow to the desired radio button and left click. To select a session, use the mouse to direct the mouse arrow to the correct session date and time and right click to highlight the selection. To proceed, use the mouse to direct the mouse arrow to the **OK** button and left click, or press [Enter.] To cancel, use the mouse to direct the mouse arrow to the **Cancel** button and left click.

Identify the SP.



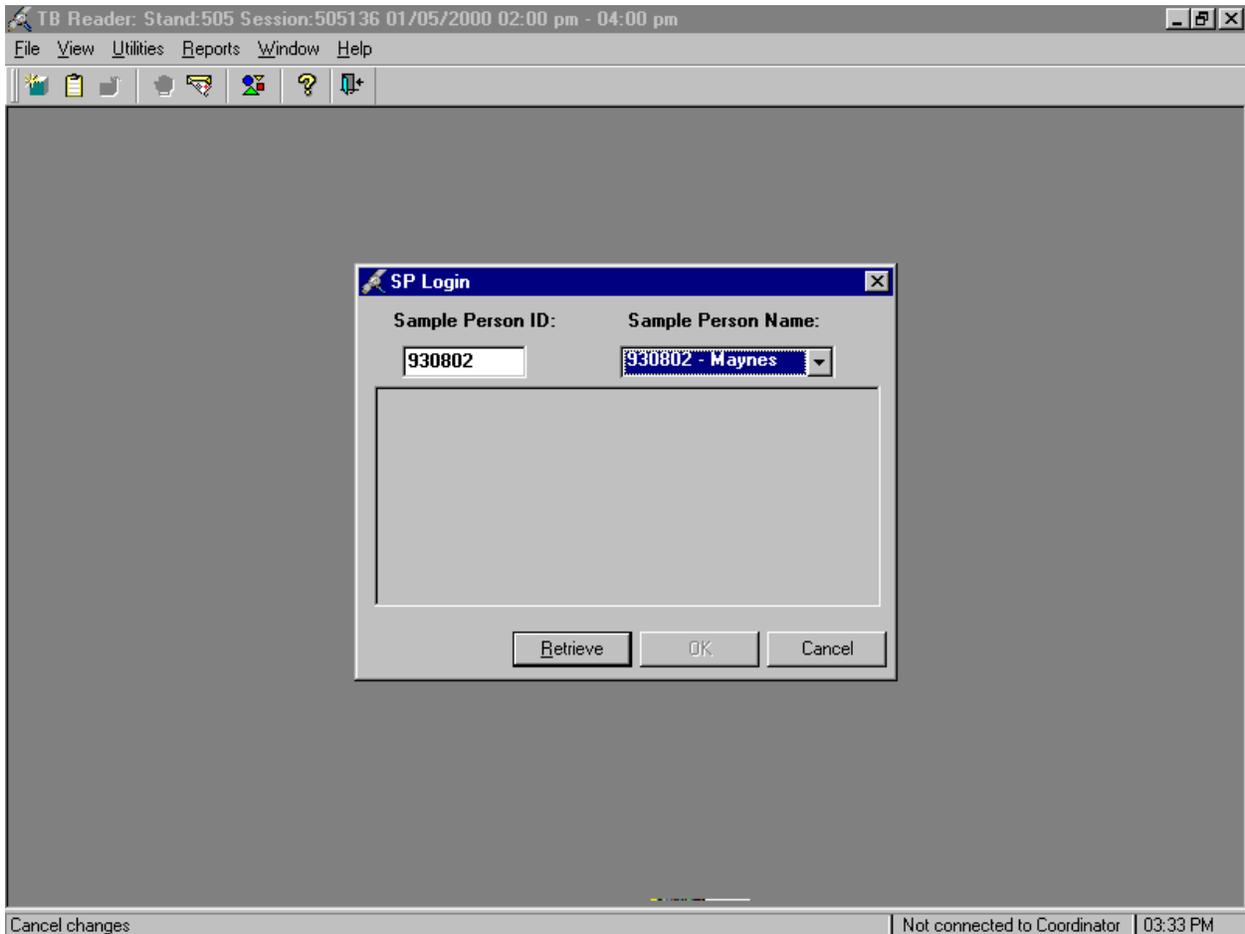
The SP Login window displays.

Continue to identify the SP.



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

Continue to select the SP.



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

Continue to select the SP.

TB Reader: Stand:505 Session:505136 01/05/2000 02:00 pm - 04:00 pm

File View Utilities Reports Window Help

**SP Login**

Sample Person ID:  Sample Person Name:

Last Name:  First Name:  Middle Name:

Date of Birth:  Gender:  Age at Interview:

Special Considerations:

Retrieve data | Not connected to Coordinator | 03:33 PM

Once the **Retrieve** button is selected, the remaining data in the SP Login window fills in. To move forward and to print the report, use the mouse to direct the mouse arrow to the **OK** button and left click or select [Enter].

