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December 19, 2019

LTC NOTICE 19-03

TO: Executive Directors and Area Agencies on Aging

FROM: Jean Stone, Division Chief
Long Term Care Programs

SUBJECT: Revised TB Skin Test Policy and Audit Tool

Effective December 1, 2019, all Area Agencies on Aging (AAAs) and Direct Service Providers (DSPs) must follow the attached revised guidelines regarding TB skin tests. Changes to the policy include the following:

1. Annual screening/ testing/chest x-ray will no longer be a requirement.
2. New hires as of 12/1/2019 will require an initial TB test and screening (see attached revised ADSS policy and Medicaid policy requirements).
3. Annual TB education will be required and must be documented. Information must include information about TB exposure risks.
4. Samples of information are attached that is available from the CDC website: <https://www.cdc.gov/tb/publications/factsheets/general/lbtbiandactivetb.htm>
5. DSPs may choose to utilize the available information sheets from the CDC. Education materials must be submitted for review and approval by ADSS.
6. Employees who have Latent TB must have a statement of such from their physician and complete the screening assessment B. The documentation must be maintained in the personnel file. The new policy recommends that the employee have treatment unless medically contraindicated.
7. Employees who are exposed to TB must follow the new policy guidelines for testing.

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December 19, 2019
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In order to be in compliance for those employees hired this month, the DSP should complete the screening assessments in addition to the TB test already performed and place in the worker's file. For those workers whose annual date falls in the month of December, ADSS will accept either a TB test or the education documentation. Please notify your DSPs of the changes as soon as possible.



Alabama Medicaid Agency

Policy Title: Home and Community Based Service (HCBS) Waiver Tuberculosis (TB) Screening Requirements	Policy Number: WAV-37
Number of Pages- 2 Attachments- A and B	Date Created: February 4, 2011 Date Revised: December 1, 2019

POLICY:

Alabama HCBS waivers require all new employees of Direct Service Providers (DSP) to have a baseline Tuberculosis (TB) screening for Latent TB Infection (LTBI) and TB disease.

Annual screening and testing of employees will no longer be a requirement. Annual TB education is required and must be documented. TB education materials must be approved by the Operating Agency.

Baseline Screening and Testing

Persons without TB disease or Latent TB- TB testing with an interferon-gamma release assay (IGRA) or a tuberculin skin test (TST) is required. The TB test must be administered, read and documented by healthcare professionals who are not employees of the Direct Service Provider.

AND

Complete the TB Screening Assessment (Attachment A). This assessment can be completed by a clinician employed by the DSP.

Persons with Latent TB- Complete the TB Screening Assessment for individuals with Latent TB (Attachment B). This assessment can be completed by a clinician employed by the DSP. Documentation of Latent TB must be included in the personnel file.

Post exposure screening and testing

For employees with a baseline negative TB test and no prior TB disease or LTBI, perform a test (IGRA or TST) when the exposure is identified. If that test is negative, do another test 8-10 weeks after the last exposure.

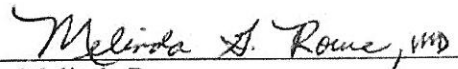
Evaluation and treatment of positive test results

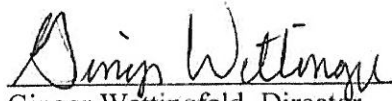
Treatment is encouraged for all employees with untreated LTBI, unless medically contraindicated.

REFERENCE:

This policy was created based upon the US Department of Health and Human Services/Centers for Disease Control and Prevention 2019 Recommendations.

Category	2019 Recommendations
Baseline screening and testing	TB screening for all HCP, including a symptom evaluation and test (IGRA or TST) for those without documented prior TB disease or LTBI (unchanged); individual TB risk assessment (new).
Post exposure screening and testing	Symptom evaluation for all HCP when an exposure is recognized. For HCP with a baseline negative TB test and no prior TB disease or LTBI, perform a test (IGRA or TST) when the exposure is identified. If that test is negative, do another test 8-10 weeks after the last exposure (unchanged)...
Serial screening and testing for employees	Not routinely recommended (new); can consider for selected HCP groups (unchanged); recommend annual TB education for all HCP (unchanged), including information about TB exposure risks for all HCP (new emphasis).
Evaluation and treatment of positive test results	Treatment is encouraged for all HCP with untreated LTBI, unless medically contraindicated (new).


Dr. Melinda Rowe
Assistant Medical Director


Ginger Wettingfeld, Director
LTC Healthcare Reform Division


Ozenia Patterson, Director
LTC Division



Alabama Medicaid Agency
TB Baseline Screening Assessment
 Attachment A to WAV-37

Symptoms	Yes	No	Comments
History of positive TB Skin Test			
Have you ever had TB disease?			
Coughed up blood			
Unplanned weight loss			
Night Sweats			
Shortness of breath			
Fatigue			
Loss of appetite			
Chest pain			
Hoarseness			
Close contact with someone who has had infectious TB disease since the last TB test.			
Temporary or permanent residence of one month or less in a country with a high TB rate. (Any country other than the U.S., Canada, Australia, New Zealand, and those in Northern Europe or Western Europe.			
Current or planned immunosuppression. Including HIV, organ transplant, treatment with a TNF-alpha antagonist, chronic steroids (equivalent of prednisone less than 15mg/day for 1 month or less) or other immunosuppressive medication			
Fever > 2 weeks duration			
Productive cough			If yes, Color _____ Consistency _____ Blood in sputum? Yes No <input type="checkbox"/> <input type="checkbox"/>

Date

Clinician Signature & Title

Date

Signature of Applicant



Alabama Medicaid Agency
TB Baseline Screening Assessment for Individuals with Latent TB
 Attachment B to WAV-37

Symptoms	Yes	No	Comments
Coughed up blood			
Unplanned weight loss			
Night Sweats			
Shortness of breath			
Fatigue			
Loss of appetite			
Chest pain			
Hoarseness			
Close contact with someone who has had infectious TB disease since the last TB test.			
Temporary or permanent residence of one month or less in a country with a high TB rate. (Any country other than the U.S., Canada, Australia, New Zealand, and those in Northern Europe or Western Europe.			
Current or planned immunosuppression. Including HIV, organ transplant, treatment with a TNF-alpha antagonist, chronic steroids (equivalent of prednisone less than 15mg/day for 1 month or less) or other immunosuppressive medication			
Fever > 2 weeks duration			
Productive cough			If yes, Color _____ Consistency _____ Blood in sputum? Yes No <input type="checkbox"/> <input type="checkbox"/>

_____ Date

_____ Clinician Signature & Title

_____ Date

_____ Signature of Applicant

Section 8.6: TB Skin Tests

Rev. 12/2019

All personnel who have contact with waiver clients must have a baseline Tuberculosis (TB) screening for Latent TB Infection (LTBI) and TB disease. All new employees must have the testing and screening assessment performed prior to providing services for waiver clients. In addition, annual TB education is required and must be documented in the employee's personnel file.

The TB Screening Assessment (WAV-37, Attachment A) must be completed as part of the baseline screening. The assessment may be completed by a clinician employed by the DSP.

In order to remain in compliance with TB screening requirements once a baseline test/screening is done, the employee must be provided TB education materials on an annual basis. The education must include information about TB exposure risks. The TB education materials must be approved by ADSS. The TB education must be completed prior to the date of the last TB test/education date. The employee must sign and date a statement indicating education was provided on that date.

Persons without TB disease or Latent TB must be tested with an interferon-gamma release assay (IGRA) or a tuberculin skin test (TST). The TB test must be administered, read, and documented by healthcare professionals who are not employees of the Direct Service Provider. The TB skin test report must be on office/clinic letterhead and indicate the date administered, the date read and the results. The report must include the name and title of the person reading the test.

Persons with Latent TB must have a TB Screening Assessment (WAV-37, Attachment B) performed. This assessment may be completed by a clinician employed by the DSP. Documentation of Latent TB (statement from physician and screening assessment) must be included in the personnel file.

Post exposure screening and testing must be performed for anyone who has been exposed to TB. A test (IGRA or TST) must be performed for those employees with a baseline negative TB test and no prior TB disease or LTBI. If that test is negative, another test should be performed 8-10 weeks after the last exposure.

Note: Treatment is encouraged for all employees with untreated LTBI, unless medically contraindicated.

Failure to comply with TB Screening Requirements will result in an audit finding and all services provided during the time of non-compliance will be considered an overpayment which is recoupable.

DSP Quality Performance Assessment

(Personnel File Review)

Name of Staff Member	Job Title of Staff Member	Hire Date of Staff Member	Audit Date
Name of Direct Service Provider		Name and Agency of Reviewer	
(The below section applies to ALL in-home workers. Also complete the section that pertains to the type of service provided by the worker.)			
Staff member's first access to client information or client contact?			DATE:
A copy of the staff member's job description is present in the employee's file (should identify responsibilities, education and experience)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains documentation that references were verified for those hired prior to 10/01/07)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted:	Comments	
Staff members and all personnel with access to client information have proof that statewide criminal background checks are documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 10/01/07.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted:	Comments	
Staff members and all personnel with access to client information have proof that sex offender checks are documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 6/30/2010.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted:	Comments	
Staff members and all personnel with access to client information have proof that nurse aide registry checks are documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 10/01/07.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted:	Comments	
Staff members and all personnel with access to client information have proof that previous employers and references are verified and documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 10/01/07.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted:	Comments	
Initial- Staff member's file contains documentation that he/she submits to a program for the testing, prevention, and control of tuberculosis. Effective for employees hired as of 12/1/2019, did the employee receive a TB test, training/education and screening at prior to client contact?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Dates:	Comments	
Annual- Has the employee received annual training/education? For employees hired prior to 12/1/2019 was their TB training/education given by the annual due date of their last TB test? Dates of last 2 trainings/education.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Dates:		
Staff member's personnel file contains an application for employment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains a record of pre-employment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains evaluations per each agency policy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains a copy of a valid, picture identification?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member meets orientation training requirements prior to service delivery?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member meets annual in-service training requirements? (These must include infection control updates. A four (4) hour annual limit for self-study i.e. videos/online is in effect.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	Previous year's hours: Current year's hours:
Staff member's file contains other forms as required by state and federal law including agreements regarding confidentiality?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's file contains an every six (6) month direct supervisory visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's file contains records of all complaints/incidents lodged by the client/family and action taken?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's file contains documentation of education (high school diploma or equivalent) (supervisor only)? (HM & CO)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
RN/LPN has a current Alabama State Board of Nursing license? (PC & SR) (530 Waiver, SN/RN or LPN)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
RN/LPN supervisor has at least two (2) years experience as a Registered Nurse or Licensed Practical Nurse? (PC & SR) (530 Waiver, SN/RN or SN/LPN)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	

DSP Quality Performance Assessment

(In-Home Worker Training Requirements)

Name of Staff Member

ADDITIONAL HOMEMAKER & UNSKILLED RESPITE (HM) REQUIREMENTS

Minimum training requirements for Homemaker prior to service delivery include all of below items. The annual in-service training is in addition to the training required prior to the provision of service. **ALL** Homemakers must have at least six (6) hours, in-service training annually from the following areas below and include topic, name and title of trainer, objective of training, date of training, outline of content, length of training, list of trainees and location. (O) = Orientation Training Requirements (A) = Annual Training Requirements

- (O) (A)
- Physical, emotional and developmental needs of population served including the need for respect of the client, his/her privacy, and his/her property.
- Maintaining a safe and clean environment;
- Providing care including individual safety, laundry, serve and prepare meals, and household management;
- First aid in emergency situations;
- Fire and safety measures;
- Client rights;
- Record keeping such as a signed service log of services delivered and a written summary to supervisor of any problems with services;
- Communication skills;
- Basic infection control/Universal Standards;
- Other areas of training as appropriate or mandated by Medicaid or the Operating Agency.

ADDITIONAL PERSONAL CARE & UNSKILLED RESPITE (PC) REQUIREMENTS

Unskilled Respite Workers must meet the same orientation and in-service training requirements as a HM and PCW dependent upon the level of care. Minimum training requirements for Personal Care prior to service delivery include all of the below items. The annual in-service training is in addition to the training required prior to the provision of service. **ALL** PC and UR Workers must have at least twelve (12) hours, in-service training annually from the following areas below and include topic, name and title of trainer, objective of training, date of training, outline of content, length of training, list of trainees and location (For PC Workers hired during the calendar year, this in-service requirement may be prorated based on date of employment as a PC Worker.)

- (O) (A)
- Physical, emotional and developmental needs of population served including the need for respect of the client, his/her privacy, and his/her property.

Activities of daily living, such as,

- Bathing (sponge, tub)
- Personal grooming
- Personal hygiene
- Meal preparation
- Proper transfer technique (assisting clients in and out of bed)
- Assistance with ambulation
- Toileting
- Feeding the client

Home support, such as,

- Cleaning
- Laundry
- Home safety

Recognizing and reporting observations of the client, such as,

- Physical condition
- Mental condition
- Emotional condition
- Prompting the client of medication regimen

Plus,

- Record keeping such as a signed service log of services delivered and a written summary to supervisor of any problems with services
- Communication skills
- Basic infection control/Universal Standards
- First aid in emergency situations
- Fire and safety measures
- Client rights and responsibilities
- Other areas of training as appropriate or mandated by Medicaid or the Operating Agency

DSP Quality Performance Assessment

(In-Home Worker Training Requirements)

Name of Staff Member

ADDITIONAL COMPANION REQUIREMENTS

Minimum training requirements for Companion prior to service delivery include all of the items below. The annual in-service training is in addition to the training required prior to the provision of service. ALL Companion Workers must have at least six (6) hours, in-service training annually from the following areas below and include topic, name and title of trainer, objective of training, date of training, outline of content, length of training, list of trainees and location.

- (O) (A)
- Physical, emotional and developmental needs of population served including the need for respect of the client, his/her privacy, and his/her property.
- Meal planning and preparation;
- Laundry/shopping;
- Provision of care and supervision including individual safety;
- First aid in emergency situations;
- Documentation of services provided per written instructions;
- Basic infection control/Universal Standards (required annually);
- Fire and safety measures;
- Assist clients with medications;
- Communication skills;
- Client rights;
- Other areas of training as appropriate or mandated by Medicaid or the Operating Agency.

ADDITIONAL SKILLED RESPITE CARE REQUIREMENTS

SKILLED RESPITE WORKER - AND SKILLED NURSING WORKER (E&D, ACT or 530 Waiver) A Licensed Practical Nurse (LPN) or Registered Nurse (RN) who meets the following additional requirements:

- (O) (A)
- Be currently licensed by the State of Alabama Board of Nursing to practice nursing.
- Have at least two (2) years of experience.
- The personnel file contains documents that the nurse submits to the program for testing, prevention, and control of tuberculosis annually.
- Be able to follow the Plan of Care with minimal supervision unless there is a change in the client's condition.
- The personnel file contains a copy of a valid, picture identification.
- The personnel file contains validation of CEUs for licensure.
- The DSP must assure Medicaid and the Operating Agency (OA) that the nurse has adequate experience and expertise to perform the skilled services and the care required.

Additional Comments

DSPQPA-1 12/2019

E&D Waiver

ACT Waiver

ADH Quality Performance Assessment

(Personnel File Review)

Name of Staff Member	Job Title of Staff Member	Hire Date of Staff Member	Audit Date
Name of Adult Day Health Provider		Name and Agency of Reviewer	
Staff member's first access to client information or client contact?			DATE: _____
A copy of the staff member's job description is present in the employee's file (should identify responsibilities, education and experience)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains documentation that references were verified for those hired prior to 10/1/ 2007)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff members and all personnel with access to client information have proof that statewide criminal background checks are documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 10/01/07.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted: _____	Comments	
Staff members and all personnel with access to client information have proof that sex offender checks are documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 6/30/2010.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted: _____	Comments	
Staff members and all personnel with access to client information have proof that nurse aide registry checks are documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 10/01/07.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted: _____	Comments	
Staff members and all personnel with access to client information have proof that previous employers and references are verified and documented in the employee's personnel file and are prior to client contact or access to client information? (This pertains to employees hired as of 10/01/07.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Date conducted: _____	Comments	
Staff member's file contains documentation that he/she submits to a program for the testing, prevention, and control of tuberculosis. Effective for employees hired as of 12/1/2019, did the employee receive a TB test, training/education and screening prior to hire?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Dates: _____	Comments	
Has the employee received annual training/education? For employees hired prior to 12/1/2019 was their TB training/education given by the annual due date of their last TB test? Dates of last 2 trainings/education.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Dates: _____		
Staff member's personnel file contains an application for employment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains a record of pre-employment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains evaluations?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's personnel file contains a copy of a valid, picture identification?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member has a valid Alabama driver's license (if transporting Adult Day Health clients)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member meets orientation training requirements prior to service delivery?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member meets annual in-service training requirements? (These must include infection control updates. A four (4) hour annual limit for self-study i.e. videos/online is in effect.)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's file contains other forms as required by state and federal law including agreements regarding confidentiality?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's file contains evidence of current CPR/first aid certification?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Staff member's file contains records of all complaints/incidents lodged by the client/family and action taken?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
RN/LPN has current Alabama State Board of Nursing license?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
RN/LPN has at least two (2) years experience as a Registered Nurse or Licensed Practical Nurse?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	

Director's personnel file contains documentation of education (high school diploma or equivalent)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Comments	
Additional Comments			

(Note: Minimum 6 hrs annual in-service training must be in the areas listed below and include topic, name and title of trainer, objective of training, date of training, outline of content, length of training, list of trainees and location.)

(O) (A)

- Behavioral interventions, acceptance, and accommodation;
- Providing care and supervision including individual safety and non-medical care;
- First aid in emergency situations;
- Documenting client's participation;
- Fire and safety measures;
- Confidentiality;
- Client rights;
- Needs of the elderly and disabled population;
- Basic infection control/Universal Standards;
- Communication skills;
- Other areas of training as appropriate or as mandated by Medicaid and the Operating Agencies.

ADHQPA-1 12/2019

E&D Waiver

ACT Waiver

Tuberculosis (TB) Facts

You Can Prevent TB

What is TB?

"TB" is short for a disease called tuberculosis. TB is spread through the air from one person to another. TB germs are passed through the air when someone who is sick with **TB disease** of the lungs or throat coughs, speaks, laughs, sings, or sneezes. Anyone near the sick person with **TB disease** can breathe TB germs into their lungs.

TB germs can live in your body without making you sick. This is called **latent TB infection**. This means you have only inactive (sleeping) TB germs in your body. The inactive germs cannot be passed on to anyone else. However, if these germs wake up or become active in your body and multiply, you will get sick with **TB disease**.

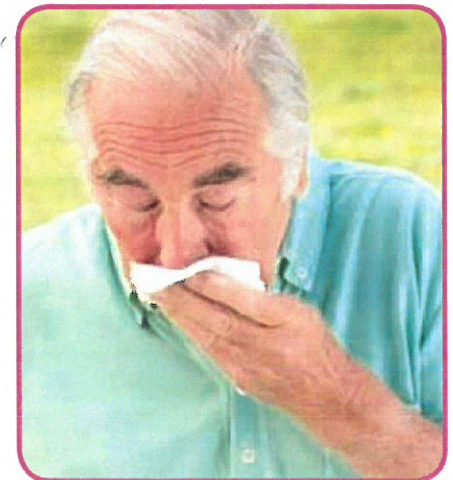
When TB germs are active (multiplying in your body), this is called **TB disease**. These germs usually attack the lungs. They can also attack other parts of the body, such as, the kidneys, brain, or spine. **TB disease** will make you sick. People with **TB disease** may spread the germs to people they spend time with every day.

How do I know if I have been infected with TB germs?

If you have been around someone who has **TB disease**, you should go to your doctor or your local health department for tests.

There are two tests that can be used to help detect **TB infection**: a TB skin test or TB blood test. The skin test is used most often. A small needle is used to put some testing material, called tuberculin, under the skin. In 2-3 days, you return to the health care worker who will check to see if there is a reaction to the test. In some cases, a TB blood test is used to test for **TB infection**. This blood test measures how a person's immune system reacts to the germs that cause TB.

To tell if someone has **TB disease**, other tests such as chest x-ray and a sample of sputum (phlegm that is coughed up from deep in the lungs) may be needed.



TB Facts: You Can Prevent TB

What should I do if I have TB?

If you have latent **TB infection**, you may need medicine to prevent getting **TB disease** later. One or more drugs are used to treat latent **TB infection**. It is important that you take your medicine exactly as your doctor or health care worker tells you.

TB disease can also be treated by taking medicine. If you have **TB disease**, it is very important that you finish the medicine, and take the drugs exactly as you are told. If you stop taking the drugs too soon, you can become sick again. If you do not take the drugs correctly, the germs that are still alive may become difficult to treat with those drugs. If you have **TB disease**, it takes six months and possibly as long as one year to kill all the TB germs.

Remember, you will always have TB germs in your body unless you kill them with the right medicine.

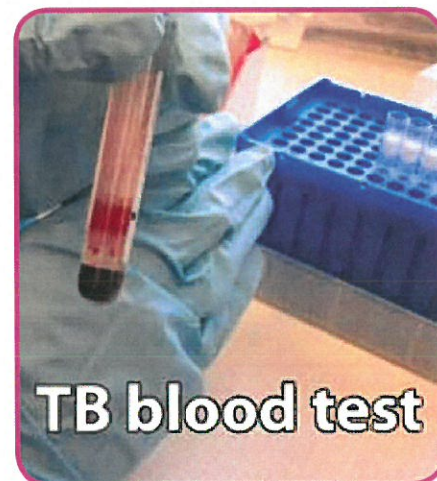
People who are more likely to get sick from **TB disease** include:

- those with HIV infection (the virus that causes AIDS);
- those who have been recently infected with TB (in the last two years);
- those who inject illegal drugs;
- babies and young children;
- elderly people;
- those who were not treated correctly for TB in the past; and
- those with certain medical conditions such as diabetes, certain types of cancer, and being underweight.

These people have conditions that make the body weaker, so it is difficult for them to fight TB germs.



Protect your family and friends from TB — take ALL your TB drugs!



Tuberculosis (TB) Facts

TB Can Be Treated

What is TB?

"TB" is short for a disease called tuberculosis. TB is spread through the air from one person to another. TB germs are passed through the air when someone who is sick with **TB disease** of the lungs or throat coughs, speaks, laughs, sings, or sneezes. Anyone near the sick person with **TB disease** can breathe TB germs into their lungs.

TB germs can live in your body without making you sick. This is called **latent TB infection**. This means you have only inactive (sleeping) TB germs in your body. The inactive germs cannot be passed on to anyone else. However, if these germs wake up or become active in your body and multiply, you will get sick with **TB disease**.

When TB germs are active (multiplying in your body), this is called **TB disease**. These germs usually attack the lungs. They can also attack other parts of the body, such as, the kidneys, brain, or spine. **TB disease** will make you sick. People with **TB disease** may spread the germs to people they spend time with every day.

If the **TB disease** is in your lungs, you may:

- cough a lot,
- cough up mucus or phlegm ("flem"),
- cough up blood, or
- have chest pain when you cough.

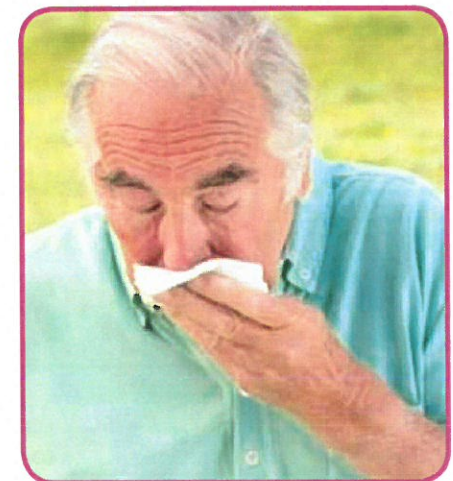
You should ALWAYS COVER YOUR MOUTH when you cough!

If you have **TB disease**, you may also:

- feel weak,
- lose your appetite,
- lose weight,
- have a fever, or
- sweat a lot at night.

These are symptoms of **TB disease**. These symptoms may last for several weeks. Without treatment, they usually get worse.

If you get **TB disease** in another part of the body, the symptoms will be different. Only a doctor can tell you if you have **TB disease**.



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TB Facts: TB Can Be Treated

How do I know if I have latent TB infection or TB disease?

If you have been around someone who has **TB disease**, you should go to your doctor or your local health department for tests.

There are two tests that can be used to help detect latent **TB infection**: a TB skin test or a TB blood test. The skin test is used most often. A small needle is used to put some testing material, called tuberculin, under the skin. In 2-3 days, you return to the health care worker who will check to see if there is a reaction to the test. In some cases, a TB blood test is used to test for **TB infection**. This blood test measures how a person's immune system reacts to the germs that cause TB.

Other tests are needed to show if you have **TB disease**. An x-ray of your chest can tell if there is damage to your lungs from TB. **TB disease** may be deep inside your lungs. Phlegm ("flem") you cough up will be tested in a laboratory to see if the TB germs are in your lungs.

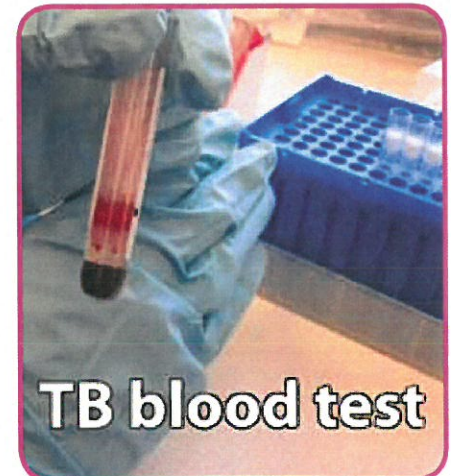
If **TB disease** is in your lungs or throat, you can give TB germs to your family and friends. They can get sick with **TB disease**. You may have to be separated from other people until you can't spread TB germs. This probably won't be for very long, if you take your medicine as your health care provider instructs.

Can TB be treated?

If you have **TB infection**, you may need medicine to prevent getting **TB disease** later. This is called "preventive" treatment.

TB disease can also be treated by taking medicine. If you have **TB disease**, it is very important that you finish the medicine, and take the drugs exactly as you are told. If you stop taking the drugs too soon, you can become sick again. If you do not take the drugs correctly, the germs that are still alive may become difficult to treat with those drugs. It takes at least six months and possibly as long as one year to kill all the TB germs.

It is very important that you take your medicine as your doctor recommends.



Protect your family and friends from TB — take ALL your TB drugs!

Tuberculosis (TB) Facts

Testing for TB

What is TB?

"TB" is short for a disease called tuberculosis. TB is spread through the air from one person to another. TB germs are passed through the air when someone who is sick with **TB disease** of the lungs or throat coughs, speaks, laughs, sings, or sneezes. Anyone near the sick person with **TB disease** can breathe TB germs into their lungs.

TB germs can live in your body without making you sick. This is called **latent TB infection**. This means you have only inactive (sleeping) TB germs in your body. The inactive germs cannot be passed on to anyone else. However, if these germs wake up or become active in your body and multiply, you will get sick with **TB disease**.

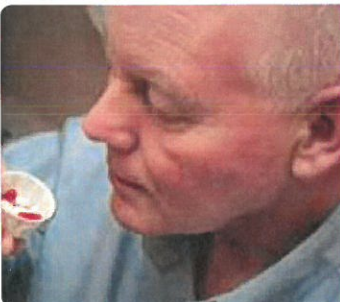
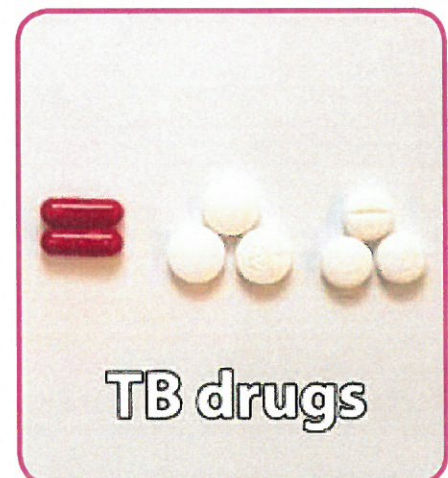
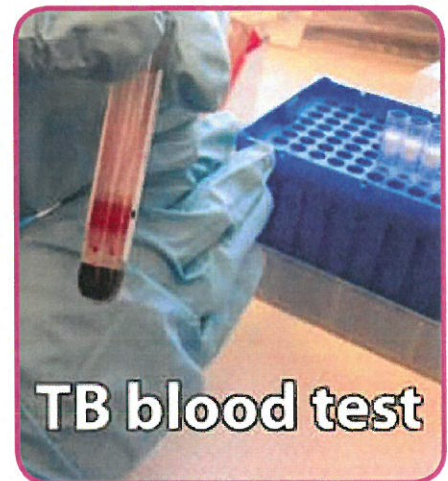
When TB germs are active (multiplying in your body), this is called **TB disease**. These germs usually attack the lungs. They can also attack other parts of the body, such as, the kidneys, brain, or spine. **TB disease** will make you sick. People with **TB disease** may spread the germs to people they spend time with every day.

How do I know if I have been infected with TB germs?

If you have been around someone who has **TB disease**, you should go to your doctor or your local health department for tests.

There are two tests that can be used to help detect **TB infection**: a TB skin test or a TB blood test. The skin test is used most often. A small needle is used to put some testing material, called tuberculin, under the skin. In 2-3 days, you return to the health care worker who will check to see if there is a reaction to the test. In some cases, a TB blood test is used to test for **TB infection**. This blood test measures how a person's immune system reacts to the germs that cause TB.

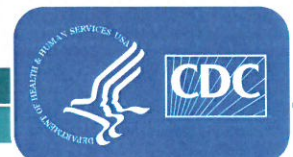
To tell if someone has **TB disease**, other tests such as chest x-ray and a sample of sputum (phlegm that is coughed up from deep in the lungs) may be needed.



Tell your health care worker if you have ever had a "positive" reaction to a TB skin test or TB blood test, or if you have been treated with TB drugs in the past.

<http://www.cdc.gov/tb>

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of Tuberculosis Elimination



Tuberculosis (TB) Facts

Exposure to TB

What is TB?

“TB” is short for a disease called tuberculosis. TB is spread through the air from one person to another. TB germs are passed through the air when someone who is sick with **TB disease** of the lungs or throat coughs, speaks, laughs, sings, or sneezes. Anyone near the sick person with **TB disease** can breathe TB germs into their lungs.

TB germs can live in your body without making you sick. This is called **latent TB infection**. This means you have only inactive (sleeping) TB germs in your body. The inactive germs cannot be passed on to anyone else. However, if these germs wake up or become active in your body and multiply, you will get sick with **TB disease**.

When TB germs are active (multiplying in your body), this is called **TB disease**. These germs usually attack the lungs. They can also attack other parts of the body, such as, the kidneys, brain, or spine. **TB disease** will make you sick. People with **TB disease** may spread the germs to people they spend time with every day.

How was I exposed to TB?

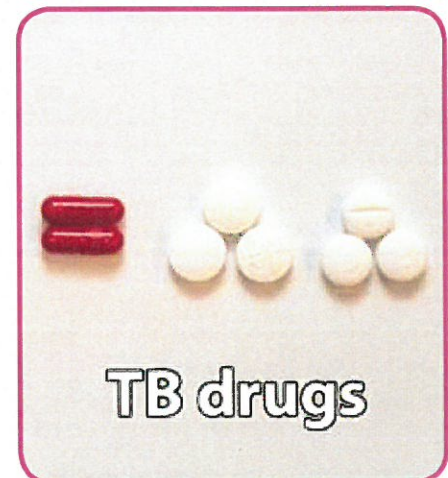
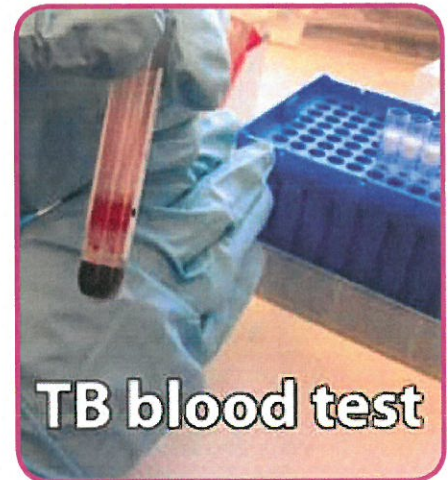
You may have been exposed to TB if you spent time near someone with **TB disease** of the lungs or throat. You can only get infected by breathing in TB germs that a person coughs into the air. You cannot get TB from someone’s clothes, drinking glass, eating utensils, handshake, toilet, or other surfaces where a TB patient has been.

How do I know if I have been infected with TB germs?

If you have been around someone who has **TB disease**, you should go to your doctor or your local health department for tests.

There are two tests that can be used to help detect **TB infection**: a TB skin test or a TB blood test. The skin test is used most often. A small needle is used to put some testing material, called tuberculin, under the skin. In 2-3 days, you return to the health care worker who will check to see if there is a reaction to the test. In some cases, a TB blood test is used to test for **TB infection**. This blood test measures how a person’s immune system reacts to the germs that cause TB.

To tell if someone has **TB disease**, other tests such as chest x-ray and a sample of sputum (phlegm that is coughed up from deep in the lungs) may be needed.



<http://www.cdc.gov/tb>

TB Elimination

Tuberculosis: General Information

What is TB?

Tuberculosis (TB) is a disease caused by germs that are spread from person to person through the air. TB usually affects the lungs, but it can also affect other parts of the body, such as the brain, the kidneys, or the spine. A person with TB can die if they do not get treatment.

What are the Symptoms of TB?

The general symptoms of TB disease include feelings of sickness or weakness, weight loss, fever, and night sweats. The symptoms of TB disease of the lungs also include coughing, chest pain, and the coughing up of blood. Symptoms of TB disease in other parts of the body depend on the area affected.

How is TB Spread?

TB germs are put into the air when a person with TB disease of the lungs or throat coughs, sneezes, speaks, or sings. These germs can stay in the air for several hours, depending on the environment. Persons who breathe in the air containing these TB germs can become infected; this is called latent TB infection.

What is the Difference Between Latent TB Infection and TB Disease?

People with latent TB infection have TB germs in their bodies, but they are not sick because the germs are not active. These people do not have symptoms of TB disease, and they cannot spread the germs to others. However, they may develop TB disease in the future. They are often prescribed treatment to prevent them from developing TB disease.

People with TB disease are sick from TB germs that are active, meaning that they are multiplying and destroying tissue in their body. They usually have

symptoms of TB disease. People with TB disease of the lungs or throat are capable of spreading germs to others. They are prescribed drugs that can treat TB disease.

What Should I Do If I Have Spent Time with Someone with Latent TB Infection?

A person with latent TB infection cannot spread germs to other people. You do not need to be tested if you have spent time with someone with latent TB infection. However, if you have spent time with someone with TB disease or someone with symptoms of TB, you should be tested.

What Should I Do if I Have Been Exposed to Someone with TB Disease?

People with TB disease are most likely to spread the germs to people they spend time with every day, such as family members or coworkers. If you have been around someone who has TB disease, you should go to your doctor or your local health department for tests.

How Do You Get Tested for TB?

There are tests that can be used to help detect TB infection: a skin test or TB blood tests. The Mantoux tuberculin skin test is performed by injecting a small amount of fluid (called tuberculin) into the skin in the lower part of the arm. A person given the tuberculin skin test must return within 48 to 72 hours to have a trained health care worker look for a reaction on the arm. The TB blood tests measures how the patient's immune system reacts to the germs that cause TB.

(Page 1 of 2)

What Does a Positive Test for TB Infection Mean?

A positive test for TB infection only tells that a person has been infected with TB germs. It does not tell whether or not the person has progressed to TB disease. Other tests, such as a chest x-ray and a sample of sputum, are needed to see whether the person has TB disease.

What is Bacille Calmette–Guèrin (BCG)?

BCG is a vaccine for TB disease. BCG is used in many countries, but it is not generally recommended in the United States. BCG vaccination does not completely prevent people from getting TB. It may also cause a false positive tuberculin skin test. However, persons who have been vaccinated with BCG can be given a tuberculin skin test or TB blood test.

Why is Latent TB Infection Treated?

If you have latent TB infection but not TB disease, your doctor may want you to take a drug to kill the TB germs and prevent you from developing TB disease. The decision about taking treatment for latent infection will be based on your chances of developing TB disease. Some people are more likely than others to develop TB disease once they have TB infection. This includes people with HIV infection, people who were recently exposed to someone with TB disease, and people with certain medical conditions.

How is TB Disease Treated?

TB disease can be treated by taking several drugs for 6 to 12 months. It is very important that people who have TB disease finish the medicine, and take the drugs exactly as prescribed. If they stop taking the drugs too soon, they can become sick again; if they do not take the drugs correctly, the germs that are still alive may become resistant to those drugs. TB that is resistant to drugs is harder and more expensive to treat. In some situations, staff of the local health department meet regularly with patients who have TB to watch them take their medications. This is called directly observed therapy (DOT). DOT helps the patient complete treatment in the least amount of time.

Additional Information

CDC. Questions and Answers About TB
<http://www.cdc.gov/tb/publications/faqs/default.htm>

<http://www.cdc.gov/tb>

TB Elimination

The Difference Between Latent TB Infection and TB Disease

What is TB?

Tuberculosis (TB) is a disease caused by a germ called *Mycobacterium tuberculosis* that is spread from person to person through the air. TB usually affects the lungs, but it can also affect other parts of the body, such as the brain, the kidneys, or the spine. When a person with infectious TB coughs or sneezes, droplet nuclei containing *M. tuberculosis* are expelled into the air. If another person inhales air containing these droplet nuclei, he or she may become infected. However, not everyone infected with TB bacteria becomes sick. As a result, two TB-related conditions exist: latent TB infection and TB disease.

What is Latent TB Infection?

Persons with latent TB infection do not feel sick and do not have any symptoms. They are infected with *M. tuberculosis*, but do not have TB disease. The only sign of TB infection is a positive reaction to the tuberculin skin test or TB blood test. **Persons with latent TB infection are not infectious and cannot spread TB infection to others.**

Overall, without treatment, about 5 to 10% of infected persons will develop TB disease at some time in their lives. About half of those people who develop TB disease will do so within the first two years of infection. For persons whose immune systems are weak, especially those with HIV infection, the risk of developing TB disease is considerably higher than for persons with normal immune systems.

Of special concern are persons infected by someone with extensively drug-resistant TB (XDR TB) who later develop TB disease; these persons will have XDR TB, not regular TB disease.

A person with latent TB infection

- Usually has a skin test or blood test result indicating TB infection
- Has a normal chest x-ray and a negative sputum test
- Has TB bacteria in his/her body that are alive, but inactive
- Does not feel sick
- Cannot spread TB bacteria to others
- Needs treatment for latent TB infection to prevent TB disease; however, if exposed and infected by a person with multidrug-resistant TB (MDR TB) or extensively drug-resistant TB (XDR TB), preventive treatment may not be an option

What is TB Disease?

In some people, TB bacteria overcome the defenses of the immune system and begin to multiply, resulting in the progression from latent TB infection to TB disease. Some people develop TB disease soon after infection, while others develop TB disease later when their immune system becomes weak.

The general symptoms of TB disease include

- Unexplained weight loss
- Loss of appetite
- Night sweats
- Fever
- Fatigue
- Chills

(Page 1 of 2)

The symptoms of TB of the lungs include

- Coughing for 3 weeks or longer
- Hemoptysis (coughing up blood)
- Chest pain

Other symptoms depend on the part of the body that is affected.

Persons with TB disease are considered infectious and may spread TB bacteria to others. If TB disease is suspected, persons should be referred for a complete medical evaluation. If it is determined that a person has TB disease, therapy is given to treat it. TB disease is a serious condition and can lead to death if not treated.

A person with TB disease

- Usually has a skin test or blood test result indicating TB infection
- May have an abnormal chest x-ray, or positive sputum smear or culture
- Has active TB bacteria in his/her body
- Usually feels sick and may have symptoms such as coughing, fever, and weight loss
- May spread TB bacteria to others
- Needs treatment to treat TB disease

Additional Information

1. American Thoracic Society (ATS) and CDC. Diagnostic standards and classification of tuberculosis in adults and children. (PDF) *Am J Respir Crit Care Med* 2000; 161. <http://ajrccm.atsjournals.org/cgi/content/full/161/4/1376>
2. CDC. Questions and Answers About TB. <http://www.cdc.gov/tb/publications/faqs/default.htm>
3. CDC. Multidrug-Resistant Tuberculosis (MDR TB). <http://www.cdc.gov/tb/publications/factsheets/drtb/mdrtb.htm>
4. CDC. Extensively Drug-Resistant Tuberculosis (XDR TB). <http://www.cdc.gov/tb/publications/factsheets/drtb/xdrtb.htm>

<http://www.cdc.gov/tb>

TB Elimination

Diagnosis of Tuberculosis Disease

When Should You Suspect Tuberculosis (TB)?

TB is a disease caused by *Mycobacterium tuberculosis*. TB disease should be suspected in persons who have the following symptoms:

- Unexplained weight loss
- Loss of appetite
- Night sweats
- Fever
- Fatigue

If TB disease is in the lungs (pulmonary), symptoms may include:

- Coughing for ≥ 3 weeks
- Hemoptysis (coughing up blood)
- Chest pain

If TB disease is in other parts of the body (extrapulmonary), symptoms will depend on the area affected.

How Do You Evaluate Persons Suspected of Having TB Disease?

A complete medical evaluation for TB includes the following:

1. Medical History

Clinicians should ask about the patient's history of TB exposure, infection, or disease. It is also important to consider demographic factors (e.g., country of origin, age, ethnic or racial group, occupation) that may increase the patient's risk for exposure to TB or to drug-resistant TB. Also, clinicians should determine whether the patient has medical conditions, especially HIV infection, that increase the risk of latent TB infection progressing to TB disease.

2. Physical Examination

A physical exam can provide valuable information about the patient's overall condition and other factors that may affect how TB is treated, such as HIV infection or other illnesses.

3. Test for TB Infection

The Mantoux tuberculin skin test (TST) or the TB blood test can be used to test for *M. tuberculosis* infection. Additional tests are required to confirm TB disease. The Mantoux tuberculin skin test is performed by injecting a small amount of fluid called tuberculin into the skin in the lower part of the arm. The test is read within 48 to 72 hours by a trained health care worker, who looks for a reaction (induration) on the arm.

The TB blood test measures the patient's immune system reaction to *M. tuberculosis*.

4. Chest Radiograph

A posterior-anterior chest radiograph is used to detect chest abnormalities. Lesions may appear anywhere in the lungs and may differ in size, shape, density, and cavitation. These abnormalities may suggest TB, but cannot be used to definitively diagnose TB. However, a chest radiograph may be used to rule out the possibility of pulmonary TB in a person who has had a positive reaction to a TST or TB blood test and no symptoms of disease.

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5. Diagnostic Microbiology

The presence of acid-fast-bacilli (AFB) on a **sputum smear** or other specimen often indicates TB disease. Acid-fast microscopy is easy and quick, but it does not confirm a diagnosis of TB because some acid-fast-bacilli are not *M. tuberculosis*. Therefore, a **culture** is done on all initial samples to confirm the diagnosis. (However, a positive culture is not always necessary to begin or continue treatment for TB.) A positive culture for *M. tuberculosis* confirms the diagnosis of TB disease. Culture examinations should be completed on all specimens, regardless of AFB smear results. Laboratories should report positive results on smears and cultures within 24 hours by telephone or fax to the primary health care provider and to the state or local TB control program, as required by law.

6. Drug Resistance

For all patients, the initial *M. tuberculosis* isolate should be tested for drug resistance. It is crucial to identify drug resistance as early as possible to ensure effective treatment. Drug susceptibility patterns should be repeated for patients who do not respond adequately to treatment or who have positive culture results despite 3 months of therapy. Susceptibility results from laboratories should be promptly reported to the primary health care provider and the state or local TB control program.

Additional Information

1. American Thoracic Society (ATS) and CDC. Diagnostic standards and classification of tuberculosis in adults and children. (PDF) *Am J Respir Crit Care Med* 2000; 161. <http://ajrccm.atsjournals.org/cgi/content/full/161/4/1376>
2. ATS, CDC, and Infectious Diseases Society of America. Treatment of tuberculosis. *MMWR* 2003; 52 (No. RR-11). <http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>
3. Centers for Disease Control and Prevention. Guidelines for the investigation of contacts of persons with infectious tuberculosis and Guidelines for using the QuantiFERON®-TB Gold test for detecting Mycobacterium tuberculosis infection, United States. *MMWR* 2005; 54 (No. RR-15). <http://www.cdc.gov/mmwr/pdf/rr/rr5415.pdf>
4. Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis. *MMWR* 2009;58(1). http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm?scid=mm5801a3_e

<http://www.cdc.gov/tb>

Testing for Tuberculosis (TB)

Tuberculosis (TB) is a disease that is spread through the air from one person to another. When someone who is sick with TB coughs, speaks, laughs, sings, or sneezes, people nearby may breathe TB bacteria into their lungs. TB usually attacks the lungs, but can also attack other parts of the body, such as the brain, spine, or kidneys.

There are two types of TB:

1. Latent TB infection
2. TB disease

TB bacteria can live in the body without making a person sick. This is called **latent TB infection**. People

with latent TB infection do not feel sick, do not have TB symptoms, and cannot spread TB bacteria to others. Some people with latent TB infection go on to develop **TB disease**. People with TB disease can spread the bacteria to others, feel sick, and can have symptoms including fever, night sweats, cough, and weight loss.

There are two kinds of tests that are used to determine if a person has been infected with TB bacteria: the tuberculin skin test and TB blood tests.

Tuberculin Skin Test (TST)

What is a TST?

The Mantoux tuberculin skin test is a test to check if a person has been infected with TB bacteria.

How does the TST work?

Using a small needle, a health care provider injects a liquid (called tuberculin) into the skin of the lower part of the arm. When injected, a small, pale bump will appear. This is different from a Bacille Calmette-Guerin (BCG) shot (a TB vaccine that many people living outside of the United States receive).

The person given the TST must return within 2 or 3 days to have a trained health care worker look for a reaction on the arm where the liquid was injected. The health care worker will look for a raised, hard area or swelling, and if present, measure its size using a ruler. Redness by itself is not considered part of the reaction.

What does a positive TST result mean?

The TST result depends on the size of the raised, hard area or swelling. It also depends on the person's risk of being infected with TB bacteria and the progression to TB disease if infected.

- Positive TST: This means the person's body was infected with TB bacteria. Additional tests are needed to determine if the person has latent TB infection or TB disease. A health care worker will then provide treatment as needed.
- Negative TST: This means the person's body did not react to the test, and that latent TB infection or TB disease is not likely.

Who can receive a TST?

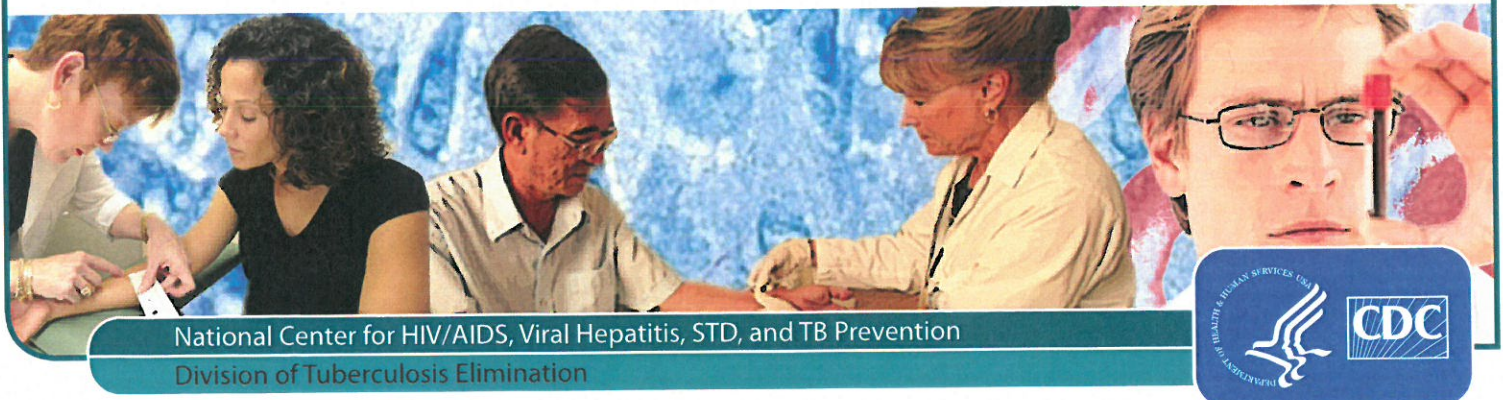
Almost everyone can receive a TST, including infants, children, pregnant women, people living with HIV, and people who have had a BCG shot. People who had a severe reaction to a previous TST should not receive another TST.

How often can a TST be given?

Usually, there is no problem with repeated TSTs unless a person has had a severe reaction to a previous TST.

Testing for TB in People with a BCG

People who have had a previous BCG shot may receive a TST. In some people, the BCG shot may cause a positive TST when they are not infected with TB bacteria. If a TST is positive, additional tests are needed.



National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of Tuberculosis Elimination



TB Blood Tests

What is an Interferon Gamma Release Assay (IGRA)?

An IGRA is a blood test that can determine if a person has been infected with TB bacteria. An IGRA measures how strong a person's immune system reacts to TB bacteria by testing the person's blood in a laboratory.

Two IGRAs are approved by the U.S. Food and Drug Administration (FDA) and are available in the United States:

- 1) QuantiFERON®-TB Gold In-Tube test (QFT-GIT)
- 2) T-SPOT®.TB test (T-Spot)

How does the IGRA work?

Blood is collected into special tubes using a needle. The blood is delivered to a laboratory as directed by the IGRA test instructions. The laboratory runs the test and reports the results to the health care provider.

What does a positive IGRA result mean?

- Positive IGRA: This means that the person has been infected with TB bacteria. Additional tests are needed to determine if the person has latent TB infection or TB disease. A health care worker will then provide treatment as needed.
- Negative IGRA: This means that the person's blood did not react to the test and that latent TB infection or TB disease is not likely.

Who can receive an IGRA?

Anyone can have an IGRA in place of a TST. This can be for any situation where a TST is recommended. In general, a person should have either a TST or an IGRA, but not both. There are rare exceptions when results from both tests may be useful in deciding whether a person has been infected with TB.

IGRAs are the preferred method of TB infection testing for the following:

- People who have received the BCG shot
- People who have a difficult time returning for a second appointment to look at the TST after the test was given

How often can an IGRA be given?

There is no problem with repeated IGRAs.

Who Should Get Tested for TB?

TB tests are generally not needed for people with a low risk of infection with TB bacteria.

Certain people should be tested for TB bacteria because they are more likely to get TB disease, including:

- People who have spent time with someone who has TB disease
- People with HIV infection or another medical problem that weakens the immune system
- People who have symptoms of TB disease (fever, night sweats, cough, and weight loss)
- People from a country where TB disease is common (most countries in Latin America, the Caribbean, Africa, Asia, Eastern Europe, and Russia)
- People who live or work somewhere in the United States where TB disease is more common (homeless shelters, prison or jails, or some nursing homes)
- People who use illegal drugs

Choosing a TB Test

Choosing which TB test to use should be done by the person's health care provider. Factors in selecting which test to use include the reason for testing, test availability, and cost. Generally, it is not recommended to test a person with both a TST and an IGRA.

Diagnosis of Latent TB Infection or TB Disease

If a person is found to be infected with TB bacteria, other tests are needed to see if the person has TB disease.

TB disease can be diagnosed by medical history, physical examination, chest x-ray, and other laboratory tests. TB disease is treated by taking several drugs as recommended by a health care provider.

If a person does not have TB disease, but has TB bacteria in the body, then latent TB infection is diagnosed. The decision about taking treatment for latent TB infection will be based on a person's chances of developing TB disease.

Related Links

CDC. Tuberculosis (TB): <http://www.cdc.gov/tb>

Basic TB Information: <http://www.cdc.gov/tb/publications/factsheets/general/tb.htm>

November 2011

TB Elimination

Interferon-Gamma Release Assays (IGRAs) – Blood Tests for TB Infection

What are they?

Interferon-Gamma Release Assays (IGRAs) are whole-blood tests that can aid in diagnosing *Mycobacterium tuberculosis* infection. They do not help differentiate latent tuberculosis infection (LTBI) from tuberculosis disease. Two IGRAs that have been approved by the U.S. Food and Drug Administration (FDA) are commercially available in the U.S. They are:

- QuantiFERON® – TB Gold In-Tube test (QFT–GIT);
- SPOT® TB test (T–Spot)

How do they work?

IGRAs measure a person's immune reactivity to *M. tuberculosis*. White blood cells from most persons that have been infected with *M. tuberculosis* will release interferon-gamma (IFN-g) when mixed with antigens (substances that can produce an immune response) derived from *M. tuberculosis*.

To conduct the tests, fresh blood samples are mixed with antigens and controls. The antigens, testing methods, and interpretation criteria for IGRAs differ (see Table 1).

What are the advantages of IGRAs?

- Requires a single patient visit to conduct the test.
- Results can be available within 24 hours.
- Does not boost responses measured by subsequent tests.
- Prior BCG (bacille Calmette-Guérin) vaccination does not cause a false-positive IGRA test result.

What are the disadvantages and limitations of IGRAs?

- Blood samples must be processed within 8-30 hours after collection while white blood cells are still viable.
- Errors in collecting or transporting blood specimens or in running and interpreting the assay can decrease the accuracy of IGRAs.
- Limited data on the use of IGRAs to predict who will progress to TB disease in the future.

Table 1: Differences in Currently Available IGRAs

	QFT–GIT	T–Spot
Initial Process	Process whole blood within 16 hours	Process peripheral blood mononuclear cells (PBMCs) within 8 hours, or if T-Cell Xtend® is used, within 30 hours.
<i>M. tuberculosis</i> Antigen	Single mixture of synthetic peptides representing ESAT-6, CFP-10 and TB7.7	Separate mixtures of synthetic peptides representing ESAT-6 and CFP-10
Measurement	IFN-g concentration	Number of IFN-g producing cells (spots)
Possible Results	Positive, negative, indeterminate	Positive, negative, borderline, invalid

(Page 1 of 3)

Limited data on the use of IGRAs for:

- » Children younger than 5 years of age;
 - » Persons recently exposed to *M. tuberculosis*;
 - » Immunocompromised persons; and
 - » Serial testing.
- Tests may be expensive.

What are the steps in administering an IGRA test?

Confirm arrangements for testing in a qualified laboratory, and arrange for delivery of the blood sample to the laboratory in the time the laboratory specifies to ensure testing of samples with viable blood cells.

- Draw a blood sample from the patient according to the test manufacturer's instructions.
- Schedule a follow-up appointment for the patient to receive test results.
- Based on test results, provide follow-up evaluation and treatment as needed.

How do you interpret IGRA test results?

IGRA interpretations are based on the amount of IFN-g that is released or on the number of cells that release IFN-g. Both the standard qualitative test interpretation (positive, negative, or indeterminate) and the quantitative assay measurements (Nil, TB, and Mitogen concentrations or spot counts) should be reported.

As with the tuberculin skin tests (TSTs), IGRAs should be used as an aid in diagnosing infection with *M. tuberculosis*. A positive test result suggests that *M. tuberculosis* infection is likely; a negative result suggests that infection is unlikely. An indeterminate result indicates an uncertain likelihood of *M. tuberculosis* infection. A borderline test result (T-Spot only) also indicates an uncertain likelihood of *M. tuberculosis* infection.

A diagnosis of LTBI requires that TB disease be excluded by medical evaluation. This should include checking for signs and symptoms suggestive of TB disease, a chest radiograph, and, when indicated, examination of sputum or other clinical samples for the presence of *M. tuberculosis*. Decisions about a diagnosis of *M. tuberculosis* infection should also include epidemiological and historical information.

Recommendations on when to use IGRA tests

- IGRAs can be used in place of (but not in addition to) TST in all situations in which CDC recommends TST as an aid in diagnosing *M. tuberculosis* infection, with preferences and special considerations noted below. This includes contact investigations, testing during pregnancy, and screening of health care workers and others undergoing serial evaluation for *M. tuberculosis* infection. Despite the indication of a preference, use of the alternative test (FDA-approved IGRA or TST) is acceptable medical and public health practice. Caution in interpretation should be used when testing certain populations because of limited data on the use of IGRAs (see [Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection, United States](#)).
- Populations in which IGRAs are preferred for testing:
 - » Persons who have received BCG (either as a vaccine or for cancer therapy); and
 - » Persons from groups that historically have poor rates of return for TST reading.
- TST is preferred over IGRAs for testing children less than 5 years of age.
- As with TST, IGRAs generally should not be used for testing persons who have a low risk of infection and a low risk of disease due to *M. tuberculosis*.
- Each institution and TB control program should evaluate the availability and benefits of IGRAs in prioritizing their use.

- Routine testing with both TST and IGRA is not recommended. However, results from both tests might be useful in the following situations:

» When the initial test is **negative** and:

- The risk for infection, the risk for progression to disease, and the risk for a poor outcome are high (e.g., HIV infected persons or children under 5 years of age who are exposed to a person with infectious TB).
- There is clinical suspicion for TB disease (e.g., signs, symptoms, and/or radiographic evidence suggestive of TB disease) and confirmation of *M. tuberculosis* infection is desired.
- Taking a positive result from a second test as evidence of infection increases detection sensitivity.

» When the initial test is **positive** and:

- Additional evidence of infection is required to encourage acceptance and adherence (e.g., foreign-born healthcare workers who believe their positive TST is due to BCG). A positive IGRA might prompt greater acceptance of treatment for LTBI as compared with a positive TST alone.
- The person has a low risk of both infection and progression from infection to TB disease. Requiring a positive result from the second test as evidence of infection increases the likelihood that the test reflects infection. An alternative is to assume, without additional testing, that the initial result is a false positive or that the risk for disease does not warrant additional evaluation or treatment, regardless of test results.

» In addition, repeating an IGRA or performing a TST might be useful when the initial IGRA result is indeterminate, borderline, or invalid and a reason for testing persists.

Multiple negative results from any combination of these tests cannot exclude *M. tuberculosis* infection. Steps should be taken to minimize unnecessary and misleading testing of persons at low risk.

Selection of the most suitable test or combination of tests for detection of *M. tuberculosis* infection should be based on the reasons and the context for testing, test availability, and overall cost of testing.

Can IGRAs Be Given To Persons Receiving Vaccinations?

As with TST, live virus vaccines might affect IGRA test results. However, the effect of live virus vaccination on IGRAs has not been studied. Until additional information is available, IGRA testing in the context of live virus vaccine administration should be done as follows:

- Either on the same day as vaccination with live-virus vaccine or 4-6 weeks after the administration of the live-virus vaccine
- At least one month after smallpox vaccination

Additional Information

Centers for Disease Control and Prevention. Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* Infection, United States. (PDF) *MMWR* 2010; 59 (No.RR-5). http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e

<http://www.cdc.gov/tb>

TB Elimination

Tuberculin Skin Testing

What is it?

The **Mantoux tuberculin skin test (TST)** is the standard method of determining whether a person is infected with *Mycobacterium tuberculosis*. Reliable administration and reading of the TST requires standardization of procedures, training, supervision, and practice.

How is the TST Administered?

The TST is performed by injecting 0.1 ml of tuberculin purified protein derivative (PPD) into the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter.

How is the TST Read?

The skin test reaction should be read between 48 and 72 hours after administration. A patient who does not return within 72 hours will need to be rescheduled for another skin test.

The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis).

How Are TST Reactions Interpreted?

Skin test interpretation depends on two factors:

- Measurement in millimeters of the induration
- Person's risk of being infected with TB and of progression to disease if infected

Classification of the Tuberculin Skin Test Reaction

An **induration of 5 or more millimeters** is considered positive in

- » HIV-infected persons
- » A recent contact of a person with TB disease
- » Persons with fibrotic changes on chest radiograph consistent with prior TB
- » Patients with organ transplants
- » Persons who are immunosuppressed for other reasons (e.g., taking the equivalent of >15 mg/day of prednisone for 1 month or longer, taking TNF- α antagonists)

An **induration of 10 or more millimeters** is considered positive in

- » Recent immigrants (< 5 years) from high-prevalence countries
- » Injection drug users
- » Residents and employees of high-risk congregate settings
- » Mycobacteriology laboratory personnel
- » Persons with clinical conditions that place them at high risk
- » Children < 4 years of age
- » Infants, children, and adolescents exposed to adults in high-risk categories

An **induration of 15 or more millimeters** is considered positive in any person, including persons with no known risk factors for TB. However, targeted skin testing programs should only be conducted among high-risk groups.

What Are False-Positive Reactions?

Some persons may react to the TST even though they are not infected with *M. tuberculosis*. The causes of these false-positive reactions may include, but are not limited to, the following:

- Infection with nontuberculosis mycobacteria
- Previous BCG vaccination
- Incorrect method of TST administration
- Incorrect interpretation of reaction
- Incorrect bottle of antigen used

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What Are False-Negative Reactions?

Some persons may not react to the TST even though they are infected with *M. tuberculosis*. The reasons for these false-negative reactions may include, but are not limited to, the following:

- Cutaneous anergy (anergy is the inability to react to skin tests because of a weakened immune system)
- Recent TB infection (within 8-10 weeks of exposure)
- Very old TB infection (many years)
- Very young age (less than 6 months old)
- Recent live-virus vaccination (e.g., measles and smallpox)
- Overwhelming TB disease
- Some viral illnesses (e.g., measles and chicken pox)
- Incorrect method of TST administration
- Incorrect interpretation of reaction

Who Can Receive a TST?

Most persons can receive a TST. TST is contraindicated only for persons who have had a severe reaction (e.g., necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST. It is not contraindicated for any other persons, including infants, children, pregnant women, persons who are HIV-infected, or persons who have been vaccinated with BCG.

How Often Can TSTs Be Repeated?

In general, there is no risk associated with repeated tuberculin skin test placements. If a person does not return within 48-72 hours for a tuberculin skin test reading, a second test can be placed as soon as possible. There is no contraindication to repeating the TST, unless a previous TST was associated with a severe reaction.

What is a Boosted Reaction?

In some persons who are infected with *M. tuberculosis*, the ability to react to tuberculin may wane over time. When given a TST years after infection, these persons may have a false-negative reaction. However, the TST may

stimulate the immune system, causing a positive, or boosted reaction to subsequent tests. Giving a second TST after an initial negative TST reaction is called two-step testing.

Why is Two-Step Testing Conducted?

Two-step testing is useful for the initial skin testing of adults who are going to be retested periodically, such as health care workers or nursing home residents. This two-step approach can reduce the likelihood that a boosted reaction to a subsequent TST will be misinterpreted as a recent infection.

Can TSTs Be Given To Persons Receiving Vaccinations?

Vaccination with live viruses may interfere with TST reactions. For persons scheduled to receive a TST, testing should be done as follows:

- Either on the same day as vaccination with live-virus vaccine or 4-6 weeks after the administration of the live-virus vaccine
- At least one month after smallpox vaccination

Additional Information

1. American Thoracic Society and CDC. Diagnostic standards and classification of tuberculosis in adults and children. (PDF) *Am J Respir Crit Care Med* 2000; 161. <http://ajrccm.atsjournals.org/cgi/content/ful/161/4/1376>
2. CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. *MMWR* 2005; 54 (No. RR-17). www.cdc.gov/tb/publications/guidelines/infectioncontrol.htm
3. CDC. Mantoux Tuberculin Skin Test: Training Materials Kit (2003).
4. CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. *MMWR* 2000; 49 (No. RR-6). www.cdc.gov/MMWR/PDF/rr/rr4906.pdf

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