

TUBERCULOSIS FAQs



BACKGROUND

Why revise the regulations?

Since the time that OPWDD’s regulations were written there have been many revisions to the standards from the Centers for Disease Control (CDC), the Occupational Safety and Health Administration (OSHA) and the New York State Department of Health Bureau of Tuberculosis Control, (NYSDOH – TBC), as well as many medical advances in the detection and treatment of active pulmonary and laryngeal tuberculosis (TB). OPWDD’s regulations were not fully consistent with many of these federal revisions. In fact, in the area of tuberculosis control, OPWDD regulations were requiring adherence to a testing schedule that was incurring unnecessary cost and administrative burden when evaluated against current standards endorsed by the medical community and the federal government.

To simplify regulatory compliance, OPWDD revised its regulations to be in accord with the various federal and state regulators. Agencies can be confident, to the extent that they meet the standard and the transition strategy explained below, that they will be in compliance with the applicable federal and state requirements, thereby reducing the risk related to tuberculosis screening and exposure, simplifying personnel management.

How will these new regulations simplify procedures and contain costs? (This section does not apply to developmental centers and other state operated campus based settings).

- Once an employee has successfully completed one of the accepted testing regimens – there is no further need for the employee to be tested again, unless there is some specific reason to suspect exposure to TB.
 - This eliminates the actual cost of the testing
 - It also eliminates administrative costs related to tracking annual employee testing and maintenance of documentation
 - It eliminates costs related to the release of the person from work and any necessary coverage costs related to testing
 - It allows for cost avoidance related to potential penalties related to non-compliance with the previous, more onerous, regulatory standards





APPLICABILITY

Where do the regulations apply?

The requirements of the regulation apply to all facilities operated and/or certified by OPWDD.

What is a certified facility?

A certified facility is a site that holds an operating certificate issued by OPWDD;

- ❖ All certified residential options:
 - Individual residential alternative (IRA)
 - Community based intermediate care facility (ICF)
 - Community residence
 - Supportive apartment
 - Supervised apartment
 - Family care
- ❖ All certified programs:
 - Day treatment
 - Day habilitation program (with walls)
 - Day training (a.k.a. sheltered workshops)
- ❖ Article 16 clinic
- ❖ Specialty hospital (Terrence Cardinal Cooke)
- ❖ Private schools – residential component

What is a developmental center?

A developmental center (DC) is a large institution operated by the State of New York. Voluntary agencies do not operate DCs.

TB TESTING

What constitutes initial TB testing?

Initial testing is defined as EITHER:

1. a two-step PPD: a tuberculin skin test (TST) using the Mantoux method with 5 tuberculin units of purified protein derivative (PPD), with two phases 1-3 weeks apart;

OR

2. an interferon-gamma release assays or IGRAs blood test. The QuantiFERON®-TB Gold test (QFT-G), QuantiFERON®-TB Gold In-Tube test (GFT-GIT) and T-SPOT®.TB test are three examples of Food and Drug Administration approved TB blood tests.

What is an IGRA test?

TB blood tests (also called interferon-gamma release assays or IGRAs) measure how the immune system reacts to the bacteria that cause TB.



Blood samples are mixed with antigens (substances that can produce an immune response) and controls. After incubation of the blood with antigens for 16 to 24 hours, the amount of interferon-gamma (IFN-gamma) is measured. Test results are generally available in 24-48 hours.

If an IGRA test is used for screening, there is no need to perform a baseline two-step PPD. The IGRA laboratory report should be documented in the employee health record.

What is a Two-step PPD?

A two-step PPD is a procedure performed to rule out the presence of an anamnestic response in people who were infected with tuberculosis in the distant past. An anamnestic phenomenon is one in which an initial negative TST triggers an immune response, resulting in a subsequent positive TST.

Why do a Two-Step PPD?

Both the CDC (See *MMWR* Dec 20, 2005) and the SDOH (see NYS DOH DAL/DQS#06-03, Feb. 16, 2006) have issued guidance indicating the need for a two step PPD for initial screening of employees and individuals receiving services in long term care facilities.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm>

http://www.nyhealth.gov/professionals/nursing_home_administrator/docs/dal_06-03_guidelines_for_tuberculosis_control.pdf

People (especially older adults) who are skin tested many years after becoming infected with *M. tuberculosis* may have a negative reaction to an initial TST, followed by a positive reaction to a TST given up to a year later. This happens because the first TST boosts the immune response.

The booster phenomenon can present a problem in TB testing programs. This is because a negative reaction to the baseline skin test, followed by a positive reaction to a subsequent skin test that is given up to a year later, may be caused by either

- Recent TB infection in a person who was NOT infected at the time of the baseline skin test, OR
- A boosted reaction in a person who WAS already infected before the baseline skin test

To avoid misinterpretation, a strategy has been developed for telling the difference between boosted reactions and reactions caused by recent infection. This strategy, called **two-step testing**, is to be used for the initial skin testing of recipients of service, employees, volunteers, contractors, family care providers and approved substitute/respite providers.

If a person has a negative reaction to an initial skin test, he or she is given a second test 1 to 3 weeks later.





- If the reaction to the second test is negative, the person is considered uninfected. In this person, a positive reaction to a skin test given later on will probably be due to recent infection and be considered a skin test conversion.
- If the reaction to the second test is positive; it probably is a boosted reaction (due to TB infection that occurred a long time ago). However, the person should be immediately screened for signs and symptoms of active pulmonary TB.

Thus, because it provides more accurate information about each person’s baseline skin test reaction, two-step PPD testing will now be used in OMRDD certified settings for recipients of care, employees, volunteers, contractors, family care providers and approved substitute/respite providers when they start their job/receipt of service.

How do you do two-step PPDs?

The tuberculin skin test (TST) can be used to screen for tuberculosis infection, using the Mantoux method with 5 tuberculin units of purified protein derivative (PPD).

To do a two step PPD:

(Visit 1), administer a Mantoux skin test by injecting 0.1 ml of 5 tuberculin units (TU) of purified protein derivative (PPD) intradermally into the dorsal or volar surface of the forearm.

(Visit 2) Between 48 to 72 hours after administration read the PPD. Test results read outside of this time limit may give an invalid result. Employees are not allowed to read or interpret their own TST results.

(Visit 3) Employees whose initial TST result is negative are given a second TST, administered 1-3 weeks after the first TST was placed.

(Visit 4) Between 48 and 72 hours after administration read the PPD.

There are three parts to completing a PPD:

1. **Planting** a PPD is injecting 0.1 ml of 5 tuberculin units (TU) of purified protein derivative (PPD – hence the name of the test) intradermally into the dorsal or volar surface of the forearm. A physician, physician’s assistant, nurse practitioner or registered nurse can plant a PPD. LPNs can **only** plant a PPD if there is a person-specific order.
2. **Reading** a PPD is the observation of the site for induration (an abnormally hard, raised spot) at the site of the test. When a TST is read, the health care professional measures the amount of induration at the site, and records this measurement in millimeters of induration. . A physician, physician’s assistant, nurse practitioner or registered nurse can read a





PPD. LPNs may read a PPD, provided the LPN is properly trained on how to read and document the test in millimeters of induration.

3. Interpretation of the PPD is determining the significance of the measurement of induration and what if any additional testing/evaluation is needed. An interpretation of a PPD is determined by the measurement of induration at the PPD test site combined with the individual’s risk factors. More information on interpretation of TST can be found in the *Interactive Core Curriculum on Tuberculosis*, Unit 3, Testing for Tuberculosis Disease and Infection which can be found on the CDC website at http://www.cdc.gov/tb/webcourses/CoreCurr/TB_Course/Menu/frameinternet.htm .

Who can do a PPD?

Only a physician, physician’s assistant, nurse practitioner or registered nurse can interpret the PPD test results. LPNs may not interpret a PPD as positive or negative.



What about people who have already had a PPD? Do they need two more?

The basic rule is a person must have two consecutively negative PPDs within 12 months.

This chart from the CDC should be helpful.

From the CDC: MMWR Vol 54/RR-17 Dec 30, 2005 pg. 29

SITUATION	REQUIRED TESTING
No previous TST result documented	Two-step PPD
Previous negative TST (documented or not) more than 12 months before	Two-step PPD
Previous documented negative TST result less than or equal to 12 months before	Single TST needed for baseline testing; this test will be the second step
2 or more previous documented negative TSTs but most recent TST was more than 12 months before	Single TST; two step testing is not necessary
2 or more previous documented negative TSTs and most recent TST	No TST needed





is less than 12 months before	
Previous documented positive TST result	No TST
Previous undocumented positive TST	Preferred: IGRA otherwise: two step TST
Previous BCG vaccination	Two step PPD or IGRA

PLEASE NOTE: This entire section is written to assist in implementation of a regulation that went into effect June 1, 2010. Thus, the assessment of whether previous TST results meet all or part of the testing requirements for a person who was an existing employee on June 1, 2010 should be evaluated as of their acceptability **on JUNE 1, 2010**. So, for example, if someone had previous TST’s in May 2009 and May 2010 – the person would have no further testing requirement because – as of the regulation’s effective date the person would have met the standard “2 or more previous documented negative TSTs and most recent TST is less than 12 months before.”

Given that this FAQ was published in September and revised in October 2010, any existing staff that only has one PPD planted as of June 1, 2010 should have a second PPD planted as soon as practical but no later than January 31, 2011.

How does this apply to a NEW EMPLOYEE

The chart above outlines necessary initial testing. Requirements for initial testing are determined by the persons past documented TST history, and the date of the last TST. Documentation of TST results can be accepted from any reputable source, such as a physician’s office, hospital, public health agency, college health service, etc. Previous test results can be used to meet the requirement even if the new employee has never worked for ANY OPWDD certified or operated setting OR If the employee worked for another agency in an OPWDD certified or operated setting.

How does this apply to a CURRENT employee – someone who was working in their current position at the time the new regulations went into effect?

The regulations do not contain a specific provision related to the transition period. Therefore, the requirements for existing employees have to be deduced from the overall guidance.

If the employee has documentation of only one TB test (which most generally will be those employees hired within the past year), that person will need one additional TST within 12 months of the last test to complete the two step process. Once that is completed, they will not need any further testing unless there is a known exposure.

If the employee had been employed continuously by your agency and/or another OPWDD operated or certified setting for more than one year and





has documentation of at least 2 sequential negative TB tests, with the last one being within the past 12 months, no further testing is needed:

Can an employee, contractor, volunteer, family care provider, approved substitute/respite provider or service recipient select testing by his/her health care provider?

Yes, any person can select testing by his/her own health care provider.

If someone chooses testing by his/her own health care providers, what documentation is required?

The results of the TB testing and any necessary follow-up evaluation must be documented and shared with the service provider or sponsoring agency prior to or on the first day of employment or service provision or receipt of services.

If the health care provider employed a two step PPD, the following information must be provided to the agency for each PPD:

- date placed,
- results in millimeters of induration,
- date read
- interpretation of results, and
- names of persons reading and interpreting the test

If the health care provider employed a whole blood interferon-gamma release assays (IGRAs) approved by the Food and Drug Administration (FDA) such as QuantiFERON-TB Gold, 2005; QuantiFERON-TB Gold In-Tube, 2007; and TSpot.TB, 2008 (or any other test approved by the FDA and/or CDC in the future), the following information must be provided to the agency:

- Date drawn
- Results
- Interpretation of results

What about people who have had a positive PPD in the past?

Individuals and/or employees with documentation of a previous positive TST or treatment for latent TB infection or TB disease do not need to undergo a TST. These people should be clinically evaluated for symptoms suggestive of TB. If the person is free of signs and symptoms of active tuberculosis disease, no further evaluation is needed unless the person displays signs and symptoms indicative of active pulmonary or laryngeal tuberculosis. No further documentation (such as reports of old X-rays, etc) is required. If the person is symptomatic, a chest x-ray examination and further clinical evaluation are indicated prior to receipt of service/employment

What about people who have had BCG vaccine?

BCG, or Bacille Calmette-Guerin, is a vaccine for tuberculosis (TB) disease. Many foreign-born persons have been BCG-vaccinated. BCG is used in



many countries with a high prevalence of TB to prevent childhood tuberculosis meningitis and military disease. However, BCG is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis* and the variable effectiveness of the vaccine against adult pulmonary TB.

According to the CDC, the TB skin test is not contraindicated for persons who have been vaccinated with BCG, particularly those who were vaccinated as an infant or small child.

According to the CDC, TST in a person with previous BCG vaccine is to be interpreted in the same manner as in a person without prior vaccination.

Who has to do annual testing?

A developmental center (a large institution operated by the State of New York). Voluntary not-for-profit agencies do not operate developmental centers. Therefore, these provisions for annual testing do **not** apply to voluntary agency providers.

Testing in community based certified facilities will only be required if there is an exposure to a known or suspected case of active pulmonary or laryngeal TB.

Are there any exclusions to TB testing?

Yes. A person can be excluded from TB testing for one of the following reasons:

- (i) prior documented significant reaction to TB testing; or
- (ii) adequate treatment for active pulmonary tuberculosis; or
- (iii) completion of adequate preventive therapy.

Please note: this means that the service provider, without consultation with the person’s health care provider, can determine that the individual will be excluded from TST because the provider has documented proof of one of the three conditions.

Are there any other exclusions to testing?

The exclusion discussed in this section differs from the one above because for this exclusion the person’s health care provider must provide written documentation that the person has a contraindication to testing.

According to the CDC (Tuberculosis Fact Sheet)

<http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm>

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.





Having said that, OPWDD does serve individuals in whom the risk of testing outweighs the benefits of testing. This risk is not limited to specific medical issue – but may be more behavioral in nature. It is never our intent for a person exhibiting no risk for TB to be barred from services due to the lack of a TST. Therefore, the regulation allows an MD, PA or NP to write a letter/note stating the contraindication, assess the person for s/s of active pulmonary TB and a statement as to when testing may be able to be conducted in the future.

Below is an example of a letter that may be written for a consumer – (in this example the person has trypanophobia):

“Richard W is a person with developmental disabilities under my care. Richard has [trypanophobia](#) (an extreme fear of needles). The condition was officially recognized in 1994 in the [DSM-IV \(Diagnostic and Statistical Manual, 4th edition\)](#) as a [specific phobia](#) of [blood/injection/injury type](#). Because of his condition, it would be necessary to put Richard under general anesthesia to plant a PPD.

I have assessed Richard. He has no signs and symptoms consistent with active pulmonary or laryngeal tuberculosis. Therefore, the risk of placing him under general anesthesia to perform a PPD far outweighs any perceived benefit.

If Richard requires general anesthesia in the future for a medical or dental procedure, or if Richard develops signs and symptoms consistent with active pulmonary or laryngeal TB, I will have a PPD planted at that time.”

How is an agency supposed to evaluate individuals excluded from TB testing?

Individuals excluded from TB testing should be evaluated the same as individuals with a history of a positive PPD. These people should be clinically evaluated for signs and/or symptoms suggestive of TB. If the person is free of signs and symptoms of active tuberculosis disease, no further evaluation is needed unless the person displays signs and symptoms indicative of active pulmonary or laryngeal tuberculosis. If the person is symptomatic, a chest x-ray examination and further clinical evaluation are indicated prior to receipt of service/employment.

OPWDD does not require, nor does it encourage, the use of annual chest x-rays for routine screening of persons for tuberculosis. Chest x-rays for persons who are excluded from testing should only be done if they have signs and symptoms of active pulmonary or laryngeal tuberculosis, or at the specific request of their own health care provider.





ADDITIONAL EMPLOYEE CONSIDERATIONS

What employees need initial TB testing?

All employees, volunteers, contractors, family care providers and approved substitute/respite providers working in a developmental center or a certified facility must have initial TB testing completed prior to their first day of employment or service provision. This requirement can be met by documentation of testing prior to this employment.

(see “**What about people who have already had a PPD? Do they need two more?**”

If the first step of the two-step PPD is negative the person may start working.

What is the first day of employment?

The first day of employment is the first day that a person is paid.

Is orientation considered employment?

Yes. OSHA’s charge is to protect staff from injury or disease related to employment. Therefore, staff must have initial testing completed prior to the first day of employment including prior to the first day of orientation. If the first step of the two-step PPD is negative the person may start orientation.

What is a contractor?

A contractor is any entity or person subject to a contractual arrangement with OMRDD or a service provider, to perform a service in exchange for financial or other consideration. This includes independent contractors and parties who are employed by contractor agencies. However, for purpose of TB testing, the term contractors does not include those parties or entities that have minimal or no contact with consumers, such as someone who plows the driveway, landscapers, roofers, etc.

Staff from temporary service agencies (nurses, sitters etc) provide services through a contract agreement and would be subject to TB testing.

What is a volunteer?

A volunteer is a person or entity that provides service without financial or other compensation. This does not include participants in groups that only periodically are in contact with persons receiving services (e.g. groups who come in to sing holiday songs). The provisions applying to volunteers in this section also apply to students, interns and senior companions.





Are there specific requirements for retention of records related to TB testing?

There are no separate requirements for record retention for Tuberculosis related testing. This information is included in the employee or volunteer records of the individual and must be maintained in a secure and confidential manner consistent with all other aspects of a personal history file.

ADDITIONAL SERVICE RECIPIENT CONSIDERATIONS

Initial testing of consumers

Because of the logistical issues involved with service recipients being TB tested prior to their first day of receipt of service, if a new recipient of service (in a developmental center or a certified facility) does not have proof of TB testing within 12 months, OPWDD has determined that they may be assessed by an RN, MD, NP or PA immediately before or on the first day of service for signs and symptoms of active pulmonary tuberculosis. The assessment is the same as that done for persons with a history of a positive PPD. If the service recipient does not have signs and symptoms of active pulmonary tuberculosis, the agency then has 7 business days to conduct the TB testing (either an IGRA or the first step of the two step PPD).

