Adopted: 9/24/2021
Effective: 12/22/2021

VIRGINIA BOARD OF PHARMACY

TUBERCULIN SKIN TESTING TWO-STEP PROTOCOL: FOR INITIAL TESTING IN ADULTS WHO MAY BE UNDERGOING ANNUAL TESTING

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration, and interpretation of the Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control. The two-step testing will help in reducing the likelihood that a boosted reaction to a subsequent TST will be misinterpreted as a recent infection.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must successfully complete the following training:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection[2] or from a comparable provider approved by the Virginia Board of Pharmacy

Records documenting completion of required training shall be maintained by the pharmacist for a minimum of six years following the last patient encounter pursuant to this protocol or subsequent iterations for which the training is required. The training records may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either onsite or offsite. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must understand and follow procedures as specified by:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing

---

[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.**

[2] CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf

- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations[3]: Sections 1 and 2
- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019[4]
- High Burden TB Country List, Virginia Department of Health[5]

INCLUSION CRITERIA

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who are receiving initial TB skin testing and may continue to receive an annual TST for employment purposes. The 2020 CDC Guidelines for Screening, Testing and Treatment of Healthcare Personnel no longer include a recommendation for serial screening for the majority of healthcare personnel after the initial screening, unless they fall into a particular high risk group (e.g., pulmonologists) or there is an exposure or on-going transmission at the healthcare facility[6].

EXCLUSTION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to a TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month[7] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a positive TST

---

[3]Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

[4] Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[5] High Burden TB Country List, Virginia Department of Health. Available at: https://www.vdh.virginia.gov/tuberculosis/screening-testing/

[6] Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[7] Fact Sheets: Tuberculin Skin Testing. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

- History of documented previous Bacilli Calmette-Guerin (BCG) vaccine

CONSIDERATIONS

- Individuals from high-burden TB countries may have received the BCG vaccine and not remember, this should be considered when administering the TST.
- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.
- Individuals who are contacts of a confirmed positive TB case may seek testing from a pharmacist. If a pharmacist becomes aware of this during the risk assessment, notification shall be made to the local health department. TST may still be performed.

MEDICATIONS

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. TST is one of two standard methods for determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

Product	Mfr. / Dist.	NDCs*
Tubersol	Sanofi Pasteur	1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22
Aplisol	Parkdale	1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05

**or any other FDA-approved tuberculin skin test antigen*

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined in this protocol and in the American Thoracic Society (ATS)/CDC Guideline.[1] In addition, the need for periodic retesting and the presence of individual risk factors for occupational exposures will be used to determine the need for two-step testing. A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self-administered by the client. The Report of Tuberculosis Screening in Appendix B must

be completed at the conclusion of the screening. The Report (Appendix B) may be provided to the patient and may be subsequently provided to an employer, if necessary, and authorized by the patient. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions

The TST is performed by injecting 0.1mL of tuberculin PPD in 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 (see Appendix C for detailed procedures for placing the TST).

PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. Schedule an appointment for the reading at the time the TST is administered. An individual 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) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline[1] (Appendix D). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

An initial positive reaction is considered a TB infection and a second TST is not required. The patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. An initial negative reaction requires a retest 1-3 weeks after the initial TST. Upon retesting, a negative reaction suggests the patient does not have a TB infection, in which case a TST can be repeated annually, if required. However, a positive reaction after retesting is considered a boosted reaction due to a TB infection that occurred a long time ago. In this case, the patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. A referral is required for this follow-up and so that treatment considerations can be made if latent TB infection is diagnosed (see Appendix E)[2].

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

- Need to return in 48-72 hours for interpretation of the TST
- If mild itchiness occurs, avoid scratching the site. Do not use creams or other treatments to treat the itchiness.
- Redness may develop. This is a normal reaction, avoid using creams or other treatments.
- Result of the TST
- Need for a second TST in 1-3 weeks if the initial result is negative
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

DOCUMENTATION

Pharmacists will document via prescription or medical record each person who receives a TST under this protocol including:

1. Documentation for the dispensing of prescription medication; and documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of the completion of the risk assessment, date and time of test placement, date and time of test reading, results and interpretation must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of the test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as a requirement of employment. The Report of TB Screening is included in Appendix B. The individual should sign a release of information indicating their consent that this information can be shared (refer to the Patient Authorization section in Appendix A).
4. Certain laws or regulations may preclude a pharmacist from signing documentation for an individual to certify the individual has been examined and is free of tuberculosis. This should be ascertained prior to administration of the TST. The individual may have to be referred back to their primary care provider to obtain necessary certification.

NOTIFICATION AND REFERRAL

Prior to screening the patient for TB, the patient must complete and sign the Patient

Authorization section of Appendix A authorizing the pharmacist to notify the primary health care provider or local health department of a positive TST result. If the patient refuses such authorization, the pharmacist shall not screen the patient for TB and shall refer the patient to a primary health care provider for evaluation. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist who administers PPD for a TST shall notify the patient's primary health care provider that the pharmacist has administered a TST and inform the provider of the test results within three (3) business days, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Note: A pharmacy may create and use an electronic format of this protocol if the questions and process are identical to the Board-adopted protocol.

VIRGINIA BOARD OF PHARMACY TUBERCULOSIS RISK ASSESSMENT FORM
(For Pharmacist Use When Screening Patient; Not intended to be a Self-Screening Document)

Name: _____ Today's Date: _____ Weight: _____
Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____
Healthcare Provider's Telephone, Fax, or Email:_____
Any Allergies to Medications? *Yes / No* If yes, list here: _____

Are you required to have a Tuberculosis (TB) Risk Assessment or Tuberculin Skin Test (TST) for your job, school, or other mandatory reason? Yes □ No□
If yes, specify reason? _____

If YES, ensure pharmacists may legally sign document certifying assessment or TST results for intended purpose. If pharmacist may not legally certify, refer patient to PCP.
If NO, proceed with completing form.

Patient Authorization:
I hereby authorize the pharmacist to perform the TB Risk Assessment and administer the TST, if warranted. I agree that the results of this test may be shared with other health care providers. I acknowledge that I have received the Notice of Privacy Practices. I understand that: this information will be used by health care providers for care and not for statistical purposes only; this information will be kept confidential; medical records must be kept at a minimum of six years following the last patient encounter except for (i) records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative, or (ii) records that are required by contractual obligation or federal law to be maintained for a longer period of time.

I agree to return to the pharmacy located at _____
to have the results of the test read by the pharmacist on this date_____.

I further authorize the pharmacist to notify the following of a positive TB Skin Test (choose one):

☐Primary Care Physician:_____ _____
(First & Last Name) (Tel. #)
☐ Local Free Clinic ☐ Local Federally-Qualified Healthcare Center

*Patient Printed Name:*_____ *Date:*_____
*Patient Signature:*_____ *Date:*_____

If patient does not agree to Patient Authorization section, refer patient to PCP.

Screening for TB Symptoms:

1.	Do you have coughing that has lasted for more than 3 weeks?	Yes □ No□
2.	Are you coughing up blood or mucous?	Yes □ No□
3.	Do you have a fever? Temperature reading:_____	Yes □ No□
4.	Have you experienced unintentional weight loss?	Yes □ No □
5.	Do you have a loss of appetite? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
6.	Are you experiencing night sweats? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
7.	Do you have fatigue? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
If patient answered YES to at least one of the questions above (taking 5, 6, and 7 in context), stop here and refer patient to PCP. If patient answered NO to all of the questions above, proceed with completing this form.		

Screening for TB History:

8.	Have you ever been treated for TB Disease/Latent Tuberculosis Infection (LTBI)?	Yes □ No□

9.	Have you ever had a documented prior positive test for TB infection? If yes, date of positive test (if known):_____ Type of Test: ☐ TST/IGRA ☐ TST Reading:_____mm If yes to prior positive test, did you have a chest radiograph performed after the positive test? CXR date (if known):_____ Results: ☐ Normal ☐ Abnormal If chest radiograph was normal after positive test, did you receive LTBI treatment?	Yes □ No□ Yes □ No□ Yes □ No□
If YES to prior positive TB test, those seeking testing for administrative purposes must have documentation of the past prior positive TB test otherwise testing will still be required for work clearance. If YES to prior positive TB test, and NO subsequent chest radiograph performed, refer patient to PCP. If YES to prior positive TB test and YES to subsequent NORMAL chest radiograph, no repeat TB testing is indicated if asymptomatic; refer for LTBI treatment if previously untreated. If NO prior positive TB test, proceed with completing this form.		
Screening for TB Infection Risk		
10.	Have you had close contact to someone with known or suspected active TB disease at any time? Name of source case:_____	Yes □ No□
If YES, report to local health department. TST may still be performed. If NO, proceed with completing this form.		
Screening for High Burden TB Countries:		
11.	Were you born in a country outside of the United States? If yes, which country? _____	Yes □ No□
12.	Have you traveled or resided in a country outside of the United States for 3 months or longer? If yes, which country? _____	Yes □ No□
13.	Have you traveled or resided in a country outside of the United States for the purpose of receiving medical treatment? If yes, which country? _____	Yes □ No□
Refer to current VDH High Burden TB Countries list. If YES and born in or traveled to/resided in country on list ≥ 3 months, refer to BCG vaccination status. If BCG vaccinated, refer for IGRA. For others, TST may still be performed. If NO or country did not appear on list, proceed with completing this form.		
Screening for BCG		
14.	Were you ever administered the BCG vaccination?	Yes □ No□
If YES, refer. If NO, proceed with completing form.		
Assessing Other Risks for Acquiring LTBI		
15.	Do you reside or work in a high TB risk congregate setting (e.g., correctional facility, nursing home, and long-term care facilities for elderly, mentally ill, or persons living with AIDS)?	Yes □ No □
16.	Are you a healthcare worker who serves high-risk clients? ***NOTE: Stop and refer patient to local health department if screening is part of an ongoing contact investigation within the facility approved by the local health department.***	Yes □ No □
17.	Have you experienced homelessness within the past two years?	Yes □ No □
18.	Do you inject drugs for recreational use or use crack cocaine?	Yes □ No □
19.	Do you have a regular health care provider? Have you received medical care within the last two years? ***If NO to both questions, patient is considered medically underserved.***	Yes □ No □ Yes □ No □
If YES to any of the questions (#15-18) or if the patient is medically underserved, and screening is NOT part of an ongoing contact investigation within a facility approved by the local health department, a TST is indicated. If NO to questions #15-18 and patient is not medically underserved, proceed with completing form.		
Assessing Risk for Developing TB Disease if Infected		
20.	Have you been diagnosed with HIV infection?	Yes □ No □

21.	Are you at risk for HIV infection? ***If YES, recommend an HIV test. Administer TST even if patient refuses HIV test or consider referral for IGRA testing.***	Yes □ No □
22.	Were you recently infected with Mycobacterium tuberculosis?	Yes □ No □
23.	Do you have any of the following medical conditions: - Low body weight due to chronic malabsorption syndromes? - Lung disease silicosis caused by breathing in tiny bits of silica? - Diabetes? - End stage renal disease or on hemodialysis? - Head or neck cancer? - Leukemia? - Lymphoma? - Hematologic or reticuloendothelial disease?	 Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □
24.	Have you ever had any of the following procedures: - Gastrectomy? - Intestinal bypass? - Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)?	 Yes □ No □ Yes □ No □ Yes □ No □
25.	Do you receive treatment with TNF-alpha antagonists (e.g., infliximab, etanercept), steroids (equivalent of prednisone ≥ 15mg/day for ≥ 1 month) or other immunosuppressive medication?	Yes □ No□
If YES to any of the questions in this section, TST test is indicated. If YES to HIV positive questions or on immunosuppressive therapy, consider referal for IGRA testing.		
Note: Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment.		

Report of Tuberculosis Screening

Name: _____ Date of Birth: _____ Date: _____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by (PRINT OR TYPE):
Name of Pharmacist: _____
Name of Pharmacy: _____ Tel. #:_____
Pharmacy Address: _____
TB Screening and/or Testing Conclusions

I. No Symptoms or Risks Identified on TB Risk Assessment

☐ A tuberculin skin test (TST) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need annual testing.

☐ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If one of these two statements applies, select the appropriate statement and skip to section IV and select statement "A".
If neither statement applies, go to section II.
If in a health care setting that requires a test for TB infection but no symptoms are present, go to Section III.

II. Symptoms Consistent with Potential Tuberculosis are Present

Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Advise of isolation precautions. Proceed to section IV and select statement "B". If there are no symptoms consistent with TB, go to section III.

III. Testing for TB Infection via Tuberculin Skin Test (record both tests if a 2-step TST was required)

#1 TST Lot: _____ Date Administered: _____ Time: _____Site: _____
Pharmacist Name: _____
Date read: _____ Time: _____Results: _____mm Interpretation: Negative ☐ Positive ☐
Pharmacist Name: _____

#2 TST Lot: _____ Date Administered: _____ Time: _____ Site: _____
Pharmacist Name: _____
Date read: _____ Time:_____Results: _____mm Interpretation: Negative ☐ Positive ☐
Pharmacist Name: _____

If test(s) above are negative, proceed to section IV and select statement "A".
If test(s) above are positive, proceed to section IV and select statement "B".

IV. TB Screening/Testing Conclusion

☐ A. Based on the TB Screening and/or TST, the individual listed above does not demonstrate a risk of having tuberculosis in a communicable form.

☐ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual was counseled and referred to (check all that apply):

☐Primary Care Provider (Name): _____ (Tel.) _____
☐ Local Health Department (Name):_____ (Tel.) _____
☐ Provided Contact Information for Primary Health Care Providers

This individual should be treated by a PCP for:

☐ Evaluation for Active TB Disease Based on Symptoms *(pharmacist must immediately call local health department);*
☐ Prior Positive Test with No Subsequent Normal Chest Radiograph;
☐ Prior Positive Test with Normal Chest Radiograph, but LTBI Previously Untreated;
☐ IGRA since Individual Born in High Burden TB Country;
☐ IGRA since Individual has Received BCG;
☐ IGRA since Individual is Immunocompromised or on Immunosuppressive Therapy;
☐ Positive TST Result.

Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date _____ *Trainer (QC by)* _____ *Trainee (TST placed by)* _____

Scoring: ✓ *or Y = Yes* *X or N = No* *NA = Not Applicable*

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

2. Syringe† filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen§

_____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.¶
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ Removes needle guard.
_____ Inserts needle into the vial.
_____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.
_____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.
_____ Removes needle from vial.
_____ Returns antigen vial to the refrigerator immediately after filling.

3. TST administration site selected and cleaned

_____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**
_____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.
_____ Cleans the site with antiseptic swab using circular motion from center to outside.
_____ Allows site to dry thoroughly before administering antigen.

4. Needle inserted properly to administer antigen

_____ Rests arm on firm, well-lit surface.
_____ Stretches skin slightly.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ Advances needle until entire bevel is under the first layer of skin.
_____ Releases stretched skin.
_____ Injects entire dose slowly.
_____ Forms wheal, as liquid is injected.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____mm).
_____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
_____ Discards used gauze or cotton ball according to local standard precautions.
_____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
_____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
_____ Uses appropriate hand hygiene methods after placing TST.

5. Explanation to the client regarding care instructions for the injection site

_____ The wheal (bump) is normal and will remain about 10 minutes.
_____ Do not touch wheal; avoid scratching.
_____ Avoid pressure or bandage on injection site.
_____ Rare local discomfort and irritation does not require treatment.
_____ May wash with soap and water (without pressure) after 1 hour.
_____ No lotions or liquids on site, except for light washing, as above.
_____ Keep appointment for reading.

* Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

† Use a ¼–½-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

§ Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. Am J Respir Crit Care Med 2000;161:1376–95.

¶ Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid–containing vaccines instead of tuberculosis skin tests. MMWR 2004;53:662–4.

** If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site. **SOURCE:** National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

†† Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

Appendix F. (*Continued*) Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

Date _____ **Trainer (QC by)** _____ **Trainee (TST placed by)** _____

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Preliminary

_____ Uses appropriate hand hygiene methods before starting.
_____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
_____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
_____ Uses well-lit area.
_____ Inspects for the site of the injection.

2. Palpate — finding margin ridges (if any)

_____ Palpates with arm bent at elbow at a 90° angle.
_____ Lightly sweeps 2-inch diameter from injection site in four directions.
_____ Uses zigzag featherlike touch.
_____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

If induration is present, continue with these steps†:

3. Placing marks

_____ Holds palm over injection site.
_____ Cleanse site with antiseptic swab using circular motion from center to outside.
_____ Uses fingertips to find margins of the induration.
_____ Marks the induration by placing small dots on both sides of the induration.
_____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.
_____ Marks dots transverse (perpendicular) to long axis of forearm.

4. Placing and reading ruler

_____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
_____ Uses appropriate hand hygiene methods after reading TST result.

5. Documenting results

_____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
_____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; http://www.fda.gov/medwatch report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.
† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).
§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

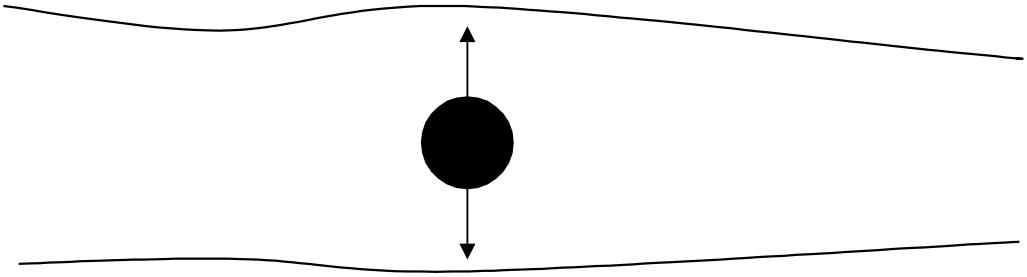
Classification of the Tuberculin Skin Test Reaction[1]

≥5 mm Induration	≥10 mm Induration	≥15 mm Induration
Considered positive in the following persons: ● Persons living with the human immunodeficiency virus (HIV) ● Recent contacts of a person with Tuberculosis (TB) disease ● Persons with a chest radiography (CXR) findings suggestive of previous TB disease ● Patients with organ transplants ● Persons who are immunosuppressed for other reasons (e.g., prolonged therapy with corticosteroids equivalent of ≥15 mg per day of prednisone for for 1 month or longer or those taking tumor necrosis factor-alpha [TNF-alpha] antagonists)	Considered positive in the following persons: ● Persons born in countries where TB disease is common including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB ● Persons with substance use disorders ● Mycobacteriology laboratory personnel ● Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities ● Persons with certain medical conditions that place them at high risk for TB, such as silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions ● Persons <90% of ideal body weight ● Children aged <5 years ● Infants, children, and adolescents exposed to adults in high-risk categories	Considered positive in any person, inducing persons with no known risk factors for TB.

*All tests should be interpreted based on patient risk and test characteristics.

A negative TST result does not exclude LTBI or active TB disease.

[1] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations, Appendix 1: Interpretation of Test Results.(NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration



Measure TSTs Transversely

CDC LTBI: A Guide for Primary Health Care Providers

https://www.cdc.gov/tb/publications/ltbi/pdf/LTBIbooklet508.pdf

Figure 1: The TST Booster Phenomenon

As the years pass, the person's ability to react to tuberculin lessens. Occurs mainly in previously infected older adults whose ability to react to tuberculin has decreased over time. These people should still be considered for LTBI treatment after ruling out TB disease, particularly if they have risk factors for progression to disease.

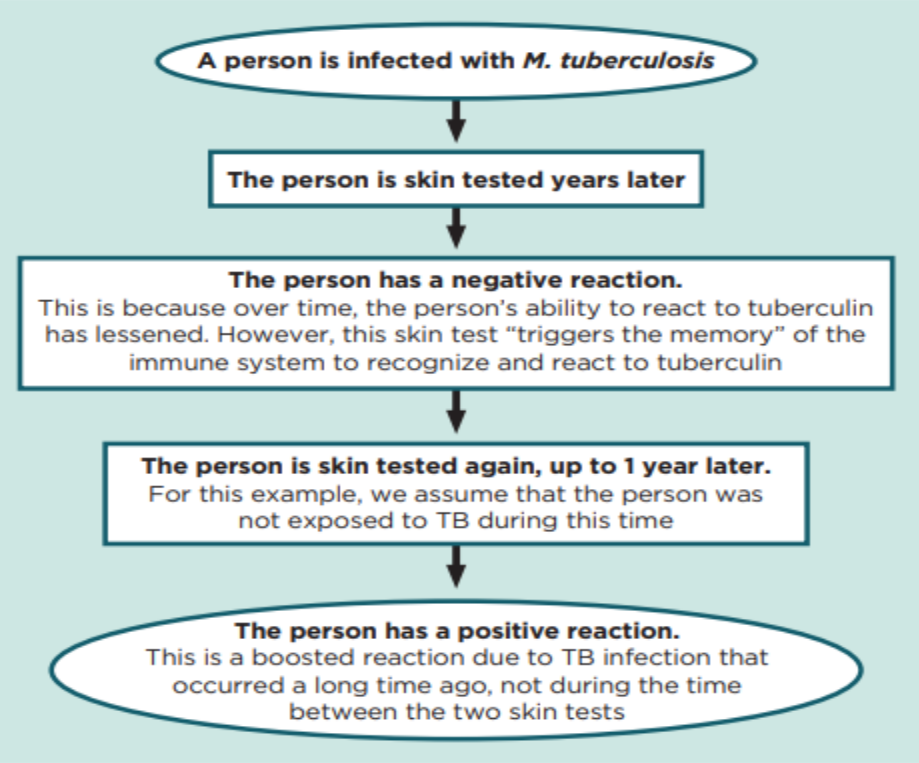
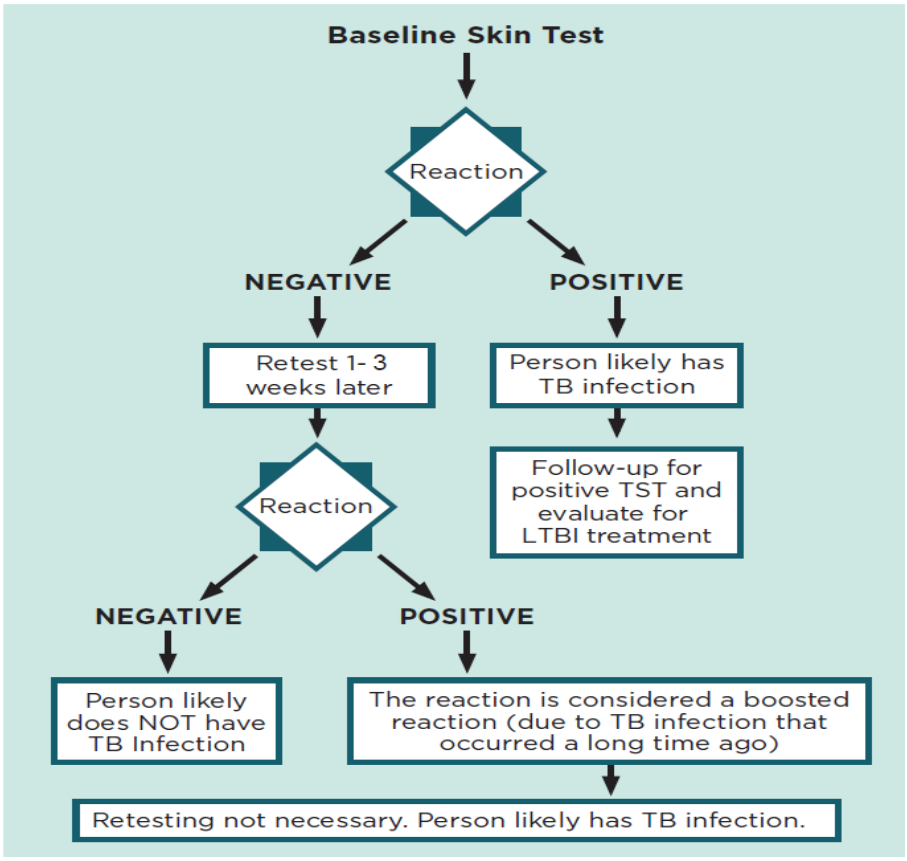


Figure 2: Two-Step TST Testing

Two-step testing is a strategy used to reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection (Figure 2). Two-step testing should be used for the initial skin testing of persons who will be retested periodically. If the reaction to the first TST is classified as negative, a second TST should be repeated 1 to 3 weeks later. A positive reaction to the second TST likely represents a boosted reaction. Based on this second test result, the person should be classified as previously infected. This would not be considered a skin test conversion or a new TB infection; however, the patient may still be a candidate for LTBI treatment. If the second skin test result is also negative, the person should be classified as having a negative baseline TST result. **If either the first or second test result is positive, the individual should be referred for follow-up and evaluation for LTBI treatment.**


Baseline Skin Test
Reaction
NEGATIVE
POSITIVE
Retest 1- 3 weeks later
Person likely has TB infection
Follow-up for positive TST and evaluate for LTBI treatment
Reaction
NEGATIVE
POSITIVE
Person likely does NOT have TB Infection
The reaction is considered a boosted reaction (due to TB infection that occurred a long time ago)
Retesting not necessary. Person likely has TB infection.