

**Pharmacy Name:** \_\_\_\_\_

**Pharmacy Permit Number:** \_\_\_\_\_

## **TUBERCULIN SKIN TESTING PROTOCOL**

**V1**

**Approved 11/19/2025**

### **PURPOSE**

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration and interpretation of the Mantoux Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control.

### **PHARMACIST EDUCATION AND TRAINING**

Prior to initiating the dispensing, administration and interpretation of TST under this protocol, the pharmacist(s) must successfully complete training and follow procedures as specified by the US Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing<sup>1</sup> from a provider accredited by the Accreditation Council for Pharmacy Education, completion of Module 3 of the CDC Core Curriculum on Tuberculosis: Targeted testing and the diagnosis of latent tuberculosis infection and tuberculosis disease<sup>2</sup>, or by a comparable provider approved by the Kentucky Board of Pharmacy.

### **Inclusion Criteria**

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration and interpretation of TST to adults ages  $\geq 18$  years of age who:

- Are at increased risk for latent or active tuberculosis disease
- Need TST documented for school attendance or insurance purposes (for One-Step TST)
- Receiving an annual TST for employment purposes (for Two-Step TST)

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<sup>1</sup> 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>.

<sup>2</sup> Self-Study Module 3: Targeted Testing and the Diagnosis of Latent Tuberculosis Infection and Tuberculosis Disease Available at: [https://www.cdc.gov/tb/media/pdfs/Self\\_Study\\_Module\\_3\\_Testing\\_and\\_Diagnosis\\_of\\_Latent\\_TB\\_Infection\\_and\\_TB\\_Disease.pdf](https://www.cdc.gov/tb/media/pdfs/Self_Study_Module_3_Testing_and_Diagnosis_of_Latent_TB_Infection_and_TB_Disease.pdf)

## Exclusion Criteria

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to 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 28 days
- History of positive TST
- History of documented previous bacilli Calmette-Guerin (BCG) vaccination

## MEDICATIONS

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The Mantoux tuberculin skin test (TST) is the standard method of 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<sup>3</sup>

- Tubersol
- Aplisol
- Or any other FDA-approved tuberculin skin test antigen

## PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined in the ATS/CDC Guideline.<sup>1</sup> In addition, the need for periodic retesting and individual risk factors for occupational exposures will be used to determine the need for two-step testing.

### Relevant Medical and Social History

- Past medical history, including vaccination history
- Current medications
- Allergies and hypersensitivities
- Current living environment
- History of TST and reactions to TST

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<sup>3</sup> David M. Lewinsohn, Michael K. Leonard, Philip A. LoBue, David L. Cohn, Charles L. Daley, Ed Desmond, Joseph Keane, Deborah A. Lewinsohn, Ann M. Loeffler, Gerald H. Mazurek, Richard J. O'Brien, Madhukar Pai, Luca Richeldi, Max Salfinger, Thomas M. Shinnick, Timothy R. Sterling, David M. Warshauer, Gail L. Woods, Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children, *Clinical Infectious Diseases*, Volume 64, Issue 2, 15 January 2017, Pages e1–e33, <https://doi.org/10.1093/cid/ciw694>.

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 A for detailed procedures).

## **PROCEDURES FOR MONITORING AND FOLLOW UP**

The skin test reaction should be read between 48 and 72 hours after administration. 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<sup>1</sup> (Appendix B). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred to a healthcare provider for treatment and further advised regarding isolation precautions.

For two-step testing, an initial positive reaction is considered a TB infection and a second TST is not required. 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 TST can be repeated annually. 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 has a latent TB infection and referral is required such that treatment considerations can be made (see Appendix D)<sup>2</sup>.

## **EDUCATION REQUIREMENTS**

Individuals receiving TST will receive education regarding:

- Need to return in 48-72 hours for interpretation of the TST
- Result of the TST
- For two-step testing, 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 (see Appendix C), patient must be immediately referred to a health care provider for treatment and further advised regarding isolation precautions.

## DOCUMENTATION

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

1. Documentation as required in 201 KAR 2:171 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 test and result must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of 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 requirement of employment.

## NOTIFICATION AND REFERRAL

Pharmacist shall ask all persons receiving TST under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the test performed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive a TST under this protocol provided all other applicable requirements of the protocol are met.

Guidance provided by KRS 215.590 and 902 KAR 20:205 indicates **all positive results** must be sent to the local health department within one (1) business day and, if available, the individual's primary care provider for follow-up.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of individuals receiving TST under this protocol within 7 days of initiating dispensing.]

**TERMS**

This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

**SIGNATURES**

\_\_\_\_\_  
Prescriber Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Prescriber Kentucky License Number

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Pharmacist Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Pharmacist Kentucky License Number

\_\_\_\_\_  
Pharmacist Signature

Course Taken for Training: \_\_\_\_\_

Provider of Training: \_\_\_\_\_

Date Training Completed: \_\_\_\_\_

**Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.**

**For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.**

## ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol,  
entitled: \_\_\_\_\_  
and that I will follow all guidelines and requirements included in the Board-authorized  
protocol.

\_\_\_\_\_  
Pharmacist Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Pharmacist Kentucky License Number

\_\_\_\_\_  
Pharmacist Signature

Course Taken for Training: \_\_\_\_\_

Provider of Training: \_\_\_\_\_

Date Training Completed: \_\_\_\_\_

## Appendix A: Procedural Checklist for Placing/Reading Tuberculin Skin Tests

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MMWR

December 30, 2005

### 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) _____	
<b>Scoring:</b> ✓ or Y = Yes    X or N = No    NA = Not Applicable			
<b>1. Preliminary</b>			
<input type="checkbox"/> Uses appropriate hand hygiene methods before starting.	<input type="checkbox"/> Holds needle bevel-up and tip at 5°–15° angle to skin.		
<input type="checkbox"/> Screens patient for contraindications (severe adverse reactions to previous TST).*	<input type="checkbox"/> Inserts needle in first layer of skin with tip visible beneath skin.		
<input type="checkbox"/> Uses well-lit area.	<input type="checkbox"/> Advances needle until entire bevel is under the first layer of skin.		
<b>2. Syringe<sup>†</sup> filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen<sup>§</sup></b>			
<input type="checkbox"/> Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen. <sup>¶</sup>	<input type="checkbox"/> Releases stretched skin.		
<input type="checkbox"/> Checks label and expiration date on vial.	<input type="checkbox"/> Injects entire dose slowly.		
<input type="checkbox"/> Marks opening date on multidose vial.	<input type="checkbox"/> Forms wheal, as liquid is injected.		
<input type="checkbox"/> Fills immediately after vial removed from refrigeration.	<input type="checkbox"/> Removes needle without pressing area.		
<input type="checkbox"/> Cleans vial stopper with antiseptic swab.	<input type="checkbox"/> Activates safety feature of device per manufacturer's recommendations, if applicable.		
<input type="checkbox"/> Twists needle onto syringe to ensure tight fit.	<input type="checkbox"/> Places used needle and syringe immediately in puncture-resistant container without recapping needle.		
<input type="checkbox"/> Removes needle guard.	<input type="checkbox"/> Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____ mm).		
<input type="checkbox"/> Inserts needle into the vial.	<input type="checkbox"/> If blood or fluid is present, blots site lightly with gauze or cotton ball.		
<input type="checkbox"/> Draws slightly over 0.1 mL of 5 TU PPD into syringe.	<input type="checkbox"/> Discards used gauze or cotton ball according to local standard precautions.		
<input type="checkbox"/> 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.	<input type="checkbox"/> 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.		
<input type="checkbox"/> Removes needle from vial.	<input type="checkbox"/> 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).		
<input type="checkbox"/> Returns antigen vial to the refrigerator immediately after filling.	<input type="checkbox"/> Uses appropriate hand hygiene methods after placing TST.		
<b>3. TST administration site selected and cleaned</b>			
<input type="checkbox"/> Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site.**	<b>5. Explanation to the client regarding care instructions for the injection site</b>		
<input type="checkbox"/> Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.	<input type="checkbox"/> The wheal (bump) is normal and will remain about 10 minutes.		
<input type="checkbox"/> Cleans the site with antiseptic swab using circular motion from center to outside.	<input type="checkbox"/> Do not touch wheal; avoid scratching.		
<input type="checkbox"/> Allows site to dry thoroughly before administering antigen.	<input type="checkbox"/> Avoid pressure or bandage on injection site.		
<b>4. Needle inserted properly to administer antigen</b>			
<input type="checkbox"/> Rests arm on firm, well-lit surface.	<input type="checkbox"/> Rare local discomfort and irritation does not require treatment.		
<input type="checkbox"/> Stretches skin slightly. <sup>††</sup>	<input type="checkbox"/> May wash with soap and water (without pressure) after 1 hour.		
	<input type="checkbox"/> No lotions or liquids on site, except for light washing, as above.		
	<input type="checkbox"/> 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			
<b>1. Preliminary</b> _____ 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.	_____ Marks dots transverse (perpendicular) to long axis of forearm.		
<b>2. Palpate — finding margin ridges (if any)</b> _____ 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.	<b>4. Placing and reading ruler</b> _____ 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.		
<b>If induration is present, continue with these steps†:</b>  <b>3. Placing marks</b> _____ 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.	<b>5. Documenting results</b> _____ 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 _____		

\* 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.

**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.



## Appendix B: Interpretation of the Tuberculin Skin Test

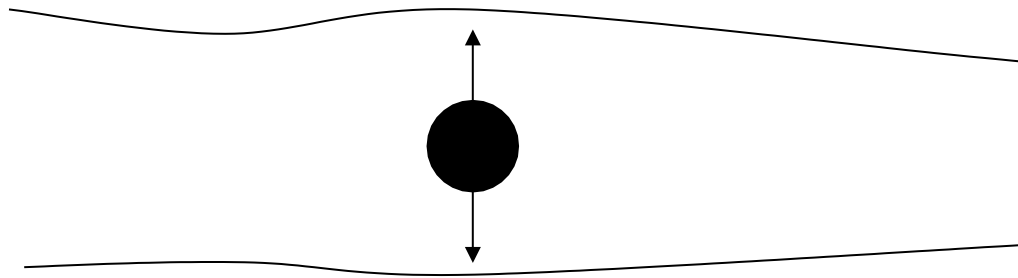
The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

Classification of the Tuberculin Skin Test Reaction (Table 5 page12)

**TABLE 5.**  
**Interpretation of Tuberculin Skin Test (TST) Reactions**

5 or more millimeters
<p>A TST reaction of <b>≥5 mm</b> of induration is considered positive for:</p> <ul style="list-style-type: none"><li>• People living with HIV</li><li>• Recent contacts of people with infectious TB</li><li>• People with chest x-ray findings suggestive of previous TB disease</li><li>• People with organ transplants</li><li>• Other immunosuppressed patients (e.g., patients on prolonged therapy with corticosteroids equivalent to/greater than 15 mg per day of prednisone or those taking TNF-alpha antagonists)</li></ul>
10 or more millimeters
<p>A TST reaction of <b>≥10 mm</b> of induration is considered positive for:</p> <ul style="list-style-type: none"><li>• People born in countries where TB disease is common, including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala</li><li>• People who abuse drugs</li><li>• Mycobacteriology laboratory workers</li><li>• People who live or work in high-risk congregate settings (e.g., nursing homes, homeless shelters, or correctional facilities)</li><li>• People with certain medical conditions that place them at risk for TB (e.g., silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, or certain intestinal conditions)</li><li>• People with a low body weight (&lt;90% of ideal body weight)</li><li>• Children younger than 5 years of age</li><li>• Infants, children, and adolescents exposed to adults in high-risk categories</li></ul>
15 or more millimeters
<p>A TST reaction of <b>≥15 mm</b> of induration is considered positive for:</p> <ul style="list-style-type: none"><li>• People with no known risk factors for TB</li></ul>

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



**Measure TSTs Transversely**

CDC Latent Tuberculosis Infection: A Guide for Primary Health Care Providers—Table 5

<https://www.cdc.gov/tb/media/pdfs/Latent-TB-Infection-A-Guide-for-Primary-Health-Care-Providers.pdf>

Appendix C: Kentucky Department for Public Health TB Risk Assessment Forms (Example of TB-4 TB Risk Assessment Form (Rev. July2024); TB-4a Instructions for TB Risk Assessment; TB-4b Additional Instructions) *Please check the Kentucky*

*Department for Public Health website for updates to TB Risk Assessment forms under Clinical Service Guide Forms and Teaching Sheets:*

<https://chfs.ky.gov/agencies/dph/dpqi/hcab/Pages/ccsguide.aspx>

INSERT LOGO HERE	<b>Kentucky Department For Public Health Tuberculosis (TB) Risk Assessment</b>		
Patient name (L,F,M): _____ DOB: _____ Race: ____ Sex: ____ SSN: _____			
Address: _____ City, State, Zip: _____			
Home/Work #: _____ Cell#: _____ Patient Pregnant: ____ No ____ Yes; If Yes, LMP _____			
Language: _____ Country of Origin: _____ Year arrived in US: _____ Interpreter needed: ____ No ____ Yes			
Allergies: _____ Current Medications: _____			

<b>I. <u>Screen for Active TB Symptoms (Check all that apply)</u></b> <input type="checkbox"/> None (Skip to Section II, "Screen for TB Infection Risk") <input type="checkbox"/> Cough for $\geq 3$ weeks $\rightarrow$ Productive: ____ YES ____ NO <input type="checkbox"/> Hemoptysis <input type="checkbox"/> Fever, unexplained <input type="checkbox"/> Unexplained weight loss <input type="checkbox"/> Poor appetite <input type="checkbox"/> Night sweats <input type="checkbox"/> Fatigue <div style="border: 1px solid black; padding: 5px; margin-top: 5px; width: fit-content;"> <i>Evaluate these symptoms in context</i> </div> <div style="border: 1px solid black; padding: 5px; margin-top: 10px; width: fit-content;"> <b>Pediatric Patients (<math>\leq 5</math> years of age):</b>  <input type="checkbox"/> Wheezing  <input type="checkbox"/> Failure to thrive  <input type="checkbox"/> Decreased activity, playfulness and/or energy  <input type="checkbox"/> Lymph node swelling  <input type="checkbox"/> Personality changes         </div>	<b>IV. <u>History of BCG / TB Skin Test / BAMT / TB Treatment:</u></b> History of prior BCG: ____ NO ____ YES $\rightarrow$ Year: _____ History of prior (+) TST or (+) BAMT: ____ NO ____ YES Date (+) TST / (+) BAMT _____ TST: ____ mm CXR Date: _____ CXR result: ____ ABN ____ WNL Dx: ____ LTBI ____ Disease Tx Start: _____ Tx End: _____ Rx: _____ Completed: ____ NO ____ YES Location of Tx: _____
<b>II. <u>Screen for TB Infection Risk (Check all that apply)</u></b> Individuals with an increased risk for acquiring latent TB infection (LTBI) or for progression to active disease once infected should have a TST. Screening for persons with a history of LTBI should be individualized.  <b>Assess Risk for Acquiring LTBI. The Patient:</b> <input type="checkbox"/> is a current high risk contact of a person known or suspected to have TB disease. <input type="checkbox"/> has been in another country for - 3 or more months where TB is common, and has been in the US for $\leq 5$ years <input type="checkbox"/> is a resident or an employee of a high TB risk congregate setting <input type="checkbox"/> is a healthcare worker who serves high-risk patients <input type="checkbox"/> is medically underserved <input type="checkbox"/> has been homeless within the past two years <input type="checkbox"/> is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories <input type="checkbox"/> injects illicit drugs or uses crack cocaine <input type="checkbox"/> is a member of a group identified by the health department to be at an increased risk for TB infection <input type="checkbox"/> needs baseline/annual screening approved by the health department	<b>V. <u>Finding(s) (Check all that apply)</u></b> <input type="checkbox"/> Previous Treatment for LTBI and/or TB disease <input type="checkbox"/> No risk factors for TB infection <input type="checkbox"/> Risk(s) for infection and/or progression to disease <input type="checkbox"/> Possible TB suspect <input type="checkbox"/> Previous (+) TST or (+) BAMT, no prior treatment
<b>III. <u>Assess Risk for Developing TB Disease if Infected The Patient...</u></b> <input type="checkbox"/> is HIV <u>positive</u> <input type="checkbox"/> has <u>risk for HIV infection, but HIV status is unknown</u> <input type="checkbox"/> was recently infected with <i>Mycobacterium tuberculosis</i> <input type="checkbox"/> has certain clinical conditions, placing them at higher risk for TB disease: _____ <input type="checkbox"/> injects illicit drugs (determine HIV status): _____ <input type="checkbox"/> has a history of inadequately treated TB <input type="checkbox"/> is $>10\%$ below ideal body weight <input type="checkbox"/> is on immunosuppressive therapy (this includes treatment for rheumatoid arthritis with drugs such as REMICADE, HUMIRA, etc.)	<b>VI. <u>Action(s) (Check all that apply)</u></b> <input type="checkbox"/> Issued screening letter <input type="checkbox"/> Issued sputum containers <input type="checkbox"/> Referred for CXR <input type="checkbox"/> Referred for medical evaluation <input type="checkbox"/> Administered the Mantoux TB Skin Test <input type="checkbox"/> Draw BAMT / Interferon-gamma Release Assay ((IGRA) <input type="checkbox"/> Other: _____

<b>TST Brand/Lot # _____ TST Brand/Lot# _____</b>	
Arm: ____ Left ____ Right Date/Time _____ Induration _____ mm	Arm: ____ Left ____ Right Date/Time _____ Induration _____ mm
<b>____ BAMT ____ T-SPOT.TB ____ QFT-TB-Gold-Plus</b>	
Date/Time drawn: _____	
Result: ____ Pos ____ Neg ____ Borderline/Indeterminate	
Screener's signature: _____	
Screener's name (print): _____	
Screener's title: _____	
Date: _____ Phone #: _____	
Comments: _____	

- I hereby authorize the doctors, nurses, or nurse practitioners of the \_\_\_\_\_ Department for Public Health to administer a Tuberculin Skin Test (TST) or draw blood from me or my child named above for a Blood Assay for *Mycobacterium tuberculosis* (BAMT) test.
- I agree that the results of this test may be shared with other health care providers.
- I understand that:
  - this information will be used by health care providers for care and for surveillance /statistical purposes only.
  - this information will be kept confidential

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

**IMPORTANT: A decision to test is a decision to treat.** Given the high rates of false positive TB skin test results, the Kentucky TB Prevention and Control Program discourages administration of the Mantoux TST to persons who are at a low risk for TB infection.



## Kentucky Department For Public Health Instructions for the TB Risk Assessment

### Purpose of Form

The TB Risk Form is a tool to assess and document a patient's TB symptoms and/or risk factors. Completing this form will also help in determining the need for further medical testing and evaluation.

### Directions for Completing the Form

Print clearly and complete this form according to the instructions provided below.

### I. Screen for Presence of TB Symptoms

- Screen the patient for symptoms of active TB disease
- All symptomatic individuals who have not had a positive tuberculin skin test (TST) in the past should: (1) receive a TST or a Blood Assay for *Mycobacterium tuberculosis* (BAMT or Interferon Gamma Release Assay [IGRA]); (2) have their sputum collected; and (3) be referred for an immediate chest x-ray and medical evaluation regardless of the TST or BAMT result.
- If the patient does not have symptoms of active TB disease, go to Section II and assess risk for LTBI and/or disease.
- **Symptoms of active TB disease are more subtle in children.** Children with symptoms of active TB disease should receive a TST, CXR and immediate medical evaluation by medical personnel knowledgeable about pediatric TB.

### II. Screen for TB Infection Risk (check all that apply)

Section II "Assess Risk for Acquiring LTBI":

- If a patient has one or more risk factors for LTBI, then go to Section III (check all that apply) and administer the TST or BAMT.
- If a patient does not have risk factors for LTBI, do not administer the TST or BAMT. Go to Section V and place a check next to "No Risk Factors for TB Infection."

If the patient's school, employment, etc. requires a TB screening, place a check next to "Issued Screening Letter" (Section VI) and provide that document to the patient.

#### **Access Risk for Acquiring LTBI – The following are definitions of select categories of persons at risk for LTBI**

- **Person is a current close contact of another individual known or suspected to have TB disease --**  
Person is part of a current TB contact investigation
- **Person is a resident/employee of high TB risk congregate settings--**  
These settings are correctional facilities, nursing homes, and long-term care institutions for the elderly, mentally ill, and persons with AIDS.
- **Person is a health care worker who serves high-risk clients --**  
Screen for the individual risk factors for TB infection, unless screening efforts are part of an ongoing facility infection control program approved by local health department.
- **Person is medically underserved --**  
Person does not have a regular health care ~~provider and~~ has not received medical care within the last 2 years.
- **Person is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories --**  
Child has foreign-born parents, or child's parents/caretakers are at high risk for acquiring TB infection.
- **Person is a member of a group identified by a local health department to be at an increased risk for TB infection --**  
Identification of a group is based on local epidemiologic data showing an increase in the number of persons with TB disease or TB infection in the given group
- **Person needs baseline/annual screening approved by health department --**  
Screening program that is approved by the local health dept. for facilities or individuals at an increased risk for LTBI

#### **III. Access Risk for Developing TB Disease if infected - The following are definitions of select categories of persons at risk for TB disease if infected.**

- **Person's HIV Status is unknown but has risk for HIV infection**  
Offer HIV test. Proceed with the TB Skin Test or BAMT, even if the patient refuses the HIV test.
- **Person with clinical conditions that place them at high risk --**  
Conditions include substance abuse, chest x-ray findings that suggest previous TB, diabetes mellitus, silicosis, prolonged corticosteroid therapy, cancer of the head and neck, leukemia, lymphoma, hematologic and reticuloendothelial diseases, end stage renal disease, smoker, intestinal bypass or gastrectomy, and chronic malabsorption syndromes.
- **Person is on immunosuppressive therapy --**  
Person is taking  $\geq 15$  mg/day of prednisone for  $\geq 1$  month; person is receiving treatment for rheumatoid arthritis with medications such as REMICADE, Enbrel, or HUMIRA and/or person needs baseline evaluation prior to start of arthritis treatment with the medications cited here.

### IV. History of BCG / TB Skin Test / BAMT / TB Treatment:

In this section, you will assess prior history related to TB.

### V. Findings (Check all findings that apply.)

In this section, indicate findings from the assessments in all previous sections.

### VI. Action(s) (Check all actions that apply.)

- Indicate the action(s) to take ~~as a result of~~ the findings in Section III
- If administering a TST or BAMT, provide all requested data.
- Write other pertinent patient information in "Comments"

### Additional Follow-up to the TST or BAMT

- If the patient's TST reaction or BAMT result is interpreted as positive or if she/he has symptoms for TB disease, refer the patient immediately for a chest x-ray.
- If a person has a history of a positive TST or a positive BAMT and is currently asymptomatic, then refer him/her for a chest x-ray if the following two conditions apply: 1) patient is a candidate for LTBI treatment and 2) patient is willing to adhere to the treatment.



## Additional Guidelines for Tuberculosis (TB) Risk Assessments, Form TB-4

Since 2007, Local Health Departments (LHDs) have had more activity for "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection," <http://www.cdc.gov/MMWR/preview/MMWRhtml/rr4908a1.htm>. The TB Risk Assessment Form, TB-4, was developed to aid Local Health Departments in conducting TB risk assessments with targeted testing for those Kentuckians with increased risk for latent TB infection (LTBI).

As noted in the CDC guideline, "Targeted tuberculin testing for LTBI is a strategic component of tuberculosis (TB) control that identifies persons at high risk for developing TB who would benefit by treatment of LTBI, if detected. Persons with increased risk for developing TB include those who have had recent infection with *Mycobacterium tuberculosis* and those who have clinical conditions that are associated with an increased risk for progression of LTBI to active TB. Following that principle, targeted tuberculin testing programs should be conducted only among groups at high risk and discouraged in those at low risk. Infected persons who are considered to be at high risk for developing active TB should be offered treatment of LTBI irrespective of age."

The overall goal of these TB risk assessments at LHDs is to increase the percentage of tuberculin skin tests (TSTs) or blood assays for *Mycobacterium tuberculosis* (BAMTs) that are administered to individuals at increased risk for LTBI and to decrease the percentage of TSTs or BAMTs that are administered to individuals who have no risk factors for LTBI.

LHDs should use the TB risk assessment for all patients presenting for TB screenings, including those individuals identified in contact investigations. The TB Risk assessment form is an ideal tool for educating patients about the signs and symptoms of active TB, the risk factors for developing LTBI, and the risk factors for rapid progression of LTBI to active TB.

The TB risk assessment process also more easily enables LHD staff to determine the cut-off values for reading a TST when a TST is used for screening. A "Report of Tuberculosis Screening," Form TB-3, can be completed for those patients who need documentation of the results of TB screening for their employers or other groups.

\*The Kentucky TB Program recognizes that the LHD may choose to collaborate with other organizations for the management and treatment of LTBI or other TB-related occupational health services. In these instances, a written agreement should be initiated between the two agencies to clearly identify the roles of each organization and define a payment schedule for any TB-related services provided by the LHD.

Figure 3.5 The booster phenomenon with the TST.

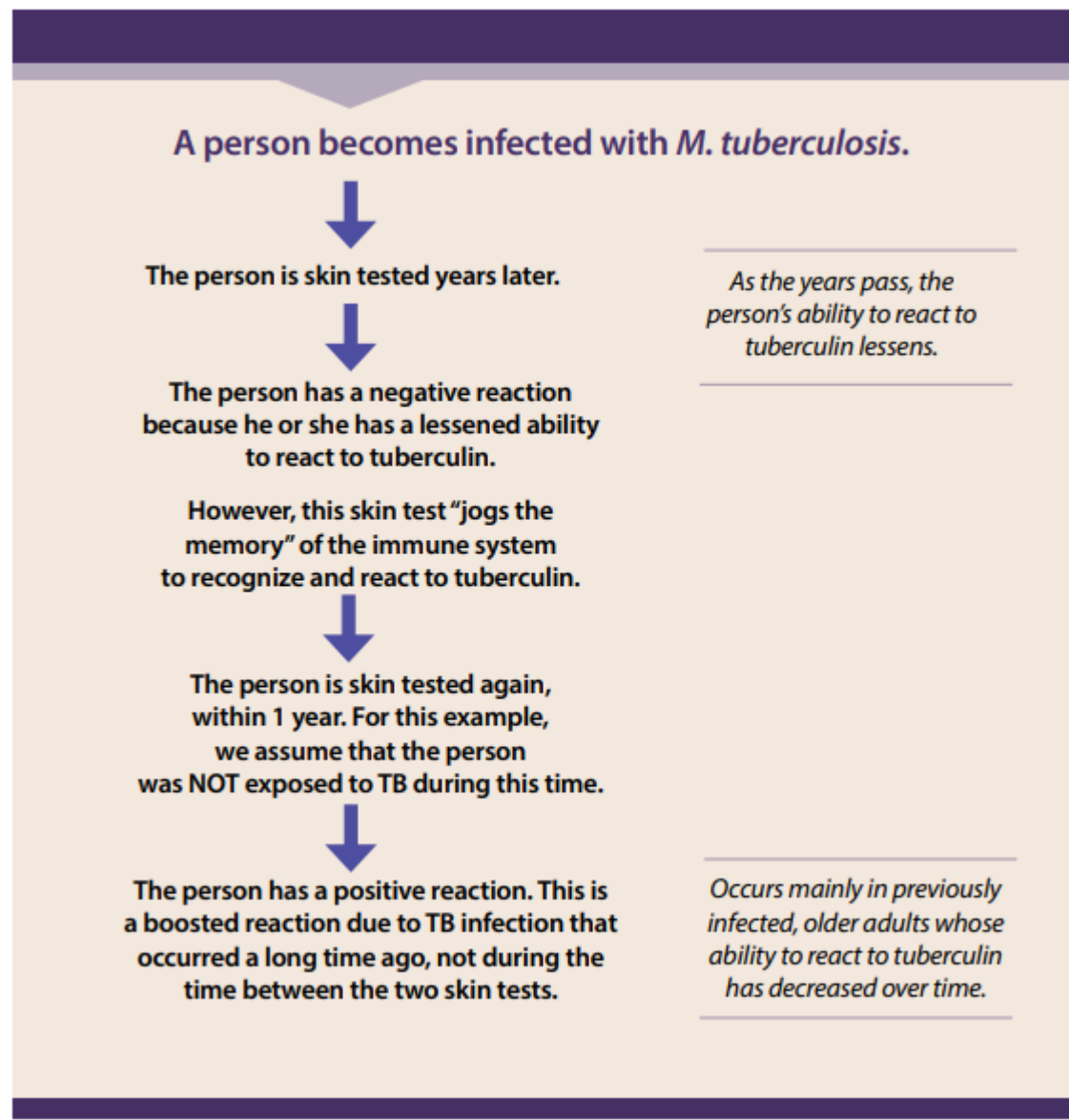


Figure 3.6 Two-step testing with the TST.

