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\(^1\) 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\(^2\), or by a comparable provider approved by the Kentucky Board of Pharmacy.

Provider of Training: _________________________________________

Date of Training: _____________________________________________

Inclusion Criteria
Pharmacists acting under this protocol are authorized to initiate the dispensing, administration and interpretation of TST to adults ages ≥ 18 years of age who:
- Are at increased risk for latent or active tuberculosis disease
- Need TST documented for school attendance or insurance purposes

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
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

\(^1\)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](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm).

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.

<table>
<thead>
<tr>
<th>Product</th>
<th>Mfr. / Dist.</th>
<th>NDCs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubersol</td>
<td>Sanofi Pasteur</td>
<td>1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22</td>
</tr>
<tr>
<td>Aplisol</td>
<td>Parkdale</td>
<td>1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05</td>
</tr>
</tbody>
</table>

*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 below and in the ATS/CDC Guideline.¹

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

Contraindications and Precautions (Refer to Exclusion 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
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)

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 Guideline¹ (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 physician for treatment and further advised regarding isolation precautions.

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
- Need for confirmatory physician evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory physician 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 physician 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 2:170 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 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 practitioner for follow-up.

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

**TERMS**

This protocol is effective as of the date all parties execute the document. It shall remain in effect for a period of one year and shall automatically renew for successive one-year periods unless otherwise terminated by any party, with or without cause. Any termination without cause shall require prior notice to all parties of no less than sixty days.

**SIGNATURES**

__________________________________ ____________________

Practitioner Name   Date

__________________________________

Practitioner Signature

__________________________________ ____________________

Pharmacist Name  Date

__________________________________

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

5

Appendix F. Quality control (QC) procedural observation checklists

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Trainer (QC by)</th>
<th>Trainees (TST placed by)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**1. Preliminary**
- Uses appropriate hand hygiene methods before starting.
- Screens patient for contraindications (severe adverse reactions to previous TST).*
- Uses well lit area.
- 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 wheel, as liquid is injected.
- Removes needle without pressing area.
- Activates safety feature of device per manufacturer’s recommendations, if applicable.

**2. Syringe**
- Stilet 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.
- Puts 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 by exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wastage 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.
- Snips skin slightly.†
- If severe adverse reactions to the TST are rare but include urticaria, rash, vaso-occlusion, 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 1/2 inch 27 gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.
-verting syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastic. 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 Diseases Society of America. Diagnostic standards and classification of tuberculosis in adults and children, Am J Respir Crit Care Med 2000;161:376-95.
- Preventing tuberculosis antigen and vaccine (e.g., T-cell) macrolide 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 2004:53:692–4.
- 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 Nurses Consultant Coalition. Tuberculinn nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association. 1995.
- Sterilize skin by placing nondominant hand of health-care worker (HCW) on patient’s forearm before 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 HCW. 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.

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

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

<table>
<thead>
<tr>
<th>Date</th>
<th>Date (QC by)</th>
<th>Date (TST placed by)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scoring: ✓ or Y = Yes</th>
<th>X or N = No</th>
<th>NA = Not Applicable</th>
</tr>
</thead>
</table>

#### 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-illuminated area.
- Inspects 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.
- Cleansse 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.

#### 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 (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.
- Trainer’s measurement ________ mm.
- Trainer’s (gold standard) measurement ________ mm.
- Trainer’s result within 2 mm of gold standard reading? Yes ________ No ________

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

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1. 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 pin method.

2. If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).

3. For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainer’s TST reading should be between 9–13 mm to be considered correct.
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 8: page 1390)

<table>
<thead>
<tr>
<th>Induration of ≥5mm</th>
<th>Induration of ≥10mm</th>
<th>Induration of ≥15mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive if certain factors present:</td>
<td>Positive if certain factors present:</td>
<td>• Positive for any individual, including persons with no known risk factors for TB testing</td>
</tr>
<tr>
<td>• HIV positive</td>
<td>• Recent immigrants (&lt;5years) from high prevalence country</td>
<td>• However, targeted skin testing programs should only be conducted among high-risk groups</td>
</tr>
<tr>
<td>• Recent contact with active TB patient</td>
<td>• Injection drug users</td>
<td></td>
</tr>
<tr>
<td>• Individuals with fibrotic changes on chest radiograph consistent with prior TB</td>
<td>• Residents and employees of high-risk congregant settings</td>
<td></td>
</tr>
<tr>
<td>• Individuals with organ transplants</td>
<td>• Mycobacteriology lab personnel</td>
<td></td>
</tr>
<tr>
<td>• Individuals who are immunosuppressed for other reasons</td>
<td>• Persons with clinical conditions that place them at high risk</td>
<td></td>
</tr>
</tbody>
</table>

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

Measure TSTs Transversely

CDC LTBI: A Guide for Primary Health Care Providers

Sample Risk Assessment

http://www.cdc.gov/tb/publications/ltbi/appendixa.htm
Kentucky Department For Public Health
Tuberculosis (TB) Risk Assessment

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: ____________________

I. Screen for Active TB Symptoms (Check all that apply)

___ None (Skip to Section II, “Screen for TB Infection Risk”)

___ Cough for ≥ 3 weeks → Productive: ___ YES ___ NO

___ Hemoptysis

___ Fever, unexplained

___ Unexplained weight loss

___ Poor appetite

___ Night sweats

___ Fatigue

--- Pediatric Patients (≤ 5 years of age):

___ Wheezing

___ Failure to thrive

___ Decreased activity, playfulness and/or energy

___ Lymph node swelling

___ Personality changes

--- Evaluate these symptoms in context

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

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.

A. Assess Risk for Acquiring LTBI. The Patient:

___ is a current high risk contact of a person known or suspected to have TB disease.

___ has been in another country for - 3 or more months where TB is common, and has been in the US for ≤ 5 years

___ is a resident or an employee of a high TB risk congregant setting

___ is a healthcare worker who serves high-risk patients

___ is medically underserved

___ has been homeless within the past two years

___ is an infant, a child or an adolescent exposed to an adult(s) in high-risk categories

___ injects illicit drugs or uses crack cocaine

___ is a member of a group identified by the health department to be at an increased risk for TB infection

--- needs baseline/annual screening approved by the health department

B. Assess Risk for Developing TB Disease if Infected The Patient...

___ is HIV positive

___ has risk for HIV infection, but HIV status is unknown

___ was recently infected with Mycobacterium tuberculosis

___ has certain clinical conditions, placing them at higher risk for TB disease:

 ___ injects illicit drugs (determine HIV status):

 ___ has a history of inadequately treated TB

 ___ is >10% below ideal body weight

 ___ is on immunosuppressive therapy (this includes treatment for rheumatoid arthritis with drugs such as REMICADE, HUMIRA, etc.)

--- History of BCG / TB Skin Test / BAMT / TB Treatment:

___ History of prior BCG: ___ NO ___ YES → 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:

--- III. Finding(s) (Check all that apply)

___ Previous Treatment for LTBI and/or TB disease

___ No risk factors for TB infection

___ Risk(s) for infection and/or progression to disease

___ Possible TB suspect

___ Previous (+) TST or (+) BAMT, no prior treatment

--- IV. Action(s) (Check all that apply)

___ Issued screening letter ___ Issued sputum containers

___ Referred for CXR ___ Referred for medical evaluation

___ Administered the Mantoux TB Skin Test

___ Draw BAMT / Interferon-gamma Release Assay ((IGRA))

___ Other: __________________

--- History of BCG / TB Skin Test / BAMT / TB Treatment:

___ TST Brand/Lot # ______ TST Brand/Lot#

--- TST

___ Arm: ___ Left ___ Right

___ Date/Time ___________ mm

___ Induration ___________

___ WNL

___  ____WNL

--- BAMT ___ T-SPOT.TB ___ QFT-TB-G-IT

___ Date/Time drawn: ___________

___ Result: ___ Pos ___ Neg ___ Borderline/Indeterminate

___ Screeners signature: __________________

___ Screeners name (print): __________________

___ Screeners title: __________________

___ Date: ___________ Phone #: ___________

--- Comments: __________________

--- 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.

X __________________________ Date: ___________

--- TB-4 (3/2014)