TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL
v2

Approved 12/11/2019

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.**

[2] CDC Core Curriculum on Tuberculosis. Available at https://www.cdc.gov/tb/education/corecurr/pdf/chapter3.pdf.

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.

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 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 Guideline[1] (Appendix B). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix C), patient must be immediately referred toa healthcare provider 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 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 2:170 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 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 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

_____ _____

Prescriber Name Date

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Signature

Appendix A: Procedural Checklist for Placing/Reading Tuberculin Skin Tests[3]

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.

[3] Guidelines for preventing the transmission of tuberculosis in Healthcare Settings, 2005. MMWR Vol. 54 / No. RR-17. Available at https://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf.

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.

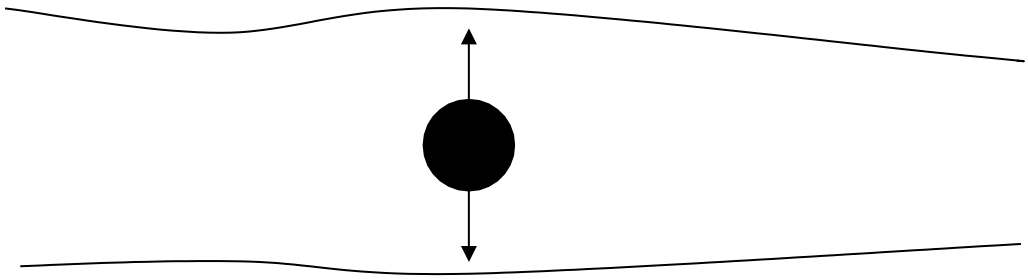
Appendix B: Interpretation of the Tuberculin Skin Test

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)

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

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

Appendix C: Kentucky Department for Public Health TB Risk Assessment Forms (Example of TB-4 TB Risk Assessment Form (Rev. July 2018); 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

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

Evaluate these symptoms in context

Pediatric Patients (≤ 5 years of age):
___Wheezing
___Failure to thrive
___Decreased activity, playfulness and/or energy
___Lymph node swelling
___Personality changes

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 congregate 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: _____

TST Brand/Lot #_____ TST Brand/Lot#_____

Arm: ___Left ___Right	Arm: ___Left ___Right
Date/Time _____	Date/Time _____
Induration_____mm	Induration_____mm

___BAMT ___T-SPOT.*TB* ___QFT-TB-Gold-Plus

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 (In subsections A and B, check all the risk factors that apply.)

Section II has 2 sections. Section A: "Assess Risk for Acquiring LTBI", Section B: "Assess Risk for Developing TB Disease if infected".

- If a patient has one or more risk factors for LTBI as listed in sections A or B, then go to Section III 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 III 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 "Issued Screening Letter" (Section IV) and provide that document to the patient.

A. Assess 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

B. Assess 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.

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

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

IV. 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 next to "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/rr4906a1.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.