

A. Background about targeted testing for TB

1. Targeted testing is an essential TB prevention and control strategy that is used to identify, evaluate, and treat clients who are at high risk for LTBI or at high risk for developing TB disease once infected with TB. Identifying clients with LTBI is important to the goal of TB control and elimination because treatment of LTBI can prevent infected clients from developing TB disease and stop the further spread of TB.
 - All testing activities should be accompanied by a plan for appropriate follow-up medical evaluation and treatment.
 - Necessary medical evaluation and treatment resources need to be identified before testing activities begin.
 - Unfocused population-based testing is not cost-effective or useful and leads to unnecessary treatment. **Clients without specific risk factors for TB infection or disease should not be tested.**
 - TB testing activities should be conducted only among high-risk groups, with the intent to treat if LTBI is detected.
 - Once TB disease has been excluded, treatment of LTBI should be offered to clients regardless of their age, unless medically contraindicated.
2. Currently, there are 2 testing methods available for the detection of *M. tuberculosis* infection in the United States:
 - Mantoux tuberculin skin test (TST).
 - Interferon-gamma release assays (IGRAs).

Two U.S. Food and Drug Administration (FDA) approved IGRAs are commercially available in the United States:

 - QuantiFERON®-TB Gold-in-Tube test (QFT-GIT).
 - T-SPOT®.TB test.
3. The IGRA is the standard screening test for clients aged 5 and above in Texas.
4. Identifying clients at risk for developing TB disease. Generally, persons at risk for developing TB disease fall into 2 broad categories:
 - Those who have an increased likelihood of exposure to persons with TB disease.
 - Those with clinical conditions or other factors associated with an increased risk of progression from LTBI to TB disease.

Clients at risk for exposure to persons with TB disease include the following:

- Known close contacts to a person with infectious TB disease.

- Clients who have immigrated from TB-endemic regions of the world.
- Clients at risk for TB, such as hospitals that care for TB patients, homeless shelters, correctional facilities, nursing homes, or residential facilities for patients with HIV infection/AIDS.

Also at risk are those with certain conditions and other factors associated with progression from LTBI to TB disease. These conditions and factors include the following:

- HIV infection.
- Injection drug use.
- Radiographic evidence of prior healed TB.
- Low body weight (10% below ideal).
- Other medical conditions, such as:
 - Silicosis.
 - Diabetes mellitus.
 - Chronic renal failure or on hemodialysis.
 - Gastrectomy.
 - Jejunioileal bypass.
 - Solid organ transplant.
 - Head and neck cancer.
 - Conditions that require prolonged use of corticosteroids or other immunosuppressive agents such as TNF- α antagonists.
- Recent TST converters (that is, persons with baseline testing results who have an increase of 10 mm or more in the size of the TST reaction within a 2-year period).
- **Clients under the age of five years** who have a positive TB test result.
- Note: the risk of progression is greatest in the first 1 or 2 years after infection.

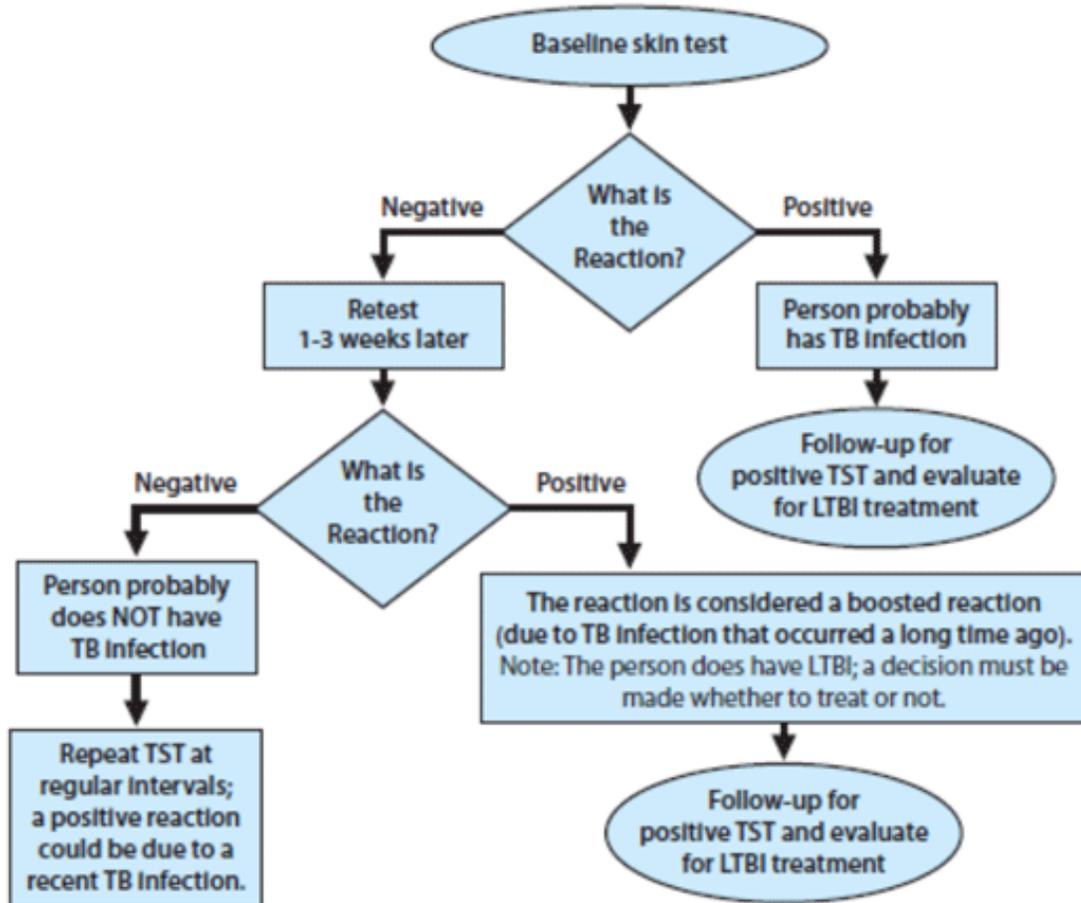
B. Tuberculin Skin Test (TST)

1. The TST should not be performed on a client who has **written documentation** of either a previous positive TST result or treatment for TB disease. Otherwise, it can, and on occasion may need to be, repeated.
2. The TST is administered intradermally using the Mantoux technique by injecting 0.1ml of 5 TU purified protein derivative (PPD) into 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.

3. The reading of TST reactions should be conducted within 48 to 72 hours of administration. A client who does not return within 72 hours will need to be rescheduled for another skin test.
4. Only a trained health care professional should measure TST results; patients or family members should never measure TST results. 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).
5. Interpretation of the TST result is the same for persons who have had BCG vaccination because a majority of BCG cross-reactivity wanes with time.
6. A TST that was not measured and recorded in millimeters (mm) of induration must be repeated at the earliest time possible.
7. The “two-step method” is recommended at the time of initial testing for individuals who may be tested periodically (e.g., health care workers).
 - If the first TST result in the two-step baseline testing is positive, consider the client infected and evaluate and treat the client accordingly.
 - If the first test result is negative, the TST should be repeated in 1–3 weeks.
 - If the second test result is positive, consider the client infected and evaluate and treat the client accordingly.
 - If both steps are negative, consider the client uninfected and classify the TST as negative at baseline testing (see Figure 1).

Figure 1: Two-Step TST Testing:



Source: CDC Core Curriculum on Tuberculosis: What the Clinician Should Know.
<http://www.cdc.gov/tb/education/corecurr/pdf/chapter3.pdf>

C. Interferon-Gamma Release Assays

1. IGRAs are used to determine if a client is infected with TB by measuring the immune response to TB proteins in whole blood. Specimens are mixed with peptides that simulate antigens derived from *M. tuberculosis* and controls. In a client infected with TB, the white blood cells recognize the simulated antigens and release interferon-gamma (IFN- γ); results are based on the amount of IFN- γ released.
2. Key points:
 - **There is no preference for the use of one IGRA or the other.**
 - Advantages of IGRAs include the following:
 - Requires a single client visit to conduct the test.
 - Does not cause booster phenomenon. When IGRAs are used for serial testing, there is no need for a second test because boosting does not occur.

- Laboratory test not affected by health care worker perception or bias.
- Results can be available within 24 hours.
- Unaffected by BCG and most environmental mycobacteria except *M. kansasii*, *M. szulgai*, and *M. marinum*.
- Limitations of IGRAs include the following:
 - Blood sample must be processed within 8-30 hours after collection.
 - Limited data exist on use in groups such as clients younger than 5 years of age, clients recently exposed to TB, immunocompromised persons, and those who will be tested repeatedly (serial testing).
 - Unknown significance of reversions and their high incidence in HCWs.

D. Selecting a test to detect TB infection

1. Based on recommendations from the DSHS 2012 Tuberculosis Expert Panel, **IGRAs are the standard test for diagnosis of TB infection in Texas, except in groups for which it is contraindicated or not indicated (such as clients under the age of 5 years).**

IGRAs are the preferred method of testing for (not in priority order):

- Congregate settings, for employees and residents (e.g., correctional facilities, nursing homes, shelters, and transitional living environments).
- Clients with diabetes or dialysis patients.
- High risk clients who have previously received a dose of BCG.
- Immunocompromised clients (e.g., chemotherapy or transplant patients).
- Clients undergoing contact investigations.
- Clients who work with individuals infected with TB.
- Clients about to receive TNF- α inhibitors or biologic response modifiers.
- Clients who have low rates of returning for TST readings.

Note: IGRA should be done *unless*

- Phlebotomy is refused.
- Phlebotomy is impractical (e.g. hard to access veins).

- Client is seen on a Friday or day before a holiday and completion of processing of specimen would be required on a weekend or a holiday; the client cannot return for phlebotomy during the specified hours.
2. TST is the preferred method for testing for:
 - **Clients under the age of 5 years.**
 3. Routine testing with both TST and IGRAs is NOT recommended; however, there are certain situations where results from both tests may be useful. Consult the authorizing physician.

E. Interpretation of test results

1. Interpretation of TST results is based on the measurement of the reaction in millimeters, the person's risk of acquiring TB infection, or the risk of progressing to disease if infected. See the risk stratification below.

A TST reaction of **≥5 mm of induration** is considered positive in:

- HIV-infected clients.
- Recent contacts of a person with infectious TB disease.
- Clients with fibrotic changes on chest radiograph consistent with prior TB.
- Clients with organ transplants and other immunosuppressed clients (including clients taking the equivalent of ≥15 mg/day of prednisone for 1 month or more or those taking TNF- α antagonists).

A TST reaction of **≥10 mm of induration** is considered positive in the following individuals:

- Recent arrivals to the United States (within last 5 years) from high-prevalence areas.
- Injection drug users.
- Residents or employees of high-risk congregate settings (e.g., correctional facilities, long-term care facilities, hospitals and other health care facilities, residential facilities for patients with HIV infection/AIDS, and homeless shelters).
- Mycobacteriology laboratory personnel.
- Clients with clinical conditions that increase the risk for progression to TB disease.
- **Clients younger than 5 years of age.**
- **Infants, children, and adolescents exposed to adults in high risk categories.**

A TST reaction of **≥15 mm of induration** is considered positive in the following individuals:

- Clients with no known risk factors for TB
2. Interpretation of IGRA results is based on the amount of IFN- γ released, in QFT, or on the number of cells that release IFN- γ , in T-SPOT®.TB.
- Laboratories should provide both the qualitative and quantitative results.
 - Qualitative results are reported as positive, negative, indeterminate or borderline.
 - Quantitative results are reported as numerical values that include a response to the TB antigen and 2 controls, nil and mitogen. Quantitative results may be useful for clinical decision making in individual cases, in combination with risk factors.

F. TB control action

TST or IGRA Result	TB Control Action
Positive	<i>M. tuberculosis</i> infection likely Action: if CXR, form TB-202 or other evidence suggests active disease, (see Attachment #4), otherwise treat for LTBI (see Attachment #2)
Negative	<i>M. tuberculosis</i> infection unlikely, but cannot be excluded 1. if client is a contact to a TB case, the test must be repeated at 8-10 weeks after break in exposure. Evaluate for eligibility for window prophylaxis (see Attachment #2) 2. if TB infection unlikely, close chart & give clearance card 3. if TB infection cannot be excluded, especially if: 1. client has TB signs or symptoms or 2. client has a high risk for developing TB disease once infected then rule out active TB disease (see Attachment #4) and consult the authorizing physician.
Indeterminate	Test failure – cannot be interpreted. Repeat the test or consult the authorizing physician.

G. Documentation

1. TST:
- Record name of antigen, manufacturer, lot number, expiration date, date of testing, and date of reading.
 - Record site of application of test if applied at site other than the left volar surface.
 - Document instructions given to the client regarding care of the injection site.

DSHS SDO: TB Clinical Services Provided by Registered Nurses and Licensed Vocational
Nurses, 2013-2014, revised January 2014
ATTACHMENT #5: Targeted Testing for TB (Tuberculin Skin Test and Interferon-Gamma
Release Assays)

- Record the size of induration in millimeters (mm). Document results on **TB 400** and/or **TB 340**.
- Record whether the result is considered positive or negative.

2. IGRA:

- Results are to be reviewed as they would for any blood test.
- Place paper copy of the results in the client's chart and notify the authorizing physician of the results.
- Document results on TB400 and/or TB340. Documentation should include date of blood draw, and results (TB antigen detected, not detected, or indeterminate).