

**Texas Department of State Health Services Standing Delegation Orders for Tuberculosis
Tuberculin Skin Testing Services Provided by Authorized Staff, Fiscal Year 2017**

The purpose of this document is to provide authority for specific acts of tuberculosis (TB) tuberculin skin testing (TST) services under authority of Rule Title 22, Texas Administrative Code §193.2, Standing Delegation Orders.

Standing delegation orders (SDOs) and standing medical orders (SMOs) are written instructions, orders, rules, regulations or procedures prepared by a physician. SDOs provide authority and a plan for use with patients presenting themselves prior to being examined or evaluated by a physician. SMOs provide authority and direction for the performance of certain prescribed acts for patients which have been examined or evaluated by a physician. SDOs and SMOs are distinct from specific orders written for a particular patient.

The intended audience for these orders is authorized staff working in Texas Department of State Health Services (DSHS) Health Service Regions.

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Standing Delegation Orders

A. Definitions

1. Authorized Staff: an employee or contractor of the Texas Department of State Health Services who has met the requirements of and signed this SDO.

2. Authorizing Physician: a physician licensed by the Texas Medical Board who executes this SDO.

B. Method Used for Development, Approval and Revision

This SDO and the relevant attachments shall be:

1. Developed by the TB SDO Revision Workgroup and the TB and Refugee Health Services Branch.
2. Reviewed and signed at least annually by the authorizing physician.
3. Revised as necessary by the TB SDO Revision Workgroup, the DSHS Infectious Diseases Medical Officer, the Regional Medical Directors, and/or the TB and Refugee Health Services Branch.

C. Level of Experience, Training, Competence, and Education Required

To carry out acts under this SDO, an authorized staff must:

1. Be an employee or contractor of the Texas Department of State Health Services.
2. Have reviewed, are familiar with, and able to readily access the recommendations within the following documents:
 - a. CDC Fact Sheet “Tuberculin Skin Testing”
<http://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm>
 - b. CDC fact sheet “Targeted Tuberculin Testing and Interpreting Tuberculin skin Test Results” <http://www.cdc.gov/tb/publications/factsheets/testing/skintestresults.htm>
 - c. CDC Mantoux Tuberculin Skin Testing Facilitator Guide:
<http://www.cdc.gov/tb/education/Mantoux/default.htm>
 - d. Tubersol package insert:
<http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm114924.pdf>
 - e. Aplisol package insert:
<http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm114912.pdf>
3. Have undergone an initial or continuing evaluation of competence relevant to TB TST services within 12 months prior to signing and providing TB TST services under this SDO:
 - Initial evaluation of competence is performed by the authorizing physician, the staff’s supervisor, or clinical designee and consists of education and skills training, as approved by the regional TB program manager.

The authorized staff must receive an initial evaluation by the authorizing physician, the staff’s supervisor, or clinical designee that documents the staff’s ability to carry out these orders in the customary manner. This training and evaluation of competence must occur before TB TST services are independently provided by the staff.

- Continuing evaluation of competence is performed annually by the authorizing physician, the staff's supervisor, or clinical designee that documents the staff's ability to carry out these orders in the customary manner.
4. Have reviewed and signed this SDO, **ATTACHMENT 1: Attestation of Authorized Staff**, within 12 months prior to providing services under this SDO.

D. Method of Maintaining a Written Record of Authorized Staff

A record of the authorized staff who completes the required training and demonstrates competence shall be documented and maintained by the staff's supervisor in the Health Service Region office.

E. Authorized Delegated Acts

Authorized staff may provide TB TST services under this SDO to clients who are undergoing evaluation for TB disease or TB infection or are a contact to a confirmed or suspected TB disease case.

It is the intent of all parties that the acts performed under this SDO shall be in compliance with the Texas Medical Practice Act, the Texas Nursing Practice Act, the Texas Pharmacy Act, and the rules promulgated under those Acts.

F. Procedures and Requirements to be Followed by Authorized Staff

1. Adhere to all Standard Precautions, including bloodborne and respiratory precautions, when participating in TB TST services.
2. Utilize interpreter services to facilitate client and staff communication as it relates to limited English proficient (LEP) clients.
3. Ensure, to the extent possible, that the person seen for TB TST services is, in fact, who the person claims to be.
4. Ensure that the client's consent and signature have been obtained by the nurse responsible for the clinical management of the client. If consent and signature have not been obtained, then obtain consent and signature in accordance with agency policy and provide copies of the *DSHS Privacy Notice* and applicable signed consent forms.
 - *DSHS General Consent and Disclosure* (L-36), available at: www.dshs.state.tx.us/rls/pubs/GeneralConsentForm042010.pdf
 - *DSHS Privacy Notice*, available at: <http://www.dshs.state.tx.us/hipaa/privacynotices.shtm>
5. Verify the client meets criteria for TST.
6. Explain the TB TST test. Discuss with the client the risks and benefits of TST testing. Confirm that the client can return for TST reading in 48 to 72 hours. Provide the opportunity for the client to ask questions. If the client has questions you cannot answer,

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contact the nurse responsible for the clinical management of the client for instructions.

7. Complete either form **TB-207** or **TB-208**.
 - The ***Targeted Tuberculin Testing Screening Form (TB-207)*** is used to determine if TST testing is indicated for the client who is not identified as a contact to TB and to document risk prior to testing.
 - If the client is identified as a contact to TB, complete the ***Tuberculosis Contact Screening Form (TB-208)*** instead.
8. Determine if the client has written documentation of a previously positive TST or previously positive interferon gamma release assay performed in the United States. If so, do not administer TST. Contact the nurse responsible for the clinical management of the client for instructions.
9. Determine if any of the following apply to the client. If so, do NOT administer the TST. Contact the nurse responsible for the clinical management of the client for instructions.
 - Allergy to any component of TUBERSOL or APLISOL or an anaphylactic or other allergic reaction to a previous test of tuberculin purified protein derivative (PPD)
 - Severe reaction to previous TST such as ulceration, necrosis, blistering, bullae, anaphylaxis
 - Documented active TB
 - A documented history of treatment for TB infection or disease
 - Extensive burns or eczema
 - Immunization with a live virus vaccine that interacts with TST within the last 4 to 6 weeks
 - TST may be performed on the same day as immunization with a live-virus vaccine; otherwise, the TST should be delayed for 4 to 6 weeks after vaccination.
 - Live virus vaccines that interact with TST include: measles, mumps, rubella, varicella, zoster, yellow fever, intranasal influenza, and oral polio.
10. If the client has no contraindications for TST, gather the required supplies and administer TST according to the procedure listed in **ATTACHMENT 2: TST Administration Procedure**.
11. Document the date and time of TST placement, PPD manufacturer, lot number and expiration date, your name, and location of injection site on the appropriate form in the client's medical record.
12. Provide instructions to the client regarding care of the injection site:
 - The wheal (bump) is normal and will remain about 10 minutes.
 - Avoid touching the wheal or scratching close to the injection site.
 - Avoid pressure or bandage on the injection site.
 - May wash with soap and water (without pressure) after 1 hour.
 - No lotions or liquids on site, except for light washing as above.

13. Give the client an appointment date and time within 48 to 72 hours of TST placement to return for TST reading and interpretation.
14. For clients requiring TST reading and interpretation, gather supplies and read the TST according to the procedure listed in **ATTACHMENT 3: TST Reading Procedure** and record the result on the appropriate form (**TB-207** or **TB-208**).
 - Record the millimeters (mm) of induration.
 - If there is no induration, inform the client that the TST result is negative. Record 0 mm of induration – do not record the result as “negative.”
 - Interpret the TST result based on the procedure listed in **ATTACHMENT 4: TST Interpretation Procedure**. Record the interpretation of the TST result (positive or negative) next to the mm of induration.
 - Note: a TST that was not measured within 48 to 72 hours and recorded in mm of induration must be repeated.

G. Client Record-Keeping Requirements

TB forms available at: <http://www.texastb.org/forms/#clinic>

Authorized staff must accurately and completely report and document each delegated act in a medical record prepared in accordance with DSHS policy and regional procedures, which will include:

1. Names of personnel involved in client services at each visit, including the name of the interpreter (if an interpreter is used).
2. Actions carried out under these standing orders.
3. Any additional physician orders.
4. Client response(s), if any.
5. Contacts with other healthcare team members concerning significant events regarding client’s status.
6. Documentation that the appropriate forms are completed and included in the medical record, if required, and copies, when applicable, are provided to the client.

H. Scope of Supervision Required

This SDO gives the authorized staff authority to perform the acts described in this SDO in consultation with the authorizing physician as needed.

I. Specialized Circumstances to Immediately Communicate with the Authorizing Physician

Specific circumstances that the authorized staff providing services under this SDO should immediately contact the authorizing physician by phone include, but are not limited to, when medical direction or consultation is needed.

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In an emergency situation, the authorized staff is to call 911, provide care according to his or her skills and ability, and contact the nurse responsible for the clinical management of the client and/or the authorizing physician by phone as soon as possible.

J. Limitations on Setting

Authorized staff can provide services under these standing orders in the clinic setting, in the client's home, or other field settings when the authorizing physician can be contacted by phone.

K. Date and Signature of the Authorizing Physician

This SDO shall become effective on the date that it is signed by the authorizing physician, below, and will remain in effect until it is either rescinded, upon a change in the authorizing physician, or at the end of business on the last day of the current DSHS fiscal year (August 31, 2017), whichever is earlier.

Authorizing Physician's Signature: _____

Authorizing Physician's Title: _____

Printed Name: _____

Effective Date: _____

Emergency Contact Information: _____

ATTACHMENT 2: *TST Administration Procedure*

1. Remove PPD from refrigerated storage. To avoid reducing the potency of the PPD, do not store on the door of a refrigerator. When the TST is to be administered in the field, transport and store the PPD in an insulated cooler to protect from heat and light.
2. Confirm that the concentration of PPD is 5 tuberculin units (TU) of PPD per test dose of 0.1 mL.
3. Confirm that the PPD has not expired and that the vial has not been opened for more than 30 days. When opening a new vial, mark the vial with the date opened and initial.
4. Clean vial stopper with antiseptic swab.
5. Draw up slightly more than 0.1 mL of PPD into tuberculin syringe as soon as the PPD is removed from refrigeration in order to protect from heat. PPD should be used immediately in order to avoid adsorption onto the syringe.
6. Remove excess volume or air bubbles to exactly 0.1 mL of PPD while needle remains in vial to avoid wasting of antigen.
7. Remove needle from vial.
8. Return antigen vial to refrigeration immediately after filling.
9. Rest the client's arm on a firm, well-lit surface. Prepare injection site using aseptic technique.
10. Slightly stretch the skin of the inner aspect of the forearm to facilitate the introduction of the needle. Stretch skin by placing your non-dominant hand on the client's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place your non-dominant hand opposite the administration needle if the client is likely to move during the procedure.
11. Hold the tuberculin syringe close to the skin, bevel up, so that the hub of the needle touches the skin as the needle is introduced. Insert the needle in the first layer of skin with the tip visible beneath the skin. Advance the needle approximately 3mm until the entire bevel is under the first layer of skin. Release the stretch in the skin and hold the syringe in place on the forearm. (Holding the syringe in this position will reduce the needle angle to about 5 to 15 degrees at the skin surface, promoting the correct entry for a proper intradermal injection.)
12. Inject the PPD into the superficial layer of the skin to form a wheal 6 mm to 10 mm in diameter.
13. Remove needle without pressing the skin at the test site and activate the safety feature of the syringe according to manufacturer's recommendations.

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14. Place used needle and syringe in a puncture resistant container without recapping the needle.
15. Immediately measure the wheal to insure that it is 6 to 10 mm in diameter. If a wheal does not appear (because the injection was made too deeply), or the wheal is smaller than 6 mm (because the needle was not under the skin and part of the antigen leaked on the outer surface of the skin), reapply test at another site at least 5 centimeters (2 inches) from the original site.
16. If blood or fluid is present, blot site lightly with gauze or cotton ball and discard used gauze or cotton according to local standard precautions. Do not apply pressure or cover the site with a bandage or other material.

ATTACHMENT 3: TST Reading Procedure

1. Place the client's arm in a good light. Flex the client's forearm slightly at the elbow.
2. Inspect for the presence of induration (hardening or thickening of the tissues). Inspect from a side view against the light and again by direct light. If the reaction does not look normal or looks severe (blisters, ulcers or necrosis) contact the nurse responsible for the clinical management of the client for instructions.
3. Bend the client's arm at elbow to a 90 degree angle and palpate: lightly rub your clean and sanitized finger across the injection site from the area of normal skin about 2 inches from injection site to the area of induration. Do this from four directions. Use a zigzag featherlike touch.
4. Repeat palpation with arm bent at elbow at a 45 degree angle to determine presence or absence of induration.
5. Outline the diameter of induration, if present, with a pen by placing small dots on both sides of the induration. Erythema (redness) without induration is not significant to the TST result. When the induration is not symmetrical, the transverse (at right angles to the long axis of the body) diameter will usually be smaller.
6. Inspect placement of dots relative to the induration. Repeat finger movements and reposition dots if needed.
7. Note the dots that are transverse (perpendicular) to the long axis of the forearm. To insure consistency, measure the maximum transverse diameter of induration (not erythema) in millimeters with a flexible ruler.
8. Place the "0" ruler line inside the edge of the left dot. Read the ruler line inside right dot edge. Use the lower measurement if between two gradations on millimeter scale.
9. Record the TST result as a single measurement in millimeters. If there is no induration, record the result as 0 mm, not as "negative."
10. Record the interpretation of the TST result (positive or negative) next to the mm of induration.

ATTACHMENT 4: *TST Interpretation Procedure*

A. Definition of TST Reaction:

- **Negative reaction:** An induration less than the specified criteria based on risk factors shows either a lack of tuberculin sensitivity or a low grade sensitivity that most likely is not caused by *Mycobacterium tuberculosis* complex (*M.tb*). A negative test does not rule out the presence of TB.
- **Positive Reaction:** An induration greater than or equal to the specified criteria based on risk factors indicates infection with *M.tb*.

B. TST Interpretation:

1. An induration of **5 mm or more** is considered to be positive for:
 - HIV-infected persons
 - Recent contacts to a known TB case
 - Individuals with fibrotic changes on chest radiograph consistent with old TB
 - Persons with organ transplants and other immunosuppressed persons (such as taking the equivalent of greater than 15mg/day prednisone for longer than 1 month or taking tumor necrosis factor- α antagonists)
2. An induration of **10 mm or more** is considered to be positive for:
 - Recent arrivals (less than 5 years) from high-prevalence countries
 - Injection drug users
 - Residents and employees of high-risk congregate settings: correctional facilities, nursing homes and other healthcare or long-term care facilities, residential facilities for AIDS patients, and homeless shelters
 - Mycobacteriology laboratory personnel
 - Persons with high-risk clinical conditions: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of >10% of ideal body weight, gastrectomy, jejunioileal bypass
 - Children younger than 4 years of age
 - Infants, children, and adolescents exposed to adults in high-risk categories
3. An induration of **15 mm or more** is considered to be positive in individuals with no known risk factors for tuberculosis.