

**Texas Department of State Health Services Standing Delegation Orders for
Tuberculosis Blood Specimen Collection Services
Provided by Authorized Staff, Fiscal Year 2022**

The purpose of this document is to provide authority for specific acts of tuberculosis (TB) blood specimen collection services described by the TB and Hansen’s Disease Unit and under the 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 local health department TB programs and in Texas Department of State Health Services (DSHS) Public Health 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 Hansen's Disease Unit.
2. Reviewed and signed at least annually by the authorizing physician.
3. Revised as necessary by the DSHS Infectious Diseases Medical Officer, the Regional Medical Directors, and/or the TB and Hansen's Disease Unit.

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 regional or local TB policies and procedures relevant to TB blood specimen collection, packaging, and shipping.
3. Have undergone an initial or continuing evaluation of competence relevant to TB blood specimen collection services within 12 months prior to signing and providing TB blood specimen collection 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 or local 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 blood specimen collection 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**

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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 local health department or Public Health Region office.

E. Authorized Delegated Acts

Authorized staff may provide TB blood specimen collection 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, 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 blood specimen collection procedures.
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 blood specimen collection 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: dshs.texas.gov/rls/pubs/GeneralConsentForm042010.pdf
 - **DSHS Privacy Notice**, available at: dshs.texas.gov/hipaa/privacynotices.shtm
5. Verify the client meets criteria for TB blood specimen collection.
6. Explain the TB blood specimen collection process. Discuss with the client the risks and benefits of TB blood specimen collection. Provide the opportunity for the client to ask questions. If the client has questions you cannot answer, contact the nurse responsible for the clinical management of the client for instructions.
7. Gather the required supplies and prepare to collect the TB blood specimen.
8. Perform venipuncture, as described in **ATTACHMENT 2: Venipuncture**

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Procedure, and collect the specimen in the proper tube(s), according to laboratory submission requirements. See **ATTACHMENT 3 and 4** for preferred IGRA test collection procedure.

9. Label and correctly package the specimen, according to shipping requirements and local or regional procedures. Submit specimen to an approved laboratory for processing.

10. Document all specimen collection dates, test types, and circumstances affecting collection in the client's medical record.

G. Client Record-Keeping Requirements

TB forms available at: dshs.texas.gov/disease/tb/forms/. Authorized staff must accurately and completely report and document each delegated act in a medical record prepared in accordance with DSHS policy and local or 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.

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

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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, 2022), whichever is earlier.

Authorizing Physician's Signature:

Authorizing Physician's Title:

Printed Name:

Effective Date:

Emergency Contact Information:

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ATTACHMENT 1: *Attestation of Authorized Staff*

I, _____ have read and understand the
printed name of authorized staff
*Texas Department of State Health Services Standing Delegation Orders for
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Fiscal Year 2022 ("SDO")* that was signed by

Dr. _____ on _____.
printed name of authorizing physician date of authorizing physician's signature

- I agree that I meet all qualifications for authorized staff outlined in the SDO.
- I agree to follow all instructions outlined in the SDO.

Signature of Authorized Staff

Date

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ATTACHMENT 2: *Venipuncture Procedure*

1. Assess client for an acceptable site to perform venipuncture.
 - Median cubital and cephalic veins are the optimal choices and provide the least risk of nerve damage.
 - If those sites are unacceptable, the wrist or hand veins may be used.
2. Position client, extending upper extremity comfortably.
3. Verify blood specimen tubes to be used correspond to tests requested and are not expired.
4. Apply tourniquet 3 to 4 inches above the selected puncture site. Do not leave tourniquet on more than 2 minutes.
5. Ask the client to make a fist without pumping his/her hand.
6. Cleanse puncture site with alcohol in circular pattern, beginning at site and working outward. Allow to air dry.
7. Remove needle cap.
8. Draw skin taut to anchor the vein.
9. Insert the needle (bevel up) at a 15 to 30-degree angle, avoiding trauma and excessive probing.
10. Hold needle completely still while inserting tubes onto vacutainer. Fill blood specimen tubes in correct order, if order specified.
11. Remove the tourniquet as the last blood specimen tube is filling and ask client to open fist.
12. Remove the last blood specimen tube.
13. Remove the needle from the client's arm using a swift backward motion. While withdrawing the needle from the client's skin, engage the safety mechanism.
14. Press down on gauze over the puncture site with adequate pressure or ask client to apply direct pressure on gauze while keeping arm straight.
15. Place the needle into the sharps container.
16. Gently invert the tubes 5 to 10 times and correctly label all tubes while at the client's side.
17. Assure that puncture site bleeding has stopped. Apply band-aid/Coban™/other bandage, if necessary.

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**ATTACHMENT 3: T-SPOT®-TB Test
Collection Procedure**

1. Check blood collection tubes to ensure they are not expired.
2. Using a 9 mL lithium heparin (green top) collection tube (A Greiner tube provided by Quest), collect the blood volume as follows:
 - 9 mL: Immunocompromised adults and children 10 years of age and older
 - 6 mL: Non-immunocompromised adults & children 10 years of age and older
 - 4 mL: Children 2-9 years of age
 - 2 mL: Children up to 2 years of ageNOTE: Pediatric tubes for TSPOT (4 or 6 mL size) are available from Quest.
3. Gently invert tube gently 8-10 times after draw to ensure the blood is mixed properly with the anticoagulant.
4. Store blood samples at room temperature, between 64 to 77°F (18 to 25°C), until packaged for transport. Do not centrifuge.
5. Complete the laboratory requisitions form and place this form in the side pocket of the specimen bag.
6. Package the specimen in the shipping container provided by Quest Laboratories as follows:
 - Place a **liquid** gel pack in the insulated container.
 - The clinical specimen should be placed with the absorbent material in a clinical sample bag and placed on top of the liquid pack.
 - Place a **solid** gel pack on top of the diagnostic sample bag. Solid gel packs may have to be kept in the refrigerator in order for them to obtain the solid state. If this is done leave the pack at room temperature for 30 minutes after removing it from the refrigerator before packaging the specimen.
 - Close the corrugated box around the clinical sample.
 - Place the box in the Fed Ex UN3373 clinical pack.
 - Affix the FedEx waybill onto the clinical pack.
 - Do not tape the box shut.
7. **Ship to Quest Laboratories using Fed Ex as the shipping agent the same day the blood specimen is collected.**

Contact Quest Laboratories at T-SPOT Client Services: 866-697-8378 for collection or testing questions specific to T-SPOT.

Further details are found at: testdirectory.questdiagnostics.com/test/test-detail/37737/t-spottb?cc=MASTER

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**ATTACHMENT 4: *QuantIFERON®-TB Gold Plus One-Tube Test
Collection Procedure***

1. Specimens will be picked up by Quest couriers; contact Quest Laboratories at 866-MYQUEST (866-697-8378) **in advance** to arrange pick-up.
2. Check blood collection tubes to ensure they are not expired.
3. Using a **lithium** heparin* (green top) collection tube provided by Quest for QFT, collect 6 mL of the client's blood by venipuncture.
 - If a butterfly needle is used, a purge tube, such as a plain red top tube, should be used first to ensure the tube is filled with blood before filling the QFT green top tube.
 - If collection tube is too large for small or fragile veins (i.e. pediatrics), contact Quest directly to discuss options. Using a smaller single tube is not an option for QFT but using the 4-tube collection method may be possible.

**ensure tubes are lithium heparin NOT sodium heparin*

4. Gently invert QFT tube 8-10 times, just firmly enough to ensure the entire inner surface of the tube is coated with blood to dissolve antigens on tube walls.
 - Over-energetic shaking may cause gel disruption and could lead to invalid results.
5. Place the tube UPRIGHT at room temperature 63 to 77°F (17 to 25°C) for at least 15 minutes and up to 3 hours after collection.
6. Complete the Quest laboratory requisition and place collection tube in QuantiFERON®-TB Gold Plus gold collection bag. Write the collection date/time on the bag, tube and requisition.
7. Refrigerate at 36-46 °F (2 to 8°C) while awaiting shipment to Quest laboratories. Ensure tubes are not placed in the freezer or in direct contact with frozen material (i.e. frozen ice packs, dry ice, temperatures below 8°C, etc.). If lockboxes are used, ensure the proper cold packs are used to keep specimens at refrigerated-not frozen- temperatures. **Specimen must be received by Quest Diagnostics within 48 hours of collection.**

Quest Collection and Handling Instructions for QFT-Plus 1 Tube is found at:
questdiagnostics.com/dms/Documents/Other/QuantIFERON/QFT-Plus_1_Tube_Instructions.pdf

Details on the *QuantIFERON®-TB Gold Plus One-Tube Test* are found at:
questdiagnostics.com/home/physicians/testing-services/by-test-name/quantiferon/tb-plus-resources/

Quest QFT Client Services: 866-697-8378.