

Texas Department of State Health Services Standing Delegation Orders for Tuberculosis Blood Specimen Collection Services Provided by Authorized Staff, Fiscal Year 2017

The purpose of this document is to provide authority for specific acts of tuberculosis (TB) blood specimen collection 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 regional 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 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 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 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: 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 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 Procedure**, and collect the specimen in the proper tube(s), according to laboratory submission requirements. See **ATTACHMENT 3: QuantiFERON®-TB Gold In-Tube Test (QFT-GIT) Collection Procedure** for specific steps to be taken when collecting the QFT-GIT

test. See ATTACHMENT 4: *T-SPOT®-TB Test Collection Procedure for specific steps to be taken when collecting the T-SPOT®.TB test.*

9. Label and correctly package the specimen, according to shipping requirements and 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: <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.

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

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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: *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 over the puncture site 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.

ATTACHMENT 3: *QuantiFERON®-TB Gold In-Tube (QFT-GIT) Test Collection Procedure*

1. **Blood collection tubes MUST be checked to ensure they are not expired.**
2. Collect 1 mL of the client's blood by venipuncture into each QFT-GIT blood collection tube. The tubes should be collected in the order of Grey, Red, then Purple (GRaPe).
 - As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for 2 to 3 seconds once the tube appears to have completed filling, to ensure that the correct volume is drawn.
 - **Check fill-volume to ensure each is between 0.8 to 1.2 mL.**
 - 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 QFT-GIT tubes.
3. **SHAKE QFT-GIT tubes 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.**
4. **As soon as possible**, transfer the tubes to a 37°C (98°F) incubator and incubate the tubes **UPRIGHT** for 16 to 24 hours.
 - **Re-mix tubes by inverting 10 times immediately prior to incubation.**
 - Do not refrigerate specimens prior to incubation.
 - Incubation must occur within 16 hours of collection or results may be compromised.
5. After the incubation at 37°C, centrifuge tubes for 15 minutes at 2000 to 3000 RCF (g). The gel plug will separate the cells from the plasma. If this does not occur, the tubes should be re-centrifuged at a higher speed.
 - **Once centrifuged, tubes should be refrigerated at 4 to 8°C (39 to 46°F) before shipment to DSHS.**
6. Deliver/ship to the DSHS Laboratory with cold packs within 28 days from the time removed from the incubator. Shipment must be received cold.
 - **Do not freeze the samples in QFT-GIT blood collection tubes.**
7. Submit completed G2A form and before shipping to DSHS lab,
 - Check / Circle "Yes" to indicate that incubation has been completed.
 - Check / Circle "Yes" to indicate that centrifugation is completed.

Contact the DSHS lab at 512-776-7760 or 512-776-7514 or 512-776-2450 for shipping guidelines.

ATTACHMENT 4: *T-SPOT®-TB Test Collection Procedure*

1. **Blood collection tubes MUST be checked to ensure they are not expired.**
2. Using one lithium or sodium heparin (green top) collection tube collect the blood volume as follows:
 - 6 mL: Adults & children over 10 years of age
 - 4 mL: Children 2-9 years of age
 - 2 mL: Children up to 2 years of age
 - Note: If the client is immunosuppressed collect two tubes of blood.
3. Store blood samples at room temperature, between 64 to 77°F (18 to 25°C), until packaged for transport. Do not centrifuge.
4. Complete the Oxford Diagnostic Laboratories Test Requisition form and place this form in the side pocket of the biohazard specimen bag.
5. Package the specimen in the shipping container provided by Oxford Laboratories as follows:
 - Place a liquid gel pack in the shipping box.
 - Place the biohazard bag in the shipping box.
 - Place a solid gel pack in the shipping box. 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 box and seal with packaging tape.
 - Place the box in the Fed Ex pack, seal, and put label on the pack.
6. Ship to Oxford Diagnostic Laboratories using Fed Ex as the shipping agent the same day the blood specimen is collected.

Contact Oxford Diagnostic Laboratories Client Support Team at 1-877-598-2522 if you have questions.