The purpose of this document is to provide authority for specific acts of blood specimen collection.

The intended audience for this policy is authorized licensed and non-licensed staff working in Texas Department of State Health Services (DSHS) Health Service Regions.

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

B. Method Used for Development, Approval and Revision

This procedure and the relevant attachments shall be:

1. Developed by the Regional Medical Directors (RMDs), a team of DSHS public health nurses appointed by the RMDs, and the Director of Public Health Nursing at DSHS Central Office.
2. Reviewed and signed at least annually by the authorizing physician, a physician licensed by the Texas Medical Board who authorizes this procedure.
3. Revised as necessary the RMDs and a team of public health nurses appointed by the RMDs.

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 undergone an initial or continuing evaluation of competence relevant to blood specimen collection services within the 12 months prior to the date services are provided under this procedure:
    a. Initial evaluation of competence is performed by the authorizing physician or clinical designee, and consists of education and skills training approved by the regional program director or clinical designee, and documents the staff's ability to competently carry out these procedures.
        i. Training and evaluation of competence must occur before blood specimen collection is independently performed by the staff.
    b. Continuing evaluation of competence is performed annually by the authorizing physician or clinical designee and consists of skills review approved by the regional program director or clinical designee, and documents the staff's ability to competently carry out these procedures annually.
3. Have reviewed and signed this procedure, **ATTACHMENT 1: *Attestation of Authorized Staff***, within 12 months prior to performing phlebotomy under this set of procedures.

D. Method of Maintaining a Written Record of Authorized Staff

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

E. Authorized Acts

Authorized licensed and non-licensed staff may provide blood specimen collection services under this procedure to clients undergoing evaluation for communicable disease or infection, or who are a contact to a confirmed or suspected communicable disease case, and for determination of immune status prior to vaccination (e.g., prior to employee vaccination to meet job requirements per DSHS policy).

F. Procedures and Requirements to be Followed by Authorized Staff

1. Adhere to all Universal/Standard Precautions, including bloodborne and respiratory precautions when participating in 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 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, or by other DSHS staff

responsible to obtain blood specimens as part of evaluation for communicable disease or infection. 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.

a. ***DSHS General Consent and Disclosure*** (L-36), available at: www.dshs.state.tx.us/rls/pubs/GeneralConsentForm042010.pdf
b. ***DSHS Privacy Notice***, available at: http://www.dshs.state.tx.us/hipaa/privacynotices.shtm

5. Verify the client meets criteria for blood specimen collection. Criteria include:
   a. Client is at risk for Tuberculosis, HIV, Syphilis, Gonorrhea, Chlamydia, Hepatitis A, Hepatitis B, Hepatitis C, or another communicable disease under investigation. Testing may include immunity for Hepatitis A, B, and C, HIV antigen/antibody testing (such as Anti-HIV-1 and Anti-HIV-2 Ab, Western Blot), rapid plasma reagin testing (RPR), Nucleic-Acid Amplification Testing (NAAT) Interferon Gamma Release Assay (IGRA)-Quantiferon/T-Spot testing.
   b. Employee requires immunity testing. Testing may include Hepatitis B, Varicella, and Measles, Mumps, and Rubella (MMR).
   c. Client requires evaluation for adverse effects of communicable disease treatment. Testing may include hepatic profile/liver function testing (LFT), which may include tests such as Alanine Aminotransferase (ALT), Alkaline Phosphatase (ALP), Aspartate Aminotransferase (AST), Bilirubin, Albumin, Total Protein, Gamma-Glutamyl Transferase (GGT), Prothrombin Time and International Normalized Ratio, Lactate Dehydrogenase (LD), Comprehensive Metabolic Panel, and Complete Blood Count (CBC).
   d. Other criteria, as identified, resulting from an epidemiological outbreak, event, or disaster response.
6. Verify the order.
7. Explain the blood specimen collection process. Discuss with the client the risks and benefits of blood specimen collection. Provide the opportunity for the client to ask and receive satisfactory answers to questions. If the client has questions you cannot answer, contact the healthcare provider responsible for the clinical management of the client for instructions.
8. Gather the required supplies and prepare to collect the blood specimen sample(s).
9. Follow infection control policies outlined in *DSHS Infection Control Manual for Ambulatory Care Clinics, 2009 Fourth Edition*, washing, rinsing, and drying hands thoroughly using soap, hand antiseptic, or surface antiseptic from a dispenser.
10. Wear disposable latex examination gloves, or a suitable equivalent, during every vascular access procedure.
11. Perform venipuncture as follows.
    a. Assess client for an acceptable site to perform venipuncture.
       i. Median cubital and cephalic veins are the optimal choices and provide

the least risk of nerve damage.

ii. If those sites are unacceptable, the cephalic vein on the superior lateral aspect of the wrist (thumb side) or metacarpal (hand) veins may be used. (see Fig. 1 below).

iii. At no time should veins on the feet, legs, or palmar aspect of the hands be used.

b. Factors to consider in site selection:

i. Extensive scarring or healed burn areas should be avoided.

ii. Specimens should not be obtained from the arm on the same side as a mastectomy. Lymphostasis may occur.

iii. Avoid areas of hematoma.

iv. Do not obtain specimens from an arm having a cannula, fistula, or vascular graft.

12. Position client, extending upper extremity comfortably.
13. Verify blood specimen tubes to be used correspond to tests requested and are not expired.
14. Apply tourniquet 3-4 inches above the selected puncture site. Do not leave tourniquet on more than 2 minutes.
15. Ask the client to make a fist without pumping his/her hand.
16. Cleanse puncture site with alcohol in circular pattern, beginning at site and working outward. Allow to air dry.
17. Remove needle cap.

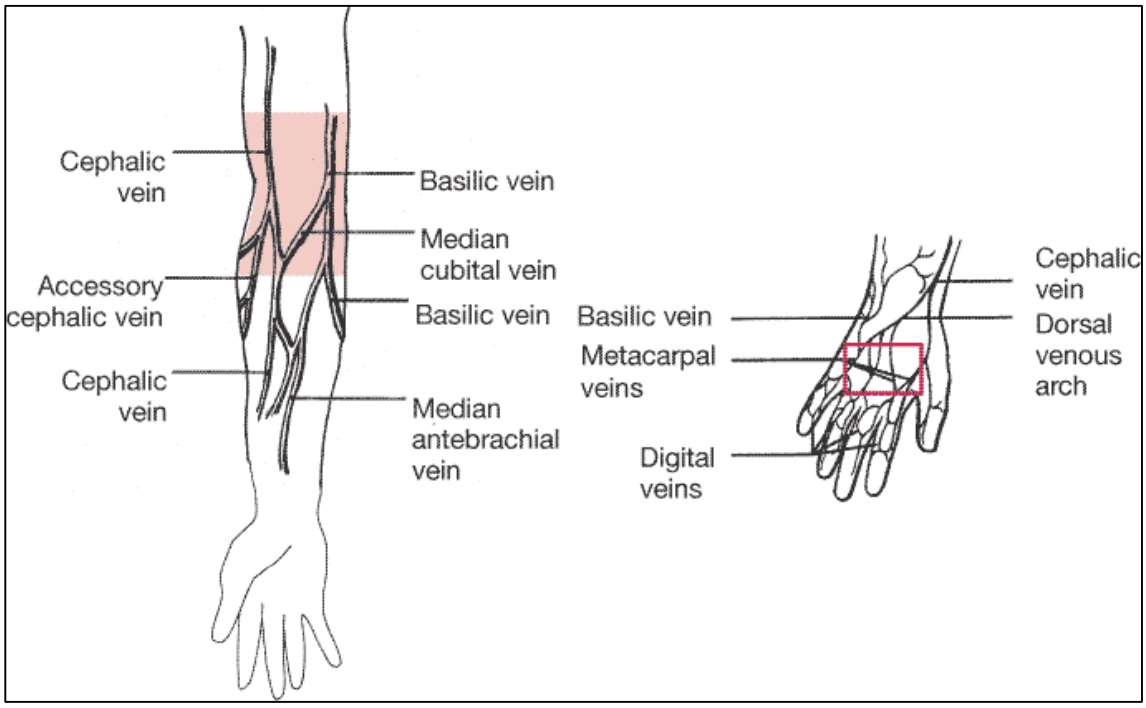

Figure 1

18. Draw skin taut to anchor the vein.

19. Insert the needle (bevel up) at a 15- to 30-degree angle, avoiding trauma and excessive probing.
20. Hold needle completely still while inserting tubes onto vacutainer. Fill blood specimen tubes in correct order, if order specified.
21. Remove the tourniquet as the last blood specimen tube is filling and ask client to open fist.
22. Remove the last blood specimen tube.
23. 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.
24. 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.
25. Place the needle into the sharps container.
26. Gently invert the tubes 5 to10 times, or per the specific procedure required by the laboratory for the blood test to be performed, and correctly label all tubes while at the client's side.
27. Assure that puncture site bleeding has stopped. Apply adhesive bandage, if necessary.
28. Remove gloves and discard in an appropriate waste container.
29. Instruct the client on when and where to follow up for results or additional testing.
30. Instruct the client on what conditions require a medical re-evaluation.
31. Label and correctly package the specimen, according to laboratory and shipping requirements and regional procedures. Submit specimen to an approved laboratory for processing.
32. Document all specimen collection dates, test types, and circumstances affecting collection, including adverse events, on the applicable form and in the client's medical record, if applicable.
33. In the event of an adverse event, such as fainting by the client, provide appropriate supportive measures and notify the healthcare provider responsible for the clinical management of the client
34. In the case of blood-borne pathogen exposure, refer to the *DSHS Infection Control Manual for Ambulatory Care Clinics, 2009 Fourth Edition*, and report to the supervisor immediately.
35. Wash hands and change gloves between every patient.

G. 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**.**

H. Date and Signature of the Authorizing Physician

This procedure 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 1: *Attestation of Authorized Staff*

I,_____have read and understand the
printed name of authorized staff

Texas Department of State Health Services Procedures for Blood Specimen Collection Services Provided by Authorized Staff, Fiscal Year 2016-2017 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 procedures.
- I agree to follow all instructions outlined in the procedures.

Signature of Authorized Staff Date

ATTACHMENT 2: *Syphilis EIA IgG, Human immunodeficiency virus (HIV AG/AB EIA), and Hepatitis C Virus Test Collection Procedure*

1. Blood collection tubes MUST be checked prior to use to ensure the tubes are not expired.
2. Collect 1 mL of the client's blood by venipuncture into a gold-top (7 mL) blood collections tube.
3. As soon as possible, transfer the tube to a refrigerator. The tube may be kept at an ambient temperature until refrigerated.
4. Blood specimen processing:
    a. HCV -Take blood specimen to designated laboratory for processing or spin blood within 6 hours of blood draw.
        - If unable to submit blood specimen or spin blood within 6 hours of blood draw, do not submit specimen for HCV testing; notify team lead or manager of situation
    b. HIV and syphilis – Take blood specimen to designated laboratory for processing or spin blood within 24 hours of blood draw
5. Blood may be refrigerated for up to 7 days. If storage of the specimen is required for more than 7 days, freeze only serum (do not freeze whole blood).
6. Complete appropriate laboratory form(s) to accompany specimen.
7. Deliver/ship specimen with required form(s) to the appropriate laboratory for processing. Contact appropriate laboratory for shipping guidelines.

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 (**GR**a**P**e).
   - 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 0.8-1.2 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 (98ºF**)** 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 8ºC (39 to 46ºF) 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. Label the collection tubes with the following information:

- Patient first and last name
- Date of birth
- Date and time of sample collection

4. Put the collection tubes in an absorbent tube holder and then in the biohazard specimen bag.

4. Store blood samples at room temperature, between 64-77 degrees F (18-25 degrees C), until packaged for transport. Do not centrifuge.

5. Complete the Oxford Diagnostic Laboratories Test Requisition form and place this form in the side pocket of the biohazard specimen bag.

6. 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 tap
- Place the box in the Fed Ex pack, seal, and put label on the pack.

7. Ship to Oxford Diagnostic Laboratories using Fed Ex as the shipping agent the same day the blood specimen is collected.

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

ATTACHMENT 5: *Venipuncture Performance Evaluation*

Name: _____ Date: _____

Instructions:

1. Practice performing a venipuncture.
2. Demonstrate the procedure for performing venipuncture satisfactorily as graded by the observer using the rubric below.

Materials and equipment:

1. Gloves
2. Hand disinfectant
3. Tourniquet
4. Cotton swabs
5. 70% isopropyl alcohol
6. Sterile, disposable hypodermic needle, 20-22 gauge
7. Vacutainer™ holder/Saf-T-Clik™/other safer needle device
8. Collection tubes
9. Approved sharps container for needle disposal
10. Surface disinfectant
11. Biohazard waste receptacle
12. Aromatic spirits of ammonia (for inhalation in faintness)

S=Satisfactory U-Unsatisfactory

PROCEDURE	s	u	COMMENTS
1. Wash hands with hand disinfectant or soap and water if available.			
2. Assemble equipment and materials.			
3. Place venipuncture equipment within easy reach.			
4. Identify patient properly.			
5. Explain venipuncture procedure to patient and position patient properly. If patient has a history of getting dizzy or fainting after having blood drawn, try to have patient lying down or reclining instead of sitting up, if possible.			
6. Attach a sterile capped needle to vacutainer Holder if using straight needles.			
7. Remove cap and position needle so that the bevel faces upward.			
8. Inspect the needle to see that the point is smooth and sharp.			

ATTACHMENT 5: Venipuncture Performance Evaluation, Continued

PROCEDURE	s	u	COMMENTS
9. Partially push vacutainer tube onto needle in holder if using straight or butterfly needles.			
10. To increase circulation, instruct the patient to open and close the hand three times, making a fist when closing the hand the third time.			
11. Inspect the bend of the elbow to locate a suitable vein.			
12. Palpate the vein with the fingertip(s) to determine the direction of the vein, and to estimate its size and depth. *Note:* The vein most frequently used is the median cephalic vein of the forearm.			
13. Cleanse the skin of the puncture site using a alcohol prep or cotton ball soaked with alcohol.			
14. Allow alcohol to dry.			
15. Hold the needle at a 30° angle to the arm and insert the needle into the vein. Watch for blood flash in the needle hub.			
16. Push the collecting tube onto the needle in the vacutainer holder or needle at the end of the catheter if using a butterfly collection system that fills the tube with blood.			
17. Instruct the patient to open the fist when tube is almost filled.			
18. Release the tourniquet when the desired amount of blood is obtained.			
19. Place a dry cotton ball over the puncture site and withdraw the needle from the vein *(do not press down on the needle).*			
20. Instruct the patient to press the cotton ball over the wound for one minute.			
21. Adhere to Universal Precautions when disposing of all contaminated items including gloves, needles, vacutainer holder, cotton balls and other contaminated equipment.			

ATTACHMENT 5: Venipuncture Performance Evaluation, Continued

22. Check patient to be sure that bleeding has stopped; apply bandaid or bandage.			
23. Clean work area with surface disinfectant.			
24. Wash hands with hand sanitizer or soap and water if available.			
Comments:			

Evaluator signature/date:

_____

Adapted from: Walters, Norma J., Estridge, Barbara, Reynolds, Anna, P., Basic Medical Laboratory Techniques, Del Mar Publisher, 2nd Edition.