Guidance for Collection and Shipping of Specimens for HIV-1 RNA Testing at the Texas DSHS Laboratory

Specimen Collection Instructions

1. **Provide Patient Identifiers** Label the collection tube with the patient's name and at least one other unique identifier (e.g., date of birth, or patient ID number. The date and time of collection should also be recorded on the collection tube. Make sure to complete all required fields in the G-2A specimen submission form. Each patient tube and specimen submission form **must have at least two matching patient identifiers** to be accepted for testing.

2. **Clean the Collection Site** Wipe the venipuncture site well with an alcohol swab and allow to dry.

3. **Collect Blood Samples** Venous blood should be collected in serum tubes and/or plasma tubes. Suitable collection tubes for the HIV-1 RNA test are silicone coated (red-top) tubes, serum separator tubes with clot activator and gel for serum separation (red-gray, "tiger", or "speckled" top tubes), or EDTA-treated plasma tubes (purple-top, or lavender-top tubes). The assay requires at least **4mLs of whole blood per tube**.

4. **Tube Handling Instructions**

Serum Tubes (Red Top Tubes)

Gently invert tube five times to facilitate clotting. Allow specimen to sit for 60-minutes in a vertical position at room temperature until a clot forms. Once a clot forms, the specimen is ready for centrifugation.

After centrifugation, carefully transfer the serum to a plastic, screw-top transport tube labelled with the patient's name and another unique patient identifier, and the date and time of collection.

Make sure the screw top of the transport tube is sealed tightly to prevent leakage.

Ship serum cold on ice packs if it is to be received at DSHS within five days of collection. If serum will be received at DSHS more than five days after collection, ship frozen on dry ice. If shipping frozen, the temperature during the entire shipment should remain at or below -20°C. *Serum may be stored frozen at -20ºC for no longer than 90 days from the date of collection*.

Serum Separator Tubes with Clot Activator (Gold, or Red-Gray "Tiger" or "Speckle" Top Tubes)

Gently invert tube five times to mix clot activator with blood. Allow specimen to sit for a minimum of 30 minutes in a vertical position at room temperature to facilitate clotting. Once a dense clot has formed, the specimen is ready for centrifugation.

Centrifuge at full speed (between 1100 and 1300 rpm) for 10 minutes for swing-head unit or 15 minutes for fixed angle units. Centrifugation will cause a barrier to form, separating the serum from the clot.

If specimen is to be received at DSHS within five days, ship the specimen cold on ice packs.

If specimen is to be received at DSHS more than five days after collection, do the following:

- Carefully transfer the serum to a plastic, screw-top transport tube labeled with the patient's name and at least one other unique patient identifier, and the date and time of collection.
- Make sure the screw top of the transportation tube is sealed tightly to prevent leakage.
- Ship serum in transportation tubes on dry ice. The temperature level during the entire shipment should remain at or below -20°C. ***Note**: **DO NOT** freeze serum separator tubes*.
- *Serum can be stored frozen at -20ºC for no longer than 90 days from the date of collection.*

Plasma Tubes with EDTA Anticoagulant (Purple Top Tubes or Lavender Top Tubes)

Gently invert tube five times to mix the EDTA with the blood and separate by centrifugation.

After centrifugation, carefully transfer the plasma to a plastic, screw-top transport tube labeled with the patient's name and another unique patient identifier, and the date and time of collection.

Make sure the screw top of the transportation tube is sealed tightly to prevent leakage.

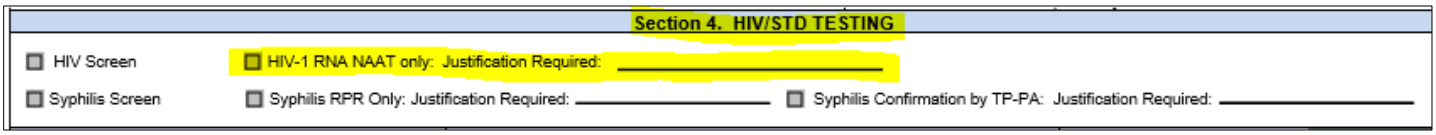
Ship plasma in transport tubes cold on ice packs if it is to be received at DSHS within five days of collection. If the plasma is to be received at DSHS more than five days after collection, ship the tubes frozen, on dry ice. If shipping frozen, the temperature during the entire shipment should remain at or below -20°C. *Plasma may be stored frozen between -20ºC and -70ºC for no longer than 90 days from the date of collection*.

Complete the Texas DSHS Submission Form

The following information **must** be included on the G-2A specimen submission form:

- ✓ **Submitter/Ordering Physician's Complete Contact Information**
- ✓ **Submitter/Ordering Physician's Texas Provider Identifier (TPI) Numbers**
- ✓ **Patient's Name, Date of Birth, Sex, and Address**
- ✓ **Specimen Collection Date and Time**
- ✓ **Type of Test Requested**: In Section 4 of the form (highlighted below),
    a. Check the HIV-1 RNA, NAAT box
    b. Provide a justification for the NAAT test request.
        i. To monitor the effects of antiretroviral treatment,
        ii. as part of the new PrEP testing algorithm,
        iii. to assess for perinatal exposure, and
        iv. to resolve discordant HIV serology results.

Note: Plasma is the only acceptable specimen source for monitoring antiretroviral treatment.



Shipping Instructions (Class 6.2, Category B, UN3373- Biological Substance)

Submitters are responsible for shipping specimens that conform to all safety and labeling regulations. When using any carrier, including the bus service or the U.S. Postal Service, package specimens carefully and adequately to avoid leakage or breakage. Be aware that many commercial carriers **no longer accept biological specimens** for shipping.

Sturdy Mailing Containers Required to Avoid Breakage
All specimen mailing containers supplied by the Laboratory meet current Department of Transportation (DOT) and United States Postal Service (USPS) requirements for the shipment of Category B Biological Substances. Per Biological Substances shipping requirements, specimens must be packed in triple containment with enough absorbent material enclosed to absorb the entire volume of liquid in the specimen. The container used *must* meet current DOT and USPS regulations.

Training Required for Specimen Handlers

Personnel responsible for handling and packing infectious agents are required to be trained on correct specimen handling and correct specimen submission protocols. Shipping infectious substances also requires the use of United Nations (UN)-approved packaging that the Laboratory does not provide to submitters.
Please note, it is the responsibility of submitters, not the Laboratory, to ensure **all** personnel who handle and submit specimens are properly trained.

Always use the appropriate level of caution in preparing and packing specimens for the sake of the people who handle the parcels, and to avoid jeopardizing the health and safety of those involved in transporting and delivering the specimens.

Important Laboratory Policy: **ALL blood specimens in a container will be considered broken if one tube in that container breaks during shipment.**

Ship specimen at the correct temperature (see Specimen Collection Instructions, above) via courier by overnight delivery. **Make sure the package will arrive on a weekday, not on a weekend or holiday.**

Send to:

Texas Department of State Health Services
Laboratory Services Section,
MC-1947
1100 W. 49th Street,
Austin, TX 78756

For questions about shipping, call:

Specimen Acquisition Branch **512-776-7598 or 512-776-2385**

For all other questions, call:

Serological Analysis Group **512-776-2450 or 512-776-7657**