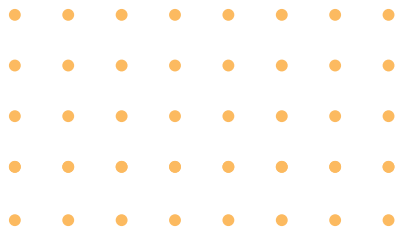




Sample Collection, Processing & Shipping

1 Sample Collection

- Complete and verify patient information** on the Sera Provider Portal for established users, or by filling in the hard copy PreTRM Test Request Form (TRF).
- Verify that patient information listed in the portal**, or on the hard copy TRF, matches the information on the labeled SST draw tube and transport tube.
- Collect required draw supplies.** This must include either a gold top or tiger top serum separator tube (SST) and a polypropylene specimen transport tube. Ensure that all supplies are not expired and are stored within manufacturer's guidelines.
- Verify patient identification** by checking at least two of the patient identifiers listed above prior to collecting specimen.
- In the presence of the patient, label the SST collection tube and transport tube** and ensure at least 2 patient-specific identifiers are present. (Acceptable patient identifiers include, but are not limited to patient name, date of birth, and LP-ID#, etc.)
- Collect whole venous blood** according to the collection facility's standard procedures for venipuncture.
- Gently invert the filled tube 8 – 10 times.**
- Record Draw Site Name, Collected By Name, Draw Date (MM/DD/YY), and Draw Time** in the portal, or on the hard copy TRF.



2 Processing

- Allow the blood to clot thoroughly**, while keeping the SST tube vertical, before centrifugation (recommended clotting time is 30 minutes).
- Centrifuge the tube** per standard practice at controlled room temperature, 15°C - 30°C. Centrifugation must take place within 2 hours of Draw Time.
- Remove the tube from the centrifuge, and **ensure sample is not hemolyzed**. Samples with hemoglobin levels greater than 100mg/dL will not be accepted for testing.
- Verify specimen and transport tube labeling matches** prior to transferring sample.
- Transfer** a minimum 1mL of serum into the transport tube by pouring off or using a transfer pipette.
- Place the **transport tube into a biohazard bag** with absorbent sheet and freeze (-10°C to -20°C).
- Specimens must be frozen** within 2.5 hours of Draw Time
- Do not allow specimens to thaw.** If samples will not be shipped immediately, store in non-defrosting freezer (-10°C to -20°C) for no longer than 120 hours (5 Days). Use ultra-low temperature freezer (-70°C to -80°C) or dry ice if greater than 120 hours to transport time.

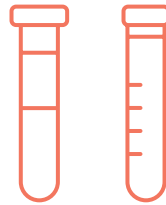
3 Shipping

- If the order is placed using the hard copy TRF check to **make sure it is complete and accurate**, then fold and slide TRF into the sleeve on the outside of the biohazard bag.
- If the order is placed through the Sera Provider Portal, **the user will need to release the pending orders** through the General Information>Activity Logs>Manifest List
- Select '**Manifest Lists**'
- Select '**All**' under '**Status**'.
- Select '**All**' under '**Search by Date**'
- Check applicable patient orders** which are ready for shipment.
- Select '**Transmit Selected**' from the 'Choose Action' drop down.
- You will **receive a confirmation** that the order(s) have been submitted to Sera, pending receipt of the sample.
- Place a layer of dry ice** in the bottom of an insulated shipping box, lay biohazard bag containing the frozen specimen(s) on the dry ice and cover with additional dry ice until box is full to the top.
- Place the lid on the insulated shipping box** and securely tape the outer cardboard shipping box closed.
- Complete the shipping air bill or generate shipping label** and adhere to the top of the cardboard shipping box. If shipping directly to Sera Prognostics, ensure the shipping label is completed and marked for Overnight and Saturday Delivery, and that applicable dry ice labels are filled out.
- Ensure specimens are properly packaged and labeled** to indicate the nature of materials transported, and that contents have been packaged and shipped according to all applicable federal, state, and local regulations.
- Contact approved carrier** for pick-up and transport.
- For questions or additional information, please contact Sera Customer Support at **801.990.6600**, or **support@pretrm.com**

SAMPLE COLLECTION, PROCESSING & SHIPPING



Complete and verify the patient information in Sera Provider Portal, or by filling in the hard copy



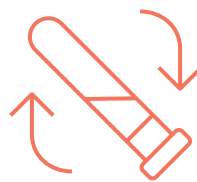
Label transport tube and SST collection tube with at least two unique identifiers



Verify labels are correct with patient by verifying 2 unique identifiers (Name, DOB &/or LP-ID)



Collect blood in approved draw tubes



Gently invert filled tube 8-10 times



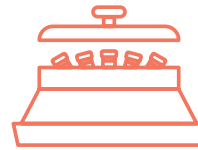
Record draw site name and draw date and time in Sera e-order, or by filling in the hard copy

SAMPLE COLLECTION, PROCESSING & SHIPPING



Allow blood to clot before centrifugation

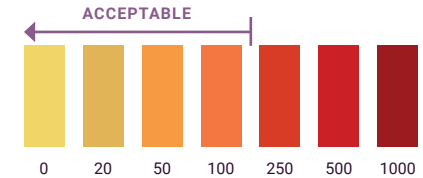
Manufacturer's recommendations is clot for 30 minutes



Centrifuge collection tube

Centrifuge at controlled room temperature, 15-30° C (59-86° F)

Centrifugation must take place within 2 hours of collection time



Compare the serum color against the Hemolysis Chart above

Hemoglobin levels are greater than 100mg/dL are not acceptable



Transfer serum into the approved polypropylene transport tubes using transfer pipette



Place pour-off tube in biohazard bag with absorbent sheet and freeze

If samples will not be shipped immediately, store in freezer (-10-20°C)
Use ultra-low temperature freezer (-70 to -80°C) or dry ice if greater than 120 hours

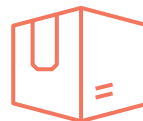


In-Office phlebotomy sites using Sera E-Order must release orders in the manifest list via General Information > Activity Logs

Sites not using portal (hard copy TRF) must place Test Requisition Form in the shipment



Place biohazard bag containing sample between layers of dry ice inside shipping cooler



Place cooler lid on top

Close and seal cardboard box



Place shipping label on the top of box and schedule for pickup