

APPENDIX 8

MassBiologics

Serum Sample Handling Instructions

Diphtheria Anti-toxin Serum Samples

Required Supplies for Sample Processing:

- 7 mL red top blood tube or serum separator tube
- Centrifuge
- Pipette
- Cryovials
- Cryovial labels
- Cryovial freezer boxes
- Cryovial freezer box labels
- Serum sample transmittal form

Processing of Serum Samples

1. Collect blood in a 7 mL red top tube or serum separation tube (SST).
2. If using an SST, gently invert the tube several times to mix the clot activator. Do not shake the specimen. If using a red top tube for collection, do not invert.
3. Place the blood tube upright in a rack; allow the tube to clot for 30 minutes at room temperature.
4. Separate the serum by centrifugation for 15-20 minutes at 1,300 rpm.
5. Samples should be aliquoted immediately.
 - If a red top tube is used and aliquoting will be delayed, the serum should be transferred to a new tube after centrifugation. Serum can be stored at 2-8°C for a maximum of 48 hours prior to aliquoting.
 - If an SST is used and aliquoting will be delayed, centrifuged samples may be stored upright at 2-8°C for up to 48 hours before aliquoting.

Aliquoting and Labeling the Cryovials

1. Remove the serum from the blood tube and transfer into 1.5 mL cryovials. Take care not to transfer any red cells, lipids, or other particulates into vials.
 - Fill each cryovial with at least 1 mL of serum. Use as many cryovials as needed. Do not discard any serum.

2. Complete a cryovial label with the following information: patient identifier, date, and time sample was drawn. Affix a completed label to each cryovial in a lengthwise (vertical) manner covering the shaded area. Avoid covering the cap seal on the cryovial.
3. Each time point must have one “TO SEND” sample.
4. All remaining cryovials should be designated as “TO RETAIN” samples.
5. Maintain two cryovial freezer boxes in your freezer:
 - Mark one cryovial box “TO SEND”.
 - Mark the second cryovial box “TO RETAIN”.
6. Place the cryovials into the appropriate cryovial freezer boxes (either the “TO SEND” box or the “TO RETAIN” box).
7. Freezer boxes must be stored at a temperature of at least -20°C .

Completing the Sample Transmittal Form

1. All serum samples should be entered onto a sample transmittal form. One transmittal form should be used for the “TO SEND” samples and a separate transmittal form should be used for the “TO RETAIN” samples.
 2. There should be a separate entry for each labeled cryovial. Each entry should include the patient identifier, and the date and time that the sample was drawn.
 3. Also record the date and time that the diphtheria antibody was administered on the transmittal form.
 4. Keep the sample transmittal form in a secure location until samples are shipped to MassBiologics.
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Required Supplies for Sample Shipping:

- Insulated container with outer cardboard box
- Sealable biohazard bag with absorbent material
- Dry ice
- “Keep Frozen” label
- “UN3373: Biological Substance Category B” label
- “DRY ICE; UN 1845” label
- Federal Express air bill

Preparing Serum Samples for Shipment

1. The site will be notified regarding the schedule for sending samples to MassBiologics. The “TO SEND” samples will be requested first. Once these are received and processed at MassBiologics, the “TO RETAIN” samples will be requested.

Note: • The following is a detailed description of the “TO SEND” sample shipping procedure. Repeat this procedure when the “TO RETAIN” samples are requested.

2. Include a copy of the “TO SEND” sample transmittal form with the “TO SEND” sample shipment. Record the date the samples are shipped to MassBiologics, the name of the institution, and the shipper’s name and contact information on the sample transmittal form.
3. Place the “TO SEND” cryovial freezer boxes in a sealable biohazard bag with absorbent material and then place the bag in an insulated container in an upright position. Pack in sufficient dry ice to keep the samples frozen for 48 hours.
4. Place the completed copy of the sample transmittal form into a waterproof bag, and place that bag between the insulated container and the outer cardboard box.
5. Place a “KEEP FROZEN” label on the outside of the shipping container.
6. Place a “UN3373: Biological Substance Category B” label on the outside of the shipping container.
7. Place a “DRY ICE; UN 1845” label on the outside of the shipping container. Complete the shipper’s name and address and the recipient’s (consignee) name and address. The weight of dry ice (in kg) must be recorded on both this label and on the Federal Express air bill.
8. In the section of the Federal Express air bill that asks “Does this shipment contain dangerous goods?” check the box indicating “Yes, Shipper’s Declaration not required”.
9. Ship overnight priority via Federal Express, using FedEx account #3196-2484-8:
Clinical Samples- QC IND
MassBiologics
460 Walk Hill Street
Boston, MA 02126
Telephone: 617-474-3125
10. Boxes labeled “UN3373: Category B” must be picked up by Federal Express personnel or dropped off at a staffed Federal Express location. Do not leave this package in a drop box.
11. Contact MassBiologics by email at MBLClinicalDirector@umassmed.edu on the day the samples are shipped with the FedEx tracking number.