

Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory

Purpose

This standard operating procedure describes methods for the handling, storing, and shipping serum specimens that will be tested for recent HIV-1 infection using STARHS. Results from these tests will help estimate HIV incidence.

Introduction

Remnant serum from HIV-positive diagnostic specimens is to be collected and frozen by using vials and labels specified or supplied by the CDC STARHS laboratory. Ideally, 0.5 mL should be collected for each aliquot. Frozen serum will be shipped to the CDC STARHS laboratory for testing.

CDC STARHS Laboratory

The CDC STARHS laboratory is the Wadsworth Center Retroviral Immunology Diagnostic HIV Testing Laboratory which is part of the New York State Department of Health. Frozen aliquots will be shipped to:

NYSDOH Wadsworth Center
Axelrod Institute
Diagnostic HIV Testing Lab: STARHS
120 New Scotland Avenue
Albany, New York 12208
Attn: N'ko Lea Ali-Napo

Setting and Personnel for Specimen Processing

- Centrifugation, aliquoting, and shipping should be performed at or under the auspices of a laboratory that is certified under the Clinical Laboratory Improvement Amendments (CLIA) for handling HIV+ specimens.
- All personnel handling specimens should receive blood borne pathogens training. See the **Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard**:
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- Personnel handling or processing specimens should have appropriate laboratory training in the relevant laboratory techniques for handling HIV+ specimens and for performing the specific tasks required.

- The setting in which centrifugation, aliquoting, and shipping occurs should meet Biosafety Level 2 specifications required by the U.S. Department of Health and Human Services for handling of specimens containing HIV:
 - ♦ *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 4th ed. Washington: 1999. p. 20–27, 171–175. Available from URLs: <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> and <http://www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf>

Materials

- Cryogenic vials—Supplied by CDC STARHS laboratory
- Specimen labels—Supplied by CDC STARHS laboratory: label will identify sample (barcode, number, etc.) by STARHS identification number
- Cardboard storage boxes for cryogenic vials—Can be supplied by CDC STARHS laboratory if requested
- Freezer—STARHS samples can be refrigerated at 2–8°C, but for long-term storage and shipping, samples should be frozen at -20°C
 - ♦ If not already in practice, a daily temperature log should be kept to ensure the freezer is operating properly
 - ♦ The freezer should be housed in a location with proper ventilation to avoid overheating and freezer failure
 - ♦ Staff must be certain there is adequate space in freezer to store specimens
- A supply of dry ice in pellet form
- Insulated shipping containers certified to ship frozen diagnostic specimens (HIV+ serum and dry ice)
- Shipping courier air bills
- Materials for shipper packing—See [Packing Procedures for Shipping to the CDC STARHS Laboratory](#) in this document
- [HICSB Incidence Surveillance STARHS Specimen Submission Form](#)

Specimen Collection and Processing

All processing of specimens should be done by personnel qualified to handle HIV+ specimens under the auspices of a laboratory equipped for the handling of HIV+ specimens [*Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 4th ed. Washington: 1999. p. 20–27, 171–175. Available from URLs: <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm> and <http://www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf>].

- Aliquot the serum (0.5 mL per cryogenic vial). Use labels to identify the specimen and record this information in the proper setting (specimen log for eventual transfer to HIV Incidence Surveillance database).
- Store aliquots in refrigerator or freezer until specimen disposition has been determined and scheduled shipping date has arrived.

Shipping

- Specimens for STARHS should be sent to the CDC STARHS laboratory at the address on the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#) and in the [CDC STARHS Laboratory](#) section of this document. All specimens will be shipped as diagnostic specimens according to the International Air Transport Association (IATA) Packing Instructions 650. Dry ice will be included with each shipment per IATA Packing Instructions 904.
 - ♦ Because samples will be shipped with dry ice, shipping personnel must be trained and certified to ship dangerous goods. See [Training and Certification for Shipping Infectious Substances](#) for a list of companies that provide training.
 - ♦ Establish contact with Lea N'ko Ali-Napo (nla01@health.state.ny.us) at the CDC STARHS laboratory.
 - ♦ Ensure that adequate STP320 or equivalent shipping containers are available. The CDC STARHS laboratory will return them to the submitting laboratory if a return air bill is included in the shipment. The shippers are expensive and need to be re-used.
 - ♦ Ensure that you have an adequate supply of shipping courier air bills, which can be obtained free of charge from most couriers.

Packing Procedures for Shipping to the CDC STARHS Laboratory

All of the following steps should be read and understood **before** starting the preparation of the actual shipment:

- Bring the STP320 shipper or equivalent that is to be used for the shipment and materials needed for packing the specimens into the area in which the shipment will be prepared.
- If the shipper is new and being used for the first time, check to be sure that it includes the following items:
 - ♦ Two (2) sheets of bubble wrap
 - ♦ Two (2) STP 710 or equivalent certified secondary containers
 - ♦ Two (2) 250-mL absorbent strips
 - ♦ Class 9 label and dry ice quantity label
 - ♦ Other hazard and handling labels
 - ♦ One (1) instruction sheet

- For a diagram of the above contents, refer to the Saf-T-Pak catalog.
- Use only what is needed of the above contents for each individual shipment. Save leftover supplies for future shipments.
- If the shipper is being re-used, the proper labels will already be in place on the outer cardboard container. Ensure that adequate supplies of the other materials listed above are on hand.
- Put on personal protective equipment.
- Remove cryogenic vials from freezer and accurately record the specimen accession or STARHS identification numbers. The specimen numbers can either be written directly onto the STARHS Specimen Submission Form or on a separate list that will be attached to the form. Return them to the freezer. Repeat the process until all specimen numbers have been recorded for each vial that is going to be shipped.
- **These specimens should remain frozen at all times and therefore should not be removed from a freezing temperature environment for more than a few minutes.**
- Prepare 3 copies of the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#) listing or attaching the specimen number for each vial to be shipped.
 - ♦ Copy 1 (original) should be sent with the specimens in the shipment.
 - ♦ Copy 2 should be mailed to ISC as notification of shipment.
 - ♦ Copy 3 should be retained by the submitting laboratory for its records.
- If possible, on a floppy disk or CD, also include an encrypted electronic version of the list of specimen numbers in the shipment. This will help the CDC STARHS laboratory staff minimize the amount of data entry they have to do when logging in the samples, thereby minimizing errors.
- Prepare the shipping courier air bill that the CDC STARHS laboratory will use to return the shipper back to the submitting laboratory for re-use. The air bill **MUST** be completely filled in with the return address, the CDC STARHS laboratory address, and the proper billing number.
- If dry ice is in another location which requires leaving the area in which the shipment is prepared, use a separate container to bring the dry ice that is needed for shipping back into the shipping area at this time.
- Bring the specimens to the area in which the shipment is prepared. Work quickly, keeping in mind that **these specimens should remain frozen at all times and therefore should not be removed from a freezing temperature environment for more than a few minutes.**
- Re-check the screw-cap lids on the specimen vials and tighten if necessary.

- Place the specimens into the secondary leak-proof container and make sure samples are surrounded by bubble wrap and absorbent strips. The vials should not move around or rattle inside the vessel.
- Place the secondary vessel into the inner box and place the inner box into the polystyrene cooler.
- Pack dry ice pellets in the shipper and around the inner box. The STP320 shipper will hold ~8 kg of dry ice (~10 lb) and, if packed completely, will keep the contents frozen for greater than 80 hours.
- **DO NOT PUT DRY ICE INSIDE THE INNER BOX.**
- Place the lid on the polystyrene cooler.
- Place one copy of the completed [HICSB Incidence Surveillance STARHS Specimen Submission Form](#) on top of the shipping box return form with the completed *return* FedEx air bill stapled to it. Fold in half and place on top of the polystyrene lid.
- Fold over the top flaps and seal the shipping container with clear shipping tape.
- The outer box must have a mark in the form of a square set at an angle of 45° (diamond shaped). The mark must be at least 2 inches by 2 inches and include the UN 3373 designation. The proper shipping name—“Diagnostic specimens”—must be marked on the outer package adjacent to the diamond-shaped mark. Labels can be purchased to place on the outer box that fulfill this requirement.
- Apply the Class 9 Hazard Label over the lower diamond-shaped outline on the box.
- Apply the net quantity dry ice label to the outlined area adjacent to the Class 9 Hazard Label. Write the approximate amount (in kg) of dry ice you used to pack the container.
- Prepare the shipping courier paper work addressed to the CDC STARHS laboratory. Select the overnight shipping option.
- Call or email the CDC STARHS laboratory to notify them of the shipment. Provide the CDC STARHS laboratory with the shipment tracking information and the total number of samples in the shipment.

Note: *Do not fax or email laboratory-assigned specimen accession numbers or STARHS identification numbers.*

HICSB Incidence Surveillance STARHS Specimen Submission Form

Please complete this form and send it with each shipment. Specimens should be sent to
NYSDOH Wadsworth Center
Axelrod Institute
Diagnostic HIV Testing Lab: STARHS
120 New Scotland Avenue
Albany, NY 12208
Attn: N'ko Lea Ali-Napo

SHIPPING FACILITY INFORMATION:

Name: _____

Address: _____

Phone Number: _____

Fax: _____

Email: _____

Contact Person: _____

RESULTS SENT TO:

Name: _____

Address: _____

Phone Number: _____

Fax: _____

Email: _____

Mark the box for the appropriate surveillance activity for these specimens:

INCIDENCE SURVEILLANCE (HICSB)

Note: List of which specimens are appropriate to test for HIV incidence surveillance may be sent separately.

BEHAVIORAL SURVEILLANCE (BCSB)

EVALUATION OF DRIED FLUID SPOT SURVEILLANCE (DFS)

RANGE OF SPECIMEN NUMBERS SENT (OR ATTACH LIST):

Please identify any specimens on your list that are collected under a research protocol and that should not be tested using the BED HIV-1 Capture EIA.

01/08/2007

Training and Certification for Shipping Infectious Substances

FedEx 800-GO-FEDEX

- 3-day, IATA-based training covers all hazardous materials. Cost is \$650.

Saf-T-Pak 800-814-7484

- Specifically for infectious and diagnostic substances and dry ice. Three options: one-day seminar, on-site programs, or interactive CD (staff can be trained in 3 to 5 hours using interactive CD). Certificate is good for 2 years OR until regulations change. Cost is ~\$250.

Viking Packing Specialist (Oklahoma; David Weilert, President) 800-788-8525

- Seminars conducted monthly in Tulsa. Cost is \$300 per person. Covers all nine classes of hazardous materials, covers shipping under IATA, and certificate is good for 2 years. Will do group classes in local area (\$3,000 plus travel costs).

These are some companies that provide training for dangerous goods shipping. The Centers for Disease Control and Prevention does not endorse any particular company.

Appendix A

Statistical Method for Generating Population-Based HIV Incidence Estimates

This document is in development and will be added soon.