



California HIV/AIDS Incidence Surveillance

Standard Operating Procedures

External

Guidelines for the Handling, Storage, and Shipping of Remnant HIV-Positive Specimens from Private and Public Health Laboratories to the California Department of Public Health, Viral & Rickettsial Disease Laboratory (VRDL)

Version 2.0

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REVISION HISTORY

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1.0	02/3/2009	Initial draft	
2.0	03/18/2015	Edited and updated	Jessica Brown & Anna Wong

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1 Purpose

This document presents the standard operating procedures for private and public health laboratories participating in HIV Incidence Surveillance (HIS) in California to ship remnant HIV positive serum specimens to the California Department of Public Health (CDPH), Viral & Rickettsial Disease Laboratory (VRDL) for processing and subsequent transport to the Centers for Disease Control and Prevention (CDC), STARHS Laboratory (New York State Department of Health, Wadsworth Center) to be tested for recent HIV infection using the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS). Results from these tests help provide more accurate estimates of HIV incidence, which are important for public health policy, planning, and resource allocation. This document covers procedures and guidelines for specimen preparation, handling, and shipping, and for communicating with the VRDL.

1.1 Overview

Surplus HIV positive sera, also referred to as 'remnant specimens,' are collected and frozen using vials and labels specified or supplied by the VRDL. Ideally, 0.5 mL of serum should be collected from each specimen; alternatively, the entire specimen may be sent if it is no longer needed by the submitting laboratory. If less than 0.5 mL remains from the diagnostic specimen, whatever volume is available should be sent. Frozen sera are shipped to the VRDL for processing and relabeling, and then forwarded to the STARHS Laboratory for testing.

2 California Department of Public Health, Viral & Rickettsial Disease Laboratory (VRDL)

For purposes of HIS, the VRDL liaisons between participating commercial, private, and public health laboratories, and the STARHS Laboratory. In this role, VRDL receives and re-aliquots serum specimen from the laboratories, stores the specimen, and provides an inventory of serum samples to the CDPH, Center for Infectious Diseases, Office of AIDS (OA) HIV/AIDS Surveillance Section for the determination of whether the specimen are eligible for STARHS testing. The VRDL also supplies shipping materials, including cryovials, to participating laboratories, and covers the cost of shipping specimens. Specimen that are identified as eligible for STARHS testing by OA are then shipped by the VRDL to the STARHS Laboratory for testing.

2.1 Shipping Materials Provided by VRDL

VRDL provides a range of shipping materials for participating commercial, private, and public health laboratories, including International Air Transport Association (IATA)-approved dangerous goods shipping containers for specimen transport, sterile polyethylene capped 2 ml vials for serum aliquots, and pre-paid FedEx shipping labels for transport. Below is a list of the materials that VRDL can provide to assist with shipping your specimen:

- 5"(L) x 5"(W) x 1 ¾"(H), 9x9-slot specimen boxes
- 2 ml blue-cap sterile polyethylene vials
- STP-310 insulated Styrofoam dangerous goods shipping containers (IATA-approved)

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- STP-111 inner box for the freezer boxes
- STP-730 Tyvek pouch for diagnostic specimens
- STP-731 plastic bag to go inside Tyvek pouch (STP-730)
- STP-152 absorbent strip to go inside plastic bag (STP-731)
- STP-303 fiberboard flap, for VRDL to return shipper (STP-310) back to submitter
- Pre-Paid FedEx shipping labels for transport, which can be sent to you by email

2.2 VRDL Contact Information and Shipping Address

2.2.1 Contact Information

To obtain shipping materials or pre-paid FedEx labels, learn more about shipping specimen to VRDL, discuss shipping procedures, or notify VRDL before you ship, please use the following contacts:

Primary Contact

Anna Wong
Public Health Microbiologist II, VRDL
Retrovirus Disease Section
(510) 307-8901
Anna.Wong@cdph.ca.gov

Alternate Contact

Dr. Carl Hanson, Ph.D.
Chief, VRDL Retrovirus Disease Section
(510) 307-8540
Carl.Hanson@cdph.ca.gov

2.2.2 Shipping address

All shipments to VRDL should be addressed as follows:

Anna Wong (510) 307-8901
CA Department of Public Health
Viral & Rickettsial Disease Laboratory (VRDL)
850 Marina Bay Pkwy
Richmond, CA 94804-6403

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3 Laboratory and Training Requirements

3.1 Diagnostic Laboratory Requirements

Centrifugation, aliquoting, and shipping should be performed at or under the auspices of a laboratory that is CLIA-certified, by personnel familiar with handling HIV-positive specimens. The laboratory should meet Biosafety Level-2 specifications required by the U.S. Department of Health and Human Services for the handling of specimens containing HIV. For more information, see *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 5th edition, pages 20–27 and 171–175: <http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf>.

3.2 Shipping Materials Supplied by Participating Laboratories

Participating laboratories that ship specimen to VRDL are expected to provide the following:

- Specimen labels that fit properly on specimen vials (e.g., they do not wrap-around the vial and obscure specimen information)
- A freezer capable of storing specimen at -20 °C
- Dry ice for shipment
- A scale
- Clear packing tape
- A printed description of the shipment contents for each shipment
- A password-protected copy of a completed specimen manifest for each shipment provided on a CD sent along with the shipment or uploaded to the OA Secure File Transfer (SFT) site beforehand.

3.3 Personnel Training Requirements

3.3.1 Bloodborne Pathogens Training

All personnel handling or processing specimens should receive bloodborne pathogens exposure training. Please see OSHA *Occupational Exposure to Bloodborne Pathogens Standard* for more information: <https://www.osha.gov/Publications/osh3186.pdf>.

3.3.2 Lab-Specific Training

All personnel handling or processing specimens should have appropriate laboratory training in biosafety techniques for handling HIV-positive specimens and for performing the specific tasks required.

3.3.3 Dangerous Goods Shipping Training

The Federal Department of Transportation requires that all personnel who prepare, transport, or receive dangerous goods shipments be appropriately trained at least once every 2 years.

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Those responsible for shipping must be trained and certified in the International Air Transport Association (IATA) dangerous goods regulations (DGR) for infectious substances. The Federal Aviation Administration (FAA) imposes steep fines for shipments found to be packed incorrectly, with steep monetary penalties for each infraction. The person preparing specimens for shipment must be trained in the IATA-DGR in order to ship safely and legally. Refer to Appendix A for a list of companies that provide training. Please note that while these companies will evaluate training participants for competency in the DGR, they cannot certify an employee for shipping. That assessment is left to the employee's supervisor; it is to this person that the FAA will look for records and evidence of shipper training.

3.3.4 Security and Confidentiality Training

Staff should review the Advised Laboratory Procedures for Maintaining the Security and Confidentiality of HIV Incidence Surveillance Data included in Appendix B.

4 Storing and Preparing Specimen

All storage and processing of specimens should be done according to laboratory standard operating procedures by personnel qualified to handle HIV-positive specimens under the auspices of a laboratory equipped to function at a Biosafety Level-2 capacity.

4.1 Storing Specimen

Store aliquots in a -20°C freezer until the scheduled shipping date has arrived. Once serum aliquots are frozen, they should be kept in this condition to avoid unnecessary freeze-thaw cycles, which may negatively affect the STARHS assay. It is recommended that a daily temperature log 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 that there is adequate freezer space to store specimens.

4.2 Preparing Specimen

Aliquot the serum (0.5 mL per cryogenic vial) or submit the entire sample. Use cryogenic vials, which can be provided by the VRDL. Use labels to identify the specimens with laboratory accession numbers and the specimen collection dates. Barcode labels can also be used. Labels should not wrap-around the vial and obscure specimen information.

5 Shipping Specimen to VRDL

These instructions are only meant to serve as guidelines for packing specimens using STP-310 for transport. For complete instructions, please refer to your IATA-DGR training, the IATA-DGR manual, and the user's manual for Saf-T-Pak shipping products.

5.1 Create a Password-Protected Shipping Manifest

Once specimens have been prepared for shipping, prepare an electronic shipping manifest of the shipment contents. A Microsoft Excel template VRDL Laboratory Shipping Manifest—which is the preferred format for the inventory list—is available for download on the OA website at: <http://www.cdph.ca.gov/programs/aids/Pages/OAHISResLabs.aspx>. The shipping manifest should include the following information for each specimen: laboratory-assigned specimen

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accession number; specimen collection date; patient's first name; patient's last name; patient's date of birth; the unique OA case number (STATENO), if known; and any notes (e.g. if submitting a plasma specimen, please indicate "P"). See Appendix C for an example of the shipping manifest format and for more information about the data elements to include for each specimen; the manifest should be limited to the data elements listed.

There are two options to submit the shipping manifest to VRDL. The first option is to save the shipping manifest as a password protected file and upload the file on a CD. Please include CD when sending your shipment. In addition, send the password for the shipping manifest by email to VRDL. Please ensure that the designation of [secure] (including the brackets) is on the subject line of the email. The second option is to upload the shipping manifest on to the OA Secure File Transfer (SFT) site. Once the shipping manifest is uploaded to the SFT site, please contact the HIV Surveillance Laboratory Coordinator, who will send the manifest to VRDL. Contact Jessica Brown, OA HIV Surveillance Laboratory Coordinator at Jessica.Brown@cdph.ca.gov for details about using the SFT method and SFT account information.

5.2 Preparing the Specimens for Shipment

Shipments are to be sent using IATA Packing Instruction 650. In no case should a Class 6 Label or shipper's declaration for dangerous goods be used. Ensure that specimens are kept frozen during the packing process. If this process is interrupted, be sure that specimens are placed back in the freezer or are kept on dry ice. Send an email request to VRDL to obtain a pre-paid FedEx label that can be sent to you by email, prior to shipping specimens to VRDL.

1. Place the 5"(L) x 5"(W) x 1 ¾"(H), 9 x 9 slot specimen-box containing sera in a plastic bag (STP-731). Insert one absorbent strip (STP-152) and seal. Place the packaged specimen box inside the white Tyvek pouch (STP-710) and seal. Use one set of STP packaging materials for each specimen box.
2. Fit packaged specimen box(es) into the inner fiberboard box (STP-111) and close flaps.
3. Open the shipper (STP-310). You will notice a square-shaped recessed area at the Styrofoam base. This is the "seat" for the inner box (STP-111). Place the inner box in the "seat."
4. Note the weight of the package in pounds and kilograms.
5. Surround STP-111 with dry ice (pelleted form or block form broken into small pieces). Fill the inner Styrofoam container (STP-310), but leave room for the lid to sit flush with the lip of the container.
6. Place the lid on the Styrofoam container (STP-310). Slip the return mailing flap (STP-303) between the Styrofoam and the cardboard box. Include a written description of the shipment contents. If the password-protected shipping manifest is to be included along with the shipment, place it on top of Styrofoam lid. Otherwise upload it to the OA SFT prior to shipping. Close the cardboard flaps of the shipper and seal with clear packaging

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tape (3M or Scotch brands work best).

7. Note the new weight of the shipper in pounds and kilograms before and after loading dry ice. Subtract the weights before and after weighing the package, and record the weight of the dry ice on the front panel of the box labeled “Dry Ice UN 1845 _____ Kg Net Wt.”
8. Attach the FedEx air bill in a FedEx plastic sleeve on top of the sealed shipper (STP-310).

5.3 Verify the Shipping Date with VRDL Prior to Shipping

Contact the VRDL and verify that they will be able to receive the shipment prior to actually shipping. The VRDL can only accept shipments during the work-week, so only ship from Monday to Thursday. The VRDL will also notify laboratories of any State holidays that may affect shipping schedules.

5.4 Notify VRDL and OA and Ship the Specimen

Advanced email notification to the VRDL is critical to ensure that VRDL knows when to expect the shipment and can track the delivery process in case of delayed or missed shipments. On the day of shipment, email VRDL and OA to notify them of the pre-planned specimen arrival date. Please structure the email as follows:

1. Format the subject line as follows: “STARHS shipment: <courier/shipping company> <tracking number> (e.g., STARHS SHIPMENT: FEDEX TRACKING 4325 2455 6961).
2. Include in the email body the laboratory name and contact information, the shipment date, and the name of the courier, if not FedEx.
3. Please cc Jessica Brown, OA HIV Surveillance Laboratory Coordinator, at Jessica.Brown@cdph.ca.gov.

5.5 Delivery Confirmation & Shipment Discrepancies

VRDL will communicate with the sending laboratory to confirm delivery, report any problems with the shipment (e.g., delays resulting in compromised specimens, lost shipments, etc.) and to clarify any discrepancies with the shipment (e.g., specimens in electronic manifest, but not included in the shipment).

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6 Appendix A: Training and Certification for Shipping Infectious Substances

Companies known to provide training and certification for shipping infectious substances are shown below for convenience. There are other companies that provide training for dangerous goods shipping that can be found by searching the internet. The CDPH and CDC do not endorse any particular company.

6.1 FedEx

This 3-day IATA based training is comprehensive and covers all biological and hazardous materials. If your laboratory anticipates handling of infectious substances only for shipment, this option may be too broad for its needs. For additional information on training, contact FedEx at 1-800-GO-FEDEX or: <http://www.fedex.com/us/hazardous-materials/training/>

6.2 Saf-T-Pak

This training is specifically for shipping infectious/biological diagnostic substances and the use of dry ice. There are three training options: a 1 day seminar, on-site programs, or interactive CD. For the interactive CD, one sitting can be done in 3–5 hours. The certification is good for 2 years when signed by the supervisor or until regulations change. For additional information on training, contact Saf-T-Pak at 1-800-814-7484 or <http://www.saftpak.com/Training/training.aspx>

6.3 UPS Hazardous Materials/Dangerous Goods Seminar

This 2-day seminar covers all aspects of shipping hazardous materials by ground or air within the U.S. and via ground to Canada, including basic terminology, packaging requirements, marking and labeling, documentation, and proper UPS shipping procedures. UPS also offers a 3-day seminar that covers all aspects of domestic and international shipping of dangerous goods, including basic terminology, classification, identification, packaging requirements, marking and labeling, and documentation, and proper UPS shipping procedures. Prior knowledge of 49CFR and/or IATA regulations is suggested. For additional information on training, contact UPS at 1-800-634-5656 or upshazmatseminars.com

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7. Appendix B: Advised Laboratory Procedures for Maintaining the Security and Confidentiality of HIV Incidence Surveillance Data

7.1 Overview

The purpose of HIV incidence surveillance is to track recent HIV infections in the population using the STARHS. On March 1, 2005, OA implemented an HIS program to enhance existing HIV/AIDS case surveillance. This program is now fully incorporated into Core HIV Surveillance, and provides data for determining local and national HIV incidence estimates. The data enable public health communities to monitor and assess trends in the epidemic, and improve efforts to prevent HIV transmissions.

7.2 Purpose

Maintaining the security and confidentiality of data used in conducting HIV surveillance is the responsibility of all staff involved in public health and health care activities. This document summarizes how laboratory personnel should manage HIV incidence surveillance related data, as informed by the CDC guidelines for HIV/AIDS surveillance.¹

The following security standards and staff responsibilities are advisements to manage data for the purpose of HIV Incidence Surveillance at private and local public health programs and laboratories, VRDL including transfer of data between laboratories and surveillance programs. These procedures and responsibilities will ensure that the confidentiality of persons reported as having HIV infection is strictly upheld as data are stored, transferred, and disposed.

7.3 Confidentiality and HIPAA Regulations

STARHS procedures conducted by laboratories must ensure the confidentiality of HIV-related laboratory information is protected and maintained to meet requirements under California Health and Safety Code, Sections 120980 (private laboratories) and 121025 (public health laboratories). The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) regulations permit laboratories and other HIPAA-covered providers to share protected health information with public health authorities and their agents (such as CDPH) for the purposes of public health activities, including surveillance.² HIPAA does not restrict the originating laboratories from sending specimens labeled with their laboratory-assigned accession numbers to either the VRDL or the STARHS Laboratory, where samples to be tested using STARHS will be reassigned a unique STARHS identification number before testing.³ This process minimizes relabeling errors and simplifies the shipment procedures for private laboratories. However, the state/local public health department must have the laboratory accession numbers to link the test results to the patient information in surveillance

¹ Centers for Disease Control and Prevention and Council of State and Territorial Epidemiologists. *Technical Guidance for HIV/AIDS Surveillance Programs, Volume III: Security and Confidentiality Guidelines*. Atlanta, Georgia: Centers for Disease Control and Prevention; 2006.

² HIPAA Privacy Rule (45 C.F.R. §§ 160.203(c); 164.512(b))

³ U.S. Department of Health and Human Services. *Health Information Privacy*. Available at <http://www.hhs.gov/ocr/privacy/>

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records. Therefore, laboratory accession numbers must be included on the HIV laboratory reports sent to the state/local public health department by originating laboratories.

7.4 Security Standards

HIV incidence surveillance data and information should be maintained in physically secured, locked areas. Access to surveillance-related information should be limited to authorized personnel.

Computers that store surveillance-related information and data should be secured by restricted access rights. Computers should be equipped with security precautions such as user identifications and passwords. Laptop computers or portable electronic devices must not be used to enter or store surveillance data.

Any storage media containing surveillance information should be limited to the minimum amount of information necessary to complete surveillance procedures, as directed by OA HIV Surveillance Section staff. Any storage media containing confidential surveillance information should be kept inside a locked cabinet or drawer when not in use.

Storage media containing confidential surveillance information should be sanitized immediately upon completing a given task using methods that render the data irretrievable. This process (i.e., data wiping) ensures that electronic files are permanently deleted and fragments of those files are not recoverable.

Hard copy lists containing confidential surveillance data should be shredded immediately using a commercial quality shredder with cross-cutting ability before disposal. This procedure includes specimen requisition lists transmitted to the laboratory by the OA Surveillance Section staff.

Electronic data transmission of surveillance information via email, facsimile, or text messaging is prohibited. Surveillance information should only be transferred from the secured area using traceable courier services (e.g. FedEx, UPS, Golden State Courier Service, etc) or via other secure methods approved by OA (e.g., Secure File Transfer). The transfer of surveillance data or information should be limited to the minimum amount of data necessary to perform a given task, and where possible, to minimize the sensitivity of the information. Terms that could be associated with HIV or AIDS should be avoided in the transfer of information and should not appear in either the sender or recipient address or label.

7.5 Staff Responsibilities

Persons authorized to access surveillance information and data should be trained annually and be knowledgeable about confidentiality and security procedures within their organizations. Furthermore, staff are responsible for challenging unauthorized individuals entering secured areas where surveillance information is maintained.

Suspected security breaches should be reported immediately to the Chief of the OA HIV/AIDS Surveillance Section, Scott Masten, at (916) 449-5835 or Scott.Masten@cdph.ca.gov.

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		regarding the specimens such as “not enough specimen,” the freeze status, etc.		
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Details of VRDL Shipping Manifest Variables