

**ESTIMATING HIV INCIDENCE USING POPULATION-BASED
SEROLOGIC METHODS TO DETECT RECENT HIV-1 INFECTION**

*Guidelines for the Processing, Storage, and Shipping of Remnant HIV-Positive Specimens from
Local Public Health Laboratories to the California Department of Public Health
Viral & Rickettsial Disease Laboratory*

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1 Purpose

This standard operating procedure describes methods for the handling, storage, and shipping of serum specimens that will be tested for recent HIV-1 infection using the Serologic Testing Algorithm for Recent HIV-1 Seroconversion (STARHS). Results from these tests will help provide more accurate estimates of HIV-1 incidence, which are important for public health policy, planning, and resource allocation.

1.1 Scope

This document and the procedures contained herein apply to local public health laboratories shipping samples to the California Department of Public Health, Viral & Rickettsial Disease Laboratory (CDPH VRDL) for processing and subsequent transport to the CDC STARHS Laboratory (NYSDOH Wadsworth Center). This document will cover procedures for specimen preparation for shipment, shipping guidelines, and communication with VRDL.

2 Introduction

Surplus serum from positive HIV-1 diagnostic specimens is to be collected and frozen using vials and labels specified or supplied by VRDL. Ideally, 0.5 mL specimen should be collected for each aliquot or the entire specimen may be sent if it is no longer needed by the local public health laboratory. If less than 0.5 mL is remaining from the diagnostic specimen whatever volume is available should be sent. The CDC STARHS laboratory will make every effort to STARHS test smaller volumes manually. Frozen serum will be shipped to VRDL for processing, re-labeling, and subsequent shipment to the CDC STARHS Laboratory for testing.

3 CA Dept of Public Health VRDL

VRDL will act as a liaison between the CDC STARHS Laboratory and participating local public health laboratories in California, working in conjunction with the CDPH Office of AIDS (OA). The role of VRDL will include receiving and realiquoting serum specimens received from participating laboratories, storage of those specimens, and providing an inventory of serum samples to OA for the determination of those that qualify for STARHS testing. VRDL will also be the supplier of shipping materials and cryovials to participating sites. Samples that qualify for STARHS testing will be shipped by VRDL to the CDC STARHS Laboratory as directed by OA.

3.1 Communication

3.1.1 Contacts

3.1.1.1 Administrative Contact

Participating sites will communicate with the administrative contact for shipment pre-notification and general questions.

Carl Hanson
carl.hanson@cdph.ca.gov
(510)307-8540

Anna Wong
anna.wong@cdph.ca.gov
(510) 307-8901

3.1.1.2 Supplies Contact

VRDL has available IATA approved dangerous goods shipping containers for specimen transport; including refurbishment materials for VRDL supplied shippers. In addition, VRDL will also provide sterile polyethylene capped 2ml vials for serum aliquots.

Carl Hanson
carl.hanson@cdph.ca.gov
(510)307-8540

Anna Wong
anna.wong@cdph.ca.gov
(510) 307-8901

3.1.2 Shipping Notification

On the day of shipment, participating labs are to e-mail the administrative contact, providing pre-notification of the impending specimen arrival. Please structure e-mail as follows:

- Subject line which includes STARHS designation and FedEx waybill number (e.g., RE: STARHS SHIPMENT: FEDEX TRACKING 4325 2455 6961) or alternate shipper information.
- E-mail body which includes shipper name and contact information; shipment date
- Copy to Lissa Bayang (OA) in e-mail (lissa.bayang@cdph.ca.gov, (916) 327-6945)

The e-mail notification is important so that VRDL knows to track the specimens in the event of delayed or missed delivery.

3.1.3 Delivery Confirmation & Shipment Discrepancies

VRDL will communicate with the originating laboratory to confirm delivery, report any problems with shipment (*e.g.*, delivery delay resulting in compromised specimens, lost shipments, etc.) and to clarify any discrepancies with the shipment (*e.g.*, specimens on manifest not in shipment and vice versa).

4 Setting and Personnel for Specimen Processing

4.1 Diagnostic Laboratory Requirements

Centrifugation, aliquoting, and shipping should be performed at or under the auspices of a laboratory that is CLIA-certified and familiar with handling HIV-positive specimens.

4.2 Training

4.2.1 Bloodborne pathogens

All personnel handling specimens should receive bloodborne pathogens training. Please see OSHA *Occupational Exposure to Bloodborne Pathogens Standard* for more information:

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051.

4.2.2 Lab-specific

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

4.2.3 Dangerous Goods Shipping

The Federal Department of Transportation requires that anyone who prepares, transports, or receives dangerous goods shipments undergo the appropriate training at least once every two years. Those responsible for shipping must be trained and certified in the International Air Transport Association (IATA) dangerous goods regulations (DGR) for infectious substances. The FAA imposes steep fines for shipments found to be packed incorrectly, with penalties of at least \$75,000 per infraction.

Refer to Appendix A for a list of companies that provide training.

IMPORTANT: Please note that while these companies will evaluate training participants for competency in 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.

4.3 Laboratory Setting

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 the handling of specimens containing HIV. Refer to *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 4th edition, pages 20-27, 171-175 [<http://www.cdc.gov/ohs/biosfty/bmb14/bmb14toc.htm>].

5 Materials

5.1 Supplied by VRDL

5.1.1 9x9 freezer boxes

5.1.2 2 ml sterile polyethylene capped vials

5.1.3 STP-310 insulated infectious shipper

5.1.4 STP-111 Inner box for 9 x 9 grid freezer boxes

5.1.5 STP-710 Shipping bag for diagnostic specimens

5.1.6 STP-711 Plastic bag to go inside STP-710

5.1.7 STP-152 Absorbent strip to go inside STP-711

5.1.8 STP-303 Labeled return mailing flap for STP-310

5.1.9 Shipping labels

5.2 Responsibility of Local Public Health Laboratory

5.2.1 Specimen labels

5.2.2 Freezer

STARHS samples can be refrigerated at 2 to 8 °C, but for long term storage and shipping, samples should be frozen at –20°C. It is recommended that, if not already in practice, 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 there is adequate space in freezer to store specimen

5.2.3 Dry ice

5.2.4 Scale

5.2.5 Clear packing tape

5.2.6 A printed description of shipment contents.

5.2.7 Copy of specimen manifest on 3.5” floppy diskette or CD which includes the following information for each specimen: Accession number, Collection date, Client ID and Notes (e.g. collected out-of-state).

6 Specimen Collection and Processing

All processing of specimens should be done according to laboratory SOP's by personnel qualified to handle HIV-positive specimens under the auspices of a laboratory equipped for the handling of HIV-positive specimens. (Please refer to Section 4:)

6.1 Specimen preparation

Aliquot the serum (0.5 mL per cryogenic vial) or submit the entire sample. Use cryogenic vials provided by VRDL. Use labels to identify the specimen with lab accession number and (if possible) specimen collection date. If available, use scannable barcode labels.

6.2 Specimen storage

Store aliquots in freezer until scheduled shipping date has arrived. Once serum aliquots are frozen, they should be kept in this condition to avoid unnecessary freeze/thaws, which may negatively affect the STARHS assay.

7 Shipping

7.1 Shipping address

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

7.2 Manifest

Once specimens have been designated for shipping, prepare an inventory of the shipment contents using the Microsoft Excel spreadsheet template provided by the VRDL administrative contact. Save file. The shipping manifest data file format is specified in Appendix B.

7.3 Security and Confidentiality

The manifest should be limited to the data elements listed in Appendix B. While these data are not considered to be confidential information, staff should review the HIV surveillance data security and confidentiality advisement included in Appendix C.

7.3.1 Preparing specimens for shipment

7.3.1.1 Training and Qualifications

The person preparing specimens for shipment must be trained in the IATA DGR in order to ship safely and legally. (Please refer to Section 4.2.3: Dangerous Goods Shipping)

7.3.1.2 Packing procedures using STP-310

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

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.

- 7.3.1.2.1 **IMPORTANT**: Obtain verification that VRDL will be able to receive the shipment. In general, ship only on Monday through Thursday. VRDL can only accept shipments during the week. VRDL will also notify labs of any state holidays, which may also affect shipping schedule.
- 7.3.1.2.2 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.
- 7.3.1.2.3 Place 9 x 9 grid box containing specimens inside STP 711 (plastic bag). Insert one absorbent strip (STP 152) and seal. Place the filled STP 711 inside STP 710 (white bag), remove adhesive strip from STP 710 and seal. Repeat for any additional grid boxes, using only one grid box per STP 710.
- 7.3.1.2.4 Fit sealed grid box(es) into the inner cardboard box (STP 111). Close this outer box.
- 7.3.1.2.5 Open the STP-310. You will a notice square-shaped recessed area at the bottom of the STP-310 shipper. This is the seat for the outer box (STP 111). Place this filled STP 111 in the seat.
- 7.3.1.2.6 Note the weight of the package.
- 7.3.1.2.7 Surround STP 111 with dry ice (pelleted form or block form broken into small pieces), filling the inner Styrofoam container of the STP 310, but leaving room for the lid to sit flush against the rest of the package.
- 7.3.1.2.8 Place lid on shipper. Place return mailing flap (STP 303 – Important!), description of shipment contents, and manifest diskette on top of Styrofoam lid. Close flaps and seal with packing tape.
- 7.3.1.2.9 Note new weight of package. Subtract the weight of package before the addition of dry ice to obtain the weight of the dry ice. Record weight on a dry ice weight label and place on appropriate area of shipper.

- 7.3.1.2.10 Attach correctly filled-out FedEx air waybill, or alternate shipper waybill, to top of sealed STP-310, being sure not to obscure the “Air Eligible” label. Use “Priority” delivery option on waybill.

Note: VRDL will cover the cost of shipping of STARHS specimens. Use FedEx account number 4432-0502-0 on your FedEx waybill. BE SURE TO NOTE PCA CODE: 90270 and INDEX CODE: 5413 on the FedEx waybill.

APPENDIX A

TRAINING AND CERTIFICATION FOR SHIPPING INFECTIOUS SUBSTANCES

FedEx 800-GO-FEDEX 3 day IATA based training is comprehensive and covers all hazardous materials. If laboratory anticipates handling of infectious substances only for shipment, this option may be too broad for its needs. Cost as of May 2005 is \$550.

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. For interactive CD, one sitting can be done in 3-5 hours. Certificate good for 2 years when signed by supervisor OR until regulations change. Cost as of May 2005 is approximately \$250.

Viking Packaging (Oklahoma) 800-788-8525—David Weilert Seminars monthly in Tulsa at \$300 per person. Like FedEx training, this covers all nine classes of hazardous materials Covers shipping under IATA. Certificate 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. There may be others. The California Department of Public Health and the Centers for Disease Control and Prevention do not endorse any particular company.

APPENDIX B

Shipping Manifest Data File Format

Use Excel spreadsheet template provided by VRDL administrative contact. File is an Excel spreadsheet with the following fields. Include the Field names as a header row.

Field No.	Field	Description	Type	Length	Notes
1	Accession#	Lab-assigned specimen accession number	Text	20	
2	Collection	Specimen collection date	Date/Time	10	mm/dd/yyyy
3	PriorAcc#	Specimen accession number assigned by lab submitting EIA positive specimen for confirmatory testing, if applicable	Text	20	
4	Client First Name	Patient's First Name	Text		
5	Client Last Name	Patient's First Name	Text		
6	Client DOB	Patient's Date of Birth	Date/time	10	mm/dd/yyyy
7	Notes	Any notes regarding the specimens such as not enough specimen, or freeze status, etc.	Text		
Field No.	Field	Description	Type	Length	Notes
1	Accession#	Lab-assigned specimen accession number	Text	20	
2	Collection	Specimen collection date	Date/Time	10	mm/dd/yyyy
3	Client ID	Unique Office of AIDS Client Number	Text	20	xxxxxxxx

APPENDIX C

Advised Laboratory Procedures for Maintaining the Security and Confidentiality of HIV Incidence Surveillance Data

HIV/AIDS Case Registry
Office of AIDS (OA)
California Department of Public Health (CDPH)

Overview

The purpose of HIV incidence surveillance is to track recent HIV infections in the population using the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS). On March 1, 2005, OA began implementing incidence surveillance in order to enhance existing HIV/AIDS case surveillance. This system, once fully incorporated into routine case surveillance, will provide local and national HIV incidence estimates. The data will enable the public health community to more accurately monitor trends in the epidemic and improve efforts to prevent HIV transmission.

Maintaining the security and confidentiality of data used in conducting HIV incidence surveillance is the foremost responsibility of all staff involved in surveillance activities. This document summarizes how laboratory personnel should manage HIV incidence surveillance related data, as informed by the Centers for Disease Control and Prevention (CDC) guidelines for HIV/AIDS surveillance¹. Furthermore, this advisement is not intended to supersede existing state and federal statutes for the protection of the confidentiality of medical records, but rather to complement these policies and procedures.

The following security standards and staff responsibilities are advised for the management of data for the purpose of HIV Incidence Surveillance at local public health labs and State Department of Public Health, Viral and Rickettsial Disease Lab (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.

Security Standards

HIV incidence surveillance data and information should be maintained in physically secure, locked area. 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

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.

as user identifications and passwords. Laptop computers or portable electronic devices must not be used to enter or store surveillance data. Do not access the Internet or email applications while simultaneously accessing confidential surveillance information.

Hardcopy lists that contain confidential surveillance information should be stored inside locked file cabinets in the secured area, and access to keys and files restricted to authorized personnel.

Any diskettes or 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 program staff. Any diskettes or storage media containing confidential surveillance information should be stored inside a locked cabinet when not in use.

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

Hardcopy lists containing confidential surveillance data should be shred immediately using a commercial quality shredder (with cross-cutting ability) before disposing of them. This procedure includes specimen requisition lists transmitted to the laboratory by OA surveillance program staff.

Electronic mail transmission (e-mail) or FAX of surveillance information or data is prohibited. Surveillance information should be transferred from the secured area using traceable courier services (e.g. FedEx, UPS, Golden State Courier Service, etc). 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, 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.

Staff Responsibilities

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

Suspected security breaches should be reported immediately to the Chief of the HIV/AIDS Case Registry Section.

Staff should ensure that surveillance information and data are protected from unauthorized use by securing any keys, passwords, and codes that would allow access to surveillance information to unauthorized persons. Staff is also responsible for securing their own workstation.