

Guidance for the Remnant HIV-Positive Specimen Transportation Activities for HIV Incidence Surveillance

Purpose

This guidance provides an overview of the incidence surveillance specimen transport activities and describes two possible specimen transport models that originating laboratories may use to ship remnant diagnostic serum specimens to the CDC STARHS laboratory for testing for recent HIV-1 infection using the serologic testing algorithm for recent HIV seroconversion (STARHS). Originating laboratories may choose to select either model but must clearly communicate their choice to and coordinate with the state/local HIV Incidence Surveillance Coordinator (ISC), who will be responsible for managing the results.

Introduction

In December 2004, an expert consultation was convened by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL). The purpose of the 5th HIV Incidence Consultation on Laboratory and Specimen Transport was to discuss the best approaches for transporting remnant HIV-positive sera from private and public laboratories to the CDC STARHS laboratory for testing using STARHS. The consultation participants included HIV incidence surveillance staff from CDC and state/local areas, and personnel from commercial, private, university, and public health laboratories, APHL, and the American Clinical Laboratory Association. The goal for the meeting was to gather input from stakeholders for developing an infrastructure for shipping specimens from private (including university and/or medical center), commercial, and public health laboratories to the CDC STARHS laboratory.

Participants concluded that two models were acceptable for shipping specimens from testing laboratories to the CDC STARHS laboratory. This guidance describes both specimen transportation models. The models differ in 1) the extent of the testing laboratories' involvement in aliquoting/labeling samples for STARHS; 2) the physical storage location of the samples until the ISC determines specimen disposition (i.e., whether to be tested using STARHS or to be discarded); and 3) the frequency of shipments to the CDC STARHS laboratory.

Each testing laboratory may choose either model, but this choice should be clearly communicated to the ISC.

Laboratory Types

For the purposes of this guidance, there are three laboratory types. Although each testing laboratory may independently decide which specimen transport model will work best for that facility, CDC has provided suggestions based on the type of laboratory and that facility's relationship with the state/local public health laboratory.

Laboratory Types

1. **Private Laboratories:**
 - a. Larger **commercial laboratories** that process samples from many states and/or jurisdictions (examples in this category are Quest Diagnostics Inc, Laboratory Corporation of America [LabCorp], ARUP Laboratories, Specialty Laboratories, and Mayo Clinic)
 - b. Smaller **private/university/hospital or medical center laboratories** that provide service primarily at the state or local level, but may also process samples for more than one state and/or jurisdiction
2. **Public health laboratories (PHLs)**

Specimen Information

Type of Specimens Shipped to CDC STARHS Laboratory

HIV-positive serum from diagnostic samples confirmed by Western blot (WB) or immunofluorescence assay (IFA) will ultimately be shipped to the CDC STARHS laboratory, depending on the specimen transport model chosen by the originating laboratory. Detailed information about which samples will be shipped is included in the model descriptions of this guidance (see [Specimen Transport Options](#)).

Specimen Volume

The optimal quantity of serum required for STARHS testing is 0.5mL per aliquot. However, if less than 0.5mL of the remnant sample is available for testing using STARHS, the sample should still be sent to the CDC STARHS laboratory. The CDC STARHS laboratory is the only laboratory that should determine whether a sample is rejected because of insufficient quantity.

Sample Storage

Short-term (less than 1 week) storage of samples in the refrigerator (temperatures ranging from 2° to 8°C) is acceptable, but for long-term storage (more than 1 week), samples must be frozen at -20°C or colder. This includes any period that the samples are kept at the originating/testing laboratory or the “pass-through” public health laboratory before shipment to the CDC STARHS laboratory or the interim period while STARHS disposition is being determined. Effort should be made to avoid repeated freezing and thawing of samples, as this may give erroneous results.

- 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
- The freezer should contain adequate space to store specimens

Specimen Numbering

The specimen number on the samples shipped to the CDC STARHS laboratory will either be the original laboratory-assigned specimen accession number or the STARHS identification number, depending on the transport model selected by the originating laboratory. Detailed information about specimen numbering is included in the model descriptions of this guidance (see [Specimen Transport Options](#)).

Specimen Retention

The ISC must coordinate with the laboratory storing HIV-positive remnant sera (the CDC STARHS laboratory and/or their state/local PHL) to identify samples that should be tested using STARHS. However, not all stored samples will be tested using STARHS, and those that will not be tested will have to be identified for disposal. The ISC should regularly notify the storage laboratory about which samples should be tested using STARHS and which should be disposed of by submitting a list of laboratory-assigned specimen accession numbers with “test” or “toss” for each specimen according to the decision reached. The state/local ISC and the storing laboratory should communicate regularly (every 1–3 months) to discuss any specimens for which no disposition has been communicated to determine whether the sample can be disposed of or whether further investigation is needed. Samples should not be destroyed or disposed of until the disposition is definitively determined.

Packaging and Shipping Procedures

Shipping Guidance

Shipping procedures are described in detail in [Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory](#). Specimens may be shipped from originating laboratories to the state PHL as a pass-through facility or to the CDC STARHS laboratory as diagnostic specimens. However, because of the requirement for dry ice, all laboratories shipping HIV-positive samples must be certified to ship dangerous goods.

Frequency of Shipments

The frequency of specimen shipments to the CDC STARHS laboratory or the pass-through facility should be on a regular schedule, every 1–3 months, and will be determined by the shipping laboratory, considering factors such as specimen retention policies and freezer/storage space, and in consultation with the ISC and the receiving laboratory.

Shipping Couriers

Specimens must be shipped on dry ice by same-day or overnight delivery service to ensure that specimens do not thaw in transit. The shipping laboratory may decide which courier service to use for specimen transport.

Shipments from private laboratories to the PHL may be shipped by Federal Express (or a similar commercial courier) or an established local courier service. Funding permitting, program areas may elect to set up a billing account with Federal Express (or a similar commercial courier) to pay for shipping costs incurred by the private laboratory to either the state/local PHL or the CDC STARHS laboratory (see [Funding for Specimen Handling](#)).

Coordinating Shipments

For larger private laboratories that process samples from multiple states and jurisdictions, program areas should collaborate to coordinate specimen shipment mechanisms. A summary of the participating commercial laboratories, primary laboratory contact, primary ISC contact, and shipping arrangements, is available on the HIV Incidence and Case Surveillance Branch (HICSB) password accessible website at:

https://team.cdc.gov/team/cdc/dispatch.cgi/hicsb_Incidence/folderFrame/100027/0/def/61fd

Additional Information for Commercial Laboratories Only

APHL set up a Federal Express billing account for the large commercial laboratories participating through an APHL contract (ARUP Laboratories, LabCorps, and Mayo Clinic) to defer costs of shipping samples to the CDC STARHS laboratory. The APHL Federal Express billing account is available through the end of 2007 only for those commercial laboratories under contract to APHL.

Tracking Shipments

The shipping laboratory should notify the receiving laboratory (state PHL or CDC STARHS laboratory) by fax or email when specimens are shipped, *including the name of the courier and the tracking number of the shipment*. The receiving laboratory will be responsible for tracking the shipments and will notify the originating laboratory if the specimens are not received.

Note: Private laboratories shipping specimens for multiple jurisdictions should provide shipment tracking information to the designated primary ISC responsible for shipping oversight, following procedures established by agreement between the laboratories and participating agencies.

Additional Information Related to APHL-Contracted Commercial Laboratories Only

As part of the contract between APHL and its participating commercial laboratories, APHL will track shipments from these commercial laboratories to the CDC STARHS laboratory. The contracted commercial laboratories must provide APHL with a list of sample numbers sent to the CDC STARHS laboratory. The CDC STARHS laboratory must notify APHL of any shipments sent from an APHL-contracted laboratory that are received by the CDC STARHS laboratory. This notification is needed for billing purposes at APHL.

Sample Rejection Criteria

Sample rejection due to thawing, breakage, insufficient quantity, or lost-in-transit status will be determined and recorded by the CDC STARHS laboratory. The CDC STARHS laboratory will include sample rejection information with the STARHS results report that is transmitted to the ISC.

Confidentiality and HIPAA Regulations

STARHS must ensure that confidentiality is protected and maintained to meet standards for HIV surveillance. The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) regulations permit protected health information to be shared for the purposes of public health surveillance activities¹. This protection allows the originating laboratories to send specimens labeled with their laboratory-assigned accession number to either the state PHL or the CDC STARHS laboratory, where samples to be tested using STARHS will be reassigned a unique STARHS identification number before testing. This process will minimize relabeling errors and simplify the shipment procedures for private laboratories. However, the state/local public health department must have the laboratory accession number to link the test result to the patient information in the surveillance record. Therefore, the laboratory accession number must be included on the HIV laboratory report sent to the state/local public health department by the originating laboratory.

Funding for Specimen Handling

As a rule, surveillance is not a remunerated activity. However, through a Cooperative Agreement with APHL (# U60/CCU303019-17), funds were made available to provide a predetermined fee to offset personnel, administrative, and handling costs incurred by participating high-volume, multijurisdictional commercial laboratories (ARUP Laboratories, Mayo Clinic, and LabCorps) for an initial start-up period. The APHL Cooperative Agreement was effective through June 2006 for covering specimen handling fees for these participating laboratories, and was extended through the end of 2007 to cover only shipping expenses for these laboratories. Reimbursement for these laboratories beyond the initial start-up period and for all other private laboratories is not covered by the APHL Cooperative Agreement; funding for specimen handling costs may be made available through the state's Cooperative Agreement with CDC for HIV/AIDS Incidence Surveillance (Program Announcement 04017), but handling fee reimbursement is not recommended.

Specimen Transport Options

Option A: Specimen Originated at Private Laboratory and Is Sent Directly to the CDC STARHS Laboratory

Transportation Overview

In this transportation model, the originating private laboratory performing the confirmatory testing will send *all* confirmed HIV-positive diagnostic specimens directly to the CDC STARHS laboratory (bypassing the state/local PHL) by overnight shipping in accordance with the procedures described in [Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory](#). The CDC STARHS laboratory will store specimens until specimen disposition is determined by the state/local ISC, at which point, the CDC STARHS laboratory will pull samples to be tested using STARHS, aliquot, relabel them with a STARHS identification number, and perform STARHS. All samples that should not be tested using STARHS (i.e., samples that are not the diagnostic specimen) will be discarded.

In this model, the originating laboratory would continue to submit laboratory report information in the current manner to the appropriate jurisdiction, but must also include the laboratory-assigned specimen accession number and the collection date on the report.

Figure 1 graphically depicts the flow of specimens and reports when samples originate at a private laboratory and are then shipped directly to the CDC STARHS laboratory.

Procedures for Specimens Sent Directly from a Private Laboratory to the CDC STARHS Laboratory

- The ISC notifies the CDC HIV Incidence Surveillance (HIS) Coordinator about each private laboratory that plans to send specimens directly to the CDC STARHS laboratory. The ISC should send the following information to the CDC HIS Coordinator for each laboratory:
 - ♦ Name of laboratory and laboratory point of contact;
 - ♦ Full contact information, including mailing address, phone number, fax, and email; and
 - ♦ Estimated number of positive samples expected per year.
- The CDC HIS Coordinator will provide the CDC STARHS laboratory with this information from private laboratories. This information is important for the CDC STARHS laboratory to plan for storage capacity.

- The state/local ISC should provide the private laboratory with a copy of the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#). The form should be prefilled with the laboratory contact information, the name and address of the person who will receive the STARHS results (ISC), and the appropriate check box marked for Incidence Surveillance:

INCIDENCE SURVEILLANCE (HICSB)

- The submitting private laboratory must include a copy of the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#) with a list of all laboratory-assigned accession numbers included in the shipment. If more than one specimen box is included in the shipping container, then each box should contain its own STARHS Specimen Submission Form. If possible, an encrypted electronic version of the list of specimen accession numbers should also be included in the shipment; this version will help the CDC STARHS laboratory log the samples with minimal chance of entry errors. **Note: the manifest should not contain any patient identifiers other than specimen accession numbers.** At the time of shipment, the submitting laboratory should also mail a copy of the shipping manifest to the ISC, notifying him/her of the shipment. This notification is critical for the ISC to be able to track specimens. As previously noted, identifying information for specimens should not be faxed or emailed, even if encrypted.
- The CDC STARHS laboratory will not provide the private laboratories with any shipping materials, labels or cryovials, but will return the shipping container if a prepaid return air bill is included in the shipment. Surveillance sites may provide the private laboratories with prepaid shipping labels or shipping account numbers (i.e., Federal Express) to cover shipping expenses.
- Specimens shipped from private laboratories directly to the CDC STARHS laboratory will be stored frozen, indicated only by their original laboratory-assigned accession number. On a monthly basis, the ISC will send to the CDC STARHS laboratory a written list of specimens (identified by the original laboratory-assigned accession number, and, if known, the name of the originating lab) that are to be tested using STARHS (test list) or to be disposed of (toss list). The CDC STARHS laboratory will not assign a STARHS identification number unless the ISC notifies the laboratory that the sample is to be tested using STARHS. The CDC STARHS laboratory will continue to hold specimens that are not on one of these two lists.
- The CDC STARHS laboratory will test the specimens and send the STARHS results back to the designated ISC listed on the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#). Samples will be tested and reported by the newly assigned STARHS identification number.
- Periodically, the CDC STARHS laboratory will review the stored specimens to reconcile the status of any samples that have been stored for a lengthy period. This review will reveal any specimens that the ISC never ordered to be tested or discarded. The length of time specimens must be held will vary widely by surveillance site depending on such factors as reporting delays, etc.

Roles of Parties Involved

Role of Private Laboratories

The private laboratories are responsible for forwarding two items for HIV incidence testing: (1) a laboratory report to the public health surveillance department per local requirements, including the collection date, the laboratory-assigned specimen accession number, and identification information about the testing facility; and (2) remnant HIV-positive serum from WB- or IFA-confirmed diagnostic samples labeled with the laboratory-assigned specimen accession number.

The private laboratories may elect to aliquot 0.5 mL of the remnant sera for shipment to the CDC STARHS laboratory so that any additional portion of the remnant sera may be stored at their facility; or they may send the entirety of their remnant sera, without any further manipulation, to the CDC STARHS laboratory.

Before sending shipments to the CDC STARHS laboratory, private laboratories should carefully review [Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory](#) to ensure proper shipping and handling of specimens.

Role of CDC STARHS Laboratory

The CDC STARHS laboratory must store all remnant HIV-positive serum samples received until specimen disposition has been determined by the appropriate jurisdiction's ISC. The ISC will provide the CDC STARHS laboratory with a list of all samples to be tested using STARHS (test list) and a list of all samples to be discarded (toss list), listed by specimen accession number. The samples on the toss list should be discarded according to established laboratory methods.

The CDC STARHS laboratory will pull all samples on the test list and aliquot them into the designated cryogenic vial for testing. The CDC STARHS laboratory will simultaneously relabel the samples to be tested using STARHS with a STARHS identification number. The CDC STARHS laboratory must provide the appropriate ISC with a link between the STARHS identification number and the original specimen accession number. After the ISC has been provided with the linkage information, the CDC STARHS laboratory will destroy the laboratory copy of the specimen accession information.

The CDC STARHS laboratory will test all samples on the test list by the STARHS identification number and send results to the ISC from the appropriate jurisdiction. The STARHS results are for surveillance purposes only therefore results will not be reported back to the originating laboratory, provider, or client.

Role of the State/Local HIV Incidence Surveillance Coordinator

The ISC from the jurisdiction where the specimen originated will determine the disposition of the specimen and coordinate with the CDC STARHS laboratory to ensure that the specimen is either tested or discarded as appropriate. The ISC will also maintain the link between the original specimen accession number and the STARHS number, and will manage the STARHS results.

Specimen Numbering

Specimens will be stored at the CDC STARHS laboratory by the original laboratory-assigned specimen accession number. Once a specimen appears on the test list the sample will be assigned a unique STARHS identification number and will be tested using STARHS. For all subsequent procedures, only the STARHS identification number will be used.

Theoretical Laboratory Types for This Transportation Model

The laboratories that would best use this model are high-volume, multijurisdictional commercial laboratories. However, other private laboratories may also choose this specimen transport model.

Note: The testing laboratory may choose either of the two transport models. With the exception of public health laboratories, the examples listed in this section are merely suggestions, not requirements, for the types of laboratories that may choose this model.

Option B: Specimen Originated at or Sent Via State / Local Public Health Laboratory

Transportation Overview

In this transportation model, confirmatory testing will have been performed at either the PHL or a private laboratory. For samples originating at a private laboratory, that laboratory will send *all* confirmed HIV-positive diagnostic specimens to the state/local PHL. The state/local PHL will store all specimens received from the private laboratories until sample disposition is determined by the ISC. All specimens on the test list (those to be tested using STARHS) will be pulled, aliquoted into the designated cryogenic vials provided by the CDC STARHS laboratory, relabeled with a STARHS identification number, and shipped to the CDC STARHS laboratory by overnight shipping in accordance with the procedures described in [Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory](#). All specimens that are on the toss list (those that are not to be tested using STARHS) will be pulled and discarded according to existing laboratory procedures.

In this model, the originating laboratory would continue to submit laboratory report information in the current manner, but must also include the laboratory-assigned specimen accession number, other relevant specimen identifiers, and testing laboratory identification on the report.

Many laboratories send enzyme immunoassay (EIA) positive specimens to a reference laboratory for confirmatory WB or IFA, which usually results in different laboratory accession numbers. In this case, care must be taken to ensure that the appropriate specimen accession numbers are associated with the correct surveillance report.

Figure 2a graphically depicts the flow of specimens and reports when samples originate at the PHL and are then shipped to the CDC STARHS laboratory. **Figure 2b** describes the flow of specimens and reports when samples originate at a private laboratory and are sent to the PHL for storage before shipment to the CDC STARHS laboratory.

Procedures for Specimens Sent from a Private Laboratory through a State Public Health Laboratory to the CDC STARHS Laboratory

- The ISC works with each private laboratory to set up procedures for shipping specimens to the state PHL.
- The ISC should provide the private laboratory with a copy of the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#). The form can be prefilled with the state PHL contact information, or a new form may be developed in agreement with the PHL. Some private laboratories already have existing mechanisms for transporting specimens to the PHL. These procedures may also be used.
- The submitting private laboratory must include a list of all laboratory-assigned specimen accession numbers included in the shipment to the PHL. At the time of shipment, the private laboratory will mail a copy of the list to the ISC, notifying him/her of the shipment. The private laboratory should also notify the PHL of the shipment by calling or emailing the PHL with the shipment tracking number, if applicable, and the number of samples sent. This information is critical for both parties to be able to track specimens.
- The PHL will store the specimens from the private laboratory, holding them until specimen disposition is determined by the ISC. Specimens should be stored frozen and according to the original laboratory-assigned specimen accession number. On a regular basis, the ISC will notify the PHL which specimens they are storing should be pulled for STARHS testing (test list) and those that can be discarded (toss list).
- The PHL will discard all specimens on the toss list and will prepare all specimens on the test list for testing using STARHS.
 - ◆ All specimens to be tested using STARHS will be pulled, thawed, and aliquoted into the designated cryovials provided by the CDC STARHS laboratory.
 - ◆ Using labels provided to the PHL by the CDC STARHS laboratory, the PHL will relabel the samples to be tested using STARHS with a unique STARHS identification number.

- ♦ The PHL will send the ISC the linkage information between the original laboratory-assigned specimen accession number and the new unique STARHS identification number.
 - ♦ The PHL will ship all relabeled specimens to the CDC STARHS laboratory according to the procedures described in [Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory](#).
 - ♦ The PHL should provide the CDC STARHS laboratory with a completed [HICSB Incidence Surveillance STARHS Specimen Submission Form](#), listing all samples in the shipment by the newly assigned STARHS identification number. The PHL should also include an encrypted electronic version of the specimen list in the shipment; this version will help minimize data entry errors at the CDC STARHS laboratory. The list of STARHS identification numbers on the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#) serves as verification from the ISC that all samples in the shipment are to be tested using STARHS.
 - ♦ A copy of the completed [HICSB Incidence Surveillance STARHS Specimen Submission Form](#) should also be mailed to the ISC as notification of the shipment.
 - ♦ The PHL should also notify the CDC STARHS laboratory of the shipment by calling or emailing the laboratory to provide the shipment tracking number and number of samples sent.
- The CDC STARHS laboratory will test all samples received from the PHL with a preassigned and labeled STARHS identification number and send STARHS results back to the designated ISC listed on the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#).
 - Periodically the PHL should review their stored specimens to reconcile the status of any samples that have been stored for a lengthy period. This review will reveal any specimens that the ISC did not order to be tested or discarded. The length of time specimens must be held will vary widely by surveillance site depending on such factors as reporting delays, etc.

Roles of Parties Involved

Role of Private Laboratories

The private laboratories are responsible for forwarding two items for HIV incidence testing: (1) a laboratory report to the public health surveillance department per local requirements with specimen identifiers, the laboratory-assigned specimen accession number, and identification information about the testing facility; and (2) remnant HIV-positive serum from WB- or IFA-confirmed diagnostic samples labeled with the laboratory-assigned specimen accession number and testing laboratory identification information.

The private laboratories may elect to aliquot 0.5 mL of the remnant sera to send to the PHL so that any additional portion of the remnant sera may be stored at their facility, or they may send the entirety of their remnant sera, without any further manipulation, to the PHL.

Before sending shipments to the CDC STARHS laboratory, private laboratories should carefully review [Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory](#) to ensure proper shipping and handling of specimens.

Role of Public Health Laboratories

The PHL must store all remnant HIV-positive serum samples (tested in their own facility or shipped from a private laboratory) until specimen disposition has been determined by the ISC. The ISC will provide the PHL with a list of all samples to be tested using STARHS (test list) and a list of all samples to be discarded (toss list) listed by specimen accession number.

The PHL will pull all samples that will not be tested using STARHS and discard them according to existing laboratory procedures.

The PHL will pull all samples to be tested using STARHS and aliquot them into the designated cryogenic vial provided by the CDC STARHS laboratory. Using labels provided to the PHL by the CDC STARHS laboratory, the PHL will simultaneously relabel the samples with a STARHS identification number. The PHL must also provide the ISC with a link between the STARHS identification number and the original specimen accession number. The PHL will ship all samples to be tested using STARHS, labeled only with the STARHS identification number, to the CDC STARHS laboratory according to the procedures described in [Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory](#).

Role of State/Local HIV Incidence Surveillance Coordinator

The state/local ISC from the jurisdiction where samples originated will determine the disposition of all samples stored at the PHL and coordinate with the PHL to ensure that specimens are either tested using STARHS or discarded as appropriate. The ISC will also maintain the link between the original specimen accession number and the STARHS number, and will manage the STARHS results.

Role of CDC STARHS Laboratory

Using the STARHS identification number, the CDC STARHS laboratory will test all samples received from a PHL. Once testing is complete, the CDC STARHS laboratory will return results to the appropriate jurisdiction's ISC.

Specimen Numbering

Specimens will be stored at the PHL labeled with the original laboratory-assigned specimen accession number. Once specimen disposition is determined, each sample to be tested using STARHS will be assigned a unique STARHS identification number by the PHL before shipment to the CDC STARHS laboratory. For all subsequent procedures, only the STARHS identification number is used.

Theoretical Laboratory Types for this Transportation Model

The laboratory types that would best use this model are single-jurisdiction laboratories such as hospital, medical center, university, or small independent reference laboratories, or local branches of large commercial laboratories. In many cases, these laboratories already have working relationships and established procedures for submitting samples to their state and/or local PHL and would prefer not to change their existing practices. All state/local PHLs performing confirmatory testing for HIV also fall into this category, except they would simply hold samples until the ISC determines specimen disposition.

Note: The testing laboratory may choose either of the two transport models. With the exception of public health laboratories, the examples listed in this section are merely suggestions, not requirements, for the types of laboratories that may choose this model.

Responsibilities

Private Laboratories

Selection of a Model Type

Each private laboratory performing confirmatory testing of HIV diagnostic specimens must select one of the two specimen transport model types and inform the ISC which model was chosen. The private laboratory must send remnant sera from confirmed HIV-seropositive samples to either the state/local PHL or to the CDC STARHS laboratory.

Additional Laboratory Report Information

The private laboratory must include the laboratory-assigned specimen accession number on the laboratory report form sent to the HIV surveillance department, per state/local disease reporting requirements.

Many laboratories send EIA-positive specimens to a reference laboratory for confirmatory WB or IFA. In this case, care must be taken to ensure that the appropriate specimen accession numbers are associated with the correct surveillance report.

Public Health Laboratories

Sample Storage and Retention

The PHL will often serve a dual function as a testing laboratory or a pass-through facility for private laboratories. The PHL will store all WB- or IFA-confirmed positive samples and/or all samples received from private laboratories until sample disposition is determined by the ISC.

Aliquoting and Sample Shipment

Once sample disposition has been determined by the ISC, the PHL will be responsible for pulling the identified samples, aliquoting samples into the appropriate tubes, and relabeling the samples with a STARHS identification number for testing. The PHL will send the ISC the linkage information between the laboratory-assigned specimen accession number and the STARHS identification number. The PHL will ship all samples to be tested using STARHS (test list) to the CDC STARHS laboratory and discard all samples on the toss list according to existing laboratory procedures.

State/Local HIV Incidence Surveillance Coordinator

Sample Disposition

The ISC will determine sample disposition for all HIV-seropositive diagnostic samples tested in the jurisdiction. The ISC will coordinate with the PHL and/or the CDC STARHS laboratory to ensure the proper samples are tested.

Data Management

To ensure that STARHS results can be matched to surveillance data, the ISC will retain the linkage information between the laboratory-assigned specimen accession number and the STARHS identification number. The ISC will send cumulative incidence data to CDC monthly on or before the 15th of each month. If the ISC is in a local jurisdiction, then results should be sent to the state ISC for matching purposes before submitting data to CDC.

CDC STARHS Laboratory

Sample Rejection Criteria

Sample rejection due to thawing, breakage, insufficient quantity, or lost-in-transit status will be determined and recorded by the CDC STARHS laboratory. The CDC STARHS laboratory will include sample rejection information with the STARHS results report that is transmitted to the ISC.

Sample Storage and Retention

All samples that are shipped directly from a private laboratory and not a state PHL must be stored (see [Sample Storage](#)) at the CDC STARHS laboratory until sample disposition is determined by the ISC. Storage time may vary from state-to-state depending on the state's surveillance practices. Once sample disposition has been

determined by the ISC, the CDC STARHS laboratory will be responsible for pulling all samples on the ISC's test and toss lists. The samples on the toss list will be discarded. The samples on the test list will be aliquoted into the appropriate tubes and relabeled with a STARHS identification number for testing. The CDC STARHS laboratory will apply a label to the sample tube and then to a line listing of specimen accession numbers received from the ISC or PHL for those samples to be tested using STARHS. The CDC STARHS laboratory will send the ISC the linkage information and then destroy the linkage information held at the CDC STARHS laboratory. All subsequent testing and results will refer only to the STARHS identification number and will no longer include the original specimen accession number.

Results Reporting

The CDC STARHS laboratory will report STARHS results by the STARHS identification number only to the ISC with jurisdiction over the sample as designated by the [HICSB Incidence Surveillance STARHS Specimen Submission Form](#). The results reporting mechanism will adhere to the methods agreed upon between CDC and the CDC STARHS laboratory.

References

1. CDC. HIPAA Privacy Rule and public health: guidance from CDC and the U.S. Department of Health and Human Services. *MMWR* 2003;52:1–12. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>.

Figure 1. Specimen originates at national commercial laboratory or private laboratory and is sent directly to the CDC STARHS laboratory

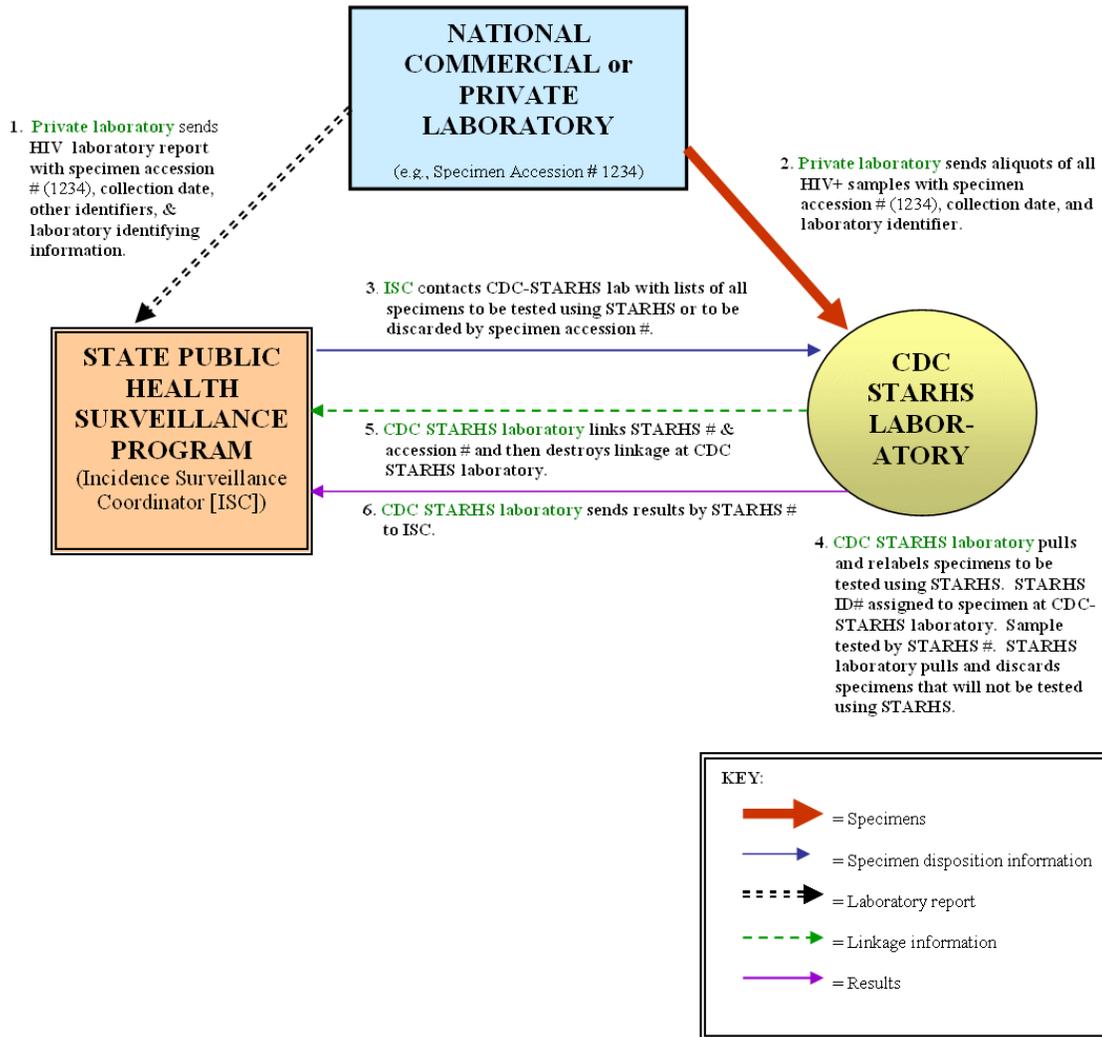


Figure 2a. Specimen originates at a public health laboratory (PHL performed the confirmatory HIV testing)

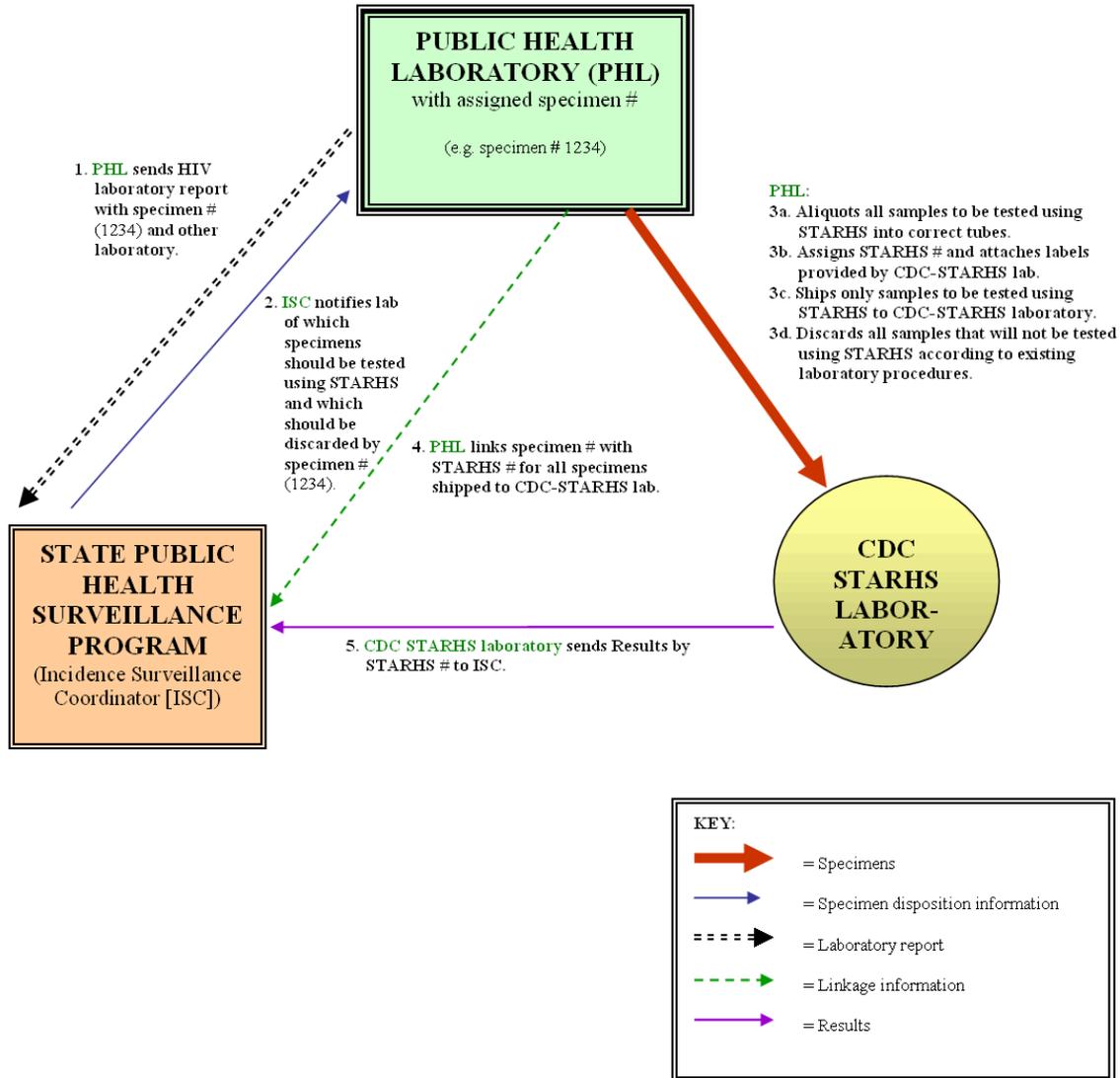


Figure 2b. Specimen originates at a private laboratory (for example, a university hospital laboratory, regional or local independent commercial laboratory) and sample is sent to state public health laboratory (serves as a pass-through facility)

