Attachment 4(b)

Adult and Pediatric HIV/AIDS Confidential Case Reports
for National HIV/AIDS Surveillance OMB No. 0920-0573

Supplemental Surveillance Activity 1: HIV Incidence Surveillance Technical Guidance

Technical Guidance for HIV/AIDS Surveillance Programs

HIV Incidence Surveillance

HIV Incidence and Case Surveillance Branch
Atlanta, Georgia

Notes

Contents — HIV Incidence Surveillance

Technical Guidance for HIV/AIDS Surveillance Programs — Policies and Procedures for HIV Incidence Surveillance

Background

Introduction

Although historically AIDS surveillance data have been of great value, current data do not represent the entire population affected by the HIV epidemic. Unlike AIDS data, HIV data provide a window into the epidemic at an earlier stage of disease, thereby allowing public health officials to monitor the epidemic more effectively and completely, allocate resources, and plan and implement programs, particularly prevention programs. In the past, however, biomedical technology did not discriminate between recent and chronic HIV infection; as a result the incidence of HIV infection in the United States could not be measured directly. The serologic testing algorithm for recent HIV seroconversion (STARHS)[1] is performed on remnant serum specimens from confirmed HIV antibody positive tests and consists of a series of two tests, a standard, sensitive, HIV antibody test currently followed by a test to determine the normalized optical density (OD_N) level of the concentration of HIV-specific antibodies to total antibodies. STARHS distinguishes between recent and long-standing HIV-1 infection on a population level and should allow the estimation of local and national HIV incidence.

HIV incidence surveillance (HIS) is the aspect of the national HIV/AIDS surveillance system that uses STARHS results, as well as data on the history of testing and use of medications with antiretroviral (ARV) properties for each case reported to HIV/AIDS surveillance programs, to generate an HIV incidence estimate. HIS will give a more representative picture of the HIV epidemic, its trends, and its impact on the public's health. The Centers for Disease Control and Prevention's (CDC's) human subjects protection process has determined that the implementation of HIS programs using STARHS, like other public health surveillance activities, is not research (see National Center for HIV, STD, and TB Prevention's Non-research Determination for HIV Incidence Surveillance).

The primary functions of HIS are to:

- Incorporate STARHS into routine HIV surveillance activities by testing HIV-seropositive specimens obtained from persons with a new HIV diagnosis using an assay approved for this purpose
- Collect HIV testing and ARV use history information for persons with newly reported HIV infections as part of routine HIV surveillance
- Apply a statistical model(s) to estimate HIV incidence locally and nationally using a combination of STARHS results and information from surveillance case reports, and testing and ARV use history information for all persons with a new diagnosis of HIV infection
- Use incidence data to assist with local HIV prevention program planning and evaluation using incidence data.

The tasks to achieve the functions of HIS include:

- Elicit collection and reporting of testing and ARV use history information by all providers reporting HIV cases to the health department
- Ensure that an aliquot of each confirmed seropositive specimen from a newly diagnosed case is shipped to the CDC STARHS laboratory
- Determine the disposition of remnant HIV-positive specimens and coordinate communication between the Incidence Surveillance Coordinator (ISC) and the public health laboratory or the CDC STARHS laboratory regarding specimens shipped to and stored at the these laboratories
- Enter STARHS and testing and ARV use history information into the designated HIS database
- Electronically transfer data to CDC
- Ensure that HIS data handling procedures comply with all security and confidentiality guidelines as described in *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. III: Security and Confidentiality Guidelines*
- Analyze and disseminate data locally
- Train staff in the policies and procedures of the HIV/AIDS surveillance system as well as those of the HIS system

The prerequisites (structural requirements), best practices (process standards), and outcome standards for HIS are described next.

Structural Requirements

All persons with a new diagnosis of HIV infection who were tested confidentially should be reported to the HIV surveillance system in accordance with *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. I: Policies and Procedures*. In areas incorporating HIS into their HIV/AIDS surveillance systems, information regarding HIV testing history and ARV use, as well as the STARHS result of a remnant of the diagnostic HIV-positive specimen, should be included for all cases. HIV/AIDS surveillance case report data, in combination with these data elements, will be used to calculate population-based HIV incidence estimates.

Policies and Procedures

HIS is a fully integrated component of HIV/AIDS surveillance; therefore, documentation of HIS activities should be incorporated into locally tailored policies and procedures manuals developed for HIV/AIDS surveillance (*Technical Guidance for HIV/AIDS Surveillance Programs, Vol. I: Policies and Procedures*) to establish standardization, maintain continuity of meaning, document changes over time, and develop training programs. All manuals describing policies and procedures of the local surveillance program should address the needs of HIV/AIDS surveillance as well as the specific

policies related to HIS. In addition to the information listed in *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. I: Policies and Procedures*, HIS specific policies and procedures should include information related to

- Training of testing providers in collection of additional data used for HIV incidence estimation
- Laboratory contacts
- Determining which specimens should be tested using STARHS (and which should be discarded)
- Specimen aliquoting
- Specimen shipping guidance

The BED Assay for STARHS

The assay STARHS currently uses is the BED HIV-1 Capture enzyme immunoassay (EIA) manufactured by Calypte Biomedical Corporation. The principle of the BED HIV-1 Capture EIA is based on the observation that the ratio of HIV-specific IgG to total IgG increases with time after HIV infection[2]. The BED HIV-1 Capture EIA is applied to the diagnostic HIV-positive specimen, and the assay is sensitive to the length of time since the infection (i.e., antibody level present). The time from when a specimen would first be reactive on the standard EIA to the time when the serum or plasma, if tested with the BED HIV-1 Capture EIA, reaches an optical density (OD) level predetermined to distinguish recent from nonrecent infections is defined as the STARHS mean window period. Although the mean STARHS window period may vary slightly by HIV subtype, the mean window period for calculating population-based incidence estimates in the United States is 156 days when the BED HIV-1 Capture EIA is used.

The BED HIV-1 Capture EIA for STARHS is performed only on HIV antibody positive sera[2] and is not approved as a diagnostic test. Because of the variability in antibody development in individuals, the predictive value of an individual's STARHS result is low; the results are reliable only as part of the population-based HIV incidence estimate. The Food and Drug Administration (FDA) has ruled that the BED HIV-1 Capture EIA be labeled "For Surveillance use only. Not for diagnostic or clinical use." Under FDA regulations, results of STARHS performed for purposes of HIS cannot be returned to individuals or their health care providers or used for clinical management. As with earlier assays used for STARHS, data show that the BED HIV-1 Capture EIA can produce a substantial number of false-positive and false-negative classifications on the individual level[3]. At the population level, the number of false positives is approximately equal to the number of false negatives thus effectively "canceling" each other out. However, the number of misclassifications can be large, and each of the misclassified individual results would receive an incorrect interpretation. STARHS results may also be misclassified because of the use of ARV therapies or late stage of the disease. Evaluation of the BED HIV-1 Capture EIA has determined that the specimens of persons with low HIV-1-specific antibodies resulting from ARV therapy or disease progression (i.e., AIDS) could lead to the incorrect conclusion that these persons were recently infected. When a person has AIDS, this is thought to be due to a loss of immune response as immune deficiency

progresses. When a person is taking ARV therapy, this result is thought to be due to suppression of the HIV viral load, which in turn reduces antigenic stimulation and the quantity of circulating HIV-1-specific antibodies. The effect of ARVs taken for post-exposure prophylaxis or for concurrent hepatitis B infection, for example, is not known. Theoretically, it could take longer to develop a full immune response to HIV infection. CDC data reliably support using STARHS for estimating incidence at the population level only.

Testing and ARV Use History Data

Information on testing behavior is needed, such as recency of testing and testing frequency. Additionally, history of ARV use (for example, pre- or post-exposure prophylaxis or treatment for hepatitis) and immunological status (CD4 cell counts and viral loads) must be included for all cases reported to the surveillance system.

Information needed for HIV incidence estimation is available as part of a standard case report, and nearly all testing and ARV use history information is gathered as part of a comprehensive HIV counseling session. However, not all of the required HIS data elements have been collected uniformly, and many have not previously been recorded. Therefore, a standard set of HIV testing and ARV use history data elements needed for the HIV incidence estimate has been developed (see Standard HIV Incidence Surveillance Data Elements), and providers of HIV testing should be trained in the appropriate reporting of those data.

Staffing Needs

Implementation of the HIS system requires personnel with specific skills and dedicated time to integrate HIS into the existing core HIV/AIDS surveillance system effectively. Generally, HIS staff should have

- An understanding of HIS and the characteristics of the HIV/AIDS surveillance in their area
- Good communication skills
- Strong leadership skills
- Enthusiasm about disease reporting for public health purposes
- Dedication to the successful implementation of HIS
- Ability to work closely with CDC, other states, local sites, private providers, and laboratories

The recommended staffing plan including roles and responsibilities follows. In terms of personnel time, CDC recommends that one full-time equivalent (FTE) be dedicated to the ISC position. Successful implementation and integration of HIS requires a full-time ISC dedicated to implementing and maintaining the system. Other personnel assigned to HIS may vary depending on the implementation phase, prevalence of HIV/AIDS, and available resources.

ISC

- Provide overall management of the HIS system
  - Serve as lead on the area specific implementation of the HIS guidance
- Oversee data collection processes
  - Determine the disposition of HIV-positive specimens reported to the surveillance system
  - Receive STARHS results
  - Oversee collection of HIV testing and treatment history information from public HIV testing sites and private providers
- Collaborate with other HIS staff
  - HIV incidence epidemiologist
    - Development of training materials and courses
    - Data collection procedures
  - HIV incidence data manager
    - Data collection methods
    - Data entry and quality assessment
    - Data editing and file correction
    - Data transport procedures
    - Preparation of monthly reports
    - Security and confidentiality procedures
  - HIV incidence laboratory liaison
    - Specimen transfer
    - Specimen tracking
- Manage any employee or other service contracts related to HIS
- Serve as the primary point of contact for CDC on HIS
- Participate in CDC site visits, trainings, and workshops

Epidemiologist/Trainer

- Serve as lead on training HIV testing providers and laboratories on HIS, including development/modification of surveillance area-specific training materials
- Coordinate HIS and epidemiology activities with the ISC
- Participate in the development or modification of testing and ARV use history data elements
- Participate in data dissemination activities
  - Collaborate with stakeholders to determine data needs and frequency of reporting
  - Identify results and surveillance issues for review and dissemination
  - Develop a data dissemination plan in collaboration with the ISC and CDC
- Participate in CDC site visits, trainings, and workshops as appropriate

Laboratory Liaison

- Act as the liaison between the public health, private, and community laboratories and the ISC
- Oversee preparation and shipping of public health laboratory specimens to the CDC STARHS laboratory
- Monitor quality control procedures outlined for preparing specimens for testing using STARHS
- Monitor security and confidentiality of specimens and STARHS results
- Track specimens identified for testing using STARHS (all laboratories)
- Participate in CDC site visits, trainings, and workshops as appropriate

Data Manager

- Assist ISC with daily management of HIS data
- Conduct data collection from surveillance sites
  - Serve as subject matter expert on HIV incidence data elements and data management programs
  - Receive data transfer from other health department entities and the CDC STARHS lab, and incorporate those data into the HIS database and datasets for transfer to CDC
  - Conduct data quality assessments
- Conduct data management
  - Modify CDC's generic data management programs for use at the area level
  - Develop and implement edit checks and conduct data cleaning
  - Collaborate with the ISC, epidemiologist, and other area surveillance and prevention staff, as needed, on data cleaning, data entry, and data set preparation
  - Prepare datasets for local analysis
  - Collaborate with CDC on dataset preparation for national incidence estimates
  - Prepare HIV incidence data reports for local use in collaboration with the ISC, epidemiologist, and CDC
- Maintain security and confidentiality of HIV incidence data
- Participate in CDC site visits, trainings, and workshops as appropriate

Process Standards

HIS involves the following processes:

- Obtaining testing and ARV use history data from providers
- Identifying laboratories that perform HIV-related tests and obtaining remnant specimens for testing using STARHS

- Determining specimen disposition as it relates to testing using STARHS
- Establishing a schedule for contact between the ISC and the public health laboratory and the CDC STARHS laboratory to communicate regarding shipping, testing, and discarding remnant specimens that are housed at the laboratory
- Entering data into the HIS database
- Electronically transferring data to CDC
- Ensuring that data handling procedures comply with Security and Confidentiality Guidelines (see *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. III: Security and Confidentiality Guidelines* and Model State Public Health Privacy Act)
- Analyzing and disseminating data locally
- Training staff in HIV/AIDS surveillance and HIS methods

Obtaining Testing and ARV Use History Data

The primary purpose of gathering HIV testing and ARV use history is to calculate a statistical weight (see Statistical Method for Generating Population-Based HIV Incidence Estimates) that will allow inference to the general population. The weight reflects the probability that an individual will be tested during the STARHS window period and is related to the data elements listed in Standard HIV Incidence Surveillance Data Elements.

Testing and ARV use history data are reported by providers and surveillance staff using the area standard reporting procedures or other procedures meeting the routine security and confidentiality guidelines for HIV/AIDS surveillance. These data

- Should be included for all adult/adolescent (> 13 years at diagnosis) HIV/AIDS cases newly reported to the HIV/AIDS surveillance system by all providers of HIV testing
- May be collected through client/patient interview and/or chart abstraction
- If based on patient self-report, should be collected when an individual presents for an HIV test or returns for the results
  - Takes advantage of the individual's ability to recall information that is more proximal to the event
  - Should be recorded and reported to the surveillance system on the basis of the patient's self-report within 3 months of the HIV diagnosis
  - Longer intervals may increase the risk of recall bias, yet this consideration should not prevent efforts to obtain the information even after 3 months if necessary

CDC has assisted in developing materials for use in training providers to collect HIV testing and ARV use history data. These materials are available at all sites, or upon request from CDC.

Obtaining Remnant HIV-Positive Specimens for Testing Using STARHS

To be most useful, testing using STARHS should be performed on the HIV-positive diagnostic serum or plasma specimen. For the purposes of this guidance, the HIV-positive diagnostic specimen is the HIV-positive specimen from the diagnostic test that resulted or should have resulted in the case being reported to the HIV/AIDS surveillance system. Remnant specimens for all confirmed HIV-positive diagnostic specimens should be tested using STARHS.

- Laboratories performing routine diagnostic confirmatory HIV testing by Western blot, indirect fluorescent antibody (IFA) tests, immunological status tests such as CD4, or viral load counts should report to the state/local health department surveillance program per existing requirements.
- In each surveillance area, all laboratories should be identified from a review of local HIV surveillance data and laboratory licensing records and must be approached to request that remnants of all diagnostic specimens be made available for testing using STARHS
  - Surveillance areas should maintain a directory of laboratory contacts at all reporting laboratories to facilitate communication in the event that reporting or shipping of specimens is disrupted or that changes in policy or procedures need to be communicated
  - Originating laboratories are those to which a specimen is first sent for testing
  - Reference laboratories are those to which a specimen is sent for confirmatory testing when the originating laboratory does not do confirmatory testing
- All remnant specimens from HIV-diagnostic Western blot or IFA tests must be shipped to the CDC STARHS laboratory in New York for testing using STARHS.
  - A minimum of 0.5 mL HIV-positive serum or plasma specimen is necessary for testing using STARHS
  - Private or community laboratories performing HIV diagnostic testing should choose one of two options for shipping the remnant HIV-positive serum or plasma specimen to the CDC STARHS laboratory (see Guidance for the Remnant HIV-Positive Specimen Transportation Activities for HIV Incidence Surveillance)
    - Ship the specimen directly to the CDC STARHS laboratory
    - Ship the specimen to the state public health laboratory affiliated with the health department that receives the new HIV case report for processing
      - State public health laboratories can then batch and ship all specimens identified for testing using STARHS to the CDC STARHS laboratory
  - State public health laboratories conducting HIV diagnostic testing should ship their own HIV-positive specimens identified for testing using STARHS directly to the CDC STARHS laboratory

Specimen availability for testing using STARHS depends on the testing needs for the specimen. Uses of the remnant of specimens should follow the CDC HIS recommended hierarchy (described below) for specimen aliquoting to ensure adequate specimen volume

for multiple diagnostic tests. When multiple tests must be performed on a collected serum or plasma specimen, the aliquots must be made available with the following hierarchy in mind:

1. HIV diagnostic testing
2. Testing with STARHS
3. HIV drug resistance genotyping (known as Variant, Atypical, and Resistant HIV Surveillance [VARHS])

Aliquots made following this hierarchy will ensure that adequate specimen volume is available according to the priority for data determined by CDC.

Determining the Disposition of Specimens and Communicating with the Public Health and CDC STARHS Laboratories

A specimen should be held at the state public health laboratory or the CDC STARHS laboratory (i.e., specimens shipped directly from private or commercial laboratories) until the area ISC, using routine HIV/AIDS surveillance reporting procedures (i.e., HIV/AIDS Reporting System [HARS/eHARS]), determines whether the specimen represents the person's first reported positive HIV test result in the HIS area. A specimen should be tested using STARHS if

1. the specimen represents the diagnostic specimen (the HIV-positive specimen that led, or should have led, a case to be reported to HARS/eHARS) **or**
2. the diagnostic specimen is unavailable and the specimen was drawn within 3 months of the diagnostic specimen **and**
3. the specimen was drawn for an HIV-related test (viral load, polymerase chain reaction [PCR] test, CD4 level).

A specimen should not be tested using STARHS if

1. the specimen is not the diagnostic specimen that led, or should have led, the individual to be reported to HARS/eHARS **and**
2. the individual had a previous specimen that was tested using STARHS **or**
3. the individual did not have a previous specimen tested using STARHS but the specimen was drawn more than 3 months after the diagnostic specimen.

Because a remnant sample of every Western blot positive blood specimen will be shipped by originating or reference laboratories to either the state or local public health laboratory or to the CDC STARHS laboratory, the HIS program must inform the appropriate laboratory of the disposition of the specimen.

- Specimens for cases not previously reported to HARS/eHARS (or those drawn within 3 months of a diagnostic specimen that is unavailable) will constitute the test list. A test list should
  - Be compiled for the state or local public health laboratory and for the CDC STARHS laboratory

  - Include those specimens located at the individual laboratory that should be tested using STARHS
  - Be cumulative
- Specimens that are neither diagnostic specimens nor drawn within 3 months of a diagnostic specimen that is unavailable will constitute the toss list. A toss list should
  - Be compiled for the state or local public health laboratory and for the CDC STARHS laboratory
  - Include those specimens held at the laboratory that should not be tested using STARHS
  - Be cumulative

Specimens should be handled, packaged, and shipped according to the CDC STARHS laboratory shipping protocol (see Guidance for the Remnant HIV-Positive Specimen Transportation Activities for HIV Incidence Surveillance). Specimens shipped as diagnostic specimens and packed in dry ice must be handled according to the procedures for packing and shipping specimens with dry ice (see Guidance for Processing, Storage, and Shipping of Specimens to the CDC STARHS Laboratory).

The ISC should regularly, at an interval to be determined locally (e.g., monthly), inform area laboratory designees (e.g., at the public health laboratory) and the CDC STARHS laboratory of all stored specimens, or remnant specimens, with a positive HIV diagnostic test to be tested using STARHS (the test list) and those to be discarded (the toss list).

- For those specimens on the test list
  - An aliquot of blood to be used for STARHS is drawn from the specimen
    - At the local public health laboratory before shipping
    - At the CDC STARHS laboratory if the specimen was shipped directly to the CDC STARHS laboratory
  - The aliquot is relabeled with a unique STARHS identification number (SID)
  - The SID is paired with the corresponding specimen number and is sent to the ISC with no other identifying data
  - After STARHS, the results are returned to the ISC with results identified by SID only
- Specimens on the toss list should be discarded according to routine laboratory protocols for HIV-positive serum or plasma specimens.
- The ISC should inform the CDC STARHS lab to discard all specimens that have been tested with STARHS. If the ISC would like to have these specimens returned at the surveillance area's expense, he/she should make arrangements with the CDC STARHS lab.

Entering Data into Surveillance Databases

Data elements needed for the calculation of statistical weights used to make population-based HIV incidence estimates fall into one of four categories.

- Demographic data
  - Age
  - Sex
  - Race/ethnicity
  - HIV risk factors
- HIV testing and ARV use history data
- Clinical data
  - CD4 count
  - Viral load
- Laboratory data
  - Specimen collection date
  - SID
  - STARHS results

All data elements needed for HIS are included in eHARS, but could not be added to HARS. Only demographic data and clinical data are included in the HARS database. As a result, an HIS Access database was developed to store the additional data related to HIS. Until a surveillance area begins using eHARS and eHARS accommodates this information, the jurisdiction should enter data into both HARS/eHARS and the HIS Access database as appropriate. Testing and ARV use history information and laboratory data related to the diagnostic HIV test (including specimen collection date and SID) are variables that should be entered into the separate HIS Access database along with the unique state number (HARS/eHARS "stateno") assigned to each case. A list of data elements necessary for HIS, but not included in HARS can be found in Standard HIV Incidence Surveillance Data Elements.

Creating the HIS Dataset and Transferring Data to CDC

HIS data entry and management take place at state or local health departments by using one of three data management systems:

- HIS Access database (until conversion to eHARS)
- eHARS
- Software that is compatible with CDC software

Information is merged into the data management systems from other sources:

- Excel spreadsheet containing STARHS results identified by SID only from the CDC STARHS laboratory
- Program Evaluation Monitoring System (PEMS)
- Other databases

For states that have not transitioned to eHARS, data are merged by using unique identifiers reported with each case for data transfer to CDC:

- the HARS/eHARS stateno links HARS/eHARS records to corresponding HIS Access database records

When eHARS has the ability to import HIS data, merging datasets before transferring data to CDC will no longer be necessary.

Before the 15th of each month, the complete dataset from the preceding month (see *Access Database 3.1a Users Manual* and *Access Database Version 3.1 Data Dictionary*) should be transmitted to CDC over the Secure Data Network (SDN). Data transmitted to CDC must include no personal identifiers and must be encrypted and password protected according to *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. III: Security and Confidentiality Guidelines*.

Ensuring Security and Confidentiality

HIV testing is a medical procedure. Therefore, policies and procedures are in place to protect the confidentiality of tested persons and their medical records. STARHS should be performed only on specimens that have tested positive for HIV. HIS data are considered part of routine HIV surveillance data and should be held to the standards of security and confidentiality for HIV/AIDS surveillance outlined in *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. III: Security and Confidentiality Guidelines*. Policies and procedures, based on these guidelines and local laws, are already in place at state and local health departments and are used to secure hard copy and electronic information to protect the confidentiality of persons reported as having HIV infection. These measures must be extended to protect the STARHS information held locally. Access by HIS staff to information in HARS, HIV testing and ARV use history, and STARHS data is governed by the same security and confidentiality requirements.

Analyzing and Disseminating Data

Data from persons who choose to have a confidential HIV test and who test positive will be used to estimate the incidence of HIV nationally and in participating areas, including the incidence of undiagnosed HIV infection. HIV incidence estimates can be used to assess current HIV prevention programs locally, regionally, and nationally. HIS data will be stratified by selected factors such as demographic or behavioral factors, thus creating subpopulation data at the national and local levels. If the sampling procedure has sufficient statistical power, this stratification will allow comparisons between areas and among groups with different risk factors. The methods used to generate the population-based incidence estimate are described in Statistical Method for Generating Population-Based HIV Incidence Estimates, which introduces the methods, statistical formulas, and different groups for which incidence estimates will be made.

CDC will have the primary responsibility for analyzing interpreting, and disseminating these data; surveillance areas will contribute as appropriate. Results from the aggregate CDC database will be analyzed regularly and feedback will be provided to participating areas. Aggregate results will also be published in CDC's HIV/AIDS Surveillance Reports. Area-specific analyses should be conducted at the discretion of participating areas. As

appropriate, results will be presented at conferences and published in peer-reviewed journals. The number of representative authors from participating areas and CDC will be determined for each presentation or paper.

In addition to the variables needed to estimate HIV incidence, the following data elements will be used to evaluate the performance of the BED HIV-1 Capture EIA for determining of estimates of HIV incidence:

- Whether AIDS has been diagnosed and if so, the date of diagnosis
- At the time of HIV diagnosis,
  - whether HIV ARV agents have been used for post-exposure prophylaxis or for any other medical condition (e.g., lamivudine for treatment of hepatitis B), and if so, the name(s) of the agent, and dates and duration of use
  - where available, CD4 count, viral load, and HIV-1 subtype along with the type of test used to determine the subtype

As a result, all HIV-positive diagnostic specimens should be tested using STARHS irrespective of the time to AIDS diagnosis for an individual, or evidence of previous ARV use.

Training Staff

Because HIS is a fully integrated component within the HIV/AIDS surveillance system, all HIS staff should receive training in the local policies and procedures for core surveillance including

- active and passive surveillance methods
- laboratory reporting mechanisms
- data management processes

In accordance with *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. III: Security and Confidentiality Guidelines*, HIS staff must also receive training in security and confidentiality procedures, and should sign a confidentiality statement upon being hired and annually thereafter.

Outcome Standards

Outcome standards described in the "Introduction to Policies and Procedures" and "Data Quality" sections of *Technical Guidance for HIV/AIDS Surveillance Programs, Vol. I: Policies and Procedures* can be applied to HIS. These sections address issues of completeness of case ascertainment, timeliness of reporting, evaluation of standard data edits, and missing/unknown information. Meeting core surveillance standards for case ascertainment and timeliness is essential for HIS to be successful given the time-sensitive nature of HIS data elements, including testing and ARV use history data and STARHS. The quality of the HIV incidence estimate depends on the quality of data included in the HIS system. All outcome standards for HIS relate only to cases that reside within the surveillance area at the time of diagnosis.

- The minimum standard for passing standard data edits related to HIS data is 97% with a target of 100%
- At least 85% of newly reported HIV/AIDS cases for a diagnosis year should have testing history and ARV use data within 12 months of the date of the initial HIV/AIDS case report, measured at 12 months after the close of the diagnosis year
- At least 85% of cases newly reported to the surveillance system and diagnosed using a serum/plasma specimen or having a follow-up HIV-related test conducted on a serum/plasma specimen within 3 months of the diagnosis should have a specimen transported to the CDC STARHS laboratory within 12 months of diagnosis assessed for the most recent diagnosis year at 12 months after that diagnosis year

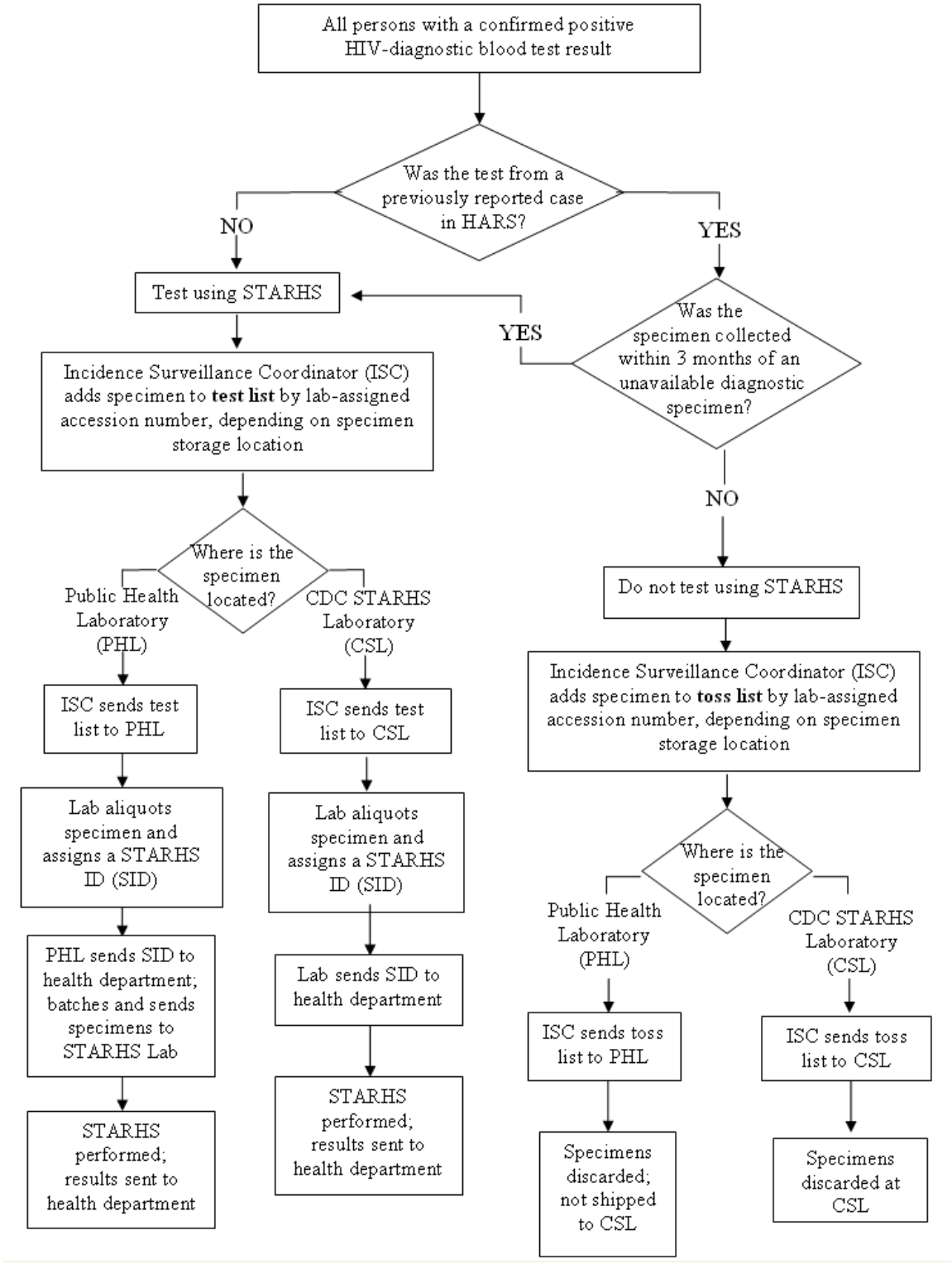
References

1. Janssen RS, Satten GA, Stramer SL, et al. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. *JAMA* 1998; 280:42–48.

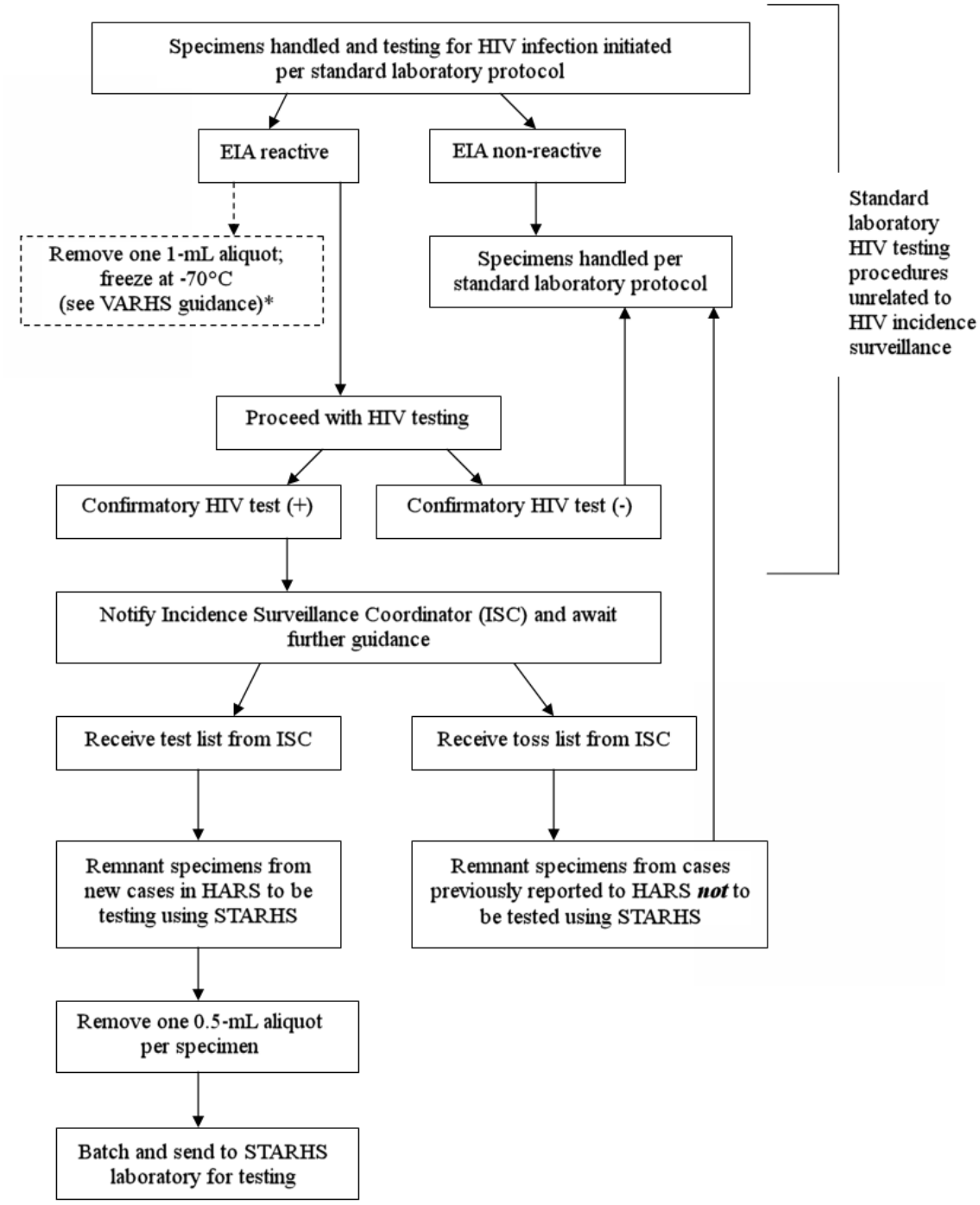
2. Parekh B, Kennedy MS, Dobbs T, et al. Quantitative detection of increasing HIV type 1 antibodies after seroconversion: a simple assay for detecting recent HIV infection and estimating incidence. *AIDS Research & Human Retroviruses* 2002;18(4):295–307.

3. Linley L, Reed C. Applicability of Population-Based STARHS HIV Incidence Measure in Determining Recency of Individual Infection among Patients Attending STD Clinics. In Program and abstract of the 11th Annual Conference on Retroviruses and Opportunistic Infections; February 2004; San Francisco. Abstract 854.

Epidemiologic Flow Chart for HIV Incidence Surveillance



Operational Public Health Laboratory Flow Chart for HIV Incidence Surveillance



* Applies only to laboratories participating in Variant, Atypical, and Resistant HIV Surveillance (VARHS)

National Center for HIV, STD, and TB Prevention's Non-research Determination for HIV Incidence Surveillance

NCHSTP Research/Non-research Determination

(Request to Classify Project as Not Involving Human Subjects or Research)

This form should be used to submit to NCHSTP ADS materials for projects involving CDC investigations that are not subject to human subjects regulations. Projects are eligible for this classification either as "non-research" projects (primary intent is not to generate generalizable knowledge) or as research projects that do not involve identifiable human subjects. Such projects do not require submission to the CDC Human Subjects Office for IRB review. Do **NOT** use this form for IRB "EXEMPT" research.

Project Title___ Standard HIV Incidence Surveillance Procedures Guidance _____

Project Locations/Sites: _____33 funded incidence sites, eventually all HIV/AIDS Surveillance areas___

Project Officer(s)____Lisa M. Lee, PhD __ Division:__ DHAP-SE _____ Telephone: __404.639.2052

Proposed Project Dates: Start: 03/__01__/_2005_ End: N/A, routine surveillance _____/_____/_____

Categories of data collection that do not constitute human subjects research include are listed below. Please check appropriate category:

_X__ I. **Activity is not research** . Primary intent is public health practice or a disease control activity.
- ___ **A**. Epidemic/endemic **disease control** activity; collected data directly relate to disease control needs.
- _X__ **B**. Routine **disease surveillance** activity; data used for disease control program or policy purposes.
- ___ **C**. **Program evaluation** activity; data are used primarily for that purpose.
- ___ **D**. **Post-marketing surveillance** of efficacy and/or adverse effects of a new regimen, drug or device.
- ___ E. **Activity is purely administrative** (e.g., purchase orders or contracts for services or equipment) and not related to research [this category I-E may be determined by Divisional ADS]

-OR-

___ II. **Activity is research but does NOT involve identifiable human subjects.**
- ___ **A.** Activity is research involving collection/analysis of data about health facilities or other organizations or units which are not individual persons....**or**...
- ___ **B.** Activity is research involving data and/or specimens from deceased persons...**or**...
- ___ **C.** Activity is research using unlinked anonymous data or specimens: **All** (1-4) of the following are required:
  - ___ 1. No contact with human subjects is involved for the proposed activity...**and**...
  - ___ 2. Data or specimens are/were collected for another purpose...**and**...
  - ___ 3. No extra data/specimens are/were collected for **this** purpose...**and**...
  - ___ 4. Identifying information either was not obtained **or** has been removed so that data cannot be linked or re-linked with identifiable human subjects. (Note: under certain conditions, research *may* qualify as non-human subjects when identifiers are removed by local staff; contact NCHSTP ADS office for details.)

Attach project description (standard format at end of this form) in enough detail to clarify its non-human subject research nature. Submit through division ADS/Director to: NCHSTP ADS, Attn: Janella Dodson (MS E-07)

☐ Check here if this request is an **amendment** of an existing non-research determination.

Approval initials: _____ 3/2/05 _____ 3/2/05
Branch/Section Chief Date **ADS or Div. Director** Date

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Page 2

Project Title_____ Standard HIV Incidence Surveillance Procedures Guidance _____

NCHSTP ADS Review **Date rec'd in NCHSTP ADS Office:**_____

X **Concur, project does not constitute human subjects research**

or

___**Project constitutes human subjects research**, submission for Human Subjects review required

This project is national HIV/AIDS surveillance & not research.

Comments/Rationale:

Additional Comments:

1. This form cannot be used to document "IRB Exempt Research," which must instead be submitted to the CDC IRB. (Please contact the NCHSTP ADS Office for details).
2. Although CDC Human Subjects (IRB) review is not required in this instance, investigators/project officers are expected to adhere to ethical principles and standards by respecting and protecting to the maximum extent possible the privacy, confidentiality and autonomy of participants. All applicable State and Federal privacy laws must be followed.
3. Although this project does not constitute human subjects research, informed consent may be appropriate. Information disclosed in the consent process should address the eight standard consent elements.
4. Other:

Signed: _____ 3/9/05

Terence Chorba, MD, MPH, MPA, MA
Acting Associate Director for Science, NCHSTP
National Center for HIV, STD, and TB Prevention

Date

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Standard HIV Incidence Surveillance Data Elements

	Required Surveillance Data Elements
	Required Laboratory/Specimen Related Variables

Variable Description	Valid Value
Antiretroviral use	0 = no 1 = yes 7 = refused 9 = don't know
Antiretroviral (ARV) medications taken	22 = Agenerase (amprenavir) 30 = Aptivus (tipranavir, TPV) 32 = Atripla (efavirenz/emtricitabine/tenofovir DF) 24 = Combivir (lamivudine/ zidovudine) 06 = Crixivan (indinavir, IDV) 11 = Emtriva (emtricitabine, FTC) 03 = Epivir (lamivudine, 3TC) 28 = Epzicom (abacavir/lamivudine) 25 = Fortovase (saquinavir, SQV) 10 = Fuzeon (enfuvirtide, T20) 19 = Hepsera (adefovir) 02 = Hivid (zalcitabine, ddC) 23 = Hydroxyurea 18 = Invirase (saquinavir, SQV) 16 = Kaletra (lopinavir/ ritonavir) 31 = Lexiva (fosamprenavir, 908) 07 = Norvir (ritonavir, RTV) 88 = Other 33 = Prezista (darunavir, DRV) 09 = Rescriptor (delavirdine, DLV) 26 = Retrovir (zidovudine, ZDV, AZT) 15 = Reyataz (atazanavir, ATV) 08 = Saquinavir (Fortavase, Invirase) 21 = Sustiva (efavirenz, EFV) 13 = Trizivir (abacavir/lamivudine/zidovudine) 27 = Truvada (tenofovir DF/emtricitabine) 99 = Unspecified 01 = Videx (didanosine, ddl) 14 = Videx EC (didanosine, ddl) 17 = Viracept (nelfinavir, NFV) 05 = Viramune (nevirapine, NVP) 12 = Viread (tenofovir DF, TDF) 04 = Zerit (stavudine, d4T) 20 = Ziagen (abacavir, ABC)

Variable Description	Valid Value
Date Highly Active Antiretroviral Treatment (HAART) use began	yyyymmdd
Date HAART use ended	yyyymmdd
Date information is extracted either from the client by interview or the medical chart by abstraction	yyyymmdd
Date of first positive HIV test	yyyymmdd
Date of last negative HIV test	yyyymmdd
Ever tested negative	0 = no 1 = yes 7 = refused 9 = don't know
Number of HIV tests in the 2 years before first positive test	1–99 R = refused D = don't know
Clinical Laboratory Improvement Amendments (CLIA) code for source lab where specimen originated	text
Date of STARHS test	yyyymmdd
Date specimen was obtained	yyyymmdd
Specimen approved for STARHS	0 = no 1 = yes 2 = pending
Laboratory ID	33D0654341 = NYST 33D0654341 = CDCSTARHS 33D0654341 = NY 33D0654341 = CDCSTAR 21D0649758 = MARY01 50D0661430 = WASH
Optical density	text
Reason STARHS not performed	1 = quantity not sufficient (QNS) 2 = specimen never received at public lab 3 = broken in transit 4 = other
Results received	0 = no 1 = yes
Specimen identification number from source lab	text
STARHS identification number (SID)	text
STARHS regional laboratory specimen identification number (same as STARHS laboratory imported variable SPECIMEN ID)	text

Variable Description	Valid Value
STARHS test result	01 = long term 02 = recent 91 = QNS 92 = not received by STARHS lab 93 = broken 94 = other
State laboratory CLIA code	text
State laboratory specimen ID number	text
Test assay	BED = BED BVLS = BVLS (Vironostika LS) OTLS = OTLS (Vironostika LS) OTV = OTV (Vironostika LS) AVID = AVID
Type of test performed on specimen (Logical Observation Identifiers Names and Codes [LOINC])	5220-9 = EIA/ELISA 21009-6 = Western blot 5472-6 = CD4 25835-0 = Viral Load (NASBA) 5017-9 = Viral Load (bDAN) 25836-8 = Viral Load (RT-PCR)
Type of specimen obtained	1 = blood finger stick 2 = blood venipuncture 3 = blood spot 4 = oral mucosal transudate 5 = urine 8 = other 9 = unknown

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 activities[1]. 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

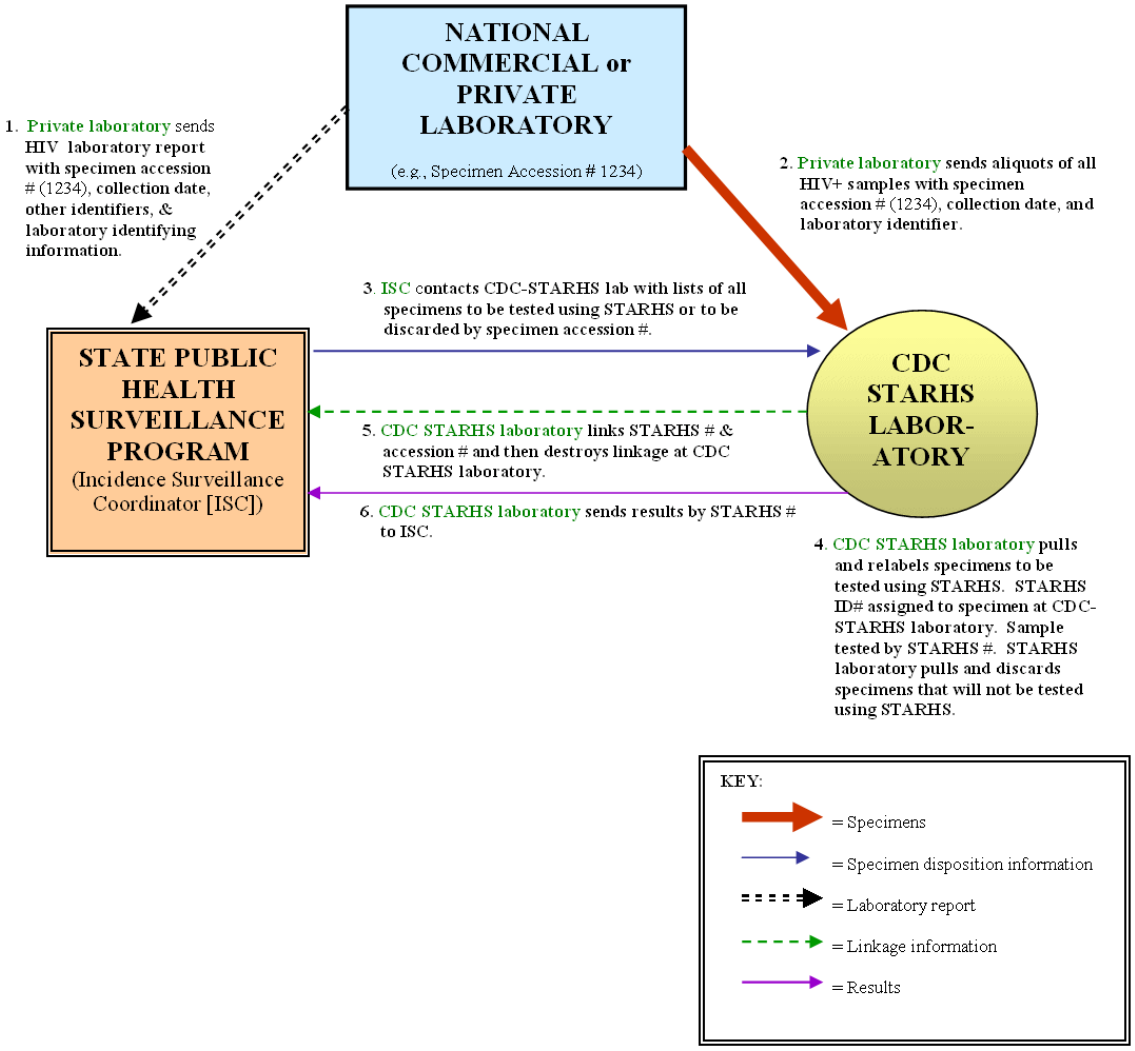


Figure 2a. Specimen originates at a public health laboratory (PHL performed the confirmatory HIV testing)

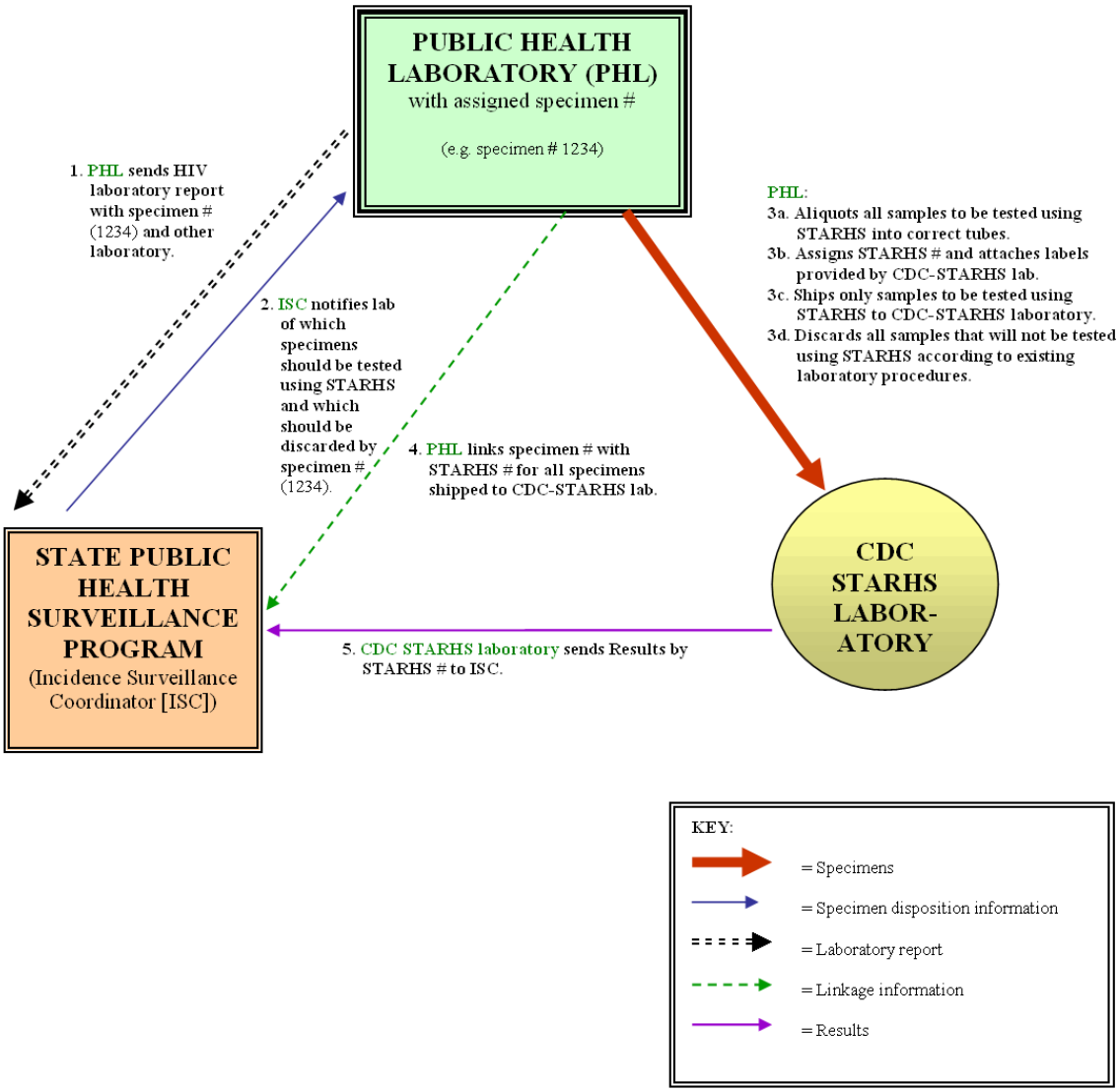
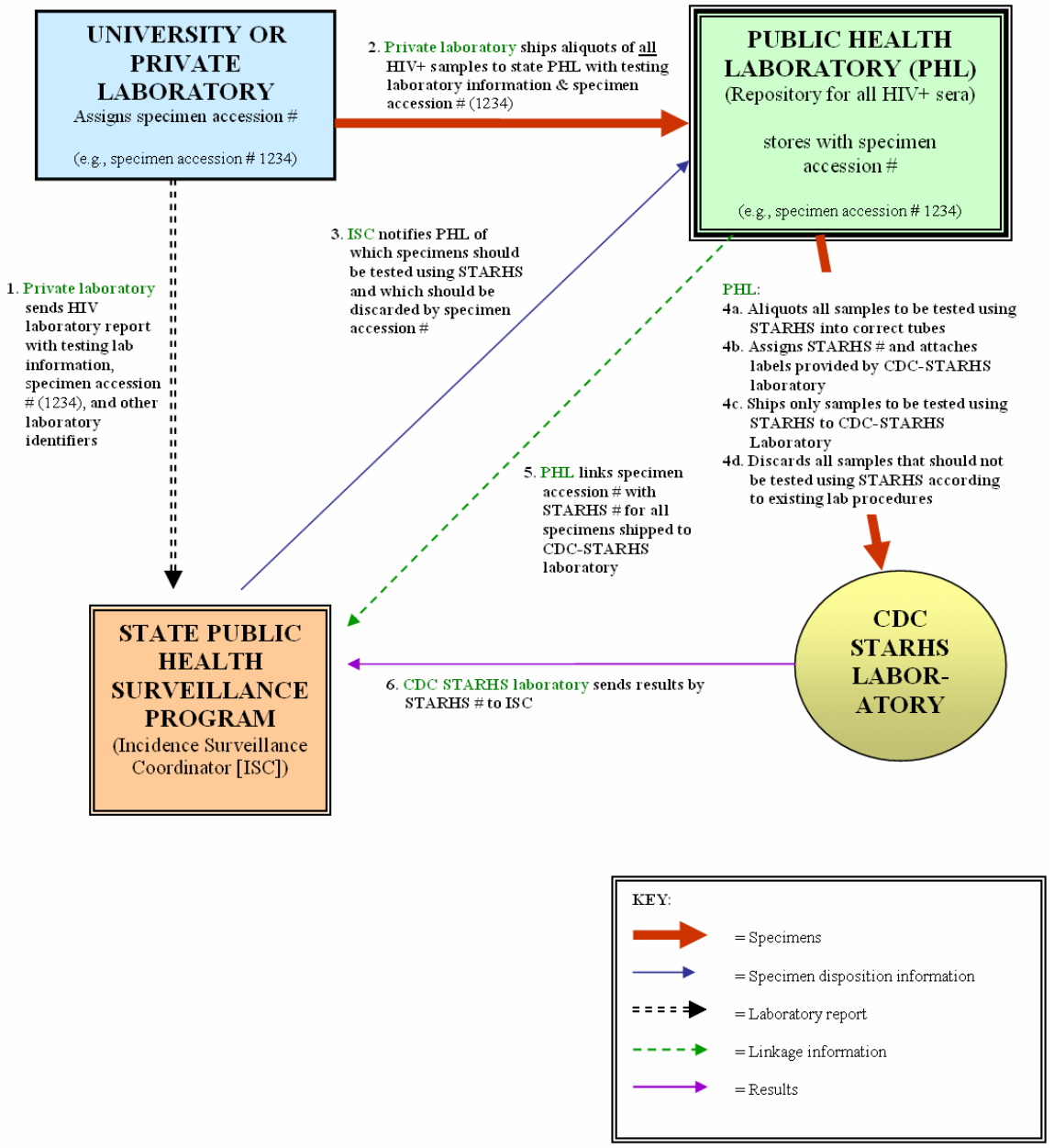


Figure 2b. Specimen originates at a private laboratory (for example, a university hospital laboratory, regional or local independent commercial laboratory) and sample is sent to state public health laboratory (serves as a pass-through facility)



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.