



California HIV/AIDS Surveillance
Standard Operating Procedures

External

HIV Incidence Surveillance (HIS)

Version 2.0

April 17, 2015

HIS Standard Operating Procedures

REVISION HISTORY

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1.0	12/2011	Initial draft	Arvin Magusara
1.5	03/2014	Updates to Procedures	Lissa Bayang
2.0	04/2015	Updated	Jessica Brown & Scott Masten

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1 What is HIV Incidence Surveillance (HIS)?

Core HIV/AIDS Surveillance allows the California Department of Public Health, Center for Infectious Diseases, Office of AIDS (OA) HIV/AIDS Surveillance Section to summarize reported HIV/AIDS cases and provides a picture of the overall HIV/AIDS burden in California. It includes cases that were newly diagnosed and total number of new and existing HIV/AIDS cases (prevalence). However, a newly diagnosed case may not have been recently infected. HIV Incidence Surveillance (HIS) is a component of the HIV Surveillance that focuses on identifying cases that are newly infected, and using that information to improve our understanding of HIV transmission patterns. The table below illustrates the key differences between Core HIV/AIDS Surveillance and HIV Incidence Surveillance.

	Core Surveillance	Incidence Surveillance
Measures	<u>HIV Prevalence</u> <ul style="list-style-type: none"> • New <i>diagnoses</i> • People living with HIV 	<u>HIV Incidence</u> <ul style="list-style-type: none"> • New <i>infections</i>
Data collected	Demographic information HIV risk exposures HIV laboratory results & specimen identifiers (CLIA; Accession numbers) AIDS indicators HIV testing and treatment history (TTH) Medications to treat or prevent HIV (ART)	Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) test result from remnant blood specimen

Core HIV/AIDS Surveillance versus HIV Incidence Surveillance

In conjunction with the Centers for Disease Control and Prevention (CDC) and local health departments, OA uses HIS data to generate reliable and scientifically valid national, state, and local estimates of the numbers of new HIV infections. By estimating new infections rather than just new diagnoses, HIV incidence estimates provide a window into recent changes in the epidemic that might not yet be reflected in core surveillance data. This makes it possible to more accurately assess the recent scope of the epidemic, its impact on population subgroups, and current HIV transmission risk. HIS data are used for local, state, and national HIV/AIDS prevention program planning and evaluation.

Although the focus is only on new infections, HIS is fully integrated in to Core HIV/AIDS Surveillance and it relies heavily on key data components from Core HIV/AIDS Surveillance to assist with determining if new HIV diagnoses are actually new HIV infections. Together, HIS and Core HIV/AIDS Surveillance allow OA to estimate total new infections; estimate the number of HIV positive people who are unaware of their infections; identify emerging demographic or geographic groups for whom infections are increasing; better inform and guide prevention and care activities and resource allocation; and develop new HIV interventions and approaches to prevention.

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2 Responsible Parties and Contacts for HIS

OA is responsible for maintaining the HIS program within the California Project Area (CPA). Note that HIS is NOT a pilot project; it has been fully integrated into routine HIV surveillance activities and therefore all local health jurisdictions in the CPA participate in the HIS program. San Francisco and Los Angeles Counties run the HIS programs in their jurisdictions

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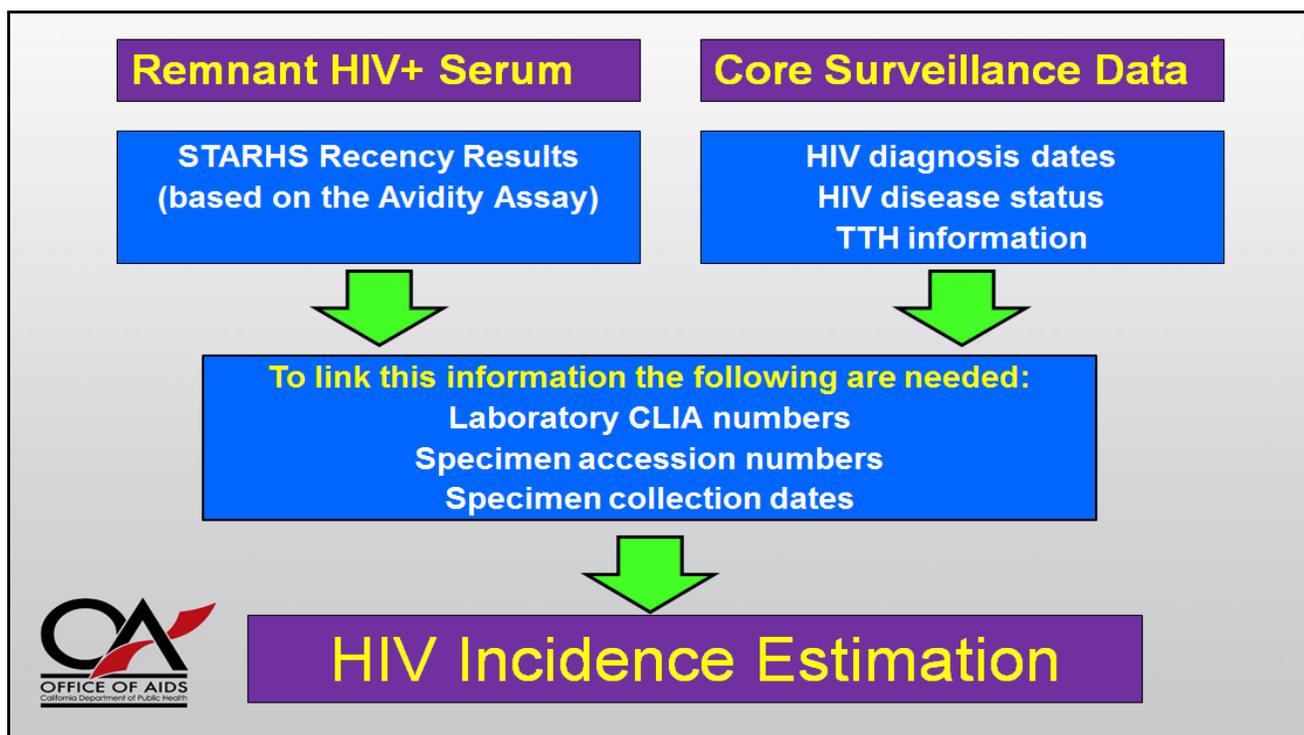
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3 Requirements for an Effective HIS Program

An effective HIS program: (a) identifies probable new cases of HIV infection, (b) obtains corresponding remnant serum specimens for those cases, (c) sends those serum specimens for recency testing, and (d) receives results of the recency tests that establish whether the HIV infections were indeed recent. By applying a statistical algorithm to adjust for underreporting and other relevant parameters, these results are then used to generate reliable and scientifically valid estimates of new HIV infections.

HIS requires two required data sources to effectively calculate incidence estimates:

(a) Recency test results from remnant HIV positive serum or plasma collected within 90 days of HIV diagnosis; and (b) Core HIV/AIDS Surveillance data. Remnant HIV positive specimens from persons likely to be new cases of HIV infection are sent by private, commercial, or public health laboratories for recency testing using the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS). Core HIV/AIDS Surveillance data are collected by Local Health Jurisdictions (LHJs) and consist of case HIV diagnosis dates, HIV disease statuses, and testing and treatment histories (TTH), which are collected on Adult Case Report Forms (ACRF) and sent to OA. Identifiers for the remnant specimen, such as Clinical Laboratory Improvement Amendments (CLIA) numbers, laboratory-assigned specimen accession numbers, and specimen collection dates, which are also reported to OA along with HIV-infection-related laboratory results, are used to match the specimen to its corresponding case in the Core HIV/AIDS Surveillance data to determine if the case and associated remnant specimen meet HIS eligibility criteria for STARHS testing. Hence, both data sources are required for HIV incidence estimation.



Primary Data Requirements for HIV Incidence Surveillance

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4 Key HIS Partners and Responsibilities

HIS relies on key partnerships with health care providers, local health departments, and private, commercial, and public health laboratories to operate effectively. The following briefly describes the responsibilities of key HIS partners.

Health Care Providers:

- Document patient clinical information in medical records include testing and treatment histories
- Diagnose HIV infection following a positive result from an approved HIV testing algorithm
- Facilitate the completion of adult case report forms (ACRF)

Local Health Departments:

- Collect and record core surveillance information, including complete testing and treatment histories, from providers and through medical record reviews
- Accurately record specimen collection dates, laboratory CLIA numbers, and specimen accession numbers in laboratory reports, and attach copies of the laboratory reports to the ACRFs for all newly diagnosed HIV cases

Laboratories:

- Store remnant HIV positive serum collected within 90 days of new HIV diagnoses
- Transfer remnant specimens to the OA-designated laboratory for STARHS testing either routinely (for all specimens) or on request (for OA-specific specimens)

5 Key HIS Data Components

The HIS program relies on several key data elements, which are discussed in more detail in the following sections of this document:

1. HIV diagnosis date (available on ACRFs and laboratory result reports)
2. HIV disease status (HIV or AIDS) (available on ACRFs and laboratory result reports)
3. Testing and treatment histories (TTH) (available on ACRFs)
4. Laboratory and specimen information (available on laboratory result reports):
 - a. Specimen collection dates
 - b. Clinical Laboratory Improvement Amendments (CLIA) numbers
 - c. Laboratory-assigned specimen accession numbers
5. STARHS results (provided by the Wadsworth laboratory in New York)

5.1 HIV Diagnosis Dates

In 2014 the CDC revised the surveillance case definition for HIV Infection. A confirmed case that meets the criteria for diagnosis of HIV infection can be classified into one of five HIV infection stages (0, 1, 2, 3, or unknown). The stage characterizes the status of HIV disease at a particular point in time. Stage 0 is the term for acute HIV infection and Stage 3 is the new term for AIDS. To assist with classifying HIV infections into these stages, the CDC

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recommends that providers use a specific recommended HIV testing algorithm, which includes a 4th generation antigen/antibody combination immunoassay (EIA), an HIV-1/HIV-2 antibody differentiation Test (such as Multispot), and possibly an HIV-1 nucleic acid test (NAT). Using these tests according to the recommended algorithm improves detection of acute HIV infection.

HIV diagnosis dates are calculated based on specimen collection dates recorded from laboratory results sent to LHJs or gathered during medical record reviews. LHJs send the specimen collection dates to OA on ACRFs or as uploads of laboratory results from the Laboratory Data Entry Tool (LDET), both of which are imported into the Enhanced HIV/AIDS Reporting System (eHARS).

VII. Laboratory Data (Record All Dates as mm/dd/yyyy) (See Instructions for Details)

HIV Antibody Tests (Non-Type Differentiating) [HIV-1 vs. HIV-2]	
TEST 1: <input type="checkbox"/> HIV-1 EIA <input type="checkbox"/> HIV-1/2 EIA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 EIA <input type="checkbox"/> HIV-2 WB <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Manufacturer: _____	RAPID TEST (check if rapid): <input type="checkbox"/> Collection Date: ____/____/____
TEST 2: <input type="checkbox"/> HIV-1 EIA <input type="checkbox"/> HIV-1/2 EIA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 EIA <input type="checkbox"/> HIV-2 WB <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Manufacturer: _____	RAPID TEST (check if rapid): <input type="checkbox"/> Collection Date: ____/____/____
TEST 3: <input type="checkbox"/> HIV-1 EIA <input type="checkbox"/> HIV-1/2 EIA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 EIA <input type="checkbox"/> HIV-2 WB <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Manufacturer: _____	RAPID TEST (check if rapid): <input type="checkbox"/> Collection Date: ____/____/____
HIV Antibody Tests (Type Differentiating) [HIV-1 vs. HIV-2]	
TEST: <input type="checkbox"/> HIV-1/2 Differentiating (e.g. Multispot)	
RESULT: <input type="checkbox"/> HIV-1 <input type="checkbox"/> HIV-2 <input type="checkbox"/> Both (undifferentiated) <input type="checkbox"/> Neither (negative)	Collection Date: ____/____/____

Source for HIV Diagnosis Dates from Laboratory Results Reported on ACRFs

Add Lab Test

Add Lab Test for Stateno Validate/Exit

Labels in yellow are required information and blue labels are highly recommended when importing a lab document into eHARS

Lab CLIA No	<input type="text"/>	Lab Name (only if not in CLIA list)	<input type="text"/>
<input type="button" value="Lab Shortlist Setup"/>		Manufacturer	<input type="text"/>
Date Entered	<input type="text" value="2/23/2015"/>	Date Received from Lab	<input type="text"/>
Specimen Collection Date	<input type="text" value="01/02/2015"/>	Result Date	<input type="text"/>
		Accession No	<input type="text"/>
Lab Test Name	<input type="text"/>		

Source for HIV Diagnosis Dates from Laboratory Results Reported through LDET

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Add Lab Test

Add Lab Test for Stateno

Labels in yellow are required information and blue labels are highly recommended when importing a lab document into eHARS

Lab CLIA No

Date Entered Date Received from Lab

Specimen Collection Date
Date Entered - Collection Date = 1hr 21d

Lab Test Name

Source for HIV Disease Status from Immunologic Laboratory Results Reported through LDET

HIV disease status is used by OA to ensure that remnant specimen collected for HIS belong to probable new cases of HIV infection, and are therefore eligible for STARHS testing. eHARS calculates the date of AIDS diagnosis for a case as the date when the first AIDS-defining condition occurred under the current definition, defined as the earlier of (a) the date of the earliest T-cell (CD4) test where the count is less than 200 or the percent is less than 14, or in some cases (b) the date of the first AIDS-defining opportunistic infection. Specimen belonging to cases with an AIDS diagnosis date that is within 6 months of their HIV diagnosis date are ineligible for STARHS testing.

5.3 Testing and Treatment Histories (TTH)

Prior testing and antiretroviral treatment histories are collected by LHJ staff during medical record abstractions when new HIV/AIDS cases are identified. TTH data are collected for all persons aged 13 years and older with a new diagnosis of HIV infection and are recorded in the TTH section on the ACRF and then sent to OA. After the ACRFs are processed, OA identifies cases with inconsistent, missing, or incomplete TTH information and follows up with LHJ staff to correct the errors or omissions. These data are used by OA to help identify probable new cases of HIV infection and develop weights for incidence estimates.

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X. HIV Testing and Antiretroviral Use History (TTH) <i>(Record All Dates as mm/dd/yyyy) (Required Sections for New Case Report Only)</i>			
Main Source of Testing and Treatment History Information <i>(select one)</i> : <input type="checkbox"/> Patient Interview <input type="checkbox"/> Medical Record Review <input type="checkbox"/> Provider Report <input type="checkbox"/> NHM&E/PEMS <input type="checkbox"/> Other <i>(specify)</i> : _____			Date Patient Reported Information: _____/_____/_____
1 Ever Had a Positive HIV Test? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't Know/Unknown	Date of First Positive HIV Test: _____/_____/_____	2 Ever Had a Negative HIV Test? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't Know/Unknown	Date of Last Negative HIV Test: <i>(If date is from a lab test with test type, enter in Laboratory Data Section.)</i> _____/_____/_____
3 Number of Negative HIV Tests Within 24 Months Before First Positive Test (#): _____ <input type="checkbox"/> Refused <input type="checkbox"/> Don't Know/Unknown			
4 Ever Taken Any Antiretrovirals (ARVs)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't Know/Unknown		If Yes, What ARV Medications? _____	
5 Date ARVs First Taken: _____/_____/_____		Date ARVs Last Taken (mm/dd/yyyy): _____/_____/_____	

Source for Testing and Treatment Histories Reported on ACRFs

There are five TTH data elements collected on ACRFs that are used for HIS:

1. Ever Had a Positive HIV Test? (Yes/No and date)
2. Ever had a Negative HIV Test? (Yes/No and date)
3. Number of Negative HIV Tests within 24 Months before First Positive Test
4. Ever Taken Any Antiretrovirals (ARVs)? (Yes/No and medication names)
5. Dates ARVs were First Taken and Last Taken

Local HIV/AIDS Surveillance Coordinators are responsible for ensuring that their staff obtain and record as accurately as possible all information in the TTH section of the ACRF. TTH information can be obtained via medical record abstractions, reviews of other HIV-related documents or data sources, or in some cases, through patient interviews. During record abstractions, local surveillance staff should reference the TTH section of the ACRF and search for TTH-related information in the patient's charts and other medical records. The importance of collecting complete TTH information should be emphasized to local surveillance staff frequently to send the message that compliance with the HIS program is valued by the Local HIV/AIDS Surveillance Coordinator. See Appendix A for Tips for Improving TTH Data Collection, which were gathered from LHJs with high levels of TTH completeness.

While complete TTH data is by far preferable, Local HIV/AIDS Surveillance Coordinators should at a minimum always complete the following three TTH data elements to the fullest extent possible so that rudimentary incidence estimates can still be calculated:

1. Ever Had a Positive HIV Test? (Yes/No and date);
2. Ever had a Negative HIV Test? (Yes/No and date); and
3. Number of Negative HIV Tests within 24 Months before First Positive Test.

TTH information regarding HIV testing frequency is used by OA to classify cases as "new testers" (i.e., people whose first-ever HIV test result was positive) or "repeat testers" (i.e., people who tested HIV-positive after having previously tested HIV-negative at least once). This distinction is important for HIS because the algorithm for being classified as a new case of HIV infection is calculated separately for new testers and repeat testers.

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Another purpose of gathering information about prior HIV tests and antiretroviral use history is for OA to calculate statistical weights corresponding to the probability that a person would be tested for HIV during the STARHS recency period. These weights are used to calculate HIV incidence estimates wherein recency status is imputed using a CDC algorithm for persons lacking STARHS results. In addition, TTH data elements on antiretroviral use are important because antiretroviral use impacts the STARHS test results.

5.4 Laboratory and Specimen Information

California Health and Safety Code (HSC) Section [121022\(a\)](#) requires all laboratories licensed to test biological samples that originate in California—regardless of whether or not the laboratories are actually located within California—report confirmed test results that verify the presence of HIV (including, but not limited to: EIA; Western blot; antibody differentiation, such as Multispot; NAAT; or genotyping) or are used to monitor HIV infection (including, but not limited to: viral load, and CD4+ T-Cell count and percent) to the health officer of the LHJ in California where the ordering health care provider facility is located. The information that must be included in these reports is detailed in California Code of Regulations (CCR), Title 17, Section [2643.10\(a\)](#).

Local HIV/AIDS Surveillance Coordinators are responsible for obtaining and reporting complete laboratory data. LHJs send the laboratory and specimen information to OA on ACRFs or as uploads of laboratory results from LDET, both of which are imported into eHARS. For all newly diagnosed HIV cases, LHJs should also attach copies of the laboratory reports to the ACRF. Complete and accurate reporting of laboratory and specimen information to LHJs, and by LHJs to OA, is important for the success of HIS. These data allow OA to match probable new cases of HIV infection to remnant serum specimen so they can be sent for STARHS testing. To ensure that the correct specimen is sent to STARHS for testing, and that the STARHS test results can be matched back to the probable new case, it is critical that the following be included when laboratory results are reported to LHJs, and when LHJs report laboratory results to OA:

1. Specimen collection dates
2. Clinical Laboratory Improvement Amendments (CLIA) numbers
3. Laboratory-assigned specimen accession numbers

Laboratories should always include these data elements when reporting HIV-infection-related results to LHJs. In turn, LHJs should always report specimen collection dates and performing laboratory CLIA numbers for all HIV-infection-related laboratory results—regardless of the type of test performed—when reporting results to OA. While LHJs are only required to report specimen accession numbers for HIV-infection-related laboratory results—regardless of the type of test performed—for specimen that were collected during the first 90 days of HIV diagnosis, they are encouraged to report accession numbers even if specimen collection dates fall outside this 90-day window. Additional information about these three critical elements is presented in the following subsections.

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5.4.1 Specimen Collection Dates

The specimen collection date is the date that the specimen upon which the result was based was drawn from the patient. This information should always be reported by laboratories to LHJs, and by LHJs to OA—regardless of the type of test performed. Specimen collection dates are used by OA to determine if the specimen were collected within 90 days of the date of HIV diagnosis, and hence are eligible for STARHS testing. LHJs send the specimen collection dates to OA on ACRFs or as uploads of laboratory results from LDET. For all newly diagnosed HIV cases, LHJs should also attach copies of the laboratory reports to the ACRF.

VII. Laboratory Data <small>(Record All Dates as mm/dd/yyyy) (See Instructions for Details)</small>	
HIV Antibody Tests (Non-Type Differentiating) [HIV-1 vs. HIV-2]	
TEST 1: <input type="checkbox"/> HIV-1 EIA <input type="checkbox"/> HIV-1/2 EIA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 EIA <input type="checkbox"/> HIV-2 WB <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Manufacturer: _____	RAPID TEST (check if rapid): <input type="checkbox"/> Collection Date: ____/____/____
TEST 2: <input type="checkbox"/> HIV-1 EIA <input type="checkbox"/> HIV-1/2 EIA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 EIA <input type="checkbox"/> HIV-2 WB <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Manufacturer: _____	RAPID TEST (check if rapid): <input type="checkbox"/> Collection Date: ____/____/____
TEST 3: <input type="checkbox"/> HIV-1 EIA <input type="checkbox"/> HIV-1/2 EIA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-1 WB <input type="checkbox"/> HIV-1 IFA <input type="checkbox"/> HIV-2 EIA <input type="checkbox"/> HIV-2 WB <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Manufacturer: _____	RAPID TEST (check if rapid): <input type="checkbox"/> Collection Date: ____/____/____
HIV Antibody Tests (Type Differentiating) [HIV-1 vs. HIV-2]	
TEST: <input type="checkbox"/> HIV-1/2 Differentiating (e.g. Multispot)	
RESULT: <input type="checkbox"/> HIV-1 <input type="checkbox"/> HIV-2 <input type="checkbox"/> Both (undifferentiated) <input type="checkbox"/> Neither (negative) Collection Date: ____/____/____	
HIV Detection Tests (Qualitative)	
TEST 1: <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Qual) <input type="checkbox"/> HIV-1 P24 Antigen <input type="checkbox"/> HIV-1 Culture <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Qual) <input type="checkbox"/> HIV-2 Culture	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Collection Date: ____/____/____	
TEST 2: <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Qual) <input type="checkbox"/> HIV-1 P24 Antigen <input type="checkbox"/> HIV-1 Culture <input type="checkbox"/> HIV-2 RNA/DNA NAAT (Qual) <input type="checkbox"/> HIV-2 Culture	
RESULT: <input type="checkbox"/> Positive/Reactive <input type="checkbox"/> Negative/Nonreactive <input type="checkbox"/> Indeterminate Collection Date: ____/____/____	
HIV Detection Tests (Quantitative Viral Load) <i>Note: Include earliest test after diagnosis</i>	
TEST 1: <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative Viral Load) <input type="checkbox"/> RT-PCR <input type="checkbox"/> bDNA <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Detectable <input type="checkbox"/> Undetectable Copies/mL: _____ Log: _____ Collection Date: ____/____/____	
TEST 2: <input type="checkbox"/> HIV-1 RNA/DNA NAAT (Quantitative Viral Load) <input type="checkbox"/> RT-PCR <input type="checkbox"/> bDNA <input type="checkbox"/> Other (specify test): _____	
RESULT: <input type="checkbox"/> Detectable <input type="checkbox"/> Undetectable Copies/mL: _____ Log: _____ Collection Date: ____/____/____	
Immunologic Tests (CD4 Count and Percentage)	
CD4 at or closest to current diagnosis status: CD4 count: _____ cells/ μ L CD4 percentage: _____ Collection Date: ____/____/____	
First CD4 result <200 cells/ μ L or <14%: CD4 count: _____ cells/ μ L CD4 percentage: _____ Collection Date: ____/____/____	
Other CD4 result <200 cells/ μ L or <14%: CD4 count: _____ cells/ μ L CD4 percentage: _____ Collection Date: ____/____/____	

Specimen Collection Dates for Laboratory Results Reported on ACRFs

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Add Lab Test

Add Lab Test for Stateno 77899 Validate/Exit

Labels in yellow are required information and blue labels are highly recommended when importing a lab document into eHARS

Lab CLIA No Lab Shortlist Setup Lab Name (only if not in CLIA list)

Date Entered 2/23/2015 Date Received from Lab

Specimen Collection Date 01/02/2015 Result Date Accession No ?

Manufacturer

Lab Test Name

Specimen Collection Dates for Laboratory Results Reported through LDET

5.4.2 Clinical Laboratory Improvement Amendments (CLIA) Numbers

All laboratories certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 have a number that uniquely identifies the laboratory. Laboratories must report these CLIA numbers to LHJs for all HIV-infection-related tests per California Code of Regulations (CCR), Title 17, Section [2643.10\(a\)](#). CLIA numbers should always be reported by LHJs to OA, regardless of the type of test performed. Some laboratory reports provide more than one CLIA number; in such cases, the desired CLIA number to report is for the laboratory that performed the test and is holding the remnant specimen. OA uses CLIA numbers to identify the specific laboratories holding remnant specimen so that the specimen can then be sent for STARHS testing. If you do not know the CLIA number of a laboratory, you can look it up using the name, or a partial name, at: <http://www.cdc.gov/clia/Resources/LabSearch.aspx>. Most LHJs send CLIA numbers to OA as uploads of laboratory results from LDET, which are subsequently uploaded into eHARS.

Add Lab Test

Add Lab Test for Stateno 77899 Validate/Exit

Labels in yellow are required information and blue labels are highly recommended when importing a lab document into eHARS

Lab CLIA No 05D0642827-QUEST DIAGNOSTICS, 8401 FALLBROOK AVE, WEST Lab Name (only if not in CLIA list)

Date Entered 2/23/2015 Date Received from Lab

Specimen Collection Date 1/2/2015 Result Date Accession No EN123456w ?

Manufacturer

Date Entered - Collection Date = 1m 21d

Lab Test Name

Laboratory CLIA Numbers for Laboratory Results Reported through LDET

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Sometimes LHJs send laboratory results to OA on ACRFs or they input their data directly into eHARS. Unfortunately, there is no place on the existing ACRF form or in the Lab Data Tab of eHARS for LHJs to report CLIA numbers for laboratory results. The solution to this issue is for LHJs to attach copies of the laboratory reports to the ACRF for all newly diagnosed HIV cases. When the laboratory results are entered into eHARS, the CLIA number is entered into the “Sample ID(Specimen)” field of the Lab Data Tab, preceded by an asterisk. For example, below CLIA “05D0642827” for the West Hills location of Quest Diagnostics has been typed into the “Sample ID(Specimen)” field on the Lab Data Tab in eHARS as “*05D0642827”.

The screenshot shows the 'Adult Case Report' form in eHARS, specifically the 'Lab Data' tab. The 'Sample ID(Specimen)' field is highlighted with a red circle and contains the text '*05D0642827'. Other fields include 'Accession Number', 'Collection Date', 'Received Date', 'Test', 'Manufacturer', 'Immunologic Tests (CD4 count and percentage)', and 'Documentation of Tests'.

eHARS Entry of Laboratory CLIA Numbers for Laboratory Results Attached to ACRFs

5.4.3 Laboratory-Assigned Specimen Accession Numbers

Laboratory-assigned specimen accession numbers are tracking or inventory numbers found on laboratory reports and specimen vials that are used to track specimens and link them to cases. Laboratories must report these accession numbers to LHJs for all HIV-infection-related tests per California Code of Regulations (CCR), Title 17, Section [2643.10\(a\)](#). LHJs are only required to report specimen accession numbers to OA for HIV-infection-related laboratory results—regardless of the type of test performed—when the specimen collection date is within 90 days of the HIV diagnosis date for the case. Accession numbers are needed so OA can request that the laboratory holding the specimen send it for STARHS testing. While accession numbers are not required once the specimen collection date is past this 90-day window, including them allows OA to better identify duplicate laboratory results in eHARS, so LHJs are encouraged to always enter accession numbers.

Extra caution should be observed when it comes to recording specimen accession numbers because: the numbers may not be obvious on the laboratory reports, what they are called on laboratory reports varies, and their structure and format are different across laboratories. While the content and formatting of accession numbers varies across laboratories, they are usually a string of numbers or combination of letters and numbers. The formats of accession numbers for several common laboratories are shown in Appendix B. For guidance identifying the accession numbers on laboratory reports for other common laboratories, see the Guide to Accession Number Identification from Common Laboratories at:

<http://www.cdph.ca.gov/programs/aids/Documents/GuideToAccessionNumberIdentificationFromCommonLaboratories2.pdf>

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Most LHJs send accession numbers to OA as uploads of laboratory results from LDET, which are subsequently uploaded into eHARS. Because diagnosis date is not yet available in LDET, accession numbers are required for all laboratory results entered into LDET with a specimen collection date that is within 90 days of the date of the first HIV positive laboratory result reported in LDET for the case.

Add Lab Test for Stateno 77899 Validate/Exit

Labels in yellow are required information and blue labels are highly recommended when importing a lab document into eHARS

Lab CLIA No: 05D0642827-QUEST DIAGNOSTICS, 8401 FALLBROOK AVE, WEST Lab Name (only if not in CLIA list)

Lab Shortlist Setup Manufacturer

Date Entered: 2/23/2015 Date Received from Lab

Specimen Collection Date: 1/2/2015 Result Date

Date Entered - Collection Date = 1m 21d

Accession No: EN123456W ?

Lab Test Name

Specimen Accession Numbers for Laboratory Results Reported through LDET

Sometimes LHJs send laboratory results to OA on ACRFs or they input their data directly into eHARS. Unfortunately, there is no place on the existing ACRF form for LHJs to report accession numbers for laboratory results. The solution to this issue is for LHJs to attach copies of the laboratory reports to the ACRF for all newly diagnosed HIV cases. When the laboratory results are entered into eHARS, the accession number is entered into the “Accession Number” field of the Lab Data Tab. For example, specimen accession number “EN123456W” has been typed below into the “Accession Number” field on the Lab Data Tab in eHARS.

Adult Case Report

Name: State No:

Form Info | Identification | Demographics | Facility | History | **Lab Data** | Clinical | Treatment | Local Fields | Duplicate Review | Retired | Comments

Laboratory Information

Sample ID (Specimen): *05D0642827 Accession Number: EN1 234 56 W

Collection Date: Result Date:

Received Date:

Lab Test

Test: <Select> Rapid Test Type Sample Type: <Select>

Manufacturer: <Select>

Immunologic Tests (CD4 count and percentage)

CD4 at or closest to current diagnostic status: Please enter the CD4 test results in the Lab Test section above.

First CD4 result <200 cells/uL or <14%:

Documentation of Tests

Complete only if none of the following was positive: HIV-1 Western blot, IFA, culture, p24 Ag test, viral load, or qualitative NAAT (RNA or DNA). Did the documented laboratory test results meet approved alternative HIV testing algorithm criteria? If YES, provide specimen collection date of earliest positive result for the approved alternative HIV testing algorithm:

Date of last documented negative HIV test? Please enter the last documented negative HIV test in the Lab Test section above.

If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician? If YES, provide date of documentation by physician:

eHARS Entry of Specimen Accession Numbers for Laboratory Results Attached to ACRFs

6 Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) Testing

The last component of HIS is to test eligible specimen using the Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS). STARHS testing is conducted the New York State Public Health Laboratory, also known as the Wadsworth Laboratory in Albany, New York; the Wadsworth Laboratory is funded by CDC to conduct recency testing. This laboratory, which is also known as the “STARHS Laboratory”, analyzes remnant HIV positive serum to determine whether HIV infections occurred recently (i.e., new infections) versus some time earlier (i.e., older infections). Cases diagnosed through 2013 were tested for STARHS using the BED HIV-1 Capture Enzyme Immunoassay (BED assay). Starting with cases diagnosed in 2014, the laboratory test used for STARHS is the Bio-Rad HIV O ELISA (Bio-Rad Avidity assay), which was modified by the CDC Division of HIV/AIDS Prevention Laboratory Branch for detection of recent HIV-1 infections. The Bio-Rad Avidity assay distinguishes between new (< 156 days before specimen collection) and older (\geq 156 days before specimen collection) HIV infections.

STARHS testing should be conducted for all newly diagnosed HIV cases ages 13 years and older, excluding those whose infection was classified as Stage 3 HIV (AIDS) within 6 months of initial HIV diagnosis. Results of the STARHS test for recent infection are obtained by locating and determining the disposition of remnant specimens, preparing STARHS eligibility lists, transporting remnant HIV-positive specimen to the STARHS Laboratory, STARHS testing the specimen, and having the STARHS test results reported back to OA.

6.1 Laboratory Participation in HIS

Some commercial, private, and public health laboratories routinely (e.g., monthly or quarterly) send remnant HIV positive serum from *ALL* HIV-positive initial diagnostic and supplemental tests for specimen originating from California to the STARHS Laboratory in New York or the Viral and Rickettsial Disease Laboratory (VRDL) in Richmond, California. This is the most straightforward way that laboratories can participate in HIS. Other laboratories—such as those with lower HIV testing volumes—do not routinely ship all of their HIV positive specimen; instead they are sent quarterly lists containing the accession numbers of eligible specimen that need to be sent for STARHS testing, and then ship only those specimen to the STARHS Laboratory or the VRDL. Occasionally OA staff will also send lists of additional eligible specimen that need to be shipped for STARHS testing to the laboratories that routinely send their remnant specimen, if the eligible specimen was not from an initial diagnostic or supplemental test (e.g., specimen from a follow-up viral load test that was also collected within 90 days of diagnosis).

6.1.1 Shipping to the STARHS Laboratory versus to the VRDL

While it is preferable that participating laboratories ship their specimen directly to the STARHS Laboratory, some laboratories in California instead ship their specimen to the VRDL. For the HIS program, the VRDL liaises between participating commercial, private, and public health laboratories, and the STARHS Laboratory. In this role, VRDL receives and re-aliquots serum specimen from the laboratories, stores the specimen, and provides an inventory of serum samples to OA so that OA can determine whether a specimen is eligible for STARHS testing.

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The VRDL also supplies shipping materials, including cryovials, to participating laboratories. Specimens that are identified as eligible for STARHS testing by OA are then shipped by the VRDL to the STARHS Laboratory for testing. If your laboratory cannot ship specimen directly to STARHS, but could participate in HIS by instead shipping to VRDL, please contact the OA HIV Surveillance Laboratory Coordinator to discuss this possibility.

6.1.2 Important Shipping Dates

To meet the key CDC data submission deadlines of June and December each year, commercial, private and public health laboratories should ship their remnant HIV positive serum at least twice a year (in April and September) to the STARHS Laboratory or VRDL. Most laboratories send their remnant serum more frequently (e.g., monthly or quarterly), which is preferable.

6.2 Shipping Remnant Serum to the STARHS Laboratory

The laboratory procedures for processing and shipping remnant specimen to the STARHS Laboratory, as well as the STARHS Laboratory Shipping Manifest (Excel spreadsheet), are available at: <http://www.cdph.ca.gov/programs/aids/Pages/OAHISResLabs.aspx>

6.2.1 Contacts for STARHS

N'ko Lea Ali-Napo (Lea)
Research Scientist, Bloodborne Viruses
Laboratory: STARHS
(518) 473-3567
nko.ali-napo@health.ny.gov

William Carmichael
Bloodborne Viruses Laboratory: STARHS
(518)-486-5447
william.carmichael@health.ny.gov

Cheryl Brunner
Research Scientist, Bloodborne Viruses
Laboratory: STARHS
cheryl.brunner@health.ny.gov

6.3 Shipping Remnant Serum to the VRDL

The laboratory procedures for processing and shipping remnant specimen to the VRDL, as well as the VRDL Laboratory Shipping Manifest (Excel spreadsheet), are available at: <http://www.cdph.ca.gov/programs/aids/Pages/OAHISResLabs.aspx>

6.3.1 Contacts for VRDL:

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

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

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7 Appendix A: Tips for Improving TTH Data Collection

The following are recommendations and suggestions for collecting Testing and Treatment Histories (TTH) for newly diagnosed HIV cases:

1. Discuss the collection of TTH and the importance of collecting this information at each surveillance staff meeting.
2. Adopt a policy of considering ACRFs to be incomplete if they do not include complete TTH information.
3. Review a firm definition for each of the elements on the TTH form. Once staff has become familiar with the definitions for each element, they can develop a routine when reviewing medical records that will lead to improved identification of prior testing histories.
4. Medical records tend to be the most fruitful for identifying prior testing histories. When requesting to review medical records do not only review the electronic medical record, also ask to review paper medical records (the record prior to the electronic medical record), because important information sometimes gets lost in the transcription process.
5. When information for TTH elements is not readily available in medical records, ask the staff nurses about previous testing histories of the cases, particularly at facilities with large HIV/AIDS caseloads. They develop a rapport with their clients/members and often know a great deal of information that may not be readily available to the surveillance coordinators in the medical records.
6. Check with county-associated HIV testing sites and review the information on their Client Information Forms (CIF) to improve the collection of TTH information. Frequently you can find prior testing histories, including information about prior negative HIV tests, on the CIF.
7. At care and treatment facilities with a social worker on staff, it may be helpful to also review the social worker's notes, as prior testing histories of the cases may be included in his or her encounter documentation.
8. Establish a relationship with the individuals who work with LEO (Local Evaluation Online) at local testing sites, as this system also contains information about prior testing histories.

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8 Appendix B: Excerpt from the Guide to Accession Number Identification from Common Laboratories

Lab CLIA	Lab name	City	Typical accession number				Comments
			Field name	Format	Starting digit(s)	Examples	
05D0571200	Laboratory Corporation of America (LabCorp)	San Diego	Accession Number Specimen Number	11 digit number	001-366 (DDD Julian specimen collection date)	00123456789 01234567890 12345678900	Only includes leading zeros for Julian dates in the beginning of the year. Accession numbers are recycled . The Julian dates are used as the first 3 numbers of the accession number, it starts over at the first of each year.
05D0642827	Quest Diagnostics	West Hills	Accession Number Specimen Number	9 digits starting with 2 letters; then 6 numbers; ending with a D, E, X, A, B, F, W, C, Y, V, G, U	Two letters, usually EN or WD	WD123456D EN012345G EN123456W	Only the first two digits and the last digit will be letters. Accession numbers are recycled .
05D1066369	Los Angeles County Public Health Laboratory	Downey	Accession Number	4-6 digits starting with a letter	M, T, W, H, F, S, X (day of week specimen received)	W123 H1234 M12345	Accession numbers consist of computer generated values. Accession Numbers are recycled .
05D0698400	Southern CA Kaiser Permanente	North Hollywood	Accession Number Batch Number	19 digits, starting with a	C0000220 (facility ID);	C000022014169123456	Always include all zeros that

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	Med Group Lab			'C' then 18 numbers	then 5-digit Julian date specimen received (YYDDD), then 6 numbers		follow the 'C' Usually 12 digits. All numerical and end with a letter (A,B,C,D). Accession Numbers are not recycled.
05D0543401	LAC & USC Medical Center Main Lab	Los Angeles	Accession Number	6 digits starting with a letter.	M, T, W, H, F, S, X (day of week specimen received)	W123456 M123456	Accession numbers consist of computer generated values. Accession Numbers are recycled.
05D0716369	San Francisco Gen Hospital Clinical Lab	San Francisco	Accession Number	3-6 digits starting with a letter	M, T, W, H, F, S, X (day of week specimen received)	M12 T123 F1234 T12345 M12345	Accession numbers consist of computer generated values. Accession Numbers are recycled monthly.
05D0939429	Quest Diagnostics	West Hills	Accession Number Specimen Number	9 digits starting with 2 letters; then 6 numbers; ending with a D, E, X, A, B, F, W, C, Y, V, G, U	Two letters, usually EN or WD	WD123456D EN012345G EN123456W	Only the first two digits and the last digit will be letters. Accession numbers are recycled.

For guidance identifying the accession numbers on laboratory reports for other common laboratories, see the Guide to Accession Number Identification from Common Laboratories at: <http://www.cdph.ca.gov/programs/aids/Documents/GuideToAccessionNumberIdentificationFromCommonLaboratories2.pdf>