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# HIV INCIDENCE SURVEILLANCE (HIS) USING STARHS

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## What is STARHS?

**STARHS:** Serologic Testing Algorithm for Recent HIV Seroconversion.

**Test:** BED HIV-1 Capture EIA (Calypte®).

**Principle:** Ratio of HIV IgG to total IgG increases with time following HIV infection.

**Test results:** STARHS applied to HIV diagnostic specimens can determine whether an HIV infection is recent (in the past six months) or long-standing.

**Use:** The Food and Drug Administration has approved STARHS (BED HIV-1) for population-based HIV incidence estimation only. The BED is not a diagnostic test. Results cannot be returned to patients/providers or used for clinical case management.

## Goals of HIS

1. Expand routine HIV/AIDS case surveillance to include STARHS testing;
2. Link STARHS results to surveillance data to identify current trends in HIV transmission;
3. Estimate the number of new HIV infections per year in California and nationwide; and
4. Target prevention programs to those who are most susceptible to HIV infection today.

## Why track new HIV infections?

- New biomedical technology, STARHS, makes it possible to distinguish between recent and long-term HIV infections.
- Since more people have been getting tested, an increase in the number of HIV diagnoses no longer indicates an increase in the number of new infections.
- Furthermore, existing HIV surveillance data only provide the date of HIV diagnosis. This date may be well past the actual date of infection.
- An estimate of the number of new infections will more accurately describe the epidemic in “real time.”
- A more accurate description of the epidemic will help local health agencies target prevention programs to the populations at greatest risk.
- The Centers for Disease Control and Prevention (CDC) has recommended enhancing HIV surveillance using STARHS.

## What is needed from public and private laboratories statewide?

- All residual HIV-positive serum specimens confirmed by Western Blot/Immunofluorescence Assay testing.
- No specimen processing or re-aliquoting necessary – ship leftover specimens as they are.
- Label with specimen accession number.
- Schedule routine shipments to the California Department of Health Services, Viral and Rickettsial Disease Laboratory (VRDL).

**\*All packaging and shipping costs are covered through VRDL\***



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### California Commercial, Private, Hospital, and Public Health Laboratories Providing HIV Diagnostic Specimens for STARHS

Participating Lab	Start Date	Specimens Shipped to:	Specimens / Yr
Los Angeles County PHL	March 2005	California state PHL	500
Orange County PHL	March 2005	California state PHL	110
Riverside County PHL	March 2005	California state PHL	50
San Francisco County PHL	March 2005	California state PHL	300
Contra Costa County PHL	April 2006	California state PHL	50
Fresno County PHL	April 2006	California state PHL	50
Sacramento County PHL	April 2006	California state PHL	30
Santa Clara County PHL	April 2006	California state PHL	35
San Diego County PHL	May 2006	California state PHL	325
Kern County PHL	June 2006	California state PHL	50
Alameda County PHL	August 2006	California state PHL	125
San Francisco General Hospital	August 2006	California state PHL	475
San Joaquin County PHL	December 2007	California state PHL	20
San Bernardino County PHL	January 2008	California state PHL	225
LabCorp San Diego	March 2007	California state PHL	3,000
Quest Nichols San Juan Capistrano	May 2007	CDC STARHS Lab	3,600
Quest Diagnostics West Hills	November 2007	California state PHL	3,600
Specialty Laboratories, Inc.	February 2008	CDC STARHS Lab	150
TPMG Regional Laboratory	April 2008	California state PHL	960
Focus Technologies	July 2008	California state PHL	40

#### Participating Laboratories Nationally

- Major national commercial laboratories including ARUP, LabCorp, and Specialty
- Twenty-five state and municipal public health labs covering 85 percent of the HIV/AIDS epidemic in the United States.

#### Health Insurance Portability and Accountability Act (HIPAA) Exemption

- HIV incidence surveillance using STARHS is a permitted disclosure to public health authorities under HIPAA.
- Submission of remnant HIV diagnostic serum specimens by HIV testing laboratories for the purpose of tracking new HIV infections under CDC protocols is a public health disease surveillance activity exempt from HIPAA.
- HIPAA Privacy Rule does not restrict ongoing HIV/AIDS surveillance practices, including access to health information for the purpose of disease surveillance, investigation, or intervention.