Revised Recommendations for HIV Testing in Health-Care Settings (MMWR September 2006)

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Presentation Outline

- HIV epidemic in LAC
- Events leading up to the revised CDC HIV testing recommendations
  - Rationale for increased testing
- CDC's recommendations, 2006
- Implications for California
  - Assembly Bill 682
- HIV reporting
- HIV Testing
- HIV Resources

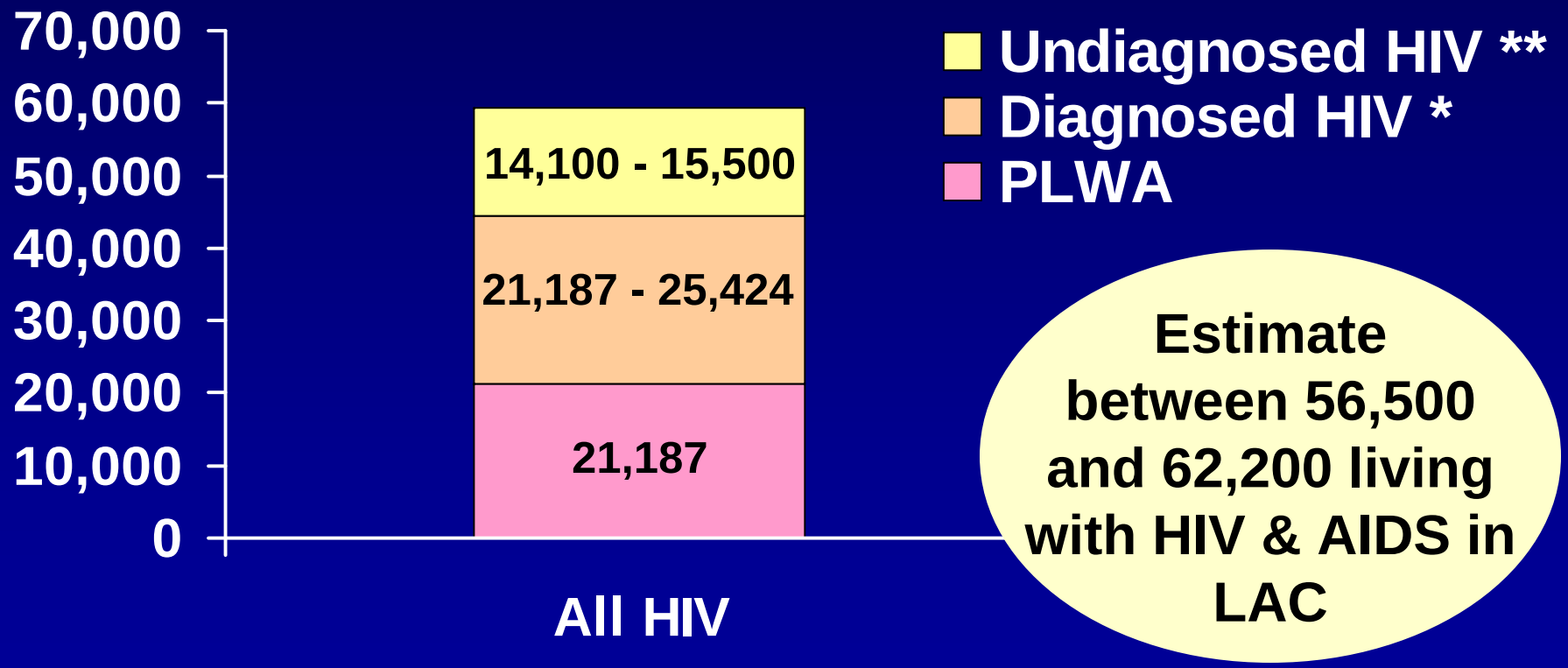
The Issue

September 22, 2006 – **Routine opt-out** HIV testing was recommended by the CDC for persons **13-64** years of age in **all healthcare settings**

CDC-MMWR, September 22, 2006 / 55(RR14);1-17

HIV Epidemic

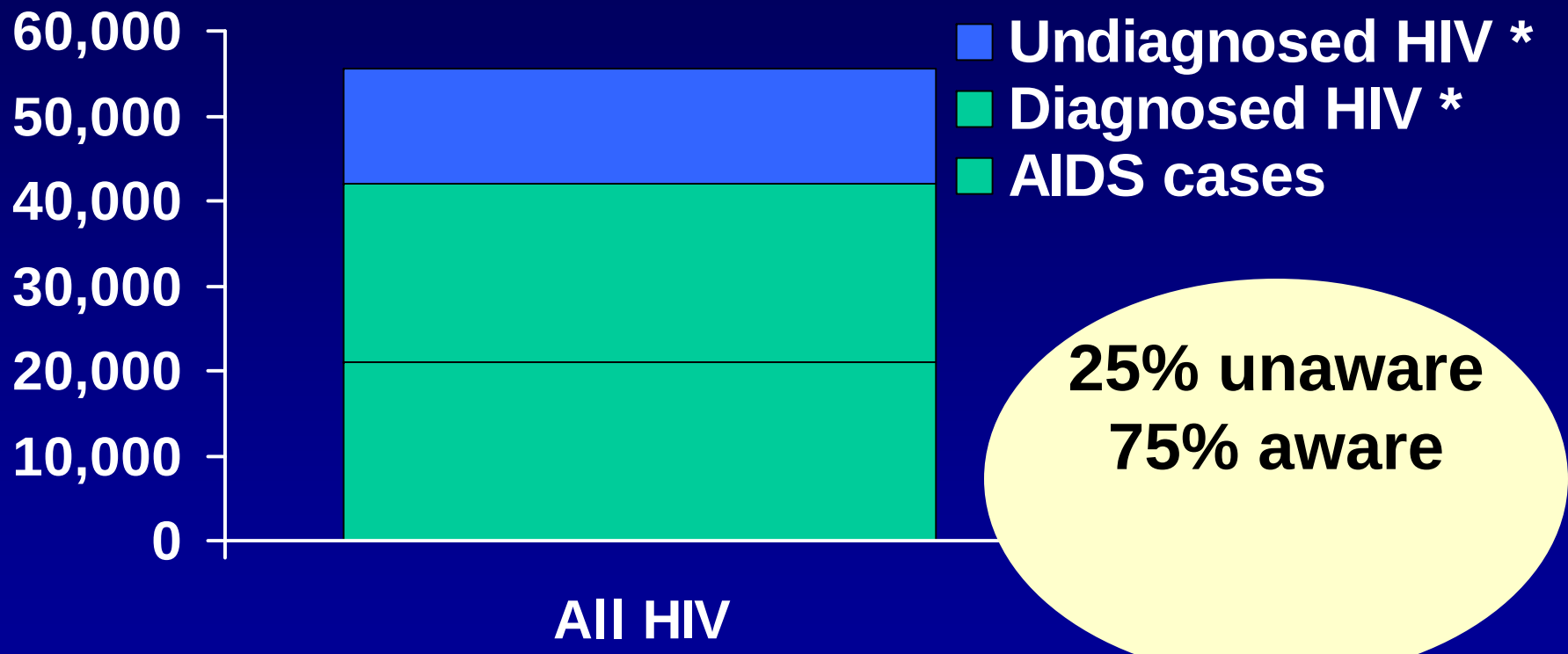
Estimated Number of Persons Living with HIV/AIDS in LAC as of April 2007



*Estimates based on a range of 1:1 to 1.2:1 ratio of HIV (non-AIDS) to AIDS cases

**Estimates based on CDC's estimate that 25% are unaware of their HIV infection (Glynn, 2005)

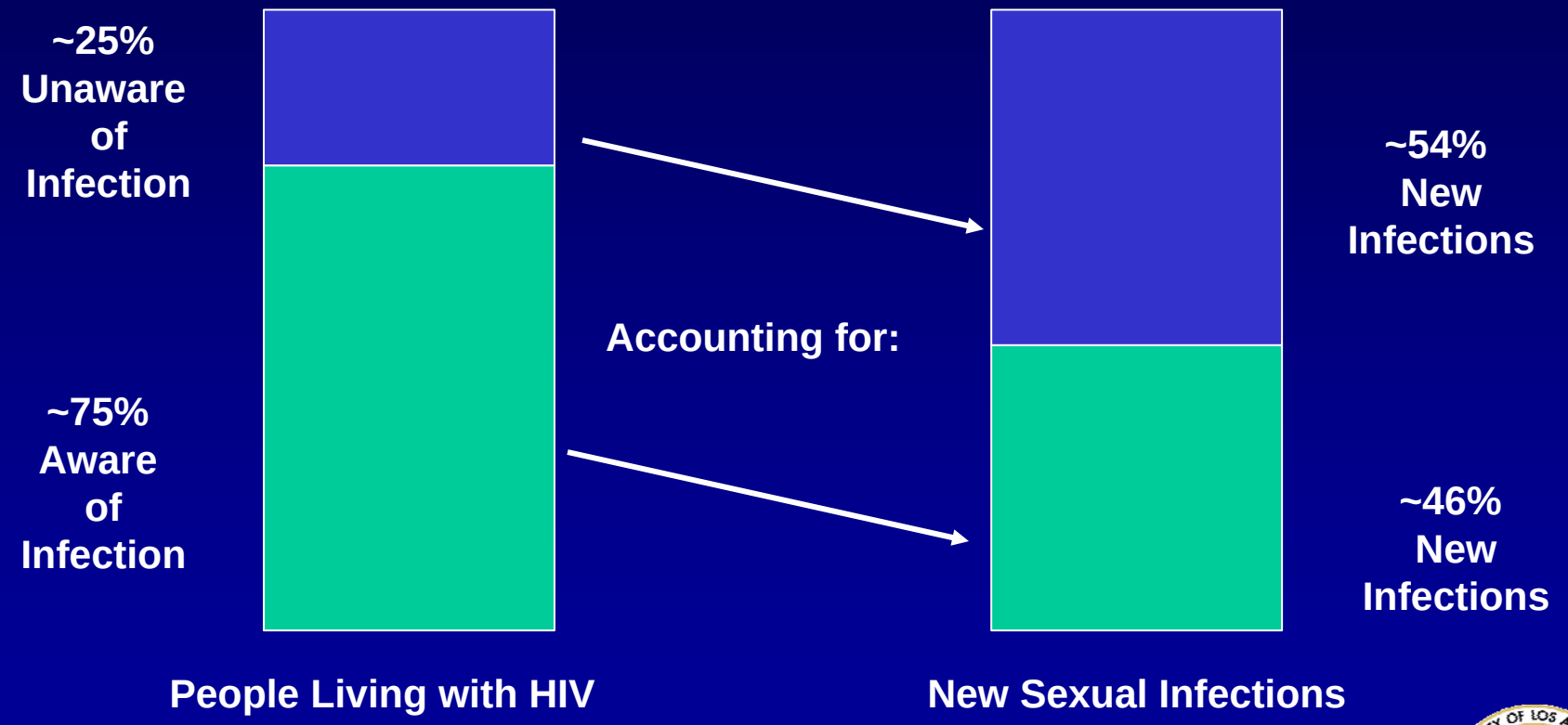
Average Estimated Number of Persons Living with HIV/AIDS in LAC



25% unaware
75% aware

•Estimates from LAC HIV Epidemiology Program and CDC, as of July 1, 2006

Awareness of Serostatus Among People with HIV and Estimates of Transmission



Marks, et al, AIDS 2006;20:1447-50

Los Angeles County Department of Public Health
HIV Epidemiology Program
AIDS Semi-annual Surveillance Summary, July-December 2007

World (WHO data) Cumulative Cases	**34-46 million**
Los Angeles County[1]	
New cases reported this period	777
Deaths reported this period	153
Cumulative cases	53,198
Cumulative deaths	30,743
Living cases	22,455
California[2]	
Cumulative cases	147,821
Cumulative deaths	84,532
Living cases	63,289
United States[3]	
Cumulative cases	984,155
Cumulative deaths	550,394
Living cases	433,761

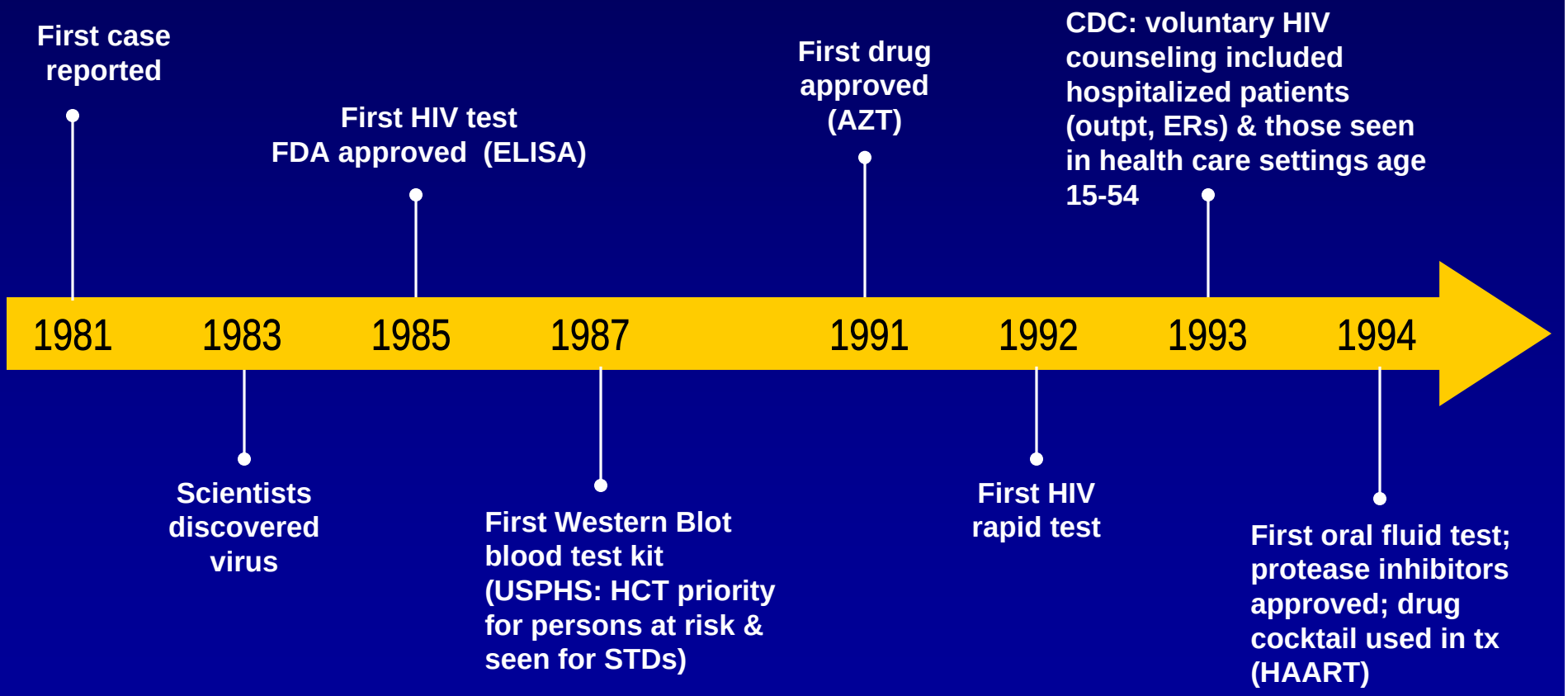
[1] Includes all cases reported to the HIV Epidemiology Program as of December 31, 2007.
[2] California Office of AIDS. AIDS Surveillance Report for California, December 31, 2007.
[3] Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report, 2005. Vol. 17. Rev ed. Atlanta The figures do not represent an enumeration of actual cases for this category. Rather, it is a point estimate of cases for this category that has been adjusted for reporting delay, but not adjusted for incomplete reporting.

www.lapublichealth.org/hiv

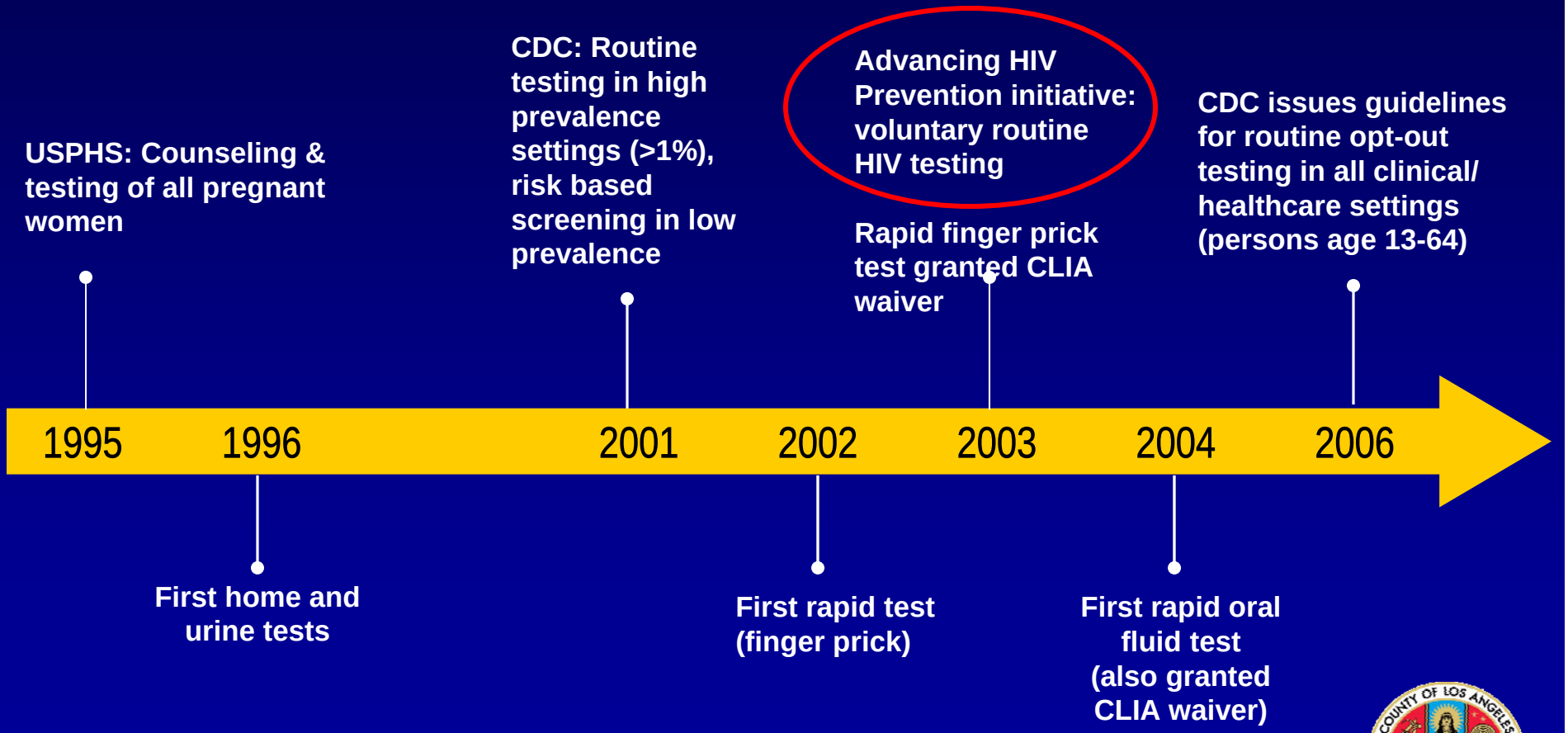
Events Leading up to the Revised CDC HIV Testing Recommendations

Rationale for Increased Testing

History of HIV Testing Recommendations



History of HIV Testing Recommendations



Source of HIV Tests and Positive Tests

	HIV tests*	HIV+ tests**
Private doctor/HMO	44%	17%
Hospital, ED, Outpatient	22%	27%
Community Clinic (Public)	9%	21%
HIV Counseling/testing	5%	9%
Correctional Facility	0.6%	5%
STD Clinic	0.1%	6%
Drug Treatment Clinic	0.7%	2%

*National Health Interview Survey, 2002
**Suppl. To HIV/AIDS Surveillance, 2000-2003

Rationale for Routine Testing

- 2003 [Advancing HIV Prevention (AHP)] recommendations did not have their intended effect and were not implemented
  - Only a fraction of ED STD clients screened
  - Stable number of new HIV cases since 1998
    - 2000 in LAC
  - Only 38-44% persons have tested (2002)
  - 25% still unaware of HIV status

Rationale: Reduced Effectiveness of Risk Based Screening

- Increased rates of new HIV infections in groups that do not belong to high risk groups
  - Persons <20 years
  - Women
  - Racial and ethnic minorities
  - Rural residents
  - Heterosexual men and women

Rationale: Late Testers

- Minimal decline in late testers (within 12 months of AIDS diagnosis)

1990-1992	51% positives tested <1 yr before AIDS
1993-2004	39% positives tested <1yr before AIDS

MMWR June 27, 2003

Rationale: Late Testers

- Characteristics of Late Testers
  - Younger (18-29)
  - Heterosexual
  - Less educated
  - African American or Hispanic

Rationale: Opt Out Successes

- Routine testing opt out
  - Pregnant women has reduced perinatal transmission in US <2%
  - Increases testing rates and reduces stigma associated with HIV testing
  - Patients report less anxiety about testing

Revised Recommendations

CDC Recommendation

September 22, 2006 – **Routine opt-out** HIV testing in **all healthcare settings** is recommended for persons that are **13-64** years

Routine testing – offered like other screening tests (pap smears, mammograms etc)

Opt out screening – patient notified of test; test performed unless patient declines

Objectives of the Recommendations

- Increase HIV screening
- Foster early detection of HIV infection
- Identify & counsel patients with unrecognized HIV infection
- Improve linkage to HIV care/counseling
- Further reduce perinatal HIV transmission

Target Population

- Individuals seen in health-care settings only
  - ER, urgent care, inpatient units, substance abuse treatment clinics, public health & community clinics, correctional healthcare facilities
- Recommendations **do not** impact non-clinical settings
  - Mobile vans, community-based organizations & other non-medical care settings designed to provide anonymous or confidential HIV tests and prevention interventions

Target Population

- Persons 13-64 years
- Patients initiating TB Therapy
  (10-30% of TB patients are HIV+)
- Patients seeking STD treatment
  (60% of syphilis cases are HIV+)
  - During each new complaint
  - Suspected of behaviors to put them at risk

Repeat Screening

- High risk persons screened annually
  - IVDU and their partners
  - Exchange of sex for money or drugs
  - Sex partners of HIV positive
  - MSM / heterosexuals or their partners who have more than one partner since last HIV test
- Before initiation of new sexual relationship

Major Changes in Recommendations

- Includes non-acute healthcare settings
- Opt-out procedure
  - Patient notified; testing done unless pt. declines
  - General consent for medical services is adequate (separate HIV consent not needed)
- Annual screening for patients at risk
- Prevention & counseling not required

Changes- Pregnant Women

- HIV should be included in routine perinatal panel of tests
- True opt-out testing
- Separate written consent **not** needed
- Repeat screening during the 3rd trimester in certain cases

Testing Later in Pregnancy

- Certain jurisdictions with high incidence
- Facilities with 1 HIV infected woman/1,000
- Women known to be at risk
  - IVDU and partners, exchange for money, partners of HIV infected, women with more than one partner
- Women with symptoms of HIV

Implications for Stakeholders

- Patients
- Providers
- Payors
- Local / State / National

Implications for California Assembly Bill 682

Implications: California State

Historical Perspective

- *Incorporation of consent for an HIV test into a general medical consent form. Separate written consent for HIV testing not recommended*

  - CA state law previously required specific written consent for HIV testing; general consent for medical care not sufficient (except in case of a treating physician & surgeon)
  - Physicians could obtain informed consent (oral or written)

    Health & Safety (H&S) Code Section 120990

CDHS Guidance Memo, 1/10/2007

Implications: California State

- *HIV testing of people at high risk for HIV infection at least once a year*
  - No current mandates on the number of times a person should be tested for HIV
  - Recommendation may be implemented as deemed appropriate by the health care provider

CDHS Guidance Memo, 1/10/2007

Implications: California State

- *Prevention & counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health care settings*
  - **No requirements under California law for HIV prevention counseling except in two circumstances: (1) partner notification – *H&S Code Section 121015*; and (2) prenatal/intra-partum care of a pregnant woman – *H&S Code Section 125090***
  - **DHS-OA funded HIV C&T sites currently require face-to-face counseling session to obtain reimbursement from OA for HIV testing**

CDHS Guidance Memo, 1/10/2007

Implications: California

- *Inclusion of HIV screening in routine panel of prenatal screening tests for all pregnant women, unless patient declines (opt-out screening)*
  - CA law now aligns with this recommendation
  - Pregnant woman does not need to sign specific form agreeing to the test; form filed in patient's medical records (which was required under previous guidance)

CDHS Guidance Memo, 1/10/2007

AB 682 (Berg, Garcia, Huffman), the California Routine HIV Screening signed 10/12/07

- Bi-Partisan Bill, sponsored by:
  - AIDS Healthcare Foundation
  - California Medical Association
  - Health Officers Association California
- Cleared the two chambers of the California Legislature in 9/07 with only a single vote against it
- Signed by Governor Schwarzenegger 10/07
- AB 682 will serve to modernize California law

- **Effective January 1, 2008,** a separate consent for HIV testing is not required.
- General consent for medical treatment is now sufficient for medical procedures including HIV testing.
- Patients must be informed about inclusion of HIV testing and can “opt out”
- AB 682 clears obstacles for the full implementation of CDC’s new opt-out HIV testing guidelines

Next Steps

- Administration
  - Update policies and procedures in the public and private sector
- Education and Training
  - Train public and private sector on new laws and CDC recommendations
- Care and Treatment
  - Increase capacity
  - Anticipate new types of clients

Next Steps

- Evaluation
  - Baseline and adherence to recommendations
  - Outcomes of recommendations
- Prevention
  - Acknowledge changing dynamics of HCT
  - Push alternative testing models in the non health-care settings
    - **Consider emphasis on post-test counseling and reduction of pre-test counseling**

Summary

- HIV screening is recommended for all patients in all health care settings after the patient is notified that testing will be performed unless the patient declines
- Separate written consent for HIV testing should not be required
- Prevention counseling should not be required as a part of HIV screening programs
- Prevention counseling is strongly encouraged for persons a high behavioral risk for HIV

Summary contd.

- HIV test results should be provided in the same manner as results of other diagnostic and screening tests
- HIV negative results may be conveyed without direct personal contact between patient and provider

Summary contd.

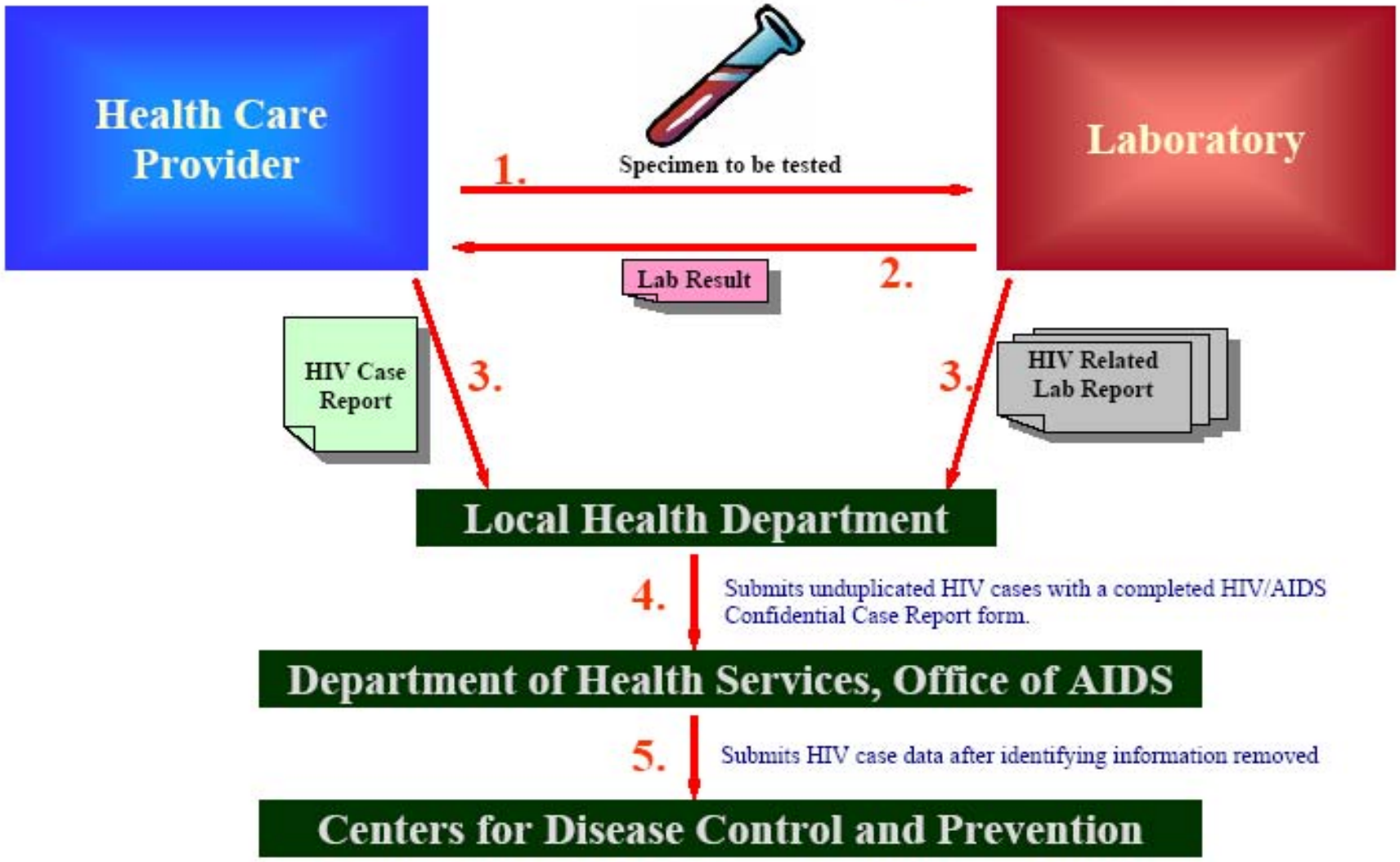
- HIV positive results should be communicated confidentially through personal contact by a clinician, nurse or counselor
  - Ideally should be face-to-face
  - Neither the law nor guidelines preclude alternative means of communication
  - Phone results policy
- Efforts to normalize HIV testing in our clinics + increase capacity to evaluate and test patients for STD/HIV

HIV Test Reporting

California HIV/AIDS Reporting Laws

- 1983 AIDS added to California State list of reportable diseases and conditions
  - CA Code of Regs: Title 17, Section 2500
- 2002 California starts code-based reporting and laboratory-based reporting of HIV
- 2006 California law signed by Governor makes HIV reporting by name mandatory
  - CCR Title 17 Sections 2641.5-2543.20
  - Health and Safety Code Section 121022

California Name Based HIV Reporting System



Dual Reporting System: Labs

- Laboratory Reports HIV tests to Provider & Local Health Department (HIV EPI Prgm)
  - Confirmed HIV-Antibody Tests
  - Viral Load
  - Other HIV diagnostic test
- *HIV test slip sent to lab must include: full client name, gender, DOB, provider name and address*

Dual Reporting System: Providers

- *For confirmed positive HIV test*, Provider must provide within 7 days to HIV EPI a Case Report Form, including:
  - Full client name
  - DOB
  - Address
  - *Full* Social Security Number
  - Gender
  - Race/ethnicity
  - Mode of exposure

Reporting Information

HIV Epidemiology Program

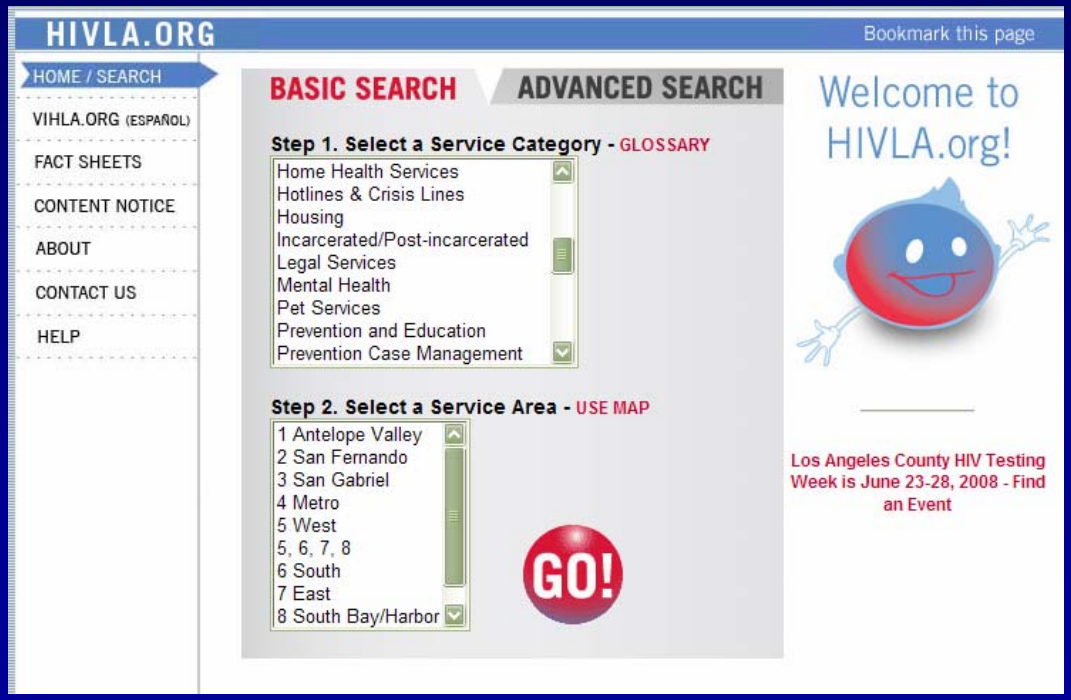
Phone 213 351-8516 / 213-351-8190

www.lapublichealth.org/hiv

600 S. Commonwealth Avenue
Suite 1920
Los Angeles, CA 90005

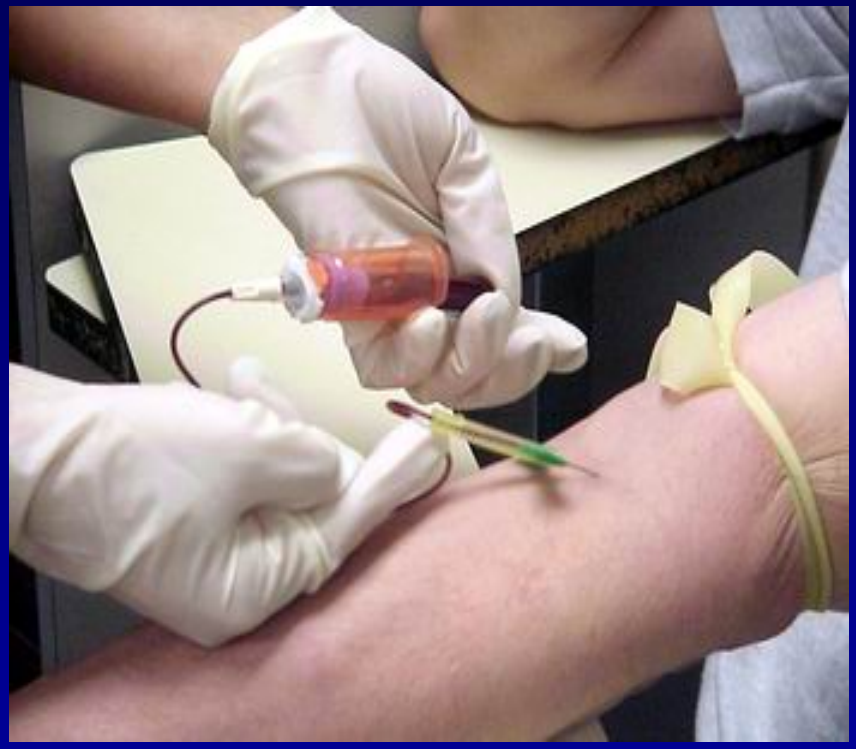
HIV Resources

http://www.hivla.org/search.cfm



HIV Testing

Traditional HIV Testing



1985 FDA approved HIV test

- **Blood draw**
- **Elisa-antibody**
- **Small tube of blood**
- **Western blot confirmation**
- **Results in 4-10 days**
- **Pre-test and post-test counseling**

FDA approved *CLIA-waived* rapid HIV tests available for use in the US

Rapid HIV Test	Specimen Type	Sensitivity	Specificity	Manufacturer
OraQuick Advance Rapid	Oral fluid	99.3%	99.8%	OraSure Technologies, Inc.
HIV-1/2 Antibody Test	Whole blood (fingerstick or venipuncture)	99.6%	100%	
Clearview HIV 1/2 Stat-Pak	Whole blood (fingerstick or venipuncture)	99.7%	99.9%	Inverness Medical Professional Diagnostics
Clearview HIV 1/2 Complete	Whole blood (fingerstick or venipuncture)	99.7%	99.9%	Inverness Medical Professional Diagnostics
Uni-Gold Recombigen HIV	Whole blood (fingerstick or venipuncture)	100%	99.7%	Trinity Biotech

Obtain finger stick specimen…

CDC
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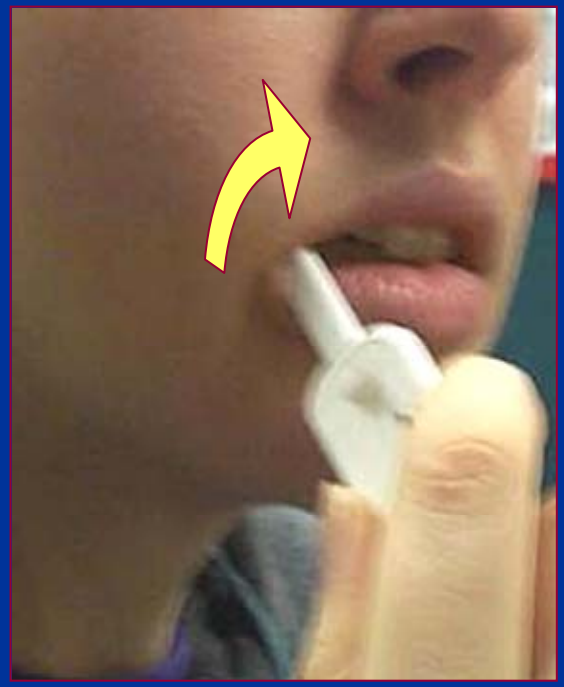


Collect oral fluid specimens by swabbing gums with test device

CDC
Centers for Disease Control and Prevention

Insert device; test develops in 20 minutes

CDC
Centers for Disease Control and Prevention

Thank You

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