

## ***HIV Testing in Health Care Settings: Implementing the CDC Recommendations for Routine Testing in Florida***



USF Center for HIV Education and Research  
University of South Florida



Florida Department of Health  
Bureau of HIV/AIDS



**Florida/Caribbean AIDS Education and Training Center**

## **Presentation Outline**

- The Epidemiology of HIV/AIDS
- Clinical Signs and Symptoms
- HIV Testing Trends
- CDC's Revised Recommendations for HIV Testing
- Legal Issues
- Practical Issues
- Summary



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## HIV/AIDS in the U.S.

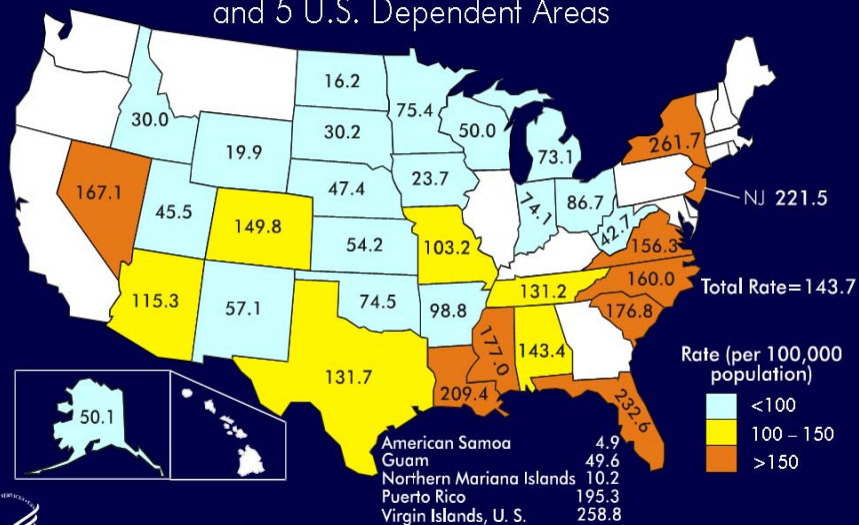
- An estimated 1,039,000 to 1,185,000 persons are living with HIV/AIDS
- 56,300 new HIV infections annually
  - 73% among males
  - 45% among African Americans
  - 34% among individuals ages 13-29



CDC

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Estimated Prevalence Rates for Adults and Adolescents Living with HIV Infection (not AIDS), 2006—33 States and 5 U.S. Dependent Areas



## HIV in Florida, 2007

- An estimated 125,000 Floridians are currently thought to be HIV positive
- 6,071 HIV cases were reported in 2007
- Ranked #2 in the U.S. for new cases among women and children
- HIV/AIDS is the leading cause of death among African Americans ages 25 - 44

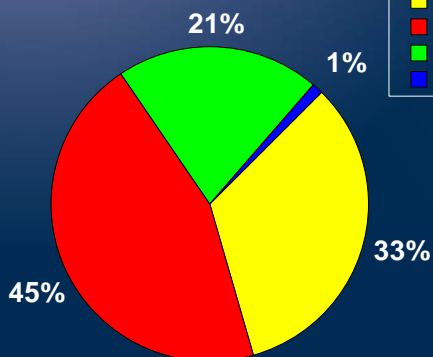


Florida Department of Health (DOH)

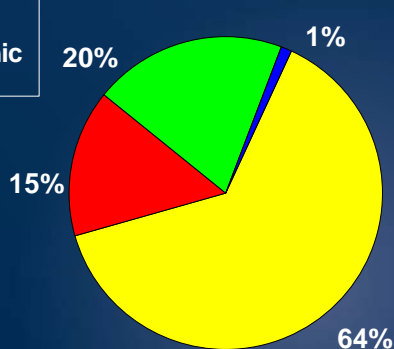
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## HIV Cases by Ethnicity Compared to FL Population Estimates

Reported HIV Cases in 2007  
(N=6,071)

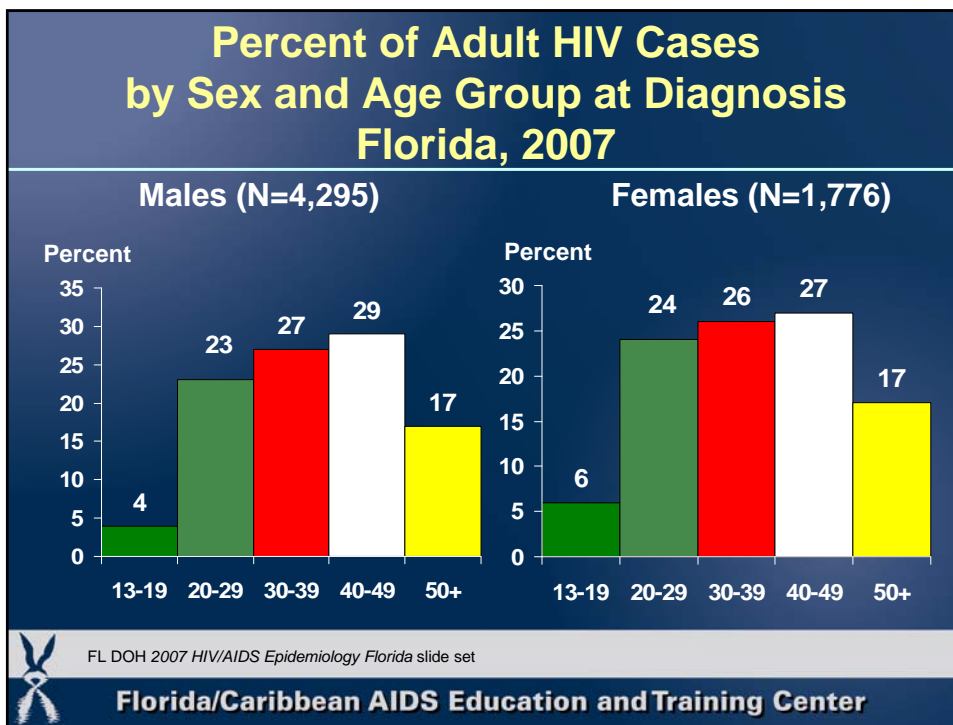
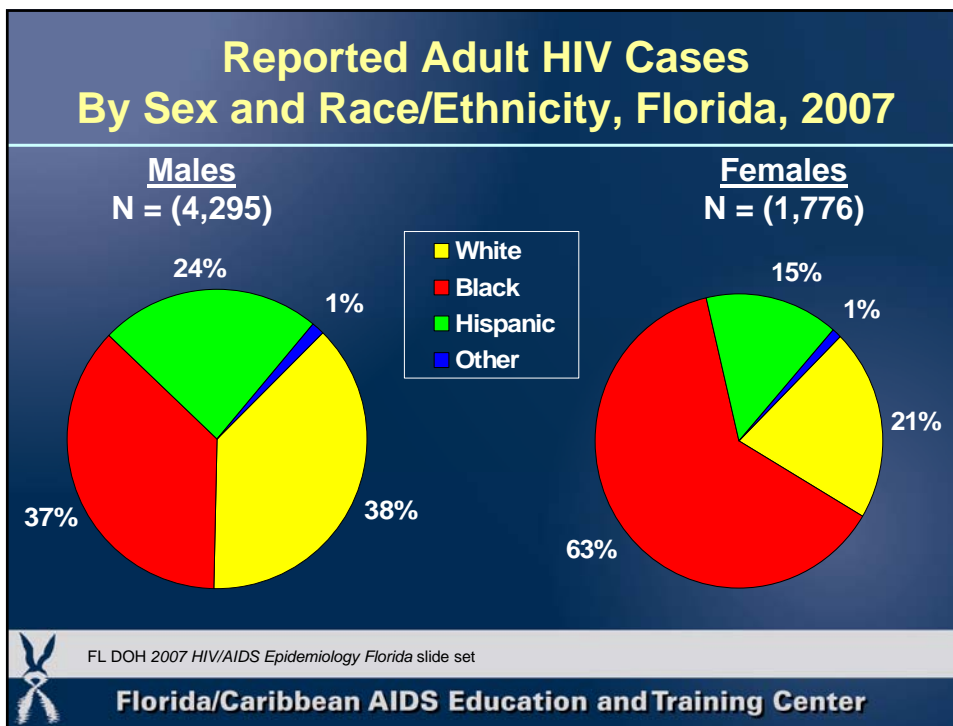


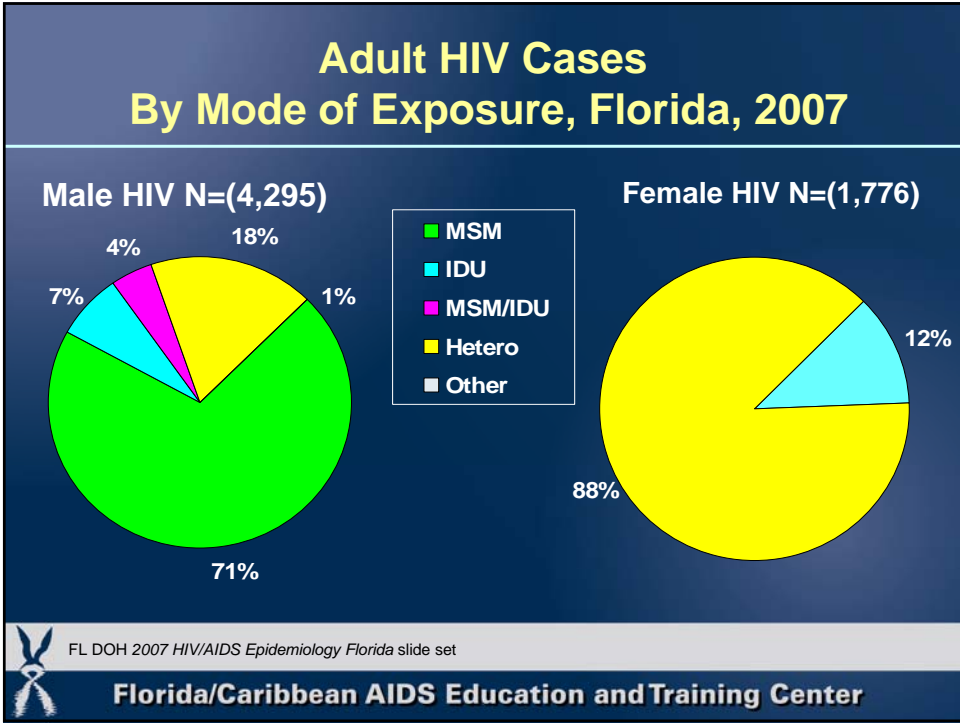
2007 Florida Population Estimates\*  
(N=15,793,585)



FL DOH 2007 HIV/AIDS Epidemiology Florida slide set

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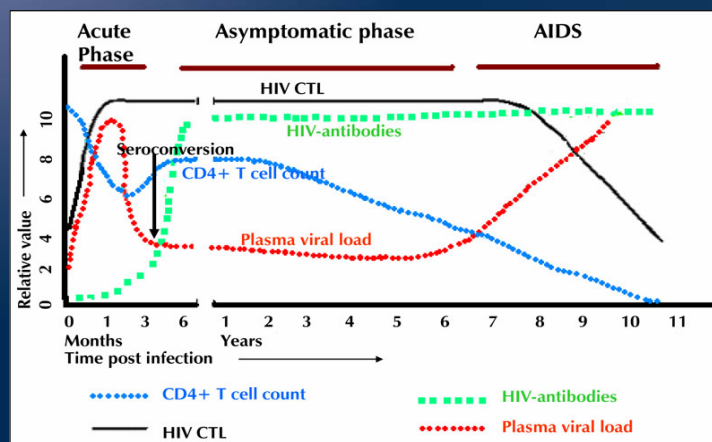




## HIV Infection: Clinical Signs and Symptoms

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## Immunological and Virological Events in Natural Course of HIV Infection



WHO, 2007

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## Stages of HIV Infection

### Acute Phase (Window Period)

- Surge of HIV viremia & loss of CD4s (2-3 weeks)
- Immune response is generated to help control virus multiplication (seroconversion)
- Seroconversion is often accompanied by a short flu-like illness
- Time from infection to appearance of anti-HIV antibodies (usually 3-6 weeks, but can take up to 6 months)
- HIV antibody test done before seroconversion is complete may not be positive



WHO, 2007

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## Stages of HIV Infection

### Asymptomatic Stage

- Clinical latent period typically lasts 5-8 years
- No major symptoms
- HIV viral load drops to lower level & remains stable
- CD4s are being destroyed
- HIV antibody test will show positive



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## Stages of HIV Infection

### Causes of immune system damage by HIV:

- Lymph nodes & lymph tissues damaged by years of activity
- Possible mutation of HIV virus leading to more pathogenic type
- Immune system unable to keep replacing CD4 cells that are lost
- Initial symptoms are mild but worsen with deterioration of the immune system



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## AIDS

- AIDS diagnosis confirmed if a person with HIV develops one or more of a specific number of severe opportunistic infections or cancers
- May also be diagnosed with AIDS if patients have a very low count of CD4 cells (T helper cells) in their blood (CD4 <200 or percentage < 14%)
- AIDS diagnosis NEVER goes away even when the patient's condition improves and no longer meets the criteria



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## HIV Testing



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## U.S. HIV Testing Trends

- 38% - 44% of adults age 18-64 have ever been tested
- 16 - 22 million persons age 18-64 tested annually

BUT:

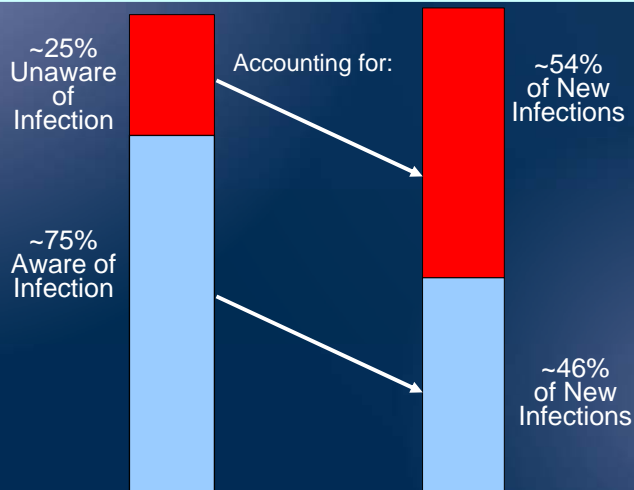
- 24% - 27% of all HIV + persons (or 252,000 - 312,000 individuals) are unaware of their status



Branson, B. *Revised Recommendations for HIV Testing in Health Care Settings in the U.S.* presentation

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## Awareness of Serostatus Among People with HIV and Estimates of Transmission



Marks, et al. (2006)

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## Late HIV Testing is Common

- Among 4,127 persons with AIDS\*, 45% were first diagnosed HIV-positive within 12 months of AIDS diagnosis ("late testers")
  - Late testers, compared to those tested early (>5 yrs before AIDS diagnosis) were more likely to be:
    - Younger (18 -29 yrs)
    - Heterosexual
    - Less educated
    - African American or Hispanic
- \*16 states



MMWR June 27, 2003

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## 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%



Branson, B. *Revised Recommendations for HIV Testing in Health Care Settings in the U.S.* presentation.

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## HIV Testing in Florida, 2007

- 324,934 HIV tests performed in Florida
- 5,041 were positive: overall positivity rate of 1.53%
- 58.1% of HIV tests performed on females: 0.85% positivity rate
- 40.4% of HIV tests performed on males: 2.47% positivity rate

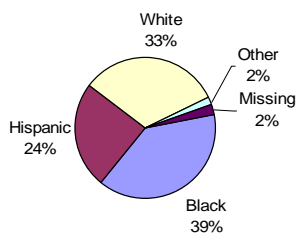


FL DOH

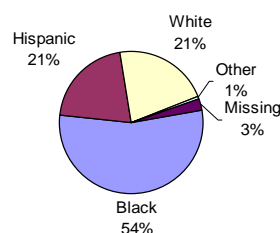
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## HIV Testing in Florida, 2007

**Total HIV Tests by Race/Ethnicity, N=330,145**



**Total HIV Positive Tests by Race/Ethnicity, N=5,041**



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## CDC Revised Recommendations For Adults, Adolescents, and Pregnant Women



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### Definitions

Routine Testing – HIV screening that is performed routinely during health care visits.

Screening – Performing an HIV test for all persons in a defined population.

Diagnostic Testing – Performing an HIV test for persons with clinical signs or symptoms consistent with HIV infection.

Rapid Testing – Testing with any of the six FDA approved rapid HIV tests that produce results in thirty minutes or less.



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## Definitions

Informed Consent – A process of communication between a patient and a provider through which the informed patient can either choose or decline to test.

Opt-in – Patients are provided pre-HIV test education then must specifically consent, either orally or in writing, to an HIV test.

Opt-out – Performing an HIV test after notifying a patient that the test is done routinely unless the patient declines. Assent is inferred unless the patient declines.



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## CDC Objectives: Routine Screening for HIV

- Increase HIV screening of patients, including pregnant women, in health care settings.
- Foster earlier detection of HIV infection.
- Identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services.
- Further reduce perinatal transmission of HIV in the United States.



CDC, 2006

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## Rationale for Routine HIV Testing

The effectiveness of using risk-based testing to identify HIV-infected persons has diminished due to increases in infection among:

- individuals ages < 20
- Individuals residing in non-metropolitan areas
- minorities
- heterosexual individuals who are unaware they are infected

Therefore, no specific population should be targeted for HIV testing.



CDC, 2006

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## CDC Revised Recommendations for Adults and Adolescents

- Routine, voluntary HIV screening for all persons 13 - 64 in health care settings, not based on risk.
- Repeat HIV screening of persons with known risk at least annually.
- Opt-out HIV screening with the opportunity to ask questions and the option to decline.
- Include HIV consent with general consent for care; separate signed informed consent not recommended.
- Prevention counseling in conjunction with HIV screening in health care settings is not required.



CDC, 2006

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## CDC Revised Recommendations for Adults and Adolescents

### Intended for all health care settings:

- Inpatient services
- Emergency Departments
- Urgent care clinics
- STD clinics
- TB clinics
- Public health clinics
- Community clinics
- Substance abuse treatment centers
- Correctional health facilities
- Primary care settings



CDC, 2006

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## Rapid HIV Testing

- Results in less than an hour, but a confirmatory test is required.
- Multiple FDA approved tests available.
- Promising strategy to expand HIV testing:
  - In labor and delivery, provides immediate test results for possible preventive measures to reduce mother-to-child transmission.
  - Option to reach populations who use the Emergency Department for healthcare.



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**FDA-Approved Rapid HIV Antibody Screening Tests**

February 4, 2008

	FDA Approval Received	Specimen Type	CLIA Category*	Sensitivity** (95% CI)	Specificity** (95% CI)	Manufacturer	Approved for HIV-2 Detection?	List Price Per Device <sup>^</sup>	External Controls
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	Nov 2002	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)	OraSure Technologies, Inc. <a href="http://www.orasure.com">www.orasure.com</a>	Yes	\$17.50	Sold Separately (\$25 each)
		Whole Blood (finger stick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)				
		Plasma	Moderate Complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)				
Uni-Gold Recombigen HIV	Dec 2003	Whole blood (fingerstick or venipuncture)	Waived	100% (99.5-100)	99.7% (99.0-100)	Trinity Biotech <a href="http://www.unigoldhiv.com">www.unigoldhiv.com</a>	No	\$15.75 \$8.00 <sup>-</sup>	Sold Separately (\$26.25 each)
		Serum & Plasma	Moderate Complexity	100% (99.5-100)	99.8% (99.3-100)				
Reveal G-3 Rapid HIV-1 Antibody Test	Apr 2003	Serum	Moderate Complexity	99.8% (99.2-100)	99.1% (98.8-99.4)	MedMira, Inc. <a href="http://www.medmira.com">www.medmira.com</a>	No	\$14.00	Included
		Plasma	Moderate Complexity	99.8% (99.0-100)	98.6% (98.4-98.8)				

<sup>-</sup> "Public health" price for public health programs that are recipients of CDC funds for expanded HIV testing

\* Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity

\*\* Sensitivity is the probability that the test result will be reactive if the specimen is a true positive, specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.

<sup>^</sup> Actual price may vary by purchasing agreements with manufacturers

Note: Trade names are for identification purposes only and do not imply endorsement. This information was compiled from package inserts and direct calls to manufacturers.



Prepared by Kali Stanger & Frances Margolin at HRET; Margaret Lampe, Jill Clark, and Bernard Branson at CDC.

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MultiSpot HIV-1/HIV-2 Rapid Test	Nov 2004	Serum	Moderate Complexity	100% (99.94-100)	99.93% (99.79-100)	BioRad Laboratories <a href="http://www.biorad.com">www.biorad.com</a>	Yes - differentiates HIV-1 from HIV-2	\$25.00	Included
		Plasma	Moderate Complexity	100% (99.94-100)	99.91% (99.77-100)				
Clearview HIV 1/2 STAT-PAK	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.9% (99.6-100)	Inverness Medical Professional Diagnostics <a href="http://www.invernessmedical.com">www.invernessmedical.com</a>	Yes	\$17.50 \$8.00 <sup>-</sup>	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				
Clearview COMPLETE HIV 1/2	May 2006	Whole Blood (finger stick or venipuncture)	Waived	99.7% (98.9-100)	99.90% (99.6-100)	Inverness Medical Professional Diagnostics <a href="http://www.invernessmedical.com">www.invernessmedical.com</a>	Yes	\$18.50 \$9.00 <sup>-</sup>	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				

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Prepared by Jeannette Lyons & Frances Margolin at HRET; Margaret Lampe, Jill Clark, and Bernard Branson at CDC.



## Rapid HIV Testing

- Sometimes results warrant caution
- Test may not identify newly-infected and late-stage infected individuals who fail to mount a response to the test antigen
- When clinical signs point to HIV infection, do not be deterred by a negative rapid test:
  - Do a confirmatory test
  - Measure viral load



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## CDC Recommendations and Legal Issues



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## CDC Revised Recommendations for Adults and Adolescents

- Recommendations should be implemented within the framework of existing state and agency regulations
- Private healthcare settings can adopt the CDC recommendations to do routine testing
- Florida Department of Health testing sites must provide:
  - Pre-test counseling and risk assessment
  - Signed informed consent
  - Post-test counseling



CDC, 2006; Florida DOH

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## Florida Law: HIV Testing

### Informed consent is always required:

- In the private sector: oral consent should be documented in the patient's medical record.
- Sites registered with the Department of Health: must have written consent.

### All Clients must be notified:

- Anonymous (no name used) testing is available.
- HIV is a reportable disease.
- Results are confidential.



Florida Statutes: s.381.004 HIV Testing

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## Florida Law: HIV Testing

### In addition, consent process can include:

- An HIV test is a test to determine if an individual is infected with the virus which causes AIDS;
- The potential uses and limitations of the test;
- The procedures to be followed; and
- HIV testing is voluntary and consent to be tested can be withdrawn at any time prior to testing.



Florida Statutes: s.381.004 HIV Testing

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## Florida Law: Testing Pregnant Women

If a pregnant woman presents at the Emergency Department after 12 weeks gestation with no prenatal care, the ED should refer her to the local county health department for the needed testing.

- The referral should be in writing.
- A copy shall be submitted to the Health Department having jurisdiction over the area in which the ED is located.



64D-3.042, Florida Administrative Code

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## Insurance Coverage of HIV Testing in Florida

- **Medicaid:** testing is covered under "medical screenings." For County Health Departments, clinic-based services including HIV/AIDS services will be reimbursed by Medicaid at the CHD's cost-based reimbursement rate and no prior authorization is required.
- **Private insurance plans:** coverage varies depending on the plan, but many should reimburse for physician-ordered or "routine screening" of patients for HIV.
- **H.R. 2137:** 'Routine HIV Screening Coverage Act of 2009' is currently under consideration at the national level



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## Insurance Coverage of HIV Testing in Florida

- Clients without insurance are responsible for payment, just like any other screening or treatment.
- However, local health departments charge a sliding fee for testing and some community-based organizations offer free testing
- Find a local testing site at: <http://www.hivtest.org/> or click on "Testing by County" on the Florida DOH Bureau of HIV/AIDS webpage:  
[http://www.doh.state.fl.us/Disease\\_ctrl/aids/index.html](http://www.doh.state.fl.us/Disease_ctrl/aids/index.html)



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## Practical Issues in HIV Testing: A Discussion



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## Contributing Factors to HIV Infection in your patients?

1. Sexual Risk Factors
2. Lack of Awareness of HIV Serostatus
3. Substance Use
4. Sexually Transmitted Infections
5. Denial
6. Stigma
7. Socioeconomic Conditions
8. Concurrent Relationships
9. Lack of Treatment Knowledge



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## If you are doing HIV testing, how many people do you test per month?

1. 0
2. 1-5
3. 6-10
4. >10



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## What do you see as the most significant barriers to HIV testing in your facility?

1. Lack of time
2. Lack of training
3. Lack of resources
4. Cost
5. Stigma
6. Confidentiality concerns
7. Consent form issues
8. Lack of risk factors
9. Patient refusal
10. Other?



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## Other Thoughts?

- What are your experiences with testing?
- Why should we expand routine HIV testing?
- Where do we go from here?



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## Summary

- There is an urgent need to increase the proportion of persons who are aware of their HIV-infection status.
- Many patients with HIV visit health care providers but their infection goes undetected.
- People tend to decrease their risk behaviors when they find out they are infected with HIV.
- HIV meets the criteria for screening, is cost effective, and successful treatment is available.



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## Resources

Florida Department of Health Bureau of HIV/AIDS and Hepatitis:  
[http://www.doh.state.fl.us/Disease\\_ctrl/aids/index.html](http://www.doh.state.fl.us/Disease_ctrl/aids/index.html)

Florida HIV/AIDS-related Information,  
 Community Referrals, and Supportive Telephone Counseling:

- Florida HIV/AIDS Hotline:  
 Monday – Friday, 8am – 9pm Saturday, 10:30am – 6:30pm
- English: 800-FLA-AIDS (800-352-2437)
- Spanish: 800-545-SIDA (800-545-7432)
- Haitian Creole: 800-AIDS-101 (800-243-7101)
- TYY: 888-503-7118



National Hotline for Provider and Patient Information and Resources:

- CDC STD/HIV/AIDS 24-hours/everyday Hotline:
- 800-CDC-INFO (800-232-4636)
- Available in English or Spanish
- TYY: 888-232-6348
- E-mail: [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov)



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## For Further Information, Training, and Technical Assistance

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 Tampa, FL 33612  
 (866) 352-2382  
<http://www.fcaetc.org>

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 resource materials to health care professionals throughout Florida,  
 Puerto Rico, and the U.S. Virgin Islands.*



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