

## ***HIV Testing in Health Care Settings: Implementing the CDC Recommendations for Routine Testing in Florida among Adolescent and Young Adult Populations***



USF Center for HIV Education and Research  
University of South Florida



**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.

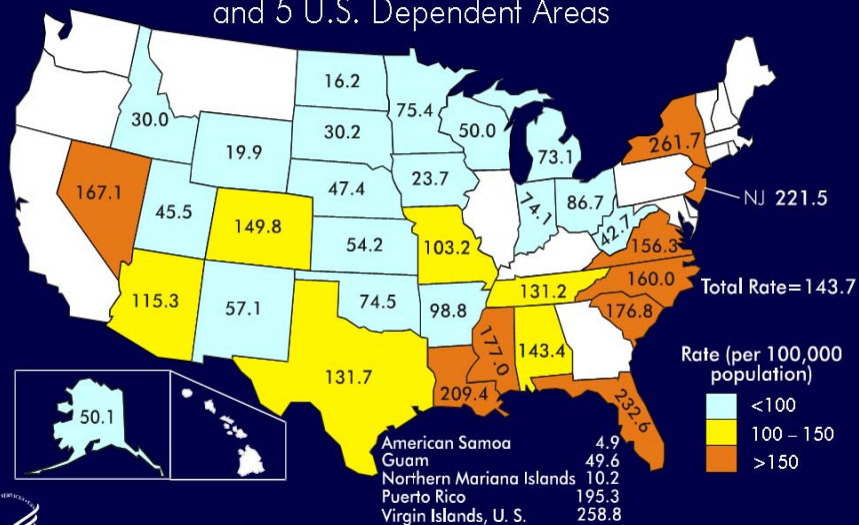
- An estimated 1,039,000 to 1,185,000 persons are living with HIV/AIDS
- ~56,500 young people (13-24) living with HIV/AIDS
- Young men who have sex with men, African Americans, and Hispanics disproportionately affected



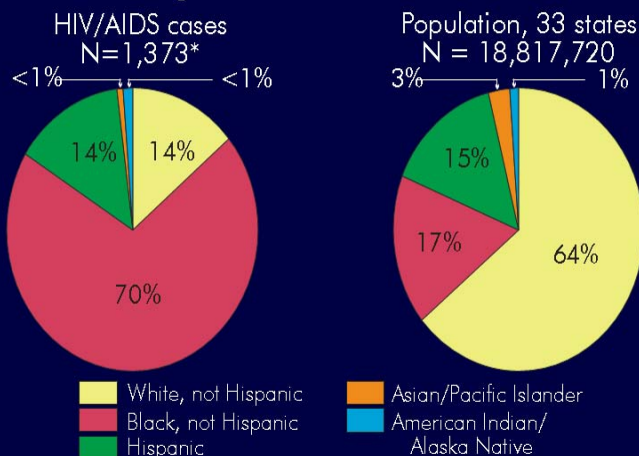
CDC

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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



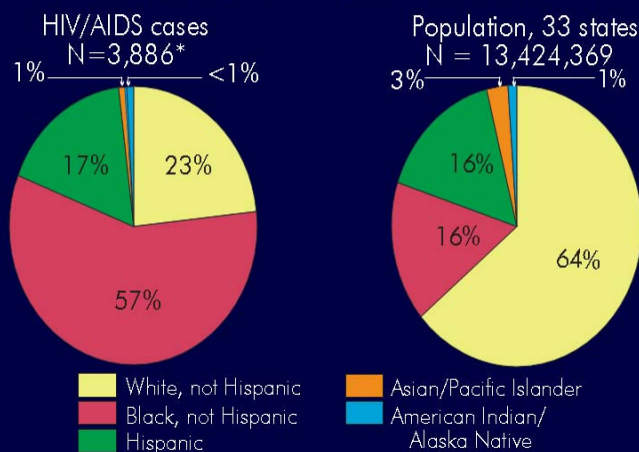
### Proportion of HIV/AIDS Cases and Population among Adolescents 13 to 19 Years of Age, by Race/Ethnicity Diagnosed in 2006—33 States



Note. Data include persons with a diagnosis of HIV infection regardless of their AIDS status at diagnosis. Data from 33 states with confidential name-based HIV infection reporting since at least 2003. Data have been adjusted for reporting delays.  
\*Includes 22 persons of unknown race or multiple races.



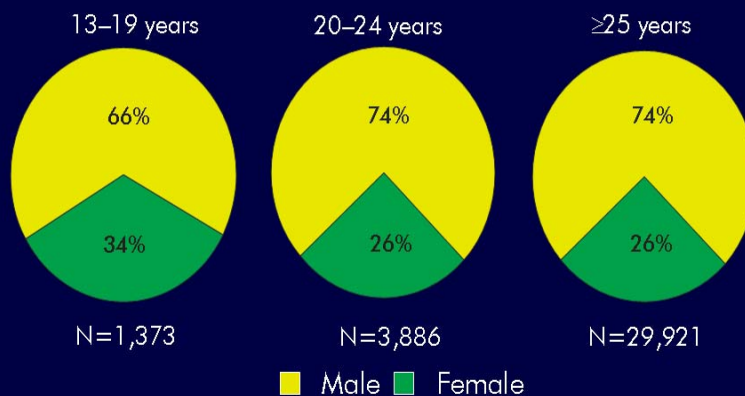
### Proportion of HIV/AIDS Cases and Population among Young Adults 20 to 24 Years of Age, by Race/Ethnicity Diagnosed in 2006—33 States



Note. Data include persons with a diagnosis of HIV infection regardless of their AIDS status at diagnosis. Data from 33 states with confidential name-based HIV infection reporting since at least 2003. Data have been adjusted for reporting delays.  
\*Includes 22 persons of unknown race or multiple races.



### Proportion of HIV/AIDS Cases among Adults and Adolescents, by Sex and Age Group Diagnosed in 2006—33 States



Note. Data include persons with a diagnosis of HIV infection regardless of their AIDS status at diagnosis. Data from 33 states with confidential name-based HIV infection reporting since at least 2003. Data based on person's age at diagnosis. Data have been adjusted for reporting delays.



### HIV/AIDS Cases among Male Adolescents and Young Adults, by Transmission Category 2003–2006—33 States

Transmission	13–19 years		20–24 years	
	N	%	N	%
Male-to-male sexual contact	2,286	81	7,756	78
Injection drug use (IDU)	146	5	645	7
Male-to-male sexual contact and IDU	100	4	454	5
High-risk heterosexual contact*	277	10	1,013	10
Other/not identified†	9	<1	20	<1
<b>Total</b>	<b>2,817</b>	<b>100</b>	<b>9,888</b>	<b>100</b>



Note. Data include persons with a diagnosis of HIV infection regardless of AIDS status at diagnosis. Data from 33 states with confidential name-based HIV infection reporting since at least 2003. Data have been adjusted for reporting delays.

\*Heterosexual contact with a person known to have, or to be at high risk for, HIV infection. †Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.



## HIV/AIDS Cases among Female Adolescents and Young Adults, by Transmission Category 2003–2006—33 States

Transmission Category	13–19 years		20–24 years	
	N	%	N	%
Injection drug use	233	13	597	14
High-risk heterosexual contact*	1,546	86	3,492	85
Other/not Identified†	15	<1	32	<1
Total	1,793	100	4,121	100



Note. Data include persons with a diagnosis of HIV infection regardless of AIDS status at diagnosis.  
Data from 33 states with confidential name-based HIV infection reporting since at least 2003.  
Data have been adjusted for reporting delays and cases without risk factor information were proportionally redistributed.  
\*Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.  
†Includes blood transfusion, perinatal exposure, and risk factor not reported or not identified.



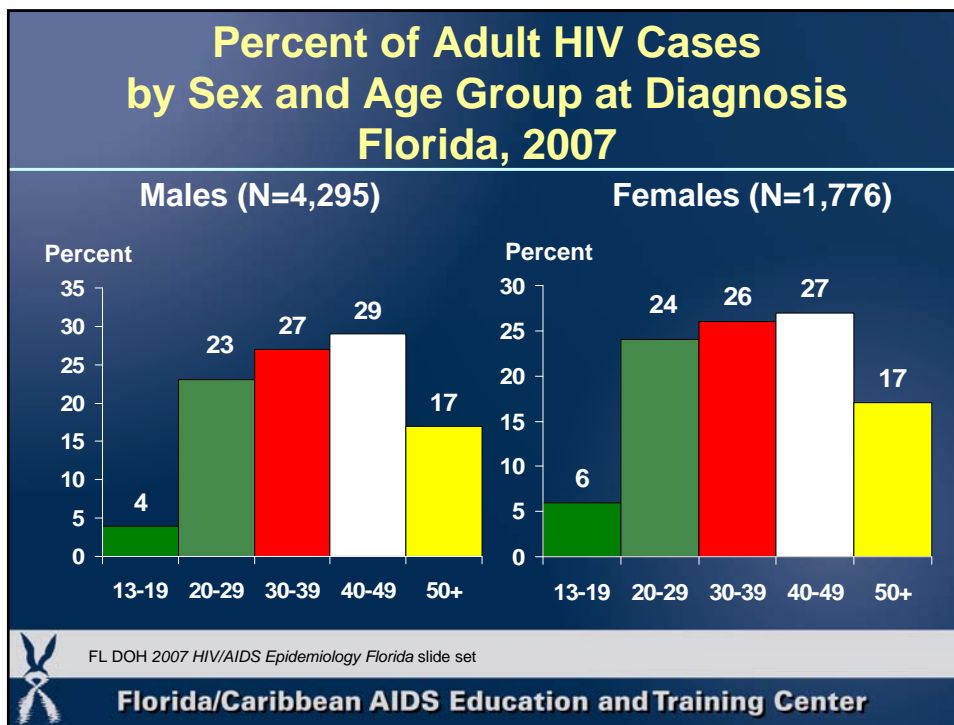
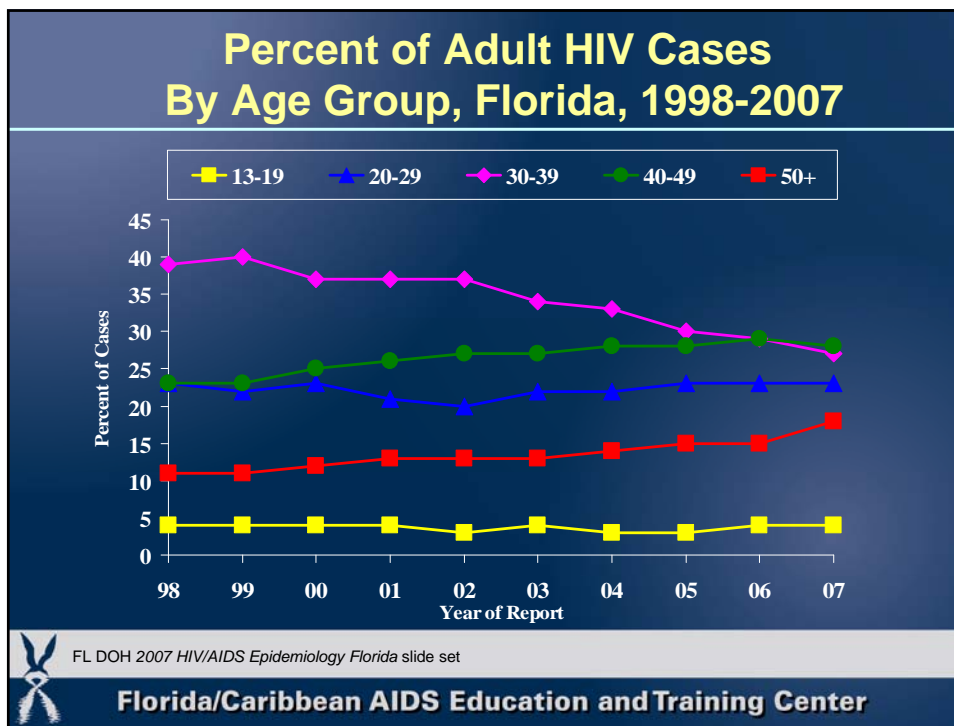
## HIV in Florida, 2007

- An estimated 125,000 Floridians are currently thought to be HIV positive
- 6,071 HIV cases were reported in 2007
- Through 2007, there were 3,331 HIV/AIDS cases among 13-24 year olds:
  - 51% male
  - 70% black
  - 70% ages 20-24

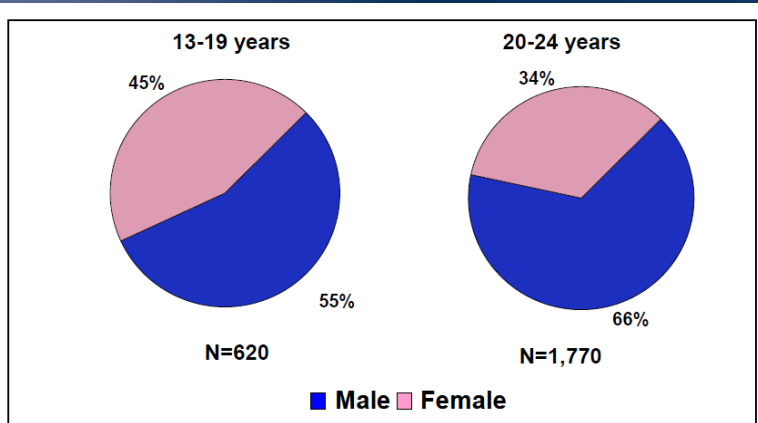


Florida Department of Health (DOH)

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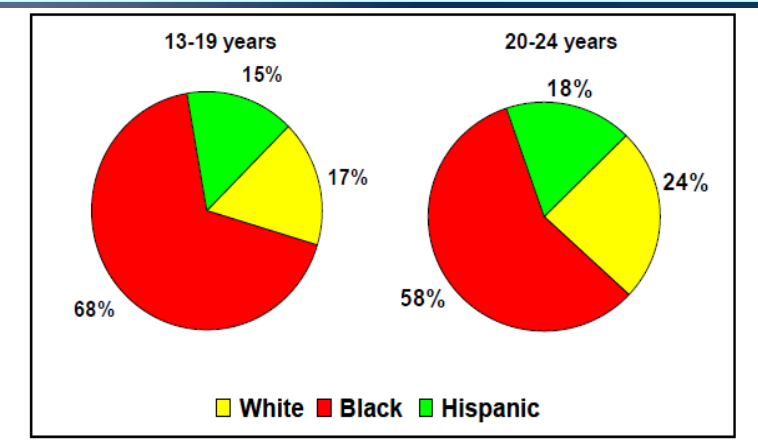


## HIV cases among adolescents and young adults, Florida 2005-2007



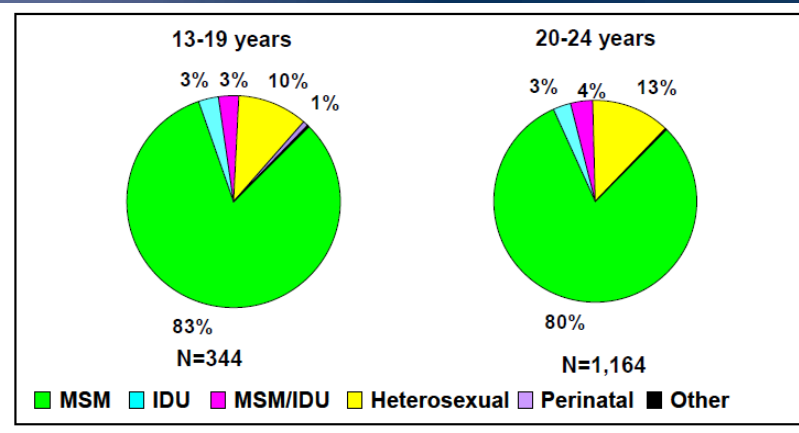
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## HIV cases by ethnicity among adolescents and young adults, Florida 1998-2007



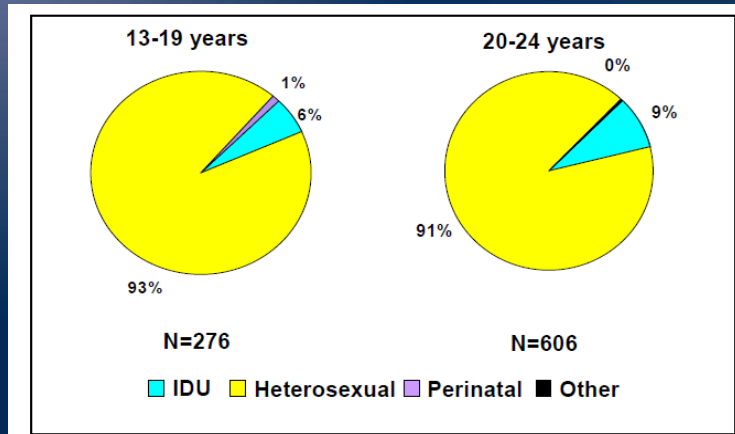
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### HIV cases among adolescents and young adult males, by mode of exposure and age at diagnosis, reported in 2005-2007, Florida



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### HIV cases among adolescents and young adult females, by mode of exposure and age at diagnosis, reported in 2005-2007, Florida



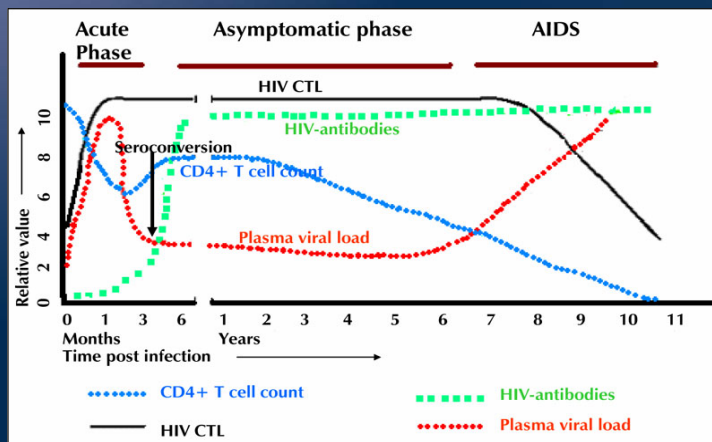
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# HIV Infection: Clinical Signs and Symptoms



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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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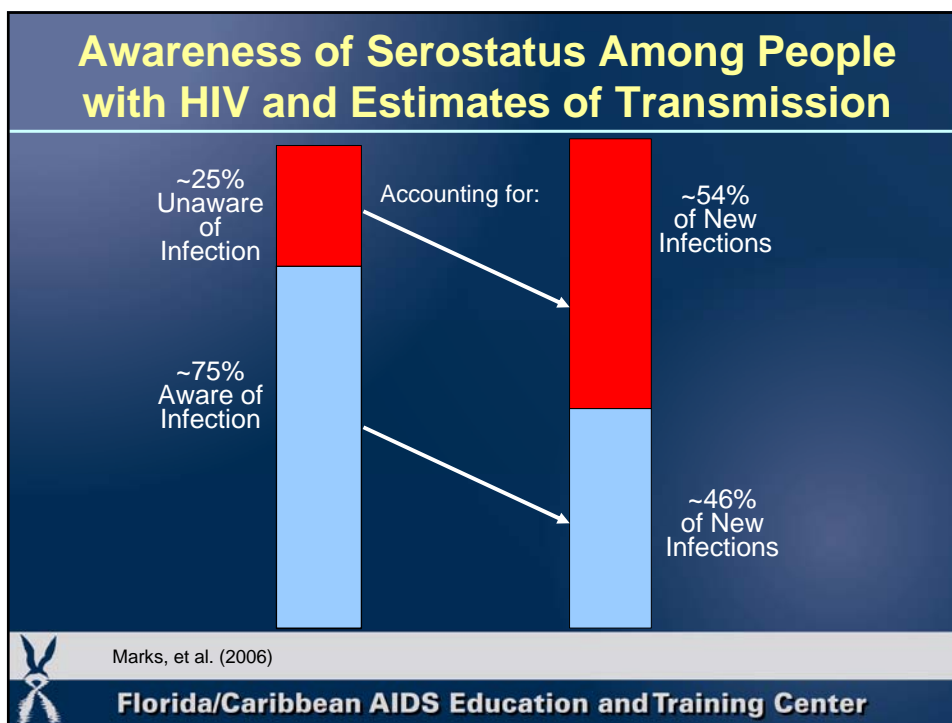
## U.S. HIV Testing Trends

- Approximately 38% - 44% of adults ages 18-64 have ever been tested
- BUT:
- 24% - 27% of all HIV + persons (or 252,000 - 312,000 individuals) are unaware of their status
- ~ 50% of adolescents do not know they are infected



Branson, B. *Revised Recommendations for HIV Testing in Health Care Settings in the U.S.* presentation; CDC 2009

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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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## Why test adolescents?

Among U.S. high school students:

- 48% have had sexual intercourse at least once
- 15% have had four or more sex partners
- 38% of sexually active students did not use a condom the last time they had sex
- According to the 2007 Youth Risk Behavior Survey (YRBS) just 13% have been tested for HIV



CDC, 2009

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## Why test adolescents?

- Testing presents an opportunity to talk to young people how they can protect themselves and others from HIV/AIDS
- Studies show that people who know they are infected are less likely to have unprotected sex than those who do not
- Early identification of HIV infection enables earlier treatment and better health outcomes



CDC, 2009

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## HIV Testing in Florida, 2007

- 330,150 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



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## HIV Testing in Florida, 2007

Site Type	% of tests conducted n=329,979	% of positive tests n=5,047
Anonymous	1.8	1.7
CHD STD	23.9	24.5
Drug Treatment Center	4.1	2.5
CHD Family Planning	16.3	1.2
CHD Prenatal/OB	9.5	0.7
CHD TB	0.8	0.5
Adult Health	5.8	14.7
Correctional Facility	9.9	8.2
College/University	0.9	1.0
Private M.D.	1.2	3.9
Special Study/TOPWA	1.5	3.1
Community-based Organization	20.3	32.8
CHD Field Visit	4.1	5.1
Unknown	0.0	0.1
<b>Total</b>	<b>100.0</b>	<b>100.0</b>

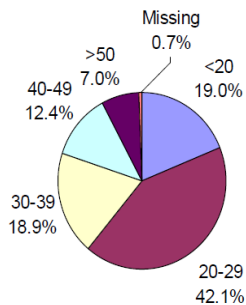


Calculations based on FL DOH data

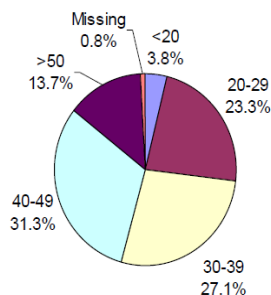
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## HIV Testing in Florida, 2007

**Figure 9a. Total HIV Tests by Age Group, Florida, 2007**  
(N=330,150)



**Figure 9b. HIV-Positive Tests by Age Group, Florida, 2007**  
(N=5,047)

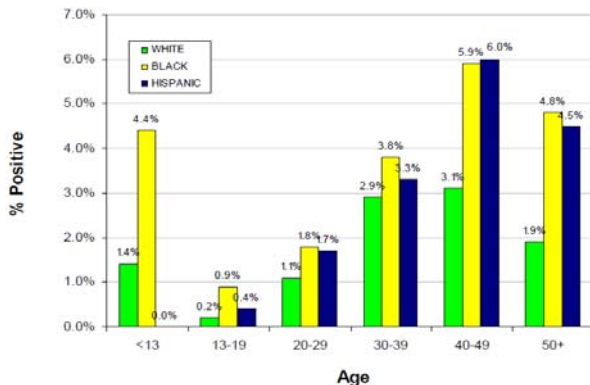


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## HIV Testing in Florida, 2007

Figure 13a. Seropositivity Among Males, by Age and Race/Ethnicity, Florida, 2007

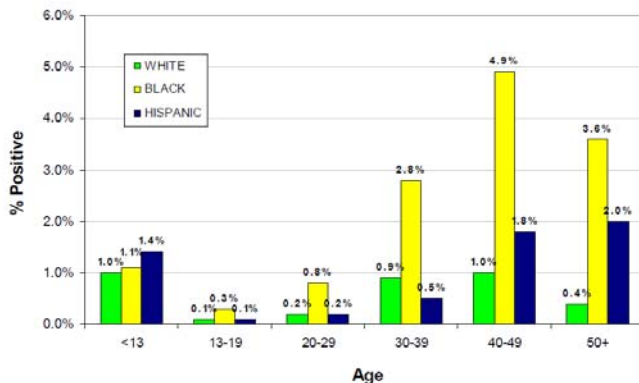


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## HIV Testing in Florida, 2007

Figure 13b. Seropositivity Among Females, by Age and Race/Ethnicity, Florida, 2007



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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 and ensure that patients receive their results



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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^	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-	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)				

\* "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.  
 ^ 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-	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-	Sold Separately (\$50/set)
		Serum & Plasma	Non-waived	99.7% (98.9-100)	99.9% (99.6-100)				

\* "Public health" price for public health programs that are recipients of CDC funds; for expanded HIV testing  
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Prepared by Jeanette 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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## 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 status
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 among adolescents?
- 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.
- Adolescents and young adults, particularly minority populations, warrant increased attention to testing and prevention efforts.
- Clinicians should talk to their patients about risky sexual behavior (i.e. anal sex, MSM, multiple partners) and provide information on how they can protect themselves and their partners.



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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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## References

- Branson, Bernard. (n.d.). *Revised Recommendations for HIV Testing in Health Care Settings in the U.S.* Centers for Disease Control and Prevention Slide Set.
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## For Further Information, Training, and Technical Assistance

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