

<p>BROWN UNIVERSITY</p> <hr/> 	<h2>Session C: Advancements in HIV Testing Technologies &amp; Interpretation of Lab Reports</h2> <p>Division of Disease Control Annual Infectious Disease Conference Augusta Civic Center, Augusta, Maine 10:45-11:45am, Wednesday, November 15<sup>th</sup>, 2017</p> <p><b>Philip A. Chan, MD, MS</b> Rhode Island Department of Health, Providence, Rhode Island Brown University, Providence, Rhode Island</p>
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HIV Testing Technologies

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	<h3>Disclosures</h3>
	<p>Funding from the National Institutes of Health (NIH) and the Rhode Island Department of Health.</p>
	<p>No commercial conflicts of interest.</p>

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## Objectives

1. Describe current state of HIV testing and algorithms for diagnosis of infection;
2. Review point-of-care (rapid) HIV testing;
3. Discuss implementation of HIV testing in clinical and non-clinical settings.



## I. Importance of HIV Testing



# STOPPING HIV: WE HAVE ALL THE TOOLS!



Our goal in the United States is to get to **ZERO** new HIV diagnoses



### HIV Prevention Approaches



Adapted from: AIDS Vaccine Advocacy Coalition. *Piecing together the HIV Prevention Puzzle*. 2009.



### Who should be tested for HIV?



**All people aged 13-64 years  
(CDC, 2006)**



**All people aged 13-75 years  
(ACP, 2009)**



**All people aged 15-65 years  
(USPSTF, 2013)**





## Who should be tested for HIV?

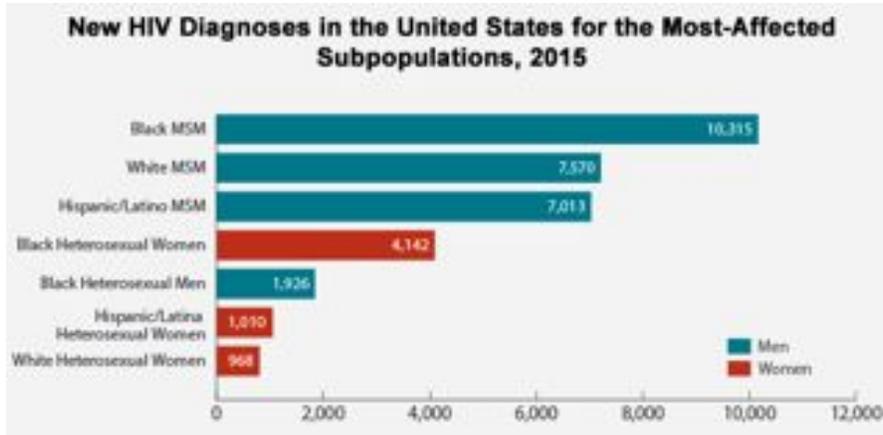
- Opt-out screening should be performed at least once as part of routine healthcare
- All pregnant women should be screened
- Persons who are at-risk for HIV should be screened at least annually (3-6 months for some MSM)
- Written consent should not be required
- Counseling is not required

## Rationale for Routine HIV Testing



1. Improvements in HIV Testing
2. Reduces stigma
3. Early diagnosis and treatment improves outcomes
4. Knowing one's status leads to less risky behavior (Marks et al., 2006)
5. Cost-effective (Paltiel et al., 2005)



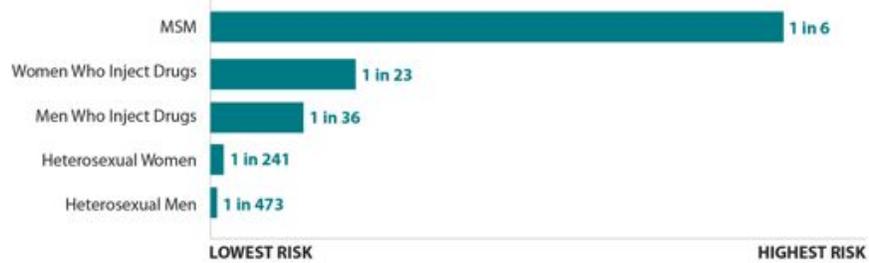


Source: Centers for Disease Control and Prevention



## Disparities in HIV infection

Lifetime Risk of HIV Diagnosis by Transmission Group

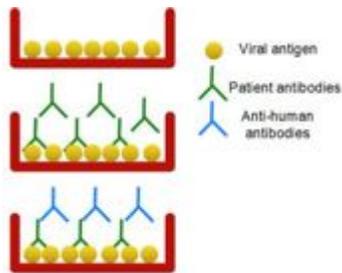


Source: Centers for Disease Control and Prevention

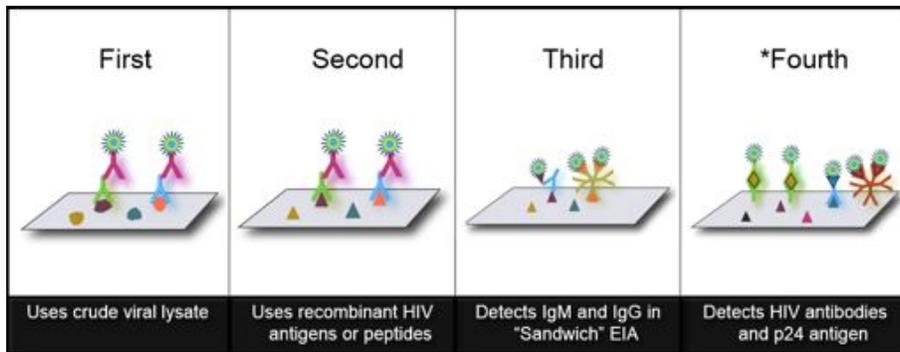




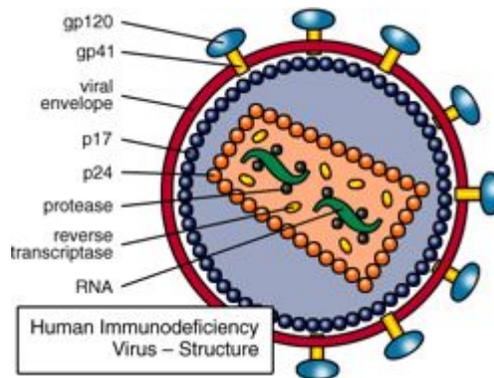
## Spectrum of HIV diagnostic testing



1. Enzyme Immunoassays (EIAs)
2. Chemiluminescent Immunoassay (CIA)
3. Indirect Immunofluorescence Assays (IFA)
4. Western blots (WB)



## HIV p24 Antigen



1. Core protein of the virus
2. Detected 2-3 weeks after HIV infection
3. Detected 1 week before antibody tests become reactive
4. Challenges include the need for specialty equipment



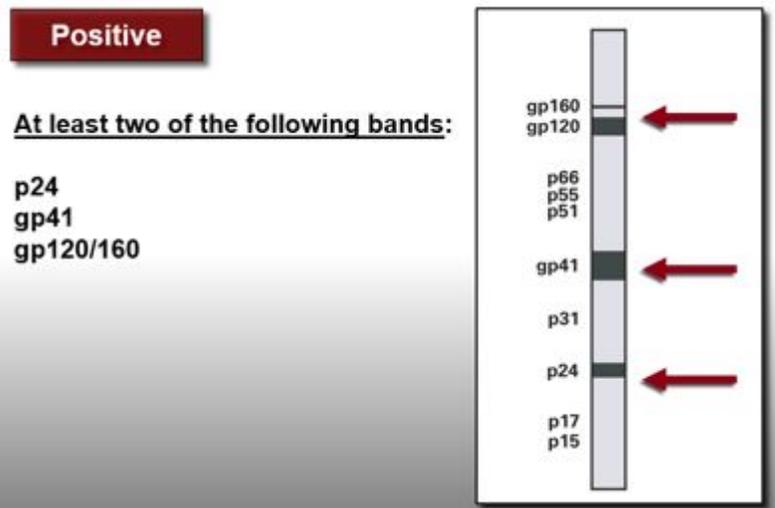
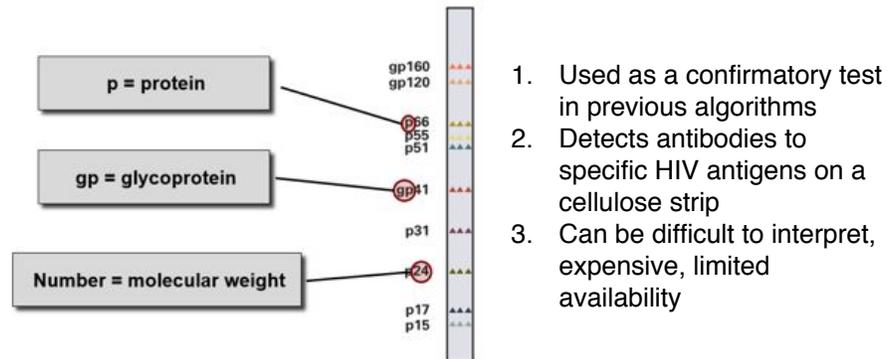
## Enzyme Immunoassays (EIAs)



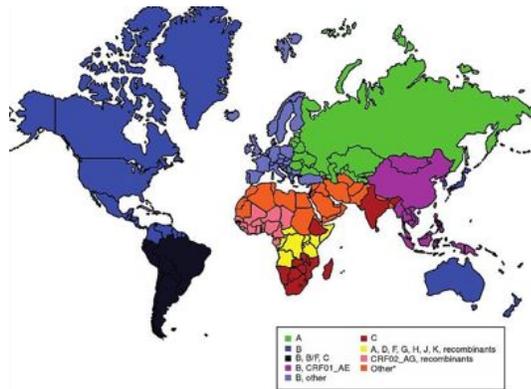
1. Quantitative assay to measure HIV antibodies
2. Most detect antibodies to HIV-1 and HIV-2
3. Some detect antigen (p24)
4. HIV antibody/antigen reaction detected by color change
5. Intensity of color reflects amount of antibody present in serum
6. Requires skilled lab technicians, specialty equipment



## Western Blot Testing



## Challenges of HIV testing

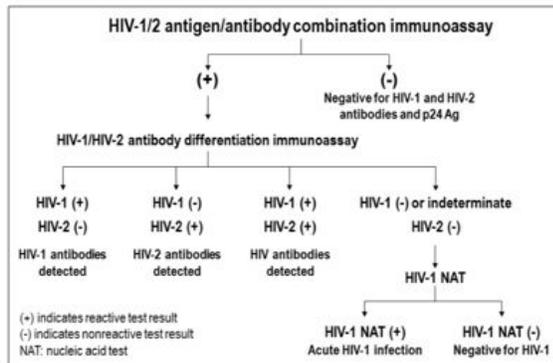


1. Early detection of acute HIV infection
2. Effect of HIV-2 and other subtypes on test performance
3. Impact of other health conditions on test performance
4. Product specific equipment
5. Technical skill



## Recommended HIV Testing Algorithm

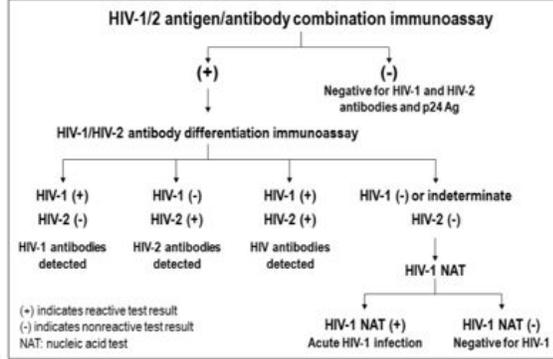
Box 1. Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens





## Recommended HIV Testing Algorithm

Box 1. Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens

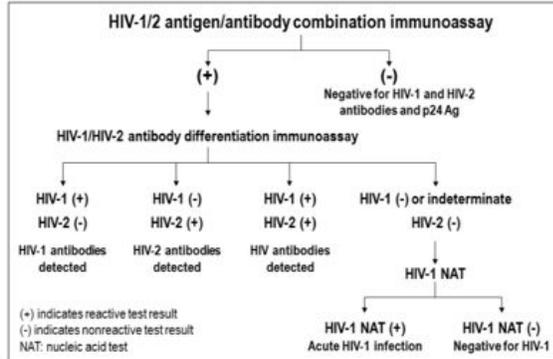


**\*Fewer indeterminate results and generally faster turnaround time for test results**



## Recommended HIV Testing Algorithm

Box 1. Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



**\*The HIV-1 Western blot and HIV-1 IFA are no longer recommended (more false-negatives and indeterminate results in early HIV infection)**



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**W**

UW Medicine

**Laboratory Test Catalog**

Department of Laboratory Medicine



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Test Name Code

within other orders

UW Medicine

ORCA CPOE Lab Help

Laboratory Medicine

Lab Medicine

Licenses & Accreditation

Clinical test information

Isotonic tests

Specimen Collection

Critical Values

Color coded tube guide

Reference Ranges

Notifiable Conditions

Staff Links

Staff Only Test Catalog

Staff Only Website

**HIV\_2 RNA Quantitation [Code: HIV2VL]**

**Lab Name** HIV\_2 RNA Quantitation

**Synonyms** HIV-2 viral load, HIV-2 RNA

**Specimen Type** Blood, CSF

**ORCA Name** HIV 2 RNA Quantitation

Components	Component Name	Lab Code	Component Type
	HIV_2 Specimen	H2DES	Test
	HIV_2 RNA Result	H2RSLT	Test
	HIV_2 RNA Copies/mL (Loa10)	H2LOG	Test
	HIV_2 RNA Interpretation	H2INTP	Test

**Ref. Range Notes** Normal = not detected. Quantitative range of assay is 10 to 100,000 HIV-2 RNA copies/mL plasma/CSF

**Collection and Handling**

**Collection** 10 mL blood in LAVENDER TOP (EDTA) tube  
or  
Blood in a **single** 5 or 8.5 mL PEARL TOP (EDTA) PPT tube  
or  
3 - 4 mL of CSF in sterile collection tube

**Handling** Send sample to lab for processing within 6 hours of collection.

**Amount** 3 to 4 mL EDTA plasma or CSF

**Minimum** 2 mL EDTA plasma or CSF

**\*HIV-2 viral load testing is not common, but available at some labs**

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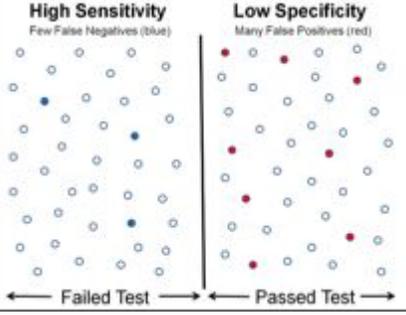
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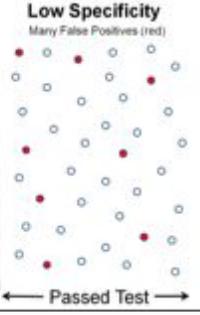
## Sensitivity and Specificity

**High Sensitivity**  
Few False Negatives (blue)



← Failed Test | Passed Test →

**Low Specificity**  
Many False Positives (red)



1. **Sensitivity** is the probability that the test is positive if the person is infected (most important in a screening test)
  - Out of 100 people with HIV, the test will detect 99 and miss **one** person (99% sensitivity)
2. **Specificity** is the probability that the test is negative if the person is not infected
  - Out of 100 people without HIV, the test will be falsely positive for **one** person (99% specificity)
3. Initial antibody tests have a specificity of >98%, confirmatory tests >99%

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## False Negatives

"The window period is the time between the initial HIV infection and the time when the body has produced enough HIV antibodies to be detected by an HIV antibody test."

1. **Acute HIV infection**
2. Advanced HIV infection
3. Antiretroviral therapy



## False Positives



1. Other viral diseases
2. Hematologic disorders
3. Liver disease
4. Immunizations
5. Autoimmune disorders
6. Pregnancy

**\*Influenza vaccine!**

### Influenza Vaccination and False Positive HIV Results

**TO THE EDITOR:** Six weeks after an occupational needle-stick injury, a 35-year-old man presented to a clinic in the Los Angeles area for testing to rule out acute infection with the human immunodeficiency virus (HIV). The patient had no other risk factors for HIV infection and reported having had no symptoms suggestive of an acute retroviral syndrome. His recent medical history was notable only for his having received an influenza vaccination 11 days before presentation.

N ENGL J MED 354:73 www.nejm.org MARCH 30, 2006



## Positive Predictive Value

The probability that a person with a positive screening test will truly have HIV (Depends on prevalence in the population).

**High sensitivity (99%)  
and high specificity  
(99%) test**



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The probability that a person with a positive screening test will truly have HIV (Depends on prevalence in the population).

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**A 99% specificity means that there will be 1 false positive out of a 100. Out of 1000 HIV tests, there will be 10 false positives.**



## Positive Predictive Value

The probability that a person with a positive screening test will truly have HIV (Depends on prevalence in the population).

**High sensitivity (99%) and high specificity (99%) test**

**A 99% specificity means that there will be 1 false positive out of a 100. Out of 1000 HIV tests, there will be 10 false positives.**

**Assuming a very low prevalence of HIV (1 in a 1000 or 0.1%), the positive predictive value will be 1 out of 11 or 9.1%. This means there is a significant chance the person does not have HIV despite a positive test.**



### III. Acute HIV infection



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**Detection of Acute HIV Infection: We Can't Close the Window**

**Table 1.**  
Human Immunodeficiency Virus (HIV) Testing Assays and Their Window Periods

HIV Test	Assay Method	Approximate Window Between Infection and Positive Test Result, d
First-generation EIA	Disrupted viral particles used to bind patient HIV antibody, detected by marker conjugated to anti-human IgG antibody	35-45
Second-generation EIA (including most rapid tests)	Synthetic or recombinant HIV antigen used to bind patient HIV antibody; detected by marker conjugated to anti-human IgG antibody	25-35
Third-generation EIA (also some rapid tests)	"Antigen sandwich": synthetic or recombinant HIV antigen used to bind patient HIV antibody; detected by marker conjugated to additional HIV antigen; detects IgM and IgG antibody	20-30
Fourth-generation EIA	Third-generation EIA method to bind patient antibody to HIV plus monoclonal antibody to bind p24 antigen; detects IgM and IgG antibodies and p24 antigen	15-20
RNA	Extraction of HIV nucleic acid, amplification by PCR or other methods; detects HIV RNA	10-15

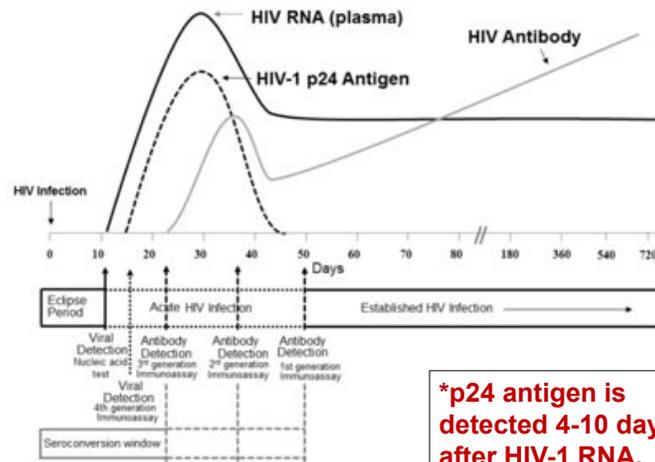
Abbreviations: EIA, enzyme immunoassay; Ig, immunoglobulin; PCR, polymerase chain reaction.

J Infect Dis. (2012) 205 (4): 521-524.

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Laboratory Testing for the Diagnosis of HIV Infection, CDC 2014

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Transmission Direction	Viral Load Category (copies/ml)	Transmission Rate (per 100 Person-Years)
All Subjects	<100	~4
	100-1000	~12
	1000-10000	~14
	>10000	~23
Male to Female Transmission	<100	~5
	100-1000	~15
	1000-10000	~11
	>10000	~25
Female to Male Transmission	<100	~3
	100-1000	~11
	1000-10000	~18
	>10000	~20

- The risk of HIV transmission among serodiscordant couples (N=415) according to viral load (Quinn et al., 2000).
- The rate of HIV transmission during acute infection is 26x higher than established infection, may account for 10-50% of all new HIV-1 transmissions!

BROWN UNIVERSITY  Quinn et al., 2000

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### Pooled Viral Load Testing (Detection of Acute HIV Infection)

**Original Investigation**  
February 16, 2016

**Screening Yield of HIV Antigen/Antibody Combination and Pooled HIV RNA Testing for Acute HIV Infection in a High-Prevalence Population**

Philip J. Peters, MD<sup>1</sup>, Emily Westheimer, MS<sup>2</sup>, Stephanie Cohen, MD, MPH<sup>3</sup>, et al.  
JAMA. 2016;315(7):682-690. doi:10.1001/jama.2016.0286

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## IV. Rapid HIV Tests



## HIV Rapid Tests



1. Qualitative assay to detect HIV antibodies
2. Most detect HIV-1 and HIV-2
3. Similar to EIAs
4. Challenges include training and interpretation



## FDA-Approved Rapid HIV Tests

Test	Specimen	Time (Minutes)	Other
Oraquick (2002)	Oral, blood, plasma	20	HIV-1/2
Uni-Gold (2003)	Blood, serum	10	HIV-1
Reveal (2003)	Serum	<2	HIV-1
MultiSpot (2004)	Serum	15	HIV-1/2
Clearview (2006)	Blood, serum	15-20	HIV-1/2
Chembio (2006)	Blood, serum	15	HIV-1/2
Determine (2013)	Blood, serum	20	HIV-1/2, p24
INSTI (2015)	Blood, serum	<2	HIV-1/2



## Detection of Acute HIV Infection: A Field Evaluation of the Determine® HIV-1/2 Ag/Ab Combo Test

Nora E. Rosenberg,<sup>1</sup> Gift Kamanga,<sup>5</sup> Sam Phiri,<sup>6</sup> Dominic Nsona,<sup>6</sup> Audrey Pettifor,<sup>1</sup> Sarah E. Rutstein,<sup>2</sup> Deborah Kamwendo,<sup>5,3</sup> Irving F. Hoffman,<sup>3</sup> Maria Keating,<sup>5,3</sup> Lillian B. Brown,<sup>1,3</sup> Beatrice Ndalama,<sup>5</sup> Susan A. Fiscus,<sup>6</sup> Seth Congdon,<sup>5</sup> Myron S. Cohen,<sup>1,3,4</sup> and William C. Miller<sup>1,3</sup>

Departments of <sup>1</sup>Epidemiology, <sup>2</sup>Health Policy and Management, <sup>3</sup>Medicine, and <sup>4</sup>Microbiology and Immunology, University of North Carolina, Chapel Hill; and the <sup>5</sup>UNC Project, Lilongwe, Malawi; and <sup>6</sup>Lighthouse Trust, Lilongwe, Malawi

**Results.** Of the participants 838 were HIV negative, 163 had established HIV infection, and 8 had acute HIV infection. For detecting acute HIV infection, the antigen portion had a sensitivity of 0.000 and a specificity of 0.983. For detecting established HIV infection, the antibody portion had a sensitivity of 0.994 and a specificity of 0.992.

**Conclusions.** Combo RT displayed excellent performance for detecting established HIV infection and poor performance for detecting acute HIV infection. In this setting, Combo RT is no more useful than current algorithms.



## HIV Rapid Tests: Advantages



1. Same-day diagnosis and counseling
2. Easy to use
3. Results in 20 minutes (at the longest)
4. No refrigeration
5. No additional equipment required
6. Minimal technical skill



## HIV Rapid Tests: Disadvantages



1. Individual-use tests
2. Need for quality controls
3. Test performance varies by product
4. Interpretation of results may vary
5. False positives/negatives



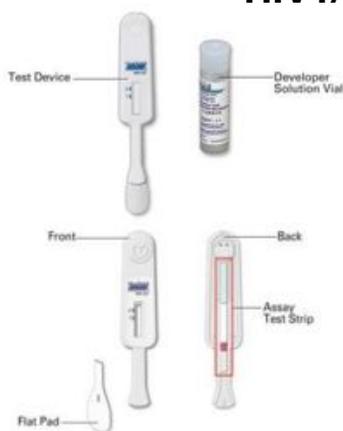
## Body Fluids Used for HIV Rapid Testing



1. Serum
2. Plasma
3. Whole blood
4. Oral fluids



## The OraQuick ADVANCE Rapid HIV1/2 Antibody Test



1. Detects HIV-1 and HIV-2 antibodies.
2. The following samples may be used for the test.
3. Oral fluid containing cheek cells collected by oral swab.
4. Blood collected by finger stick.
5. Blood collected by venous sample.
6. Results in 20 minutes.
7. FDA approved for clinical screening, but not for blood or tissue donors.
8. Each test is single use only.
9. Not to be used if manufacture date exceeds 12 months from the current date.



## The OraQuick ADVANCE Rapid HIV1/2 Antibody Test



### Simple two step procedure

1. Swab upper and lower gums once with each flat pad of the test device
2. Insert device in the developer vial. Read result between 20 and 40 minutes



## The OraQuick ADVANCE Rapid HIV1/2 Antibody Test



1. Apply slight pressure to the finger.
2. Verbally warn the client that you are about to prick their finger and that it may hurt a little.
3. Ask the client if they are ready. When they say yes, prick their finger.
4. Wipe first drop of blood with gauze.
5. Apply pressure to the finger.
6. Collect drop of blood with loop.
7. Immediately put loop in solution.
8. Swirl loop in solution.
9. Insert labeled testing device into solution for 20 minutes.



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Non-reactive or "Negative" (NR)  
Reactive or "Positive" (R)  
Invalid (I)

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**R I NR I I R**

Non-reactive or "Negative" (NR)  
Reactive or "Positive" (R)  
Invalid (I)

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## V. HIV Testing Implementation in Clinical Settings



### Routine HIV Screening in an Urban Community Health Center: Results from a Geographically Focused Implementation Science Program

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CAITLIN TOWRY, MPH<sup>1</sup>  
PHILIP A. CHAN, MD, MSPH<sup>2</sup>  
SHARON PARKER, PhD, MSW<sup>3</sup>  
EMILY NICHOLS, MPH<sup>4</sup>  
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ANNJANE YOLKEN, BA<sup>6</sup>  
JULIA HARVEY, BA<sup>7</sup>  
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THOMAS STOPKA, PhD, MHS<sup>9</sup>  
STACEY TROOSKEN, MD, PhD<sup>10</sup>

#### ABSTRACT

**Objective.** CDC has recommended routine HIV screening since 2006. However, few community health centers (CHCs) routinely offer HIV screening. Research is needed to understand how to implement routine HIV screening programs, particularly in medically underserved neighborhoods with high rates of HIV infection. A routine HIV screening program was implemented and evaluated in a Philadelphia, Pennsylvania, neighborhood with high rates of HIV infection.

PUBLIC HEALTH REPORTS / 2016 SUPPLEMENT 1 / VOLUME 131



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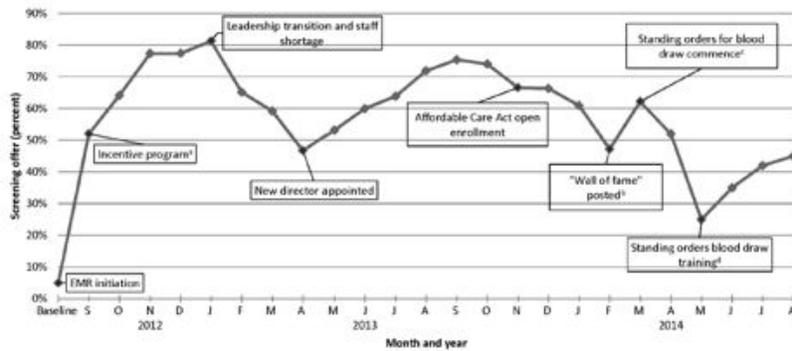
Vital Signs	Risk Factors	Audio/Visual/Neb	Urine Testing	Additional Testing
<b>Pulse Oximetry</b> O2 Saturation: <input type="text"/> % Post-nebulizer: <input type="text"/> % <b>Peak Flow</b> Peak Flow: <input type="text"/> L/min. Post-nebulizer: <input type="text"/> L/min. <b>Spirometry</b> <input type="text"/>	<b>Blood Tests</b> <input type="button" value="Now"/> Date Processed: <input type="text"/> <input type="button" value="Now"/> Glucose (random): <input type="text"/> mg/dL Glucose (fasting): <input type="text"/> mg/dL Glucose (2 hour PP): <input type="text"/> mg/dL Mono: <input type="radio"/> Negative <input type="radio"/> Positive H. pylori: <input type="radio"/> Negative <input type="radio"/> Positive HGBA1C: <input type="text"/> % Hgb: <input type="text"/> Hct: <input type="text"/>	<b>Rapid Strep</b> <input type="button" value="Now"/> Date Processed: <input type="text"/> <input type="button" value="Now"/> <input type="radio"/> Negative <input type="radio"/> Positive <b>Stool - Occult Blood</b> <input type="button" value="Now"/> Date Processed: <input type="text"/> <input type="button" value="Now"/> #1: <input type="radio"/> Negative <input type="radio"/> Positive #2: <input type="radio"/> Negative <input type="radio"/> Positive #3: <input type="radio"/> Negative <input type="radio"/> Positive	<b>HIV Test</b> <input type="radio"/> Consent <input type="radio"/> Decline	<input type="checkbox"/> Include in note <input type="button" value="Enter Prior"/> Last Result: Negative on 04/30/2012.

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Figure 2. Policy changes and HIV screening offer rates by month at an urban health center in Philadelphia, Pennsylvania, 2012–2014



\*The incentive program provided a financial incentive structure to reward medical assistants who improved their HIV screening offer rates; the medical assistant with the highest testing rate was awarded a \$50 gift card.  
 †Publicly displayed monthly testing offer and acceptance rates by medical assistant  
 ‡Standard protocols for carrying out HIV screening using blood draw  
 ††Training on standing orders for HIV screening using blood draw for medical assistants  
 HIV = human immunodeficiency virus  
 EMR = electronic medical record

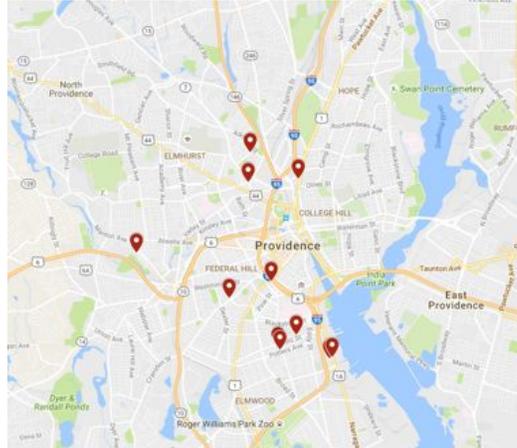
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## Routine opt-out HIV testing In Rhode Island



1. In 2014, PCHC provided care to 44,515 patients with a total of 171,927 patient visits.
2. PCHC has 16,771 patients under the age of nineteen years old. 90% of patients are at or below 200% of the Federal Poverty Level, even though some work full time. 20% of our patients are uninsured.
3. PCHC services patients from all across the City of Providence and surrounding communities.



## V. HIV Testing Implementation in Non-Clinical Settings



## Examples of non-clinical settings

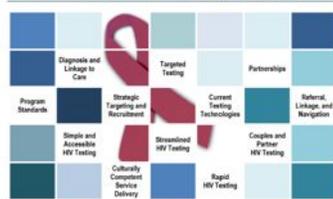


1. Community-based organizations (CBOs)
2. Mobile testing units
3. Churches
4. Bathhouses
5. Parks
6. Shelters
7. Syringe service programs
8. Homes
9. School
10. Other social organizations



## Implementing HIV Testing in Nonclinical Settings

A Guide for HIV Testing Providers



March 2, 2016  
 Program guidance intended for use by CDC-funded HIV testing providers in nonclinical settings.  
 HIV testing providers not funded by CDC may also find this information useful.



## Guiding Principles

1. Voluntary, informed consent (verbal)
2. Confidential or anonymous
3. "Testing Together"
4. Linkage to HIV+ care or HIV-services (e.g. PrEP)
5. No extensive pretest or posttest counseling





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**SCRUFF™**



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## Grindr

**Grindr users are highly engaged on the app daily**

1. Active users: 2+ million
2. Number of logins: 9
3. Average time spent: 54 minutes
4. Messages sent: 70+ million
5. Photos sent: 5+ million

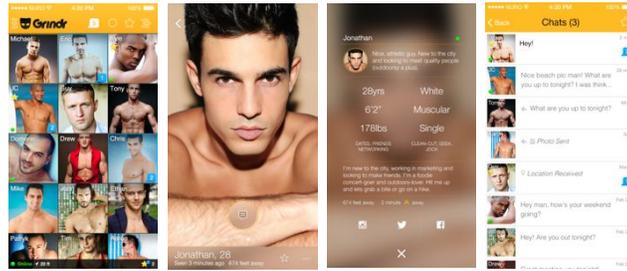


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### MSM Presenting to the Rhode Island Sexually Transmitted Disease Clinic

Ever used the Internet to meet a man	<b>90%</b>
Physically met online partner	<b>97%</b>
Had sex with online partner	<b>95%</b>
Met a partner online in the last 12 months	<b>75%</b>
Grindr to meet a partner in the last 12 months	<b>77%</b>
First sex with online partner	<b>33%</b>



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CASE STUDIES AND PRACTICE

## Online Hookup Sites for Meeting Sexual Partners Among Men Who Have Sex with Men in Rhode Island, 2013: A Call for Public Health Action

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 CAITLIN TOWEY, MPH<sup>2</sup>  
 JOANNA POCETA, BA<sup>3</sup>  
 JENNIFER ROSE, PhD<sup>4</sup>  
 THOMAS BERTRAND, MPH<sup>1</sup>  
 RAMI KANTOR, MD<sup>5</sup>  
 JULIA HARVEY, BA<sup>6</sup>  
 E. KARINA SANTAMARIA, MPH<sup>7</sup>  
 NICOLE ALEXANDER-SCOTT, MD,  
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 AMY NUNN, ScD, MS<sup>9</sup>

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The infographic features a central text 'DO IT RIGHT' in large, bold, black letters, with 'GET TESTED FOR HIV & STDs' and the website 'www.doitRight.org' below it. Surrounding this central text are eight circular icons, each with a corresponding text label: a condom icon for 'CONDOMS', a thumbs up icon for 'GET TESTED FOR HIV', a syringe icon for 'HOME BASED HIV TEST', a pill icon for 'PRE-EXPOSURE PROPHYLAXIS', a speech bubble icon for 'KNOW YOUR PARTNERS', a question mark icon for 'KNOW RISKY BEHAVIORS', a pill icon for 'POST-EXPOSURE PROPHYLAXIS', a plus sign icon for 'HIV+ TREATMENT', and a checkmark icon for 'GET TESTED FOR STDs'. At the bottom left, the text 'BROWN UNIVERSITY' is followed by the university's crest.

**CONDOMS**

**GET TESTED FOR HIV**

**HOME BASED HIV TEST**

**PRE-EXPOSURE PROPHYLAXIS**

**DO IT RIGHT**  
GET TESTED FOR HIV & STDs  
www.doitRight.org

**KNOW YOUR PARTNERS**

**KNOW RISKY BEHAVIORS**

**POST-EXPOSURE PROPHYLAXIS**

**HIV+ TREATMENT**

**GET TESTED FOR STDs**

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**VI. Home Based HIV Testing**

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## Home Based HIV Test

1. OraQuick Rapid Antibody Test
2. Available at Pharmacies
3. Cost of \$39.99
4. Oral swab
5. Results in 20 minutes



### Conference Dates and Location:

February 23-26, 2015 | Seattle, Washington

### Abstract Number:

1098

## Using Grindr™, a Social-Media-Based Application, to Increase HIV Self Testing Among High-Risk Men Who Have Sex With Men in Los Angeles, California, 2014

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## Acceptability of Using Electronic Vending Machines to Deliver Oral Rapid HIV Self-Testing Kits: A Qualitative Study

Sean D. Young , Joseph Daniels, ChingChe J. Chiu, Robert K. Bolan, Risa P. Flynn, Justin Kwok, Jeffrey D. Klausner

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HIV Testing Technologies

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# Free HIV Self-Test Program

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**Welcome to the UCLA Free HIV Self-Test Program!**

Vending Machine Location



**1. How would you like to get your HIV self-test?**

Choose one of the three options below.

- Local vending machine
  - [Click here to view the vending machine location.](#)
- A printable voucher for a self-test kit at select drugstores
  - [Click here to view store locations.](#)
  - [Click here to see what the voucher looks like.](#)
- Mailed to your preferred address

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## Conclusions

1. Testing is a critical component for both prevention and to identify new infections (first step in the HIV care continuum);
2. Advances in HIV testing have led to improved detection algorithms;
3. Need for improved implementation of routine HIV testing in both clinical and non-clinical settings;
4. Need to engage MSM for HIV testing.

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