Strategies for Effective HIV Testing and Finding Acute Infection

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The Evolving Landscape of HIV Diagnosis

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HIV/STD/TB/Viral Hepatitis Unit
<table>
<thead>
<tr>
<th>Year</th>
<th>Test Description</th>
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<tr>
<td>1985</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; Gen HIV-1 IA</td>
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<td>HIV-2 IA HIV-1 IA DBS</td>
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<td>3&lt;sup&gt;rd&lt;/sup&gt; Gen HIV 1/2 IA HIV 1 IFA</td>
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<td>Oral collection device HIV 1 IA</td>
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<td>HIV Home Specimen Collection</td>
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<td>HIV 1 IA Rapid Blood</td>
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<td>CLIA Waived Rapid IA blood Group O</td>
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<td>CLIA Waived Rapid HIV 1/2 IA</td>
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<td>2006</td>
<td>Rapid IA Differentiates 1/2</td>
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<td>2006</td>
<td>Random Access Microparticle CIA</td>
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<td>2010</td>
<td>Qualitative HIV 1 NAT</td>
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<td>4&lt;sup&gt;th&lt;/sup&gt; Gen Antibody/Antigen</td>
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<td>CLIA Waived Rapid IA Immediate Results</td>
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<td>2013</td>
<td>Over the counter Rapid IA Oral</td>
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<tr>
<td>2013</td>
<td>Rapid 4&lt;sup&gt;th&lt;/sup&gt; Gen Antibody/Antigen</td>
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HIV Infection and Laboratory Markers

HIV RNA (plasma) day 11
HIV Abs day 21-24
HIV p24 Ag day 16
The Public Health Service recommends that no positive test results be given to clients/patients until a screening test has been repeatedly reactive on the same specimen and a supplemental, more specific test such as the Western blot has been used to validate those results.
Limitations of the 1989 Algorithm

- Western blot is less sensitive during early infection than most screening tests in current use,
- Antigen/antibody combo tests can detect most antibody-negative persons during highly infections acute infection stage,
- Because of cross-reactivity more than 60% of persons with HIV-2 infection are misclassified as HIV-1 by Western blot
Sequence of Test Possitivity Relative to WB (plasma)

166 specimens, 17 Seroconverters - 50% Positive Cumulative Frequency

4th Generation

 Detects HIV 1 p24 Antigen HIV 1/2 IgG and IgM Antibodies

• Bio-Rad GS HIV Combo Ag/Ab EIA

• Abbott Architect Ag/AB Combo
  Time to results ~ 29 minutes
Determine Combo Rapid HIV 1/2 Ag-Ab Test

Alere – 4th generation technology
Moderately Complex – NOT CLIA Waived
MultiSpot
FDA-approved HIV-1/HIV-2 Antibody Differentiation Assay

Reactive Control
Recombinant HIV-1
Peptide HIV-2
Peptide HIV-1
Acute Viral Infection

- Malaise/fatigue
- **Fever**/chills/night sweats
- Weight loss, loss of appetite
- Sore throat
- Nausea/vomiting/diarrhea
- **Swollen lymph nodes**
- Aching muscles or joints
- Rash
- Rarely headache, neurologic symptoms
Clinical Syndrome of Acute HIV

40% – 90% develop symptoms of Acute HIV

→ 50% – 90% w/ symptoms seek medical care

Of those diagnosed with Acute HIV

→ 50% of patients were seen at least 3 times before diagnosis

Acute Infection: Increased Risk of Sexual Transmission of HIV

HIV RNA in Semen (Log₁₀ copies/ml)

- 5
- 4
- 3
- 2

1/30 - 1/200

1/1000 - 1/10,000

1/500 - 1/2000

1/100 - 1/1000

Virus 75-750 times more infectious

Acute Infection

6 wks

Asymptomatic Infection

HIV Progression

AIDS

Ma, J Virol 2009

Cohen & Pilcher, J Infect Dis. 2005
HIV Testing Recommendations from CDC/APHL
New HIV Testing Algorithm

4th generation HIV-1/2 Combo Ag/Ab Immunoassay

(-)  

Negative for HIV-1 & HIV-2 antibodies and p24 Ag

HIV-1/HIV-2 differentiation immunoassay (MultiSpot)

(+)  

HIV-1 antibodies detected

HIV-2 antibodies detected

HIV antibodies detected *

*Additional testing required to rule out dual infection

HIV-1 RNA (+)  
Acute HIV-1 infection

HIV-1 RNA (-)  
Negative for HIV-1
Laboratory Testing for the Diagnosis of HIV Infection
Updated Recommendations

Laboratory Tests

In this section we provide resources for all FDA-approved diagnostic HIV tests for use in moderate and high complexity laboratories.

Laboratory Testing Guidance

- NEW! Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations
- NEW! Quick Reference: Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens
- APHL Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm

FDA Approved HIV Tests

- NEW! Advantages and Disadvantages of Different Types of HIV tests
- NEW! List of Moderate Complexity Rapid HIV Tests for Laboratory Use
- NEW! List of Moderate and High Complexity HIV tests for Laboratory Use
# Routine Medical Setting NAAT Submissions and Results 2012-July 2014

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<tr>
<th>Submitter</th>
<th># Samples</th>
<th>AHI</th>
<th>Positivity Rate</th>
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<td>9</td>
<td>7.89</td>
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<td>1</td>
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<td>3</td>
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<tr>
<td>Hospital 8</td>
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<td>0.00</td>
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<tr>
<td>Medical System 9</td>
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<td><strong>TOTAL</strong></td>
<td><strong>317</strong></td>
<td><strong>27</strong></td>
<td><strong>8.52</strong></td>
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</table>
Transition to Best Practices

- Current Test Technology Used
- Staff training
  - Technology
  - Specimen Collection
  - Messaging/Counseling
- Administration
- Link to Care
- Public Health Follow up
Resources

To order materials from the DSHS Warehouse:
http://www.dshs.state.tx.us/hivstd/info/edmat.shtm

- www.aphl.org/aphlprograms/infectious/hiv/Pages/HIV-Diagnostic-Testing-Algorithm.aspx
- www.hivtestingconference.org
- www.hivforum.org/index.php?option=com_content&task=view&id=774&Itemid=92
- http://jid.oxfordjournals.org/content/202/Supplement_2/S270.full.pdf+html
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DSHS HIV/STD/TB Viral Hepatitis Unit