Rapid HIV Antibody Testing Update

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CLIAC meeting, February 15, 2007
Purpose: Why Rapid HIV Testing?

- An example of an infectious disease test that has been waived
- Controversy around the waiver decision
- Previous CLIAC discussions
- Update CLIAC on testing scope and performance
Rapid HIV Testing
Overview of Presentations

- Introduction
- Results from the Model Performance Evaluation Program (MPEP)
- Use of waived rapid HIV testing in public health settings
- Use of rapid HIV testing in the private sector - hospitals and community settings
Waived Tests Available for Infectious Diseases

Direct antigen detection
- H. pylori
- Streptococcus, Group A
- Adenovirus
- Influenza A
- Influenza A/B
- Influenza B
- Respiratory syncytial virus
- Trichomonas

Serological assays
- HIV-1 antibodies
- HIV-1/2 antibodies
- H. pylori antibodies
- Infectious mononucleosis
- Lyme disease (B. burgdorferi) antibodies
Rapid HIV Antibody Tests
Objectives for Use

- Decrease the time needed to obtain a result
  - Screening in high risk settings
  - Post-exposure for healthcare workers
- Increase access to testing
- Reduce the number of unrecognized infections
- Support CDC’s 2006 recommendations to include HIV testing as a routine part of healthcare
Examples of Sites Offering Rapid HIV Antibody Tests

• Hospitals –
  - ER, L&D, Occ Health
• Public health – state, county, city testing sites
• Counseling & testing sites
• STD clinics
• Drug treatment programs
• Mobile vans serving high-risk communities

• Community health centers
• Community based organizations
• Correctional facilities
• Student health clinics
• Homeless shelters
• Other outreach settings
## Timeline for Introduction of Rapid HIV-1 Antibody Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Date approved</th>
<th>Specimen type</th>
<th>CLIA complexity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murex SUDS (no longer available)</td>
<td>5/22/92</td>
<td>Serum/plasma</td>
<td>Moderate</td>
</tr>
<tr>
<td>OraSure OraQuick</td>
<td>11/7/2002</td>
<td>Fingerstick WB</td>
<td>Moderate</td>
</tr>
<tr>
<td>OraSure OraQuick</td>
<td>1/31/2003</td>
<td>Fingerstick WB</td>
<td>Waived</td>
</tr>
<tr>
<td>MedMira Reveal</td>
<td>4/16/2003</td>
<td>Serum, plasma</td>
<td>Moderate</td>
</tr>
<tr>
<td>OraSure OraQuick</td>
<td>9/30/2003</td>
<td>Venipuncture WB</td>
<td>Waived</td>
</tr>
<tr>
<td>Trinity Biotech Uni-gold Recombigen</td>
<td>12/23/2003</td>
<td>Venipuncture WB</td>
<td>Waived</td>
</tr>
</tbody>
</table>

WB = whole blood
# Waived Rapid HIV Antibody Tests Currently Available

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Manufacturer</th>
<th>Specimen type</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick Advance Rapid HIV-1/2 Antibody Test</td>
<td>OraSure Technologies, Inc</td>
<td>Whole blood</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oral fluid</td>
</tr>
<tr>
<td>Uni-Gold Recombigen HIV Test</td>
<td>Trinity Biotech</td>
<td>Whole blood</td>
</tr>
<tr>
<td>Clearview HIV 1/2 Stat Pak</td>
<td>Chembio Diagnostic Systems</td>
<td>Whole blood</td>
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## Moderate Complexity Rapid HIV Antibody Tests Currently Available

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<td>Plasma</td>
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<tr>
<td>Reveal G3 Rapid HIV-1 Antibody Test</td>
<td>MedMira Laboratories</td>
<td>Serum/plasma</td>
</tr>
<tr>
<td>Uni-Gold Recombigen HIV Test (HIV-1)</td>
<td>Trinity Biotech</td>
<td>Serum/plasma</td>
</tr>
<tr>
<td>Multispot HIV-1/HIV-2 RapidTest</td>
<td>Bio-Rad Laboratories</td>
<td>Serum/plasma</td>
</tr>
<tr>
<td>Clearview HIV 1/2 Stat Pak</td>
<td>Chembio Diagnostic Systems</td>
<td>Serum/plasma</td>
</tr>
<tr>
<td>Clearview Complete HIV 1/2 (Sure Check)</td>
<td>Chembio Diagnostic Systems</td>
<td>Whole blood</td>
</tr>
</tbody>
</table>


Past CLIAC Discussions
RE: Waiving Rapid HIV Tests

- May 2001: recommendation to BPAC expressing that HIV tests are inappropriate for the waived category
- September 2002: Controversial issues of access and quality, recommended waiver not appropriate at this time
- Fall 2002: Interagency HHS task force formed to debate the issues
- January 2003: First test waived (OraQuick® HIV-1 Antibody Test)
Efforts to Promote Quality Assurance for Rapid HIV Testing

- January 2003: CDC workgroup convened to draft QA guidelines
- June 2003: Quality Assurance Guidelines for Testing Using the OraQuick® Rapid HIV-1 Antibody Test (under revision)
- 2003-2004: CDC training sessions for states, public health testing sites
- Training through State public health departments
- FDA sales restrictions for quality assurance
FDA Sales Restrictions Apply to All Rapid HIV Tests

- Sale restricted to clinical laboratories that have an adequate quality assurance program
  - including planned systematic activities to provide adequate confidence that requirements for quality will be met; and
  - where there is assurance that operators will receive and use the instructional materials;
- Approved for use only by an agent of a clinical laboratory;
- Test subjects must receive the "Subject Information" pamphlet prior to specimen collection and appropriate information when test results are provided;
- The test is not approved for use to screen blood or tissue donors.
Rapid HIV Testing
Overview of Presentations

- Results from the Model Performance Evaluation Program (MPEP) – Dev Howerton (CDC)
- Use of waived rapid HIV testing in public health settings – Duncan Mackellar (CDC)
- Use of rapid HIV testing in the private sector - hospitals and community settings – Laura Bogart, PhD (RAND Corp)