Rapid Testing in Healthcare Facilities

M. Orticke, RN, MPH
Chief, Clinical Services Division
Office of AIDS Programs & Policy

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HIV Rapid Testing (RT)

- Update on RT programs in OAPP funded medical outpatient clinics
- 5P21’s RT program
- Funding for RT
- Explore interest in implementing RT
- Technical assistance for RT program set-up & implementation
Rapid HIV Tests

• Simple to use & require little or no specialized equipment
• Test results are provided at the time of testing
• Six rapid HIV tests approved by the U.S. Food & Drug Administration
• Tests are either “waived” or categorized as “moderate complexity”

http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt-lab.htm
Requirements for Performing Rapid HIV Tests

• Any organization that performs a rapid HIV test in order to provide results to patients is considered a laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

• All laboratories must comply with regulations of the CLIA program & applicable State requirements (http://www.cms.hhs.gov/CLIA/)
Requirements for Performing Rapid HIV Tests

- **Options for organizations**: apply for its own CLIA certificate, or if authorized by CMS, make arrangements to be included with a CLIA-certified laboratory under a multiple site exception.
Waived Testing

• No federal requirements for personnel, quality assessment, or proficiency testing

• Performed in traditional laboratories, clinical settings, HIV counseling & testing sites, mobile vans, health fairs

• Organizations must obtain a certificate of waiver from CLIA, be included in a CLIA - certified laboratory under a multiple site exception and follow manufacturer’s instructions for the test (http://wwwn.cdc.gov/clia/regs/toc.aspx)
Moderate Complexity Testing

- Must register with CLIA program & meet specific standards for personnel, quality assessment, proficiency testing and inspections (http://wwwn.cdc.gov/clia/moderate.aspx)
# Rapid Tests Available in the U.S.

<table>
<thead>
<tr>
<th>Test Kit Name</th>
<th>Specimen Type</th>
<th>CLIA Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick Advance Rapid HIV 1/2 Antibody Test</td>
<td>Whole blood, Oral fluid</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>Moderate complexity</td>
</tr>
<tr>
<td>Reveal G3 Rapid HIV-1 Antibody Test</td>
<td>Serum, Plasma</td>
<td>Moderate complexity</td>
</tr>
<tr>
<td>Uni-Gold Recombigen HIV Test</td>
<td>Whole blood, Serum, Plasma</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Moderate complexity</td>
</tr>
<tr>
<td>Multispot HIV-1/HIV-2 Rapid Test</td>
<td>Serum, plasma</td>
<td>Moderate complexity</td>
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Rapid HIV Testing in Medical Outpatient Clinics

- 9 of 23 (40%) medical outpatient clinics are performing RT
- Testing partners & their family, walk-ins
- Approx. 10,000 RTs in 2006
- 2% - 11% positivity rate

OAPP-Clinical Services Division Survey of rapid testing in OAPP funded medical outpatient clinics, August 2007