Overview of CLIA-Waived Rapid HIV Tests and the HIV Rapid Testing Algorithm (RTA) Project

Jacqueline Rurangirwa, MPH
Office of AIDS Programs and Policy Planning and Research Division

HIV Prevention Planning Committee
HIV Counseling and Testing Work Group
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FDA Approved CLIA-Waived Rapid HIV Tests

Overview
## FDA Approved CLIA-Waived Tests

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Rapid HIV Test</th>
<th>Specimen Type</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraSure Technologies, Inc.</td>
<td>OraQuick Advance Rapid HIV-1/2</td>
<td>Oral fluid</td>
<td>99.3%</td>
<td>99.8%</td>
</tr>
<tr>
<td><a href="http://www.orasure.com">www.orasure.com</a></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inverness Medical Professional Diagnostics</td>
<td>Clearview HIV 1/2 STAT-PAK</td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>99.7%</td>
<td>99.9%</td>
</tr>
<tr>
<td><a href="http://www.invernessmedicalpd.com">http://www.invernessmedicalpd.com</a></td>
<td>Clearview HIV 1/2 COMPLETE</td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>99.7%</td>
<td>99.9%</td>
</tr>
<tr>
<td>Trinity Biotech</td>
<td>Uni-Gold Recombigen HIV</td>
<td>Whole blood (fingerstick or venipuncture)</td>
<td>100%</td>
<td>99.7%</td>
</tr>
<tr>
<td><a href="http://unigoldhiv.com">http://unigoldhiv.com</a></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
OraQuick Advance Rapid HIV-1/2

- Blood or Oral Specimen
- Store at room temperature
- Screens for HIV-1 and HIV-2
- Results read in 20-40 minutes
- Read window is 20 minutes
Clearview STAT-PAK HIV 1/2

- Blood Specimen Only

- Store at room temperature

- Screens for HIV-1 and HIV-2

- Results read in 15-20 minutes

- Read window is 5 minutes
Clearview COMPLETE HIV 1/2

- Blood Specimen Only
- Store at room temperature
- Screens for HIV-1 and HIV-2
- Results read in 15-20 minutes
- Read window is 5 minutes
Uni-Gold Recombigen HIV

- Blood Specimen Only
- Store at room temperature
- Screens for HIV-1
- Results read in 10-12 minutes
- Read window is 2 minutes
CLIA-Waived Tests Run Times

#1 ORAQUICK
Run Time
Min: 20 min
Max: 40 min.
Read Window
Between: 20-40 min.

#2 STAT-PAK and COMPLETE
Run Time
Min: 15 min.
Max: 20 min.
Read Window
Between: 15-20 min.

#3 UNI-GOLD
Run Time
Min: 10 min.
Max: 12 min.
Read Window
Between: 10-12 min.
HIV Rapid Testing Algorithm (RTA)

Project Overview
RTA Project Objectives

- Evaluate feasibility and cost of implementing a RTA in public point-of-care HIV testing settings
- Validate use of a RTA to provide accurate diagnosis of HIV infection
- Assess the impact of same-day diagnosis of HIV on the linkage to medical care
- Develop written protocols and best practices for implementation of a RTA
RTA Project Structure

• Eligibility: All clients 12 years or older presenting for HIV rapid testing

• Locations:
  – Los Angeles Department of Public Health
  – San Francisco Department of Public Health

• Standard HIV testing consent forms

• RTA intervention Sites
  – 9 publicly funded point-of-care settings
    • Jails, mobile testing units, clinics, store fronts

• Comparison Sites
  – 23 publicly funded sites providing standard rapid HIV testing
HIV Rapid Testing Algorithm (RTA) – Intervention Sites

1st Test
Oral Fluid or Whole Blood
Oraquick

Non-Reactive (-)
Client considered HIV Negative

Reactive (+)
2nd Test Performed
Clearview Stat-Pak
Whole Blood

2nd Test Non-Reactive (+ -)
3rd Test Performed
Uni-Gold Recombigen
Whole Blood

2nd Test Reactive (+ +)
Client considered HIV positive

3rd Test Non-Reactive (+ - -)
Client considered HIV Negative

3rd Test Reactive (+ - +)
Client considered HIV positive
Referred to medical care

REFER TO CARE
### HIV Rapid Tests used in the RTA

<table>
<thead>
<tr>
<th>OraQuick</th>
<th>Stat-Pak</th>
<th>Uni-Gold</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="OraQuick" /></td>
<td><img src="image2.png" alt="Stat-Pak" /></td>
<td><img src="image3.png" alt="Uni-Gold" /></td>
</tr>
<tr>
<td>Oral fluid directly or fingerstick with a loop</td>
<td>Collect blood from the vacutainer tube Using a <strong>loop</strong> (add 1 loop)</td>
<td>Collect blood from the vacutainer tube Using <strong>eye dropper</strong> (add only 1 drop)</td>
</tr>
<tr>
<td>Buffer in vial</td>
<td>3 drops of Stat-Pak buffer</td>
<td>4 drops of Uni-Gold buffer</td>
</tr>
<tr>
<td>Run for <strong>20 – 40 min.</strong></td>
<td>Run for <strong>15 – 20 min.</strong></td>
<td>Run for <strong>10 – 12 min.</strong></td>
</tr>
<tr>
<td>Run temps <strong>59°F - 99°F</strong></td>
<td>Run temps <strong>64°F - 86°F</strong></td>
<td>Run temps <strong>59°F - 80°F</strong></td>
</tr>
<tr>
<td>Storage temps <strong>35°F - 80°F</strong></td>
<td>Storage temps <strong>46°F - 86°F</strong></td>
<td>Storage temps <strong>35°F - 80°F</strong></td>
</tr>
</tbody>
</table>

**Run temps**
- **OraQuick**: 59°F - 99°F
- **Stat-Pak**: 64°F - 86°F
- **Uni-Gold**: 59°F - 80°F

**Storage temps**
- **OraQuick** and **Uni-Gold**: 35°F - 80°F
- **Stat-Pak**: 46°F - 86°F
Current Rapid HIV Testing Standard – Control Sites

OraQuick HIV Rapid Test (Oral or finger stick)

<table>
<thead>
<tr>
<th>Negative</th>
<th>Preliminary Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Confirmatory Testing</td>
</tr>
<tr>
<td></td>
<td>EIA/WB</td>
</tr>
<tr>
<td></td>
<td>1 Week Later:</td>
</tr>
<tr>
<td></td>
<td>Confirmatory Results</td>
</tr>
<tr>
<td>Negative/Inconclusive</td>
<td>Confirmed Positive</td>
</tr>
<tr>
<td></td>
<td>REFER TO CARE</td>
</tr>
</tbody>
</table>

Follow-up/ additional Testing
<table>
<thead>
<tr>
<th></th>
<th>Los Angeles</th>
<th>San Francisco</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td></td>
<td>(8/15/07 – 9/1/08)</td>
<td>(8/1/07 – 7/31/08)</td>
</tr>
<tr>
<td># Tested</td>
<td>5,187</td>
<td>5,511</td>
</tr>
<tr>
<td># Screened Reactive</td>
<td>127 (2.45%)(^1)</td>
<td>104 (1.89%)(^1)</td>
</tr>
<tr>
<td># RTA Positive</td>
<td>39 (0.75%)(^2)</td>
<td>76 (1.38%)</td>
</tr>
<tr>
<td># False Positive</td>
<td>4 (0.08%)</td>
<td>24 (0.44%)</td>
</tr>
<tr>
<td>Mean # Days Referred to Medical Care</td>
<td>0 days</td>
<td>0 days</td>
</tr>
</tbody>
</table>

\(^1\) 84 clients from Los Angeles and 4 clients from San Francisco with reactive screening did not proceed to RTA due to refusal of confirmatory testing or reported prior HIV positive result.

\(^2\) 1 Western Blot Result did not match RTA reactive Results (EIA/WB negative).
# RTA Control Site Results

<table>
<thead>
<tr>
<th></th>
<th>Los Angeles</th>
<th>San Francisco</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N (%))</td>
<td>(N (%))</td>
</tr>
<tr>
<td># Tested</td>
<td>16,495</td>
<td>7,829</td>
</tr>
<tr>
<td># Screened Reactive</td>
<td>320 (1.94%)</td>
<td>145 (1.85%)</td>
</tr>
<tr>
<td># False Positive</td>
<td>25 (0.15%)</td>
<td>27 (0.34%)</td>
</tr>
<tr>
<td># Received Confirmatory Test Results</td>
<td>135 (42.2%)</td>
<td>87 (60.0%)†</td>
</tr>
<tr>
<td>Mean # Days Referred to Medical Care (range)</td>
<td>11.3 days (1 – 55 days)</td>
<td>7.6 days (7 – 21 days)</td>
</tr>
</tbody>
</table>

* HIV counseling and testing data are provisional due to reporting delays.

† Estimate due to reporting delays.
RTA Data Summary

• Intervention Sites
  – All clients received their test results on the same day
  – All RTA reactive clients were referred to medical care on the same day
  – 28 individuals had a false positive result resolved on the same day
  – The number of false positive OraQuick results are within the limits of the FDA approved package insert
  – Out of over 10,000 screening tests, one anomaly (RTA +/- WB result - ) was observed
RTA Data Summary

- **Control Sites**
  - 42% – 60% of clients with initial reactive rapid HIV test returned for confirmatory test results
    - Intervention sites 100% of clients received final results
  - Mean 7.6 – 11.3 days before referred to medical care
    - Intervention sites mean 0 days
RTA Skills Required

Department of Public Health (DPH)
- Resources for start up
- Data systems in place
- Know your sites and assess site “readiness”

Agency/Testing Site
- Stable testing site
- Good track record with rapid testing
  • Adherence to quality assurance and testing protocols
- Great communication with DPH
RTA Skills Required – Continued

Agency/Testing Site Counselor

• Qualities needed for OraQuick
  – Ability to document
  – Attention to detail
  – Good eyesight, to see line
  – Good math skills

• Qualities needed for Stat-Pak & Uni-Gold
  – Need steady hand
  – Good eyesight to introduce control fluid into port
Lessons Learned

• Sites that had good history providing rapid testing were more successful with RTA

• RTA not for all sites
  – Sustaining phlebotomy capacity, staff turnover and training, adherence to RTA protocol

• The more Technical Assistance, the more successful

• Slow roll-out: staff and resources must be adequate

• A quality assurance plan and work flow plan must be developed and refined before implementation
RTA Next Steps

• Complete study period

• Link HIV counseling and testing data to HIV/AIDS surveillance data to determine:
  – If and when client entered into care
  – Differences between control and intervention sites

• Perform cost analysis of RTA

• Share best practices and lessons learned
Thanks!

Kevin Delaney
Project Officer
Centers for Disease Control and Prevention (CDC)

Los Angeles Project Team
Office of AIDS Programs and Policy
County of Los Angeles Department of Public Health
Community Partners – Intervention Sites

San Francisco Project Team
AIDS Office, HIV Prevention Section
San Francisco Department of Public Health
Community Partners – Intervention Sites
For More Information

Jacqueline Rurangirwa, MPH
Epidemiologist
Office of AIDS Programs and Policy
600 South Commonwealth Ave., 10th Floor
Los Angeles, California  90005-4001
Phone: 213-351-8000
Fax: 213-381-8023
E-mail: jrurangirwa@ph.lacounty.gov

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www.publichealth.lacounty.gov/aids