Can a second rapid HIV test discriminate false positives as effectively as a Western Blot? The NJ Experience

Evan M. Cadoff, MD
Robert Wood Johnson Medical School
New Brunswick, NJ
Can a second rapid HIV test confirm preliminary positives as effectively as a Western Blot?  
The NJ Experience

Evan M. Cadoff, MD  
Robert Wood Johnson Medical School  
New Brunswick, NJ
New Jersey CTS sites

- 23 primary sites

Conventional testing:
- Blood/oral specimens sent to NJ-DHSS lab
- 65% receive post-test counseling
- 35% do not return for results

Rapid testing needed
New Jersey rapid testing

OraQuick started Nov 1, 2003:
- 23 primary licensed sites
- 32 satellite sites
- Western Blot confirmation at state lab
- Over 70 CTS activities, including:
  - Hospitals/EDs
  - FQHCs
  - CBOs
  - STD clinics
  - Health departments
  - Mobile vans
  - One-time community events
Clients receiving post-test counseling

Marked improvement with introduction of rapid testing
Clients receiving post-test counseling

Marked improvement with introduction of rapid testing

Preliminary positives:
- 7.1% refused blood draw for confirmation
- 25.8% of those drawn did not return for results
- 70.1% of confirmed positives got their results and post-test counseling
Clients receiving post-test counseling

Marked improvement with introduction of rapid testing

Preliminary positives:
- 7.1% refused blood draw for confirmation
- 25.8% of those drawn did not return for results
- 70.1% of confirmed positives got their results and post-test counseling

Can rapid confirmation extend our success to preliminary positives?
Questions for rapid confirmation

- Will a finger stick be more acceptable for confirmation?
- Can rapid immunoassays perform as well as the ‘gold standard’ Western Blot?
## BBI Seroconversion Panel Results:

<table>
<thead>
<tr>
<th>Member #</th>
<th>Days since first bleed</th>
<th>EIA</th>
<th>Western blot</th>
<th>Viral load</th>
<th>Rapid test</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRB959-01</td>
<td>0</td>
<td>0.1</td>
<td>No bands</td>
<td>$2 \times 10^5$</td>
<td>Negative</td>
</tr>
<tr>
<td>PRB959-02</td>
<td>7</td>
<td>0.1</td>
<td>No bands</td>
<td>$&gt;8 \times 10^5$</td>
<td>Negative</td>
</tr>
<tr>
<td>PRB959-03</td>
<td>9</td>
<td>0.2</td>
<td>No bands</td>
<td>$&gt;8 \times 10^5$</td>
<td>Negative</td>
</tr>
<tr>
<td>PRB959-04</td>
<td>14</td>
<td>1.8</td>
<td>p24, gp160</td>
<td>$8 \times 10^5$</td>
<td>Positive</td>
</tr>
<tr>
<td>PRB959-05</td>
<td>19</td>
<td>7.3</td>
<td>p24, gp160</td>
<td>$5 \times 10^5$</td>
<td>Positive</td>
</tr>
<tr>
<td>PRB959-06</td>
<td>21</td>
<td>7.6</td>
<td>p24, gp160</td>
<td>$3 \times 10^5$</td>
<td>Positive</td>
</tr>
<tr>
<td>PRB959-07</td>
<td>26</td>
<td>7.8</td>
<td>p24, gp160</td>
<td>$&gt;8 \times 10^5$</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Bennett, 2005
Rapid confirmation trial

July 1, 2004 through April 19, 2005

- 15,923 OraQuick tests statewide
- 363 preliminary positive samples to state lab for confirmatory testing
  - 355 Western Blot positive
  - 8 Western Blot negative
Rapid confirmation trial

- All 8 Western Blot negative clients:
  - Included in CDC Post-marketing surveillance study (PMS-2)
  - 6/6 negative on follow-up at least 8 weeks later, both antibody and nucleic acid testing
  - 4/7 reacted with non-viral components of OraQuick device

All 8 were false positive OraQuick tests
Rapid confirmation trial

Samples re-tested with:

- Trinity Uni-Gold
- BioRad Multispot
- OraSure OraQuick
- MedMira Reveal
## Confirmatory test results

<table>
<thead>
<tr>
<th>Test</th>
<th>8 positive</th>
<th>355 positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraSure OraQuick</td>
<td>8</td>
<td>355</td>
</tr>
<tr>
<td>Trinity Uni-Gold</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BioRad Multispot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MedMira Reveal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Followup of &gt;2 months</td>
<td>6/6 negative Western Blot</td>
<td>6/6 negative viral load</td>
</tr>
</tbody>
</table>
## Confirmatory test results

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Result</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 Western Blot negative</td>
<td>(False Positive OraQuick)</td>
<td>355</td>
</tr>
<tr>
<td>355 Western Blot positive</td>
<td>(True Positive OraQuick)</td>
<td></td>
</tr>
<tr>
<td>OraSure OraQuick</td>
<td>8 positive</td>
<td>355</td>
</tr>
<tr>
<td>Trinity Uni-Gold</td>
<td>8 negative</td>
<td>355</td>
</tr>
<tr>
<td>BioRad Multispot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MedMira Reveal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Followup of &gt;2 months</td>
<td>6/6 negative Western Blot</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6/6 negative viral load</td>
<td></td>
</tr>
</tbody>
</table>
## Confirmatory test results

<table>
<thead>
<tr>
<th>Test</th>
<th>8 Western Blot negative (False Positive OraQuick)</th>
<th>355 Western Blot positive (True Positive OraQuick)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraSure OraQuick</td>
<td>8 positive</td>
<td>355 positive</td>
</tr>
<tr>
<td>Trinity Uni-Gold</td>
<td>8 negative</td>
<td>355 positive</td>
</tr>
<tr>
<td><strong>BioRad Multispot</strong></td>
<td>7 negative 1 positive</td>
<td><strong>354 positive 1 QNS</strong></td>
</tr>
<tr>
<td>MedMira Reveal</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Followup of &gt;2 months</strong></td>
<td>6/6 negative Western Blot 6/6 negative viral load</td>
<td></td>
</tr>
</tbody>
</table>
## Confirmatory test results

<table>
<thead>
<tr>
<th>Test</th>
<th>8 Western Blot negative (False Positive OraQuick)</th>
<th>355 Western Blot positive (True Positive OraQuick)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraSure OraQuick</td>
<td>8 positive</td>
<td>355 positive</td>
</tr>
<tr>
<td>Trinity Uni-Gold</td>
<td>8 negative</td>
<td>355 positive</td>
</tr>
<tr>
<td>BioRad Multispot</td>
<td>7 negative 1 positive</td>
<td>354 positive 1 QNS</td>
</tr>
<tr>
<td>MedMira Reveal</td>
<td>8 negative</td>
<td>340 positive 15 sample interference</td>
</tr>
<tr>
<td>Followup of &gt;2 months</td>
<td>6/6 negative Western Blot 6/6 negative viral load</td>
<td></td>
</tr>
</tbody>
</table>
Rapid confirmation trial

- **Repeat OraQuick** (CLIA waived for whole blood or oral fluid)
  - All samples reproduced
  - Not approved for serum testing, or stored samples

- **UniGold** (CLIA waived for whole blood, CLIA moderate for serum)
  - All samples matched Western Blot
  - Study used serum, clinics would perform whole blood testing

- **Multispot** (CLIA moderate for serum/plasma)
  - 1 false positive

- **Reveal** (CLIA moderate for serum/plasma)
  - No false positives, or false negatives
  - Several unreadable samples
A second rapid HIV test can confirm a positive OraQuick result as reliably as a Western Blot.
Western Blot Confirmation

- Failures to confirm results:
  - No confirmatory sample collected
  - Not all clients return for confirmatory results
- 29.9 got no result—as effective as a false negative result (but follow-up data is not yet complete)

Effective sensitivity of Western Blot confirmation is somewhere above 70.1%
Using OraQuick with Uni-Gold confirmation:

- Matched OraQuick with Western Blot confirmation in 100% of 15,923 clients studied
- Finger stick confirmation may reduce the refuse-to-confirm rate
- Rapid confirmation may virtually eliminate the non-returners
- Effective sensitivity may approach 99-100%
- Counseling, contact elicitation and referral for treatment can be done immediately
Next steps

Prospective evaluation of algorithm of OraQuick with Uni-Gold confirmation:

- Real world performance of a rapid test as confirmation
- Effect on post-test counseling rate
- Reduction in time delay in delivering confirmed result to clients using different confirmatory test algorithms
- Expansion to Notification Assistance Program