Overview of the FDA-Approved OraQuick® Rapid HIV-1 Antibody Test

CLIAC
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On November 7, 2002, FDA approved the OraQuick® Rapid HIV-1 Antibody Test as a moderate complexity device under CLIA

Intended use:
- To detect antibodies to HIV-1 in fingerstick whole blood specimens
- A point-of-care test to aid in the diagnosis of infection with HIV-1
- Suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results
OraQuick® is Approved as a Restricted Device

✦ Sale is 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
OraQuick® Restrictions, cont.

- Test subjects must receive the “Subject Information” pamphlet prior to specimen collection and appropriate information when test results are provided.

- Not approved for use to screen blood or tissue donors.

- Customer letter included with all kits:
  - “By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the…restrictions on the sale, distribution, and use of the device…”
Description of the OraQuick® Test
Description of the OraQuick® Test

SUBJECT INFORMATION

What You Should Know About HIV and the OraQuick® Rapid HIV-1 Antibody Test Prior to Being Tested
Description of the OraQuick® Test
Description of the OraQuick® Test
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Description of the OraQuick® Test

20-60 minutes

Follow CDC guidelines to inform the test subject of the test result and its interpretation.
OraQuick® Results and Interpretation

RESULT: NON-REACTIVE
INTERP: NEGATIVE
RESULT: REACTIVE
INTERP: PRELIM POSITIVE
OraQuick® Results and Interpretation

INVALID TEST RESULTS
## OraQuick® Clinical Trial Data: Sensitivity

<table>
<thead>
<tr>
<th>Group</th>
<th>Total Samples</th>
<th>OQ Reactive</th>
<th>Licensed EIA RR</th>
<th>WB+</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Known HIV-1+</td>
<td>481</td>
<td>479</td>
<td>481</td>
<td>481</td>
</tr>
<tr>
<td>High Risk</td>
<td>625</td>
<td>17</td>
<td>20*</td>
<td>17</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1146</td>
<td>536</td>
<td>541</td>
<td>538</td>
</tr>
</tbody>
</table>

*2 specimens negative and 1 indeterminate by WB

**SENSITIVITY IN TRIAL: 99.6% (98.5%-99.9%)**
## OraQuick® Clinical Trial Data: Specificity

<table>
<thead>
<tr>
<th>Group</th>
<th>Total Samples</th>
<th>OQ NR</th>
<th>Licensed EIA NR</th>
<th>True Neg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Risk</td>
<td>1250¹</td>
<td>1248</td>
<td>1247</td>
<td>1248</td>
</tr>
<tr>
<td>High-Risk</td>
<td>625</td>
<td>608</td>
<td>605</td>
<td>608</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1875</td>
<td>1856</td>
<td>1852</td>
<td>1856</td>
</tr>
</tbody>
</table>

*Two specimens from low-risk study gave Reactive results with OQ, RR results with EIA, and positive results with WB.

**SPECIFICITY IN TRIAL:** 100% (99.7%-100%)
OraQuick® Clinical Trial Data: Reproducibility

◆ 3 sites, 3 lots, 3 different days, 3 operators/site (9 total)

◆ Blind-coded panel of 5 contrived whole blood specimens
  – 4 antibody-positive and 1 antibody-negative specimen

◆ Results
  – 20-minute read time: 404/405 = 99.8%
  – 55-60 minute read time: 405/405 = 100%
OraQuick® CLIA Waiver

- OraQuick® was granted a CLIA waiver on January 31, 2003

- Data submitted in support of waiver
  - At 4 sites, 100 lay users with no laboratory experience tested panels of 6 masked randomized specimens
    » 2 negative, 2 low positive, 2 high positive
  - No statistically significant difference between lay user results and correct results
OraQuick® CLIA Waiver, cont.

- Package insert for waived device in preparation
  - Will contain details on waiver studies

- Sales and use restrictions remain in place for the waived test

- Quality Assurance program recommendations for rapid HIV tests are being developed by CDC