Step 1. Collect Sample

Oral Fluid

Swab lower and upper gum once. DO NOT swab the roof of the mouth, cheeks or tongue.

Fingerstick Whole Blood


Venous Whole Blood
Validated for EDTA, sodium heparin and sodium citrate

Collect blood using standard phlebotomy procedures. Fill the Collection Loop.

- Whole blood may be stored at 2-30°C (35-86°F) for up to 5 days.
- Invert the tube several times to mix.

Plasma
Validated for EDTA

Collect blood using standard phlebotomy procedures. Fill the Collection Loop.

- Centrifuge at 1000-1300 x g for approximately 5 minutes.
- Plasma may be stored up to 7 days at 2-8°C (35-46°F).
- Whole blood may be stored at 2-30°C (35-86°F) for up to 5 days.

Go to Step 2
Step 2. Perform the Test

- Insert device into buffer.
- Start the timer.
- Pink fluid travels through the Result Window.
- Do NOT remove the device from the Developer Solution while the test is running.

Step 3. Read Results between 20 and 40 minutes

Non-reactive: Line in C Zone

- CDC recommendations for reporting HIV negative results:
  - HIV-negative test results may be conveyed without direct personal contact between the patient and the health-care provider.
  - Persons known to be at high risk for HIV infection also should be advised of the need for periodic retesting and should be offered prevention counseling or referred for prevention counseling.

Invalid: Repeat Test

- No Line in C Zone
- Red background obscures results
- Lines are outside of C or T Zones

Reactive: Lines in C and T Zones. Report as preliminary positive. Order Western blot to confirm.

- Examples of preliminary positive results.
  - Line in T Zone.
  - Line in C Zone in each test.
  - Faint line in T Zone

- CDC recommendations for reporting HIV positive results:
  - HIV positive test results should be communicated confidentially through person contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff.
  - Active efforts are essential to ensure that HIV-infected patients receive their positive test results and linkage to clinical care, counseling, support and prevention services.
  - If the necessary expertise is not available in the health-care venue in which screening is performed, arrangements should be made to obtain necessary services from another provider, local health department, or community-based organization.

Performance Characteristics

Multiple clinical studies were conducted to determine sensitivity and specificity of the OraQuick ADVANCE® HIV-1/2 Test. Confirmation was performed by a licensed Western blot, with confirmation of indeterminate results by IFA or radioimmunoprecipitation assay (RIPA).

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Total Samples</th>
<th>OraQuick Reactive</th>
<th>True Positive</th>
<th>OraQuick Sensitivity (%)</th>
<th>95% CI</th>
<th>Total Samples</th>
<th>OraQuick Non-reactive</th>
<th>True Negative</th>
<th>OraQuick Specificity (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Fluid</td>
<td>3917</td>
<td>834</td>
<td>840</td>
<td>99.3%</td>
<td>98.4-99.7%</td>
<td>3755</td>
<td>3674</td>
<td>3682</td>
<td>99.8%</td>
<td>99.6-99.9%</td>
</tr>
<tr>
<td>Fingerstick</td>
<td>1146</td>
<td>536</td>
<td>538</td>
<td>99.6%</td>
<td>98.5-99.9%</td>
<td>1875</td>
<td>1856</td>
<td>1856</td>
<td>100.0%</td>
<td>99.7-100%</td>
</tr>
<tr>
<td>Plasma</td>
<td>1424</td>
<td>901</td>
<td>905</td>
<td>99.6%</td>
<td>98.9-99.8%</td>
<td>1636</td>
<td>1620</td>
<td>1622</td>
<td>99.9%</td>
<td>99.6-99.9%</td>
</tr>
</tbody>
</table>

Order Information

- Description: Box of 25 tests
- Box of 100 tests
- Controls

Reimbursement Information

CPT Code: 86703-92

Advance Awareness™

OraQuick Rapid HIV-1/2 Antibody Test

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