OraQuick ADVANCE® Rapid HIV1/2 Antibody Test (Oral Specimen)

**PURPOSE:** The standard laboratory HIV testing algorithm consists of screening with an enzyme immunoassay (EIA) and confirmation of repeatedly reactive EIAs using a Western blot test. Results are typically not available for 48 hours to two weeks, making these standard screening tests inadequate to meet the need of rapid HIV diagnosis. The OraQuick ADVANCE® Rapid HIV1/2 Antibody test addresses this issue by providing prompt results during the initial visit and enabling immediate counseling.

**SCOPE:** The OraQuick ADVANCE® Rapid HIV1/2 Antibody test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluids. This rapid HIV test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

**PRINCIPLE:** The OraQuick ADVANCE® Rapid HIV1/2 Antibody test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in human oral fluid. This test is comprised of a single use test device and single use vial containing a pre-measured amount of buffered developer solution. The test device holds an assay strip comprised of several materials that provide a matrix for the immunochromatography of the specimen. The oral fluid specimen is collected using the flat pad on the test device, followed by insertion of the test device into the vial of developer solution. Through lateral flow, the developer solution facilitates the flow of the specimen into the device and onto the test strip. The results are viewed in the results window, which consists of a Test (T) zone and a procedural Control (C) zone. Test results are read after 20 minutes, but not more than 40 minutes after placement of the specimen in the developer solution.

The rapid test can be non-reactive, reactive or invalid. All reactive samples are tested using a Western blot confirmatory assay. Samples which are non-reactive are considered negative and do not require additional testing. Samples, which are invalid, are those that do not produce a typical reaction in the rapid assay. Invalid samples are retested and may require a follow-up sample.
PERSONNEL:
Intended for use by clinical personnel who have been trained and demonstrated competency in this procedure. In the ambulatory setting, this includes:

- Medical Assistants,
- Licensed Vocational Nurses,
- Registered Nurses,
- Nurse Practitioners,
- Physician Assistants,
- Physicians,
- Clinical Laboratory Scientists, and
- Other Licensed Technologists

Individuals who are color blind must demonstrate their ability to read the test results.

EQUIPMENT & REAGENTS:
Supplies
- Rapid HIV Antibody Kit (OraQuick, OraSure Technologies, distributed by Abbott Laboratories, North Chicago, IL).
  - 25 Test Pouches. Each test pouch contains:
    - Test device
    - Developer solution (1 ml vial)
  - Collection Loops
  - 5 Reusable Test Stands
- External control materials (OraQuick, OraSure Technologies, distributed by Abbott Laboratories, North Chicago, IL)
  - HIV-1 Positive Control, Black cap vial
  - HIV-2 Positive Control, Red cap vial
  - Negative Control, White cap vial
- Gloves, gauze and other disposable items as needed
- Biohazard container
- Timer

Storage & Handling
- Store unused kits 35-80°F (2-27°C)
- If stored refrigerated, ensure pouch is brought to operating temperature, 59-99°F (15-37°C) before opening pouch
- Do not use after expiration date printed on each pouch
- Do not mix components from different kit lots.
- Do not block holes on back of test device
- Do not touch flat pad of test device
- Store Control reagents 35-46°F (-2°-8°C)

SPECIMEN REQUIREMENTS:
Using the flat pad of the test device, an oral sample is collected (see PROCEDURE for detail).
• The specimen must be inserted into the Developer Solution vial within 30 minutes of collection.
• If testing is not performed within 10 minutes, return the test device to the pouch after the dessicant has been removed, for up to 20 minutes. Ensure test device is stored in a horizontal position until placed in developer solution.
• Specimens not tested immediately by the person collecting the specimen must be labeled in the presence of the patient, using two forms of patient identification. Do not block holes on back of test device when applying a patient ID label.

QUALITY CONTROL:
Quality Control must be performed:
• Each new operator, to demonstrate competency, prior to performing patient testing
• Each new lot of test kits
• Each new shipment of test kits
• Each new box of test kits when first opened
• If the temperature of the storage area falls outside of 35-80°F (2-27°C)
• If the temperature of the testing area falls outside of 59-99°F (15-37°C)

Built-In Procedural Control:

The OraQuick ADVANCE® Rapid HIV1/2 Antibody test has a built in procedural control that demonstrates assay validity. A reddish-purple line in the Control (C) area of the result window indicates that a specimen was added and that the fluid migrated appropriately through the test device. The Control line must appear for a test result to be considered valid. If control line fails to appear, test is invalid and must be repeated. For each patient, procedural control is documented.

External Liquid Controls:

HIV-1 Positive Control, HIV-2 Positive Control, and Negative Control,
1. Open the two chambers of the kit and remove developer solution from pouch. Label with appropriate control level name
2. Open vial of HIV-1 Positive Control reagent. Insert unused Collection Loop into control reagent. Visually inspect the loop to ensure that it is completely filled with the control reagent.
3. Immerse Collection loop into developer solution vial labeled HIV-1 Positive Control and use loop to stir contents.
4. Remove collection loop and dispose of in Biohazard waste container.
5. Remove test device from second pouch of kit, do not touch flat pad. Ensure dessicant package is present. If package does not contain dessicant, discard device and developer solution and obtain new kit.
6. Label test device as HIV-1 positive control and place test device in developer solution with test window facing you. Ensure flat pad touches bottom of vial
7. Start timing the QC test; do not remove device from vial while test is running.
8. Read results after 20 minutes, but before 40 minutes.
9. Verify reddish purple line in the Control (C) region and a fainter line in the Test (T) region. Document results on QC log sheet.
11. Repeat steps 1-7 using Negative control and verify reddish-purple line in Control region only. There should be no line in the Test region. Document results on QC log sheet.
12. Initial, date and write “QC’d” on box after liquid QC has passed.
13. IF QC fails, repeat QC. If QC fails a second time, return remaining product to Materials Services and call Point of Care Coordinator at 353-1630 or 353-8750.

PROCEDURE/PATIENT TESTING

1. Using two patient identifiers, identify patient and explain procedure to patient and/or family.
2. Obtain verbal patient consent for HIV testing and provide patient with HIV information pamphlet. Verbal consent will be documented in the log book.
3. Open the two chambers of the kit. To prevent contamination, leave the test device in the pouch and remove developer solution from pouch.
4. Hold the vial firmly, carefully remove cap and slide vial into blue test stand.
5. Remove Test Device from the pouch and ensure dessicant is present. If package does not contain dessicant, discard the test Device and obtain new kit.
6. Do not touch flat pad of test device.
7. Direct patient to place the flat pad above the teeth, against the outer gum and swab both upper and lower gum one time. Both sides of the flat pad may be used. **NOTE:** DO NOT swab roof of mouth, inside of cheek or tongue.
8. Immediately insert flat pad of the test device into the developer solution, making sure flat pad touches bottom of vial and Result Window is facing toward you.
9. Start timing the test. DO NOT remove the device from the vial while the test is running. Pink fluid will appear and travel up the result window. Pink fluid will gradually disappear as test develops.
10. Read the result after 20 minutes, but not before 40 minutes, in a fully lighted area.
11. Verify reddish purple line in the Control (C) region before reading results. If control line does not appear, test is invalid. Repeat test.
12. If not testing immediately, label the Test Device with appropriate patient identification, in the presence of the patient. Do NOT cover the two holes in the back of the Test Device with the label or any other materials.
13. Perform test within 10 minutes of collection or (after removing dessicant) store test device/sample in kit pouch placed on flat surface, for up to 30 minutes.
15. If results are Reactive (Positive), specimen must be sent to the Clinical Labs for confirmatory testing.

READING AND REPORTING RESULTS:
Results can be Non-Reactive(Negative), Reactive(Positive) or Invalid:

<table>
<thead>
<tr>
<th>Non-Reactive (Negative)</th>
<th>Reactive(Positive)</th>
<th>Invalid</th>
</tr>
</thead>
<tbody>
<tr>
<td>C line is reddish-purple.</td>
<td>C line is reddish-purple.</td>
<td>C line is blank, NO line.</td>
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</table>
1. Read the procedural control (C) and verify that control line appeared as expected. If procedural control fails, test is invalid and must be repeated.
2. Record the procedural control results and patient results in the log and/or the patient’s chart.
3. If the patient sample has an invalid result the test must be repeated.
4. Call the ordering MD or RNP with the result.
5. If the rapid HIV antibody test is non-reactive the result is given as "Negative".
6. If the rapid HIV antibody test is reactive the result is given as "Positive." Confirmatory testing must be done and results of Lab tests will be noted in the log book. NOTE: confirmatory testing is performed by western blot at China Basin in Immunology. Specimen must be drawn and sent to the Clinical Laboratory.

PROCEDURE NOTES:
1. Use Collection Loops, Test Devices and Developer Solution vials only once. Dispose of all specimens and used supplies in a Biohazard waste container.
2. Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
3. Do not interchange Test Devices and Developer Solution vials from kits with different lot numbers.
4. Avoid microbial contamination and exercise care in handling the kit components.
5. To ensure accurate results, the Test Device must be inserted into the Developer Solution within 30 minutes of collection. Specimens that are not inserted into the Developer Solution within 10 minutes of collection should be returned to the divided pouch, after the dessicant has been removed and stored on a flat surface. Testing must be performed within 30 minutes of specimen collection.
6. Adequate lighting is required to read a test result.

PRECAUTIONS:
1. Test subjects must receive the HIV Information pamphlet prior to specimen collection and appropriate information when test results are provided.
2. The OraQuick ADVANCE® Rapid HIV1/2 Antibody test is not approved for use to screen blood or tissue donors.

LIMITATIONS:
1. Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.
2. Clinical data has not been collected to demonstrate the performance of the OraQuick ADVANCE® Rapid HIV1/2 Antibody testing on persons under 12 years of age.

3. A reactive result suggests the presence of HIV-1 and/or HIV-2 antibodies in the specimen. This test is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically.

4. For a reactive result, the intensity of the test line does not necessarily correlate with the titer of antibody in the specimen.

5. A non-reactive result does not preclude the possibility of exposure to HIV. An antibody response to recent exposure may take several months to reach detectable levels.

REFERENCES:
OraQuick ADVANCE® Rapid HIV1/2 Antibody Test package insert #3001-1215 (rev.10/07), OraSure Technologies, Inc., Bethlehem, PA 18015

OraQuick ADVANCE® Kit Controls package insert #3001-1202 (rev. 08/06), OraSure Technologies, Inc., Bethlehem, PA 18015

Rapid HIV Antibody Testing procedure, NCPL