



STEP-BY-STEP INSTRUCTIONS

FOR ORAQUICK® ADVANCE™ RAPID HIV-1/2 ANTIBODY TEST

Complexity: WAIVED for Oral Fluid, Fingerstick Whole Blood, and Venipuncture Whole Blood
Complexity: MODERATE for Plasma

- *These instructions are only a Reference Guide. For complete information, refer to the OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test Package Insert.*
- *Read these instructions completely before using the product. Follow the instructions carefully when performing testing. Not doing so may result in inaccurate test results.*
- *Before performing testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Blood-borne pathogens in Health-Care Settings.¹*

OraQuick®
ADVANCE™
Rapid HIV-1/2 Antibody Test



■ INTENDED USE:

The OraQuick® *ADVANCE*™ Rapid HIV-1/2 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 fluid, fingerstick whole blood, venipuncture whole blood, and plasma specimens.

FOR *IN VITRO* DIAGNOSTIC USE

**THIS IS A RESTRICTED DEVICE.
SALES, DISTRIBUTION AND USE RESTRICTIONS APPLY.
SEE CUSTOMER LETTER AND PACKAGE INSERT.**

THE FOLLOWING ITEMS ARE NEEDED TO DO THE TEST:

■ THE ORAQUICK® *ADVANCE*™ RAPID HIV-1/2 ANTIBODY TEST CONSISTS OF A DIVIDED POUCH CONTAINING THE FOLLOWING:

- Test Device (including an absorbent packet)
- Developer Solution Vial (containing 1 mL)

NOTE: The pouch is divided into two chambers. One chamber holds the Test Device while the other chamber holds the Developer Solution Vial.

■ MATERIALS PROVIDED IN THE MASTER SHIPPING CARTON:

- Reusable Test Stand
- Subject Information Pamphlet
- Customer Letter
- Specimen Collection Loop (5 microliter)
- Package Insert

■ MATERIALS REQUIRED BUT NOT PROVIDED:

- Timer or Watch capable of timing 20 to 40 minutes
- Clean, Disposable, Absorbent Workspace Cover
- Biohazard Waste Container

Additional items required for fingerstick and venipuncture whole blood collection, and plasma specimens:

- Antiseptic Wipe
- Sterile Lancet to Obtain a Fingerstick Whole Blood Specimen, or Materials Required to Obtain a Venipuncture Whole Blood Specimen
- Latex, Vinyl or Nitrile Disposable Gloves (Optional for Oral Fluid Testing)
- Sterile Gauze Pads
- Centrifuge to process a plasma specimen

NOTE: Handle all blood specimens and materials contacting specimens as if capable of transmitting infectious agents. Dispose of all test specimens and materials used in the test procedure in a biohazard waste container.¹ Oral fluid is not considered potentially infectious unless it contains blood.²

¹ See "Universal Precautions," CDC, MMWR, 1988; 37(24):377-388. ² CDC, MMWR, 2001; 50(RR-11):1-42.

For answers to questions regarding the OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Test or for more information on other OraSure Technologies' products, call: 1-800-ORASURE (800-672-7873) or visit our web site: www.orasure.com

External Quality Control

OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Test Kit Controls are available separately for use only with the OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Test. The Kit Controls are specifically formulated and manufactured to ensure performance of the Test, and are used to verify your ability to properly perform the test and interpret the results. Refer to the Kit Control Package Insert for complete instructions.

Run the Kit Controls under the following circumstances:

- Each new operator prior to performing testing on patient specimens,
- When opening a new test kit lot,
- Whenever a new shipment of test kits is received,
- If the temperature of the test kit storage area falls outside of 2 ° – 27 ° C (35 ° – 80 ° F),
- If the temperature of the testing area falls outside of 15 ° – 37 ° C (59 ° – 99 ° F),
- At periodic intervals as dictated by the user facility.

Set Up Your Work Space

- Gather the materials you will need.
- Allow the test kit to come to operating temperature (15 ° – 37 ° C; 59 ° – 99 ° F) before use.
- Refer to the *External Quality Control* section above to determine when the Kit Controls should be run.
- Cover your workspace with a clean, disposable, absorbent workspace cover.
- Set an OraQuick® *ADVANCE*™ Reusable Test Stand (“Stand”) up on your workspace cover. Use only the Stand provided.
- Put on your disposable gloves if you are planning to perform the test using a blood specimen. Use of gloves is optional for oral fluid testing.

Prior to testing, provide the “Subject Information” pamphlet to the person being tested.



General Test Preparation



Two Chambers

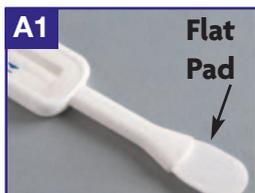


NOTE: DO NOT cover the two holes in the back of the Device with labels or other materials. Doing so may cause an Invalid result.

- Open the two chambers of the OraQuick® *ADVANCE*™ Divided Pouch (“Pouch”) by tearing at the notches on the top of each side of the Pouch (*see picture a and b*).
- To prevent contamination, leave the Test Device (“Device”) in the Pouch until you are ready to use it.
- Remove the Developer Solution Vial (“Vial”) from the Pouch.
- Hold the Vial firmly in your hand.
- Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off.
- Set the cap on your workspace cover.
- Slide the Vial into the top of one of the slots in the Stand (*see picture c*).
- **DO NOT** force the Vial into the stand from the front of the slot as splashing may occur.
- Make sure the Vial is pushed all the way to the bottom of the slot in the stand (*see picture c*).



ORAL FLUID – Specimen Collection and Testing Procedure



STEP 1 – COLLECT

- Have the person being tested remove the Device from its Pouch.
- DO NOT allow the person to touch the Flat Pad (*see picture A1*).
- Check to make sure that an Absorbent Packet is included with the Device (*see picture A2*). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Direct the person to place the Flat Pad above the teeth against the outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the Flat Pad (*see picture A3 and A4*). **DO NOT** allow the person to swab the roof of the mouth, the inside of the cheek or the tongue. NOTE: Both sides of the Flat Pad may be used during this procedure.

STEP 2 – TEST

- Instruct the person being tested to insert the Flat Pad of the Device all the way into the Vial (*see picture A5*). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (*see picture A6*).
- Start timing the test (*see picture A7*). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (*see picture A8*).
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections on the back of these instructions.

FINGERSTICK - WHOLE BLOOD – Specimen Collection and Testing Procedure



B1

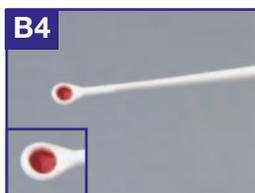


B2

Handle



B3



B4

NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.



B5



B6



B7



B8

Flat Pad



B9

Absorbent Packet



B10



B11



B12



B13

STEP 1 – COLLECT

- Using an antiseptic wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
- Using a sterile lancet, puncture the skin just off the center of the finger pad.
- Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed (*see picture B1*).
- Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
- Pick up an unused Specimen Collection Loop (“Loop”) by the thick “handle” end (*see picture B2*).
- Put the “rounded” end of the Loop on the drop of blood (*see picture B3*). Make sure that the Loop is completely filled with blood (*see picture B4*).

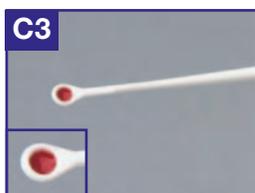
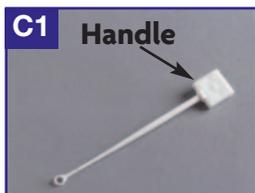
STEP 2 – MIX

- Immediately insert the blood-filled end of the Loop all the way into the Vial (*see picture B5*).
- Use the Loop to stir the blood sample in the Developer Solution (“Solution”) (*see picture B6*).
- Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.
- Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (*see picture B7*). If the Solution is not pink, discard all the test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.

STEP 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (*see picture B8*).
- Check to make sure that an Absorbent Packet is included with the Device (*see picture B9*). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (*see picture B10*). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (*see picture B11*).
- Start timing the test (*see picture B12*). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (*see picture B13*).
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections on the back of these instructions.

VENIPUNCTURE - WHOLE BLOOD – Specimen Collection and Testing Procedure



NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the blood sample.



STEP 1 – COLLECT

- Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender top), sodium heparin (green top), or sodium citrate (light blue top). **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the whole blood may be stored at 2 ° – 30 ° C (35 ° – 86 ° F) for up to 5 days.
- Prior to testing, mix the blood tube gently by inversion several times to ensure a homogeneous sample.
- Pick up an unused Specimen Collection Loop ("Loop") by the thick "handle" end (see picture C1).
- Put the "rounded" end of the Loop into the tube of blood (see picture C2). Make sure the Loop is completely filled with blood (see picture C3).

STEP 2 – MIX

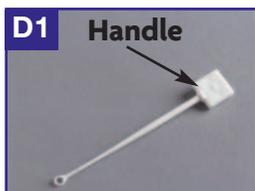
- Immediately insert the blood-filled end of the Loop all the way into the Vial (see picture C4).
- Use the Loop to stir the blood sample in the Developer Solution ("Solution") (see picture C5).
- Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.
- Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution (see picture C6). If the Solution is not pink, discard all the test materials in a biohazard waste container. Start the test over. Use a new Pouch and a new blood sample.

STEP 3 – TEST

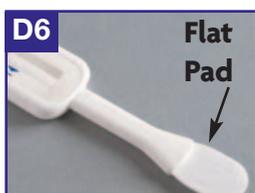
- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture C7).
- Check to make sure that an Absorbent Packet is included with the Device (see picture C8). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (see picture C9). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture C10).
- Start timing the test (see picture C11). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture C12).
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections on the back of these instructions.

PLASMA – Specimen Collection and Testing Procedure

NOTE: Testing of plasma samples may only be performed by laboratories certified to perform moderate complexity tests.



NOTE: If the Loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Get a new Loop for the collection of the plasma sample.



STEP 1 – COLLECT

- Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing EDTA (lavender top) anticoagulant. **Other anticoagulants have not been tested and may give an incorrect result.** If the specimens are not tested at the time of collection, the specimen may be stored as whole blood for up to 5 days at 2 °–30 °C (35 °–86 °F) or as plasma for up to 7 days at 2 °–8 °C (35 °–46 °F).
- Centrifuge the tube of blood (1000-1300 x g, for approximately 5 minutes, no refrigeration required) to separate the cells from the plasma.
- Carefully uncap the tube by gently rocking the stopper towards you so that it vents away from you.
- Pick up an unused Specimen Collection Loop (“Loop”) by the thick “handle” end (see picture D1).
- Put the “rounded end” of the Loop into the tube of plasma (see picture D2).
- Make sure that the Loop is completely filled with plasma (see picture D3).

STEP 2 – MIX

- Immediately insert the plasma-filled end of the Loop all the way into the Vial (see picture D4).
- Use the Loop to stir the plasma sample in the Developer Solution (“Solution”) (see picture D5).
- Remove the used Loop from the Solution. Throw the used Loop away in a biohazard waste container.

STEP 3 – TEST

- Remove the Device from the Pouch. **DO NOT** touch the Flat Pad (see picture D6).
- Check to make sure that an Absorbent Packet is included with the Device (see picture D7). If no Absorbent Packet is present, discard the Device and obtain a new Pouch for testing.
- Insert the Flat Pad of the Device all the way into the Vial containing the blood sample (see picture D8). Make sure that the Flat Pad touches the bottom of the Vial. The Result Window on the Device should be facing towards you (see picture D9).
- Start timing the test (see picture D10). **DO NOT** remove the Device from the Vial while the test is running. Pink fluid will appear and travel up the Result Window. The pink fluid will gradually disappear as the test develops (see picture D11).
- Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.
- Refer to the *Reading Test Result and Interpretation of Test Result* sections on the back of these instructions.

General Test Clean Up

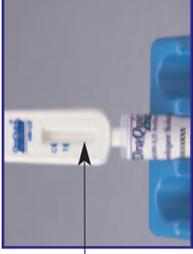
- Dispose of the used test materials in a biohazard waste container.
- When using gloves, change your gloves between each test to prevent contamination. Throw away the used gloves in a biohazard waste container.
- Use a freshly prepared 10% solution of bleach to clean up any spills.

ADEQUATE LIGHTING REQUIRED



Reading Test Result

Look at the Result Window of the Test Device



Read results after 20 minutes but not more than 40 minutes.

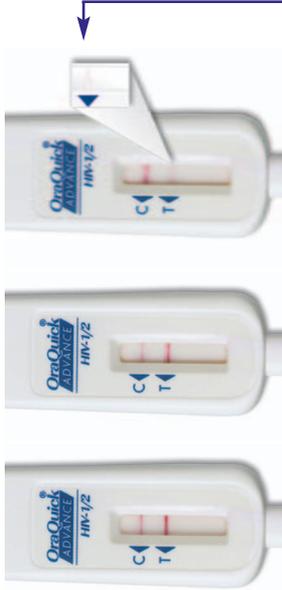
Non-Reactive



Test is Non-Reactive if:

- A reddish-purple line appears next to the triangle labeled "C" and **NO** line appears next to the triangle labeled "T".

Reactive



Test is Reactive if:

- A reddish-purple line appears next to the triangle labeled "C" and a reddish-purple line appears next to the triangle labeled "T". One of these lines may be darker than the other.
- NOTE:** The test is **Reactive** if any reddish-purple line appears next to the "T" triangle and next to the "C" triangle, no matter how faint these lines are.

Invalid



Test is Invalid if:

- NO** reddish-purple line appears next to the triangle labeled "C" (see Diagram a and b), or
- A red background in the Results Window makes it difficult to read the result **after 20 minutes** (Diagram c), or
- if any of the lines are **NOT** inside the "C" or "T" triangle areas (see Diagram d1 and d2).

Interpretation of Test Result

- A **Reactive** test result means that HIV-1 or HIV-2 antibodies have been detected in the specimen. The test result is interpreted as **PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies**. Follow CDC Guidelines to inform the test subject of the test result and its interpretation.

- A **Non-Reactive** test result means that HIV-1 and HIV-2 antibodies were not detected in the specimen. The test result is interpreted as **NEGATIVE for HIV-1 and HIV-2 antibodies**. Follow CDC

Guidelines to inform the test subject of the test result and its interpretation.

- An **Invalid** test result means that there was a problem running the test, either related to the specimen or to the Device. An **Invalid result cannot be interpreted**. Repeat the test with a new Pouch and a new oral fluid, fingerstick or venipuncture whole blood, or plasma sample. Contact OraSure Technologies' Customer Service if you are unable to get a valid test result upon repeat testing.



OraSure Technologies, Inc.
diagnostic solutions for the new millennium

Bethlehem, PA 18015 USA • Ph. 800-ORASURE (800-672-7873) • Fax 610.882.3572 • www.orasure.com

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