RAPID HIV-1/2 TEST (Oraquick ADVANCE)

Policy and Principle

This HIV Rapid test is performed on Labor and Delivery patients, who have no record of previous HIV test and for the Occupational Health department when needle stick injuries occur. **[Note: Rapid HIV ½ Antibody test should be performed on source patients].**

For orders that are received from any other area, the laboratory must call the ordering provider to determine if the order is in response to a needlestick injury. If the ordering provider cannot be reached to confirm the appropriateness of the order, then the test **must** be performed as ordered.

OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test is a single-use, **CLIA-Waived**, Qualitative Immunoassay to detect antibodies to Human Immuno-deficiency Virus Type 1 [HIV-1] and Type 2 [HIV-2].

This HIV Rapid test is **not recommended** for persons under 12 years of age. For this age group (<12 years old), the recommended screening test is the HIV 1/2 EIA.

Materials and Reagents

- Unused, unopened OraQuick® ADVANCE Rapid HIV-1/2 kits may be stored in the refrigerator, or at room temperature [2° - 27°].
- Do not open pouch until ready to perform test.
- If stored refrigerated, bring to room temperature [15° - 37°] before opening.

The kit consists of:

- Divided pouches containing a test device, absorbent packet and developer solution.
- Reusable test stands
- Specimen collection loops.

Other materials needed required but not provided:

- Timer
- Clean, disposable, absorbent workspace cover
- Biohazard waste container to dispose of used materials
- Sterile gauze pads

Specimen

Whole blood [**with EDTA anti-coagulant**] specimen collected by venipuncture is the required specimen for Rapid HIV 1/2 Test. Simultaneously, another sample, SST serum tube is collected and accessioned for HIV 1/2 EIA.

If the specimens cannot be tested STAT or at the time of collection, **the whole blood may be stored at refrigerated temperature [2-8ºC] for up to 30 hours. DO NOT freeze EDTA sample.** Do not perform the HIV Rapid test if the collection time has exceeded the 30-hour limit.

Quality Assurance

1. The Quality Assurance Plan for Rapid HIV testing is designed to:
   - Ensure accurate and reliable test results
   - Monitor the performance and effectiveness of the test system
   - Assure competency of testing personnel
   - Identify and correct problems associated with the test methodology

2. The Quality Plan assures the integrity of the pre-analytic, analytic, and post-analytic phases of the testing process by the following means:
   - Procedures are written and available to testing personnel describing all aspects of the testing process.
   - Integrity of test kits if verified by performing quality control on each new lot, each new shipment, and each day of patient testing thereafter.
   - The ability to perform a test properly is assured by appropriate training when a new test system is introduced, and annual skills evaluations thereafter.
   - Proficiency testing samples are distributed at scheduled times, and serve to assess operator performance.
   - Temperature of reagent storage and testing area is monitored and recorded to assure that testing takes place within the range specified by the manufacturer.
   - Quality Control and temperature records are reviewed monthly to verify that the test is being performed per protocol.
   - Quality Improvement reports are generated to investigate and resolve problems associated with the performance of any lab test. Problems may be pre-analytic, analytic, or post-analytic.

Quality Control Kit and Storage

- OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test Kit Controls
  - Are ordered separately
  - Must be stored at **refrigerator** temperature [2° - 8°C]

- The QC kit consists of:
  - HIV-1 Positive Control, 1 vial, black cap
  - HIV-2 Positive Control, 1 vial, red cap
  - Negative control, 1 vial, white cap

Note: Dispose of unused portions of opened Kit Control vials after **8 WEEKS**.

Quality Control

External quality controls are to be tested as follows:

- Whenever new test kit lot # is received.
- Whenever a new shipment of test kits is received.
- Each day of patient testing.
- Perform in the same manner as a patient test.

Built in procedural control

- A line at the Control (“C”) area of the result window indicates that the specimen was added, and has migrated appropriately through the test device.
- The Control line will appear on all valid tests (both positive and negative).

Set Up Your Workspace

- If kits are stored at refrigerated temperature, gather the materials you will need. Allow the test kit and quality control 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.

Safety and Handling Precautions

All specimens, reagents and controls should be handled as though capable of transmitting infectious diseases. Wear appropriate personal protective equipment when running patient samples or performing schedule maintenance. Refer to: Policy and Procedures Safety Manual Infection Control and Procedures 11-085-01.

Follow the safety and handling precautions listed below when performing HIV Rapid Test.

Step	Action
1	Observe Standard precautions for handling infectious agents when performing this test. Handle blood specimens and materials contacting blood specimens as if capable of transmitting infectious agents.
2	Use all Specimen Collection Loops, Test Devices, and Developer Solution Vials only once and dispose of properly (see Safety Precautions). **Do not reuse any of these test components**
3	Do not use the test beyond the expiration date printed on the Divided Pouch. Always check expiration date prior to testing.
4	Do not interchange Test Devices and Developer Solution Vials from kits with different lot numbers.
5	Insert the Test Device into the Developer Solution Vial **within 60 minutes after introducing the venipuncture whole blood sample**, to ensure accurate test results.

Procedure

Step	Action
1	Open the OraQuick® ADVANCE Divided Pouch • Remove the Developer Solution Vial • Label with patient name. • Remove the cap by gently rocking back and forth and place the vial into a slot in the stand **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
2	Add the whole blood EDTA specimen as follows: • Prior to sampling, mix the tube gently to ensure a homogeneous sample.

Procedure, continued

Step	Action
2	• Remove an aliquot of blood using an unused Specimen Collection Loop (if the loop is dropped or comes in contact with any other surface, discard it in a biohazard waste container. Obtain a new loop.) • Insert the blood-filled end of the loop into the developer vial and stir. • Discard loop in a biohazard container, and verify that the solution is pink (if the solution is not pink, start the test over using a new pouch).
3	Remove the Test Device from the pouch (do not touch pad): • Use only if the absorbent packet is present. • With the Result Window facing forward, insert the flat pad of the device into the vial. • The flat pad must touch the bottom of the vial.
4	Set the timer for 20 minutes • Do not remove the device from the vial while the test is running • Read the results between 20 and 40 minutes in a fully lighted area.

Test Resulting and Interpretation

Refer to table below for test resulting and interpretation.

Step	Action
1	**Refer to the Result Window on the Test Device.**

If the Result Window shows….	**Then the result is…**
a **reddish-purple line** appears next to the triangle labeled “C”, **<u>and</u> NO** line appears next to the triangle labeled “T”…	**Non-Reactive**
A **reddish-purple line appears next to the triangle labeled “C” <u>and</u>** a **reddish-purple line appears next to the triangle labeled “T”**. [One of these lines may be darker than the other.]	**Reactive**
no reddish-purple line appears next to the triangle labeled “C”, or	**Invalid**
a **red background in the Result Window makes it difficult to read** the result after 20 minutes, or	**Invalid**
if any of the **lines** are **NOT inside the “C” or “T”** triangle areas	**Invalid**

Test Resulting and Interpretation, continued

Step	Action
2	**Test result is interpreted as follows:**

If the result is…	Then it is interpreted as…
Non-Reactive [A **Non-Reactive** test result means that HIV-1 and HIV-2 antibodies <u>were not detected</u> in the specimen.]…..	Non-reactive for HIV-1 and HIV-2 antibodies. **Medical Center Laboratory** • reports Rapid HIV as non-reactive, and call L&D or ordering provider of needle stick source patient with the result. • retains the whole blood EDTA and serum separator tube [SST-7] (refrigerated) for one week. Do not send to RRL.
A **Reactive** test result means that HIV-1 and/or HIV-2 antibodies <u>have been detected</u> in the specimen	Preliminary Positive for HIV-1 and/or HIV-2 antibodies. **Medical Center Laboratory** • reports Rapid HIV as Reactive, and call L&D or ordering provider of needle stick source patient with the result. • gives the SST7 tube to the Send Out Dept. to accession for Procedure code **9855400** [HIV-1 Western Blot] [**Laboratory orderable only**], and send the labeled Western Blot tube to the Regional Reference Laboratories. • retains the Rapid HIV 1/2 [whole blood EDTA] specimen (refrigerated)
An **Invalid** test result means that there was a problem running the test, either related to the specimen or to the Test Device	• Result <u>cannot be interpreted.</u> • **Repeat the test with a new Divided Pouch and a new Whole blood sample.** • Reject the test, cancel and use **"Technical error, Test not performed"** option. Contact Customer Service at OraSure Technologies. Inc., (1-800-672-7873) if you are unable to get a valid test result upon repeat testing.

Test Reporting

Use message codes below when reporting results for HIV Rapid test:

Step	Action
1	Report the result as follows:

IF	THEN
NON- REACTIVE	Choose **"Non-Reactive"** in the drop down menu in CERNER.
REACTIVE	Choose **"Preliminary Positive"** in the drop down menu in CERNER, which translates into "Preliminary positive for HIV-1 and/or HIV-2 antibodies. Additional sample will be sent to the Regional Reference Laboratories for confirmation and final testing.

Reference

Package insert of OraQuick® *ADVANCE* Rapid HIV-1/2 Antibody Test
Note: for current version refer to: http://www.orasure.com/products/

Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Lab Manager reviewed/ date	Date change Implemented
Minor	Page 6: added “retain the specimens for one week” [under Non-Reactive result section].	Diana Davodi 12-21-10			
Major	Page 1, added instructions on what to do when can’t reach provider to confirm order.	Stephanie Prien 2/27/2012			
Minor	Page 7, Changed resulting codes to NR and R	Cindy Schwartz 4/12			
Minor	Page 2, Added: Dispose of unused portions of opened Kit Control vials after eight weeks.	Cindy Schwartz 7/12			
Minor	Removed requirement that EDTA must be “virgin” un-entered tube	Cindy Schwartz 11/12			
Minor	1) Updated format 2) Updated the result reporting section for INVALID test on pg. 6 3) Removed INVALID section on pg.7 4) Removed urinalysis department on #2 of Test Reporting on pg.7	Julius Salomon 6/11/14			
Minor	Updated format and revised index number.	Julius Salomon, 7/1/17			