PROCEDURE: ORA QUICK ADVANCE RAPID HIV-1/2 ANTIBODY TEST

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PRINCIPLE:

The OraQuick® Advance Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1/2 in capillary finger stick, whole blood and oral fluid. The OraQuick Advance® rapid test utilizes a proprietary lateral flow immunoassay procedure. The test device holds an assay test strip that provides the matrix for the immunochromatography of the specimen. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold colorimetric reagent contained in the device. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear at the T indicator, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen.

CLINICAL SIGNIFICANCE:

Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex, and pre-AIDS are thought to be caused by the Human Immunodeficiency Virus (HIV). HIV is known to be transmitted by sexual contact, by exposure to blood by sharing contaminated needles, contaminated blood products, or by an infected mother to her fetus. Rapid testing for the presence of antibodies to HIV in body fluids is an accurate diagnosis of HIV infection and can provide HIV status to the care giver at the initial visit and enable counseling.

SPECIMEN:

PATIENT PREPARATION
- Explain procedure to patient.

SPECIMEN TYPE & HANDLING CONDITIONS
- Whole Blood from a Lavender top tube or Capillary sample is acceptable. Perform blood collection according to hospital policy. Completely fill specimen collection loop.
- Oral Fluid is acceptable. Place the flat pad of the test device above the teeth against the outer gum. Gently swab completely around the outer gums, both upper and lower, one time around. Do not swab the roof of the mouth, inside cheek or the tongue.

EQUIPMENT & MATERIALS:

1. Timer with two channels.

2. DISPOSABLE GLOVES – Allegiance Non-sterile synthetic Examination Gloves or equivalent brand.
REAGENTS & SUPPLIES:

1. OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test (100 test kit) - Catalog No. = 1001-007. OraSure Technologies, Inc. 220 East First Street, Bethlehem, PA 18015-1360.

   - **INGREDIENTS & PREPARATION** – Do not touch flat pad or collection loop of test device. The test device and developing solution vial are packaged in a divided pouch and ready for use.

   - **STORAGE & STABILITY** - The test kits should be stored at temperatures of 2 - 27 ºC. Do not open the divided pouch until ready for use. If stored refrigerated, ensure that the divided pouch is brought to operating temperature (15 - 37ºC) before opening. SLCH stores them at Room Temperature in the EU Command Center or Core Laboratory. Lots are sequestered. Lots are checked monthly by Point of Care.

   - Room Temperature is monitored by Facility Services.

QUALITY CONTROL:


   - **INGREDIENTS & PREPARATION** – No preparation necessary. Each control kit contains three vials. One black capped HIV-1 positive control vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HIV-1, diluted in a defibrinated pool of normal human plasma. One red capped HIV-2 positive control vial containing 0.2 mL of photochemically inactivated human plasma positive for antibodies to HIV-2, diluted in a defibrinated pool of normal human plasma. One white capped HIV-1 and HIV-2 negative control vial containing 0.2 mL of defibrinated pool of normal human plasma.

   - **STORAGE & STABILITY** - The antibody controls should be stored at temperatures of 2 - 8 ºC. Do not use kit controls beyond expiration date printed on the outer carton. Open vials are good for eight weeks after open date. Document new open expiration date on vials after opening.

2. **QUALITY CONTROL FREQUENCY** – Run the kit controls under the following circumstances
   - 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 the 2 - 27 ºC.
   - Performed by the Core Lab Staff when new lots and shipments arrive, or when assay problems arise.
   - Point of Care performs quality control monthly in the lab on the current lot(s) of HIV kits.

3. **QUALITY CONTROL ANALYSIS PROCEDURE**

   a. Set the OraQuick® reusable test stand up on a level workspace. Use only the stand provided.

   b. Open the two chambers of the OraQuick® divided pouch by tearing at the notches on the top of each side of the pouch. To prevent contamination, leave the Test device in the pouch until ready for use.

   c. Remove the developer solution vial from the pouch. Mark one Developer Solution Vial with the Negative QC information. Carefully remove the cap from the Vial by gently rocking the cap back and forth while pulling it off.
d. Slide the vial into the top of one of the slots in the stand. 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.

e. Insert the round end of an unused specimen collection loop into the vial of control reagent.

f. Visually inspect the loop to make sure that it is completely filled with the HIV negative control reagent.

g. Immediately immerse the control-reagent-filled specimen loop in the developer solution inside the developer solution vial. Use the specimen collection loop to stir the specimen in the developer solution.

h. Remove the specimen collection loop from solution vial and discard in biohazard waste container.

i. Remove the test device from the divided pouch without touching the flat pad. Check to make sure that absorbent packet is included with device. If no absorbent packet is present, discard the device and obtain a new pouch for testing. Write the QC information on the test device and the developer solution with a marker. Do not cover the two holes in the back of the Device with labels or other materials. Doing so may cause an invalid result.

j. Insert the test device, flat pad first, into the developer solution vial containing the control specimen. Be sure the result window faces forward and the flat pad touches the bottom of the developer solution vial.

k. Leave the test device in the developer solution vial and start a timer. Do not move the test device.

l. Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.

m. Record results on Quality Control Log.

n. Dispose of the used developer solution vial and the test device in a biohazard waste container.

o. Repeat steps above for the HIV-1 and HIV-2 control reagent.

**PROCEDURE:**

- Documentation in the patient permanent record of a physician’s order and of the medical necessity for each test performed is required before a point of care test can be performed. Documentation may include nurse’s notes, physician progress notes, and/or history.

- Documentation of physician notification of test results prior to the next lab testing, including point of care testing, and documentation of test orders resulting from that notification is required. This may include entry into an electronic clinical data system(s), nurse’s notes, etc.

1. Set the OraQuick® reusable test stand up on a level workspace. Use only the stand provided.

2. When ready to collect the specimen, open the collection chamber of the OraQuick® divided pouch by tearing at the notches on the top of each side of the pouch. To prevent contamination, leave the Test device in the pouch until ready for use.

3. Remove the test device from the pouch. DO NOT touch the flat end. Check to make sure that absorbent packet is included with device, and discard. If no absorbent packet is present, discard the device and obtain a new pouch for testing. Please instruct patient not to eat, drink or chew gum prior to testing.
4. For Oral fluid – Place the flat pad of the test device above the teeth against the outer gum. Gently swab completely around the outer gums, both upper and lower, one time around. DO NOT SWAB the roof of the mouth, inside cheek or the tongue.

5. Immediately LABEL the test device. DO NOT COVER the two holes in the back of the device with labels or other materials, doing so may cause an invalid result. Return to the collection pouch.

6. Remove the developer solution vial from the pouch. Slide the vial into the top of one of the slots in the stand. DO NOT force the vial into the stand from the front. Make sure the vial is pushed all the way to the bottom of the slot in the stand.

7. Carefully remove the cap from the vial by gently rocking the cap back and forth while pulling it off.

8. Insert the flat pad of the test device into the developer solution. Make sure the flat pad touches the bottom of the vial. The result window on the device should be facing towards 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. The pink fluid will gradually disappear as the test develops.

10. Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.

11. Read and record patient results in Patient's Electronic Medical Record. Refer to the Result Window on the Test Device.
   - Record Non-reactive if a reddish-purple line appears next to the triangle labeled “C” and NO line appears next to the triangle labeled “T”.
   - Record 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.
   - Record Invalid if any of the following occurs:
     - NO reddish-purple line appears next to the triangle labeled “C”.
     - A red background in the Result Window makes it difficult to read the result after 20 minutes.
     - If any of the lines are NOT inside the “C” or “T” triangle areas.
     - Any partial line on one side of the “C” or “T” triangle areas.
   - NOTE: Repeat invalid testing with a new pouch and a new oral swab collection or whole blood.

12. When an oral swab is reactive a venous specimen of blood is drawn for confirmation in the Core laboratory. Repeat the Rapid testing on whole blood before sending specimen to the Core Laboratory.

13 Fill the specimen collection loop with the whole blood from the tube. Place the collection loop into the developer solution vial and mix. Check the solution to make sure that it appears pink. This indicates that the blood was correctly mixed into the solution. If the solution is not pink, discard all test materials in a biohazard waste container and start over.

14. Insert the flat pad of the device all the way into the vial containing the blood sample. Make certain the flat pad touches the bottom of the vial. The result window on the device must be facing toward you. Label the device with the patients name, DO NOT cover the two holes in the device with the labels.

15. Start timing the test. DO NOT remove the device from the vial while the test is running.

16. Read the results after 20 minutes, but not more than 40 minutes in a fully lighted area.

17. Record as stated above in Electronic Medical Record Refer to #11 above for test results.
Results: Non-Reactive
Reactive
Invalid

18. Wellsoft Rapid HIV results are entered in Cerner Lab Information system to downstream systems.

**INTERPRETATION:**

**REFERENCE INTERVAL** – Non-reactive for HIV-1 and/or HIV-2 antibodies at the time of testing.

**CALCULATIONS:**

None

**LIMITS OF TEST PROCEDURE:**

1. **CLINICAL LABORATORY TESTING** – analysis by the central clinical laboratories should be considered for the same and/or other tests when any one or more of the following conditions exist:
   - All positive rapid HIV tests must be followed with a specimen sent to the Core Lab for HIV testing.

2. **INTERFERING SUBSTANCES & CONDITIONS** –
   - Individuals infected with HIV-1 and/or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.
   - HIV infection cannot be ruled out completely if within 3 months patients were engaged in high risk activities.

**POINT OF CARE TESTING:**

1. **Authority & Accreditation – Point-of-Care Testing (POCT) programs are established and governed accordance:**
   a) Missouri Dept. of Health and Senior Services
   b) Joint Commission of Accredited Healthcare Organizations (JCAHO)
   c) College of American Pathologists (CAP)
   d) Clinical Laboratory Improvement Act (CLIA) – Federal Register 42CFR493
   e) Healthcare Insurance Portability and Accountability Act (HIPAA)

2. **PURPOSE & OBJECTIVE – Point-of-Care Testing (POCT) programs are established, supported and monitored to assure that they will meet or exceed the needs for patient care and safety by ensuring that:**
   a) There is a clear and justifiable need, advantage and benefit for the diagnosis, treatment and overall care and safety of the patient versus analysis in the central/main laboratories.
   b) Laboratory testing performed in POCT settings is done with staff trained in and that remains competent in procedures and techniques consistent with quality laboratory practices.
   c) The highest quality methods, materials, equipment and processes are used that will consistently and reliably produce values reflecting the actual patient status.

**REFERENCES:**

Donna Walck Point of Care Coordinator
Written By:

Lab Manager/Technical Supervisor  Date

Laboratory Medical Director  Date

Medical Director (Individual lab area)  Date

Annual Review: Medical Director/Designee  Date

Location of hard copy location(s):  Core Lab Office

HIV procedure POC 1.10110.0

Date Archived: ______________________

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