ANTI-HIV 1 / 2 ANTIBODY SCREENING by Clearview® STAT-PAK

PRINCIPLE:

The Clearview® HIV 1/2 STAT-PAK™ assay is a single-use immunochromatographic test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venous whole blood, serum or plasma specimens. The Clearview® HIV 1/2 STAT-PAK™ assay is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

No special patient preparation is needed. However, all test subjects should have received the "Subject Information" pamphlet prior to specimen collection.

Fingerstick blood samples should be collected using antiseptic technique. The sample must be collected immediately with the collection loop provided in the test kit, and must be tested immediately.

The test devices are stable until the expiration date on the box and pouch. They must be stored at a temperature between 8°-30° C (46°-86°F). If refrigerated, the pouch must be brought to room temperature before opening as the temperature range for testing is 18°-30° C (64°-86° F).

MATERIALS PROVIDED:

Each package contains the components to perform HIV tests:

- 20 STAT-PAK™ Individually Pouched Test Devices
- 20 Copies of Subject Information Notice
- 20 Disposable 5uL Sample Loops
- 1 HIV Running Buffer (3.5 mL)
- 1 Product Insert for the HIV 1 / 2 STAT-PAK Assay

QUALITY CONTROL:

The controls must be stored at (2° - 8°C; 36°- 46° F) and are stable until the manufacturer's expiration date as stated on the box label. The date the controls are received, opened as well as the expiration date must be clearly marked on the box containing the controls. The Control Reagents are clear to straw-colored. Do not use if the Control Reagent appears visually cloudy or discolored.

EXTERNAL QUALITY CONTROL:

Clearview® HIV 1/2 Reactive/Nonreactive Controls contain:

- HIV-1 Reactive Control, 1 vial (0.25 mL)
- HIV-2 Reactive Control, 1 vial (0.25 mL)
- Nonreactive Control, 1 vial (0.25 mL)

When to Perform External Quality Control?

1. Whenever a new shipment of reagents is put into use, a set of controls shall be run on the first new box used from that shipment. Validation of each reagent lot will be performed prior to release through the RWJMS Rapid Testing Support Program. For this reason, each lot does not need to be re-validated on receipt at the testing site—just each shipment.
2. At the beginning of each week, one set of controls must be run, to make sure that the reagents have not deteriorated in storage.
3. Whenever there has been a change is the test environment including such items as:
   - The temperature in the test storage area falling outside of 8°-30° C (46°-86°F).
   - A new location has been selected to perform testing.
4. After Invalid client test results on two consecutive attempts. Cease client testing until controls are run with valid results.

Reminder: If refrigerator storage temperature is out of range (2-8° C; 36° - 46° F), record the temperature and note any corrective action taken. This temperature problem may mean that the control solutions may give wrong results in the future. You need to know this in case you have a problem in the future, but a problem with refrigerator temperature does not mean that you need to run controls.

How to Perform Quality Control?

1. Check the expiration date of the external control solutions. DO NOT USE EXPIRED CONTROL SOLUTIONS.
2. If you open new controls, write the date the controls are opened, and the new expiration date on the box containing the controls.
3. Label the test device to indicate which control is being run on each device.
4. Insert the round end of an unused Specimen Collection Loop into the vial of the control reagent. Visually inspect the loop to make sure that it is completely filled with the control reagent. Use separate unused Specimen Collections Loops for each control reagent. Only open one vial at a time, so that you don't accidentally put cap back on the wrong vial. NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
5. Immediately, touch the filled Specimen Collection Loop to the sample pad in the center of the SAMPLE well of the Test Device to dispense the fluid from the loop onto the sample pad. Discard used loop directly into a biohazard waste container.
6. Put the Kit Control Reagent vials back in their box and in the refrigerator (2°-8° C; 36°-46° F).
7. Invert the Running Buffer bottle and hold it vertically (not at an angle) over the sample well. Add 3 drops (approximately 105 uL) of buffer slowly, dropwise, into the SAMPLE well. Do not touch tip of buffer bottle to well.
8. Start timing the test. Record the start time on the test log sheet.
9. Read the results between 15 and 20 minutes after the addition of the Running Buffer. Record the read time on the test log. If the test is not read within 20 minutes, discard the test materials and start again. The test may not be accurate and should be recorded as an operator error, (Code 3 on log sheet).
10. Dispose of the used Test Device in a biohazard waste.
11. If controls do not give their expected results, you cannot do client testing. You must first figure out what's wrong. Check all temperature logs for out of range temperatures and then repeat the controls. If you do not get the expected results, discard the opened controls and if available open a new box. If you still do not get the expected results call the HIV support staff for instructions. You cannot test any patients until the controls perform correctly. Offer to draw two white top tubes and call our discordant line at (732) 236-7013.

INTERNAL QUALITY CONTROL:

In addition, the Clearview® HIV-1/2 STAT-PAK Test has a built in quality control feature. A pink-purple line develops next to the letter "C" on the test devices as a positive procedural control. If the line does not develop, the test result is invalid. The procedure for interpreting the internal quality control is included in the Interpretation of Test Results section below.

TEST PROCEDURE:

1. Check to see whether client testing can be done by first following the Quality Control checklist (Section 2.6).
2. Check room temperature and record it on the test log. DO NOT continue if the temperature is outside the following range (18° -30° C) (64° – 86° F).
3. Make sure you are wearing disposable gloves
4. Open the test pouch. Make sure that an absorbent packet was packed with the test device. If not, discard the device and open a new pouch.
5. Label the Test Device with the client's ID number.
6. Using Fingerstick Whole Blood
   - Clean the finger of the person being testing with an antiseptic wipe, and allow to it dry.
   - Using a sterile lancet, puncture the skin on the side of the finger pad (toward the thumb).
   - Hold the finger downward. Apply gentle pressure beside the point of the puncture.
   - Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
   - Take a clean, unused Specimen Collection Loop, and fill the loop completely with blood.
   - Holding the specimen loop straight over and touch it to the center of the SAMPLE well of the device to dispense the sample onto the sample pad.
   - Hold the Running Buffer bottle upside down (not at an angle) over the sample well. Avoid touching the tip of the bottle to Sample well. Add 3 drops of buffer slowly, drop wise, into the SAMPLE well.
7. Start timing the test. Record the start time on the test log sheet.

8. Read the results between 15 and 20 minutes. Record the read time on the test log. If the test is not read within 20 minutes, discard the test materials and start again. If the test is not read within 15 to 20 min it may not be accurate. Record it as an operator error, (Code 3).
9. After recording result immediately discard test device into a biohazard waste container.

TEST INTERPRETATION:

Preliminary Positive	A pink-purple line in the zone next to the letter "T" (test) and a pink-purple line next to the letter "C" (control) in the result window. For positive (reactive) results, the intensity of the " T" line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease
Negative	No pink-purple line next to the letter "T", and a pink-purple control line next to the letter "C" (control) in the result window.
No Result(Invalid)	If either: No pink-purple line appears next to the letter "C" (control). Any line that appears outside of the Control (C) Area or Test (T) Area cannot be interpreted. ANY INVALID TEST, THE SUBJECT MUST BE RE-TESTED USING A NEW TEST KIT.

IF YOU WERE UNABLE TO GET A VALID RESULT AFTER TWO ATTEMPTS, RUN BOTH POSITIVE AND NEGATIVE CONTROLS, AND CALL THE NJ RAPID HIV TESTING SUPPORT OFFICE (732) 743-3624 FOR ASSISTANCE. OFFER TO DRAW TWO WHITE TOP TUBES AND CALL OUR DISCORDANT LINE AT (732) 236-7013.

Record Test Results:

- Record results on the testing log and if indicated report the result to the appropriate person for documentation.
- Control and patient results should be recorded on the same log. Enter the patient identification number in the Patient/Control ID column.
- Utilize NJHIV RAPID HIV TEST LOGS only. Every test kit utilized must be logged including controls run, wasted test kits and so on.
- As log pages are completed they must be faxed to the NJ Rapid HIV Testing office (utilizing the fax number on the test log), and they must be kept for at least two years. If there is a problem with the test materials or methods, we need to track back and see which test subjects were tested when, and with which lot of reagents.
- Each site is responsible for maintaining inventory of the test kits. Every test kit is accounted for and recorded on the test log. Do not throw out expired test kits. They should be returned to RWJMS and noted on log with reason code 7. There is a reference sheet listing the reasons for non-patient test kit use with accompanying codes which should be noted on the test logs when a specific situation arises.
- The log sheet is a communication tool between the test site and the NJ Rapid HIV Testing Support team.

Expected Values:

- Negative if the person has not been exposed to the HIV virus.
- This test is a screening test. If the result of this test is preliminary positive, please refer to the Rapid-2-Rapid procedure for steps to follow.

Procedural Notes:

- Reading the result earlier than 15 minutes or later than 20 minutes may yield erroneous results. If the result is not read within 20 minutes, the test is invalid and must be repeated.
- This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 13 years and greater than 64 years of age.
- For positive (reactive) results, the intensity of the line does not necessarily correlate with the amount of antibody in the specimen, or with the stage of disease.

Limitations of the Procedure:

A negative (non-reactive) result does not preclude the possibility of exposure to, or infection with, HIV. It can take several months for antibodies to appear after exposure to the HIV virus. No test is 100% accurate:

- In one study of 601 specimens that were repeatedly reactive using a licensed EIA and positive by Western blot, 599 gave a reactive (positive) result with the Clearview® HIV-1/2 STAT-PAK Test.

- In another study of 776 high-risk subjects, 41 were repeatedly reactive by EIA. Of those 41, 36 were positive by the Clearview® HIV-1/2 STAT-PAK Test, and 35 were also positive by Western Blot.

Counseling should reflect these imperfections of testing.

References:

Product Insert, *Clearview® HIV-1/2 STAT-PAK Test,* Inverness Medical Professional Diagnostics, 2006.

Product Insert, *Clearview® HIV-1/2 Rapid Test Control Pack,* Inverness Medical Professional Diagnostics, 11/2006.

Product Insert, *Clearview® HIV-1/2 Rapid Test Control Pack,* Inverness Medical Professional Diagnostics, 1/2009.

Product Insert, *Clearview® HIV-1/2 Rapid Test Control Pack,* Inverness Medical Professional Diagnostics, 9/2011

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