ANTI-HIV 1 ANTIBODY SCREENING by Uni-Gold™ Recombigen® HIV

PRINCIPLE:

The Uni-Gold™ Recombigen® HIV was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 and/or HIV-2 in human serum, plasma and whole blood (venipuncture and fingerstick). The Uni-Gold™ Recombigen® HIV uses proteins representing regions of the HIV virus. If antibodies to HIV-1 and/or HIV-2 are present in the sample, they combine with these proteins and a color reagent and this complex binds to the proteins in the test forming a visible pink/red band in the test region of the device adjacent to the word "test". A control line should always appear as a visible pink/red band in the "control" region of the device to indicate that the device is functioning correctly.

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 2°-27° C (36°-81°F). If refrigerated, the pouch must be brought to room temperature before opening as the temperature range for testing is 15°-27° C (59°-81° F).

MATERIALS PROVIDED:

Each Kit contains the components to perform HIV tests:

- 20 Individually Pouched Test Devices
- 20 Copies of Subject Information Notice
- 20 Disposable Pipettes
- 20 Disposable Fingerstick Sample Collection and Transfer Pipettes
- 1 Bottle Wash Solution (5.0 mL)
- 1 Package Insert

QUALITY CONTROL:

The controls are human serum or plasma reactive for antibody for HIV-1 and HIV-2. They have been treated to inactivate any HIV virus that may be present. The positive controls contain antibodies that will show REACTIVE results and the Negative Control will show NONREACTIVE results when run with the Uni-Gold™ Recombigen®. The controls are liquid, ready touse and require no reconstitution or dilution. Uni-Gold™ Recombigen® HIV Controls and all human blood products should be handled as though capable of transmitting infectious disease and should be disposed into biohazardous waste containers or bags.

The controls must be stored at (2° - 8°C; 36°- 46° F) and are stable for one month after opening or the manufacturers expiration date as stated on the box label, which ever is sooner. The date the controls are received, opened and the one-month expiration date must be clearly marked on the box containing the controls.. Do not use if the Control Reagent appears visually cloudy or discolored.

EXTERNAL QUALITY CONTROL:

Uni-Gold™ Recombigen® HIV Controls contain:

- HIV-1 Positive Control, 1 vial (0.5 mL) with red cap.
- HIV-2 Positive Control, 1 vial (0.5 mL) with green cap.
- Negative Control, 1 vial (0.5 mL) with black top.

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 2°-27° C (36°-81°F).
    - A new location has been selected to perform testing.

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 External 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 on the box containing the controls or on the individual vials. Write the new expiration date on the box (one month from the date opened, unless the printed expiration date is earlier than that).
3. Label the test device to indicate which control is being run on each device.
4. Mix contents of vials by gentle swirling or inversion.
5. Draw up adequate sample to the first gradation on the larger Disposable Pipette (included in the kit). Use separate unused Disposable Pipette for each control reagent. NOTE: The Kit Control reagents are clear to straw-colored. Do not use if the reagent appears visually cloudy or discolored.
6. Holding the Disposable Pipette vertically over the sample port, add one (1) free falling drop of sample carefully. Do not add the full volume contained within the Disposable Pipette.
7. Allow the sample to absorb into the paper in the sample port. Ensure there are no air bubbles in the sample port. Discard the Disposable Pipette in a biohazard waste container.
8. Reseal the Kit Control Reagent vials and store them in their original container at (2°-8° C; 36°-46° F).
9. Holding the dropper bottle of Wash Solution in a vertical position, add 4 drops of Wash Solution into the SAMPLE port.
10. Start timing the test. Record the start time on the test log sheet.
11. Read the results at 10 minutes, but no more than 12 minutes. Record the read time on the test log. If the test is not read within 12 minutes, discard the test materials and start again. The test is invalid.
12. Results should be determined in the same manner as that used for unknown specimens when testing with Uni-Gold™ Recombigen® HIV assay.
13. Dispose of the used Test Device in a biohazard waste.
14. 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 the repeat the controls. If you do not get the expected results, discard the controls and if available, open a new box of controls and label open and expiration dates. If you still do not get expected results call the HIV support team. You can not test any patients until the controls perform correctly. Draw two 7 ml serum separator tubes and one 5 ml white top tube (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.)and call our discordant line at (732) 236-7013 for pick up.
15. Control and patient results should be recorded on the same log. Enter the control lot number in the Patient/Control ID column.

INTERNAL QUALITY CONTROL:

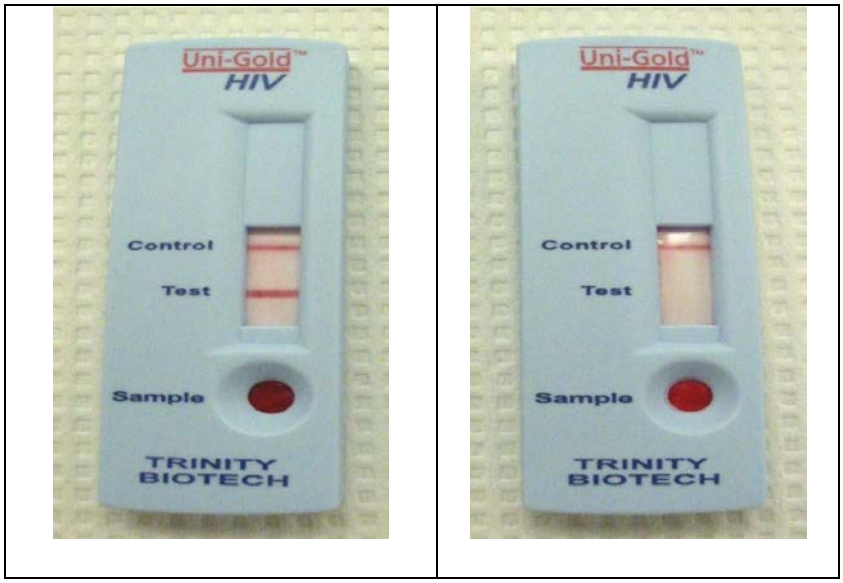
In addition, the Uni-Gold™ Recombigen® HIV assay has a built in quality control feature. A red/pink line develops next to the letter "C" on the test devises as a positive procedural control. If the line does not develop, the test result is invalid. The procedure for interpreting the internal quality 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 (15° -27° C) (59° – 81° F).
3. Allow the kit (unopened devices and wash solution) to reach room temperature (at least 20 minutes) if previously stored in the refrigerator.
4. Make sure you are wearing disposable gloves
5. 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. Document on test log as Code 6, manufacturer error.
6. Label the Test Device with the client's ID number.
7. Lay the device on a clean flat surface. .
8. Using Fingerstick Whole Blood
    A. Clean the finger of the person being tested with an antiseptic wipe, and allow to dry.
    B. Using a sterile lancet capable of producing a large drop of blood, puncture the skin on the side of the finger pad.
    C. Hold the finger downward. Apply gentle pressure beside the point of the puncture.
    D. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop to form.
    E. Collect the blood into the pipette provided following the procedure below:
        - Hold the Pipette bulb gently in a sideways (horizontal) position to the blood sample to be collected (specimen may not be adequately drawn if held upright).
        - Place the tip of the pipette into the drop of blood on the finger; take care not to squeeze the bulb. Maintain this position until the flow of sample into the pipette has stopped. The sample should fill to the first mark on the pipette. If the sample is not collected to the mark, discard this sample and obtain another sample from a new fingerstick.
        - Fully discharge the sample by squeezing the pipette bulb into the sample port. Should the sample not fully discharge, cover the small opening at the mark on the pipette with a gloved finger. Then squeeze the bulb until the sample is fully discharged.
        - Allow the sample to absorb into the paper in the sample port. Make sure air bubbles are not introduced into the sample port.
        - Dispose of the Pipette in biohazard waste.
    F. Hold the dropper bottle of Wash Solution in an upright (vertical) position; add four (4) drops of Wash Solution to the Sample Port.
    G. Start timing the test. Record the start time on the test log sheet.
    H. Read the results at 10 minutes, but no more than 12 minutes. Record the read time on the test log. *If the test is not read within 12 minutes, discard the test materials and start again*. The test may not be accurate and should be recorded as an operator error, Code 3.

TEST INTERPRETATION:



REACTIVE or POSITIVE	NON-REACTIVE or NEGATIVE RESULT

Positive	A **red-pink** line in the zone next to the letter "T" (test), a **red-pink** line next to the letter "C" (control) in the result window, with a **red** sample port
Negative	No **red-pink line** next to the letter "T", a **red-pink** control line next to the letter "C" (control) in the result window, with a **red** sample port.
No Result (Invalid)	If either: No **red-pink line** appears next to the letter "C" (control). Any line that appears outside of the Control (C) Area or Test (T) Area or **no red** sample port, 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 SUPPORT OFFICE (732) 743-3624 FOR ASSISTANCE. DRAW TWO WHITE TOP TUBES AND CALL THE DISCORDANT LINE AT (732) 236-7013 FOR PICK UP..

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.

Expected Values:

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

Procedural Notes:

- Reading the result earlier than 10 minutes or later than 12 minutes may yield erroneous results. If the result is not read within 12 minutes, the test is invalid and must be repeated.
- 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 1000 specimens that were repeatedly reactive using a licensed EIA, and positive by Western blot, 1000 gave a reactive (positive) result with the Uni-Gold™ Recombigen® HIV assay.
- In another study of 1000 high-risk subjects, 32 were repeatedly reactive by EIA. Of those 34 were positive by the Uni-Gold™ Recombigen® HIV assay, and 32 were also positive by Western Blot.

Counseling should reflect these imperfections of testing.

References:

Product Insert, *Uni-Gold™ Recombigen® HIV assay,* TRINITY BIOTECH, 07/2004.

Product Insert, *Uni-Gold™ Recombigen® HIV assay,* TRINITY BIOTECH, 11/2008.

Product Insert, *Uni-Gold™ Recombigen® HIV assay,* TRINITY BIOTECH, 9/2010.

Product Insert, *Uni-Gold™ Recombigen® HIV assay,* TRINITY BIOTECH, 2/2013

Written by: Claudia E. Carron, RN,MSN Date: 11/5/2007
Revised by: Patricia A Ribeiro, MT (ASCP) Date: 5/28/13
Reviewed by: Joanne Corbo, MBA , MT (ASCP) Date: 5/29/13
Approved by: Gratian Salaru, M.D. Date: 8/6/2013
Approved by: Parisa Javidian, M.D. Date: 8/6/2013