Quick Reference Guide for Uni-Gold™ Recombigen® HIV

CLIA Complexity: WAIVED - Venipuncture Whole Blood and Fingerstick Whole Blood Only

Before beginning testing obtain a CLIA Certificate of Waiver. Failure to follow instructions including quality control will result in a high complexity rating and subject to all applicable CLIA requirements for high complexity.

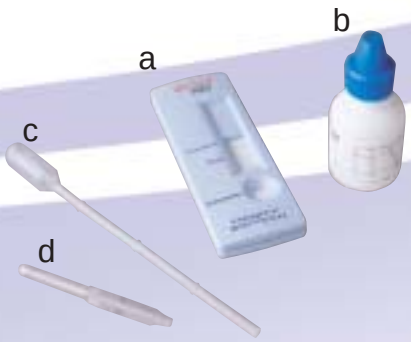
- These instructions are only a reference guide. For complete information please refer to the Package Insert included with the Uni-Gold™ Recombigen® HIV test.
- Read and follow the instructions including quality control carefully when performing the test. Not doing so may result in inaccurate results.
- Before performing the test, 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.
- Laboratories using this test must hold a certificate of CLIA Waiver.

Intended Use

Uni-Gold™ Recombigen® HIV is a single use rapid immunoassay for the qualitative detection of antibodies to HIV-1 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-Gold™ Recombigen® HIV is intended for use in point of care settings as an aid in the diagnosis of infection with HIV-1. This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.

For *In Vitro* diagnostic use.
This is a restricted device.
Sales, distribution and use restrictions apply. See customer letter and package insert.

The following materials are needed to perform the test.



The Uni-Gold™ Recombigen® HIV kit contains

a) 20 Test Devices (individually pouched)
b) Wash Solution (5.0 ml)
c) 20 Disposable pipettes for use with venipuncture blood and controls
d) 20 Disposable fingerstick sample collection and transfer pipettes
20 Subject Information Leaflets
1 Package Insert

Materials required but not provided;

- Test site with adequate lighting ● Uni-Gold™ Recombigen® HIV Kit Controls. Catalog number 1206530. ● Timer or stopwatch ● Biohazard disposal container ● Disposable gloves
- Adhesive bandages ● Sterile Lancet to obtain fingerstick whole blood sample or materials required to obtain a venipuncture whole blood sample ● Antiseptic wipes and Sterile gauze pads

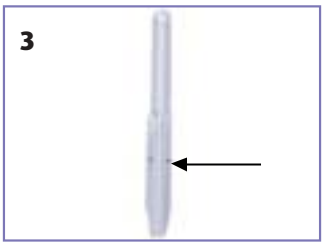
General Preparation

Ensure that the Subject Information Leaflet has been given to the person being tested.

- Allow the kit (unopened devices and Wash Solution) to reach room temperature (15 – 27°C / 59.0 – 80.6°F) (at least 20 minutes), if previously stored in the refrigerator. Once at room temperature remove, the required number of Uni-Gold™ Recombigen® HIV devices from their pouches.
- Check expiration date – DO NOT USE PAST EXPIRATION DATE.
- Lay the device on a clean flat surface.
- Label the device with the appropriate patient information / ID.
- Use worksite with adequate lighting.

Test Procedure
Sample Collection and Addition to Device

A. Finger Stick Whole Blood



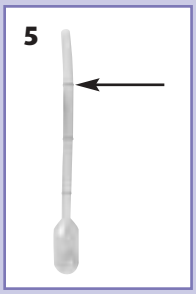
Sample Collection

- 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, capable of producing a 50µl blood let, puncture the skin just off the center of the finger pad. See picture 1.
- Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile gauze pad. Allow a new drop of blood to form. If blood flow is inadequate the subject's finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid 'milking' the finger.
- Collect the blood into the fingerstick sample transfer pipette provided, following the procedure presented below. See picture 2.
  - Hold the pipette bulb gently in a horizontal position to the sample to be collected. **This is important, as the specimen may not be adequately drawn in the pipette if the pipette is held in a vertical position.**
  - Place the tip of the pipette into the sample, taking 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 mark on the pipette. See picture 3. If sample is not collected to the mark, the pipette should be safely discarded and another specimen should be collected from another finger by repeating the sample collection process.

Sample Addition

- Squeeze the bulb until the sample is fully discharged in to the Uni-Gold™ Recombigen® HIV sample port. See picture 4. Should the sample not fully discharge, cover the small opening at the mark on the pipette with gloved fingers. Then squeeze the bulb until the sample is fully discharged. Allow the sample to absorb into the paper in the sample port. Ensure air bubbles are not introduced into the sample port. Dispose of the pipette in biohazard waste.

B. Venipuncture Whole Blood



Sample Collection

- Using standard phlebotomy procedures, collect a venipuncture whole blood sample using a blood collection tube containing either EDTA, Heparin or Acid Citrate Dextran (ACD).
- Draw up adequate sample to the first gradation See picture 5 on the pipette using one of the disposable pipettes included in the kit. **Use only the pipette included in the kit and do not reuse.** See picture 6.

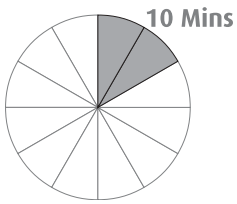
Sample Addition

- Holding the pipette vertically over the sample well, add one (1) free falling drop of sample carefully, See picture 7. Do not add the full volume contained within the pipette.
- Allow the sample to absorb into the paper in the sample well. Ensure air bubbles are not introduced into the sample well.
- Discard the pipette in a biohazard waste container.

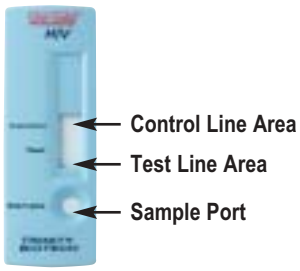
Run Sample

Holding the dropper bottle of Wash Solution in a vertical position, add four (4) drops of Wash Solution to the Sample Port. See picture 8.

Set the timer for 10 minutes and start timing the test. See picture 9.



Interpret Result



Read test results after 10 minutes but not more than 12 minutes incubation time. If the test is not read between 10-12 minutes repeat test on new device

Refer to the Interpretation of Results for Whole Blood Samples section on the back page.

Check if test results are valid. **For a test result to be valid, the sample port must contain red color AND a control line must also be present. If no red color is seen in the sample port OR there is no control line, repeat the test with fresh device.**

Note: Handle all blood samples and materials containing blood samples as if capable of transmitting infectious agents. Dispose of all test blood samples and materials used in test procedure in a biohazard waste container.

External Quality Control

Uni-Gold™ Recombigen® HIV Kit Controls (Product Code: 1206530) are available separately for use only with the Uni-Gold™ Recombigen® HIV test. ● The Kit Controls are used to verify your ability to perform the test and interpret the test result. ● The Positive Control will produce a Reactive test result and has been manufactured to produce a very faint test line. ● The Negative Control will produce a Non-Reactive test result (refer to the Test Results and Interpretation Section).

Note that a red color at the sample well will not be seen if using the Uni-Gold™ Recombigen® HIV kit controls (Product Code: 1206530).

Run the Kit Controls under the following circumstances:

All new operators performing testing on patient samples. ● Each new 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 / 35.6 – 80.6˚F. ● If the temperature of the testing area falls outside of 15 – 27°C / 59.0 – 80.6°F. ● At periodic intervals as specified in your Quality Assurance program

If you have any questions regarding Uni-Gold™ Recombigen® HIV, or for more information on other Trinity Biotech products please call:

Trinity Biotech USA
Phone: 1-800-325-3424
E-mail: hiv@trinitybiotech.com or visit
www.trinitybiotech.com

If you wish to obtain information on obtaining a CLIA Certificate of Waiver, please call:
Centres for Medicare & Medicaid Services
Phone: 1-877-267-2323 or visit www.cms.hhs.gov/clia/cliaapp.asp

INTERPRETATION FOR WHOLE BLOOD SAMPLE

Invalid Results

FOR A TEST TO BE VALID A CONTROL LINE MUST BE PRESENT AND THE SAMPLE PORT MUST CONTAIN FULL RED COLOR

REPORT AS INVALID

Test line present
No control line present
Full red color at Sample Port

No line appears in the device window adjacent to word "Control" whether or not a line appears in the device window adjacent to word "Test".

The test should be repeated in duplicate with fresh devices.

REPORT AS INVALID

No test line present
No control line present
Full red color at Sample Port

No line appears in the device window adjacent to word "Control" whether or not a line appears in the device window adjacent to word "Test".

The test should be repeated in duplicate with fresh devices.

REPORT AS INVALID

No test line present
Control line present
No red color at Sample Port

Red color is not seen in the Sample Port.

The test should be repeated in duplicate with fresh devices.

REPORT AS INVALID

No test line present
Control line present
Not full red color at Sample Port

Red color is not seen in full sample well. White of sample pad remains.

The test should be repeated in duplicate with fresh devices.

REPORT AS INVALID

Test line present
Control line present
No red color at Sample Port

Red color is not seen in the Sample Port.

The test should be repeated in duplicate with fresh devices.

Valid Results

REPORT AS PRELIMINARY POSITIVE

Test line present
Control line present
Full red color at Sample Port

Reactive Test Result
A line of **any** intensity appears in the device window adjacent to word "Test" AND a second line of any intensity appears adjacent to word "Control" AND a full red color appears in the Sample Port.
This indicates a Reactive result that is interpreted as Preliminary Positive for HIV-1 antibodies.

REPORT AS NEGATIVE

No test line present
Control line present
Full red color at Sample Port

Non-Reactive Test Result
A line of **any** intensity appears in the device window adjacent to word "Control" AND a full red color appears in the Sample Port, but no line appears in the device window adjacent to "Test".
This indicates a Non-Reactive result that is interpreted as Negative for HIV-1 antibodies.

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