

INTERPRETATION FOR WHOLE BLOOD SAMPLE



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045-147 02/13

Invalid Results



| REPORT AS | INVALID | INVALID | INVALID | INVALID | INVALID |
|---|---|--|--|--|--|
| Test line present | No control line present | No test line present | No test line present | No control line present | No control line present |
| Full red color at Sample Port | No control line present | Full red color at Sample Port | Full red color at Sample Port | 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". | 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. | The test should be repeated in duplicate with fresh devices. | The test should be repeated in duplicate with fresh devices. | The test should be repeated in duplicate with fresh devices. |

Valid Results



| REPORT AS | PRELIMINARY POSITIVE | REPORT AS | NEGATIVE |
|--|--|-------------------------------|-------------------------------|
| Test line present | Control line present | No test line present | Control line present |
| Full red color at Sample Port | Full red color at Sample Port | Full red color at Sample Port | Full red color at Sample Port |
| 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, but no line appears in the device window adjacent to "Test". | This indicates a Reactive result Sample Port. A full red color appears in the device window adjacent to word "Control" AND adjacent to word "Test" AND a second line of any intensity appears in the device window adjacent to word "Control" AND a full red color appears in the Sample Port. This indicates a Non-Reactive result that is interpreted as Preliminary Positive for HIV-1 and/or HIV-2 antibodies. | No test line present | Control line present |
| Reactive Test Result | Reactive Test Result | Non-Reactive Test Result | Non-Reactive Test Result |

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-1/2 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

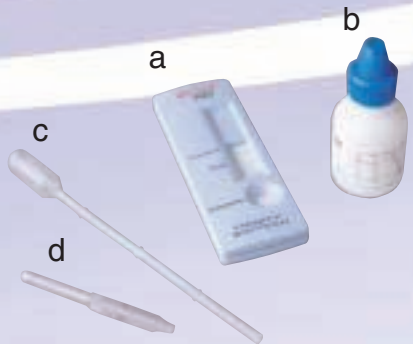
Uni-Gold™ Recombigen® HIV-1/2 is a single use rapid immunoassay for the qualitative detection of antibodies to HIV-1 and/or HIV-2 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-Gold™ Recombigen® HIV-1/2 is intended for use in point of care settings as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. 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-1/2 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-1/2 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-1/2 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



1

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.



2



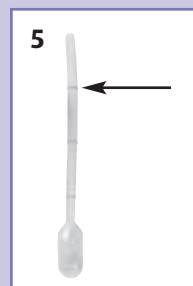
3



4

Sample Addition

- Squeeze the bulb until the sample is fully discharged in to the Uni-Gold™ Recombigen® HIV-1/2 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.



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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), citrate phosphate dextrose (CPD) or heparin.
- 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.](#)



6



7

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.

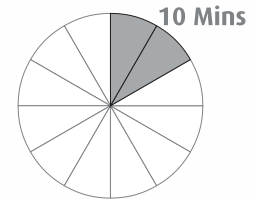
Run Sample



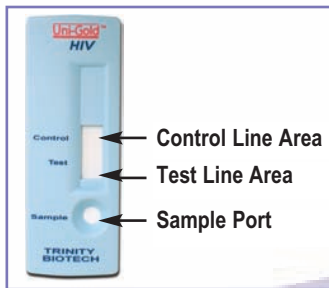
Holding the dropper bottle of Wash Solution in a vertical position, add four (4) drops of Wash Solution to the Sample Port. See picture 8.



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-1/2 Kit Controls (Product Code: 1206530) are available separately for use only with the Uni-Gold™ Recombigen® HIV-1/2 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 appear of lesser intensity and can vary with each control i.e. HIV 2 control can be lighter than HIV 1 control. ● 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-1/2 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-1/2, 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