



**Uni-Gold™ Recombigen® HIV  
Product No. 1206506**

**CLIA COMPLEXITY:  
WAIVED FOR WHOLE BLOOD FINGERSTICK AND VENIPUNCTURE SAMPLES  
MODERATE COMPLEXITY FOR SERUM AND PLASMA SAMPLES**

**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 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.

**RESTRICTIONS**

- Sale of Uni-Gold™ Recombigen® HIV is limited to clinical laboratories
  - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met
  - where there is assurance that operators will receive and use the instructional materials.
- Uni-Gold™ Recombigen® HIV is approved for use only by an agent of a clinical laboratory.
- The test subjects must receive the "Subject Information Leaflet" prior to specimen collection, and appropriate information when test results are provided.
- Uni-Gold™ Recombigen® HIV is not approved for use to screen donors of blood, plasma, cells or tissues

**BACKGROUND**

HIV-1 is one of the causes of AIDS (Acquired Immunodeficiency Syndrome). AIDS is the end stage of a drawn out process in which the immune system of an infected person and its ability to control infections or malignant proliferative disorders are progressively destroyed (1). HIV is mainly transmitted by unprotected sexual intercourse or from mother to child (1). Most frequently, HIV infection is diagnosed by tests that assess whether an individual's immune system has produced an HIV-specific immune response (antibodies to HIV) (1).

In the USA the standard laboratory test algorithm (set of different tests) may take 48 hours to one week before results may be made available. This algorithm consists of screening with an enzyme immunoassay (EIA) followed by confirmation by Western Blot (WB) or immuno-fluorescent (IFA) methods.

During the last 20 years, HIV infection and severe HIV-related diseases (e.g. AIDS) have become a leading cause of illness and death in the United States. Approximately 800,000-900,000 persons in the United States are infected with HIV and approximately 275,000 of these persons might not know they are infected (2).

Approximately 25 million persons each year in the United States are tested for HIV. Publicly funded counseling and testing programs conduct approximately 2.5 million of these tests each year. In 1995, 25% of these individuals testing HIV positive and 33% of persons testing HIV negative at publicly funded clinics did not return for their test results. Rapid tests to detect HIV antibody can be performed within 20 minutes, enabling health-care providers to supply definitive negative and preliminary positive results to patients at the time of testing, potentially increasing the overall effectiveness of counseling and testing programs. In comparison, results from enzyme immunoassays (EIAs) currently used for HIV screening often are not available for 1-2 weeks (3). Using rapid tests, during 1995, a total of 697,495 more persons would have learned their HIV status (3).



Many advances have been made in HIV/AIDS prevention and treatment, including the development of effective antiretroviral therapies that have reduced HIV-related illness and death. Early knowledge of HIV infection is now recognized as a critical component in controlling the spread of HIV infection (2). Rapid HIV testing allows clients to receive results the same day in a single visit, which is useful in urgent medical circumstances and settings where clients tend not to return for HIV test results (e.g., some STD clinics) (2). Advances in these areas have resulted in revised recommendations for HIV screening of pregnant women (4,5), treating opportunistic infections and other sexually transmitted and blood-borne diseases and managing occupational and non-occupational exposures and prophylaxis (6,7).

#### **PRINCIPLES OF THE PROCEDURE**

Uni-Gold™ Recombigen® HIV was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 in human serum, plasma and whole blood (venipuncture and finger stick). Uni-Gold™ Recombigen® HIV uses proteins representing regions of the HIV virus. If antibodies to HIV-1 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'. The control line should always appear as a visible pink/red band in the control region of the device to indicate that the test device is functioning correctly. A reactive result is indicated by a pink/red band in the test region of the device. A non-reactive result occurs in the absence of detectable levels of antibodies to HIV-1 in the specimen; consequently no visually detectable band develops in the test region of the device.

#### **SPECIMEN COLLECTION AND STORAGE**

**For venipuncture whole blood and plasma: EDTA, acid citrate dextran (ACD) or heparin should be used as the anticoagulant. Other anticoagulants have not been tested and may give incorrect results.**

##### **Whole blood collected by fingerstick:**

Whole blood samples collected by fingerstick should be used on the Uni-Gold™ Recombigen® HIV **immediately** after collection.

##### **Whole blood collected by venipuncture:**

Using standard phlebotomy procedures, collect a venipuncture whole blood specimen using a blood collection tube containing either EDTA, acid citrate dextran (ACD) or heparin. **Other anticoagulants have not been tested and may give incorrect results.**

It is recommended that specimens should be tested immediately but can be tested within 8 hours of collection if stored at ambient temperature (15°C- 27°C/ 59.0°F – 80.6°F). If specimens are not to be tested within 8 hours of collection, a plasma sample should be generated and stored at 2-8°C/ 35.6 – 46.4°F for up to five (5) days to allow testing. For long term storage plasma specimens should be frozen at -20°C or below. Grossly hemolysed or lipemic samples should not be used. Avoid multiple freeze thaw cycles. **(note: Plasma may only be tested in laboratories certified to run moderate complexity tests).**

##### **Serum and Plasma (note: Serum and Plasma may only be tested in laboratories certified to run moderate complexity tests):**

Using standard phlebotomy procedures, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing either EDTA, acid citrate dextran (ACD) or heparin. **Other anticoagulants have not been tested and may give incorrect results.** Centrifuge the tube of blood (1000-1300 x g, for approximately 5 minutes, no refrigeration required) to separate the cells from the plasma. Carefully uncap the tube by gently rocking the stopper towards you so that it vents away from you.



Specimens may be tested immediately upon receipt or stored at 2-8°C/ 35.6 –46.4°F for up to five (5) days to allow testing. Specimens should be stored at -20°C or below if storage is necessary for more than five (5) days. Grossly hemolysed or lipemic samples should not be used. Avoid multiple freeze thaw cycles.

#### **MATERIALS PROVIDED**

Each kit contains:

- a) 20 Test Devices (individually pouched)
- b) Wash solution 5.0 ml
- c) 20 Disposable Pipettes for use with serum, plasma or venipuncture whole blood. To be used also with Controls (Catalog number 1206530)
- d) 20 Disposable Fingerstick Sample Collection and Transfer Pipettes for use with fingerstick whole blood
- e) 20 Subject Information Leaflets
- f) 1 Package Insert

#### **Materials required and available as an accessory to the kit**

Uni-Gold™ Recombigen® HIV Kit Controls. Catalog number 1206530.

Each pack of Kit Controls contains Positive Control, 1 vial (red cap), (0.5ml) and Negative Control, 1 vial (black cap) (0.5ml) and a package insert.

#### **MATERIALS REQUIRED BUT NOT PROVIDED**

Timer or stopwatch

Blood collection devices, for testing of venipuncture whole blood, serum or plasma

Biohazard disposal container

Disposable gloves

For Fingerstick samples the following additional material are required.

- Adhesive bandages
- Lancet capable of producing a 50µl droplet
- Sterile wipes and sterile gauze pads

#### **WARNINGS**

For *in vitro* diagnostic use

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. Before performing testing all operators must read and become familiar with the Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus and other Blood-Borne Pathogens in Health-Care settings (8).
3. The FDA has approved this kit for use with serum, plasma and whole blood (venipuncture and fingerstick) specimens. Use of the kit with specimens other than those specifically approved for use with this device may result in inaccurate test results.
4. This test kit is CLIA-waived for use only with fingerstick whole blood and venipuncture whole blood samples.
5. Uni-Gold™ Recombigen® HIV is for diagnostic use only and is not to be used for screening donors of blood, plasma, cells or tissues.
6. Perform test at room temperature (15°C – 27°C / 59.0°F – 80.6°F).



## **PRECAUTIONS**

### **Safety Precautions**

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear standard protective clothing such as a lab coat and disposable gloves when handling specimens and assay reagents in accordance with local regulations.
3. Wash hands thoroughly after use.
4. In the case of Wash Solution contact with eyes, rinse immediately with plenty of water and seek medical advice.

### **Appropriate biosafety practices should be followed when handling specimens and reagents. These precautions include, but are not limited to, the following:**

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas where specimens are handled.
2. Dispose of all specimens, used devices and pipettes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclaving at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach. For additional information on biosafety refer to "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B virus and Other Blood-Borne Pathogens in Health Care Settings"(8).
3. When disposing of wash buffer, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a solution of 10% bleach.
5. Use a separate disposable pipette and device for each specimen tested.
6. Do not pipette by mouth.

### **Handling Precautions**

1. Do not use any device if the pouches have been perforated.
2. Each device is for single use only.
3. Do not mix reagents from different kit lots.
4. Do not use the kit past the expiration date (this date is printed on the box).
5. Adequate lighting is required to read the test results.
6. Read results 10 minutes following the addition of Wash Solution. Do not read results more than 12 minutes following the addition of Wash Solution.
7. Lancets should be placed in a puncture resistant container prior to disposal.

### **STORAGE INSTRUCTIONS**

Uni-Gold™ Recombigen® HIV device and Wash Solution should be stored between 2°C-27°C / 35.6°F – 80.6°F.

Kit components are stable until expiration date when stored as directed.

If stored refrigerated, ensure that the pouched device is brought to room temperature (15°C – 27°C / 59.0°F – 80.6°F before opening).

Do not use beyond expiration date.

Do not freeze the kit.

**Store the separately supplied Uni-Gold™ Recombigen® HIV Kit Controls at 2°C-8°C/35.6°F-46.4°F.**



## **TEST PROCEDURE AND INTERPRETATION FOR CLIA WAIVED AND CLIA MODERATE SETTINGS**

### **Test Procedure For Fingerstick Whole Blood**

1. Ensure that the Subject Information Leaflet has been given to the subject.
2. Allow the kit (unopened devices and Wash Solution) to reach room temperature (15°C – 27°C / 59.0°F – 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.

#### **PERFORM ONLY ONE TEST AT A TIME.**

3. Lay the device on a clean flat surface.
4. Label the device with the appropriate patient information.
5. Sample collection and addition to device:
  - 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 centre of the finger pad. 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.
    - a. 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.
    - b. 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, (Figure 1). 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. The sample should be used immediately.
    - c. Squeeze the bulb until the sample is fully discharged into the Uni-Gold™ Recombigen® HIV 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. Ensure air bubbles are not introduced into the sample port.
    - d. Dispose the Pipette in biohazard waste.
6. Holding the dropper bottle of Wash Solution in a vertical position, add four (4) drops of Wash Solution to the Sample Port.
7. Set the timer for 10 minutes and start timing the test.
8. Read test results after 10 minutes but not more than 12 minutes incubation time.
9. Refer to the Test Results and Interpretation of Whole Blood Samples below. Note there is a different interpretation for Whole Blood Samples from that for Plasma or Serum Samples.
10. If testing whole blood check for full red color in sample port. The sample port must contain red color for test to be valid. A red/pink line must appear adjacent to the word control. A red/pink line may appear adjacent to the word test. If no red color is seen in the sample port repeat test with fresh device.

### **Test Procedure Venipuncture Whole Blood**

1. Ensure that the Subject Information Leaflet has been given to the subject.
2. Allow the kit (unopened devices and wash solution) to reach room temperature (15°C – 27°C / 59.0°F – 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. Perform no more than 10 tests at one time.

3. Lay the devices on a clean flat surface.
4. Label each device with the appropriate patient information / ID.
5. Draw up adequate sample to the first gradation 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.
6. Holding the pipette vertically over the sample port, add one (1) free falling drop of sample carefully. Do not add the full volume contained within the pipette. Allow the sample to absorb into the paper in the sample port. Ensure air bubbles are not introduced into the sample port. Discard the pipette in a biohazard waste container.
7. Holding the dropper bottle of Wash Solution in a vertical position, add four (4) drops of Wash Solution to the Sample Port.
8. Set the timer for 10 minutes and start timing the test.
9. Read test results after 10 minutes but not more than 12 minutes incubation time.
10. Refer to the Test Results and Interpretation of Whole Blood Samples below. Note there is a different interpretation for Whole Blood Samples from that for Plasma or Serum Samples.
11. If testing whole blood check for full red color in sample port. The sample port must contain red color for test to be valid. A red/pink line must appear adjacent to the word control. A red/pink line may appear adjacent to the word test. If no red color is seen in the sample port repeat test with fresh device.

#### **INTERPRETATION FOR WHOLE BLOOD SAMPLE**

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

#### **Invalid Results**





### Invalid Results

### Valid Results

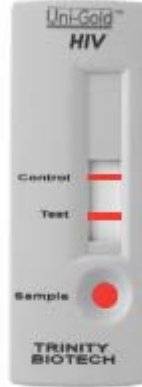


#### REPORT AS INVALID

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.



#### 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.



**TEST PROCEDURE SERUM, PLASMA AND CONTROLS:  
SERUM AND PLASMA SUITABLE FOR CLIA MODERATE SETTING ONLY**

**Test Procedure**

1. Ensure that the Subject Information Leaflet has been given to the subject.
2. Allow the kit (unopened devices and wash solution) to reach room temperature (15°C – 27°C / 59.0°F – 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. Perform no more than 10 tests at onetime.
3. Lay the devices on a clean flat surface.
4. Label each device with the appropriate patient information / ID.
5. Draw up adequate sample to the first gradation on the Pipette using one of the disposable pipettes included in the kit. Use only the Disposable Pipette included in the kit and do not reuse. If Kit Controls are being run, these must be used as described in the package insert provided with the Kit Controls.
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 Allow the sample to absorb into the paper in the sample port. Ensure air bubbles are not introduced into the sample port. Discard the Disposable Pipette in a biohazard waste container.
7. Holding the dropper bottle of Wash Solution in a vertical position, add four (4) drops of Wash Solution to the Sample Port
8. Set the timer for 10 minutes and start timing the test.
9. Read test results after 10 minutes but not more than 12 minutes incubation time.
10. Refer to the interpretation guide for serum and plasma. A red/pink line must appear adjacent to the word control. A red/pink line may appear adjacent to the word test.

**INTERPRETATION FOR SERUM PLASMA SAMPLE SERUM AND PLASMA SAMPLES  
SUITABLE FOR CLIA MODERATE SETTING ONLY TEST RESULTS AND INTERPRETATION  
OF RESULTS**

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". This indicates a Reactive result that is interpreted as Preliminary Positive for HIV-1 antibodies.

Non-Reactive Test Result

A line of any intensity appears in the device window adjacent to word "Control", 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.

Invalid Result

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". This is an Invalid result that cannot be interpreted. The test should be repeated in duplicate with fresh devices.

**QUALITY CONTROL**

**Built-In Control Features:**

The Uni-Gold™ Recombigen® HIV test has a built in procedural control that demonstrates assay validity. A red / pink line appearing adjacent to the word 'control' indicates that the test is running correctly. In addition, when using whole blood samples, there must be a red color in the sample port to validate the addition of the sample. The control line will appear on all valid tests, whether



or not the sample is Reactive or Non-Reactive (refer to the test results and interpretation sections).

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 port 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 specimens
- 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°C-27°C / 35.6°F –80.6°F
- If the temperature of the testing area falls outside of 15°C – 27°C / 59.0°F –80.6°F
- At periodic intervals as specified in your Quality Assurance program.

The Kit Controls must give the expected reactive or non-reactive results, otherwise the test results are not valid. Refer to the Uni-Gold™ Recombigen® HIV Kit Control package insert for instructions on the use of these reagents. It is the responsibility of each laboratory using the Uni-Gold™ Recombigen® HIV test to establish an adequate quality assurance program to assure the performance of the device under its specific locations and conditions of use. Contact Trinity Biotech Customer Service if the Kit Controls do not produce the expected results.

#### **LIMITATIONS**

1. Uni-Gold™ Recombigen® HIV must be used in accordance with the instructions in this package insert to obtain an accurate result.
2. Uni-Gold™ Recombigen® HIV is designed to detect antibodies to HIV-1 in undiluted whole blood (venipuncture and fingerstick) serum, and plasma. For venipuncture whole blood and plasma, EDTA, acid citrate dextran (ACD) or heparin should be used as the anticoagulant. Other anticoagulants have not been tested and may give incorrect results. Other body fluids may not give accurate results and must not be used.
3. Immunosuppressed or immunocompromised individuals infected with HIV-1 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results in this incidence and would not be a reliable test method for such patients.
4. The intensity of a line at the "Test" region is not an indication of the level of antibody in the specimen.
5. A Reactive result by Uni-Gold™ Recombigen® HIV suggests the presence of anti-HIV-1 antibodies in the specimen. Uni-Gold™ Recombigen® HIV is intended as an aid in the diagnosis of infection with HIV-1. AIDS and AIDS-related conditions are clinical symptoms and their diagnosis can only be established clinically.
6. Reading test results earlier than 10 minutes or later than 12 minutes may give incorrect results.
7. A Non-Reactive result with Uni-Gold™ Recombigen® HIV does not exclude the possibility of infection with HIV. A false negative result may occur in the following circumstances:
  - Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels.
  - The test procedure has not been correctly followed.
  - Antibodies to a variant strain of HIV-1 in the patient that do not react with specific antigens utilized in the assay configuration.
  - Improper specimen handling.
  - Failure to add sample.



8. A person who has antibodies to HIV-1 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

#### REFERENCES

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- (3) CDC. Update: HIV Counseling and Testing using Rapid Tests-United States, 1995. MMWR 1998; 47(11).
- (4) Dabis et al., 6-month efficacy, tolerance and acceptability of a short regimen of oral zidovudine to reduce vertical transmission of HIV in breastfed children in Cote d'Ivoire and Burkina Faso: a double-blind placebo controlled multi centre trial. Lancet 1999; 353:786-92
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- (8) CDC. Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other blood-borne pathogens in health-care settings. MMWR 1988; 37(24):377-388.
- (9) CDC Revised guidelines for HIV counseling MMWR Recommendations and Reports, 2001; 50 (RR-19)

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