Early knowledge of HIV infection is now recognized as a critical component in controlling the disease. Approximately 25 million persons each year in the United States are tested for HIV. Publicly sponsored tests are available 24 hours a day, 7 days a week, in more than 1,900 outpatient laboratories throughout the United States. These tests are performed on an average of 8.1 million persons annually.

Rapid tests, such as Uni-Gold™ Recombigen® HIV-1/2, are widely used in point of care settings, including hospitals, clinics, and other healthcare settings where patients need to know they are infected quickly. Uni-Gold™ Recombigen® HIV-1/2 is a single-use rapid immunoassay that detects antibodies to HIV-1 and/or HIV-2 in serum, plasma, and whole blood (venipuncture and fingerstick). This test is suitable for use in appropriate multi-test algorithms designed for the statistical validation of rapid HIV test results.

### CLIA COMPLEXITY:

**WAIVED FOR WHOLE BLOOD FINGERSTICK AND VENIPUNCTURE SAMPLES**

### MODERATE COMPLEXITY FOR SERUM AND PLASMA SAMPLES

### NAME AND 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 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.

### RESTRICTIONS

- Sale of Uni-Gold™ Recombigen® HIV-1/2 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.
- There is assurance that operators will receive and use the instructional materials.
- Uni-Gold™ Recombigen® HIV-1/2 is approved for use only by a laboratory of clinical staff.
- 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-1/2 is not approved for use to screen donors of blood, plasma, and other tissues.

### SUMMARY

HIV is the causative agent of AIDS (Acquired Immunodeficiency Syndrome). AIDS is the end stage of a group of diseases that involve the immune system of an infected person and its ability to control infections or malignant proliferative disorders. HIV is mainly transmitted by unprotected sexual intercourse or from mother to child. 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). In the USA, it is estimated that approximately 12.5 million persons are infected with HIV.

In the USA, the standard laboratory test algorithm (set of different tests) may take 48 hours to one week. In 1995, 25% of these individuals testing HIV positive and 33% of persons testing HIV negative were not aware of their HIV status 1-2 years after testing. The 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. 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 and/or HIV-2 in the specimen; consequently, no visually detectable band develops in the test region of the device.

### MATERIALS PROVIDED

- Each kit contains:
  - 20 Test Devices (individually packaged)
  - Wash solution 5.0 ml
  - 20 Disposable Pipettes for use with serum, plasma, or whole blood.
  - Sterile wipes and sterile gauze pads

For Fingerstick samples the following additional material are required:

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

### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Blood collection devices, for testing of venipuncture whole blood, serum or plasma
- Biohazard disposal containers

### WARNING

For in vitro diagnostic use

Read the package insert completely before use. It is very important that the correct procedure is followed. Not adding the patient sample may lead to a false negative result (i.e., a missed positive).

### 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:

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*Uni-Gold™ Recombigen® HIV-1/2 was designed as a rapid immunoassay and is intended to detect antibodies to HIV-1 and HIV-2 in human serum, plasma and whole blood (venipuncture and fingerstick).*

*Uni-Gold™ Recombigen® HIV-1/2 uses proteins representing regions of the HIV virus. If antibodies to HIV-1 and 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’.*

*The 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. 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 and/or HIV-2 in the specimen; consequently, no visually detectable band develops in the test region of the device.*
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”.^1,2^  
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 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-1/2 device and Wash Solution should be stored between 2-27°C / 35.6 – 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 (19°C – 27°C / 66.2 – 80.6°F before opening). Do not use beyond expiration date. Do not freeze the kit.

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

**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-1/2 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 – 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 unscrew the tube by gently rocking the stopper towards you so that it vena 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.

**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 – 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. **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 / ID.
5. Sample collection and addition to device:
   - Collected the blood into the fingerstick sample transfer pipette provided following the procedure and figure presented below.
   - Using an antisepctic 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.
6. 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 pink/red line must appear adjacent to the word control. A pink/red 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 – 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. 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 pink/red line must appear adjacent to the word control. A pink/red 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**

<table>
<thead>
<tr>
<th>REPORT AS PRELIMINARY POSITIVE</th>
<th>REPORT AS NEGATIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test line present</td>
<td>Test line present</td>
</tr>
<tr>
<td>Control line present</td>
<td>Control line present</td>
</tr>
<tr>
<td>Full red color at Sample Port</td>
<td>Full red color at Sample Port</td>
</tr>
</tbody>
</table>

**Invalid Results**

- No test line present
- No control line present
- No pink/red line appears in the device window adjacent to word "Control" whether or not a pink/red line appears in the device window adjacent to word "Test". The test should be repeated in duplicate with fresh devices.

**Non-Reactive Test Result**

- A pink/red line of any intensity appears in the device window adjacent to word "Control" AND a second pink/red 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 Negative for HIV-1 and/or HIV-2 antibodies.

**Reactive Test Result**

- A pink/red 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 pink/red line appears in the device window adjacent to "Test". This indicates a Non-Reactive result that is interpreted as Negative for HIV-1 and/or HIV-2 antibodies.

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

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 – 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. 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 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 pink/red line may appear adjacent to the word control. A pink/red line may appear adjacent to the word test.
**PERFORMANCE CHARACTERISTICS**

**SENSITIVITY**

The sensitivity of Uni-Gold™ Recombigen® HIV-1/2 was evaluated testing fresh serum, plasma and whole blood (venipuncture) samples. A total of 1032 HIV-1 positive samples were run on Uni-Gold™ Recombigen® HIV-1/2. 1000 of these were collected from individuals known to be HIV-1 sero-positive, and previously confirmed as positive by Western blot.

A further 32 samples were collected from individuals with high risk populations of unknown HIV serostatus who were subsequently found to be repeatedly reactive using a licensed HIV-1 EIA and positive by Western Blot.

The sensitivity of the Uni-Gold™ Recombigen® HIV-1/2 was also evaluated testing fresh venipuncture whole blood and fresh fingerstick whole blood from the same person. 100% agreement was achieved.

Uni-Gold™ Recombigen® HIV-1/2 test was reactive for all these samples when tested using the serum, plasma and whole blood (venipuncture) portion of each sample set, to give 100% sensitivity in these studies (1032/1032 = 100% 95% C.I. = 99.5 – 100.0%).

Two samples reactive by Uni-Gold™ Recombigen® HIV-1/2, from individuals known to be positive for HIV-1 were initially non-reactive by the FDA licensed screening assay. These samples were treated as per the protocol as positive samples and included in the calculations presented in Table 1. In the calculations the sensitivity of Uni-Gold™ Recombigen® HIV-1/2 has been based on the initial and not repeat test result.

**Table 1: Performance of Uni-Gold™ Recombigen® HIV-1/2 on initial serum, plasma and whole blood venipuncture samples, in comparison to EIA and Western blot from individuals seropositive for HIV-1**

<table>
<thead>
<tr>
<th>Test Group</th>
<th>Uni-Gold Recombigen HIV Serum Positive</th>
<th>Uni-Gold Recombigen HIV Plasma Positive</th>
<th>Uni-Gold Recombigen HIV Whole Blood Positive</th>
<th>EIA Reactive</th>
<th>Western Blot positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk (n=1000)</td>
<td>35</td>
<td>34</td>
<td>34</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Known HIV positive (n=100)</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1035</td>
<td>1034</td>
<td>1034</td>
<td>1030</td>
<td>1032</td>
</tr>
</tbody>
</table>

*S2 samples were initially non-reactive by the EIA. These samples were reactive on EIA repeat testing.

The sensitivity of Uni-Gold™ Recombigen® HIV-1/2 in detecting known HIV-2 antibody positive samples was assessed using a total of 266 samples that were previously shown to be positive for only HIV-2 antibodies using an FDA approved HIV-1/HIV-2 differentiation Rapid test (Table 2). All samples were frozen plasma sourced from Sierra Leone (n=66) and Ivory Coast (n=200). The Uni-Gold™ Recombigen® HIV-1/2 detected 266 of the 268 specimens known to be positive for only HIV-2 antibodies.

In a separate study, a total of 500 plasma samples from two HIV-2 endemic areas in West Africa (Ivory Coast n=250 and Sierra Leone n=250) were initially screened using Uni-Gold™ Recombigen® HIV-1/2 and an FDA licensed anti-HIV-1/2 EIA. Further confirmatory testing was performed using an FDA licensed HIV-1 Western blot and both a research use HIV-2 Western blot and an FDA approved HIV-1/HIV-2 differentiation rapid test for determination of the HIV-2 status. Twenty (20) samples were HIV-2 positive on the HIV-2 detection tests of these, 5 samples were classified as HIV-2 positive only. The remaining 15 specimens were also positive on the HIV-1 Western blot and were likely co-infected with HIV-1. Uni-Gold™ Recombigen® HIV-1/2 detected all 20 HIV-2 positive samples including the 5 HIV-2 only positive samples.

Table 2 presents a summary of the HIV-2 results. The overall sensitivity of Uni-Gold™ Recombigen® HIV-1/2 for the detection of antibodies to HIV-2 was shown to be 271/273 = 99.3% (95% C.I. = 97.1% - 99.9%).

**LIMITATIONS**

1. Uni-Gold™ Recombigen® HIV-1/2 must be used in accordance with the instructions in this package insert to obtain an accurate result.
2. Uni-Gold™ Recombigen® HIV-1/2 is designed to detect antibodies to HIV-1 and/or HIV-2 in undiluted whole blood (venipuncture and fingerstick) serum, and plasma. For venipuncture whole blood and plasma, EDTA, acid citrate dextar (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 and/or HIV-2 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 pink/red 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-1/2 suggests the presence of anti-HIV-1 and/or HIV-2 antibodies in the specimen. Uni-Gold™ Recombigen® HIV-1/2 is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2. 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-1/2 does not exclude the possibility of infection with HIV. A false negative result may occur in the following circumstances:
Eleven HIV-1 seroconversion panels were tested in comparison to FDA licensed EIA and Western blot tests. Each panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of 79 specimens. The results of this study are shown in Table 3. The Uni-Gold™ Recombigen® HIV-1/2 test detected HIV-1 antibodies at the same bleed or at an earlier bleed than the most sensitive of the licensed EIA's in 8 out of 11 panels. In the remaining 3 panels the Uni-Gold™ Recombigen® HIV-1/2 test detected HIV-1 antibodies one bleed later that the most sensitive EIA.

** Of the remaining 59 samples, 20 samples were HIV-2 antibody positive based on an HIV-1 and HIV-2 differentiation test and research use HIV-2 Western blot, of which 15 samples were positive on an FDA licensed HIV-1 Western blot (likely co-infection with HIV-1). In addition, using HIV-1 Western blot, 11 specimens were HIV-1 only positive and 28 samples were HIV-1 Indeterminate.

*** The 5 samples that were true HIV-2 only antibody positive were both positive on HIV-2 Western blot and HIV-2 only positive (i.e., HIV-1 negative) on the FDA approved HIV-1/HIV-2 differentiation rapid test.

Table 3: Summary of Seroconversion panel results in comparison to FDA licensed EIA's.

<table>
<thead>
<tr>
<th>Test Group</th>
<th>Samples</th>
<th>HIV-2 Antibody Reactive on HIV-1/HIV-2 Differentiation test</th>
<th>Reactive with Uni-Gold™ Recombigen® HIV-1/2</th>
<th>True HIV-2 Only Antibody Positive Specimens Detected by Uni-Gold™ Recombigen® HIV-1/2</th>
<th>Known HIV-2 antibody positive samples</th>
<th>HIV-2 endemic samples of unknown status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>268</td>
<td>268</td>
<td>266</td>
<td>266</td>
<td>*500</td>
<td>**20</td>
</tr>
<tr>
<td></td>
<td>768</td>
<td>288</td>
<td>286</td>
<td>271</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Of these 500 samples, 441 were negative on the FDA licensed tests, of which all 441 tested negative on Uni-Gold™ Recombigen® HIV-1/2.

** Of the remaining 59 samples, 20 samples were HIV-2 antibody positive based on an HIV-1 and HIV-2 differentiation test and research use HIV-2 Western blot, of which 15 samples were positive on an FDA licensed HIV-1 Western blot (likely co-infection with HIV-1). In addition, using HIV-1 Western blot, 11 specimens were HIV-1 only positive and 28 samples were HIV-1 Indeterminate.

*** The 5 samples that were true HIV-2 only antibody positive were both positive on HIV-2 Western blot and HIV-2 only positive (i.e., HIV-1 negative) on the FDA approved HIV-1/HIV-2 differentiation rapid test.
Two commercially available low titre HIV-1 panels and one in-house low titre panel were tested by Uni-Gold™ Recombigen® HIV-1/2 in comparison with FDA licensed EIA tests. In this study, Uni-Gold™ Recombigen® HIV-1/2 was shown to have comparable sensitivity to FDA licensed EIAs.

Results are presented in Tables 4, 5 and 6.

### Table 4: Result Summary of First Low Titre Panel: PRB 107

<table>
<thead>
<tr>
<th>Panel</th>
<th>Uni-Gold™ Recombigen® HIV-1/2</th>
<th>EIA 1</th>
<th>EIA 2</th>
<th>EIA 3</th>
<th>EIA 4</th>
<th>EIA 5</th>
<th>Western Blot</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>POS</td>
</tr>
<tr>
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<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>NEG</td>
</tr>
<tr>
<td>03</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<td>IND</td>
</tr>
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<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NEG</td>
</tr>
<tr>
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<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NEG</td>
</tr>
<tr>
<td>06</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>NEG</td>
</tr>
<tr>
<td>07</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NEG</td>
</tr>
<tr>
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<td>R</td>
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<td>R</td>
<td>R</td>
<td>R</td>
<td>POS</td>
</tr>
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<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
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<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>POS</td>
</tr>
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<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>POS</td>
</tr>
<tr>
<td>15</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>POS</td>
</tr>
</tbody>
</table>

Key: R = Reactive, NR = Not Reactive, POS = Positive, NEG = Negative, IND = Indeterminate

### Table 5: Result Summary of Second Low Titre Panel: PRB 108

<table>
<thead>
<tr>
<th>Panel</th>
<th>Uni-Gold™ Recombigen® HIV-1/2</th>
<th>EIA 1</th>
<th>EIA 2</th>
<th>EIA 3</th>
<th>Western Blot</th>
<th>Rapid Test</th>
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</tbody>
</table>

Key: R = Reactive, NR = Not Reactive, POS = Positive, NEG = Negative, IND = Indeterminate (according to Western blot specifications)

### Table 6: Third Low Titre Panel: In-House

<table>
<thead>
<tr>
<th>In-House Panel</th>
<th>Uni-Gold™ Recombigen® HIV-1/2</th>
<th>EIA 1</th>
<th>EIA 2</th>
<th>Western Blot</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRC 42015</td>
<td>R</td>
<td>R</td>
<td>NR</td>
<td>POS</td>
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<tr>
<td>CRC 42013</td>
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<td>R</td>
<td>R</td>
<td>NR</td>
<td>IND</td>
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<td>CRC 42049</td>
<td>R</td>
<td>R</td>
<td>NR</td>
<td>IND</td>
</tr>
<tr>
<td>CRC 42071</td>
<td>R</td>
<td>R</td>
<td>NR</td>
<td>POS</td>
</tr>
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<td>CRC 42075</td>
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<td>R</td>
<td>NR</td>
<td>POS</td>
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<td>CRC 42119</td>
<td>R</td>
<td>R</td>
<td>NR</td>
<td>POS</td>
</tr>
</tbody>
</table>

Key: R = Reactive, NR = Not Reactive, POS = Positive, NEG = Negative, IND = Indeterminate, EIA = FDA licensed EIA

The sensitivity of Uni-Gold™ Recombigen® HIV-1/2 was further investigated by testing samples from people with unrelated medical conditions and samples containing interfering substances. 200 samples from subjects with other medical conditions were spiked with HIV-1 antibody positive serum. The medical conditions included Cytomegalovirus, Rubella IgG, Epstein Barr Virus, Anti-Nuclear Antibody, Hepatitis B Core Antibody, Hepatitis B Surface Antigen, Hepatitis C Virus Antibody, other autoimmune diseases, other disease states and samples from persons recently vaccinated against viruses. None of the unrelated medical conditions affected the sensitivity of Uni-Gold™ Recombigen® HIV-1/2. In addition, 20 samples with interfering substances, such as hemolyzed, lipemic, high protein, high bilirubin, sarcoid and multiple myeloma samples were spiked with HIV-1 antibody positive serum and tested. These potentially interfering conditions do not affect the performance of Uni-Gold™ Recombigen® HIV-1/2.

### Table 7: Performance of Uni-Gold™ Recombigen® HIV-1/2 from individuals presumed negative for HIV infection.

<table>
<thead>
<tr>
<th>Test Group</th>
<th>Uni-Gold™ Recombigen® HIV-1/2</th>
<th>Uni-Gold™ Recombigen® HIV-1/2 Plasma</th>
<th>Uni-Gold™ Recombigen® HIV-1/2 Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>988</td>
<td>988</td>
<td>988</td>
</tr>
<tr>
<td>High Risk</td>
<td>985</td>
<td>985</td>
<td>985</td>
</tr>
</tbody>
</table>

*This sample set consisted of 32 true HIV-1 positive samples

The specificity of Uni-Gold™ Recombigen® HIV-1/2 was also evaluated testing fresh venipuncture whole blood and fresh fingerstick whole blood from the same person. 100% agreement was achieved.

To further evaluate the specificity of Uni-Gold™ Recombigen® HIV-1/2, the product was challenged for antibody cross reactivity with sera from individuals with other disease states. Two hundred (200) specimens from patients with non HIV-1 medical conditions, and confirmed as HIV-1 negative were tested. The results are summarized in Table 8.

### Table 8: Results from samples with other medical conditions

<table>
<thead>
<tr>
<th>Disease State</th>
<th>Sample Tested</th>
<th>Number Tested</th>
<th>Number Correctly Identified (Non-Reactive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytomegalovirus Positive</td>
<td>20</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Rubella IgG Positive</td>
<td>20</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Epstein Barr Virus Positive</td>
<td>20</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Rheumatoid Factor Positive</td>
<td>10</td>
<td>10</td>
<td>100%</td>
</tr>
<tr>
<td>Anti-Nuclear Antibody Positive</td>
<td>20</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Hepatitis B Core Antibody Positive</td>
<td>20</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Hepatitis B Surface Antigen Positive</td>
<td>20</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Hepatitis C Virus Antibody Positive</td>
<td>30</td>
<td>30</td>
<td>100%</td>
</tr>
<tr>
<td>Other auto immune samples</td>
<td>10</td>
<td>10</td>
<td>100%</td>
</tr>
<tr>
<td>Other disease states</td>
<td>20</td>
<td>20</td>
<td>100%</td>
</tr>
<tr>
<td>Recently Vaccinated against Viruses</td>
<td>10</td>
<td>10</td>
<td>100%</td>
</tr>
</tbody>
</table>

Total | 200 | 200 | 100% |

In addition, 20 samples with interfering substances, such as hemolyzed, lipemic, high protein, high bilirubin, sarcoid and multiple myeloma samples were tested. These potentially interfering conditions do not affect the performance of Uni-Gold™ Recombigen® HIV-1/2.

### Table 9: Reproducibility of Uni-Gold™ Recombigen® HIV-1/2

Uni-Gold™ Recombigen® HIV-1/2 was found to be consistent and stable when three different lots of Uni-Gold™ Recombigen® HIV-1/2 were tested by 2 operators, at 2 separate sites, testing 7 coded and blinded samples, 5 times a day, over 4 days. 840 tests were run (420 per site), with a total of 60 tests per sample. The overall reproducibility of the device was found to be excellent.

The overall reproducibility of the Uni-Gold™ Recombigen® HIV-1/2 was found to be 99.8% (95% Confidence interval = 99.2 - 100%) for serum, 99.9% (95% Confidence interval = 99.3 - 100%) for plasma and 99.7% (95% Confidence interval = 99.0 - 100%) for whole blood.

### Table 10: Results from untrained user study

An 'untrained' user study was conducted at 3 sites with 100 participants in total who had no professional medical laboratory training, personnel or prior experience using Uni-Gold™ Recombigen® HIV-1/2. Each participant in the study was asked to perform Uni-Gold™ Recombigen® HIV-1/2 tests with a blinded panel of 6 samples without prior training, solely by using the provided package insert.

Three different samples were included in the study with each participant testing all three in a blinded manner. The samples consisted of a negative sample, a positive sample and a low positive sample. The low positive sample represented a weak positive sample close to the visual detection limit of the test.

The overall rate of correct results for the study was 97.7% (580/600). Table 10 below summarizes the study findings. There were no invalid results reported in the study. As part of the untrained user study each participant completed a questionnaire on the use of the product.
### TABLE 9: Untrained users rate of correct results

<table>
<thead>
<tr>
<th></th>
<th>Low Positive</th>
<th>High positive</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>94.0%</td>
<td>100%</td>
<td>97.7%</td>
</tr>
<tr>
<td>(198/200)</td>
<td>(198/200)</td>
<td>(200/200)</td>
<td>(596/600)</td>
</tr>
<tr>
<td>95%CI</td>
<td>99.9% CI</td>
<td>95%CI</td>
<td>95%CI</td>
</tr>
<tr>
<td>(96.1-99.7)</td>
<td>(98.2-100)</td>
<td>(96.1-98.7)</td>
<td></td>
</tr>
</tbody>
</table>

**REFERENCES**

9) CDC. Revised guidelines for HIV counseling MMWR Recommendations and Reports, 2001; 50 (RR-19).

**GUIDE TO SYMBOLS**

- **Consult Instructions for Use**
- **Temperature limitation**
- **Catalogue number**
- **For in vitro Diagnostic Use**
- **Manufacturer**
- **LOT**
- **Batch code**

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Bray, Co. Wicklow, Ireland
Phone: 353-1-276 9800
Fax: 353-1-276 9808
hiv@trinitybiotech.com
www.trinitybiotech.com

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2823 Gris Road,
Jamestown, NY 14701.
Phone: 1-800-325 3424

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