WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: Uni-Gold HIV
WHO reference number: PQDx 0149-052-00

Uni-Gold HIV with product codes **1206502, 1206502N**, **1206502N-100, 1206502-100, 1206502-C, and 1206502-C100**, manufactured by **Trinity Biotech Manufacturing Ltd.**, **rest of the world regulatory version**, was accepted for the WHO list of prequalified diagnostics and was listed on 20 December 2012.

Summary of WHO prequalification assessment for Uni-Gold HIV

	Date	Outcome
Prequalification listing	20 December 2012	listed
Dossier review	3 December 2012	MR
Site inspection(s) of quality management systems	18-20 July 2016 (Key Supplier) 19-22 September 2022	MR
Product performance evaluation	17 December 2012	MR

MR: Meets Requirements

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Reason for amendment	Date of report amendment
2.0	Changes in packaging.	2013
3.0	Changes in Instructions for Use (IFU).	2014
4.0	Changes in labelling.	2015
5.0	Change in manufacturing processes.	2015
6.0	Change in desiccant.	2016
7.0	Change in the wash solution.	2016

8.0	Update to IFU and addition of new packaging configuration for the Nigerian market	2017
9.0	-This change was raised to capture the verification activities required to include lancets and swabs in the Uni-Gold HIV kit box. This involves the creation of new product part numbers 1206502-C and 1206502E-C for kits sold in Ethiopia. This kit will contain the current kit components: device P/N 565-006, wash P/N 595-231, pipette P/N 565-001 along with lancets (P/N 065-276) and swabs (P/N 024-252). -The manufacturer submitted a change request to add a new product code. "Currently, the 1206502N-100 100 test kit is only available to customers in Nigeria. A new product code, 1206502-100, is being introduced to make the 100 test kit available to other markets. This is a change in product code; the kit contents, packaging materials and intended use are identical to the 1206502N-100 product code."	4 February 2019
10.0	The supplier of the lancets and swabs contained within the Uni-Gold HIV Complete kit 1206502C and 1206502C-E has informed Trinity Biotech Plc of a change to the EC representative listed on the label of the lancets and the swabs. The supplier of the lancets and swabs is implementing a change from a UK-based EC representative (Renault Petersen Limited) in the UK to an EU-based EC representative (MedPath GmbH).	17 June 2019
11.0	Introduction of a larger kit size of the Uni-Gold HIV Complete Kit (1206502-C) that will support the provision of 100 pouched devices, 5 bottles of wash, 5 IFUs, 100 pipettes, 100 lancets and 100 swabs. The new product code is 1206502-C100.	21 April 2021
12. 0	The Uni-Gold HIV IFU was updated with the following: i) Adding clarification regarding the correct interpretation of a grey line at the test-line region of Uni-GoldTM HIV (1206502) devices. ii) Addition of a precaution to the IFU highlighting the correct surface for testing to eliminate issues related to static.	24 April 2023

	iii) Addition of clarification to IFU in Further interpretation – Broken Lines, to specify the colour “pink/red” when discussing broken control or test lines.”	
13.0	Added the manufacturing date, GTIN and UDI (Unique Device Identifier) 2-D barcode to the laser etched information on the kit boxes of the Uni-Gold HIV kits (1206502, 1206502-100, 1206502N and 1206502N-100) and the Uni-Gold HIV Complete kits (1206502-C, 1206502-C100). Discontinuation of the Ethiopia-specific Uni-Gold HIV (1206502E) and Uni-Gold HIV Complete kits (1206502E-C). Upgrading the laser that marks packed kit boxes during the kit packing process with the lot-specific product information in a human-readable format to a new laser that will simultaneously mark the kit boxes with this product information in a human-readable format and a 2D code format.	3 July 2024

Intended use:

According to the claim of intended use from Trinity Biotech Manufacturing Ltd., *"Uni-Gold HIV is a single use rapid immunoassay, for the qualitative detection of antibodies to HIV-1 and HIV-2 in serum, plasma and whole blood (venipuncture and fingerstick). Uni-Gold HIV is intended for use in point-of-care settings as an aid in diagnosis of HIV-1 and HIV-2 infection."*

Assay description:

According to the claim from Trinity Biotech Manufacturing Ltd., "*Uni-Gold HIV is a rapid immunoassay based on the immunochromatographic sandwich principle. Recombinant proteins representing the immunodominant regions of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp41, gp120 (HIV-1) and glycoprotein gp36 (HIV-2), respectively, are immobilized at the test region of the nitrocellulose strip. These proteins are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.*

During testing two drops of serum, plasma or whole blood is applied to the sample port, followed by two drops of Wash Solution and allowed to react. Antibodies of any immunoglobulin class, specific to the recombinant HIV-1 or HIV-2 proteins, will react with the colloidal gold linked antigens. The antibody protein colloidal gold complex moves chromatographically along the membrane to the test and control regions of the test device.

Excess conjugate forms a second pink/red line in the control region of the device. The appearance of this band indicates proper performance of the reagents in the kit".

Test kit components:

Component	**20 tests (product codes 1206502, 1206502N)**	**100 tests (product codes 1206502N-100, 1206502-100)**	**20 tests (product code 1206502-C)**	**100 tests (product code 1206502-C100)**
Test Devices Individually pouched plastic cassettes	20	100	20	100
Wash Solution 2.0 mL of Wash Solution contains Tris buffer, Borate buffer, Chaotropic agent, Surfactant, Polyether compound, Sugar, Polymer and the preservative ProClin 300 at 0.06% v/v.	1 vial (2 ml)	5 vials (2 ml)	1 vial (2 ml)	5 x (2.0 mL)
Disposable Pipettes 20 plastic, non-sterile, units in a ziplock bag, pipette length 130 ± 2 mm, drop volume 25µl – 35µl.	1 x pack of 20	5 x pack of 20	1 x pack of 20	5 x pack of 20
Sterile lancets)	N/A	N/A	1 x pack of 20	5 x pack of 20
Alcohol swabs	N/A	N/A	20	100
Instructions for use	1	5	1	5

Other materials required but not provided with Uni-Gold HIV product codes 1206502, 1206502N, 1206502N-100, 1206502-100

Item
Consumables: • Blood collection devices for testing of venipuncture whole blood, serum or plasma. • Biohazard disposal waste container. Fingerstick Samples: • Lancet: A high blood flow lancet with a depth ranging between 1.5-2.0 mm is required to produce a 60 µL whole blood droplet • Sterile wipes and sterile gauze pads • Adhesive bandages.
Durables: N/A
Equipment: Timer or stopwatch Personal protective equipment

Other materials required but not provided with Uni-Gold HIV Complete product code 1206502-C and 1206502-C100

Consumables: • Blood collection devices for testing of venipuncture whole blood, serum or plasma. • Biohazard disposal waste container. Fingerstick Samples: • Sterile gauze pads. • Adhesive bandages
Durables: N/A
Equipment: Timer or stopwatch Personal protective equipment

Storage:
The test kit should be stored at 2 to 27 °C.

Shelf-life upon manufacture:
20 months.

Warnings/limitations:
Please refer to the IFU attached to this public report.

Prioritization for prequalification:
Based on the established eligibility criteria, Uni-Gold HIV was accepted for WHO prequalification assessment.

Product dossier assessment

Trinity Biotech Manufacturing Ltd. submitted a product dossier for Uni-Gold HIV as per the Instructions for compilation of a product dossier (PQDx_018 v1). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the nonconformities found during dossier screening and assessment findings were accepted on 4 December 2012.

Commitments for prequalification:
The manufacturer committed to amend and submit additional documentation on the following issues:

1. Analytical performance studies
2. Clinical performance studies
3. Shipping stability studies
4. A new version of the instructions for use.

WHO followed up on the implementation of these commitments, and the requirements were met.

Based on the product dossier screening and assessment findings, the product dossier for Uni-Gold meets WHO prequalification requirements.

Manufacturing site inspection

A comprehensive inspection was performed at the site of the legal manufacturer between 19-21 September 2022 and at the site of a key supplier between 18-20 July 2016, as per 'Information for manufacturers on prequalification inspection procedures for the sites of manufacture of diagnostics.' (PQDx_014). The inspection found that the manufacturer had an acceptable quality management system and good manufacturing practices in place that ensured the consistent manufacture of a product of good quality.

The manufacturer's responses to the nonconformities found at the time of the inspection were accepted on 8 june 2023.

Based on the site inspection and corrective action plan review, the quality management system for Uni-Gold meets WHO prequalification requirements.

Product performance evaluation

Uni-Gold HIV was evaluated by WHO in the third quarter of 2012 at the Institute of Tropical Medicine, Antwerp, Belgium – a WHO Collaborating Centre for HIV-AIDS Diagnostics and Laboratory Support. The laboratory evaluation was conducted according to the "WHO Protocol for the laboratory evaluation of HIV serology assays" (PQDx_030 V1.0) and drew the following conclusions:

Uni-Gold HIV is an immunochromatographic rapid diagnostic test for the detection of HIV-1/2 antibodies in human serum, plasma and whole blood. A volume of 60 µL of specimen is needed to perform the assay. This type of assay requires no sophisticated equipment and can, therefore, be performed in laboratories with limited facilities and non-laboratory settings. Reading of the results can be done visually, i.e. subjectively read.

In this limited performance evaluation using a panel of 1079 clinically-derived specimens, we found an initial sensitivity (95% CI) of 99.76% (98.7%-100%) and an initial specificity (95% CI) of 99.85% (99.2%-100%) compared to the reference assays. The final sensitivity (95% CI) was 99.76% (98.7%-100%), and the final specificity (95% CI) was 99.85% (99.2%-100%) compared to the reference assays. Lot-to-lot variation was acceptable. In this study, 0% of the results were recorded as indeterminate. Results were interpreted independently by three technicians; the inter-reader variability was 0.09%. The invalid rate was 0.09%.

For eight seroconversion panels, Uni-Gold HIV detected on average 0.125 specimens later than the benchmark assay, Enzygnost Anti-HIV 1/2 Plus (Siemens Healthcare Diagnostics). For the mixed titer panel, Uni-Gold HIV correctly classified all specimens. Four out of the six anti-HIV indeterminate/HIV-1 antigen positive specimens were identified as anti-HIV-1/2 reactive. For the 1st International Reference Panel for anti-HIV [NIBSC code 02/210], Uni-Gold HIV correctly classified all specimens with the exception of subtype O.

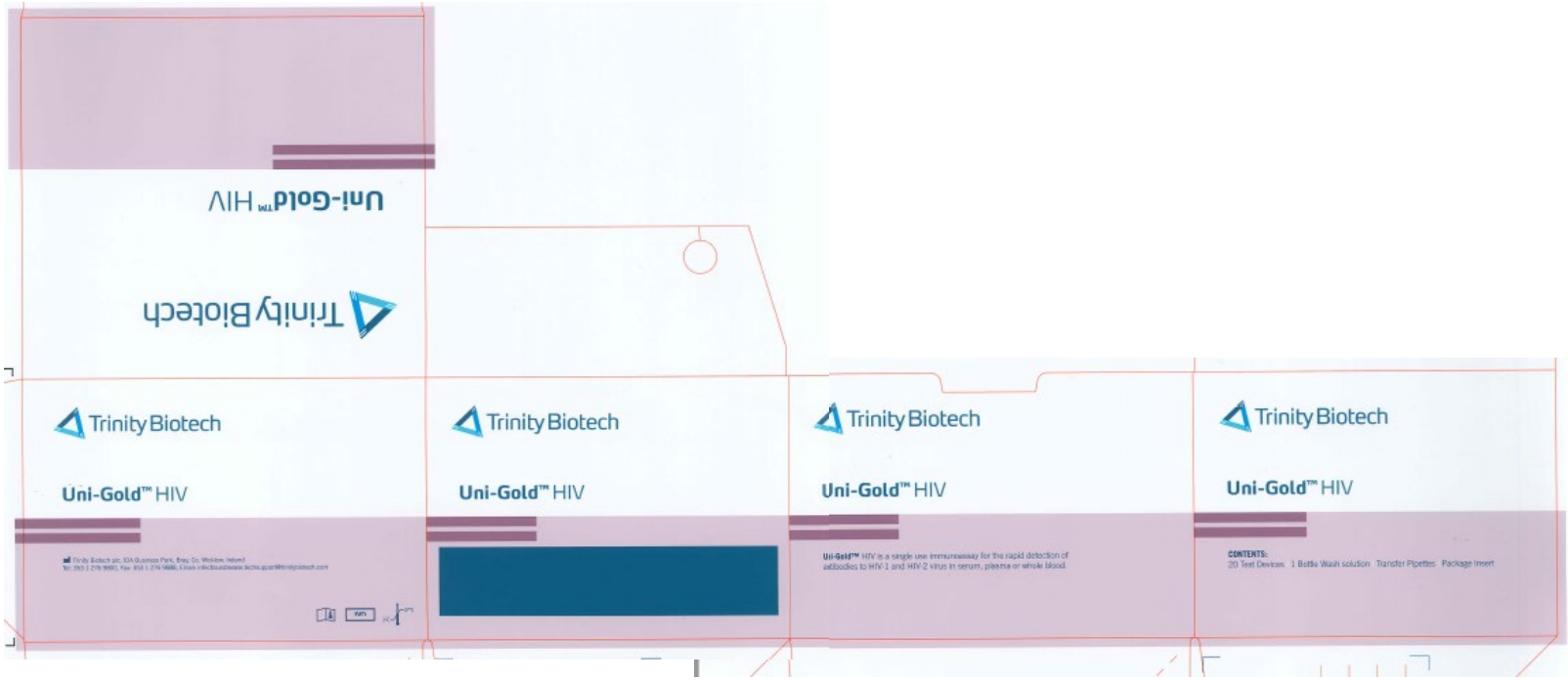
Labelling

1. Labels

2. Instructions for use

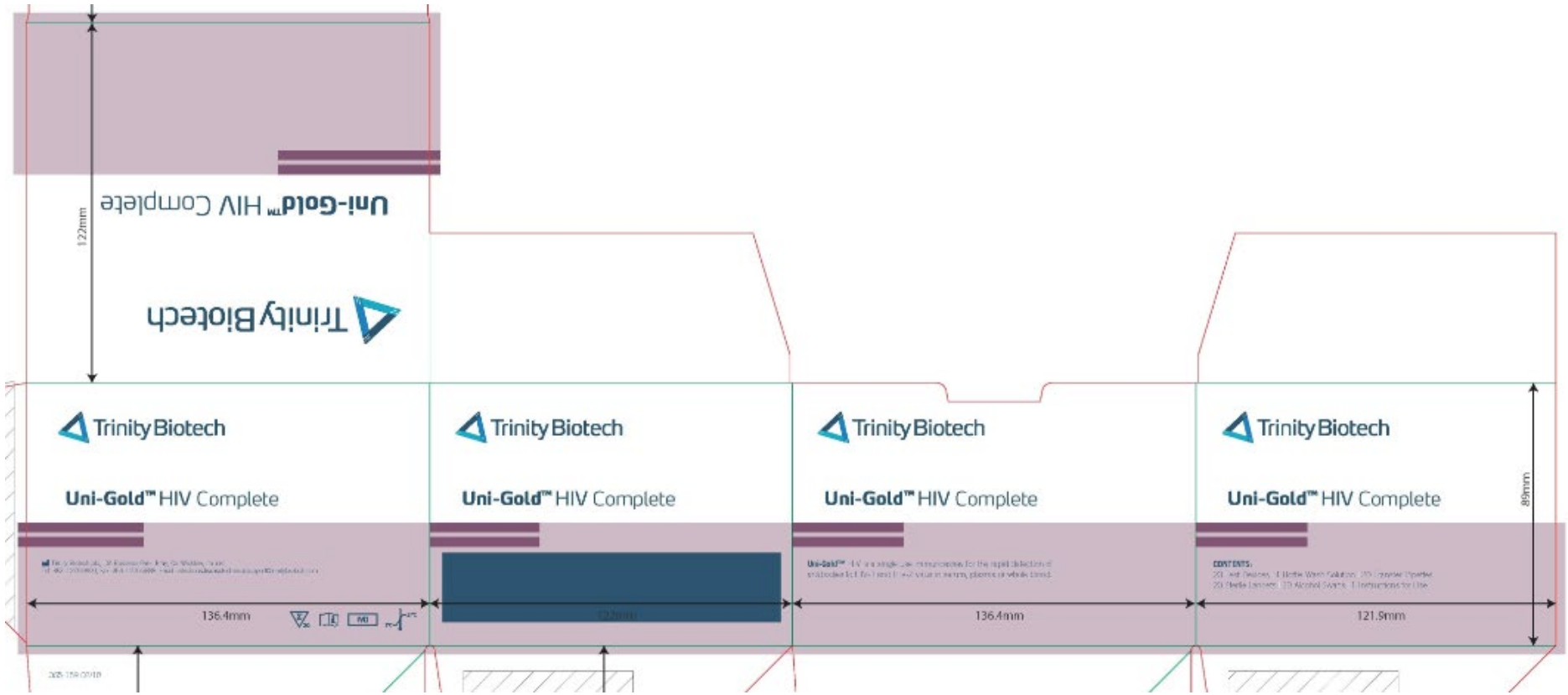
1. Labels

Kit box-Product codes 1206502, 1206502N

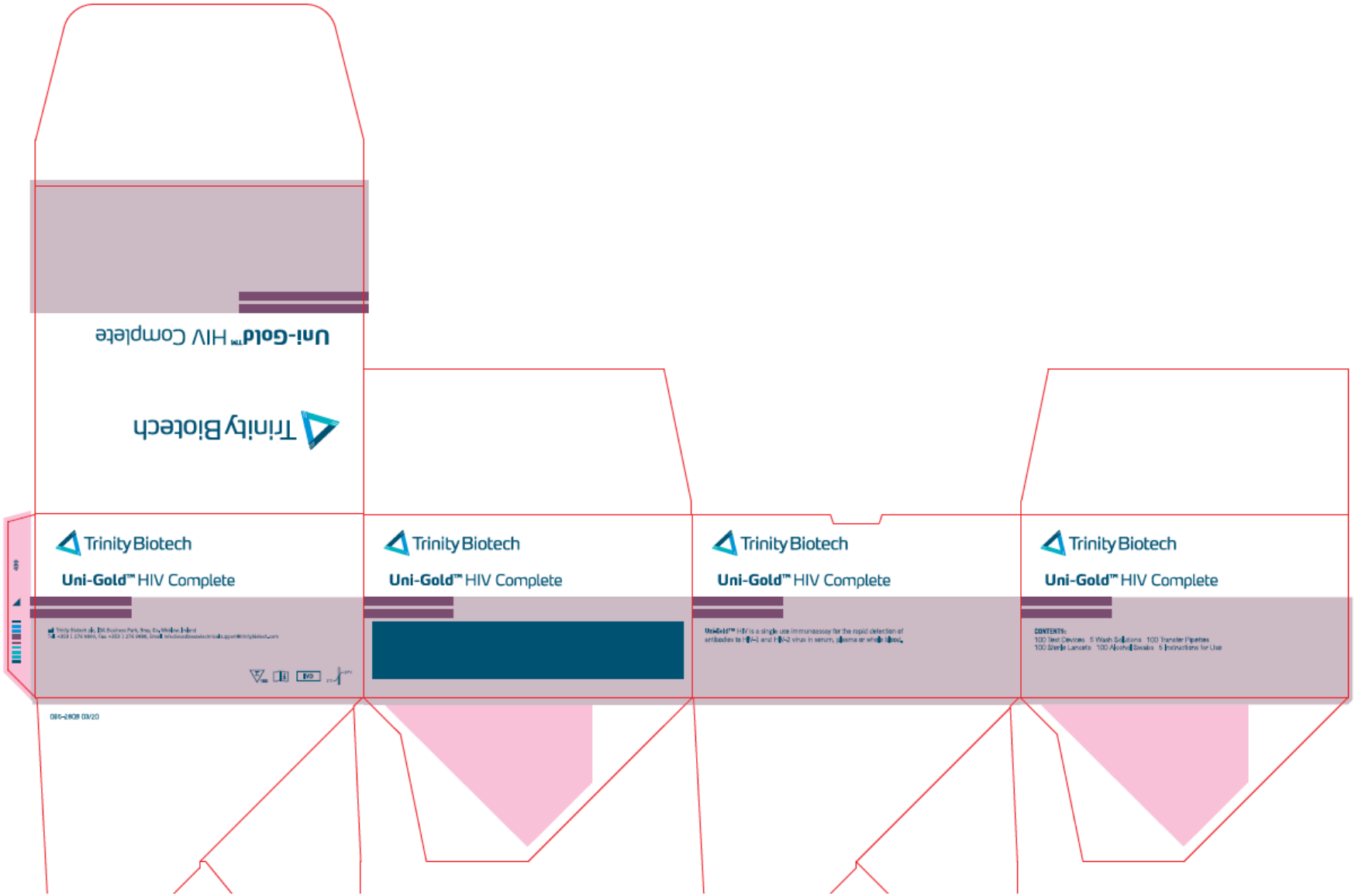


Kit box-Product codes 1206502-100, 1206502N-100

Kit box-Product code 1206502-C



Kit box- Product code 1206502-C100



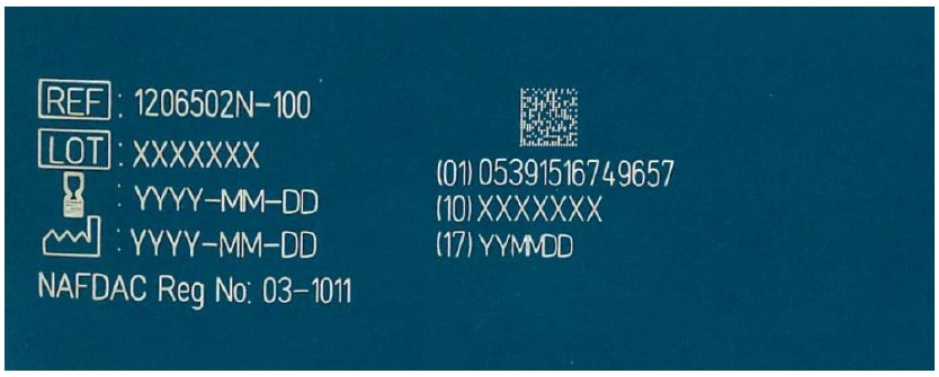
Laser-etched details for the outer kit box (left side of the box)

Laser etch for 1206502

Laser etch for 1206502N

Laser etch for 1206502-100

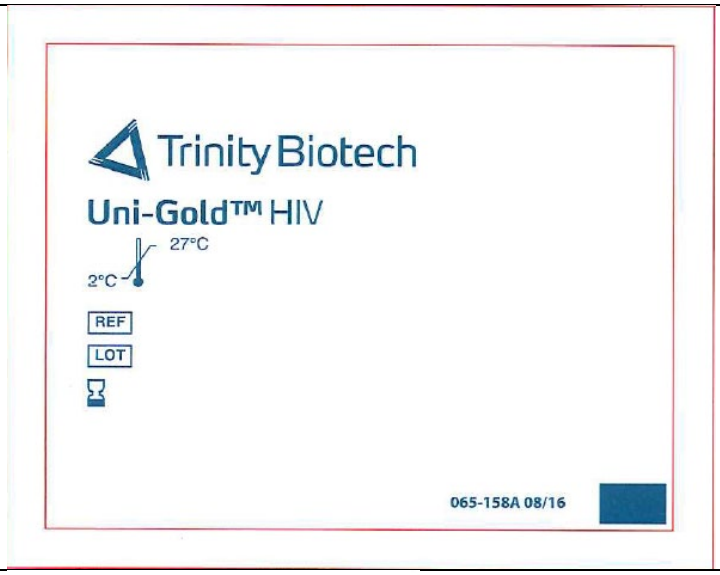
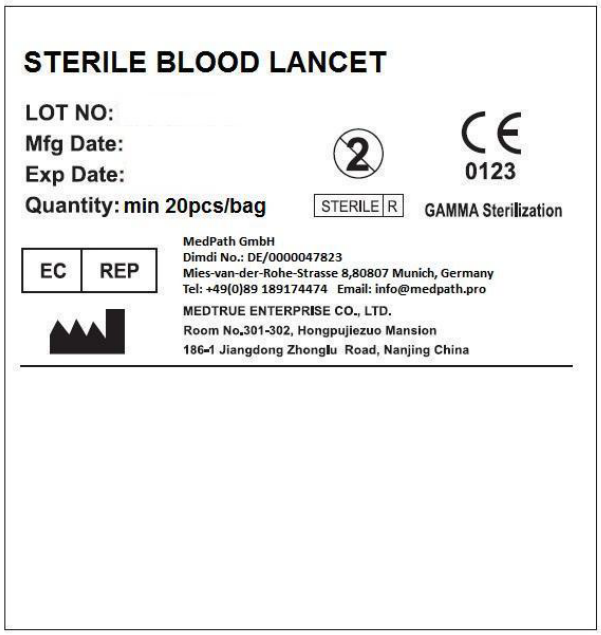
Laser etch for 1206502N-100

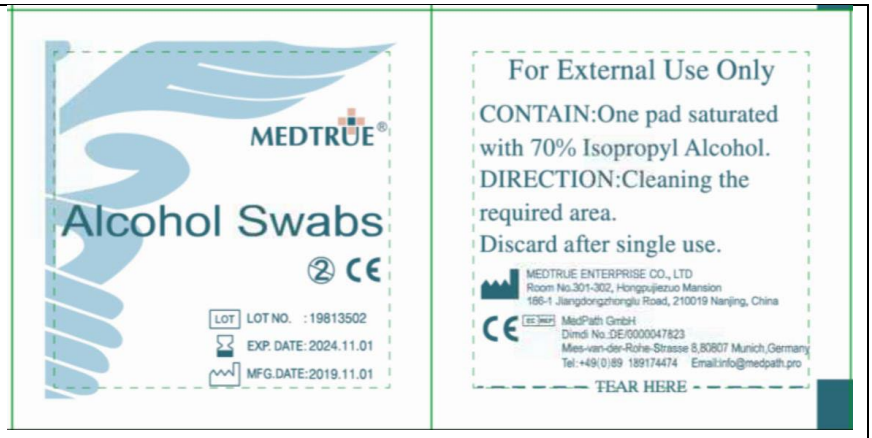


Laser etch for 1206502-C

Laser etch for 1206502-C100

Labels for device pouch, wash buffer, sterile lancet and alcohol swabs

Device pouch (ref: 1206502-D): This is the same throughout all packaging configurations The test device pouch is overprinted with the reference number (1206502-D) and lot number (e.g. X123456), expiry (e.g. 2020-01-01)	
Wash Buffer label (ref 565-231): This is the same throughout all packaging configurations	
Sterile Lancet label: This is for product code 1206502-C (not applicable to other packing configurations)	

Alcohol Swab label: This is the same for both the 1206502-C kits (not applicable to other packing configurations)	

2. Instructions for use[1]

[1] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

Uni-Gold™ HIV Complete

REF 1206502-C100

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków
Para outras línguas
Για τις άλλες λώσσες
För andra språk
For andre språk

www.trinitybiotech.com

Read these Instructions for Use completely before using the product. Follow the directions carefully. Not doing so may result in incorrect test results.

NAME AND INTENDED USE

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

SUMMARY AND PRINCIPLES OF THE PROCEDURE

HIV 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 transmitted from HIV positive individuals predominantly through unprotected sexual intercourse[2], intravenous drug abuse[3] or from mother to child transmission[4]. 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].

Uni-Gold™ HIV is a rapid immunoassay based on the immunochromatographic sandwich principle. Recombinant proteins representing the immunodominant regions of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp41, gp120 (HIV-1) and glycoprotein gp36 (HIV-2) respectively, are immobilized at the test region of the nitrocellulose strip. These proteins are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

During testing, two drops of serum, plasma or whole blood is applied to the sample port, followed by two drops of Wash Solution and allowed to react. Antibodies of any immunoglobulin class, specific to the recombinant HIV-1 or HIV-2 proteins will react with the colloidal gold linked antigens. The antibody protein colloidal gold complex moves chromatographically along the membrane to the test and control regions of the test device.

Excess conjugate forms a second pink/red band in the control region of the device. The appearance of this band indicates proper performance of the reagents in the kit.

MATERIALS PROVIDED

Each kit contains:

- Test Devices: 100 test devices individually pouched.
- Wash Solution: 5 x 2.0 mL in dropper bottle.
- Disposable Pipettes: 5 x 20 Disposable Pipettes for use with serum, plasma or whole blood.
- Lancets: 5 x 20 sterile lancets.
- Swabs: 100 alcohol swabs.

COMPONENTS OF REACTIVE INGREDIENTS

Wash Solution: 2.0 mL of Wash Solution contains Tris buffer, Borate buffer, Chaotropic agent, Surfactant, Polyether compound, Sugar, Polymer and the preservative ProClin® 300 at 0.06% v/v.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Blood collection devices, for testing of venipuncture whole blood, serum or plasma.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

Fingerstick Samples:

- Sterile gauze pads.
- Adhesive bandages

WARNINGS

1. Read the Instructions for Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. Uni-Gold™ HIV is for diagnostic use only and is not to be used for screening donors of blood, plasma, cells or tissues.
3. Perform test at room temperature.

PRECAUTIONS

1. Uni-Gold™ HIV test is for professional use only.
2. The Instructions for Use must be followed to ensure optimum test performance.
3. Uni-Gold™ HIV test is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.
5. It is recommended that spare test devices are available at all times.

Safety Precautions

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

Biosafety Precautions

Appropriate biosafety practices should be used 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 in which 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"[5].
3. When disposing of Wash Solution, 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 sodium hypochlorite solution.
5. Use a separate disposable pipette and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix Wash Solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. Use paper covered surface to perform testing, so as to eliminate any risk to product performance due to build-up of static charge.
8. The result should be read immediately after the end of the 10 minute incubation time following the addition of Wash Solution. Do not read results beyond 12 minutes.
9. Lancets should be placed in a puncture resistant container prior to disposal.

STORAGE INSTRUCTIONS

1. Uni-Gold™ HIV device and Wash Solution should be stored between 2-27°C.
2. Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the Wash Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that all components are brought to room temperature before use.
4. Do not freeze the kit.

SPECIMEN COLLECTION AND STORAGE

Whole Blood Venipuncture 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.
- Grossly hemolysed or lipemic samples should not be used.

Whole blood: Fingerstick

Use whole blood samples collected by fingerstick immediately on the Uni-Gold™ HIV device.

Collection: Whole Blood 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. This whole blood can be used directly on the device, or stored at 2-8°C for up to 3 days, or preferably, the sample should be centrifuged and the plasma retained for further testing. Do not freeze whole blood.

Collection: Serum and Plasma

If a whole blood sample is collected without anticoagulant and has started to clot, do not remix before testing, in such instances, the clear serum should be pipetted off the clotted specimen and used for analysis.

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. Plasma must be generated within 8 hours of blood draw. Following collection, 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 or stored between 2 to 8°C for up to 5 days to allow testing. Specimens must be stored at -20°C or below if storage is necessary for more than 5 days. Grossly hemolysed or lipemic samples should not be used. Avoid multiple freeze thaw cycles.

TEST PROCEDURE FOR WHOLE BLOOD FINGERSTICK

1. Kits stored at room temperature may be used immediately (Figure 1). Allow kits stored in a refrigerator to reach room temperature. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches (Figure 2). Devices must be used within 20 minutes of opening the foil pouch.

Figure 1. Uni-Gold™ HIV Complete kit components.

Figure 2. Test device pouch

2. 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. Using an alcohol swab, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
6. Using the sterile lancet provided, puncture the skin just off the centre of the finger pad (Figure 3). Hold the finger downward.
7. 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 (Figure 4). 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.
8. Never apply blood droplets directly from the fingertip onto the device as their size may vary.
9. To collect the blood into the fingerstick disposable pipette, gently press the pipette bulb, hold the pipette horizontal to the sample (Figure 5).This is important as the specimen may not be adequate if the pipette is held in a vertical position**.** Slowly release pressure on the bulb to draw up the sample.

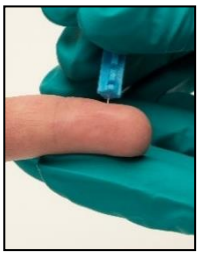


Figure 3. Position lancet.


Figure 4. Blood drop formation.


Figure 5. Draw sample into pipette.

10. Hold the pipette vertically above the sample port, squeeze the bulb and discharge two (2) drops of whole blood onto the sample pad (Figure 6). Allow the sample to fully absorb. Ensure there are no air bubbles in the sample port. Failure to hold the pipette in a vertical position may lead to erroneous test results. Do not touch the sample pad with the disposable pipette. Dispose of the pipette into biohazard waste.
11. Hold the Wash Solution dropper bottle vertically over the sample port; add two (2) drops of Wash Solution to the sample port (Figure 7). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

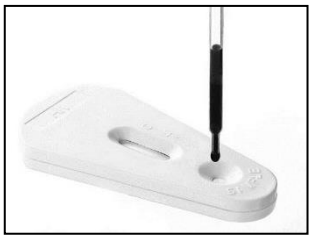


Figure 6. Add blood vertically into device.


Figure 7. Add Wash Solution vertically.

12. Read test results after 10 minutes but no later than 12 minutes incubation time.
13. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

TEST PROCEDURE FOR VENIPUNCTURE WHOLE BLOOD, SERUM AND PLASMA

1. Allow the kit (unopened devices and Wash Solution) to reach room temperature if previously stored in the refrigerator. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches. Devices must be used within 20 minutes of opening the foil pouch.
2. 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. Fill the disposable pipette included in the kit with sample. Ensure there are no air bubbles. Use only the pipette included in the kit and do not reuse.
6. Hold the pipette vertically over the sample port, squeeze the bulb and discharge two (2) drops of plasma/serum/whole blood onto the sample pad (Figure 8). Allow the sample to fully absorb. Ensure air bubbles are not introduced into the sample port. Do not touch the sample pad with the disposable pipette. Failure to hold the pipette in a vertical position may lead to erroneous test results.
7. Dispose of the pipette in biohazard waste.
8. Holding the dropper bottle of Wash Solution in a vertical position and above the sample port, add two (2) drops of Wash Solution to the sample port (Figure 9). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

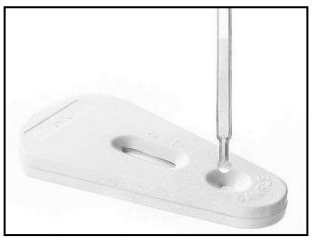


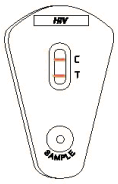
Figure 8. Add sample vertically into device.


Figure 9. Add Wash Solution vertically.

9. Read test results after 10 minutes but no later than 12 minutes incubation time.
10. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

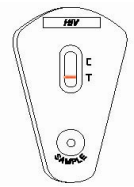
INTERPRETATION FOR WHOLE BLOOD, SERUM AND PLASMA SAMPLES

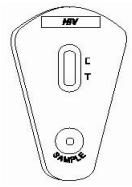
Reactive Test Result
Two pink/red lines of any intensity in the device window, the first adjacent to letter "T" (test) and the second adjacent to "C" (control). This indicates a Reactive result that is interpreted as Preliminary Positive for antibodies to HIV.



Non-Reactive Test Result
A pink/red line of any intensity adjacent to the letter "C" (control), but no pink/red line adjacent to "T" (test). This indicates a Non-Reactive result that is interpreted as Negative for antibodies to HIV.

Invalid Result
No pink/red line appears in the device window adjacent to the letter "C" (control) irrespective of whether or not a pink/red line appears in the device window adjacent to "T" (test). This is an Invalid result that cannot be interpreted. An invalid result must be repeated.





***Disclaimer**: The diagrams above are for illustration purposes only.*

Further Interpretation

Grey Lines

Where a grey line is seen, it does not indicate the presence of antibodies to HIV. It is always interpreted as non-reactive.

Broken Lines

*Test Line***:** Where a specimen produces a broken pink/red test line with Uni-Gold™ HIV, it is deemed initially reactive (conditional on the presence of a pink/red control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete pink/red line in one or both duplicates, then the sample is interpreted as preliminary positive. If both duplicates give no line at "T" (test) then the result is referred to as negative.
*Control Line***:** A broken pink/red control line does not affect the validity of the test.

Whole Blood Migration

Whole blood sample may migrate into the device window (whole blood visible at the bottom). The test is valid and can be interpreted if there is no obstruction in the test line region at 10 to 12 minutes. If the sample infringes on the test line region, the test is invalid and should be repeated.

QUALITY CONTROL

The Uni-Gold™ HIV test has a built in control that demonstrates assay validity. A pink/red line appearing adjacent to the letter "C" (control) indicates that the test is running correctly.

When using whole blood samples, a red color in the sample port validates the addition of the sample. The pink/red control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the interpretation section).

Good Laboratory Practice necessitates the use of control specimens to ensure proper device performance at least once daily and changing of kit lots.

NOTE: Commercial HIV controls may not perform properly with the Trinity Biotech Uni-Gold™ HIV kit. For further information please contact Trinity Biotech.

LIMITATIONS

1. Uni-Gold™ HIV test procedure and interpretation of results must be followed when testing for the presence of HIV antibodies in serum, plasma or whole blood.
2. Uni-Gold™ HIV has not been validated for use with other body fluids. Testing with Uni-Gold™ HIV must not be performed with such fluids as results derived may not be accurate.
3. Uni-Gold™ HIV test is intended for the testing of undiluted samples only. Do not dilute samples before testing.
4. 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.
5. Immunosuppressed or immunocompromised individuals infected with HIV-1 or HIV-2 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results and would not be a reliable test method for such patients.
6. Infants may receive antibodies from an infected mother or they may not produce antibodies in response to an infection. Therefore, it is necessary to exercise great care in interpreting their results.
7. The intensity of a pink/red line at the "T" (test) region is not an indication of the level of antibody in the specimen.
8. A reactive result by Uni-Gold™ HIV suggests the presence of anti-HIV antibodies in the specimen. Uni-Gold™ HIV is intended as an aid in the diagnosis of infection with HIV. AIDS and AIDS related conditions are clinical symptoms and their diagnosis can only be established clinically.
9. Reading test results earlier than 10 minutes or later than 12 minutes may give incorrect results.
10. A negative result with Uni-Gold™ HIV does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:

- Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels. For negative results, repeat testing after 6 months is recommended to confirm negative status.
- The test procedure has not been correctly followed.
- Antibodies to a variant strain of HIV in the patient that do not react with specific antigens utilized in the assay configuration.
- Improper specimen handling.
- Failure to add sample.
- Failure to allow kits to come to room temperature prior to use may impact results.

PERFORMANCE CHARACTERISTICS

Overall Sensitivity and Specificity
Uni-Gold™ HIV has been evaluated by a number of independent organizations (Table 1).

Clinical study 1 in 2000 was based on data derived from 471 patient samples including 102 HIV positive samples (2 serum and 100 stored plasma samples) and 369 HIV negative serum samples. The serum samples were collected from antenatal clinics. The 100 stored HIV positive plasma samples were collected from confirmed HIV positive women[6].

Clinical study 2 in 2000 used 250 EDTA-treated whole blood specimens of which 80 were HIV-1 positive and 170 were HIV negative.[7].

Clinical study 3 in 2012 included 1079 serum/plasma specimens of European, African, Latin American and Asian origin. This was comprised of 405 HIV-1 positive, 16 HIV-2 positive and 658 HIV negative specimens.

Table 1**:** Sensitivity and Specificity Evaluation

Evaluation Performed by	Sensitivity	Specificity	NPV*	PPV*
Clinical study 1	100%	99.5%	100%	98.1%
Clinical study 2	100%	100%	100%	100%
Clinical study 3	99.8%	99.9%	99.9%	99.8%

* NPV (Negative Predictive Value), PPV (Positive Predictive Value).

HIV-2 Sensitivity
The sensitivity of Uni-Gold™ HIV in detecting known HIV-2 antibody positive samples was assessed using 150 samples positive for HIV-2 antibodies only. All samples were frozen plasma sourced from the Ivory Coast. Uni-Gold™ HIV detected all 150 positive specimens, giving a sensitivity of 100%.

HIV-1 Group M Non-B Subtypes
To ensure optimal device sensitivity, an evaluation was carried out on various HIV-1 Group M Non-B Subtype specimens. A total of 42 samples shown to be HIV-1 Group M Non-B Subtypes were used. All samples were reactive with Uni-Gold™ HIV (Table 2).

Table 2: Uni-Gold™ HIV Group M Non-B Subtype evaluation.

Subtype	Number of samples tested	Uni-Gold™ HIV result	% Reactive
A	6	R	100
C	6	R	100
D	3	R	100
F	5	R	100
G	4	R	100
H	3	R	100
J	2	R	100
K	4	R	100
CRF-01 AE	3	R	100
CRF-01	1	R	100
CRF-01/15	1	R	100
CRF-02 AG	2	R	100
CRF-03-AB	2	R	100

Seroconversion panels:
Eleven (11) HIV-1 seroconversion panels were evaluated in comparison to confirmatory Western and Line blot tests. Each commercial panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of a total of 77 specimens (Table 3). Uni-Gold™ HIV detected HIV-1 antibodies at the same bleed or at an earlier bleed than the Western/Line Blot assays in 11 out of 11 panels.

Table 3: Summary of seroconversion panel results in comparison to Western Blot

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
PRB914	PRB914-01	0	R	R
	PRB914-02	4	R	R
	PRB914-03	7	R	R
	PRB914-04	25	R	R
	PRB914-05	31	R	R
PRB925	PRB925-01	0	NR	NR
	PRB925-02	10	NR	NR
	PRB925-03	18	NR	NR
	PRB925-04	22	NR	NR
	PRB925-05	44	R	IND
	PRB925-06	49	R	R
PRB926	PRB926-01	0	NR	NR

Table 3: Continued

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
	PRB926-02	2	NR	NR
	PRB926-03	7	NR	NR
	PRB926-04	9	NR	NR
	PRB926-05	27	R	R
	PRB926-06	32	R	R
PRB930	PRB930-01	0	NR	NR
	PRB930-02	3	NR	NR
	PRB930-03	7	R	IND
	PRB930-04	10	R	R
PRB955	PRB955-01	0	NR	NR
	PRB955-02	3	NR	NR
	PRB955-03	7	NR	NR
	PRB955-04	12	NR	NR
	PRB955-05	14	R	R
PRB965	PRB965-01	0	NR	NR
	PRB965-02	5	NR	NR
	PRB965-03	7	NR	NR
	PRB965-04	12	R	NR
	PRB965-05	14	R	IND
	PRB965-06	21	R	R
PRB968	PRB968-01	0	NR	NR
	PRB968-02	3	NR	NR
	PRB968-03	8	NR	NR
	PRB968-04	10	NR	NR
	PRB968-05	15	NR	NR
	PRB968-06	17	NR	NR
	PRB968-07	26	NR	NR
	PRB968-08	28	NR	NR
	PRB968-09	33	R	R
	PRB968-10	35	R	R
PRB969	PRB969-01	0	NR	NR
	PRB969-02	29	NR	NR
	PRB969-03	48	NR	NR
	PRB969-04	53	NR	NR
	PRB969-05	55	NR	NR
	PRB969-06	61	NR	NR
	PRB969-07	63	NR	NR
	PRB969-08	70	R	R
	PRB969-09	72	R	R
	PRB969-10	77	R	R
PRB924	PRB924-01	0	NR	NR
	PRB924-02	2	NR	NR
	PRB924-03	8	NR	NR
	PRB924-04	10	NR	NR
	PRB924-05	26	NR	NR
	PRB924-06	33	R	NR
	PRB924-07	35	R	IND
	PRB924-08	40	R	IND
PRB931	PRB931-01	0	NR	NR
	PRB931-02	2	NR	NR
	PRB931-03	7	NR	NR
	PRB931-04	9	NR	NR
	PRB931-05	15	NR	NR
	PRB931-06	28	R	NR
	PRB931-07	33	R	IND
	PRB931-08	35	R	R
	PRB931-09	42	R	R
PRB940	PRB940-01	0	NR	IND
	PRB940-02	7	NR	IND
	PRB940-03	11	R	IND
	PRB940-04	15	R	IND
	PRB940-05	18	R	IND
	PRB940-06	22	R	IND
	PRB940-07	25	R	IND
	PRB940-08	29	R	R

Key: R= Reactive, NR = Not Reactive, IND =Indeterminate

Interference studies
To further evaluate the specificity of Uni-Gold™ HIV, the product was challenged for antibody cross reactivity with samples from individuals with other disease states, non-HIV medical conditions and potentially interfering substances. All 95 specimens were confirmed as HIV negative prior to evaluation. These potentially cross-reacting substances did not affect the specificity of Uni-Gold™ HIV (Table 4).

The sensitivity performance of Uni-Gold™ HIV was further evaluated by testing 95 samples from people with unrelated medical conditions, various disease states and samples containing interfering substances. All samples were spiked with HIV-1 antibody positive plasma. These potentially cross reacting substances did not affect the sensitivity of Uni-Gold™ HIV (Table 4).

Table 4: Results from samples with other disease states and interfering substances

Potential Interference Samples Evaluated	No. samples tested	No. correctly identified- Non-Reactive	No. correctly identified - Reactive	%
CMV IgG	5	5	5	100
Hep A IgG	5	5	5	100
Hep B Antibody	5	5	5	100
Hep C Antibody	5	5	5	100
Hep B Antigen	5	5	5	100
Leishmaniasis	5	5	5	100
P. falciparum (Malaria)	5	5	5	100
Schistosomiasis	5	5	5	100
Anti-malarial therapies	5	5	5	100
Cancer: Kidney	5	5	5	100
Cancer: Solid tumor samples	5	5	5	100
HAMA (Human a-mouse Ab)	5	5	5	100
Haemodialysis	5	5	5	100
Haemolyzed samples	5	5	5	100
Iceteric samples	5	5	5	100
Lipemic samples	5	5	5	100
Multiparous Pregnancy	5	5	5	100
Pregnancy	5	5	5	100
Rheumatoid factor	5	5	5	100
Total	95	95	95	100

REPEATABILITY

Uni-Gold™ HIV was consistent and stable when 1 kit lot was tested over 20 days. Repeatability studies were performed twice daily, over a 20 day period, on one lot of Uni-Gold™ HIV device, one lot of pipettes and one lot of Wash Solution. One operator tested 14 samples, including HIV-1, HIV-2 positive plasma and serum, HIV negative plasma and serum, and whole blood samples. The overall repeatability was 100%.

REPRODUCIBILITY

Uni-Gold™ HIV was consistent and stable when three different kit lots were tested by 3 operators, at 3 separate sites, testing 6 coded and blinded samples, once a day, over 3 days. The overall reproducibility of the Uni-Gold™ HIV was 100%.

TECHNICAL ENQUIRIES

For any enquiries including technical support related to this product, please contact Trinity Biotech through one of the contact addresses below:

- hiv@trinitybiotech.com
- Infectiousdiseasetechnicalsupport@trinitybiotech.com
- info@trinitybiotech.com

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1. Schupbach et al, *Clinical Virology Manual*. 3rd Edition 2000; 37: 513-541.
2. Scaling up services for key populations at higher risk of HIV infection. Global HIV/AIDS Response, Progress Report 2011. Published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p125-137.
3. Risk factors for human immunodeficiency virus infection in intravenous drug users. Schoenbaum EE, Hartel D, Selwyn PA, Klein RS, Davenny K, Rogers M, Feiner C, Friedland G. *New England Journal Medicine* 1989 Sep 28;321(13):874-9.
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5. 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.
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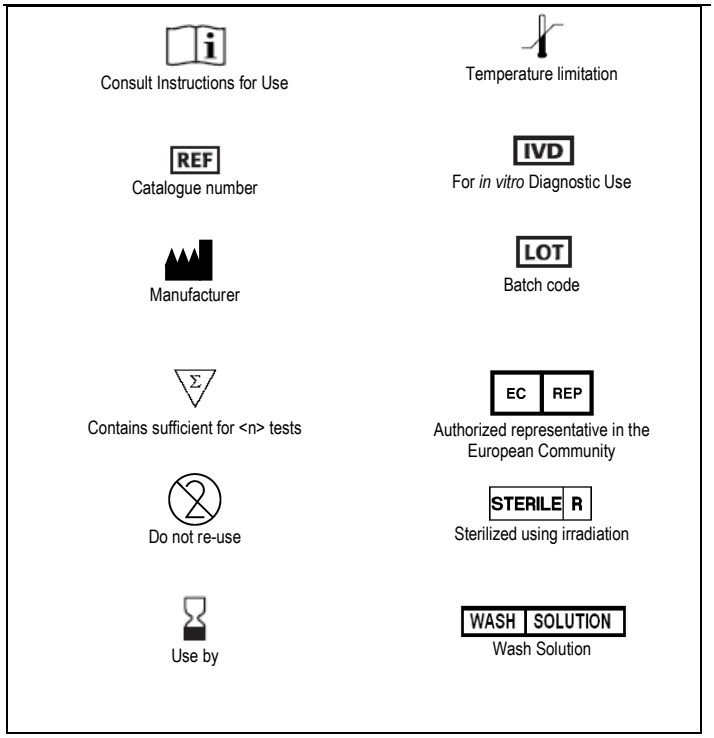
7. WHO Evaluation: Evaluation (Phase 1) of the Uni-Gold™ HIV using Whole Blood Specimens.

GUIDE TO SYMBOLS



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hiv@trinitybiotech.com
www.trinitybiotech.com

Uni-Gold™ HIV Complete

REF 1206502-C

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków
Para outras línguas
Για τις άλλες λώσσες
För andra språk
For andre språk

www.trinitybiotech.com

Read these Instructions for Use completely before using the product. Follow the directions carefully. Not doing so may result in incorrect test results.

NAME AND INTENDED USE

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

SUMMARY AND PRINCIPLES OF THE PROCEDURE

HIV 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 transmitted from HIV positive individuals predominantly through unprotected sexual intercourse[2], intravenous drug abuse[3] or from mother to child transmission[4]. 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].

Uni-Gold™ HIV is a rapid immunoassay based on the immunochromatographic sandwich principle. Recombinant proteins representing the immunodominant regions of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp41, gp120 (HIV-1) and glycoprotein gp36 (HIV-2) respectively, are immobilized at the test region of the nitrocellulose strip. These proteins are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

During testing, two drops of serum, plasma or whole blood is applied to the sample port, followed by two drops of Wash Solution and allowed to react. Antibodies of any immunoglobulin class, specific to the recombinant HIV-1 or HIV-2 proteins will react with the colloidal gold linked antigens. The antibody protein colloidal gold complex moves chromatographically along the membrane to the test and control regions of the test device.

Excess conjugate forms a second pink/red band in the control region of the device. The appearance of this band indicates proper performance of the reagents in the kit.

MATERIALS PROVIDED

Each kit contains:

- Test Devices: 20 test devices individually pouched.
- Wash Solution: 2.0 mL in dropper bottle.
- Disposable Pipettes: 20 Disposable Pipettes for use with serum, plasma or whole blood.
- Lancets: 20 sterile lancets.
- Swabs: 20 alcohol swabs.

COMPONENTS OF REACTIVE INGREDIENTS

Wash Solution: 2.0 mL of Wash Solution contains Tris buffer, Borate buffer, Chaotropic agent, Surfactant, Polyether compound, Sugar, Polymer and the preservative ProClin® 300 at 0.06% v/v.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Blood collection devices, for testing of venipuncture whole blood, serum or plasma.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

Fingerstick Samples:

- Sterile gauze pads.
- Adhesive bandages

WARNINGS

1. Read the Instructions for Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. Uni-Gold™ HIV is for diagnostic use only and is not to be used for screening donors of blood, plasma, cells or tissues.
3. Perform test at room temperature.

PRECAUTIONS

1. Uni-Gold™ HIV test is for professional use only.
2. The Instructions for Use must be followed to ensure optimum test performance.
3. Uni-Gold™ HIV test is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.
5. It is recommended that spare test devices are available at all times.

Safety Precautions

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

Biosafety Precautions

Appropriate biosafety practices should be used 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 in which 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"[5].
3. When disposing of Wash Solution, 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 sodium hypochlorite solution.
5. Use a separate disposable pipette and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix Wash Solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. Use paper covered surface to perform testing, so as to eliminate any risk to product performance due to build-up of static charge.
8. The result should be read immediately after the end of the 10 minute incubation time following the addition of Wash Solution. Do not read results beyond 12 minutes.
9. Lancets should be placed in a puncture resistant container prior to disposal.

STORAGE INSTRUCTIONS

1. Uni-Gold™ HIV device and Wash Solution should be stored between 2-27°C.
2. Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the Wash Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that all components are brought to room temperature before use.
4. Do not freeze the kit.

SPECIMEN COLLECTION AND STORAGE

Whole Blood Venipuncture 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.
- Grossly hemolysed or lipemic samples should not be used.

Whole blood: Fingerstick

Use whole blood samples collected by fingerstick immediately on the Uni-Gold™ HIV device

Collection: Whole Blood 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. This whole blood can be used directly on the device, or stored at 2-8°C for up to 3 days, or preferably, the sample should be centrifuged and the plasma retained for further testing. Do not freeze whole blood.

Collection: Serum and Plasma

If a whole blood sample is collected without anticoagulant and has started to clot, do not remix before testing, in such instances, the clear serum should be pipetted off the clotted specimen and used for analysis.

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. Plasma must be generated within 8 hours of blood draw. Following collection, 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 or stored between 2 to 8°C for up to 5 days to allow testing. Specimens must be stored at -20°C or below if storage is necessary for more than 5 days. Grossly hemolysed or lipemic samples should not be used. Avoid multiple freeze thaw cycles.

TEST PROCEDURE FOR WHOLE BLOOD FINGERSTICK

1. Kits stored at room temperature may be used immediately (Figure 1). Allow kits stored in a refrigerator to reach room temperature. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches (Figure 2). Devices must be used within 20 minutes of opening the foil pouch.

Figure 1. Uni-Gold™ HIV Complete kit and components.

Figure 2. Test device pouch.

2. 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. Using an alcohol swab, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
6. Using the sterile lancet provided, puncture the skin just off the centre of the finger pad (Figure 3). Hold the finger downward.
7. 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 (Figure 4). 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.
8. Never apply blood droplets directly from the fingertip onto the device as their size may vary.
9. To collect the blood into the fingerstick disposable pipette, gently press the pipette bulb, hold the pipette horizontal to the sample (Figure 5).This is important as the specimen may not be adequate if the pipette is held in a vertical position**.** Slowly release pressure on the bulb to draw up the sample.

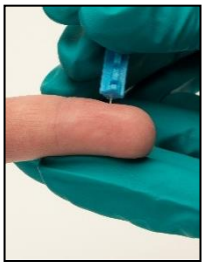


Figure 3. Position lancet.


Figure 4. Blood drop formation.

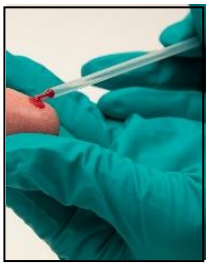


Figure 5. Draw sample into pipette.

10. Hold the pipette vertically above the sample port, squeeze the bulb and discharge two (2) drops of whole blood onto the sample pad (Figure 6). Allow the sample to fully absorb. Ensure there are no air bubbles in the sample port. Failure to hold the pipette in a vertical position may lead to erroneous test results. Do not touch the sample pad with the disposable pipette. Dispose of the pipette into biohazard waste.
11. Hold the Wash Solution dropper bottle vertically over the sample port; add two (2) drops of Wash Solution to the sample port (Figure 7). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

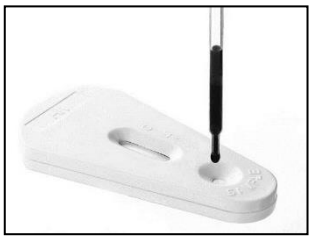


Figure 6. Add blood vertically into device.


Figure 7. Add Wash Solution vertically.

12. Read test results after 10 minutes but no later than 12 minutes incubation time.
13. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

TEST PROCEDURE FOR VENIPUNCTURE WHOLE BLOOD, SERUM AND PLASMA

1. Allow the kit (unopened devices and Wash Solution) to reach room temperature if previously stored in the refrigerator. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches. Devices must be used within 20 minutes of opening the foil pouch.
2. 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. Fill the disposable pipette included in the kit with sample. Ensure there are no air bubbles. Use only the pipette included in the kit and do not reuse.
6. Hold the pipette vertically over the sample port, squeeze the bulb and discharge two (2) drops of plasma/serum/whole blood onto the sample pad (Figure 8). Allow the sample to fully absorb. Ensure air bubbles are not introduced into the sample port. Do not touch the sample pad with the disposable pipette. Failure to hold the pipette in a vertical position may lead to erroneous test results.
7. Dispose of the pipette in biohazard waste.
8. Holding the dropper bottle of Wash Solution in a vertical position and above the sample port, add two (2) drops of Wash Solution to the sample port (Figure 9). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

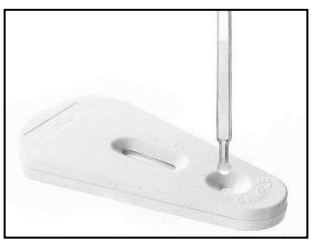


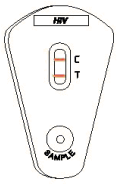
Figure 8. Add sample vertically into device.


Figure 9. Add Wash Solution vertically.

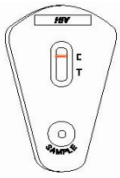
9. Read test results after 10 minutes but no later than 12 minutes incubation time.
10. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

INTERPRETATION FOR WHOLE BLOOD, SERUM AND PLASMA SAMPLES

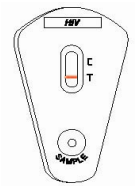
Reactive Test Result
Two pink/red lines of any intensity in the device window, the first adjacent to letter "T" (test) and the second adjacent to "C" (control). This indicates a Reactive result that is interpreted as Preliminary Positive for antibodies to HIV.

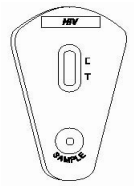


Non-Reactive Test Result
A pink/red line of any intensity adjacent to the letter "C" (control), but no pink/red line adjacent to "T" (test). This indicates a Non-Reactive result that is interpreted as Negative for antibodies to HIV.



Invalid Result
No pink/red line appears in the device window adjacent to the letter "C" (control) irrespective of whether or not a pink/red line appears in the device window adjacent to "T" (test). This is an Invalid result that cannot be interpreted. An invalid result must be repeated.





***Disclaimer**: The diagrams above are for illustration purposes only.*

Further Interpretation

Grey Lines
Where a grey line is seen, it does not indicate the presence of antibodies to HIV. It is always interpreted as non-reactive.

Broken Lines
*Test Line***:** Where a specimen produces a broken pink/red test line with Uni-Gold™ HIV, it is deemed initially reactive (conditional on the presence of a pink/red control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete pink/red line in one or both duplicates, then the sample is interpreted as preliminary positive. If both duplicates give no line at "T" (test) then the result is referred to as negative.
*Control Line***:** A broken pink/red control line does not affect the validity of the test.

Whole Blood Migration
Whole blood sample may migrate into the device window (whole blood visible at the bottom). The test is valid and can be interpreted if there is no obstruction in the test line region at 10 to 12 minutes. If the sample infringes on the test line region, the test is invalid and should be repeated.

QUALITY CONTROL

The Uni-Gold™ HIV test has a built in control that demonstrates assay validity. A pink/red line appearing adjacent to the letter "C" (control) indicates that the test is running correctly.

When using whole blood samples, a red color in the sample port validates the addition of the sample. The pink/red control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the interpretation section).

Good Laboratory Practice necessitates the use of control specimens to ensure proper device performance at least once daily and changing of kit lots.

NOTE: Commercial HIV controls may not perform properly with the Trinity Biotech Uni-Gold™ HIV kit. For further information please contact Trinity Biotech.

LIMITATIONS

1. Uni-Gold™ HIV test procedure and interpretation of results must be followed when testing for the presence of HIV antibodies in serum, plasma or whole blood.
2. Uni-Gold™ HIV has not been validated for use with other body fluids. Testing with Uni-Gold™ HIV must not be performed with such fluids as results derived may not be accurate.
3. Uni-Gold™ HIV test is intended for the testing of undiluted samples only. Do not dilute samples before testing.
4. 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.
5. Immunosuppressed or immunocompromised individuals infected with HIV-1 or HIV-2 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results and would not be a reliable test method for such patients.
6. Infants may receive antibodies from an infected mother or they may not produce antibodies in response to an infection. Therefore, it is necessary to exercise great care in interpreting their results.
7. The intensity of a pink/red line at the "T" (test) region is not an indication of the level of antibody in the specimen.
8. A reactive result by Uni-Gold™ HIV suggests the presence of anti-HIV antibodies in the specimen. Uni-Gold™ HIV is intended as an aid in the diagnosis of infection with HIV. AIDS and AIDS related conditions are clinical symptoms and their diagnosis can only be established clinically.
9. Reading test results earlier than 10 minutes or later than 12 minutes may give incorrect results.
10. A negative result with Uni-Gold™ HIV does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:
    - Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels. For negative results, repeat testing after 6 months is recommended to confirm negative status.

- The test procedure has not been correctly followed.
- Antibodies to a variant strain of HIV in the patient that do not react with specific antigens utilized in the assay configuration.
- Improper specimen handling.
- Failure to add sample.
- Failure to allow kits to come to room temperature prior to use may impact results.

PERFORMANCE CHARACTERISTICS

Overall Sensitivity and Specificity
Uni-Gold™ HIV has been evaluated by a number of independent organizations (Table 1).

Clinical study 1 in 2000 was based on data derived from 471 patient samples including 102 HIV positive samples (2 serum and 100 stored plasma samples) and 369 HIV negative serum samples. The serum samples were collected from antenatal clinics. The 100 stored HIV positive plasma samples were collected from confirmed HIV positive women[6].

Clinical study 2 in 2000 used 250 EDTA-treated whole blood specimens of which 80 were HIV-1 positive and 170 were HIV negative.[7].

Clinical study 3 in 2012 included 1079 serum/plasma specimens of European, African, Latin American and Asian origin. This was comprised of 405 HIV-1 positive, 16 HIV-2 positive and 658 HIV negative specimens.

Table 1**:** Sensitivity and Specificity Evaluation

Evaluation Performed by	Sensitivity	Specificity	NPV*	PPV*
Clinical study 1	100%	99.5%	100%	98.1%
Clinical study 2	100%	100%	100%	100%
Clinical study 3	99.8%	99.9%	99.9%	99.8%

* NPV (Negative Predictive Value), PPV (Positive Predictive Value).

HIV-2 Sensitivity
The sensitivity of Uni-Gold™ HIV in detecting known HIV-2 antibody positive samples was assessed using 150 samples positive for HIV-2 antibodies only. All samples were frozen plasma sourced from the Ivory Coast. Uni-Gold™ HIV detected all 150 positive specimens, giving a sensitivity of 100%.

HIV-1 Group M Non-B Subtypes
To ensure optimal device sensitivity, an evaluation was carried out on various HIV-1 Group M Non-B Subtype specimens. A total of 42 samples shown to be HIV-1 Group M Non-B Subtypes were used. All samples were reactive with Uni-Gold™ HIV (Table 2).

Table 2: Uni-Gold™ HIV Group M Non-B Subtype evaluation.

Subtype	Number of samples tested	Uni-Gold™ HIV result	% Reactive
A	6	R	100
C	6	R	100
D	3	R	100
F	5	R	100
G	4	R	100
H	3	R	100
J	2	R	100
K	4	R	100
CRF-01 AE	3	R	100
CRF-01	1	R	100
CRF-01/15	1	R	100
CRF-02 AG	2	R	100
CRF-03-AB	2	R	100

Seroconversion panels:
Eleven (11) HIV-1 seroconversion panels were evaluated in comparison to confirmatory Western and Line blot tests. Each commercial panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of a total of 77 specimens (Table 3). Uni-Gold™ HIV detected HIV-1 antibodies at the same bleed or at an earlier bleed than the Western/Line Blot assays in 11 out of 11 panels.

Table 3: Summary of seroconversion panel results in comparison to Western Blot

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
PRB914	PRB914-01	0	R	R
	PRB914-02	4	R	R
	PRB914-03	7	R	R
	PRB914-04	25	R	R
	PRB914-05	31	R	R
PRB925	PRB925-01	0	NR	NR
	PRB925-02	10	NR	NR
	PRB925-03	18	NR	NR
	PRB925-04	22	NR	NR
	PRB925-05	44	R	IND
	PRB925-06	49	R	R
PRB926	PRB926-01	0	NR	NR
	PRB926-02	2	NR	NR
	PRB926-03	7	NR	NR
	PRB926-04	9	NR	NR

Table 3: Continued

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
	PRB926-05	27	R	R
	PRB926-06	32	R	R
PRB930	PRB930-01	0	NR	NR
	PRB930-02	3	NR	NR
	PRB930-03	7	R	IND
	PRB930-04	10	R	R
PRB955	PRB955-01	0	NR	NR
	PRB955-02	3	NR	NR
	PRB955-03	7	NR	NR
	PRB955-04	12	NR	NR
	PRB955-05	14	R	R
PRB965	PRB965-01	0	NR	NR
	PRB965-02	5	NR	NR
	PRB965-03	7	NR	NR
	PRB965-04	12	R	NR
	PRB965-05	14	R	IND
	PRB965-06	21	R	R
PRB968	PRB968-01	0	NR	NR
	PRB968-02	3	NR	NR
	PRB968-03	8	NR	NR
	PRB968-04	10	NR	NR
	PRB968-05	15	NR	NR
	PRB968-06	17	NR	NR
	PRB968-07	26	NR	NR
	PRB968-08	28	NR	NR
	PRB968-09	33	R	R
	PRB968-10	35	R	R
PRB969	PRB969-01	0	NR	NR
	PRB969-02	29	NR	NR
	PRB969-03	48	NR	NR
	PRB969-04	53	NR	NR
	PRB969-05	55	NR	NR
	PRB969-06	61	NR	NR
	PRB969-07	63	NR	NR
	PRB969-08	70	R	R
	PRB969-09	72	R	R
	PRB969-10	77	R	R
PRB924	PRB924-01	0	NR	NR
	PRB924-02	2	NR	NR
	PRB924-03	8	NR	NR
	PRB924-04	10	NR	NR
	PRB924-05	26	NR	NR
	PRB924-06	33	R	NR
	PRB924-07	35	R	IND
	PRB924-08	40	R	IND
PRB931	PRB931-01	0	NR	NR
	PRB931-02	2	NR	NR
	PRB931-03	7	NR	NR
	PRB931-04	9	NR	NR
	PRB931-05	15	NR	NR
	PRB931-06	28	R	NR
	PRB931-07	33	R	IND
	PRB931-08	35	R	R
	PRB931-09	42	R	R
PRB940	PRB940-01	0	NR	IND
	PRB940-02	7	NR	IND
	PRB940-03	11	R	IND
	PRB940-04	15	R	IND
	PRB940-05	18	R	IND
	PRB940-06	22	R	IND
	PRB940-07	25	R	IND
	PRB940-08	29	R	R

Key: R= Reactive, NR = Not Reactive, IND =Indeterminate

Interference studies
To further evaluate the specificity of Uni-Gold™ HIV, the product was challenged for antibody cross reactivity with samples from individuals with other disease states, non-HIV medical conditions and potentially interfering substances. All 95 specimens were confirmed as HIV negative prior to evaluation. These potentially cross-reacting substances did not affect the specificity of Uni-Gold™ HIV (Table 4).

The sensitivity performance of Uni-Gold™ HIV was further evaluated by testing 95 samples from people with unrelated medical conditions, various disease states and samples containing interfering substances. All samples were spiked with HIV-1 antibody positive plasma. These potentially cross reacting substances did not affect the sensitivity of Uni-Gold™ HIV (Table 4).

Table 4: Results from samples with other disease states and interfering substances

Potential Interference Samples Evaluated	No. samples tested	No. correctly identified- Non-Reactive	No. correctly identified - Reactive	%
CMV IgG	5	5	5	100
Hep A IgG	5	5	5	100
Hep B Antibody	5	5	5	100
Hep C Antibody	5	5	5	100
Hep B Antigen	5	5	5	100
Leishmaniasis	5	5	5	100
P. falciparum (Malaria)	5	5	5	100
Schistosomiasis	5	5	5	100
Anti-malarial therapies	5	5	5	100
Cancer: Kidney	5	5	5	100
Cancer: Solid tumor samples	5	5	5	100
HAMA (Human a-mouse Ab)	5	5	5	100
Haemodialysis	5	5	5	100
Haemolyzed samples	5	5	5	100
Iceteric samples	5	5	5	100
Lipemic samples	5	5	5	100
Multiparous Pregnancy	5	5	5	100
Pregnancy	5	5	5	100
Rheumatoid factor	5	5	5	100
Total	95	95	95	100

REPEATABILITY

Uni-Gold™ HIV was consistent and stable when 1 kit lot was tested over 20 days. Repeatability studies were performed twice daily, over a 20 day period, on one lot of Uni-Gold™ HIV device, one lot of pipettes and one lot of Wash Solution. One operator tested 14 samples, including HIV-1, HIV-2 positive plasma and serum, HIV negative plasma and serum, and whole blood samples. The overall repeatability was 100%.

REPRODUCIBILITY

Uni-Gold™ HIV was consistent and stable when three different kit lots were tested by 3 operators, at 3 separate sites, testing 6 coded and blinded samples, once a day, over 3 days. The overall reproducibility of the Uni-Gold™ HIV was 100%.

TECHNICAL ENQUIRIES

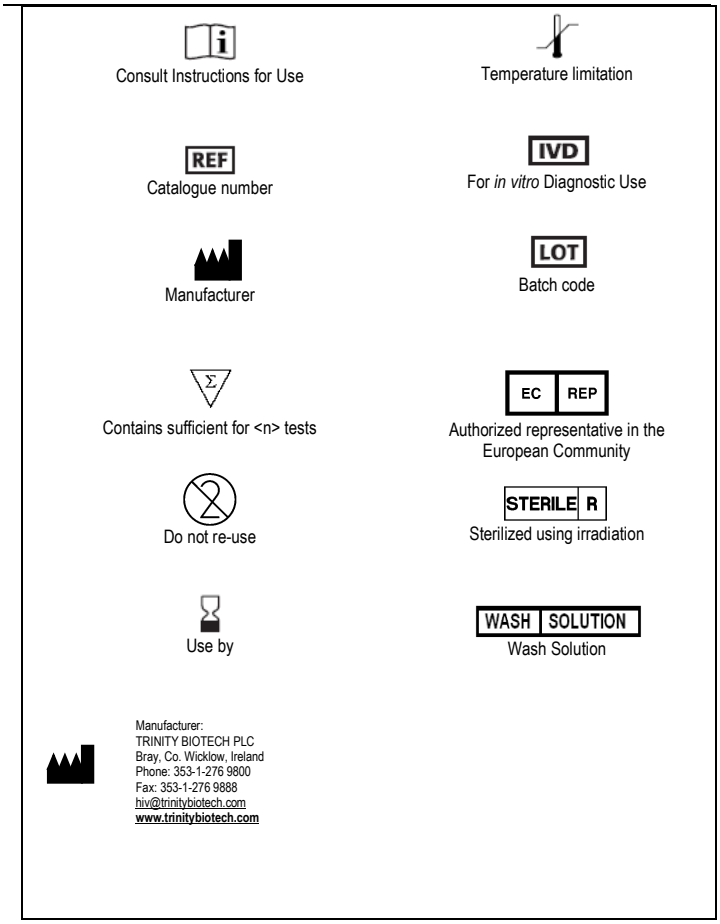
For any enquiries including technical support related to this product, please contact Trinity Biotech through one of the contact addresses below:

- hiv@trinitybiotech.com
- Infectiousdiseasetechnicalsupport@trinitybiotech.com
- info@trinitybiotech.com

REFERENCE

1. Schupbach et al, *Clinical Virology Manual*. 3rd Edition 2000; 37: 513-541.
2. Scaling up services for key populations at higher risk of HIV infection. Global HIV/AIDS Response, Progress Report 2011. Published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p125-137.
3. Risk factors for human immunodeficiency virus infection in intravenous drug users. Schoenbaum EE, Hartel D, Selwyn PA, Klein RS, Davenny K, Rogers M, Feiner C, Friedland G. *New England Journal Medicine* 1989 Sep 28;321(13):874-9.
4. Scaling up HIV services for women and children: towards eliminating mother-to-child transmissions and improving maternal and child health in the context of HIV. Global HIV/AIDS Response, Progress Report 2011, published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p139-164
5. 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.
6. Caribbean Epidemiology Centre CARE/PAHO/WHO Evaluation of Three Rapid HIV Assays.
7. WHO Evaluation: Evaluation (Phase 1) of the Uni-Gold™ HIV using Whole Blood Specimens.

GUIDE TO SYMBOLS



Uni-Gold™ HIV

REF 1206502-100

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków
Para outras línguas
Για τις άλλες λώσσες
För andra språk
For andre språk

www.trinitybiotech.com

Read these Instructions for Use completely before using the product. Follow the directions carefully. Not doing so may result in incorrect test results.

NAME AND INTENDED USE

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

SUMMARY AND PRINCIPLES OF THE PROCEDURE

HIV 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 transmitted from HIV positive individuals predominantly through unprotected sexual intercourse[2], intravenous drug abuse[3] or from mother to child transmission[4]. 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].

Uni-Gold™ HIV is a rapid immunoassay based on the immunochromatographic sandwich principle. Recombinant proteins representing the immunodominant regions of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp41, gp120 (HIV-1) and glycoprotein gp36 (HIV-2) respectively, are immobilized at the test region of the nitrocellulose strip. These proteins are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

During testing, two drops of serum, plasma or whole blood is applied to the sample port, followed by two drops of Wash Solution and allowed to react. Antibodies of any immunoglobulin class, specific to the recombinant HIV-1 or HIV-2 proteins will react with the colloidal gold linked antigens. The antibody protein colloidal gold complex moves chromatographically along the membrane to the test and control regions of the test device.

Excess conjugate forms a second pink/red band in the control region of the device. The appearance of this band indicates proper performance of the reagents in the kit.

MATERIALS PROVIDED

Each kit contains:
1. Test Devices: 100 test devices individually pouched.
2. Wash Solution: 5 x 2.0 mL dropper bottles.
3. Disposable Pipettes: 100 Disposable Pipettes for use with serum, plasma or whole blood.

COMPONENTS OF REACTIVE INGREDIENTS

Wash Solution: 2.0 mL of Wash Solution contains Tris buffer, Borate buffer, Chaotropic agent, Surfactant, Polyether compound, Sugar, Polymer and the preservative ProClin® 300 at 0.06% v/v.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Blood collection devices, for testing of venipuncture whole blood, serum or plasma.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

Fingerstick Samples:
- Lancet: A high blood flow lancet with a depth ranging of between 1.5-2.0 mm is required to produce a 60 µL whole blood droplet
- Sterile wipes and sterile gauze pads.
- Adhesive bandages.

WARNINGS

1. Read the Instructions for Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. Uni-Gold™ HIV is for diagnostic use only and is not to be used for screening donors of blood, plasma, cells or tissues.
3. Perform test at room temperature.

PRECAUTIONS

1. Uni-Gold™ HIV test is for professional use only.
2. The Instructions for Use must be followed to ensure optimum test performance.
3. Uni-Gold™ HIV test is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.
5. It is recommended that spare test devices are available at all times.

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

Biosafety Precautions
Appropriate biosafety practices should be used 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 in which 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"[5].
3. When disposing of Wash Solution, 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 sodium hypochlorite solution.
5. Use a separate disposable pipette and device for each specimen tested.

Handling Precautions
1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix Wash Solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. Use paper covered surface to perform testing, so as to eliminate any risk to product performance due to build-up of static charge.
8. The result should be read immediately after the end of the 10 minute incubation time following the addition of Wash Solution. Do not read results beyond 12 minutes.
9. Lancets should be placed in a puncture resistant container prior to disposal.

STORAGE INSTRUCTIONS

1. Uni-Gold™ HIV device and Wash Solution should be stored between 2-27°C.
2. Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the Wash Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that all components are brought to room temperature before use.
4. Do not freeze the kit.

SPECIMEN COLLECTION AND STORAGE

Whole Blood Venipuncture 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.
- Grossly hemolysed or lipemic samples should not be used.

Whole blood: Fingerstick
Use whole blood samples collected by fingerstick immediately on the Uni-Gold™ HIV device

Collection: Whole Blood 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**.** This whole blood can be used directly on the device, or stored at 2-8°C for up to 3 days, or preferably, the sample should be centrifuged and the plasma retained for further testing. Do not freeze whole blood.

Collection: Serum and Plasma
If a whole blood sample is collected without anticoagulant and has started to clot, do not remix before testing, in such instances, the clear serum should be pipetted off the clotted specimen and used for analysis.

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. Plasma must be generated within 8 hours of blood draw. Following collection, 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 or stored between 2 to 8°C for up to 5 days to allow testing. Specimens must be stored at -20°C or below if storage is necessary for more than 5 days. Grossly hemolysed or lipemic samples should not be used. Avoid multiple freeze thaw cycles.

TEST PROCEDURE FOR WHOLE BLOOD FINGERSTICK

1. Kits stored at room temperature may be used immediately (Figure 1). Allow kits stored in a refrigerator to reach room temperature. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches (Figure 2). Devices must be used within 20 minutes of opening the foil pouch.

Figure 1. Uni-Gold™ HIV kit and components.

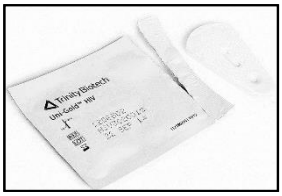


Figure 2. Test device pouch.

2. 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. Using a sterile wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
6. Using a sterile lancet capable of producing a 60µl blood let, puncture the skin just off the centre of the finger pad (Figure 3). Hold the finger downward.
7. 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 (Figure 4). 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.
8. Never apply blood droplets directly from the fingertip onto the device as their size may vary.
9. To collect the blood into the fingerstick disposable pipette, gently press the pipette bulb, hold the pipette horizontal to the sample (Figure 5). This is important, as the specimen may not be adequate if the pipette is held in a vertical position. Slowly release pressure on the bulb to draw up the sample.


Figure 3. Position lancet.


Figure 4. Blood drop formation.

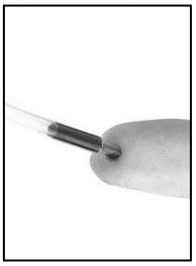


Figure 5. Draw sample into pipette.

10. Hold the pipette vertically above the sample port, squeeze the bulb and discharge two (2) drops of whole blood onto the sample pad (Figure 6). Allow the sample to fully absorb. Ensure there are no air bubbles in the sample port. Failure to hold the pipette in a vertical position may lead to erroneous test results. Do not touch the sample pad with the disposable pipette. Dispose of the pipette into biohazard waste.
11. Hold the Wash Solution dropper bottle vertically over the sample port; add two (2) drops of Wash Solution to the sample port (Figure 7). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

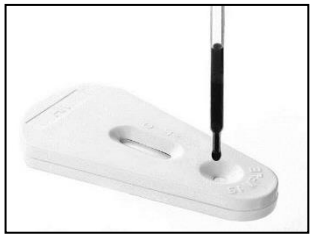


Figure 6. Add blood vertically into device.


Figure 7. Add Wash Solution vertically.

12. Read test results after 10 minutes but no later than 12 minutes incubation time.
13. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

TEST PROCEDURE FOR VENIPUNCTURE WHOLE BLOOD, SERUM AND PLASMA

1. Allow the kit (unopened devices and Wash Solution) to reach room temperature if previously stored in the refrigerator. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches. Devices must be used within 20 minutes of opening the foil pouch.
2. 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. Fill the disposable pipette included in the kit with sample. Ensure there are no air bubbles. Use only the pipette included in the kit and do not reuse.
6. Hold the pipette vertically over the sample port, squeeze the bulb and discharge two (2) drops of plasma/serum/whole blood onto the sample pad (Figure 8). Allow the sample to fully absorb. Ensure air bubbles are not introduced into the sample port. Do not touch the sample pad with the disposable pipette. Failure to hold the pipette in a vertical position may lead to erroneous test results.
7. Dispose of the pipette in biohazard waste.
8. Holding the dropper bottle of Wash Solution in a vertical position and above the sample port, add two (2) drops of Wash Solution to the sample port (Figure 9). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

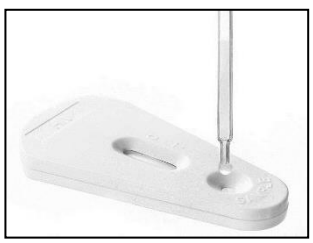


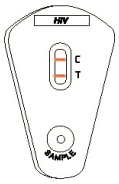
Figure 8. Add sample vertically into device.


Figure 9. Add Wash Solution vertically.

9. Read test results after 10 minutes but no later than 12 minutes incubation time.
10. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

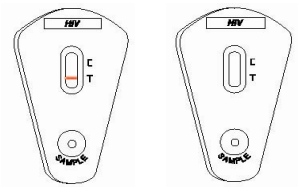
INTERPRETATION FOR WHOLE BLOOD, SERUM AND PLASMA SAMPLES

Reactive Test Result
Two pink/red lines of any intensity in the device window, the first adjacent to letter "T" (test) and the second adjacent to "C" (control). This indicates a Reactive result that is interpreted as Preliminary Positive for antibodies to HIV.



Non-Reactive Test Result
A pink/red line of any intensity adjacent to the letter "C" (control), but no pink/red line adjacent to "T" (test). This indicates a Non-Reactive result that is interpreted as Negative for antibodies to HIV.

Invalid Result
No pink/red line appears in the device window adjacent to the letter "C" (control) irrespective of whether or not a pink/red line appears in the device window adjacent to "T" (test). This is an Invalid result that cannot be interpreted. An invalid result must be repeated.



***Disclaimer**: The diagrams above are for illustration purposes only.*

Further Interpretation

Grey Lines
Where a grey line is seen, it does not indicate the presence of antibodies to HIV. It is always interpreted as non-reactive.

Broken Lines
Test Line: Where a specimen produces a broken pink/red test line with Uni-Gold™ HIV, it is deemed initially reactive (conditional on the presence of a pink/red control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete pink/red line in one or both duplicates, then the sample is interpreted as preliminary positive. If both duplicates give no line at "T" (test) then the result is referred to as negative.
Control Line: A broken pink/red control line does not affect the validity of the test.

Whole Blood Migration
Whole blood sample may migrate into the device window (whole blood visible at the bottom). The test is valid and can be interpreted if there is no obstruction in the test line region at 10 to 12 minutes. If the sample infringes on the test line region, the test is invalid and should be repeated.

QUALITY CONTROL

The Uni-Gold™ HIV test has a built in control that demonstrates assay validity. A pink/red line appearing adjacent to the letter "C" (control) indicates that the test is running correctly.

When using whole blood samples, a red color in the sample port validates the addition of the sample. The pink/red control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the interpretation section).

Good Laboratory Practice necessitates the use of control specimens to ensure proper device performance at least once daily and changing of kit lots.

NOTE: Commercial HIV controls may not perform properly with the Trinity Biotech Uni-Gold™ HIV kit. For further information please contact Trinity Biotech.

LIMITATIONS

1. Uni-Gold™ HIV test procedure and interpretation of results must be followed when testing for the presence of HIV antibodies in serum, plasma or whole blood.
2. Uni-Gold™ HIV has not been validated for use with other body fluids. Testing with Uni-Gold™ HIV must not be performed with such fluids as results derived may not be accurate.
3. Uni-Gold™ HIV test is intended for the testing of undiluted samples only. Do not dilute samples before testing.
4. 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.
5. Immunosuppressed or immunocompromised individuals infected with HIV-1 or HIV-2 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results and would not be a reliable test method for such patients.
6. Infants may receive antibodies from an infected mother or they may not produce antibodies in response to an infection. Therefore, it is necessary to exercise great care in interpreting their results.
7. The intensity of a pink/red line at the "T" (test) region is not an indication of the level of antibody in the specimen.
8. A reactive result by Uni-Gold™ HIV suggests the presence of anti-HIV antibodies in the specimen. Uni-Gold™ HIV is intended as an aid in the diagnosis of infection with HIV. AIDS and AIDS related conditions are clinical symptoms and their diagnosis can only be established clinically.
9. Reading test results earlier than 10 minutes or later than 12 minutes may give incorrect results.
10. A negative result with Uni-Gold™ HIV does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:

- Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels. For negative results, repeat testing after 6 months is recommended to confirm negative status.
- The test procedure has not been correctly followed.
- Antibodies to a variant strain of HIV in the patient that do not react with specific antigens utilized in the assay configuration.
- Improper specimen handling.
- Failure to add sample.
- Failure to allow kits to come to room temperature prior to use may impact results.

PERFORMANCE CHARACTERISTICS

Overall Sensitivity and Specificity
Uni-Gold™ HIV has been evaluated by a number of independent organizations (Table 1).

Clinical study 1 in 2000 was based on data derived from 471 patient samples including 102 HIV positive samples (2 serum and 100 stored plasma samples) and 369 HIV negative serum samples. The serum samples were collected from antenatal clinics. The 100 stored HIV positive plasma samples were collected from confirmed HIV positive women[6].

Clinical study 2 in 2000 used 250 EDTA-treated whole blood specimens of which 80 were HIV-1 positive and 170 were HIV negative.[7].

Clinical study 3 in 2012 included 1079 serum/plasma specimens of European, African, Latin American and Asian origin. This was comprised of 405 HIV-1 positive, 16 HIV-2 positive and 658 HIV negative specimens.

Table 1: Sensitivity and Specificity Evaluation

Evaluation Performed by	Sensitivity	Specificity	NPV*	PPV*
Clinical study 1	100%	99.5%	100%	98.1%
Clinical study 2	100%	100%	100%	100%
Clinical study 3	99.8%	99.9%	99.9%	99.8%

* NPV (Negative Predictive Value), PPV (Positive Predictive Value).

HIV-2 Sensitivity
The sensitivity of Uni-Gold™ HIV in detecting known HIV-2 antibody positive samples was assessed using 150 samples positive for HIV-2 antibodies only. All samples were frozen plasma sourced from the Ivory Coast. Uni-Gold™ HIV detected all 150 positive specimens, giving a sensitivity of 100%.

HIV-1 Group M Non-B Subtypes
To ensure optimal device sensitivity, an evaluation was carried out on various HIV-1 Group M Non-B Subtype specimens. A total of 42 samples shown to be HIV-1 Group M Non-B Subtypes were used. All samples were reactive with Uni-Gold™ HIV (Table 2).

Table 2: Uni-Gold™ HIV Group M Non-B Subtype evaluation.

Subtype	Number of samples tested	Uni-Gold™ HIV result	% Reactive
A	6	R	100
C	6	R	100
D	3	R	100
F	5	R	100
G	4	R	100
H	3	R	100
J	2	R	100
K	4	R	100
CRF-01 AE	3	R	100
CRF-01	1	R	100
CRF-01/15	1	R	100
CRF-02 AG	2	R	100
CRF-03-AB	2	R	100

Seroconversion panels:
Eleven (11) HIV-1 seroconversion panels were evaluated in comparison to confirmatory Western and Line blot tests. Each commercial panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of a total of 77 specimens (Table 3). Uni-Gold™ HIV detected HIV-1 antibodies at the same bleed or at an earlier bleed than the Western/Line Blot assays in 11 out of 11 panels.

Table 3: Summary of seroconversion panel results in comparison to Western Blot

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
PRB914	PRB914-01	0	R	R
	PRB914-02	4	R	R
	PRB914-03	7	R	R
	PRB914-04	25	R	R
	PRB914-05	31	R	R
PRB925	PRB925-01	0	NR	NR
	PRB925-02	10	NR	NR
	PRB925-03	18	NR	NR
	PRB925-04	22	NR	NR
	PRB925-05	44	R	IND
	PRB925-06	49	R	R
PRB926	PRB926-01	0	NR	NR

Table 3: Continued

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
	PRB926-02	2	NR	NR
	PRB926-03	7	NR	NR
	PRB926-04	9	NR	NR
	PRB926-05	27	R	R
	PRB926-06	32	R	R
PRB930	PRB930-01	0	NR	NR
	PRB930-02	3	NR	NR
	PRB930-03	7	R	IND
	PRB930-04	10	R	R
PRB955	PRB955-01	0	NR	NR
	PRB955-02	3	NR	NR
	PRB955-03	7	NR	NR
	PRB955-04	12	NR	NR
	PRB955-05	14	R	R
PRB965	PRB965-01	0	NR	NR
	PRB965-02	5	NR	NR
	PRB965-03	7	NR	NR
	PRB965-04	12	R	NR
	PRB965-05	14	R	IND
	PRB965-06	21	R	R
PRB968	PRB968-01	0	NR	NR
	PRB968-02	3	NR	NR
	PRB968-03	8	NR	NR
	PRB968-04	10	NR	NR
	PRB968-05	15	NR	NR
	PRB968-06	17	NR	NR
	PRB968-07	26	NR	NR
	PRB968-08	28	NR	NR
	PRB968-09	33	R	R
	PRB968-10	35	R	R
PRB969	PRB969-01	0	NR	NR
	PRB969-02	29	NR	NR
	PRB969-03	48	NR	NR
	PRB969-04	53	NR	NR
	PRB969-05	55	NR	NR
	PRB969-06	61	NR	NR
	PRB969-07	63	NR	NR
	PRB969-08	70	R	R
	PRB969-09	72	R	R
	PRB969-10	77	R	R
PRB924	PRB924-01	0	NR	NR
	PRB924-02	2	NR	NR
	PRB924-03	8	NR	NR
	PRB924-04	10	NR	NR
	PRB924-05	26	NR	NR
	PRB924-06	33	R	NR
	PRB924-07	35	R	IND
	PRB924-08	40	R	IND
PRB931	PRB931-01	0	NR	NR
	PRB931-02	2	NR	NR
	PRB931-03	7	NR	NR
	PRB931-04	9	NR	NR
	PRB931-05	15	NR	NR
	PRB931-06	28	R	NR
	PRB931-07	33	R	IND
	PRB931-08	35	R	R
	PRB931-09	42	R	R
PRB940	PRB940-01	0	NR	IND
	PRB940-02	7	NR	IND
	PRB940-03	11	R	IND
	PRB940-04	15	R	IND
	PRB940-05	18	R	IND
	PRB940-06	22	R	IND
	PRB940-07	25	R	IND
	PRB940-08	29	R	R

Key: R= Reactive, NR = Not Reactive, IND =Indeterminate

Interference studies
To further evaluate the specificity of Uni-Gold™ HIV, the product was challenged for antibody cross reactivity with samples from individuals with other disease states, non-HIV medical conditions and potentially interfering substances. All 95 specimens were confirmed as HIV negative prior to evaluation. These potentially cross-reacting substances did not affect the specificity of Uni-Gold™ HIV (Table 4).

The sensitivity performance of Uni-Gold™ HIV was further evaluated by testing 95 samples from people with unrelated medical conditions, various disease states and samples containing interfering substances. All samples were spiked with HIV-1 antibody positive plasma. These potentially cross reacting substances did not affect the sensitivity of Uni-Gold™ HIV (Table 4).

Table 4: Results from samples with other disease states and interfering substances

Potential Interference Samples Evaluated	No. samples tested	No. correctly identified- Non-Reactive	No. correctly identified - Reactive	%
CMV IgG	5	5	5	100
Hep A IgG	5	5	5	100
Hep B Antibody	5	5	5	100
Hep C Antibody	5	5	5	100
Hep B Antigen	5	5	5	100
Leishmaniasis	5	5	5	100
P. falciparum (Malaria)	5	5	5	100
Schistosomiasis	5	5	5	100
Anti-malarial therapies	5	5	5	100
Cancer: Kidney	5	5	5	100
Cancer: Solid tumor samples	5	5	5	100
HAMA (Human a-mouse Ab)	5	5	5	100
Haemodialysis	5	5	5	100
Haemolyzed samples	5	5	5	100
Iceteric samples	5	5	5	100
Lipemic samples	5	5	5	100
Multiparous Pregnancy	5	5	5	100
Pregnancy	5	5	5	100
Rheumatoid factor	5	5	5	100
Total	95	95	95	100

REPEATABILITY

Uni-Gold™ HIV was consistent and stable when 1 kit lot was tested over 20 days. Repeatability studies were performed twice daily, over a 20 day period, on one lot of Uni-Gold™ HIV device, one lot of pipettes and one lot of Wash Solution. One operator tested 14 samples, including HIV-1, HIV-2 positive plasma and serum, HIV negative plasma and serum, and whole blood samples. The overall repeatability was 100%.

REPRODUCIBILITY

Uni-Gold™ HIV was consistent and stable when three different kit lots were tested by 3 operators, at 3 separate sites, testing 6 coded and blinded samples, once a day, over 3 days. The overall reproducibility of the Uni-Gold™ HIV was 100%.

TECHNICAL ENQUIRIES

For any enquiries including technical support related to this product, please contact Trinity Biotech through one of the contact addresses below:

- hiv@trinitybiotech.com
- Infectiousdiseasetechnicalsupport@trinitybiotech.com
- info@trinitybiotech.com

REFERENCE

1. Schupbach et al, *Clinical Virology Manual*. 3rd Edition 2000; 37: 513-541.
2. Scaling up services for key populations at higher risk of HIV infection. Global HIV/AIDS Response, Progress Report 2011. Published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p125-137.
3. Risk factors for human immunodeficiency virus infection in intravenous drug users. Schoenbaum EE, Hartel D, Selwyn PA, Klein RS, Davenny K, Rogers M, Feiner C, Friedland G. *New England Journal Medicine* 1989 Sep 28;321(13):874-9.
4. Scaling up HIV services for women and children: towards eliminating mother-to-child transmissions and improving maternal and child health in the context of HIV. Global HIV/AIDS Response, Progress Report 2011, published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p139-164
5. 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.
6. Caribbean Epidemiology Centre CARE/PAHO/WHO Evaluation of Three Rapid HIV Assays.
7. WHO Evaluation: Evaluation (Phase 1) of the Uni-Gold™ HIV using Whole Blood Specimens.

GUIDE TO SYMBOLS


Consult Instructions for Use


Temperature limitation

Catalogue number

For *in vitro* Diagnostic Use


Manufacturer

Batch code


Use by

Wash Solution

Manufacturer:
TRINITY BIOTECH PLC
Bray, Co. Wicklow, Ireland
Phone: 353-1-276 9800
Fax: 353-1-276 9888
hiv@trinitybiotech.com
www.trinitybiotech.com

Uni-Gold™ HIV

REF 1206502N-100

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków

Para outras línguas
Για τις άλλες λώσσες
För andra språk
For andre språk

www.trinitybiotech.com

Read these Instructions for Use completely before using the product. Follow the directions carefully. Not doing so may result in incorrect test results.

NAME AND INTENDED USE

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

SUMMARY AND PRINCIPLES OF THE PROCEDURE

HIV 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 transmitted from HIV positive individuals predominantly through unprotected sexual intercourse[2], intravenous drug abuse[3] or from mother to child transmission[4]. 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].

Uni-Gold™ HIV is a rapid immunoassay based on the immunochromatographic sandwich principle. Recombinant proteins representing the immunodominant regions of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp41, gp120 (HIV-1) and glycoprotein gp36 (HIV-2) respectively, are immobilized at the test region of the nitrocellulose strip. These proteins are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

During testing, two drops of serum, plasma or whole blood is applied to the sample port, followed by two drops of Wash Solution and allowed to react. Antibodies of any immunoglobulin class, specific to the recombinant HIV-1 or HIV-2 proteins will react with the colloidal gold linked antigens. The antibody protein colloidal gold complex moves chromatographically along the membrane to the test and control regions of the test device.

Excess conjugate forms a second pink/red band in the control region of the device. The appearance of this band indicates proper performance of the reagents in the kit.

MATERIALS PROVIDED

Each kit contains:
1. Test Devices: 100 test devices individually pouched.
2. Wash Solution: 5 x 2.0 mL dropper bottles.
3. Disposable Pipettes: 100 Disposable Pipettes for use with serum, plasma or whole blood.

COMPONENTS OF REACTIVE INGREDIENTS

Wash Solution: 2.0 mL of Wash Solution contains Tris buffer, Borate buffer, Chaotropic agent, Surfactant, Polyether compound, Sugar, Polymer and the preservative ProClin® 300 at 0.06% v/v.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Blood collection devices, for testing of venipuncture whole blood, serum or plasma.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

Fingerstick Samples:
- Lancet: A high blood flow lancet with a depth ranging of between 1.5-2.0 mm is required to produce a 60 µL whole blood droplet
- Sterile wipes and sterile gauze pads.
- Adhesive bandages.

WARNINGS

1. Read the Instructions for Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. Uni-Gold™ HIV is for diagnostic use only and is not to be used for screening donors of blood, plasma, cells or tissues.
3. Perform test at room temperature.

PRECAUTIONS

1. Uni-Gold™ HIV test is for professional use only.
2. The Instructions for Use must be followed to ensure optimum test performance.
3. Uni-Gold™ HIV test is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.
5. It is recommended that spare test devices are available at all times.

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

Biosafety Precautions
Appropriate biosafety practices should be used 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 in which 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"[5].
3. When disposing of Wash Solution, 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 sodium hypochlorite solution.
5. Use a separate disposable pipette and device for each specimen tested.

Handling Precautions
1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix Wash Solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. Use paper covered surface to perform testing, so as to eliminate any risk to product performance due to build-up of static charge.
8. The result should be read immediately after the end of the 10 minute incubation time following the addition of Wash Solution. Do not read results beyond 12 minutes.
9. Lancets should be placed in a puncture resistant container prior to disposal.

STORAGE INSTRUCTIONS

1. Uni-Gold™ HIV device and Wash Solution should be stored between 2-27°C.
2. Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the Wash Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that all components are brought to room temperature before use.
4. Do not freeze the kit.

SPECIMEN COLLECTION AND STORAGE

Whole Blood Venipuncture 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.
- Grossly hemolysed or lipemic samples should not be used.

Whole blood: Fingerstick
Use whole blood samples collected by fingerstick immediately on the Uni-Gold™ HIV device

Collection: Whole Blood 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**.** This whole blood can be used directly on the device, or stored at 2-8°C for up to 3 days, or preferably, the sample should be centrifuged and the plasma retained for further testing. Do not freeze whole blood.

Collection: Serum and Plasma
If a whole blood sample is collected without anticoagulant and has started to clot, do not remix before testing, in such instances, the clear serum should be pipetted off the clotted specimen and used for analysis.

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. Plasma must be generated within 8 hours of blood draw. Following collection, 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 or stored between 2 to 8°C for up to 5 days to allow testing. Specimens must be stored at -20°C or below if storage is necessary for more than 5 days. Grossly hemolysed or lipemic samples should not be used. Avoid multiple freeze thaw cycles.

TEST PROCEDURE FOR WHOLE BLOOD FINGERSTICK

1. Kits stored at room temperature may be used immediately (Figure 1). Allow kits stored in a refrigerator to reach room temperature. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches (Figure 2). Devices must be used within 20 minutes of opening the foil pouch.

Figure 1. Uni-Gold™ HIV kit and components.

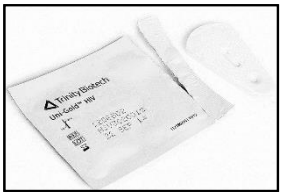


Figure 2. Test device pouch.

2. 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. Using a sterile wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
6. Using a sterile lancet capable of producing a 60µl blood let, puncture the skin just off the centre of the finger pad (Figure 3). Hold the finger downward.
7. 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 (Figure 4). 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.
8. Never apply blood droplets directly from the fingertip onto the device as their size may vary.
9. To collect the blood into the fingerstick disposable pipette, gently press the pipette bulb, hold the pipette horizontal to the sample (Figure 5). This is important, as the specimen may not be adequate if the pipette is held in a vertical position. Slowly release pressure on the bulb to draw up the sample.


Figure 3. Position lancet.


Figure 4. Blood drop formation.

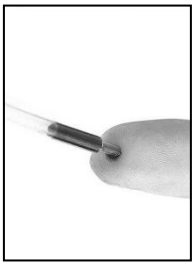


Figure 5. Draw sample into pipette.

10. Hold the pipette vertically above the sample port, squeeze the bulb and discharge two (2) drops of whole blood onto the sample pad (Figure 6). Allow the sample to fully absorb. Ensure there are no air bubbles in the sample port. Failure to hold the pipette in a vertical position may lead to erroneous test results. Do not touch the sample pad with the disposable pipette. Dispose of the pipette into biohazard waste.
11. Hold the Wash Solution dropper bottle vertically over the sample port; add two (2) drops of Wash Solution to the sample port (Figure 7). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

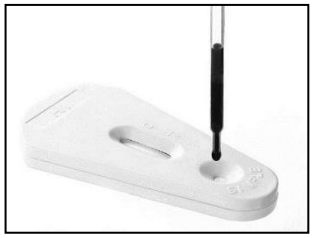


Figure 6. Add blood vertically into device.


Figure 7. Add Wash Solution vertically.

12. Read test results after 10 minutes but no later than 12 minutes incubation time.
13. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

TEST PROCEDURE FOR VENIPUNCTURE WHOLE BLOOD, SERUM AND PLASMA

1. Allow the kit (unopened devices and Wash Solution) to reach room temperature if previously stored in the refrigerator. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches. Devices must be used within 20 minutes of opening the foil pouch.
2. 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. Fill the disposable pipette included in the kit with sample. Ensure there are no air bubbles. Use only the pipette included in the kit and do not reuse.
6. Hold the pipette vertically over the sample port, squeeze the bulb and discharge two (2) drops of plasma/serum/whole blood onto the sample pad (Figure 8). Allow the sample to fully absorb. Ensure air bubbles are not introduced into the sample port. Do not touch the sample pad with the disposable pipette. Failure to hold the pipette in a vertical position may lead to erroneous test results.
7. Dispose of the pipette in biohazard waste.
8. Holding the dropper bottle of Wash Solution in a vertical position and above the sample port, add two (2) drops of Wash Solution to the sample port (Figure 9). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

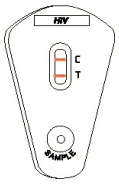

Figure 8. Add sample vertically into device.


Figure 9. Add Wash Solution vertically.

9. Read test results after 10 minutes but no later than 12 minutes incubation time.
10. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

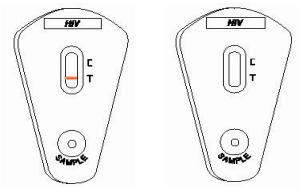
INTERPRETATION FOR WHOLE BLOOD, SERUM AND PLASMA SAMPLES

Reactive Test Result
Two pink/red lines of any intensity in the device window, the first adjacent to letter "T" (test) and the second adjacent to "C" (control). This indicates a Reactive result that is interpreted as Preliminary Positive for antibodies to HIV.



Non-Reactive Test Result
A pink/red line of any intensity adjacent to the letter "C" (control), but no pink/red line adjacent to "T" (test). This indicates a Non-Reactive result that is interpreted as Negative for antibodies to HIV.

Invalid Result
No pink/red line appears in the device window adjacent to the letter "C" (control) irrespective of whether or not a pink/red line appears in the device window adjacent to "T" (test). This is an Invalid result that cannot be interpreted. An invalid result must be repeated.



***Disclaimer**: The diagrams above are for illustration purposes only.*

Further Interpretation

Grey Lines

Where a grey line is seen, it does not indicate the presence of antibodies to HIV. It is always interpreted as non-reactive.

Broken Lines

Test Line: Where a specimen produces a broken pink/red test line with Uni-Gold™ HIV, it is deemed initially reactive (conditional on the presence of a pink/red control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete pink/red line in one or both duplicates, then the sample is interpreted as preliminary positive. If both duplicates give no line at "T" (test) then the result is referred to as negative.

Control Line: A broken pink/red control line does not affect the validity of the test.

Whole Blood Migration

Whole blood sample may migrate into the device window (whole blood visible at the bottom). The test is valid and can be interpreted if there is no obstruction in the test line region at 10 to 12 minutes. If the sample infringes on the test line region, the test is invalid and should be repeated.

QUALITY CONTROL

The Uni-Gold™ HIV test has a built in control that demonstrates assay validity. A pink/red line appearing adjacent to the letter "C" (control) indicates that the test is running correctly.

When using whole blood samples, a red color in the sample port validates the addition of the sample. The pink/red control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the interpretation section).

Good Laboratory Practice necessitates the use of control specimens to ensure proper device performance at least once daily and changing of kit lots.

NOTE: Commercial HIV controls may not perform properly with the Trinity Biotech Uni-Gold™ HIV kit. For further information please contact Trinity Biotech.

LIMITATIONS

1. Uni-Gold™ HIV test procedure and interpretation of results must be followed when testing for the presence of HIV antibodies in serum, plasma or whole blood.
2. Uni-Gold™ HIV has not been validated for use with other body fluids. Testing with Uni-Gold™ HIV must not be performed with such fluids as results derived may not be accurate.
3. Uni-Gold™ HIV test is intended for the testing of undiluted samples only. Do not dilute samples before testing.
4. 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.
5. Immunosuppressed or immunocompromised individuals infected with HIV-1 or HIV-2 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results and would not be a reliable test method for such patients.
6. Infants may receive antibodies from an infected mother or they may not produce antibodies in response to an infection. Therefore, it is necessary to exercise great care in interpreting their results.
7. The intensity of a pink/red line at the "T" (test) region is not an indication of the level of antibody in the specimen.
8. A reactive result by Uni-Gold™ HIV suggests the presence of anti-HIV antibodies in the specimen. Uni-Gold™ HIV is intended as an aid in the diagnosis of infection with HIV. AIDS and AIDS related conditions are clinical symptoms and their diagnosis can only be established clinically.
9. Reading test results earlier than 10 minutes or later than 12 minutes may give incorrect results.
10. A negative result with Uni-Gold™ HIV does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:

- Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels. For negative results, repeat testing after 6 months is recommended to confirm negative status.
- The test procedure has not been correctly followed.
- Antibodies to a variant strain of HIV in the patient that do not react with specific antigens utilized in the assay configuration.
- Improper specimen handling.
- Failure to add sample.
- Failure to allow kits to come to room temperature prior to use may impact results.

PERFORMANCE CHARACTERISTICS

Overall Sensitivity and Specificity
Uni-Gold™ HIV has been evaluated by a number of independent organizations (Table 1).

Clinical study 1 in 2000 was based on data derived from 471 patient samples including 102 HIV positive samples (2 serum and 100 stored plasma samples) and 369 HIV negative serum samples. The serum samples were collected from antenatal clinics. The 100 stored HIV positive plasma samples were collected from confirmed HIV positive women[6].

Clinical study 2 in 2000 used 250 EDTA-treated whole blood specimens of which 80 were HIV-1 positive and 170 were HIV negative.[7].

Clinical study 3 in 2012 included 1079 serum/plasma specimens of European, African, Latin American and Asian origin. This was comprised of 405 HIV-1 positive, 16 HIV-2 positive and 658 HIV negative specimens.

Table 1: Sensitivity and Specificity Evaluation

Evaluation Performed by	Sensitivity	Specificity	NPV*	PPV*
Clinical study 1	100%	99.5%	100%	98.1%
Clinical study 2	100%	100%	100%	100%
Clinical study 3	99.8%	99.9%	99.9%	99.8%

* NPV (Negative Predictive Value), PPV (Positive Predictive Value).

HIV-2 Sensitivity
The sensitivity of Uni-Gold™ HIV in detecting known HIV-2 antibody positive samples was assessed using 150 samples positive for HIV-2 antibodies only. All samples were frozen plasma sourced from the Ivory Coast. Uni-Gold™ HIV detected all 150 positive specimens, giving a sensitivity of 100%.

HIV-1 Group M Non-B Subtypes
To ensure optimal device sensitivity, an evaluation was carried out on various HIV-1 Group M Non-B Subtype specimens. A total of 42 samples shown to be HIV-1 Group M Non-B Subtypes were used. All samples were reactive with Uni-Gold™ HIV (Table 2).

Table 2: Uni-Gold™ HIV Group M Non-B Subtype evaluation.

Subtype	Number of samples tested	Uni-Gold™ HIV result	% Reactive
A	6	R	100
C	6	R	100
D	3	R	100
F	5	R	100
G	4	R	100
H	3	R	100
J	2	R	100
K	4	R	100
CRF-01 AE	3	R	100
CRF-01	1	R	100
CRF-01/15	1	R	100
CRF-02 AG	2	R	100
CRF-03-AB	2	R	100

Seroconversion panels:
Eleven (11) HIV-1 seroconversion panels were evaluated in comparison to confirmatory Western and Line blot tests. Each commercial panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of a total of 77 specimens (Table 3). Uni-Gold™ HIV detected HIV-1 antibodies at the same bleed or at an earlier bleed than the Western/Line Blot assays in 11 out of 11 panels.

Table 3: Summary of seroconversion panel results in comparison to Western Blot

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
PRB914	PRB914-01	0	R	R
	PRB914-02	4	R	R
	PRB914-03	7	R	R
	PRB914-04	25	R	R
	PRB914-05	31	R	R
PRB925	PRB925-01	0	NR	NR
	PRB925-02	10	NR	NR
	PRB925-03	18	NR	NR
	PRB925-04	22	NR	NR
	PRB925-05	44	R	IND
	PRB925-06	49	R	R
PRB926	PRB926-01	0	NR	NR

Table 3: Continued

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
	PRB926-02	2	NR	NR
	PRB926-03	7	NR	NR
	PRB926-04	9	NR	NR
	PRB926-05	27	R	R
	PRB926-06	32	R	R
PRB930	PRB930-01	0	NR	NR
	PRB930-02	3	NR	NR
	PRB930-03	7	R	IND
	PRB930-04	10	R	R
PRB955	PRB955-01	0	NR	NR
	PRB955-02	3	NR	NR
	PRB955-03	7	NR	NR
	PRB955-04	12	NR	NR
	PRB955-05	14	R	R
PRB965	PRB965-01	0	NR	NR
	PRB965-02	5	NR	NR
	PRB965-03	7	NR	NR
	PRB965-04	12	R	NR
	PRB965-05	14	R	IND
	PRB965-06	21	R	R
PRB968	PRB968-01	0	NR	NR
	PRB968-02	3	NR	NR
	PRB968-03	8	NR	NR
	PRB968-04	10	NR	NR
	PRB968-05	15	NR	NR
	PRB968-06	17	NR	NR
	PRB968-07	26	NR	NR
	PRB968-08	28	NR	NR
	PRB968-09	33	R	R
	PRB968-10	35	R	R
PRB969	PRB969-01	0	NR	NR
	PRB969-02	29	NR	NR
	PRB969-03	48	NR	NR
	PRB969-04	53	NR	NR
	PRB969-05	55	NR	NR
	PRB969-06	61	NR	NR
	PRB969-07	63	NR	NR
	PRB969-08	70	R	R
	PRB969-09	72	R	R
	PRB969-10	77	R	R
PRB924	PRB924-01	0	NR	NR
	PRB924-02	2	NR	NR
	PRB924-03	8	NR	NR
	PRB924-04	10	NR	NR
	PRB924-05	26	NR	NR
	PRB924-06	33	R	NR
	PRB924-07	35	R	IND
	PRB924-08	40	R	IND
PRB931	PRB931-01	0	NR	NR
	PRB931-02	2	NR	NR
	PRB931-03	7	NR	NR
	PRB931-04	9	NR	NR
	PRB931-05	15	NR	NR
	PRB931-06	28	R	NR
	PRB931-07	33	R	IND
	PRB931-08	35	R	R
	PRB931-09	42	R	R
PRB940	PRB940-01	0	NR	IND
	PRB940-02	7	NR	IND
	PRB940-03	11	R	IND
	PRB940-04	15	R	IND
	PRB940-05	18	R	IND
	PRB940-06	22	R	IND
	PRB940-07	25	R	IND
	PRB940-08	29	R	R

Key: R= Reactive, NR = Not Reactive, IND =Indeterminate

Interference studies
To further evaluate the specificity of Uni-Gold™ HIV, the product was challenged for antibody cross reactivity with samples from individuals with other disease states, non-HIV medical conditions and potentially interfering substances. All 95 specimens were confirmed as HIV negative prior to evaluation. These potentially cross-reacting substances did not affect the specificity of Uni-Gold™ HIV (Table 4).

The sensitivity performance of Uni-Gold™ HIV was further evaluated by testing 95 samples from people with unrelated medical conditions, various disease states and samples containing interfering substances. All samples were spiked with HIV-1 antibody positive plasma. These potentially cross reacting substances did not affect the sensitivity of Uni-Gold™ HIV (Table 4).

Table 4: Results from samples with other disease states and interfering substances

Potential Interference Samples Evaluated	No. samples tested	No. correctly identified- Non-Reactive	No. correctly identified - Reactive	%
CMV IgG	5	5	5	100
Hep A IgG	5	5	5	100
Hep B Antibody	5	5	5	100
Hep C Antibody	5	5	5	100
Hep B Antigen	5	5	5	100
Leishmaniasis	5	5	5	100
P. falciparum (Malaria)	5	5	5	100
Schistosomiasis	5	5	5	100
Anti-malarial therapies	5	5	5	100
Cancer: Kidney	5	5	5	100
Cancer: Solid tumor samples	5	5	5	100
HAMA (Human a-mouse Ab)	5	5	5	100
Haemodialysis	5	5	5	100
Haemolyzed samples	5	5	5	100
Iceteric samples	5	5	5	100
Lipemic samples	5	5	5	100
Multiparous Pregnancy	5	5	5	100
Pregnancy	5	5	5	100
Rheumatoid factor	5	5	5	100
Total	95	95	95	100

REPEATABILITY

Uni-Gold™ HIV was consistent and stable when 1 kit lot was tested over 20 days. Repeatability studies were performed twice daily, over a 20 day period, on one lot of Uni-Gold™ HIV device, one lot of pipettes and one lot of Wash Solution. One operator tested 14 samples, including HIV-1, HIV-2 positive plasma and serum, HIV negative plasma and serum, and whole blood samples. The overall repeatability was 100%.

REPRODUCIBILITY

Uni-Gold™ HIV was consistent and stable when three different kit lots were tested by 3 operators, at 3 separate sites, testing 6 coded and blinded samples, once a day, over 3 days. The overall reproducibility of the Uni-Gold™ HIV was 100%.

TECHNICAL ENQUIRIES

For any enquiries including technical support related to this product, please contact Trinity Biotech through one of the contact addresses below:

- hiv@trinitybiotech.com
- Infectiousdiseasetechnicalsupport@trinitybiotech.com
- info@trinitybiotech.com

REFERENCE

1. Schupbach et al, *Clinical Virology Manual*. 3rd Edition 2000; 37: 513-541.
2. Scaling up services for key populations at higher risk of HIV infection. Global HIV/AIDS Response, Progress Report 2011. Published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p125-137.
3. Risk factors for human immunodeficiency virus infection in intravenous drug users. Schoenbaum EE, Hartel D, Selwyn PA, Klein RS, Davenny K, Rogers M, Feiner C, Friedland G. *New England Journal Medicine* 1989 Sep 28;321(13):874-9.
4. Scaling up HIV services for women and children: towards eliminating mother-to-child transmissions and improving maternal and child health in the context of HIV. Global HIV/AIDS Response, Progress Report 2011, published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p139-164
5. 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.
6. Caribbean Epidemiology Centre CARE/PAHO/WHO Evaluation of Three Rapid HIV Assays.
7. WHO Evaluation: Evaluation (Phase 1) of the Uni-Gold™ HIV using Whole Blood Specimens.

GUIDE TO SYMBOLS


Consult Instructions for Use


Temperature limitation

Catalogue number

For *in vitro* Diagnostic Use


Manufacturer

Batch code


Use by

Wash Solution

Manufacturer:
TRINITY BIOTECH PLC
Bray, Co. Wicklow, Ireland
Phone: 353-1-276 9800
Fax: 353-1-276 9888
hiv@trinitybiotech.com
www.trinitybiotech.com

Trinity Biotech

Uni-Gold™ HIV

REF 1206502

Pour d'autres langues | Para outras línguas
Für andere Sprachen | Για τις άλλες λώσσες
Para otras lenguas | För andra språk
Per le altre lingue | For andre språk
Dla innych języków

www.trinitybiotech.com

Read these Instructions for Use completely before using the product. Follow the directions carefully. Not doing so may result in incorrect test results.

NAME AND INTENDED USE

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

SUMMARY AND PRINCIPLES OF THE PROCEDURE

HIV 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 transmitted from HIV positive individuals predominantly through unprotected sexual intercourse[2], intravenous drug abuse[3] or from mother to child transmission[4]. 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].

Uni-Gold™ HIV is a rapid immunoassay based on the immunochromatographic sandwich principle. Recombinant proteins representing the immunodominant regions of the envelope proteins of HIV-1 and HIV-2, glycoprotein gp41, gp120 (HIV-1) and glycoprotein gp36 (HIV-2) respectively, are immobilized at the test region of the nitrocellulose strip. These proteins are also linked to colloidal gold and impregnated below the test region of the device. A narrow band of the nitrocellulose membrane is also sensitized as a control region.

During testing, two drops of serum, plasma or whole blood is applied to the sample port, followed by two drops of Wash Solution and allowed to react. Antibodies of any immunoglobulin class, specific to the recombinant HIV-1 or HIV-2 proteins will react with the colloidal gold linked antigens. The antibody protein colloidal gold complex moves chromatographically along the membrane to the test and control regions of the test device.

Excess conjugate forms a second pink/red band in the control region of the device. The appearance of this band indicates proper performance of the reagents in the kit.

MATERIALS PROVIDED

Each kit contains:
1. Test Devices: 20 test devices individually pouched.
2. Wash Solution: 2.0 mL in dropper bottle.
3. Disposable Pipettes: 20 Disposable Pipettes for use with serum, plasma or whole blood.

COMPONENTS OF REACTIVE INGREDIENTS

Wash Solution: 2.0 mL of Wash Solution contains Tris buffer, Borate buffer, Chaotropic agent, Surfactant, Polyether compound, Sugar, Polymer and the preservative ProClin® 300 at 0.06% v/v.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Blood collection devices, for testing of venipuncture whole blood, serum or plasma.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

Fingerstick Samples:
- Lancet: A high blood flow lancet with a depth ranging of between 1.5-2.0 mm is required to produce a 60 µL whole blood droplet
- Sterile wipes and sterile gauze pads.
- Adhesive bandages.

WARNINGS

1. Read the Instructions for Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. Uni-Gold™ HIV is for diagnostic use only and is not to be used for screening donors of blood, plasma, cells or tissues.
3. Perform test at room temperature.

PRECAUTIONS

1. Uni-Gold™ HIV test is for professional use only.
2. The Instructions for Use must be followed to ensure optimum test performance.
3. Uni-Gold™ HIV test is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.
5. It is recommended that spare test devices are available at all times.

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

Biosafety Precautions
Appropriate biosafety practices should be used 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 in which 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"[5].
3. When disposing of Wash Solution, 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 sodium hypochlorite solution.
5. Use a separate disposable pipette and device for each specimen tested.

Handling Precautions
1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix Wash Solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. Use paper covered surface to perform testing, so as to eliminate any risk to product performance due to build-up of static charge.
8. The result should be read immediately after the end of the 10 minute incubation time following the addition of Wash Solution. Do not read results beyond 12 minutes.
9. Lancets should be placed in a puncture resistant container prior to disposal.

STORAGE INSTRUCTIONS

1. Uni-Gold™ HIV device and Wash Solution should be stored between 2-27°C.
2. Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the Wash Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that all components are brought to room temperature before use.
4. Do not freeze the kit.

SPECIMEN COLLECTION AND STORAGE

Whole Blood Venipuncture 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.
- Grossly hemolysed or lipemic samples should not be used.

Whole blood: Fingerstick
Use whole blood samples collected by fingerstick immediately on the Uni-Gold™ HIV device

Collection: Whole Blood 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. This whole blood can be used directly on the device, or stored at 2-8°C for up to 3 days, or preferably, the sample should be centrifuged and the plasma retained for further testing. Do not freeze whole blood.

Collection: Serum and Plasma
If a whole blood sample is collected without anticoagulant and has started to clot, do not remix before testing, in such instances, the clear serum should be pipetted off the clotted specimen and used for analysis.

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. Plasma must be generated within 8 hours of blood draw. Following collection, 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 or stored between 2 to 8°C for up to 5 days to allow testing. Specimens must be stored at -20°C or below if storage is necessary for more than 5 days. Grossly hemolysed or lipemic samples should not be used. Avoid multiple freeze thaw cycles.

TEST PROCEDURE FOR WHOLE BLOOD FINGERSTICK

1. Kits stored at room temperature may be used immediately (Figure 1). Allow kits stored in a refrigerator to reach room temperature. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches (Figure 2). Devices must be used within 20 minutes of opening the foil pouch.

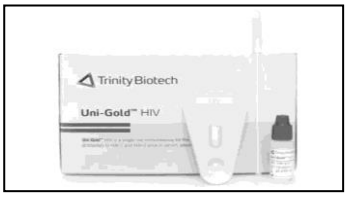


Figure 1. Uni-Gold™ HIV kit and components.

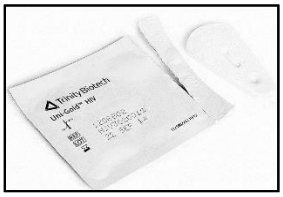


Figure 2. Test device pouch.

2. 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. Using a sterile wipe, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad.
6. Using a sterile lancet capable of producing a 60µl blood let, puncture the skin just off the centre of the finger pad (Figure 3). Hold the finger downward.
7. 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 (Figure 4). 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.
8. Never apply blood droplets directly from the fingertip onto the device as their size may vary.
9. To collect the blood into the fingerstick disposable pipette, gently press the pipette bulb, hold the pipette horizontal to the sample (Figure 5). This is important, as the specimen may not be adequate if the pipette is held in a vertical position**.** Slowly release pressure on the bulb to draw up the sample.

Figure 3. Position lancet.

Figure 4. Blood drop formation.

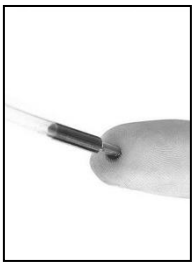


Figure 5. Draw sample into pipette.

10. Hold the pipette vertically above the sample port, squeeze the bulb and discharge two (2) drops of whole blood onto the sample pad (Figure 6). Allow the sample to fully absorb. Ensure there are no air bubbles in the sample port. Failure to hold the pipette in a vertical position may lead to erroneous test results. Do not touch the sample pad with the disposable pipette. Dispose of the pipette into biohazard waste.
11. Hold the Wash Solution dropper bottle vertically over the sample port; add two (2) drops of Wash Solution to the sample port (Figure 7). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

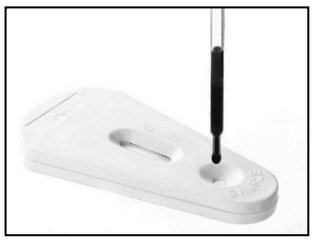


Figure 6. Add blood vertically into device.

Figure 7. Add Wash Solution vertically.

12. Read test results after 10 minutes but no later than 12 minutes incubation time.
13. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

TEST PROCEDURE FOR VENIPUNCTURE WHOLE BLOOD, SERUM AND PLASMA

1. Allow the kit (unopened devices and Wash Solution) to reach room temperature if previously stored in the refrigerator. Once at room temperature remove the required number of Uni-Gold™ HIV devices from their pouches. Devices must be used within 20 minutes of opening the foil pouch.
2. 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. Fill the disposable pipette included in the kit with sample. Ensure there are no air bubbles. Use only the pipette included in the kit and do not reuse.
6. Hold the pipette vertically over the sample port, squeeze the bulb and discharge two (2) drops of plasma/serum/whole blood onto the sample pad (Figure 8). Allow the sample to fully absorb. Ensure air bubbles are not introduced into the sample port. Do not touch the sample pad with the disposable pipette. Failure to hold the pipette in a vertical position may lead to erroneous test results.
7. Dispose of the pipette in biohazard waste.
8. Holding the dropper bottle of Wash Solution in a vertical position and above the sample port, add two (2) drops of Wash Solution to the sample port (Figure 9). Time the assay from this point. Ensure no air bubbles are introduced into the sample port. Failure to hold the bottle in a vertical position may lead to erroneous test results. Do not touch the sample pad with the dropper bottle tip.

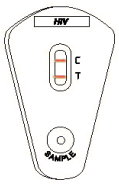
Figure 8. Add sample vertically into device.

Figure 9. Add Wash Solution vertically.

9. Read test results after 10 minutes but no later than 12 minutes incubation time.
10. To read and interpret results, refer to the Interpretation for whole blood, serum and plasma samples section.

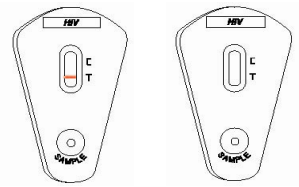
INTERPRETATION FOR WHOLE BLOOD, SERUM AND PLASMA SAMPLES

Reactive Test Result
Two pink/red lines of any intensity in the device window, the first adjacent to letter "T" (test) and the second adjacent to "C" (control). This indicates a Reactive result that is interpreted as Preliminary Positive for antibodies to HIV.



Non-Reactive Test Result
A pink/red line of any intensity adjacent to the letter "C" (control), but no pink/red line adjacent to "T" (test). This indicates a Non-Reactive result that is interpreted as Negative for antibodies to HIV.

Invalid Result
No pink/red line appears in the device window adjacent to the letter "C" (control) irrespective of whether or not a pink/red line appears in the device window adjacent to "T" (test). This is an Invalid result that cannot be interpreted. An invalid result must be repeated.



***Disclaimer**: The diagrams above are for illustration purposes only.*

Further Interpretation

Grey Lines

Where a grey line is seen, it does not indicate the presence of antibodies to HIV. It is always interpreted as non-reactive.

Broken Lines

*Test Line***:** Where a specimen produces a broken pink/red test line with Uni-Gold™ HIV, it is deemed initially reactive (conditional on the presence of a pink/red control line) but the sample must be retested in duplicate. When the duplicate results are either a broken or complete pink/red line in one or both duplicates, then the sample is interpreted as preliminary positive. If both duplicates give no line at "T" (test) then the result is referred to as negative.

*Control Line***:** A broken pink/red control line does not affect the validity of the test.

Whole Blood Migration

Whole blood sample may migrate into the device window (whole blood visible at the bottom). The test is valid and can be interpreted if there is no obstruction in the test line region at 10 to 12 minutes. If the sample infringes on the test line region, the test is invalid and should be repeated.

QUALITY CONTROL

The Uni-Gold™ HIV test has a built in control that demonstrates assay validity. A pink/red line appearing adjacent to the letter "C" (control) indicates that the test is running correctly.

When using whole blood samples, a red color in the sample port validates the addition of the sample. The pink/red control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the interpretation section).

Good Laboratory Practice necessitates the use of control specimens to ensure proper device performance at least once daily and changing of kit lots.

NOTE: Commercial HIV controls may not perform properly with the Trinity Biotech Uni-Gold™ HIV kit. For further information please contact Trinity Biotech.

LIMITATIONS

1. Uni-Gold™ HIV test procedure and interpretation of results must be followed when testing for the presence of HIV antibodies in serum, plasma or whole blood.
2. Uni-Gold™ HIV has not been validated for use with other body fluids. Testing with Uni-Gold™ HIV must not be performed with such fluids as results derived may not be accurate.
3. Uni-Gold™ HIV test is intended for the testing of undiluted samples only. Do not dilute samples before testing.
4. 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.

5. Immunosuppressed or immunocompromised individuals infected with HIV-1 or HIV-2 may not produce antibodies to the virus. Testing with any kit designed to detect antibodies may give negative results and would not be a reliable test method for such patients.
6. Infants may receive antibodies from an infected mother or they may not produce antibodies in response to an infection. Therefore, it is necessary to exercise great care in interpreting their results.
7. The intensity of a pink/red line at the "T" (test) region is not an indication of the level of antibody in the specimen.
8. A reactive result by Uni-Gold™ HIV suggests the presence of anti-HIV antibodies in the specimen. Uni-Gold™ HIV is intended as an aid in the diagnosis of infection with HIV. AIDS and AIDS related conditions are clinical symptoms and their diagnosis can only be established clinically.
9. Reading test results earlier than 10 minutes or later than 12 minutes may give incorrect results.
10. A negative result with Uni-Gold™ HIV does not exclude the possibility of infection with HIV. A false negative result can occur in the following circumstances:
    - Recent infection. Antibody response to a recent exposure may take several months to reach detectable levels. For negative results, repeat testing after 6 months is recommended to confirm negative status.
    - The test procedure has not been correctly followed.
    - Antibodies to a variant strain of HIV in the patient that do not react with specific antigens utilized in the assay configuration.
    - Improper specimen handling.
    - Failure to add sample.
    - Failure to allow kits to come to room temperature prior to use may impact results.

PERFORMANCE CHARACTERISTICS

Overall Sensitivity and Specificity
Uni-Gold™ HIV has been evaluated by a number of independent organizations (Table 1).

Clinical study 1 in 2000 was based on data derived from 471 patient samples including 102 HIV positive samples (2 serum and 100 stored plasma samples) and 369 HIV negative serum samples. The serum samples were collected from antenatal clinics. The 100 stored HIV positive plasma samples were collected from confirmed HIV positive women[6].

Clinical study 2 in 2000 used 250 EDTA-treated whole blood specimens of which 80 were HIV-1 positive and 170 were HIV negative.[7].

Clinical study 3 in 2012 included 1079 serum/plasma specimens of European, African, Latin American and Asian origin. This was comprised of 405 HIV-1 positive, 16 HIV-2 positive and 658 HIV negative specimens.

Table 1: Sensitivity and Specificity Evaluation

Evaluation Performed by	Sensitivity	Specificity	NPV*	PPV*
Clinical study 1	100%	99.5%	100%	98.1%
Clinical study 2	100%	100%	100%	100%
Clinical study 3	99.8%	99.9%	99.9%	99.8%

* NPV (Negative Predictive Value), PPV (Positive Predictive Value).

HIV-2 Sensitivity
The sensitivity of Uni-Gold™ HIV in detecting known HIV-2 antibody positive samples was assessed using 150 samples positive for HIV-2 antibodies only. All samples were frozen plasma sourced from the Ivory Coast. Uni-Gold™ HIV detected all 150 positive specimens, giving a sensitivity of 100%.

HIV-1 Group M Non-B Subtypes
To ensure optimal device sensitivity, an evaluation was carried out on various HIV-1 Group M Non-B Subtype specimens. A total of 42 samples shown to be HIV-1 Group M Non-B Subtypes were used. All samples were reactive with Uni-Gold™ HIV (Table 2).

Table 2: Uni-Gold™ HIV Group M Non-B Subtype evaluation.

Subtype	Number of samples tested	Uni-Gold™ HIV result	% Reactive
A	6	R	100
C	6	R	100
D	3	R	100
F	5	R	100
G	4	R	100
H	3	R	100
J	2	R	100
K	4	R	100
CRF-01 AE	3	R	100
CRF-01	1	R	100
CRF-01/15	1	R	100
CRF-02 AG	2	R	100
CRF-03-AB	2	R	100

Seroconversion panels:
Eleven (11) HIV-1 seroconversion panels were evaluated in comparison to confirmatory Western and Line blot tests. Each commercial panel consisted of sequential specimens obtained from a single individual during seroconversion. The eleven seroconversion panels consisted of a total of 77 specimens (Table 3). Uni-Gold™ HIV detected HIV-1 antibodies at the same bleed or at an earlier bleed than the Western/Line Blot assays in 11 out of 11 panels.

Table 3: Summary of seroconversion panel results in comparison to Western Blot

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
PRB914	PRB914-01	0	R	R
	PRB914-02	4	R	R
	PRB914-03	7	R	R
	PRB914-04	25	R	R
	PRB914-05	31	R	R
PRB925	PRB925-01	0	NR	NR
	PRB925-02	10	NR	NR
	PRB925-03	18	NR	NR
	PRB925-04	22	NR	NR
	PRB925-05	44	R	IND
	PRB925-06	49	R	R
PRB926	PRB926-01	0	NR	NR
	PRB926-02	2	NR	NR
	PRB926-03	7	NR	NR
	PRB926-04	9	NR	NR
	PRB926-05	27	R	R
	PRB926-06	32	R	R
PRB930	PRB930-01	0	NR	NR
	PRB930-02	3	NR	NR
	PRB930-03	7	R	IND
	PRB930-04	10	R	R
PRB955	PRB955-01	0	NR	NR
	PRB955-02	3	NR	NR
	PRB955-03	7	NR	NR
	PRB955-04	12	NR	NR
	PRB955-05	14	R	R
PRB965	PRB965-01	0	NR	NR
	PRB965-02	5	NR	NR
	PRB965-03	7	NR	NR
	PRB965-04	12	R	NR
	PRB965-05	14	R	IND
	PRB965-06	21	R	R
PRB968	PRB968-01	0	NR	NR
	PRB968-02	3	NR	NR
	PRB968-03	8	NR	NR
	PRB968-04	10	NR	NR
	PRB968-05	15	NR	NR
	PRB968-06	17	NR	NR
	PRB968-07	26	NR	NR
	PRB968-08	28	NR	NR
	PRB968-09	33	R	R
	PRB968-10	35	R	R
PRB969	PRB969-01	0	NR	NR
	PRB969-02	29	NR	NR
	PRB969-03	48	NR	NR
	PRB969-04	53	NR	NR
	PRB969-05	55	NR	NR
	PRB969-06	61	NR	NR
	PRB969-07	63	NR	NR
	PRB969-08	70	R	R
	PRB969-09	72	R	R
	PRB969-10	77	R	R
PRB924	PRB924-01	0	NR	NR
	PRB924-02	2	NR	NR
	PRB924-03	8	NR	NR
	PRB924-04	10	NR	NR
	PRB924-05	26	NR	NR
	PRB924-06	33	R	NR
	PRB924-07	35	R	IND
	PRB924-08	40	R	IND
PRB931	PRB931-01	0	NR	NR
	PRB931-02	2	NR	NR
	PRB931-03	7	NR	NR
	PRB931-04	9	NR	NR
	PRB931-05	15	NR	NR
	PRB931-06	28	R	NR
	PRB931-07	33	R	IND
	PRB931-08	35	R	R
	PRB931-09	42	R	R
PRB940	PRB940-01	0	NR	IND
	PRB940-02	7	NR	IND

Table 3: Continued

Panel	Panel ID	Days since 1st bleed	Uni-Gold™HIV	Confirmatory Western Blot/Line Blot
	PRB940-03	11	R	IND
	PRB940-04	15	R	IND
	PRB940-05	18	R	IND
	PRB940-06	22	R	IND
	PRB940-07	25	R	IND
	PRB940-08	29	R	R

Key: R= Reactive, NR = Not Reactive, IND =Indeterminate

Interference studies

To further evaluate the specificity of Uni-Gold™ HIV, the product was challenged for antibody cross reactivity with samples from individuals with other disease states, non-HIV medical conditions and potentially interfering substances. All 95 specimens were confirmed as HIV negative prior to evaluation. These potentially cross-reacting substances did not affect the specificity of Uni-Gold™ HIV (Table 4).

The sensitivity performance of Uni-Gold™ HIV was further evaluated by testing 95 samples from people with unrelated medical conditions, various disease states and samples containing interfering substances. All samples were spiked with HIV-1 antibody positive plasma. These potentially cross reacting substances did not affect the sensitivity of Uni-Gold™ HIV (Table 4).

Table 4: Results from samples with other disease states and interfering substances

Potential Interference Samples Evaluated	No. samples tested	No. correctly identified- Non-Reactive	No. correctly identified - Reactive	%
CMV IgG	5	5	5	100
Hep A IgG	5	5	5	100
Hep B Antibody	5	5	5	100
Hep C Antibody	5	5	5	100
Hep B Antigen	5	5	5	100
Leishmaniasis	5	5	5	100
P. falciparum (Malaria)	5	5	5	100
Schistosomiasis	5	5	5	100
Anti-malarial therapies	5	5	5	100
Cancer: Kidney	5	5	5	100
Cancer: Solid tumor samples	5	5	5	100
HAMA (Human a-mouse Ab)	5	5	5	100
Haemodialysis	5	5	5	100
Haemolyzed samples	5	5	5	100
Iceteric samples	5	5	5	100
Lipemic samples	5	5	5	100
Multiparous Pregnancy	5	5	5	100
Pregnancy	5	5	5	100
Rheumatoid factor	5	5	5	100
Total	95	95	95	100

REPEATABILITY

Uni-Gold™ HIV was consistent and stable when 1 kit lot was tested over 20 days. Repeatability studies were performed twice daily, over a 20 day period, on one lot of Uni-Gold™ HIV device, one lot of pipettes and one lot of Wash Solution. One operator tested 14 samples, including HIV-1, HIV-2 positive plasma and serum, HIV negative plasma and serum, and whole blood samples. The overall repeatability was 100%.

REPRODUCIBILITY

Uni-Gold™ HIV was consistent and stable when three different kit lots were tested by 3 operators, at 3 separate sites, testing 6 coded and blinded samples, once a day, over 3 days. The overall reproducibility of the Uni-Gold™ HIV was 100%.

TECHNICAL ENQUIRIES

For any enquiries including technical support related to this product, please contact Trinity Biotech through one of the contact addresses below:

- hiv@trinitybiotech.com
- Infectiousdiseasetechnicalsupport@trinitybiotech.com
- info@trinitybiotech.com

REFERENCE

1. Schupbach et al, *Clinical Virology Manual*. 3rd Edition 2000; 37: 513-541.
2. Scaling up services for key populations at higher risk of HIV infection. Global HIV/AIDS Response, Progress Report 2011. Published by WHO, UNAIDS & UNICEF. ISBN 978 92 4 150298 6. p125-137.
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5. 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.
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7. WHO Evaluation: Evaluation (Phase 1) of the Uni-Gold™ HIV using Whole Blood Specimens.

GUIDE TO SYMBOLS


Consult Instructions for Use


Temperature limitation

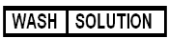
Catalogue number

For *in vitro* Diagnostic Use


Manufacturer

Batch code


Use by



Wash Solution

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