



DRAFT

Uni-Gold™
HIV

FOR INFORMATION USE ONLY
Not to be used for performing the assay.
Refer to insert accompanying kit

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1. Intended Use

The Trinity Biotech Uni-Gold™ HIV test is a single reagent assay for the detection of antibodies to human immunodeficiency virus types 1 and 2 in serum, plasma or wholeblood.

2. Summary and Explanation of the Test

Human Immunodeficiency Virus (HIV) has been recognised as the etiological agent of the acquired immunodeficiency syndrome (AIDS).

The Trinity Biotech Uni-Gold™ HIV test is a rapid immunoassay based on the immunochromatographic sandwich principle.

3. Principles of the Procedure

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 immobilised 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 sensitised 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 buffer 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.

A positive reaction is visualised by a pink/red band in the test region of the device.

A negative reaction occurs in the absence of human immunoglobulin antibodies to HIV in the analysed specimen. Consequently no visually detectable band develops in the test region of the 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.

a) 20 Test Devices

Each test device contains colloidal gold labelled with recombinant HIV proteins, recombinant HIV proteins as test zone, and a control line.

b) Wash Reagent (2 ml)

Single reagent for whole blood, serum or plasma.

c) 20 Disposable Pipettes

d) Package Insert

Materials required but not provided.

* Timer or stopwatch

* Blood collection devices (i.e., lancets, capillary tubes/ test tubes)

5. Storage and Stability

The Trinity Biotech Uni-Gold™ HIV test device and wash solution can be stored at 2-27°C.

No kit components should be used after the kit expiry date.

6. Precautions

- The Trinity Biotech Uni-Gold™ HIV test is for professional use only.
- The package insert instructions must be followed to ensure optimum test performance.
- The Trinity Biotech Uni-Gold™ HIV test is intended for *in vitro* use.
- Controls where supplied have been certified virus free. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

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

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

- Do not smoke, eat, drink, apply cosmetics or handle contacts lenses in areas in which specimens are handled.
- 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.
- When disposing of wash buffer, avoid contact with acid to prevent liberation of a toxic gas.
- All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
- Use a separate disposable pipette and device for each specimen tested.
- Do not pipette by mouth.
- In a small number of cases it has been noted that the control or the test line may appear "broken". While this does not effect the test result it is recommended that the testing of that sample is repeated on another Uni-Gold™ HIV test device.

Handling Procedures

Do not use any device if the pouches have been perforated.

Each device is for single use only.

Do not mix reagents from different kits.

Do not use the kit past the expiration date.

Whole blood, serum or plasma may be used.

Whole Blood: If fingerstick whole blood is used, drops of blood produced should be taken up from the finger-tip by the pipette supplied and dropped from the pipette onto the device. Blood droplets **should not** be dropped directly from the fingertip onto the device as their size may vary.

Whole blood specimens should be used within ten minutes of collection for optimum performance.

If a specimen 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.

If an anticoagulant has been used in the blood sample, whole blood can be used directly on the device using the pipette supplied. If testing is not to be carried out immediately, samples should be stored at 2-8°C for up to three days, or preferably, the sample should be centrifuged and the plasma retained for future testing.

Serum or Plasma:

Serum or plasma may be kept for seven days at 2-8°C. Samples should be frozen for longer storage. Avoid repeated freezing and thawing of samples.

8. Quality Control

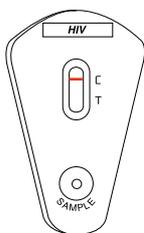
Good Laboratory Practice necessitates the use of control specimens to ensure proper device performance at least once daily.

A built in procedural control on the test device indicates that the test is functioning correctly. A pink/red band should always appear at the control window.

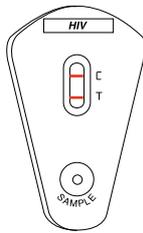
Please note certain commercial controls designed for ELISA may not preform properly with the Trinity Biotech Uni-Gold™ kit. For further information please contact Trinity Biotech.

9. Test Procedure

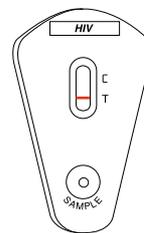
1. If any reagent/sample has been in refrigerated storage, remove and allow to stand for at least 20 minutes to reach room temperature.
2. Remove the required number of Trinity Biotech Uni-Gold™ HIV test devices from their protective wrappers.
3. Label each test with the appropriate patient information.
4. Using one of the disposable pipettes supplied, fill with sample (serum/plasma/whole blood).
5. Holding the pipette over the sample port add two drops of sample (approx. 60 µl) carefully.
6. Add 2 drops (approx. 60 µl) of the wash reagent to sample port.
7. Allow 10 minutes from the time of wash reagent addition for reaction to occur. The result should be read immediately after the end of the 10 minute incubation time but is stable for a further 10 minutes after the incubation time. Do not read results after 20 minutes following sample addition.



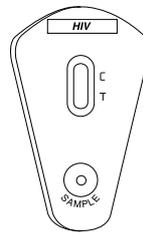
NEGATIVE
A line in the control region only indicates a negative test result.



POSITIVE
A line of any intensity forming in the test region, plus a line forming in the control region, indicates a positive result.



INCONCLUSIVE
No line appears in the control region. The test should be repeated with a fresh device. Irrespective of a line developing in the test region.



11. Limitations

The Trinity Biotech Uni-Gold™ HIV test procedure and interpretation of results must be followed closely when testing for the presence of HIV antibodies in serum, plasma or whole blood.

The Trinity Biotech Uni-Gold™ HIV test is intended for the testing of undiluted samples only. Samples should not be diluted before testing.

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.

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.

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:

- low levels of antibody (e.g., early seroconversion specimens) are below the detection limit of the test
- infection with a variant of the virus that is less detectable by the Uni-Gold™ HIV assay configuration
- HIV antibodies in the patient that do not react with specific antigens utilized in the assay configuration
- specimen handling conditions which result in the loss of HIV antibody multivalency.

12. Performance

Uni-Gold™ HIV has been evaluated by a number of Independent organizations.

Evaluation Performed by	Sensitivity	Specificity	NPV	PPV	Test Efficiency
Caribbean Epidemiology Centre* CAREC/PAHO/WHO	100%	99.70%	99%	100%	99.40%
WHO Evaluation (Phase 1)** (Draft report)	100%	100%	100%	100%	N/A

* 471 sera including 102 HIV positive and 369 HIV negative sera which were in the main collected from antenatal clinics. Along with 100 stored plasma samples collected from confirmed HIV women.

**250 whole blood specimens were evaluated compared to the reference test.

Feorino, P.M., Jaffe, H.W., Palmer, E., et al. Transfusion-associated Acquired Immunodeficiency Syndrome: evidence for persistent infection in blood donors. New Engl. J. Med 312: 1293-6. 1985

Alter, H.J., Leitman, S.F., Klein, H.G., et al. Clinical significance of anti-HIV antibodies in asymptomatic blood donors. A Prospective Study. III. International AIDS Conference, Washington DC (abs) 74. 1987

Butler, J.E. In Enzyme-Immunoassay (Maggiolo et, ED.) CRC Press, Boca Raton, FL, Chpt 2. 1980.

Caribbean Epidemiology Centre
Evaluation of Three Rapid HIV Assays.

WHO Evaluation
Evaluation (Phase 1) of the Uni-Gold™ HIV using Whole Blood Specimens.