Uni-Gold™ Recombigen® HIV Controls

(HIV-1 / HIV-2 Positive and Negative Controls)

REF 1206530

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	For andre sprog

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NAME AND INTENDED USE

Uni-Gold™ Recombigen® HIV Controls are intended for use only with Uni-Gold™ Recombigen® HIV-1/2.

SUMMARY

Controls should be used in conjunction with Good Laboratory Procedures. Controls should be run as required and as specified in the Uni-Gold™ Recombigen® HIV-1/2 test pack insert.

PRINCIPLES OF THE PROCEDURE

Uni-Gold™ Recombigen® HIV Controls have been designed for use with the Uni-Gold™ Recombigen® HIV-1/2 assay to validate the correct performance of the device in the hands of the user.

Uni-Gold™ Recombigen® HIV-1 and HIV-2 positive controls are prepared from inactivated human serum or plasma. It is negative for HbsAg and anti-HCV by U.S. FDA licensed test procedures. Source materials are reactive for antibodies to HIV-1 or HIV-2.

Positive controls do not have assigned quantitative values, each lot of material has been designed to produce a positive reaction within a target range, when tested on the Uni-Gold™ Recombigen® HIV-1/2 assay.

Uni-Gold™ Recombigen® HIV negative control is prepared from defibrinated delipidised human serum which has been screened for Anti-HIV-1 and HIV-2, HbsAg and Anti-HCV. Uni-Gold™ Recombigen® HIV negative control has been designed to give a negative reaction when tested on the Uni-Gold™ Recombigen® HIV-1/2 assay.

REAGENTS

- Uni-Gold™ Recombigen® HIV-1 Positive Control: 1 vial (0.5ml) with red cap.
- Uni-Gold™ Recombigen® HIV-2 Positive Control: 1 vial (0.5ml) with green cap.
- Uni-Gold™ Recombigen® Negative Control: 1 vial (0.5ml) with black cap.

The positive controls contain human serum or plasma reactive for antibody for HIV-1 or HIV-2. HIV-1 source material has been treated with beta-propiolactone and ultraviolet irradiation (BP/UV). HIV-2 source material has been heat inactivated. Negative control contains defibrinated delipidised human serum. The positive and negative controls may contain 0.1% Sodium Azide as a preservative.

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE ONLY

CAUTION: Handle Uni-Gold™ Recombigen® HIV Controls and all human blood products as though capable of transmitting infectious agents.

Safety Precautions

1. Do not pipette by mouth.
2. Do not eat, drink, apply cosmetics or handle contact lenses where specimens are being tested.
3. Clean any spillages by immediately and thoroughly wiping up with a suitable disinfectant such as 1% sodium hypochlorite solution.
4. Handle carefully and dispose of all specimens, controls and materials as though they contained infectious agents.

Handling Procedures

1. Do not use Uni-Gold™ Recombigen® HIV Controls beyond the expiration date.
2. Avoid microbial contamination of the controls when opening and closing the vials.

STORAGE INSTRUCTIONS

1. Store Uni-Gold™ Recombigen® HIV Controls at 2-8ºC / 35.6–46.4ºF.
2. Store in the upright position at all times to prevent leakage.
3. Ensure cap is securely fastened when controls are not in use.
4. Once opened Uni-Gold™ Recombigen® HIV Controls are stable for one month.
5. Record the date to discard the controls (one month after opening) on the space provided on the box. This date cannot be after the expiry date of the controls printed on the box.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Alterations in physical appearance may indicate instability or deterioration of Uni-Gold™ Recombigen® HIV Controls. Solutions that are visibly turbid should be discarded in accordance with safety procedures.

PROCEDURE

Materials Required but not Provided

- Uni-Gold™ Recombigen® HIV-1/2 pack insert. (Kit 1206506).

Instructions for use

1. Read the Uni-Gold™ Recombigen® HIV-1/2 package insert prior to using Uni-Gold™ Recombigen® HIV Controls.
2. Remove from storage at 2-8°C/35.6-46.4°F and allow the controls to reach room temperature prior to use. (Return controls to storage at 2-8°C/35.6-46.4°F after use).
3. Mix contents of vials by gentle swirling or inversion.
4. Refer to test procedure section of the Uni-Gold™ Recombigen® HIV-1/2 pack insert.
5. Treat Uni-Gold™ Recombigen® HIV positive and negative controls as "patient specimens".

Quality Control

Results should be determined in the same manner as that used for unknown specimens when testing using the Uni-Gold™ Recombigen® HIV-1/2 assay.

INTERPRETATION OF RESULTS

Reactive Test Result

For both Uni-Gold™ Recombigen® HIV-1 and HIV-2 controls, a reactive result is indicated by a pink/red line of any intensity in the device window adjacent to the word “Test”. A second pink/red line of any intensity appears adjacent to word "Control". The control material is manufactured to produce a very faint pink/red “Test” line and line intensity can vary between the controls i.e. the HIV-2 control can be less intense than the HIV-1 control.

This indicates a Reactive result that is interpreted as Preliminary Positive for HIV-1 or HIV-2 antibodies.

Non-Reactive Test Result

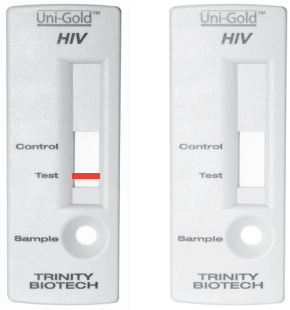
A pink/red line of any intensity appears in the device window adjacent to word "Control", but no line appears in the device window adjacent to word "Test".

This indicates a Non-Reactive result that is interpreted as Negative for HIV-1 or HIV-2 antibodies.

Invalid Result

No line appears in the device window adjacent to the word "Control" whether or not a line appears in the device window adjacent to word "Test". This is an Invalid result that cannot be interpreted.

The test should be repeated in duplicate with fresh devices.



LIMITATIONS OF THE PROCEDURE

Uni-Gold™ Recombigen® HIV Controls are only validated for use with Uni-Gold™ Recombigen® HIV-1/2 assay.

1. TEST PROCEDURES and INTERPRETATION OF TEST RESULTS section in the Uni-Gold™ Recombigen® HIV-1/2 assay pack insert must be adhered to when testing Uni-Gold™ Recombigen® HIV Controls.
2. Deviations from the procedure outlined in the Uni-Gold™ Recombigen® HIV-1/2 assay pack insert may produce unreliable results.
3. Uni-Gold™ Recombigen® HIV Controls are intended for use in undiluted form.
4. Adverse shipping and storage conditions or use of expired reagents may produce erroneous results.

EXPECTED RESULTS

Uni-Gold™ Recombigen® HIV Controls do not have assigned values. Results should be determined in the same manner as used for unknown specimens when testing with the Uni-Gold™ Recombigen® HIV-1/2 test. Each laboratory should determine its own range of acceptable values.

SPECIFIC PERFORMANCE CHARACTERISTICS

Uni-Gold™ Recombigen® HIV Controls have been validated for use with Uni-Gold™ Recombigen® HIV-1/2.

A positive reaction is produced when positive controls are run in the same manner as unknown specimens. Conversely a negative reaction is produced when negative controls are run in the same manner as unknown specimens.
All testing must be carried out in accordance with the Uni-Gold™ Recombigen® HIV-1/2 pack insert.

GLP must be followed when using Uni-Gold™ Recombigen® HIV-1/2.

GUIDE TO SYMBOLS

Consult Instructions for Use

Store at 2-8°C

REF

Catalogue number

IVD

For *in vitro* Diagnostic Use

Manufacturer

LOT

Batch code

Use by

Biological Risk

OPEN | DATE

Open Date

DISCARD | DATE

Discard Date

HIV-1 Control | +

HIV-1 Positive Control

Control | −

Negative Control

HIV-2 Control | +

HIV-2 Positive Control

CONT

Contents

Acute toxicity

Discard Controls one (1) month after opening

Manufacturer:
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