

SEROLOGY I POSITIVE CONTROL (SEROLOGY I | | | |---------|---| | CONTROL | + | |---------|---|)

Cat. No. SR10352

Lot No. 008SR

Size: 3 x 5ml

Expiry: 2021-10-28

GTIN: 05055273216509

INTENDED USE

Serology I Positive Control is intended for use with *in vitro* assays for determination of antibodies to Human Immunodeficiency Virus Type 1 and 2 (HIV-1/2), antibodies to Human T-Lymphotropic Virus Type 1 and 2 (HTLV-1/2), antibodies to Hepatitis C Virus (HCV), Hepatitis B Surface Antigen (HBsAg), IgG antibodies to Hepatitis B Core Antibodies (HBc) and IgG antibodies to *Treponema pallidum*. Serology I Positive Control is unassayed without target values and is suitable for use on many analysers. These controls must not be used as a substitute for the mandatory manufacturer's kit controls provided with the assay.

Serology I Positive Control is helpful in determining the precision of testing systems and in identifying sources of variation.

ANALYTES

Anti HIV 1/2

Anti HTLV 1/2

Anti HCV

HBsAg

Anti HBc

Anti *Treponema pallidum* IgG

This product is prepared from processed human plasma or serum reactive for antibody to HIV-1/2, antibody to HTLV-1/2, antibody to HCV, HBsAg, antibody to HBc and antibody to *Treponema pallidum*, proteins from human sources, antimicrobial agents as preservative, and stabilizers. Human source materials reactive for viral hepatitis markers and antibodies to retroviruses have been treated to inactivate infectious agents by gamma irradiation.

SAFETY PRECAUTIONS

For *in vitro* diagnostic use only. For use only by trained personnel. Do not pipette by mouth. Wear PPE when handling this product. Any spillages must be treated immediately with a suitable disinfectant as 1% Virkon solution. Exercise aerosol-minimizing techniques. Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

Biological source material. Treat as potentially infectious.

Each human serum or plasma donor unit used in the preparation of this product has been tested for the presence of HBsAg, antibodies to HIV-1 and HIV-2 and antibodies to HCV using licensed reagents. Human source materials reactive for viral hepatitis markers and antibodies to retroviruses used to produce this product have been treated to inactivate infectious agents. However, no known test method can assure that products derived from human sources will not transmit infection. It is recommended that this product and all human specimens be handled in accordance with Biosafety Level 2 practices as described in World Health Organization Laboratory Biosafety Manual, or other equivalent guidelines.

Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). The Serology I Positive Control is stable for 60 days at +2°C to +8°C, if kept capped in original container and free from contamination.

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials. Always store upright.

PREPARATION

The Serology I Positive Control is supplied ready for use. Mix thoroughly by gentle swirling before use. Return to refrigerated (+2°C to +8°C) storage after each use.

MATERIALS PROVIDED

Serology I Positive Control 3 x 5 ml

INTERPRETATION OF RESULTS

THIS PRODUCT DOES NOT HAVE ASSIGNED VALUES.

Determination of results should be performed in the same way as used for unknown specimens when tested using commercial test kits. This product is designed to give a positive result for Anti-HIV 1/2, Anti HTLV 1/2, Anti HCV, HBsAg, Anti HBc and Anti *Treponema pallidum* (Syphilis) IgG with many commercial test kits. The reactivity table provided should be used for information purposes only. Results may vary among methodologies, among different lots of the same test kits and among different laboratories. It is recommended that each laboratory establish its own target ranges with each lot of this product.

LIMITATIONS

1. Do not substitute this product for the mandatory positive or negative control reagents provided with commercial test kits.
2. This product is provided for quality assurance only and should not be used for calibration purposes.
3. This product should not be used beyond the expiration date.
4. This product should not be used in evidence of microbial contamination or high turbidity.
5. Since this product does not have assigned values, it is recommended that each laboratory validate the use of each lot of this product with each specific assay system prior to its routine use in the laboratory.
6. Follow manufacturer's Instructions for use to avoid erroneous results.

Reactivity Table

Marker	Method	Reactivity
Anti HIV 1/2	Beckman Dxl	Reactive
Anti HTLV 1/2	Roche Cobas e41 I	Reactive
Anti HCV	Beckman Dxl	Reactive
HBsAg	Beckman Dxl	Reactive
Anti HBc	Beckman Dxl	Reactive
Anti <i>Treponema pallidum</i> (Syphilis) IgG	Roche Cobas e41 I	Reactive

www.h-h-c.com

28 Nov '19 ne