

SEROLOGY NEGATIVE CONTROL

(SEROLOGY CONTROL -)

Cat. No. SR10351

Lot No. 007SR

Size: 6 x 5ml

Expiry: 2021-10-28

GTIN: 05055273216493

INTENDED USE

Serology Negative Control is intended for use as an unassayed non-reactive quality assurance reagent with *in vitro* assays detecting antibody to Human Immunodeficiency Virus Type 1/2 (anti-HIV-1/2), antibody to Human T-Lymphotropic Virus Type I/II (anti-HTLV-I/II), Human Immunodeficiency Virus P24 Antigen (HIV P24 Ag), antibody to Hepatitis C Virus (anti-HCV), Immunoglobulin M and total antibodies to Hepatitis B core Antigen (HBc-IgM and anti-HBc Total), Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis B Surface Antigen (anti-HBs), Immunoglobulin M and total antibody to Hepatitis A Virus (HAV-IgM and anti-HAV Total), Hepatitis B Envelope Antigen (HBeAg), antibody to Hepatitis B Envelope Antigen (anti-HBe) and antibodies to *Treponema pallidum*.

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

SEROLOGY NEGATIVE CONTROL IS NON-REACTIVE FOR:

Anti-HIV 1 / 2
Anti HTLV 1 / 2
HIV P24 Ag
Anti HCV
HBsAg
Anti HBs
Anti HBc
HBc IgM
Anti HAV
HAV IgM
HBeAg
Anti HBe
Anti *Treponema pallidum*

This product is prepared from processed human plasma or serum, proteins from human sources, antimicrobial agents as preservative, and stabilizers.

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 donor unit used in the preparation of this product has been tested and found to be nonreactive for Hepatitis B Surface Antigen, antibodies to Human Immunodeficiency Virus (HIV) Types 1 and 2 and antibodies to Hepatitis C Virus. 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 the 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 Negative 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 Negative 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 Negative Control 6 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 be non-reactive for Anti-HIV 1/2, Anti HTLV 1/2, HIV P24Ag, Anti HCV, HBsAg, Anti HBs, Anti HBe, HBcIgM, Anti HAV, HAV IgM, HBeAg, Anti HBe 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	Non-reactive
Anti HTLV 1/2	Roche Cobas e41 I	Non-reactive
HIV P24 Ag	Biomerieux Vidas	Non-reactive
Anti HCV	Beckman Dxl	Non-reactive
HBsAg	Beckman Dxl	Non-reactive
Anti HBs	Beckman Dxl	Non-reactive
Anti HBc	Beckman Dxl	Non-reactive
HBcIgM	Beckman Dxl	Non-reactive
Anti HAV	Beckman Dxl	Non-reactive
HAV IgM	Beckman Dxl	Non-reactive
HBeAg	Biomerieux Vidas	Non-reactive
Anti HBe	Biomerieux Vidas	Non-reactive
Anti <i>Treponema pallidum</i> (Syphilis) IgG	Roche Cobas e41 I	Non-reactive

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