

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

Cat. No. SR10354

Size 3 x 5ml

GTIN: 05055273216523

Lot No. 010SR

Expiry: 2021-10-28

INTENDED USE

Serology III Positive Control is intended for use with *in vitro* assays for determination of IgM antibodies to Hepatitis B Core Antigen (HBc IgM) and IgM antibodies to Hepatitis A (HAV IgM). Serology III 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 III Positive Control is helpful in determining the precision of testing systems and in identifying sources of variation.

ANALYTES

HBc IgM

HAV IgM

This product is prepared from processed human plasma or serum reactive for IgM antibody to HBc and IgM antibody to Hepatitis A, proteins from human sources, antimicrobial agents as preservative, and stabilizers. Human source materials reactive for viral hepatitis markers 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 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 III 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 III 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 III 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 HBcIgM and HAV IgM 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
HBcIgM	Beckman Dxl	Reactive
HAV IgM	Beckman Dxl	Reactive

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