SEROLOGY ToRCH IgM POSITIVE CONTROL (ToRCH IgM CONTROL +)

CAT. NO. SR10349 **LOT NO.** 017SR
SIZE: 3 x 5 ml **EXPIRY:** 2021-02-28

GTIN: 05055273216424

INTENDED USE
ToRCH IgM Positive Control is intended for use with *in vitro* assays for determination of IgM antibodies to Cytomegalovirus (CMV), IgM antibodies to Rubella Virus, IgM antibodies to Toxoplasma gondii, IgM antibodies to Herpes Simplex Virus Type 1 and 2.
ToRCH IgM Positive Control is unassayed without target values and is suitable for use on many analysers. This control must not be used as a substitute for the mandatory manufacturer's kit controls provided with the assay.
ToRCH IgM Positive Control is helpful in determining the precision of testing systems and in identifying sources of variation.

ANALYTES
Cytomegalovirus (CMV) IgM
Rubella Virus IgM
Toxoplasma gondii IgM
Herpes Simplex Virus Type 1/2 (HSV-1/2) IgM

This product is prepared from processed human plasma or serum reactive for IgM antibodies to Cytomegalovirus (CMV), IgM antibodies to Rubella, IgM antibodies to Toxoplasma gondii, IgM antibodies to Herpes Simplex Virus Type 1 and 2, 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 such 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 ToRCH IgM 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 ToRCH IgM Positive Control is supplied ready for use. Allow control to come to room temperature. Mix thoroughly by gentle swirling before use. Return to refrigerated (+2°C to +8°C) storage after each use.

MATERIALS PROVIDED
ToRCH IgM 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 be reactive for CMV IgM, Rubella IgM, Toxo IgM, HSV 1/2 IgM with many commercial test kits. The reactivity table provided should be used for information purposes only.
Results may vary among methodologies, among manufacturers, among different lots of the same test kit 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 if there is 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.
7. This product should not be used if there are obvious signs of damage to the product. In this case, please contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

REACTIVITY TABLE

Marker	Method	Reactivity
CMV IgM	Biomerieux Vidas	Reactive
Rubella IgM	Biomerieux Vidas	Reactive
Toxo IgM	Biomerieux Vidas	Reactive
HSV Type 1/2 IgM	Diasorin Liaison XL	Reactive

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