

SEROLOGY ToRCH NEGATIVE CONTROL (ToRCH | | | |---------|---| | CONTROL | - | |---------|---|)

CAT. NO. SR10347 **LOT NO.** 001SR
SIZE: 6 x 5 ml **EXPIRY:** 2020-09-28
GTIN: 05055273216400

INTENDED USE

ToRCH Negative Control is intended for use as an unassayed non-reactive quality assurance reagent with *in vitro* assays detecting IgG and IgM antibodies to Cytomegalovirus (CMV), IgG and IgM antibodies to Rubella virus, IgG and IgM antibodies to Toxoplasma gondii, IgG and IgM antibodies to Herpes Simplex Type 1 and 2, IgG antibodies to Mumps Virus, IgG antibodies to Rubeola Virus (Measles), IgG antibodies to Varicella Zoster Virus, IgG antibodies to Helicobacter pylori, IgG antibodies to Treponema pallidum (Syphilis), IgG and IgM antibodies to the Viral Capsid Antigen of Epstein-Barr virus (EBV VCA) and IgG antibodies to the Viral Polypeptide Nuclear Antigen of Epstein-Barr Virus (EBV EBNA IgG).

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

ToRCH NEGATIVE CONTROL IS NON-REACTIVE FOR:

- CMV IgG
- CMV IgM
- Rubella IgG
- Rubella IgM
- Toxo IgG
- Toxo IgM
- Herpes Simplex Virus Type 1 and 2 IgG
- Herpes Simplex Virus Type 1 and 2 IgM
- Mumps IgG
- Measles IgG
- Varicella Zoster Virus IgG
- Helicobacter pylori IgG
- Anti Treponema pallidum IgG
- EBV VCA IgG
- EBV VCA IgM
- EBV EBNA IgG

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 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 ToRCH Negative Control is supplied ready for use. Allow the 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 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 CMV IgG, CMV IgM, Rubella IgG, Rubella IgM, Toxo IgG, Toxo IgM, HSV 1/2 IgG, HSV 1/2 IgM, Mumps IgG, Measles IgG, VZV IgG, *H. pylori* IgG, Anti Treponema IgG, EBV VCA IgG, EBV VCA IgM, EBV EBNA 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 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
Cytomegalovirus IgG	Biomerieux Vidas	Non-reactive
Cytomegalovirus IgM	Biomerieux Vidas	Non-reactive
Rubella IgG	Biomerieux Vidas	Non-reactive
Rubella IgM	Biomerieux Vidas	Non-reactive
Toxoplasma gondii IgG	Biomerieux Vidas	Non-reactive
Toxoplasma gondii IgM	Biomerieux Vidas	Non-reactive
Herpes Simplex Virus (HSV) Type 1 IgG	Roche Cobas E41 I	Non-reactive
Herpes Simplex Virus (HSV) Type 2 IgG	Roche Cobas E41 I	Non-reactive
Herpes Simplex Virus (HSV) Type 1/2 IgM	DiaSorin Liaison XL	Non-reactive
Mumps IgG	Biomerieux Vidas	Non-reactive
Measles IgG	Biomerieux Vidas	Non-reactive
Varicella Zoster IgG	Biomerieux Vidas	Non-reactive
Helicobacter pylori IgG	Biomerieux Vidas	Non-reactive
Anti Treponema (Syphilis) IgG	Roche Cobas E41 I	Non-reactive
EBV VCA IgG	Biomerieux Vidas	Non-reactive
EBV VCA IgM	Biomerieux Vidas	Non-reactive
EBV EBNA IgG	Biomerieux Vidas	Non-reactive

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