

SEROLOGY LYME DISEASE NEGATIVE CONTROL

(LYME | | | |---------|---| | CONTROL | - | |---------|---|)

CAT. NO. SR10345

SIZE: 1 x 5 ml

LOT NO. 005SR

EXPIRY: 2021-06-28

GTIN: 05055273216387

INTENDED USE

Lyme Disease Negative Control is intended for use as an unassayed non-reactive quality assurance reagent, with *in vitro* assays detecting IgG antibodies to *Borrelia burgdorferi* and IgM antibodies to *Borrelia burgdorferi*.

Lyme Disease 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.

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

SEROLOGY LYME DISEASE NEGATIVE CONTROL IS NON-REACTIVE FOR:

IgG antibodies to *Borrelia burgdorferi*

IgM antibodies to *Borrelia burgdorferi*

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 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). Lyme Disease 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 Lyme Disease 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

Lyme Disease Negative Control 1 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 Lyme IgG and Lyme IgM with many commercial test kits. 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.

22 Oct 19 pq

THIS PAGE IS INTENTIONALLY BLANK