NATtrol™ Cytomegalovirus Linearity Panel
Strain: AD-169

Catalog Number: NATCMV-LIN

PRODUCT DESCRIPTION:

NATtrol™ Cytomegalovirus Linearity Panel (NATCMV-LIN)* is formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable. NATCMV-LIN contains 6 x 0.25 mL vials of CMV NATtrol™ at concentrations listed in Table 1. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

*Pat.:http://www.zeptometrix.com/patent-information/

INTENDED USE:

- NATtrol™ Cytomegalovirus Linearity Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of CMV DNA. NATCMV-LIN can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATCMV-LIN contains intact organisms and should be run in a manner identical to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on the CMV stock used to formulate panel members. The inactivation was verified by the absence of viral growth in validated tissue culture based infectivity assays.
- Purified protein matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from materials that have been tested and found non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods. Heat inactivated bovine based source materials used in the manufacture of this product meet applicable USDA requirements for abattoir sourced animals, traceability and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and post mortem at the abattoir as required by the USDA.

PRECAUTIONS:

- Although NATCMV-LIN contains inactivated virus, it should be handled as if potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ Cytomegalovirus Linearity Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Extract CMV DNA prior to use in downstream assays.

Table 1: NATCMV-LIN PANEL MEMBERS

Panel Member	Target Concentration (copies/mL)**
CMV 5E6	5,000,000
CMV 5E5	500,000
CMV 5E4	50,000
CMV 5E3	5,000
CMV 5E2	500
Negative	0

**Conversion factor: 1.00 copy = 5.04 IU. Based on internal testing of the 1st WHO International Standard for Human Cytomegalovirus for Nucleic acid Amplification Techniques (NIBSC code: 09/0162)

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development, quality assurance or manufacturing use. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

REF	Catalog Number		Temperature Limitation
LOT	Lot Number		Expiration Date
RUO	For Research Use Only		Biological Risk

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