

NATtrol™ Meningitis/Encephalitis (ME) Controls

Catalog Number: NATMEC-BIO

PRODUCT DESCRIPTION:

NATtrol™ Meningitis/Encephalitis (ME) Controls (NATMEC-BIO)* are formulated with purified, intact virus particles, bacterial and fungal cells that have been chemically modified to render them non-infectious and refrigerator stable. Each control pack contains 6 x 0.2 mL vials of ME Control 1 and 6 x 0.2 mL vials of ME Control 2. NATtrol™ ME 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™ ME Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of viral, bacterial and fungal nucleic acids. NATMEC-BIO can also be used for assessing lot-to-lot test kit performance and training of laboratory personnel.
- NATMEC-BIO 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 stocks used to formulate each control. The inactivation was verified by the absence of growth in validated tissue culture based infectivity assays and growth protocols.
- 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 NATMEC-BIO contains inactivated organisms, 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™ ME Controls should be stored at 2-8°C.

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

INSTRUCTIONS FOR USE:

- These controls have been tested with the BioFire Diagnostics FilmArray® Meningitis/Encephalitis (ME) Panel assay and provide all expected results for the targets listed in Table 1.
- Follow manufacturer instructions for loading pouches.
- Extract Nucleic Acids prior to use in assays that are not sample to result.

TABLE 1: Organisms in Meningitis/Encephalitis Controls

Organism	Strain	ME Control 1	ME Control 2
Cytomegalovirus	AD-169	Positive	Negative
<i>Escherichia coli</i>	0.1285; O18:H7:K1**	Positive	Negative
Echovirus Type 11	N/A	Positive	Negative
HHV6	Z29	Positive	Negative
<i>Streptococcus pneumoniae</i>	Z022	Positive	Negative
<i>Cryptococcus gattii</i>	Z156	Positive	Negative
HSV-1	MacIntyre	Positive	Negative
<i>Neisseria meningitidis</i>	Serogroup A	Negative	Positive
<i>Streptococcus agalactiae</i>	Z019	Negative	Positive
<i>Haemophilus influenzae</i>	MinnA	Negative	Positive
HSV-2	MS	Negative	Positive
<i>Listeria monocytogenes</i>	Serotype 1/2b	Negative	Positive
Parechovirus Type 3	N/A	Negative	Positive
VZV	Ellen	Negative	Positive

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 strain, ECRC # 0.1285, was supplied by Dr. Chobi DebRoy of the *E.coli* Reference Center, through a license with the Penn State Research Foundation.

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