

## NATtrol™ Meningitis/Encephalitis (ME) Controls

**PRODUCT DESCRIPTION:**

**NATtrol™ Meningitis/Encephalitis (ME) Controls\* (Qualitative)** are formulated with purified, intact bacterial and fungal cells and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATMEC-BIO contains 12 x 0.2 mL vials of bacterial, fungal and viral NATtrol™ as listed in Table 1. The panel members are supplied in a proprietary matrix.

\*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 bacterial, fungal, and viral nucleic acids (from organisms listed in Table 1). NATtrol™ ME Controls can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.

**WARNINGS AND PRECAUTIONS:**

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This panel contains inactivated microorganisms and materials of human and animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin that have been tested and found to be 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 Fetal Bovine Serum 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.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

**RECOMMENDED STORAGE:**

- NATtrol™ ME Controls should be stored at 2-8°C.

**INSTRUCTIONS FOR USE:**

- Mix vial vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

**LIMITATION:**

- FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- Quality control materials should be used in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the assay.

**EXPECTED RESULTS:**








- Each laboratory must evaluate the product and establish their own acceptance criteria.
- These controls have been tested with the Biofire Film Array ME assay and provide all expected results for the control components listed in Table 1.
- The table shown below is for informational purposes only.

**TABLE 1: ORGANISMS IN ME CONTROLS**

Control Component	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

\*\*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.

PINATMEC-BIO  
Revision: 09  
Effective Date: 11/12/2021

	Catalog Number		Temperature Limitation
	Batch Code		Expiration Date
	For Research Use Only		Biological Risk
	Manufacturer		

PCA# 20-223 & 21-112  
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