NATtrol™ Meningitis/Encephalitis (ME) Panel

Catalog Number:
NATMEP-BIO

PRODUCT DESCRIPTION:

NATtrol™ Meningitis/Encephalitis (ME) Panel* (qualitative) is formulated with purified, intact bacterial cells, fungal cells, and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATMEP-BIO contains 14 x 0.4 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 Panel can be used to develop procedures for verification of performance of molecular assays that detect the presence of bacterial and viral nucleic acids (from organisms listed in Table 1). The panel can also be used for training and evaluation of operator proficiency.

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 Panel 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**
- Use 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 performance criteria.
- This panel has been tested with the BioFire FilmArray® ME Panel assay and provides all expected results for the panel members listed in Table 1.

TABLE 1: PANEL MEMBERS

Panel Member	Strain
E. coli	0.1285; O18:H7:K1[1]
H. influenzae	MinnA
L. monocytogenes	Serotype 1/2b
N. meningitidis	Serogroup A
S. agalactiae	Z019
S. pneumoniae	Z022
C. gattii	Z156
Cytomegalovirus	AD-169
Echovirus Type 11	N/A
HSV1	MacIntyre
HSV2	MS
HHV6	Z29
Parechovirus Type 3	N/A
VZV	Ellen

[1]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.

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

www.ZeptoMetrix.com
ZeptoMetrix LLC • 878 Main Street, Buffalo, NY 14202 USA • Tel (800) 274-5487