NATtrol™ MTB Verification Panel

Catalog Number:
NATMTBP-C

PRODUCT DESCRIPTION:

NATtrol™ MTB Verification Panel* (qualitative) is formulated with purified, intact bacterial cells. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATMTBP-C contains 5 x 0.6 mL vials of bacterial NATtrol™ and 6 x 1.6 mL vials of negative (matrix only) as listed in Table 1. The panel members are supplied in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ MTB Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial nucleic acids (from organisms listed in Table 1). NATtrol™ MTB Verification Panel 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™ MTB Verification 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**
- 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:

- Qualitative results are shown in Table 1 below.
- Each laboratory must evaluate the product and establish their own acceptance criteria.
- The table shown below is for informational purposes only.

TABLE 1: PANEL MEMBERS

Panel Member	Strain	Expected Results
M. tuberculosis	H37Ra-1	MTB Detected Rif Resistance Not Detected
M. tuberculosis	Rifampin resistant	MTB Detected Rif Resistance Detected
M. avium	Serotype 2	MTB Not Detected
M. bovis	Z321	MTB Detected Rif Resistance Not Detected
M. intracellulare	Z310	MTB Not Detected
Negative	N/A	MTB Not Detected

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

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