

PRODUCT DESCRIPTION:

NATtrol™ MTB Verification Panel (P/N NATMTBP-C)* is formulated with purified, intact bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. NATMTBP-C panel contains 5 x 0.6 mL vials each containing bacterial NATtrol™ targets listed in the Expected Results table and 6 x 1.6 mL vials of the Negative Matrix. The panel members 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™ MTB Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial nucleic acids. NATMTBP-C can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATMTBP-C 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 each member in the panel. The inactivation was verified by the absence of bacterial growth in validated growth 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 NATMTBP-C 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™ MTB Verification Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH Xpert® MTB/RIF ASSAY:

- Vortex or shake NATtrol™ sample vigorously for 5-10 seconds, and tap down vial.
- Set up sterile, plastic conical test tubes in a rack for two tests per panel member. Label test tubes with appropriate panel member ID.
- Add 750µL of the Negative Matrix to each test tube, ensuring that bubbles are minimized by pipetting slowly.
- Add 250µL of the panel member to the tube containing the Negative Matrix with the corresponding labeling; final volume is 1.0mL.
- Add 2mL of Sample Reagent to each test tube and mix by inverting 10 times.
- Incubate for 15 minutes at 20-30°C, mixing a second time halfway through the incubation by inverting 10 times.
- Using supplied pipette, draw up to the line and slowly add to Xpert® MTB/RIF cartridge sample chamber.
- Close cartridge lid firmly and follow manufacturer's instructions.

For all other assays follow manufacturer's Instructions.




EXPECTED RESULTS:

Panel Member	Strain	Expected Result
<i>M. tuberculosis</i>	H37Ra-1	MTB DETECTED; Rif Resistance NOT DETECTED
<i>M. tuberculosis</i>	Rifampin resistant	MTB DETECTED; Rif Resistance DETECTED
<i>M. avium</i>	Serotype 2	MTB NOT DETECTED
<i>M. bovis</i>	Z321	MTB DETECTED; Rif Resistance NOT DETECTED
<i>M. intracellulare</i>	Z310	MTB NOT DETECTED
Negative Matrix	NA	MTB NOT DETECTED

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
	Biological Risk		

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