NATtrol™ MERS-*S. cerevisiae* Recombinant

Catalog Number: NATCOV(MR)-BIO

PRODUCT DESCRIPTION:

NATtrol™ MERS-*S. cerevisiae* Recombinant (NATCOV(MR)-BIO)***** is formulated with purified, intact yeast cells that have been chemically modified to render them non-infectious and refrigerator stable. Each vial contains 0.6 mL of NATtrol™ Middle East Respiratory Syndrome-Coronavirus recombinant sequence in *S. cerevisiae*; the MERS specific sequence is less than 500 bp and represents a small, non-infectious portion of the virus. NATCOV(MR)-BIO is 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™ MERS-*S. cerevisiae* Recombinant is designed to evaluate the performance of nucleic acid tests for determination of the presence of MERS-Coronavirus RNA. NATCOV(MR)-BIO can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATCOV(MR)-BIO contains intact yeast cells 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 MERS-*S. cerevisiae* Recombinant stock used to formulate this product. 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 NATCOV(MR)-BIO contains inactivated yeast cells, 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™ MERS-*S. cerevisiae* Recombinant should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- This product has been tested in conjunction with NATRVP2-BIO verification panel using the BioFire Diagnostics FilmArray® Respiratory Panel 2 (RP2) assay and provides the expected result for Middle East Respiratory Syndrome Coronavirus. Follow assay manufacturer recommendations for use of the verification panel and NATCOV(MR)-BIO.
- Extract Nucleic Acids prior to use in assays that are not sample to result.

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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