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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NATtrol™ Respiratory Verification Panel 2.1

Catalog Number: NATRVP2.1-BIO

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Verification Panel 2.1* (qualitative) is formulated with purified, intact bacterial cells and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATRVP2.1-BIO contains 23 x 0.6 mL vials of bacterial and viral NATtrol™ and 1 x 0.6 mL 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™ Respiratory Verification Panel 2.1 is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial and viral nucleic acids (from organisms listed in Table 1.) NATRVP2.1-BIO enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, and can provide assistance in identifying random or systemic error.

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™ Respiratory Verification Panel 2.1 should be stored at 2-8°C.

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:

- This panel has been tested with the BioFire® Respiratory Panel 2.1 (RP2.1) assay and provides all expected results for the panel members listed in Table 1. This panel has also been tested on the BioFire® Respiratory Panel 2 (RP2) and provides all expected results.
- 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
Adenovirus 1	N/A
Adenovirus 3	N/A
Adenovirus 31	N/A
B. parapertussis	A747
B. pertussis	A639
C. pneumoniae	CWL-029
Coronavirus 229E	N/A
Coronavirus HKU-1	Recombinant[1]
Coronavirus NL63	N/A
Coronavirus OC43	N/A
Influenza A H1N1pdm	A/NY/02/09[2]
Influenza AH1	A/New Caledonia/20/99
Influenza AH3	A/Brisbane/10/07
Influenza B	B/Florida/02/06
M. pneumoniae	M129
Metapneumovirus 8[3]	Peru6-2003
Parainfluenza 1	N/A
Parainfluenza 2	N/A
Parainfluenza 3	N/A
Parainfluenza 4	N/A
Rhinovirus 1A	N/A
RSV A	N/A
SARS-CoV-2	USA-WA1/2020
Negative Control	N/A

1-This analyte only contains a short sequence of the viral genome therefore each laboratory must evaluate performance in their assay.
2-Please note that although similar in nomenclature, **this is a 2009 H1N1 pandemic Influenza strain** and does NOT correlate with the seasonal 2009 Influenza strains found in the Fludb.org database. For reference, the NCBI Taxon IDs for the seasonal Influenza strains listed in the Fludb.org database are: A/New York/01/2009 (H1N1) - 666252; B/New York/01/2009 - 664512; A/New York/02/2009 (H1N1) - 666298; and A/New York/03/2009 (H3N2) - 659637.
3-This product is sold by ZeptoMetrix Corporation under license from Vironovative B. V. under patent applications, including U.S. Patent Applications 10/371,099 and 10/371,12 and any patents that issue from applications related to PCT/NL02/00040 and PCT/US03/05271.

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