NATtrol™ Respiratory Verification Panel 2

Catalog Number: NATRVP2-BIO

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Verification Panel 2 (NATRVP2-BIO)* is formulated with purified, intact virus particles and bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. NATRVP2-BIO panel contains 23 x 0.6 mL vials each containing viral and bacterial NATtrol™ targets listed in Table 1. The panel 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™ Respiratory Verification Panel 2 is designed to evaluate the performance of nucleic acid tests for determination of the presence of viral and bacterial nucleic acids. NATRVP2-BIO can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATRVP2-BIO 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 viral and bacterial growth in validated tissue culture based infectivity 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 NATRVP2-BIO 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™ Respiratory Verification Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- This panel has been tested with the BioFire Diagnostics FilmArray® Respiratory Panel 2 (RP2) assay and provides all expected results for the panel members listed in Table 1. Follow Assay manufacturer recommendations for use of this verification panel.
- Extract Nucleic Acids prior to use in assays that are not sample to result.

Table 1: PANEL MEMBERS

Panel Member	Strain
Influenza A H1N1	A/New Caledonia/20/99
Influenza A H3	A/Brisbane/10/07
Influenza A 2009 H1N1pdm	A/NY/02/09**
Influenza B	B/Florida/02/06
Metapneumovirus 8***	Peru6-2003
Respiratory Syncytial virus A	N/A
Rhinovirus 1A	N/A
Parainfluenza virus Type 1	N/A
Parainfluenza virus Type 2	N/A
Parainfluenza virus Type 3	N/A
Parainfluenza virus Type 4	N/A
Adenovirus Type 3	N/A
Coronavirus NL63	N/A
Coronavirus 229E	N/A
Coronavirus OC43	N/A
Coronavirus HKU-1	N/A
M. pneumoniae	M129
C. pneumoniae	CWL-029
B. pertussis	A639
Adenovirus Type 31	N/A
Adenovirus Type 1	N/A
B. parapertussis	A747
Negative	NA

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.

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.

*** **"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."**

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
RUO	For Research Use Only		Biological Risk

ZeptoMetrix Corporation
878 Main Street
Buffalo, NY 14202
800-274-5487
www.zeptometrix.com