NATtrol™ Respiratory Verification Panel

Catalog Number: NATRVP-QIA

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Verification Panel (NATRVP-QIA)* is formulated with purified, intact virus particles and bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. NATRVP-QIA panel contains 20 x 0.25 mL vials each containing viral and bacterial NATtrol™ targets listed in Table 1. The panel members are supplied in a proprietary purified protein matrix.

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

INTENDED USE:

- NATtrol™ Respiratory Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of viral and bacterial nucleic acids. NATRVP-QIA can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATRVP-QIA contains intact organisms and should be run in a manner similar to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on the master stocks used to formulate each member in the panel. The inactivation was verified by the absence of growth in standard microbiological 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 NATRVP-QIA 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 QIAstat-Dx Respiratory Panel (RP) 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
Adenovirus Type 3	N/A
B. pertussis	A639
C. pneumoniae	CWL-029
Coronavirus 229E	N/A
Coronavirus HKU-1	Recombinant
Coronavirus NL63	N/A
Coronavirus OC43	N/A
Influenza A 2009 H1N1pdm	A/NY/02/09**
Influenza A H1N1	A/New Caledonia/20/99
Influenza A H3N2	A/Brisbane/10/07
Influenza B	B/Panama/45/90
M. pneumoniae	M129
Metapneumovirus 8***	Peru6-2003
Parainfluenza virus Type 1	N/A
Parainfluenza virus Type 2	N/A
Parainfluenza virus Type 3	N/A
Parainfluenza virus Type 4	N/A
Rhinovirus 1A	N/A
RSV A	N/A
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

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