NATtrol™ Pneumonia Verification Panels

Catalog Number: NATPPQ-BIO
NATPPA-BIO

PRODUCT DESCRIPTION:

NATtrol™ Pneumonia Verification Panels: NATtrol™ Pneumonia Panel – Quantifiable Bacteria (NATPPQ-BIO)* and NATtrol™ Pneumonia Panel – Atypical Bacteria & Viruses (NATPPA-BIO) are formulated with purified, intact virus particles and bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. NATPPQ-BIO panel contains 17 x 0.2 mL vials of bacterial NATtrol™ and 3 x 1.2 mL vials of Negative Control as listed in **Table 1**. NATPPA-BIO panel contains 12 x 0.2mL vials of viral and bacterial NATtrol™ and 2 x 1.2mL vials of Negative Control as listed in **Table 2**. The panels are supplied in a purified protein matrix that mimic the composition of a true clinical specimen.

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

INTENDED USE:

- NATtrol™ Pneumonia Verification Panels are designed to evaluate the performance of nucleic acid tests for determination of the presence of viral and bacterial nucleic acids. NATPPQ-BIO and NATPPA-BIO can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATPPQ-BIO and NATPPA-BIO contain 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 the stocks used to formulate each member in the panels. The inactivation was verified by the absence of viral and bacterial 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 NATPPQ-BIO and NATPPA-BIO contain inactivated organisms, they 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™ Pneumonia Verification Panels should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- This panel has been tested with the BioFire Diagnostics FilmArray® Pneumonia Panel assay and provides all expected results for the panel members listed in Tables 1 and 2. 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: NATPPQ-BIO PANEL MEMBERS

Panel Member	Strain
A. baumannii	307-0294
E. cloacae	Z101
E. coli	Z297
H. influenzae	MinnA
K. aerogenes	Z052
K. oxytoca	Z115
K. pneumoniae	KPC2
K. pneumoniae	Z138; OXA-48
K. pneumoniae	Z460; NDM-1
M. catarrhalis	Ne 11
P. aeruginosa	Z139, VIM-1
P. mirabilis	Z050
S. agalactiae	Z019
S. aureus	MRSA, COL
S. marcescens	Z053
S. pneumoniae	Z022
S. pyogenes	Z018
Negative	NA

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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Table 2: NATPPA-BIO PANEL MEMBERS

Panel Member	Strain
Adenovirus Type 3	N/A
Adenovirus Type 31	N/A
C. pneumoniae	CWL-029
Coronavirus NL63	N/A
Influenza A H3	A/Brisbane/10/07
Influenza B	B/Florida/02/06
L. pneumophila	Philadelphia
M. pneumoniae	M129
Metapneumovirus 8**	Peru6-2003
Parainfluenza virus Type 1	N/A
Rhinovirus 1A	N/A
RSV A2	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.

** **"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."**