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 proprietary matrix.

*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 (from organisms listed in Table 1). NATPPQ-BIO and NATPPA-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™ Pneumonia Verification Panels should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix vial vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

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:

- Each laboratory must evaluate the product and establish their own acceptance criteria.
- This panel has been tested with the BioFire® Pneumonia Panel assay and provides all expected results for the panel members listed in Table 1.
- The tables shown below are for informational purposes only.

Table 1. Panel Members

[1]This strain is sourced and used under license from the National Collection of Type Cultures (NCTC®), Public Health England.
[2] This product is sold by ZeptoMetrix 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.

NATPPQ-BIO		NATPPA-BIO	
Panel Member	**Strain**	**Panel Member**	**Strain**
A. baumannii	307-0294	Adenovirus Type 3	N/A
E. cloacae	Z101	Adenovirus Type 31	N/A
E. coli	Z297; IMP[1]	*C.pneumoniae*	CWL-029
H. influenzae	MinnA	Coronavirus NL63	N/A
K. aerogenes	Z052	Influenza A H3	A/Brisbane/10/07
K. oxytoca	Z115	Influenza B	B/Florida/02/06
K.pneumoniae	KPC2	*L.pneumophila*	Philadelphia
K.pneumoniae	Z138; OXA-48; CTX-M	*M.pneumoniae*	M129
K.pneumoniae	Z460; NDM-1[1]	Metapneumovirus 8	Peru6-2003[2]
M.catarrhalis	Ne 11	Parainfluenza Virus Type 1	N/A
P.aeruginosa	Z139; VIM-1	Rhinovirus 1A	N/A
P.mirabilis	Z050	RSV A2	N/A
S.agalactiae	Z019	Negative	N/A
S.aureus	MRSA; COL		
S.marcescens	Z053		
S.pneumoniae	Z022		
S.pyogenes	Z018		
Negative	N/A		

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REF	Catalog Number		Temperature Limitation
LOT	Batch Code		Expiration Date
RUO	For Research Use Only		Biological Risk
	Manufacturer		

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