ZeptoMetrix® 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 viral 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 0.2 mL vials of viral and bacterial NATtrol[™] and 2 x 1.2 mL vials of Negative Control as listed in Table 1. The panel members are supplied in proprietary matrix.

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

INTENDED USE:

NATtrol™ Pneumonia Verification Panels can be used to develop procedures for verification of performance of molecular assays that detect the presence of bacterial and viral nucleic acids (from organisms listed in Table 1). The panel can also be used for training and evaluation of operator proficiency.

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 nonreactive 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:

ZMC-PI-0041 Revision: 04

Effective Date: 04/17/2024

- 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**
- Use 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 performance 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.

Table 1. Panel Members

S. pyogenes

Negative

NATPPQ-BIO		ΝΑΤΡΡΑ-ΒΙΟ	
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 A	N/A
S. agalactiae	Z019	Negative	N/A
S. aureus	MRSA; COL		
S. marcescens	Z053		
S. pneumoniae	Z022		

¹This strain is sourced and used under license from the National Collection of Type Cultures (NCTC®), Public Health England.

Z018

N/A

²This 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.

REF	Catalog Number	X	Temperature Limitation
LOT	Batch Code	R	Expiration Date
RUO	For Research Use Only	8	Biological Risk
	Manufacturer		

PCA# 24-167 Page 1 of 1

www.ZeptoMetrix.com

ZeptoMetrix LLC • 878 Main Street, Buffalo, NY 14202 USA • Tel (800) 274-5487

This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.