

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 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). NATtrol™ Pneumonia Verification Panels can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.

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.








Table 1. Panel Members

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

¹This 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.

ZMC-PI-0041
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	Catalog Number		Temperature Limitation
	Batch Code		Expiration Date
	For Research Use Only		Biological Risk
	Manufacturer		

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