

NATtrol™ Respiratory Pathogen Panel-1

Catalog Number: NATRPP-1

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Pathogen Panel-1 (NATRPP-1)* is formulated with purified, intact virus particles and bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. NATRPP-1 contains a total of 6 x 0.25 mL vials: 5 vials of the viral/bacterial NATtrol™ targets (1 vial of each pool) and 1 vial of the Negative as listed in Table 1. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

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

INTENDED USE:

- NATtrol™ RPP-1 Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of viral and bacterial nucleic acids. NATRPP-1 can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATRPP-1 contains 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 viral and bacterial stocks used to formulate panel members. 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 NATRPP-1 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™ RPP-1 Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

 Extract Nucleic Acids prior to use in downstream assays.
Note: Please review specific manufacturer instructions or recommendations with regards to addition of internal/process control prior to nucleic acid extraction.

Table 1: PANEL MEMBERS

Panel Member (Strain)	Pool 1	Pool 2	Pool 3	Pool 4	Pool 5	Negative
Influenza A H1N1 (A/NY/02/09)	✓					
Parainfluenza Type 4A	✓					
Parainfluenza Type 4B	✓					
Rhinovirus (1A)	✓					
Adenovirus Type 3	✓					
Influenza A H1 (A/New Caledonia/20/99)		✓				
Respiratory Syncytial Virus A		✓				
Parainfluenza Type 1		✓				
Coronavirus NL63		✓				
Mycoplasma pneumoniae (M129)		✓				
Influenza A H3 (A/Brisbane/10/07)			✓			
Respiratory Syncytial Virus B (CH93(18)-18)			✓			
Coronavirus OC43			✓			
Coronavirus HKU-1			✓			
Influenza B (B/Florida/02/06)				✓		
Parainfluenza Type 3				✓		
Human Metapneumovirus (Peru6-2003)**				✓		
Legionella pneumophila (Philadelphia)				✓		
Parainfluenza Type 2					✓	
Coronavirus 229E					✓	
Human Bocavirus					√	
Chlamydophila pneumoniae (CWL-029)					✓	
Negative						✓

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.

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

REF	Catalog Number	1	Temperature Limitation
LOT	Lot Number	\geq	Expiration Date
RUO	For Research Use Only	\$€	Biological Risk

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