ZeptoMetrix®

NATtrol™ Respiratory Verification Panel

Catalog Number:
NATRVP-GMK

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Verification Panel (NATRVP-GMK)* is formulated with purified, intact virus particles and bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. NATRVP-GMK contains a total of 20 x 0.2 mL vials – 4 vials each of 5 pools containing members 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™ Respiratory Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of viral and bacterial nucleic acids. NATRVP-GMK can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATRVP-GMK 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 NATRVP-GMK 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™ Respiratory Verification Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- This panel has been tested with the Genmark Diagnostics ePlex® Respiratory Pathogen (RP) Panel assay and provides all expected results for the panel members listed in Table 1 (Note: some targets on this panel are only available on the ePlex RP Panel sold outside the US). Follow all manufacturer instructions for use of the ePlex RP Panel.
- Extract Nucleic Acids prior to use in assays that are not sample to result.

Table 1: PANEL MEMBERS

Panel Member (Strain)	Pool 1	Pool 2	Pool 3	Pool 4	Pool 5
Adenovirus Type 3	✓				
Coronavirus OC43	✓				
Human Metapneumovirus (Peru6-2003)**	✓				
Parainfluenza Type 2	✓				
B. pertussis (A639)	✓				
Coronavirus NL63		✓			
Bocavirus-Lambda (recombinant, Isolate 2)		✓			
Influenza A H1 (A/New Caledonia/20/99)		✓			
Parainfluenza Type 3		✓			
Coronavirus 229E			✓		
Rhinovirus (1A)			✓		
Influenza A H3 (A/Brisbane/10/07)			✓		
C. pneumoniae (CWL-029)			✓		
Influenza B (B/Florida/02/06)				✓	
Parainfluenza Type 4A				✓	
Respiratory Syncytial Virus B (CH93(18)-18)				✓	
M. pneumoniae (M129)				✓	
Coronavirus HKU-1 (recombinant)				✓	
Influenza A H1N1 (A/NY/02/09)					✓
Parainfluenza Type 1					✓
Respiratory Syncytial Virus A (2006 Isolate)					✓
L. pneumophila (Philadelphia)					✓

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.

ePlex is a registered trademark of GenMark Diagnostics, Inc.

****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.**

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

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