

ZeptoMetrix[®]

NATtrol™ Respiratory Verification Panel

Catalog Number:
NATRVP-GMK

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Verification Panel* (qualitative) is formulated with purified, intact bacterial cells and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATRVP-GMK contains 20 (4 of each pool) x 0.2 mL vials of bacterial and/or viral NATtrol™ as listed in Table 1. The panel members are supplied in a proprietary matrix.

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

INTENDED USE:

NATtrol™ Respiratory Verification Panel 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 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™ Respiratory Verification Panel 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**
- 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.

TABLE 1: PANEL MEMBERS








Pool	Panel Member	Strain
1	Adenovirus Type 3	N/A
	Coronavirus OC43	N/A
	Human Metapneumovirus	Peru6-2003 ¹
	Parainfluenza Type 2	N/A
	<i>B. pertussis</i>	A639
2	Coronavirus NL63	N/A
	Bocavirus-Lambda (recombinant, Isolate 2) ²	N/A
	Influenza A H1N1	A/New Caledonia/20/99
	Parainfluenza Type 3	N/A
3	Coronavirus 229E	N/A
	Rhinovirus	1A
	Influenza A H3N2	A/Brisbane/10/07
	<i>C. pneumoniae</i>	CWL-029
4	Influenza B	B/Florida/02/06
	Parainfluenza Type 4A	N/A
	Respiratory Syncytial Virus B	CH93(18)-18
	<i>M. pneumoniae</i>	M129
5	Coronavirus HKU-1 (recombinant) ²	N/A
	Influenza A H1N1pdm	A/NY/02/09 ³
	Parainfluenza Type 1	N/A
	Respiratory Syncytial Virus A	N/A
	<i>L. pneumophila</i>	Philadelphia

1-“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.”

2-This analyte only contains a short sequence of the genome therefore each laboratory must evaluate performance in their assay.

3-Please note that although similar in nomenclature, this is a 2009 H1N1 pandemic Influenza strain and does NOT correlate with the seasonal 2009 Influenza strains found in the Fludb.org database. For reference, the NCBI Taxon IDs for the seasonal Influenza strains listed in the Fludb.org database are: A/New York/01/2009 (H1N1) - 666252; B/New York/01/2009 - 664512; A/New York/02/2009 (H1N1) - 666298; and A/New York/03/2009 (H3N2) - 659637.

PINATRVP-GMK
Revision: 06
Effective Date: 04/17/2024

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

PCA# 24-167
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