ZeptoMetrix®

Catalog Number:
NATRVP-8C

NATtrol™ Respiratory Verification Panel

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Verification Panel (NATRVP-8C) contains purified, intact bacteria and viruses that have been chemically modified to render them non-infectious and refrigerator stable. The panel members are supplied in a proprietary matrix. The negative control is formulated in the absence of any microorganisms and contains proprietary matrix only.

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 bacteria and viruses listed in **Table 1**). The panel can also be used for training and evaluation of operator proficiency.

MATERIALS SUPPLIED:

Table 1

Component	Organism/Virus
2 x 1.8 mL RVP Pool 1	*Bordetella parapertussis*
	Chlamydophila pneumoniae (IOL-207)
	Influenza A H3N2 (Brisbane/10/07)
	Parainfluenza 3
	RSV A
2 x 1.8 mL RVP Pool 2	Adenovirus 31
	Coronavirus OC43
	Influenza A H1N1pdm[1] (NY/02/09)
	Human Metapneumovirus[2] (Peru6-2003)
	Human Rhinovirus
2 x 1.8 mL RVP Pool 3	*Bordetella pertussis*
	Influenza B (Florida/02/06)
	Mycoplasma pneumoniae (M129)
	SARS-CoV-2[3]
2 x 1.8 mL Negative Control	Matrix

[1]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.

[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.

[3]This reagent was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate USA-WA1/2020, NR-52281.

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

NATtrol™ Respiratory Verification Panel

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on bacteria and virus stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated bacteria and viruses 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 has 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 meets 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 postmortem 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:

- Store at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tube 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.
- Each vial is intended for single use.

LIMITATIONS:

- **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:

NATtrol™ Respiratory Verification Panel does not have assigned analyte values or ranges. Each laboratory must evaluate the panel and establish their own performance criteria using their specific assay.

Symbols used in the labeling of this product:

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

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