ZeptoMetrix®

Catalog Number:
NATRSPPOS-8C-IVD

NATtrol™ Respiratory Positive Control

IVD

INTENDED USE:

NATtrol™ Respiratory Positive Control (NATRSPPOS-8C-IVD) is a qualitative *in vitro* diagnostic external control intended to evaluate test performance of molecular assays which detect nucleic acids from the microorganisms and viruses listed in **Table 1**.

SUMMARY AND EXPLANATION:

The control should be used according to the assay manufacturer's instructions. The routine use of external controls enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, the effect of adverse environmental conditions, and can aid in the identification of random or systematic errors.

PRINCIPLE:

NATtrol™ Respiratory Positive Control contains purified, intact microorganisms and viruses that have been chemically modified to render them non-infectious and refrigerator stable. The control is formulated in a proprietary matrix. NATtrol™ Respiratory Positive Control is a full process control designed to monitor the steps of extraction, amplification, and detection in nucleic acid testing procedures.

MATERIALS SUPPLIED:

Table 1

Component	Organism/Virus	Component	Organism/Virus
2 x 0.5 mL RP Mix 1	*Chlamydophila pneumoniae* (IOL-207)	2 x 0.5 mL RP Mix 2	Coronavirus (229E)
	Coronavirus (NL63)		Influenza A H1N1pdm (NY/02/09)[2]
	Influenza A H3N2 (Brisbane/10/07)		Influenza B (Florida/02/06)
	Parainfluenza Type 1		Parainfluenza Type 2
	RSV A		RSV B (CH93(18)-18)
	SARS-CoV-2[1]		
2 x 0.5 mL RP Mix 3	Adenovirus Type 31	2 x 0.5 mL RP Mix 4	*Bordetella parapertussis* (A747)
	Coronavirus (HKU1)[3]		*Bordetella pertussis* (A639)
	Human Metapneumovirus 8 (Peru6-2003)[4]		Coronavirus (OC43)
	Parainfluenza Type 3		*Mycoplasma pneumoniae* (M129)
	Rhinovirus Type 1A		Parainfluenza Type 4

[1]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.

[2]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.

[3]This control member contains *Escherichia coli* harboring a plasmid containing a short sequence of the Coronavirus HKU1 viral genome, therefore, each laboratory must evaluate performance in their assay.

[4]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.

ADDITIONAL EXTERNAL CONTROL (sold separately):

- NATRSPNEG-8C-IVD (8 x 0.5 mL) NATtrol™ Respiratory Negative Control

www.ZeptoMetrix.com
ZeptoMetrix LLC • 878 Main Street, Buffalo, NY 14202 • Tel (800) 274-5487
This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

NATtrol™ Respiratory Positive Control

IVD

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism and virus stocks used to formulate the control. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated microorganisms 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:

- NATtrol™ Respiratory Positive Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix each vial vigorously for 5 seconds.
- Process according to the assay manufacturer's instructions.
- Each vial is intended for single use.

LIMITATIONS:

- For *In vitro* Diagnostic Use.
- Intended for professional use only.
- 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 device.

EXPECTED RESULTS:

NATtrol™ Respiratory Positive Control is an unassayed qualitative control and does not have assigned analyte values or ranges. Each laboratory must evaluate the control and establish their own performance criteria.

Symbols used in the labeling of this product:

	Manufacturer		**Temperature Limitation**
IVD	***In vitro* Diagnostic Use**		**Expiration Date**
REF	**Catalog Number**		**Biological Risk**
LOT	**Batch Code**		**Consult Instructions for Use**

www.ZeptoMetrix.com
ZeptoMetrix LLC • 878 Main Street, Buffalo, NY 14202 • Tel (800) 274-5487
This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.