NATtrol™ RP Controls

Catalog Number: NATRPC-NNS

PRODUCT DESCRIPTION:

NATtrol™ RP Controls (NATRPC-NNS)* are formulated with purified, intact bacterial cells and viral particles that have been chemically modified to render them non-infectious and refrigerator stable. NATRPC-NNS contains 12 x 0.25 mL vials of bacterial/viral NATtrol™ targets listed in Table 1: 6 vials of RP Control 1 and 6 vials of RP Control 2.

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

INTENDED USE:

- NATtrol™ RP Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial and viral nucleic acids. NATRPC-NNS can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATRPC-NNS 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 bacterial and viral stocks used to formulate controls. The inactivation was verified by the absence of bacterial/viral growth in a validated growth protocol.
- 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 from 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 NATRPC-NNS 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™ RP Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH Verigene® RP *Flex* Assay:

- Prepare cartridge and sample reagents following manufacturer's instructions.
- Vortex NATtrol™ sample for 5-10s.
- Add 200µl of sample into Extraction Tray Sample Loading Well.
- Follow manufacturer's instructions

For other assays follow manufacturer's instructions.

In highly multiplexed assays, false positives have been reported. Please refer to the test manufacturer for guidance on molecular workflow practices

Table 1: Verigene RP *Flex* Assay Expected Results:

Organism	Strain	RP Control 1	RP Control 2
Influenza B	B/Florida/02/06	Influenza B Detected	Not Detected
RSV A	N/A	RSV A Detected	Not Detected
RSV B	CH93(18)-18	RSV B Detected	Not Detected
Parainfluenza 1	N/A	Parainfluenza 1 Detected	Not Detected
Parainfluenza 2	N/A	Parainfluenza 2 Detected	Not Detected
hMPV-8**	Paru6-2003	hMPV Detected	Not Detected
Adenovirus 3	N/A	Adenovirus Detected	Not Detected
B.parapertussis	A747	B.parapertussis/ B.bronchiseptica Detected	Not Detected
Influenza A H1N1	A/Singapore/63/04	Not Detected	Influenza A Detected Influenza A/H1 Detected
Influenza A H3N2	A/Brisbane/10/07	Not Detected	Influenza A Detected Influenza A/H3 Detected
Parainfluenza 3	N/A	Not Detected	Parainfluenza 3 Detected
Parainfluenza 4	N/A	Not Detected	Parainfluenza 4 Detected
Rhinovirus 1A	N/A	Not Detected	Rhinovirus Detected
B. holmesii	F061	Not Detected	B. holmesii Detected
B. pertussis	A639	Not Detected	B. pertussis Detected

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.

Note: **"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		Temperature Limitation
LOT	Lot Number		Expiration Date
RUO	For Research Use Only		Biological Risk

ZeptoMetrix Corporation
878 Main Street
Buffalo, New York 14202
800-274-5487
www.zeptometrix.com