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NATtrol™ Respiratory Validation Panels



ZMC Catalog #: NATRVP-1
 ZMC Catalog #: NATRVP-2
 ZMC Catalog #: NATRVP-3

FOR RESEARCH USE ONLY
 Not for *in vitro* Diagnostic Use

Product Description

NATtrol™ Respiratory Validation Panels (NATRVP-1, NATRVP-2 and NATRVP-3) are formulated with purified intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable*. NATRVP-1 panel contains 13 x 0.20 mL vials; NATRVP-2 panel contains 16 X 0.20 mL vials and NATRVP-3 panel contains 17 X 0.20 mL of the viral targets listed in Table 1. These controls are supplied in a purified serum protein matrix that mimics the composition of a true clinical specimen. Each panel member is tested in virus specific real-time PCR assays.

*NATtrol™ Patents Pending.

Intended Use

- The NATtrol™ Respiratory Validation Panels (NATRVP-1, NATRVP-2 & NATRVP-3) are designed to evaluate the recovery, accuracy and sensitivity of nucleic acid tests (NAT) for the determination of respiratory virus nucleic acids. NATRVP can also be used for the validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATRVP-1, NATRVP-2 and NATRVP-3 contain intact organisms and should be run in a manner identical to that used for clinical specimens.
- **All panel members must be extracted prior to amplification.**

Virus Target	NATRVP-1	NATRVP-2	NATRVP-3
Negative	√	√	√
Influenza A H1	√	√	√
Influenza A H3	√	√	√
Influenza B	√	√	√
RSV A	√	√	√
RSV B	√	√	√
Parainfluenza 1	√	√	√
Parainfluenza 2	√	√	√
Parainfluenza 3	√	√	√
Adenovirus 3	√	√	√
Enterovirus	√	√	√
Rhinovirus	√	√	√
Metapneumovirus *	√	√	√
Coronavirus 229E		√	√
Coronavirus OC43		√	√
Coronavirus SARS		√	√
Inf. A H1N1 (2009)			√

Table 1: Viral targets in NATRVP-1, NATRVP-2 and NATRVP-3 panels.

Etiologic Status/Biohazard Testing

- NATtrol™ inactivation was carried out on each viral target in the panel. The inactivation was measured by following the absence of viral growth in validated tissue culture based infectivity assays.
- The purified serum protein matrix was sourced from licensed U.S. blood banks and screened negative for HIV 1&2 Ab, HBsAg, HTLV I&II Ab, HCV Ab, HIV RNA, HBV DNA and HCV RNA using FDA cleared kits at the individual donor level.

DO NOT USE IN HUMANS OR AS A CLINICAL DIAGNOSTIC:

These products are intended for research, product development or manufacturing use only. 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.

Precautions

- Use Universal Precautions when handling NATRVP.
- To avoid cross-contamination, use separate pipette tips for all reagents.



This product was manufactured in a facility whose Quality Management System is certified as being in compliance with ISO 9001:2008 and ISO 13485:2003 standards

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 10/371,122, and any patents that issue from applications related to PCT/NL02/00040 and PCT/US03/05271.”

ZeptoMetrix Corporation
872 Main Street
Buffalo, New York 14202
Office Phone: 716-882-0920
Fax: 716-882-0959
Customer Service: 800-274-5487
www.zeptometrix.com
E-mail: support@zeptometrix.com
custserv@zeptometrix.com

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