NATtrol™ Respiratory/Sore Throat (R/ST) Verification Panel

Catalog Number:
NATRST-BIO

INTENDED USE:

NATtrol™ Respiratory/Sore Throat (R/ST) Verification Panel (NATRST-BIO) 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.

PRODUCT DESCRIPTION:

NATtrol™ Respiratory/Sore Throat Verification Panel 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.

MATERIALS SUPPLIED:

- 25 x 0.6 mL vials (positive panel members) and 6 x 1.8 mL vials (negative control) as listed in Table 1.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on virus and microorganism stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated viruses and microorganisms and materials of human and animal origin. Safe practices suggest that the product 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/Sore Throat Verification Panel should be stored 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**
- 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.

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EXPECTED RESULTS:

The table below is for informational purposes, each laboratory must evaluate the panel and establish their own performance criteria. NATtrol™ Respiratory/Sore Throat Verification Panel is qualitative and does not have assigned analyte values or ranges.

TABLE 1: PANEL MEMBERS

Panel Member (Strain)	Panel Member (Strain)
Adenovirus Type 1	Influenza B (B/Florida/02/06)
Adenovirus Type 3	*M. pneumoniae* (M129)
Adenovirus Type 31	Metapneumovirus 8 (Peru6-2003[3])
B. parapertussis (A747)	Parainfluenza Type 1
B. pertussis (A639)	Parainfluenza Type 2
C. pneumoniae (IOL-207)	Parainfluenza Type 3
Coronavirus (229E)	Parainfluenza Type 4
Coronavirus (HKU-1) – recombinant[1]	Rhinovirus 1A
Coronavirus (NL63)	RSV A
Coronavirus (OC43)	*S. dysgalactiae*
Influenza AH1 (A/New Caledonia/20/99)	*S. pyogenes*
Influenza A H1N1pdm (A/NY/02/09[2])	SARS-Cov-2 - USA-WA1/2020[4]
Influenza AH3 (A/Brisbane/10/07)	Negative Control

[1] This analyte only contains a short sequence of the viral genome, therefore each laboratory must evaluate performance in their assay.

[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 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.

[4] 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.

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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