

## INTENDED USE:

NATtrol™ Respiratory/Sore Throat Control (NATRSTC-BIO) is a qualitative external control intended to be used with molecular assays that detect nucleic acids from the organisms listed in Table 1. The control can be used to monitor the steps of extraction, amplification, and detection, and also for training, and evaluation of operator variation.

## PRODUCT DESCRIPTION:

NATtrol™ Respiratory/Sore Throat Control contains purified, intact bacteria and viruses that have been chemically modified to render them non-infectious and refrigerator stable. The control is supplied in a proprietary matrix.

## MATERIALS SUPPLIED:

- 6 x 0.3 mL vials of R/ST Control 1 and 6 x 0.3 mL vials of R/ST Control 2. See Table 1 for control contents.

## WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on virus and microorganism stocks used to formulate the control. 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 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/Sore Throat Control 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**
- 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:**

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

**TABLE 1: Organisms/Viruses in Respiratory/Sore Throat (R/ST) Control**

R/ST Control	Organism/Virus (Strain)
R/ST Control 1	Adenovirus Type 1
	Adenovirus Type 3
	Adenovirus Type 31
	<i>C. pneumoniae</i> (IOL-207)
	Influenza AH1 (A/New Caledonia/20/99)
	Influenza A H1N1pdm (A/NY/02/09 <sup>1</sup> )
	Influenza AH3 (A/Brisbane/10/07)
	<i>M. pneumoniae</i> (M129)
	Metapneumovirus 8 (Peru6-2003 <sup>2</sup> )
	Rhinovirus 1A
	<i>S. dysgalactiae</i>
	SARS-Cov-2 - USA-WA1/2020 <sup>3</sup>
	R/ST Control 2
<i>B. pertussis</i> (A639)	
Coronavirus (229E)	
Coronavirus (HKU-1) – recombinant <sup>4</sup>	
Coronavirus (NL63)	
Coronavirus (OC43)	
Influenza B (B/Florida/02/06)	
Parainfluenza Type 1	
Parainfluenza Type 2	
Parainfluenza Type 3	
Parainfluenza Type 4	
RSV A	
<i>S. pyogenes</i>	








<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>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.

<sup>4</sup>This analyte only contains a short sequence of the viral genome therefore each laboratory must evaluate performance in their assay.

**Symbols used in the labeling of this product:**

	Manufacturer		Temperature Limitation
	For Research Use Only		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		