

NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls

PRODUCT DESCRIPTION:

NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls* (qualitative) is formulated with purified, intact bacterial cells and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATRPC2.1-BIO contains 6 x 0.3 mL vials of RP2.1 Control 1 and 6 x 0.3 mL of RP2.1 Control 2. See Table 1 for control contents. The controls are supplied in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ RP2.1 Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial and viral nucleic acids (from organisms/viruses listed in Table 1). NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism/virus stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This panel contains inactivated 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 have 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 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.
- 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 Panel 2.1 (RP2.1) Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix vial 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.








LIMITATION:

- 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:

- Each laboratory must evaluate the product and establish their own acceptance criteria.
- These controls have been tested with the BioFire® Respiratory Panel 2.1 (RP2.1) assay and provide all expected results for the targets listed in Table 1. These controls have also been tested on the BioFire® Respiratory Panel 2 (RP2) assay and provide all expected results.
- Table 1 is for informational purposes only.

PINATRPC2.1-BIO
Revision: 02
Effective Date: 11/2/2021

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

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NATtrol™ Respiratory Panel 2.1 (RP2.1) Controls

Catalog Number:
NATR2.1-BIO

TABLE 1: Organisms/Viruses in Respiratory Panel 2.1 (RP2.1) Controls

Organism/Virus	Strain	RP2.1 Control 1	RP2.1 Control 2
Adenovirus Type 1	N/A	Positive	Negative
Adenovirus Type 3	N/A	Positive	Negative
Adenovirus Type 31	N/A	Positive	Negative
<i>C. pneumoniae</i>	CWL-029	Positive	Negative
Influenza A 2009 H1N1pdm	A/NY/02/2009 ¹	Positive	Negative
Influenza A H3N2	A/Brisbane/10/07	Positive	Negative
Metapneumovirus 8	Peru6-2003 ²	Positive	Negative
<i>M. pneumoniae</i>	M129	Positive	Negative
Parainfluenza Type 1	N/A	Positive	Negative
Parainfluenza Type 4	N/A	Positive	Negative
Rhinovirus 1A	N/A	Positive	Negative
SARS-CoV-2	USA-WA1/2020 ³	Positive	Negative
<i>B. parapertussis</i>	A747	Negative	Positive
<i>B. pertussis</i>	A639	Negative	Positive
Coronavirus 229E	N/A	Negative	Positive
Coronavirus HKU-1	Recombinant ⁴	Negative	Positive
Coronavirus NL63	N/A	Negative	Positive
Coronavirus OC43	N/A	Negative	Positive
Influenza AH1	A/New Caledonia/20/99	Negative	Positive
Influenza B	B/Florida/02/06	Negative	Positive
Parainfluenza Type 2	N/A	Negative	Positive
Parainfluenza Type 3	N/A	Negative	Positive
RSV A	N/A	Negative	Positive








¹ 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.

² 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.

³ 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.

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

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