

NATtrol™ Flu/RSV/SARS-CoV-2 Swab Control Kit**INTENDED USE:**

NATtrol™ Flu/RSV/SARS-CoV-2 Swab Control Kit (NATFRCKL-SW-IVD) includes positive and negative qualitative *in vitro* diagnostic external controls intended to evaluate test performance of molecular assays which detect Influenza A, Influenza B, RSV B and SARS-CoV-2 nucleic acids.

SUMMARY AND EXPLANATION:

The controls should be used according to the assay manufacturer's instructions. The routine use of external controls enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, the effect of adverse environmental conditions, and can aid in the identification of random or systematic errors.

PRINCIPLE:

NATtrol™ Flu/RSV/SARS-CoV-2 Swab Control Kit contains NATtrol™ Flu/RSV/SARS-CoV-2 Positive Control Swabs and NATtrol™ Flu/RSV/SARS-CoV-2 Negative Control Swabs. NATtrol™ Flu/RSV/SARS-CoV-2 Positive Control Swab contains purified, intact viral particles that have been chemically modified to render them non-infectious and human A-549 cells. Each positive swab contains Influenza A (Brisbane/10/07), Influenza B (Florida/02/06), RSV B (CH93(18)-18), SARS-CoV-2 (USA-WA1/2020)¹ and A-549 cells. The analytes are formulated in a proprietary matrix and dried on swabs. NATtrol™ Flu/RSV/SARS-CoV-2 Negative Control Swab contains human A-549 cells formulated in a proprietary matrix and dried on swabs. NATtrol™ Flu/RSV/SARS-CoV-2 Positive and Negative Control Swabs are full process controls designed to monitor the steps of extraction, amplification, and detection in nucleic acid testing procedures.

¹This 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.

MATERIALS SUPPLIED:

- 2 x 1 NATtrol™ Flu/RSV/SARS-CoV-2 Positive Control Swab (0831166-SW)
- 2 x 1 NATtrol™ Flu/RSV/SARS-CoV-2 Negative Control Swab (0831167-SW)

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on virus stocks used to formulate the control. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated viruses and materials of human and animal origin. Safe practices suggest that these 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 were 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. These 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.

RECOMMENDED STORAGE:

- NATtrol™ Flu/RSV/SARS-CoV-2 Swab Control Kit should be stored at 2-30°C.

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INSTRUCTIONS FOR USE:

- Process according to the assay manufacturer's instructions.
- Each swab is intended for single use.

LIMITATIONS:

- For *In vitro* Diagnostic Use.
- Intended for professional use only.
- 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 device.

EXPECTED RESULTS:

NATtrol™ Flu/RSV/SARS-CoV-2 Swab Control Kit includes unassayed qualitative controls and does not have assigned analyte values or ranges. Each laboratory must evaluate these controls and establish their own performance criteria.

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	<i>In vitro</i> Diagnostic Use		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		Consult Instructions for Use