



INTENDED USE:

NATtrol™ Flu/RSV/SARS-CoV-2 Positive Control Swab (NATFRC-SW-IVD) is a qualitative *in vitro* diagnostic external control 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 control 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 Positive Control Swab contains purified, intact viral particles that have been chemically modified to render them non-infectious and human A-549 cells. Each swab contains Influenza A (A/Brisbane/10/07), Influenza B (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 Positive Control Swab is a full process control designed to monitor the steps of extraction, amplification, and detection in nucleic acid testing procedures.

MATERIALS SUPPLIED:

12 swabs

ADDITIONAL NATtrol™ Flu/RSV/SARS-CoV-2 EXTERNAL CONTROL (sold separately):

NATFRCNEG-SW-IVD (12 swabs) NATtrol™ Flu/RSV/SARS-CoV-2 Negative Control Swab.

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 the control 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.

RECOMMENDED STORAGE:

- NATtrol™ Flu/RSV/SARS-CoV-2 Positive Control Swab should be stored at 2-25°C.

INSTRUCTIONS FOR USE:

- Process according to the assay manufacturer's instructions for an unknown sample collected on a swab.
- 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:

The table below is for informational purposes, each laboratory must evaluate the control swab and establish their own performance criteria. NATtrol™ Flu/RSV/SARS-CoV-2 Positive Control Swab is an unassayed qualitative control and does not have assigned analyte values or ranges.

Catalog Number	Target	Expected Result
NATFRC-SW-IVD	Flu A	Detected
	Flu B	Detected
	RSV B	Detected
	SARS-CoV-2 ¹	Detected

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.

Symbols used in the labeling of this product:

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