

INTENDED USE:

NATtrol™ Flu/RSV/SARS-CoV-2 Negative Control Swab (NATFRCNEG-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 Negative Control Swab contains human A-549 cells. The cells are formulated in a proprietary matrix and dried on swabs. NATtrol™ Flu/RSV/SARS-CoV-2 Negative 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):

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

WARNINGS AND PRECAUTIONS:

- 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 Negative 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 Negative Control Swab is an unassayed qualitative control and does not have assigned analyte values or ranges.

Catalog Number	Target	Expected Result
NATFRCNEG-SW-IVD	Flu A	Not Detected
	Flu B	Not Detected
	RSV B	Not Detected
	SARS-CoV-2	Not Detected

Symbols used in the labeling of this product:

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