

ZeptoMetrix®

NATtrol™ Respiratory Negative Control

Catalog Number:
NATRSPNEG-8C-IVD



INTENDED USE:

NATtrol™ Respiratory Negative Control (NATRSPNEG-8C-IVD) is a qualitative *in vitro* diagnostic external control intended to evaluate test performance of molecular assays which detect nucleic acids from Adenovirus, *Bordetella pertussis*, *Bordetella parapertussis*, *Chlamydia pneumoniae*, Coronavirus, Human Metapneumovirus, Influenza A, Influenza B, *Mycoplasma pneumoniae*, Parainfluenza, Rhino-Enterovirus, RSV and SARS-CoV-2.

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 error.

PRINCIPLE:

NATtrol™ Respiratory Negative Control is formulated in the absence of any microorganisms and contains proprietary matrix only.

MATERIALS SUPPLIED:

- 8 x 0.5 mL vials

ADDITIONAL EXTERNAL CONTROL (sold separately):

- NATRSPPOS-8C-IVD (8 X 0.5 mL vials includes 2 vials of each RP Mix 1, 2, 3 and 4) NATtrol™ Respiratory Positive Control.

WARNINGS AND PRECAUTIONS:

- This control contains 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.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ Respiratory Negative Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix each vial vigorously for 5 seconds.
- Process according to the assay manufacturer's instructions.
- Each vial 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™ Respiratory Negative Control is an unassayed qualitative control and does not have assigned analyte values or ranges. Each laboratory must evaluate the control 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

PINATRSPNEG-8C-IVD
Revision: 01
Effective Date: 02/13/2026

PCA# 26-042
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ZeptoMetrix LLC • 878 Main Street, Buffalo, NY 14202 • Tel (800) 274-5487

This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.