

NATtrol™ Group A *Streptococcus* (GAS) Positive Control Swab

PRODUCT DESCRIPTION:

NATtrol™ Group A *Streptococcus* (GAS) Positive Control Swab (NATGAS-SW) contains purified, intact *Streptococcus pyogenes* that have been chemically modified to render them non-infectious. The control is formulated in a proprietary matrix and dried on swabs.

INTENDED USE:

NATtrol™ Group A *Streptococcus* (GAS) Positive Control Swab is an external run control intended to be used with molecular assays that detect nucleic acids from *Streptococcus pyogenes*. The control can be used to monitor the process steps of extraction, amplification and detection. The control can also be used for training and evaluation of operator variation.

MATERIALS SUPPLIED:

- 4 swabs

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the control. The inactivation was verified in a standard microbiological growth protocol.
- This product 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 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:

- Store at 2-30°C.

INSTRUCTIONS FOR USE:

- Process according to manufacturer's instructions for an unknown sample collected on a swab.
- Each swab is intended for single use.

LIMITATIONS:

- **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.

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EXPECTED RESULTS:

NATtrol™ Group A *Streptococcus* (GAS) Positive Control Swab 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
	For Research Use Only		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		