

NATtrol™ HPV 45 Stock

PRODUCT DESCRIPTION:

NATtrol™ HPV 45 Stock (NATHPV45-STQ) contains CERV-215 cells which contain human papillomavirus type 45 (HPV45) DNA. The cells have been chemically modified to render them refrigerator stable. The control is supplied in a proprietary matrix.

INTENDED USE:

NATtrol™ HPV 45 Stock is an external run control intended to be used with molecular assays that detect nucleic acids from HPV 45. 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:

- 1 x 1.0 mL vial

WARNINGS AND PRECAUTIONS:

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

RECOMMENDED STORAGE:

- Store at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tube vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.
- Each vial 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.

EXPECTED RESULTS:

- The target concentration value provided in Table 1 is tested by digital PCR.
- It is the responsibility of the end user to establish their own target range and limits for the control using their laboratory's procedures.

Table 1

Catalog Number	Target	Target Concentration (copies/mL)
NATHPV45-STQ	HPV45	1.0E+06 ¹

¹Based on digital PCR assay targeting E6 oncogene region.

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	For Research Use Only		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		