

ZeptoMetrix®

NATtrol™ Hepatitis C Virus Positive Control

IVD

Catalog Number:
NATHCV-6C-IVD

INTENDED USE:

NATtrol™ Hepatitis C Virus Positive Control (NATHCV-6C-IVD) is a qualitative *in vitro* diagnostic external control intended to evaluate test performance of molecular assays which detect Hepatitis C virus 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™ Hepatitis C Virus Positive Control contains purified, intact hepatitis C viral particles that have been chemically modified to render them non-infectious and refrigerator stable and human A-549 cells. The control is formulated in a proprietary matrix. NATtrol™ Hepatitis C Virus Positive Control is a full process control designed to monitor the steps of extraction, amplification, and detection in nucleic acid testing procedures.

MATERIALS SUPPLIED:

- 6 X 0.25 mL vials

ADDITIONAL NATtrol™ Hepatitis C Virus EXTERNAL CONTROL (sold separately):

- NATHCVNEG-6C-IVD (6 X 0.25 mL) NATtrol™ Hepatitis C Virus Negative Control.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on virus stocks used to formulate the control using a validated procedure.
- This product contains inactivated viruses 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.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ Hepatitis C Virus Positive 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:

The table below is for informational purposes, each laboratory must evaluate the control and establish their own performance criteria. NATtrol™ Hepatitis C Virus Positive Control is an unassayed qualitative control and does not have assigned analyte values or ranges.

Catalog Number	Target	Expected Result
NATHCV-6C-IVD	Hepatitis C virus	Detected









PINATHCV-6C-IVD
Revision: 00
Effective Date: 07/09/2024

PCA# N/A
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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

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