

NATtrol™ Hepatitis C Virus

PRODUCT DESCRIPTION:

NATtrol™ Hepatitis C Virus (NATHCV-0001, NATHCV-0002, NATHCV-0003, NATHCV-0004, and NATHCV-0005)* is formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable. Each vial contains 1.0 mL of HCV NATtrol™ at target concentrations listed in Table 1. NATHCV is supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

*Pat.: <http://www.zeptometrix.com/patent-information/>

INTENDED USE:

- NATtrol™ Hepatitis C Virus is designed to evaluate the performance of nucleic acid tests for determination of the presence of HCV RNA. NATHCV can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATHCV contains intact virus and should be run in a manner identical to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:




- NATtrol™ inactivation was carried out on the HCV stock used to formulate this product. The inactivation was verified by the absence of viral growth in validated tissue culture based infectivity assays.
- Purified protein matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from materials that have been tested and found 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 bovine based source materials used in the manufacture of this product meet 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 post mortem at the abattoir as required by the USDA.

PRECAUTIONS:

- Although NATHCV contains inactivated virus, it should be handled as if potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.

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

NATHCV-0001
 NATHCV-0002
 NATHCV-0003
 NATHCV-0004
 NATHCV-0005
 Revision: 08
 Effective Date: 04/01/2019

REF	Catalog Number		Temperature Limitation
LOT	Lot Number		Expiration Date
RUO	For Research Use Only		Biological Risk

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RECOMMENDED STORAGE:

- NATtrol™ Hepatitis C Virus should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Extract HCV RNA prior to use in downstream assays.

TABLE 1:

Catalog Number	Target Concentration** (IU/mL)
NATHCV-0001	200
NATHCV-0002	1,000
NATHCV-0003	10,000
NATHCV-0004	50,000
NATHCV-0005	100,000

**International Units were calibrated against the WHO International Standard (5th International Standard) for HCV RNA (NIBSC Code: 14/150)

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development, quality assurance or manufacturing use. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.