

Catalog Number: NATPARVO-0001 Catalog Number: NATPARVO-0002 Catalog Number: NATPARVO-0003 Catalog Number: NATPARVO-0004 Catalog Number: NATPARVO-0005

PRODUCT DESCRIPTION:

NATtrol™ Human Parvovirus (NATPARVO-0001, NATPARVO-0002, NATPARVO-0003, NATPARVO-0004, and NATPARVO-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 Parvovirus NATtrol™ at target concentrations listed in Table 1. NATPARVO 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[™] Human Parvovirus is designed to evaluate the performance of nucleic acid tests for determination of the presence of Parvovirus DNA. NATPARVO can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATPARVO 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 Parvovirus stock used to formulate this product. The inactivation was verified by the absence of viral growth of a surrogate virus 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 NATPARVO 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.

RECOMMENDED STORAGE:

NATtrol™ Human Parvovirus should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

Extract Parvovirus DNA prior to use in downstream assays.

TABLE 1:

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

^{**}Based on internal testing of the 3rd WHO International Standard for Parvovirus B19 DNA for Nucleic Acid Amplification Techniques (NAT) (NIBSC code: 12/208)

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.

ZMC-PI-0028 Revision: 10

Effective Date: 08/25/2021

REF	Catalog Number	X	Temperature Limitation
LOT	Batch Code	₽	Expiration Date
RUO	For Research Use Only	€	Biological Risk
***	Manufacturer		_