



NATtrol™ Varicella-Zoster Virus Strain: Ellen

Catalog Number: NATVZV-0001

Catalog Number: NATVZV-0002

Catalog Number: NATVZV-0003

Catalog Number: NATVZV-0004

Catalog Number: NATVZV-0005

PRODUCT DESCRIPTION:

NATtrol™ Varicella-Zoster Virus (NATVZV-0001, NATVZV-0002, NATVZV-0003, NATVZV-0004, and NATVZV-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 VZV NATtrol™ at target concentrations listed in Table 1. NATVZV 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™ Varicella-Zoster Virus is designed to evaluate the performance of nucleic acid tests for determination of the presence of VZV DNA. NATVZV can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATVZV 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 the VZV 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.

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

PINATVZV-0001
PINATVZV-0002
PINATVZV-0003
PINATVZV-0004
PINATVZV-0005
Revision: 06
Effective Date: 03/01/2019

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

PRECAUTIONS:

- Although NATVZV 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™ Varicella-Zoster Virus should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Extract VZV DNA prior to use in downstream assays.

TABLE 1:

| Catalog Number | Target Concentration (copies/mL) |
|----------------|----------------------------------|
| NATVZV-0001 | 100 |
| NATVZV-0002 | 500 |
| NATVZV-0003 | 1,000 |
| NATVZV-0004 | 10,000 |
| NATVZV-0005 | 50,000 |

CAUTION: NOT FOR 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.

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