

NATrol™ Zika Virus External Run Controls

Catalog Number: NATZIKV-ERCL

CatalogNumber NATZIKV-ERCM

PRODUCT DESCRIPTION:

NATrol™ Zika Virus External Run Controls (NATZIKV-ERCL and NATZIKV-ERCM)* are formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable. Each control pack contains 6 x 1.0 mL vials of NATrol™ Zika Virus at concentrations listed in Table 1. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

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

INTENDED USE:

- NATrol™ Zika Virus External Run Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of Zika Virus RNA. NATZIKV-ERCL and NATZIKV-ERCM can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATZIKV-ERCL and NATZIKV-ERCM contain intact virus and should be run in a manner identical to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATrol™ inactivation was carried out on the Zika Virus stock used to formulate each control pack. 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 NATZIKV-ERCL and NATZIKV-ERCM contain inactivated virus, they 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:

- NATrol™ Zika Virus External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Extract Zika Virus RNA prior to use in downstream assays.

TABLE 1:

Catalog Number	Concentration (Ct Range)**
NATZIKV-ERCL	28-31
NATZIKV-ERCM	25-28




**Cycle threshold (Ct) range based on in-house real time RT-PCR assay targeting envelope protein gene region.

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.

***Based on internal sequencing data, this Zika strain is closely related to the Uganda strain MR 766; NCBI GenBank Accession No. KU720415.

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

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

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