

ZeptoMetrix®

NATtrol™ Norovirus External Run Controls

Catalog Number:
 NATNOV-6MC
 NATNOVI-6MC
 NATNOVII-6MC
 NATROTA-6MC

PRODUCT DESCRIPTION:

NATtrol™ Norovirus External Run Controls (NATNOVI-6MC, NATNOVII-6MC, NATNOV-6MC and NATROTA-6MC)* are formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable. Each control contains 6 x 0.125 mL vials of NATtrol™ Norovirus GI, NATtrol™ Norovirus GII, a blend of NATtrol™ Norovirus GI/GII or NATtrol™ Rotavirus. These controls are supplied in proprietary matrix.

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

INTENDED USE:

- NATtrol™ Norovirus External Run Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of Norovirus nucleic acids. NATNOVI-6MC, NATNOVII-6MC, NATNOV-6MC and NATROTA-6MC enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation and can provide assistance in identifying random or systemic error.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on virus stocks used to formulate the controls. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated microorganisms 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 post mortem 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™ Norovirus External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tube vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

LIMITATION:

- FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- 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 assay.








EXPECTED RESULTS:

- Qualitative results are shown in Table 1 below.
- Each laboratory must evaluate the controls and establish their own acceptance criteria.
- The table shown below is for informational purposes only.

Table 1:

| Catalog Number | Virus | Expected Result |
|----------------|------------------------|---|
| NATNOVI-6MC | Norovirus GI | NORO GI is detected. |
| NATNOVII-6MC | Norovirus GII | NORO GII is detected. |
| NATNOV-6MC | Norovirus GI/GII | NORO GI is detected. NORO GII is detected. |
| NATROTA-6MC | Rotavirus (Strain: WA) | NORO GI is not detected. NORO GII is not detected. |

ZMC-PI-0038
 Revision: 14
 Effective Date: 07/20/2021

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|---|-----------------------|---|------------------------|
|  | Catalog Number |  | Temperature Limitation |
|  | Batch Code |  | Expiration Date |
|  | For Research Use Only |  | Biological Risk |
|  | Manufacturer | | |

PCA# 20-223
 Page 1 of 1