# NATtrol™ Norovirus External Run Controls

**Catalog Number: NATNOVI-6MC**
**Catalog Number: NATNOVII-6MC**
**Catalog Number: NATNOV-6MC**
**Catalog Number: 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 a purified protein matrix that mimics the composition of a true clinical specimen.

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

**INTENDED USE:**

- NATtrol™ Norovirus External Run Controls are full process controls 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 can also be used for quality control of clinical assays and training of laboratory personnel.
- NATNOVI-6MC, NATNOVII-6MC, NATNOV-6MC, and NATROTA-6MC contain intact virus particles and should be run in a manner similar to that used for clinical specimens.

**ETIOLOGIC STATUS/BIOHAZARD TESTING:**

- NATtrol™ inactivation was carried out on the virus stocks 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 from 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 NATtrol™ Norovirus External Run Controls contain inactivated virus particles, they should be handled as if potentially infectious.
- Use Universal Precautions when handling these products.
- To avoid cross-contamination, use separate pipette tips for all reagents.

**RECOMMENDED STORAGE:**

- NATtrol™ Norovirus External Run Controls should be stored at 2-8°C.

**INSTRUCTIONS FOR USE:**

- Shake NATtrol™ sample vigorously for 5 seconds.
- Follow the assay manufacturer's instructions for use to process the sample as a clinical sample.

**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.<br>NORO GII is detected. |
| NATROTA-6MC | Rotavirus (Strain: WA) | NORO GI is not detected.<br>NORO GII is not detected. |

**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.

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

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

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PINATNOVI-6MC
PINATNOVII-6MC
PINATNOV-6MC
PINATROTA-6MC
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