

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 identical 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 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.

PINATNOVI-6MC
PINATNOVII-6MC
PINATNOV-6MC
PINATROTA-6MC
Rev. No./Replaces: 6 / 10/2017
301-4355 Rev A

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 WITH Xpert® Norovirus ASSAY:




- Prepare cartridge and Sample Reagent vial following manufacturer's instructions.
- Vortex NATtrol™ sample for 5-10 seconds and add 50 µl into Sample Reagent vial. Mix well by vortexing for 10 seconds.
- Using a clean transfer pipette (not supplied), transfer the entire contents of the Sample Reagent to the sample chamber of the cartridge.
- Follow manufacturer's instructions.

EXPECTED RESULTS:

Catalog Number	Virus	Xpert® Norovirus Expected Result
NATNOVI-6MC	Norovirus GI	NORO GI DETECTED NORO GII NOT DETECTED
NATNOVII-6MC	Norovirus GII	NORO GI NOT DETECTED NORO GII DETECTED
NATNOV-6MC	Norovirus GI/GII	NORO GI DETECTED NORO GII DETECTED
NATROTA-6MC	Rotavirus (Strain: WA)	NORO GI NOT DETECTED NORO GII 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.

REF	Catalog Number		Temperature Limitation
LOT	Lot Number		Expiration Date
	Biological Risk		

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