

PRODUCT DESCRIPTION:

NATtrol™ GP (Gastrointestinal Pathogen) External Run Controls* are formulated with purified, intact organisms that have been chemically modified to render them non-infectious and refrigerator stable. Each control contains 0.5 mL of the NATtrol™ targets listed in Table 1. These controls are supplied in Stool Diluent that mimics the composition of a true clinical specimen. Each of the analytes listed in the table are available as individual controls.

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

INTENDED USE:

- NATtrol™ GP External Run Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of viral and bacterial nucleic acids. NATtrol™ GP External Controls can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATtrol™ GP External Run Controls contain intact organisms and should be run in a manner identical to that used for clinical specimens.




ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on each organism listed in Table 1. The inactivation was verified by the absence of viral growth in validated tissue culture based infectivity assays and absence of bacterial growth in a validated growth protocol.
- Stool Diluent used in the manufacture of this product contains stabilizers and antimicrobial agents. 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™ GP External Run Controls contain inactivated organisms, 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.

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

RECOMMENDED STORAGE:

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

INSTRUCTIONS FOR USE:

- Extract Nucleic Acids prior to use in downstream assays

Table 1: AVAILABLE ANALYTES

Catalog Number	Organism	Strain
NATADV40-GP	Adenovirus Type 40	Dugan
NATADV41-GP	Adenovirus Type 41	TAK
NATCDI-GP	<i>C.difficile</i>	NAP1
NATCJE-GP	<i>C.jejuni</i>	Clinical isolate
NATECO(933)-GP	<i>E.coli</i>	EDL933
NATECO(ETEC)-GP	<i>E.coli</i>	ETEC; ST+, LT+
NATEHI(DS4)-GP	<i>E.histolytica</i>	DS4-868
NATNOVI-GP	Norovirus GI	N/A
NATNOVII-GP	Norovirus GII	N/A
NATROTA-GP	Rotavirus	Wa
NATSSO-GP	<i>S.sonnei</i>	Z004
NATSTY-GP	<i>S.typhimurium</i>	Z005

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.

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