

NATtrol™ Gastrointestinal Verification Panel Mid

PRODUCT DESCRIPTION:

NATtrol™ Gastrointestinal Verification Panel Mid (NATGIPM-BIO) contains purified, intact viruses and microorganisms that have been chemically modified to render them non-infectious and refrigerator stable. The panel members are supplied in a proprietary matrix. The negative control is formulated in the absence of any microorganisms and contains proprietary matrix only.

INTENDED USE:

NATtrol™ Gastrointestinal Verification Panel Mid can be used to develop procedures for verification of performance of molecular assays that detect the presence of bacterial, parasitic and viral nucleic acids (from microorganisms and viruses listed in Table 1). The panel can also be used for training and evaluation of operator proficiency.

MATERIALS SUPPLIED:

- 13 x 0.25 mL vials (positive panel members) and 2 x 1.0 mL vials (negative control) as listed in Table 1.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on virus and microorganism stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated viruses and microorganisms and materials of 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 stool diluent used in the manufacture of this product contains 0.05% gentamicin sulfate and 0.125% 2-chloroacetamide.
- Heat inactivated Bovine Serum Albumin 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 postmortem 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:

- Store 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.
- Each vial is intended for single use.

LIMITATIONS:

- **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.

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EXPECTED RESULTS:








Each laboratory must evaluate the panel and establish their own performance criteria using their specific assay. NATtrol™ Gastrointestinal Verification Panel Mid does not have assigned analyte values or ranges.

TABLE 1: PANEL MEMBERS

Panel Member (Strain)
<i>Campylobacter coli</i> clinical isolate
<i>Campylobacter jejuni</i> clinical isolate
<i>Clostridium difficile</i> (NAP1)
<i>Cryptosporidium parvum</i> Iowa isolate
<i>Cyclospora cayentanensis</i> – <i>S. cerevisiae</i> recombinant ¹
<i>Escherichia coli</i> (EDL933; O157)
<i>Giardia lamblia</i> H3 isolate
Norovirus GI – recombinant ¹
Norovirus GII – recombinant ¹
<i>Salmonella enterica</i> Typhimurium
<i>Shigella sonnei</i>
<i>Vibrio cholera</i> non-toxigenic
<i>Yersinia enterocolitica</i> clinical isolate
Negative Control

¹This analyte only contains a short sequence of the genome, therefore each laboratory must evaluate performance in their assay.

Symbols used in the labeling of this product:

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