

INTENDED USE:

NATtrol™ GI Controls (NATGIC-BIO-IVD) are qualitative *in vitro* diagnostic external controls intended to evaluate test performance of molecular assays which detect nucleic acids from the microorganisms and viruses listed in **Table 1**.

SUMMARY AND EXPLANATION:

The controls should be used according to the assay manufacturer's instructions. The routine use of external controls enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, the effect of adverse environmental conditions, and can aid in the identification of random or systematic errors.

PRINCIPLE:

NATtrol™ GI Controls contain purified, intact microorganisms and viruses that have been chemically modified to render them non-infectious and refrigerator stable. The controls are formulated in a proprietary matrix. NATtrol™ GI Controls are full process controls designed to monitor the steps of extraction, amplification, and detection in nucleic acid testing procedures.

MATERIALS SUPPLIED:

Table 1

GI Control	Microorganism/Virus (Strain)
6 x 0.2 mL GI Control 1	Adenovirus Type 41 (Tak)
	<i>C. difficile</i> (NAP1)
	<i>C. parvum</i> Iowa isolate
	<i>E. coli</i> (92.0147; EAEC ¹)
	<i>E. coli</i> (EDL933; O157)
	<i>P. shigelloides</i>
	Rotavirus (Wa)
	<i>S. sonnei</i>
	Sapovirus – <i>S. cerevisiae</i> recombinant ²
	<i>V. cholera</i> non-toxigenic
	<i>Y. enterocolitica</i> clinical isolate
6 x 0.2 mL GI Control 2	Astrovirus – <i>S. cerevisiae</i> recombinant ²
	<i>C. cayetanensis</i> – <i>S. cerevisiae</i> recombinant ²
	<i>C. coli</i> clinical isolate
	<i>C. jejuni</i> clinical isolate
	<i>E. coli</i> (7.1493; O84:H28; EPEC ¹)
	<i>E. coli</i> (ETEC; ST+, LT+)
	<i>E. histolytica</i> (DS4-868)
	<i>G. lamblia</i> H3 isolate
	Norovirus GI – recombinant ²
	Norovirus GII – recombinant ²
	<i>S. enterica typhimurium</i>

¹These strains, 92.0147 and 7.1493, were supplied by Dr. Chobi DebRoy of the E. coli Reference Center, through a license with the Penn State Research Foundation.

²This analyte only contains a short sequence of the genome. Therefore, each laboratory must evaluate performance in their assay.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism and virus stocks used to formulate the controls. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated microorganisms and viruses 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 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 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.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ GI Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix each vial vigorously for 5 seconds.
- Process according to the assay manufacturer's instructions.
- Each vial is intended for single use.









LIMITATIONS:

- For In Vitro Diagnostic Use.
- Intended for professional use only.
- 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 device.

EXPECTED RESULTS:

NATtrol™ GI Controls are unassayed qualitative controls and do not have assigned analyte values or ranges. Each laboratory must evaluate the control and establish their own performance criteria.

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	In vitro Diagnostic Use		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		Consult Instructions for Use