NATtrol™ GI Verification Panel

Catalog Number:
NATGIP-QIA

PRODUCT DESCRIPTION:

NATtrol™ GI Verification Panel* is formulated with purified, intact bacterial cells, fungal cells, and viral particles. The cells and viral particles have been chemically modified to render them non-infectious and refrigerator stable. NATGIP-QIA contains 23 x 0.25 mL vials of bacterial, fungal, and viral NATtrol™ and 4 x 1.0 mL of negative control as listed in Table 1. The panel members are supplied in a proprietary matrix.

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

INTENDED USE:

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

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This panel contains inactivated microorganisms 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 Verification Panel should be stored 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.

LIMITATION:

- **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- Use in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the assay.

EXPECTED RESULTS:

- Each laboratory must evaluate the product and establish their own performance criteria.
- This panel has been tested with the QIAstat-Dx® Gastrointestinal Panel assay and provides all expected results for the panel members listed in Table 1.

TABLE 1: PANEL MEMBERS

Panel Member	Strain
Adenovirus Type 41	Tak
Astrovirus Type 8	ERE IID 2371
C. cayetanensis	recombinant
C. difficile	NAP1
C. jejuni	Z086
C. parvum	Iowa
E. coli	92.0147; EAEC**
E. coli	EDL933; O157
E. coli	7.1493; EPEC; O84:H28**
E. coli	ETEC; ST+, LT+
E. histolytica	DS4-868
G. lamblia	H3
Norovirus GI	recombinant
Norovirus GII	recombinant
P. shigelloides	Z130
Rotavirus	Wa
S. enterica typhimurium	Z005
S. sonnei	Z004
Sapovirus I, II, IV	recombinant
V. cholerae	Z133; non-toxigenic
V. parahaemolyticus	Z134
V. vulnificus	Z473
Y. enterocolitica	Clinical Isolate
Negative	N/A

****These 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.**

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

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