ZeptoMetrix®

NATtrol™ GI Panel

Catalog Number:
NATGIP-BIO

PRODUCT DESCRIPTION:

NATtrol™ GI (Gastrointestinal) Panel* (qualitative) 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-BIO contains 22 x 0.25mL vials of bacterial, fungal, and viral NATtrol™ and 4 x 0.85mL vials 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 Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial, fungal, and viral nucleic acids (from organisms listed in Table 1). NATtrol™ GI Panel can also be used for validation of clinical assays, development of diagnostic tests, and training of laboratory personnel.

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 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 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 Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix vial 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**
- 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.

EXPECTED RESULTS:

- Each laboratory must evaluate the product and establish their own acceptance criteria.
- This panel has been tested with the BioFire Diagnostics FilmArray® Gastrointestinal (GI) Panel assay and provides all expected results for the panel members listed in Table 1.
- The table shown below is for informational purposes only.

TABLE 1: PANEL MEMBERS

Panel Member	Strain	Panel Member	Strain
Adenovirus Type 41	TAK	*G. lamblia*	H3
Astrovirus	Recombinant[1]	Norovirus GI	Recombinant[1]
C. cayetanensis	Recombinant[1]	Norovirus GII	Recombinant[1]
C. coli	Clinical isolate	*P. shigelloides*	Z130
C. difficile	NAP1	Rotavirus	Wa
C. jejuni	Clinical isolate	*S. enterica typhimurium*	Z005
C. parvum	Iowa	*S. sonnei*	Z004
E. coli	7.1493; O84:H28; EPEC[2]	Sapovirus	Recombinant[1]
E. coli	92.0147; EAEC[2]	*V. cholerae*	Z133; non-toxigenic
E. coli	EDL933; O157	*Y. enterocolitica*	Clinical isolate
E. coli	ETEC; ST+, LT+	Negative	N/A
E. histolytica	DS4-868		

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

[2] These strains, 7.1493 and 92.0147, 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		

www.ZeptoMetrix.com
ZeptoMetrix LLC • 878 Main Street, Buffalo, NY 14202 USA • Tel (800) 274-5487