ZeptoMetrix®

Catalog Number:
NATGIPVK-DIA

NATtrol™ Gastrointestinal Panels Verification Kit

PRODUCT DESCRIPTION:

NATtrol™ Gastrointestinal Panels Verification Kit (NATGIPVK-DIA) includes positive and negative gastrointestinal verification panel controls. The positive controls contain purified, intact microorganisms and viruses that have been chemically modified to render them non-infectious and refrigerator stable and are formulated in a proprietary matrix. The negative control is formulated in the absence of any microorganisms or viruses and contains proprietary matrix only.

INTENDED USE:

NATtrol™ Gastrointestinal Panels Verification Kit can be used to develop procedures for verification of performance of molecular assays that detect the presence of nucleic acids from Adenovirus F40/41, Astrovirus, *Blastocystis spp*., *Campylobacter spp., Clostridioides difficile* (*tcdA*/*tcdB*), *Cryptosporidium spp., Cyclospora cayetanensis, Dientamoeba fragilis*, *Entamoeba histolytica*, Enterotoxigenic *E. coli* (ETEC) LT/ST, *Giardia lamblia,* Microsporidia, Norovirus GI/GII, *Plesiomonas shigelloides,* Rotavirus A, *Salmonella* spp., Sapovirus I/II/IV/V, Shiga-like toxin-producing *E. coli* (STEC) *stx1*, Shiga-like toxin-producing *E. coli* (STEC) *stx2*, Shigella/Enteroinvasive *E. coli* (EIEC), *Strongyloides stercoralis, Vibrio* spp., *Vibrio cholerae,* and *Yersinia enterocolitica*. The panel can also be used for training and evaluation of operator proficiency.

MATERIALS SUPPLIED:

Component	Organism/Virus	Component	Organism/Virus
3 x 0.2 mL GI Verification Panel Control 1	*Campylobacter jejuni*	3 x 0.2 mL GI Verification Panel Control 2	*Clostridium difficile* (NAP1)
	Cryptosporidium parvum (Iowa isolate)		*Escherichia coli* (ETEC; ST+, LT+)
	Escherichia coli with *Blastocystis hominis* plasmid[1]		*Escherichia coli* with Sapovirus plasmid[1]
	Norovirus GI Recombinant[2]		*Escherichia coli* with *Strongyloides stercoralis* plasmid[1]
	Rotavirus Group A (Wa)		*Giardia lamblia* (H3 isolate)
	Salmonella enterica Typhimurium		Rotavirus Group A (Wa)
	Vibrio cholerae (non-toxigenic)		*Yersinia enterocolitica* (clinical isolate)
3 x 0.2 mL GI Verification Panel Control 3	Astrovirus Type 8 (ERE IID 2371)[3]	3 x 0.2 mL GI Verification Panel Control 4	Adenovirus Type 40 (Dugan)
	Escherichia coli with *Cyclospora cayetanensis* plasmid[1]		Astrovirus Type 8 (ERE IID 2371)[3]
	Escherichia coli with *Encephalitozoon intestinalis* plasmid[1]		*Entamoeba histolytica* (DS4-868)
	Norovirus GI Recombinant[2]		*Escherichia coli* (O157:H7 EDL933)
	Plesiomonas shigelloides		*Escherichia coli* with *Dientamoeba fragilis* plasmid[1]
	Shigella sonnei		*Escherichia coli* with Sapovirus plasmid[1]
	Vibrio parahaemolyticus		
3 x 0.2 mL GI Negative Control	Matrix only		

[1]This analyte contains *Escherichia coli* harboring a plasmid containing a short sequence of the organism's genome therefore each laboratory must evaluate performance in their assay.

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

[3]This strain is sourced and used under license from the National Collection of Pathogenic Viruses (NCPV®), Public Health England.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism and virus stocks used to formulate the verification members. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated microorganisms and viruses and materials of animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.

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- 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.

EXPECTED RESULTS:

NATtrol™ Gastrointestinal Panels Verification Kit does not have assigned analyte values or ranges. Each laboratory must evaluate the product and establish their own performance criteria.

Symbols used in the labeling of this product:

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

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