

PRODUCT DESCRIPTION:

NATtrol™ EntericBio Panel* is formulated with purified, intact parasite and bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable. This panel contains 9 x 0.3 mL vials of parasite and bacterial NATtrol™ and 4 x 0.85 mL vial of Negative Control as listed in Table 1. These panels are supplied in a Stool Diluent that mimics the composition of a true clinical specimen.

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

INTENDED USE:

- NATtrol™ EntericBio Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of enteric parasite and bacterial nucleic acids. It can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- The panel contains intact organisms and should be run in a manner identical to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on the stocks used to formulate panel members. The inactivation was verified by the absence of bacterial growth in validated culture based infectivity assays.
- Stool Diluent used in the manufacture of this product contains stabilizers and antimicrobial agents. Heat inactivated bovine based source materials 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.

PRECAUTIONS:

- Although the panel contains inactivated organisms, it should be handled as if potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ EntericBio Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Please refer to test manufacturer for specific processing instructions.
- Extract Nucleic Acids prior to use in downstream assays.








Table 1: PANEL MEMBERS

Panel Member	Strain
<i>Campylobacter jejuni</i>	Clinical isolate
<i>Cryptosporidium parvum</i>	Iowa
<i>Escherichia coli</i>	EDL933; O157
<i>Entamoeba histolytica</i>	DS4-868
<i>Giardia lamblia</i>	H3
<i>Salmonella enterica typhimurium</i>	Z005
<i>Shigella sonnei</i>	Z004
<i>Vibrio cholerae</i>	Z133; non-toxigenic
<i>Yersinia enterocolitica</i>	Clinical isolate
Negative	N/A

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development, quality assurance or manufacturing use. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

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

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