

PRODUCT DESCRIPTION:

NATtrol™ GI Controls* (qualitative) are formulated with purified, intact cells (bacterial, fungal or parasites) and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATGIC-BIO contains 6 x 0.2 mL vials of GI Control 1 and 6 x 0.2 mL vials of GI Control 2 as listed in Table 1. The control members are supplied in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ GI Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial, parasitic and viral nucleic acids (from organisms listed in Table 1). NATtrol™ GI Controls enable laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, and can provide assistance in identifying random or systemic error.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the control members. The inactivation was verified in a standard microbiological growth protocol.
- This product 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 Controls 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 FilmArray® Gastrointestinal (GI) Panel assay and provides all expected results for the control components listed in Table 1.
- The table shown below is for informational purposes only.

TABLE 1: ORGANISMS IN GI CONTROLS.

| Control Component | Strain | GI Control 1 | GI Control 2 |
|--------------------------------|--|--------------|--------------|
| <i>C. difficile</i> | NAP1 | Positive | Negative |
| <i>P. shigelloides</i> | Z130 | Positive | Negative |
| <i>V. cholera</i> | Z133; non-toxigenic | Positive | Negative |
| <i>Y. enterocolitica</i> | clinical isolate | Positive | Negative |
| <i>E. coli</i> | 92.0147; EAEC ¹ | Positive | Negative |
| <i>S. sonnei</i> | Z004 | Positive | Negative |
| <i>E. coli</i> | EDL933; O157 | Positive | Negative |
| <i>C. parvum</i> | Iowa | Positive | Negative |
| Adenovirus Type 41 | TAK | Positive | Negative |
| Sapovirus | Recombinant ² | Positive | Negative |
| Rotavirus | Wa | Positive | Negative |
| <i>C. coli</i> | clinical isolate | Negative | Positive |
| <i>C. jejuni</i> | clinical isolate | Negative | Positive |
| <i>S. enterica typhimurium</i> | Z005 | Negative | Positive |
| <i>E. coli</i> | 7.1493; O84:H28; EPEC ¹ | Negative | Positive |
| <i>E. coli</i> | ETEC; ST+, LT+ | Negative | Positive |
| <i>C. cayetanensis</i> | Recombinant ² | Negative | Positive |
| <i>E. histolytica</i> | DS4-868 | Negative | Positive |
| <i>G. lamblia</i> | H3 | Negative | Positive |
| Astrovirus | Recombinant ² | Negative | Positive |
| Norovirus GI | Recombinant ² | Negative | Positive |
| Norovirus GII | Recombinant ² | Negative | Positive |

¹ 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.

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

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