

ZeptoMetrix®

NATtrol™ GP External Run Controls

Catalog Numbers:
 NATADV40-GP, NATADV41-GP,
 NATCDI-GP, NATCJE-GP,
 NATECO(933)-GP,
 NATECO(ETEC)-GP,
 NATEHI(DS4)-GP, NATNOVI-GP,
 NATNOVII-GP, NATROTA-GP,
 NATSSO-GP, NATSTY-GP

PRODUCT DESCRIPTION:

NATtrol™ GP (Gastrointestinal Pathogen) External Run Controls* are qualitative controls formulated with purified, intact cells (bacteria or parasites) or viral particles that have been chemically modified to render them non-infectious and refrigerator stable. Each control contains 0.5 mL of the NATtrol™ targets listed in Table 1. Each of the analytes listed in the table are sold separately. These controls are supplied in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ GP External Run Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial, parasitic or viral nucleic acids (from organisms listed in Table 1). NATtrol™ GP External 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 each control. The inactivation was verified in a standard microbiological growth protocol.
- These controls contain 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 these products contains 0.05% gentamicin sulfate and 0.125% 2-chloroacetamide.
- Heat inactivated Bovine Serum Albumin used in the manufacture of these products 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™ GP External Run 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.
- The table shown below is for informational purposes only.

Table 1: AVAILABLE ANALYTES

| Catalog Number | Organism | Strain |
|-----------------|-----------------------|--------------------------|
| NATADV40-GP | Adenovirus Type 40 | Dugan |
| NATADV41-GP | Adenovirus Type 41 | TAK |
| NATCDI-GP | <i>C. difficile</i> | NAP1 |
| NATCJE-GP | <i>C. jejuni</i> | Clinical isolate |
| NATECO(933)-GP | <i>E. coli</i> | EDL933 |
| NATECO(ETEC)-GP | <i>E. coli</i> | ETEC; ST+, LT+ |
| NATEHI(DS4)-GP | <i>E. histolytica</i> | DS4-868 |
| NATNOVI-GP | Norovirus GI | Recombinant ¹ |
| NATNOVII-GP | Norovirus GII | Recombinant ¹ |
| NATROTA-GP | Rotavirus | Wa |
| NATSSO-GP | <i>S. sonnei</i> | Z004 |
| NATSTY-GP | <i>S. typhimurium</i> | Z005 |

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

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 Revision: 10
 Effective Date: 02/08/2022

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

PCA# 20-223 & 21-112
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