ZeptoMetrix®

NATtrol™ EP Controls

Catalog Number:
NATEPC-NNS

PRODUCT DESCRIPTION:

NATtrol™ EP (Enteric Panel) Controls (NATEPC-NNS)* are qualitative controls formulated with purified, intact bacterial cells and viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. Each control pack contains 12 x 0.25 mL vials of bacterial and viral NATtrol™ (6 vials of EP Control 1 and 6 vials of EP Control 2) and 2 x 1.0 mL vials of Negative Control as listed in Table 1. These controls are supplied in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ EP Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial and viral nucleic acids (from organisms listed in Table 1). NATEPC-NNS enables 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 controls. The inactivation was verified in a standard microbiological growth protocol.
- This product 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™ EP Controls should be stored 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.

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:

- Qualitative results are shown in Table 1 below.
- Each laboratory must evaluate the product and establish their own acceptance criteria.
- The table shown below is for informational purposes only.

Table 1: ORGANISMS IN EP CONTROLS

Organism	Strain	EP Control 1	EP Control 2
C. jejuni	Clinical isolate	*Campylobacter* Detected	Not Detected
S. enterica typhimurium	Z005	*Salmonella* Detected	Not Detected
S. sonnei	Z004	*Shigella* Detected	Not Detected
V. cholerae	Z132; toxigenic	*Vibrio* Detected	Not Detected
Y. enterocolitica	Clinical isolate	*Y. enterocolitica* Detected	Not Detected
E. coli	EDL933	Not Detected	Shiga Toxin 1 Detected Shiga Toxin 2 Detected
Norovirus GI (recombinant)[1]	N/A	Not Detected	Norovirus G1C Detected
Rotavirus	Wa	Not Detected	Rotavirus Detected
Negative	N/A	All targets Not Detected	All targets Not Detected

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

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

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