

PRODUCT DESCRIPTION:

NATtrol™ EP Controls (NATEPC-NNS)* is formulated with purified, intact bacterial cells and viral particles that have been chemically modified to render them non-infectious and refrigerator stable. NATEPC-NNS contains 12 x 0.25 mL vials of bacterial/viral NATtrol™ targets (6 vials of EP Control 1 and 6 vials of EP Control 2) and 2 x 1.0 mL vials of Negative Control listed in Table 1. These controls 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™ EP Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of bacterial and viral nucleic acids. NATEPC-NNS can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATEPC-NNS 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 bacterial and viral stocks used to formulate controls. The inactivation was verified by the absence of bacterial/viral growth in a validated growth protocol.
- The Stool Diluent used to manufacture this product contains stabilizers and antimicrobial agents.

PRECAUTIONS:

- Although NATEPC-NNS 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™ EP Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH Verigene® EP:

- Prepare cartridge and sample reagents following manufacturer's instructions.
- Vortex NATtrol™ sample for 5-10s.
- Testing single panel member: Add 200µl of sample into Extraction Tray Sample Loading Well.
- Follow manufacturer's instructions

For other assays follow manufacturer's instructions..








Table 1: Verigene EP Assay Expected Results:

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

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.

PINATEPC-NNS
Revision: 12
Effective Date: 10/12/2021

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

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