



NATtrol™ *Escherichia coli* External Run Controls
Strain: O157:H7; EDL933

Catalog #: NATECO(933)-ERCL

Catalog #: NATECO(933)-ERCM

PRODUCT DESCRIPTION:

NATtrol™ *Escherichia coli* External Run Controls (NATECO(933)-ERCL and NATECO(933)-ERCM) are formulated with purified, intact bacterial cells that have been chemically modified to render them non-infectious and refrigerator stable*. Each control pack contains 6 x 1.0 mL vials of *E. coli* NATtrol™ at concentrations listed in Table 1. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ *Escherichia coli* External Run Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of *E. coli* DNA. NATECO(933)-ERCL and NATECO(933)-ERCM can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATECO(933)-ERCL and NATECO(933)-ERCM contain 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 *E. coli* stock used to formulate each control pack. The inactivation was verified by the absence of bacterial growth in validated tissue culture based infectivity assays.
- The purified protein matrix was manufactured from materials that were screened and found to be negative for HIV 1&2 Ab, HBsAg, HTLV I&II Ab, HCV Ab, HIV RNA, HBV DNA and HCV RNA using FDA cleared kits at the single donor level.

PRECAUTIONS:

- Although NATECO(933)-ERCL and NATECO(933)-ERCM contain inactivated organisms, they 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.

This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

PINATECO(933)-ERCM
PINATECO(933)-ERCL
Rev. No./Replaces: 1 / 3/2014
Research Use Only

RECOMMENDED STORAGE:

- NATtrol™ *Escherichia coli* External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Extract *E. coli* DNA prior to use in downstream assays.

TABLE 1:

Catalog Number	Target Concentration (cfu/mL)*
NATECO(933)-ERCL	5,000
NATECO(933)-ERCM	50,000

* Concentration is based on in-house real time PCR assay targeting shiga toxin 2 gene region.

DO NOT USE IN HUMANS

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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