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## NATtrol™ *Escherichia coli* External Run Controls

Strain: O157:H7; EDL933



ZMC Catalog #: NATEco(933)-ERCL  
ZMC Catalog #: NATEco(933)-ERCM

FOR RESEARCH USE ONLY  
Not for *in vitro* Diagnostic Use

## Product Description

NATtrol™ *Escherichia coli* EDL933 External Run Controls are formulated with intact bacteria that have been chemically modified to render them non-infectious and refrigerator stable\*. Each run control pack contains 6 x 1 mL vials of *E. coli* NATtrol™ at either 5,000 cfu/mL (NATEco(933)-ERCL) or 50,000 cfu/mL (NATEco(933)-ERCM). These controls are supplied in a purified serum protein matrix that mimics the composition of a true clinical specimen. External Run Control formulations are validated using an in-house real time PCR assay targeting the nuclease (*nuc*) gene. CfU/mL were calibrated against an in-house DNA standard that corresponds to known cfu counts.

\*NATtrol™ Patents Pending

## Intended Use

- NATtrol™ *E. coli* External Run Controls are full process controls designed to validate the extraction and amplification of *E. coli* from clinical samples. Controls should be run using the same protocols as those used to run clinical specimens. **NATtrol™ *E. coli* controls must be extracted prior to amplification.**

## Precautions

- Use Universal Precautions when handling NATtrol™ External Run Controls.
- To avoid cross-contamination, use separate pipette tips for all reagents.

## Etiologic Status/Biohazard Testing

- NATtrol™ inactivation was carried out on the *E. coli* in each control. The inactivation was measured by following the absence of growth in a validated growth protocol.
- The purified serum protein matrix was sourced from licensed U.S. blood banks and screened 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.

### **DO NOT USE IN HUMANS OR AS A CLINICAL DIAGNOSTIC.**

These products are intended for research, product development or manufacturing use only. 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.

### **Export Compliance**

Recipient is solely responsible for compliance with all foreign and domestic laws and regulations applicable to the use of the biological material which is the subject matter of this certificate of analysis. This includes, but is not limited to, compliance with all foreign and U.S. laws, including U.S. export control laws, which regulate shipment of the biological material and its derivatives to countries outside of the U.S.



This product was manufactured in a facility whose Quality Management System is certified as being in compliance with ISO 9001:2008 and ISO 13485:2003 standards

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