ZeptoMetrix CORPORATION
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NATtrol

NATtrol™ *Clostridium difficile* External Run Controls

Strain: NAP1

ZMC Catalog #: NATCdi(NAP1)-ERCL
ZMC Catalog #: NATCdi(NAP1)-ERCM

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

Product Description

NATtrol™ ***Clostridium difficile*** **NAP1 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 C*. difficile* NATtrol™ at either low (NATCdi(NAP1)-ERCL) or medium (NATCdi(NAP1)-ERCM) concentrations. 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 *C. difficile* toxin A (*tcdA*) and toxin B (*tcdB*) genes.

*NATtrol™ Patents Pending

Intended Use

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

Etiologic Status/Biohazard Testing

- NATtrol™ inactivation was carried out on *C. difficile* 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.

Precautions

- Use Universal Precautions when handling NATtrol™ External Run Controls.

- To avoid cross-contamination, use separate pipette tips for all reagents.

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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