

NATtrol™ *C. difficile* External Run Controls

PRODUCT DESCRIPTION:

NATtrol™ *C. difficile* External Run Controls (NATCDi-6MC and NATCSo-6MC) are formulated with purified, intact bacterial particles that have been chemically modified to render them non-infectious and refrigerator stable*. Each control pack contains 6 x 0.5 mL vials of *C. difficile* NATtrol™ or *C.sordellii* NATtrol™. These controls are supplied in a serum protein matrix that mimics the composition of a true clinical specimen.

*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ *C. difficile* External Run Controls are full process controls designed to evaluate the performance of nucleic acid tests for determination of the presence of *C.difficile* DNA. NATCDi-6MC and NATCSo-6MC can also be used for quality control of clinical assays and training of laboratory personnel.
- NATCDi-6MC and NATCSo-6MC 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 each control. The inactivation was verified by the absence of bacterial growth in a validated growth protocol.
- The 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.

PRECAUTIONS:

- Although NATtrol™ *C. difficile* External Run Controls contain inactivated organisms, they should be handled as if potentially infectious.
- Use Universal Precautions when handling these products.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

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

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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PSNATCDI-6MC
 PSNATCSO-6MC
 Rev.: 10/2011
 For Research Use Only

INSTRUCTIONS FOR USE WITH Xpert® *C.difficile*/Epi ASSAY:

- Prepare cartridge and elution buffer following manufacturer's instructions.
- Vortex NATtrol™ sample for 5-10s and add 50µl into elution buffer. Mix well by vortexing for 5-10s.
- Follow manufacturer's instructions.

For all other assays follow manufacturer's Instructions.

EXPECTED RESULTS:

Catalog Number	Organism	Xpert® <i>C.difficile</i> /Epi Expected Result
NATCDi-6MC	<i>C.difficile</i> (NAP1)	<ul style="list-style-type: none"> • Toxigenic <i>C. difficile</i> Positive • 027/NAP1/BI Presumptive Positive
NATCSo-6MC	<i>C.sordellii</i>	<ul style="list-style-type: none"> • Toxigenic <i>C. difficile</i> Negative

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.