

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 contains 6 x 0.5 mL vials of NATtrol™ *C. difficile* or NATtrol™ *C. sordellii*. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

*Pat.: <http://www.zeptometrix.com/patent-information/>

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 similar to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on the bacterial stocks used to formulate each control. The inactivation was verified by the absence of bacterial growth in a validated growth protocol.
- Purified protein matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from materials that have been tested and found non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods. Heat inactivated bovine based source materials used in the manufacture of this product meet applicable USDA requirements for abattoir sourced animals, traceability and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and post mortem at the abattoir as required by the USDA.

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.

INSTRUCTIONS FOR USE:

- Shake NATtrol™ sample vigorously for 5 seconds.
- Follow the assay manufacturer's instructions for use to process the sample as a clinical sample.

EXPECTED RESULTS:

- Qualitative results are shown in Table 1 below.
- Each laboratory must evaluate the controls and establish their own acceptance criteria.
- The table shown below is for informational purposes only.

Table 1:

Catalog Number	Organism	Expected Result
NATCDI-6MC	<i>C. difficile</i> (NAP1)	Toxigenic <i>C. difficile</i> is detected
NATCSO-6MC	<i>C. sordellii</i>	Toxigenic <i>C. difficile</i> is 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.

REF	Catalog Number		Temperature Limitation
LOT	Batch Code		Expiration Date
RUO	For Research Use Only		Biological Risk