



## NATtrol™ *C.difficile* Verification Panel

Catalog #:NATCDiVP-C

### PRODUCT DESCRIPTION:

**NATtrol™ *C. difficile* Verification Panel (NATCDiVP-C)** is formulated with purified, intact bacterial particles that have been chemically modified to render them non-infectious and refrigerator stable\*. NATCDiVP-C panel contains 6 x 1.0 mL vials each containing *C. difficile* 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* Verification Panel is designed to evaluate the performance of nucleic acid tests for the determination of the presence of *C.difficile* DNA. NATCDiVP-C can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATCDiVP-C contains 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 member in the panel. 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* Verification Panel contains 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.

### RECOMMENDED STORAGE:

- NATtrol™ *C. difficile* Verification Panel should be stored at 2-8°C.

### 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:

Panel Member	Xpert® <i>C.difficile</i> /Epi Expected Result
<i>C.difficile</i> (Ribotype 002)	<ul style="list-style-type: none"> <li>• Toxigenic <i>C. difficile</i> Positive</li> <li>• 027/NAP1/BI Presumptive Negative</li> </ul>
<i>C.difficile</i> (Ribotype 078)	<ul style="list-style-type: none"> <li>• Toxigenic <i>C. difficile</i> Positive</li> <li>• 027/NAP1/BI Presumptive Negative</li> </ul>
<i>C.difficile</i> (Ribotype 017)	<ul style="list-style-type: none"> <li>• Toxigenic <i>C. difficile</i> Positive</li> <li>• 027/NAP1/BI Presumptive Negative</li> </ul>
<i>C.difficile</i> (Ribotype 027)	<ul style="list-style-type: none"> <li>• Toxigenic <i>C. difficile</i> Positive</li> <li>• 027/NAP1/BI Presumptive Positive</li> </ul>
<i>C.difficile</i> (Ribotype 027)	<ul style="list-style-type: none"> <li>• Toxigenic <i>C. difficile</i> Positive</li> <li>• 027/NAP1/BI Presumptive Positive</li> </ul>
<i>C.sordellii</i>	<ul style="list-style-type: none"> <li>• Toxigenic <i>C. difficile</i> Negative</li> </ul>

### CAUTION: NOT FOR USE IN HUMANS.

These products are intended for research, product development, quality assurance or further manufacturing use. These products are NOT intended for use in the manufacturing 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.

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



**ZeptoMetrix Corporation**  
878 Main Street  
Buffalo, New York 14202  
Phone: 716-882-0920  
Fax: 716-882-0959  
Customer Service: 800-274-5487  
[www.zeptometrix.com](http://www.zeptometrix.com)