

USA FDA Registration Number 3000202849



## NATtrol™ CT/NG Negative Control Pack Part Number: MDZ004

### INTENDED USE:

NATtrol™ CT/NG (*Chlamydia trachomatis/Neisseria gonorrhoeae*) Negative Controls (MDZ004) consist of *in vitro* diagnostic external run controls intended for use with qualitative molecular assays. The routine and repetitive use of external run controls enables laboratories to monitor daily test variation, lot-to-lot test kit performance, individual operator variation, and can provide assistance in identifying increases in random or systemic error.

NATtrol™ CT/NG Negative Controls contain intact cells and should be run in a manner identical to that used for clinical specimens.

### PRODUCT SUMMARY AND EXPLANATION:

Each NATtrol™ CT/NG Negative Control Pack contains 6 x 1.25 mL vials of A-549 cells formulated in a Purified Protein Matrix that is fully commutable with true clinical specimens.

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

### PRINCIPLE:

NATtrol™ CT/NG Negative Controls contain A-549 cells formulated in a proprietary Purified Protein Matrix that mimics the composition of a true clinical specimen. These are full process controls designed to monitor the effectiveness of extraction, amplification, and detection in nucleic acid testing procedures. These controls are suitable for use in in-house molecular assays and commercially available platforms.

### PRECAUTIONS:

Handling and disposal of NATtrol™ CT/NG Negative Controls should be conducted as if the material is potentially infectious.

This control contains material of human and animal origin and the user should observe Universal Precautions when handling and disposing of this product. Disposal must follow local regulations, if more stringent than regulations enforced by the CDC or the FDA.

Do not pipette by mouth.

To avoid cross-contamination, use separate transfer pipettes or tips for all materials.

Do not use beyond the expiration date shown on the label.

If product is received damaged or leaking, contact ZeptoMetrix LLC for instructions.

### NOT FOR USE IN HUMANS:

These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under the USA Food and Drug Administration Section 351 of the Public Health Service Act or for any other product intended for administration to humans.

### RECOMMENDED STORAGE:

NATtrol™ CT/NG Negative Controls should be stored at 2-8°C.

When stored as directed, controls are suitable for use for up to 56 days (8 weeks) once opened.

### INSTRUCTIONS FOR USE:

Vortex NATtrol™ CT/NG Negative Control vials for 10 seconds to mix.

Follow the manufacturer instructions for use as a clinical sample.

### LIMITATIONS:

NATtrol™ CT/NG Negative Controls are USA FDA Class 1 exempt, unassayed, *in vitro* diagnostic external run controls and are intended for professional use only. NATtrol™ CT/NG Negative Controls are not intended for use as a substitute for the internal controls provided by *in vitro* diagnostic kit manufacturers. Quality control materials should be used in accordance with local, state, federal and accreditation requirements.

### EXPECTED RESULTS:

One lot of NATtrol™ CT/NG Negative Control was tested in two separate labs on three different assays. Qualitative results are shown in Table 1.

Each laboratory must evaluate the controls and establish their own acceptance criteria.

The data shown below is for informational purposes only.

**Table 1:**

| Assay                         | Site | Results n=2 |          |          |          |
|-------------------------------|------|-------------|----------|----------|----------|
|                               |      | CT          |          | NG       |          |
|                               |      | Urine       | Swab     | Urine    | Swab     |
| Cepheid Xpert® CT/NG          | 1    | Negative    | Negative | Negative | Negative |
|                               | 2    | N/T*        | N/T*     | N/T*     | N/T*     |
| BD Probetec™ ET CT/NG         | 1    | N/T*        | N/T*     | N/T*     | N/T*     |
|                               | 2    | Negative    | Negative | Negative | Negative |
| Hologic APTIMA Combo 2® CT/NG | 1    | N/T*        | N/T*     | N/T*     | N/T*     |
|                               | 2    | Negative    | Negative | Negative | Negative |

\*Not Tested

# ZeptoMetrix®

USA FDA Registration Number 3000202849



**NATtrol™ CT/NG Negative Control Pack**  
**Part Number: MDZ004**

## ETIOLOGIC STATUS/BIOHAZARD TESTING:

The 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.

## PRODUCT WARRANTY:

ZeptoMetrix LLC's limited product warranty and other terms and conditions related to the purchase and use of ZeptoMetrix products are set forth in ZeptoMetrix's Terms and Conditions of sale found on ZeptoMetrix's website at [Sales Terms and Conditions](#). If you have any questions, please contact ZeptoMetrix Customer Service at [zepto.customerservice@antylia.com](mailto:zepto.customerservice@antylia.com).

## DISCLAIMER AND LIMITATION OF LIABILITY:

ZeptoMetrix LLC disclaims all warranties with respect to this document and the information contained herein, expressed or implied, including but not limited to those of merchantability, fitness for a particular purpose, or non-infringement. To the extent allowed by law, in no event shall ZeptoMetrix LLC be liable, whether in contract, tort, warranty, or consequential damages or lost profits in connection with or arising from this document and the information contained herein, including but not limited to the use thereof even if ZeptoMetrix is advised of the possibility of such damages.

## LEGEND OF LABELING SYMBOLS:

|  |                                       |  |                                     |
|--|---------------------------------------|--|-------------------------------------|
|  | <b>Manufacturer</b>                   |  | <b>Temperature Limitation</b>       |
|  | <b><i>In vitro</i> Diagnostic Use</b> |  | <b>Use-By Date</b>                  |
|  | <b>European Mark of Conformity</b>    |  | <b>Biological Risk</b>              |
|  | <b>Catalogue Number</b>               |  | <b>Authorized Representative</b>    |
|  | <b>Batch Code</b>                     |  | <b>Consult Instructions for Use</b> |

**Manufacturer:**  
ZeptoMetrix LLC  
25 Kenwood Circle  
Franklin, MA 02038, USA

**EC Representative:**



**EMERGO EUROPE**  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

©2021 ZeptoMetrix LLC. All rights reserved. The trademarks mentioned herein are the property of ZeptoMetrix LLC (ZM) or the respective owners.

PIMDZ004-English Rev. 09  
Effective Date: 05/25/2021  
Page 2 of 2

ZeptoMetrix LLC • 25 Kenwood Circle, Franklin, MA 02038, USA • Tel (508) 553-5800 • Fax (508) 520-1525  
This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.  
For Customer Support, please visit [www.zeptometrix.com](http://www.zeptometrix.com) or email [zepto.customerservice@antylia.com](mailto:zepto.customerservice@antylia.com)