USA FDA Registration Number 3000202849

IVD CE

NATtrol™ *T. vaginalis* Negative Control
Part Number: NATTVNEG-6MC-IVD

INTENDED USE:

The NATtrol™ *Trichomonas vaginalis* (*T. vaginalis)* Negative Control is an unassayed *in vitro* diagnostic external run control intended to be used with qualitative molecular assays for detection of nucleic acids from these organisms. The control is intended to be used as an aid to diagnosis in that it is used to verify performance of the assays used to detect a physiological or pathological state. 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 errors. NATtrol™ *T. vaginalis* Negative Control contains intact organisms and should be run in a manner identical to that used for clinical specimens. The control does not have an assigned value and it is the responsibility of the end user to establish their own target specifications for the control using their laboratory's molecular procedures.

PRODUCT SUMMARY AND EXPLANATION:

NATtrol™ *T. vaginalis* Negative Control is formulated with purified, intact organisms that have been chemically modified to render them non-infectious and refrigerator stable*.

Each NATtrol™ *T. vaginalis* Negative Control contains 6 x 1.2 mL vials of NATtrol™ *Neisseria gonorrhoeae* formulated in a Purified Protein Matrix that is fully commutable with true clinical specimens.

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

PRINCIPLE:

NATtrol™ *T. vaginalis* Negative Control contains *Neisseria gonorrhoeae* inactivated by ZeptoMetrix's patented NATtrol™ process 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:

Although the NATtrol™ *T. vaginalis* Negative Control contains inactivated microorganisms, handling and disposal should be conducted as if 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 then 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™ *T. vaginalis* Negative Control 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™ *T.vaginalis* Negative Control vials for 10 seconds to mix.

Follow the manufacturer instructions for use as a clinical sample.

LIMITATIONS:

NATtrol™ *T. vaginalis* Negative Control is a USA FDA Class 1 exempt, unassayed, *in vitro* diagnostic external run control and is for professional use only. NATtrol™ *T. vaginalis* Negative Control is 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:

NATtrol™ *T. vaginalis* Negative Control tested negative for *T. vaginalis* in the Xpert® TV Assay.

Product homogeneity has been demonstrated by validation studies and quality control testing.

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

ZeptoMetrix LLC • 25 Kenwood Circle, Franklin, MA 02038 • Tel (508) 553-5800 • Fax (508) 520-1525

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ETIOLOGIC STATUS/BIOHAZARD TESTING:

NATtrol™ inactivation was completed on the stocks used to formulate each control and further verified by the absence of bacterial growth in a validated growth protocol.

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.

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LEGEND OF LABELING SYMBOLS:

	Manufacturer		**Temperature Limitation**
IVD	***In vitro* Diagnostic Use**		**Use-By Date**
CE	**European Mark of Conformity**		**Biological Risk**
REF	**Catalogue Number**	EC REP	**Authorized Representative**
LOT	**Batch Code**		**Consult Instructions for Use**

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

EC Representative:

EC REP
EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands