ZeptoMetrix®

USA FDA Registration Number 3000202849

IVD CE 2797

NATtrol™ RP Multimarker Controls
Part Number: MDZ001

INTENDED USE:

NATtrol™ RP Multimarker Controls (MDZ001) 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™ RP Multimarker Controls contain intact organisms and should be run in a manner identical to that used for clinical specimens.

PRODUCT SUMMARY AND EXPLANATION:

NATtrol™ RP Multimarker Controls are formulated with purified, intact organisms that have been chemically modified to render them non-infectious and refrigerator stable*.

Each control pack contains 3 x 0.75 mL vials of RP Multimarker 1 and 3 x 0.75 mL vials of RP Multimarker 2. Table 1 lists the respiratory targets and strains in RP Multimarker 1 and RP Multimarker 2. NATtrol™ RP Multimarker Controls are formulated in a Purified Protein Matrix that is fully commutable with true clinical specimens.

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

PRINCIPLE:

NATtrol™ RP Multimarker Controls contain viral particles and bacterial cells which have been 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™ RP Multimarker Controls contain inactivated microorganisms, handling and disposal 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 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™ RP Multimarker 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™ RP Multimarker Control vials for 10 seconds to mix.

Follow the manufacturer instructions for use as a clinical sample.

LIMITATIONS:

NATtrol™ RP Multimarker Controls are USA FDA Class 1 exempt, unassayed *in vitro* diagnostic external run controls intended for professional use only. NATtrol™ RP Multimarker Controls are not intended for use as a substitute for 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™ RP Multimarker Controls tested positive in the BioFire FilmArray® Respiratory Panel for the markers shown below in Table 1.

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

TABLE 1:

RP Multimarker 1 Targets	RP Multimarker 2 Targets
Influenza A H3N2 (Brisbane/10/07)	Influenza A H1 (New Caledonia/20/99)
Influenza A H1N1 (NY/02/2009)	Influenza B (Florida/02/06)
Rhinovirus (Type 1A)	RSV (Type A)
Adenovirus (Type 3)	Parainfluenza (Type 2)
Parainfluenza (Type 1)	Parainfluenza (Type 3)
Parainfluenza (Type 4)	Coronavirus (HKU-1 recombinant)
Metapneumovirus (Peru 6-2003)**	Coronavirus (OC43)
C. pneumoniae (CWL-029)	Coronavirus (NL63)
M. pneumoniae (M129)	Coronavirus (229E)
Coxsackievirus (Type A1)	Bordetella pertussis (A639)

** The human metapnuemovirus in this product is sold by ZeptoMetrix LLC under license from ViroNovative B.V. under patent applications, including U.S. Patent Applications 10/371,099 and 10/371,122, and any patents that issue from applications related to PCT/NL02/00040 and PCT/US03/05271."

www.h-h-c.com

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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 or email ZMC-CustomerService@antylia.com

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NATtrol™ RP Multimarker Controls
Part Number: MDZ001

MATERIALS ARE NOT FOR USE ON THE FOLLOWING ASSAYS:

Luminex® xTAG® Respiratory Viral Panel (RVP)
Luminex® xTAG® Respiratory Viral Panel Fast (RVP FAST)
Nanosphere Verigene® Respiratory Virus Plus Nucelic Acid Test (RV+)

ETIOLOGIC STATUS/BIOHAZARD TESTING:

NATtrol™ inactivation was completed on the stocks used to formulate each control and further verified by the absence of viral growth in a validated tissue culture-based infectivity assay and 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 ZMC-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
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Franklin, MA 02038, USA

EC Representative:
EC REP
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