878 Main Street, Buffalo, NY 14202
www.zeptometrix.com

Catalog Numbers:
NATCT(434)-6MC
NATNG-6MC
NATCT/NGNEG-6MC

NATtrol™ CT/NG External Run Controls

IVD

INTENDED USE:

NATtrol™ CT/NG External Run Controls are qualitative *in vitro* diagnostic external run controls intended to be used with molecular assays.

SUMMARY AND EXPLANATION:

NATtrol™ *Chlamydia trachomatis* (CT) Positive Control and NATtrol™ *Neisseria gonorrhoeae* (NG) Positive Control contain purified, intact microorganisms that have been chemically modified to render them non-infectious and refrigerator stable. NATtrol™ CT/NG Negative Control contains intact human A549 cells. The controls are formulated in a proprietary matrix.

PRINCIPLE:

Controls should be used according to assay manufacturer's instructions. The routine use of external run controls enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, and can provide assistance in identifying random or systemic error.

MATERIALS SUPPLIED:

Each control pack is supplied separately and contains 6 x 1.0 mL vials NATtrol™ *Chlamydia trachomatis* (CT) Positive Control, NATtrol™ *Neisseria gonorrhoeae (*NG*)* Positive Control, or NATtrol™ CT/NG Negative Control. Each control contains 0.09% sodium azide.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on microorganism stocks used to formulate the controls. The inactivation was verified in a standard microbiological growth protocol.
- This control contains inactivated microorganisms and materials of human and animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin that have been tested and found to be 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 Fetal Bovine Serum 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.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix vigorously for 5 seconds.
- Process according to the assay manufacturer's instructions.
- Each vial is intended for single use.

LIMITATIONS:

- For In Vitro Diagnostic Use
- Intended for professional use only
- Quality control materials should be used in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the device.

EXPECTED RESULTS:

NATtrol™ External Run Controls are unassayed qualitative controls and do not have assigned analyte values. Each laboratory must evaluate the controls and establish their own performance criteria.

Catalog Number	Organism	Expected Result
NATCT(434)-6MC	*C. trachomatis* (LGVII-434)	*C. trachomatis* detected.
NATNG-6MC	*N. gonorrhoeae*	*N. gonorrhoeae* detected.
NATCT/NGNEG-6MC	Human A549 cells	*C. trachomatis* not detected. *N. gonorrhoeae* not detected.

Symbols used in the labeling of this product:

	Manufacturer		**Temperature Limitation**
IVD	***In vitro* Diagnostic Use**		**Expiration Date**
REF	**Catalogue Number**		**Biological Risk**
LOT	**Batch Code**		**Consult Instructions for Use**

This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.