



Catalog #:NATNG-6MC

Catalog #:NATCT(434)-6MC

Catalog #:NATCT/NGNEG-6MC

NATtrol™ CT/NG External Run Controls

PRODUCT DESCRIPTION:

NATtrol™ CT/NG External Run Controls (NATCT (434)-6MC, NATNG-6MC and NATCT/NGNEG-6MC) are formulated with purified, intact bacterial particles that have been chemically modified to render them non-infectious and refrigerator stable*. Each control pack contains 6 x 1.0 mL vials of *C.trachomatis* NATtrol™, *N.gonorrhoeae* NATtrol™ or CT/NG Negative NATtrol™. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ CT/NG External Run Controls are full process controls designed to evaluate the performance of nucleic acid tests for determination of the presence of CT/NG DNA. NATCT(434)-6MC, NATNG-6MC and NATCT/NGNEG-6MC can also be used for quality control of clinical assays and training of laboratory personnel.
- NATCT(434)-6MC, NATNG-6MC and NATCT/NGNEG-6MC contain 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 control. The inactivation was verified by the absence of bacterial growth in a validated growth protocol.
- The purified protein matrix was manufactured from materials that were screened and found to be 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 CT/NG External Run Controls contain inactivated organisms, they should be handled as if potentially infectious.
- Use Universal Precautions when handling these products.
- To avoid cross-contamination, use separate pipette tips for all reagents.

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

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PINATNG-6MC
PINATCT/NGNEG-6MC
Rev.: 01/2013
For Research Use Only

RECOMMENDED STORAGE:

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

EXPECTED RESULTS:

Catalog Number	Organism	Expected Result
NATCT(434)-6MC	<i>C.trachomatis</i> (LGVII-434)	CT Detected NG Not Detected
NATNG-6MC	<i>N.gonorrhoeae</i>	CT Not Detected NG Detected
NATCT/NGNEG-6MC	N/A	CT Not Detected NG Not Detected

DO NOT USE IN HUMANS

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

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