Catalog #:NATFLUA/B-6MC
Catalog #:NATFLUAH1N1-6MC
Catalog #:NATCXVA9-6MC

NATtrol™ Influenza External Run Controls

PRODUCT DESCRIPTION:

NATtrol™ Influenza External Run Controls (NATFLUA/B-6MC, NATFLUAH1N1-6MC and NATCXVA9-6MC) are formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable*. Each control pack contains 6 x 0.5 mL vials of NATtrol™ Influenza A/B or Influenza A H1N1 (2009) or Coxsackie virus A9 NATtrol™. These controls are supplied in a serum protein matrix that mimics the composition of a true clinical specimen.
*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ Influenza External Run Controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of respiratory virus nucleic acids. NATFLUA/B-6MC, NATFLUAH1N1-6MC and NATCXVA9-6MC can also be used for quality control of clinical assays and training of laboratory personnel.
- NATFLUA/B-6MC, NATFLUAH1N1-6MC and NATCXVA9-6MC 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 virus growth in a validated tissue culture based infectivity assay.
- The serum protein matrix was sourced from licensed U.S. blood banks and screened 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 NATtrol™ Influenza 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.

RECOMMENDED STORAGE:

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

INSTRUCTIONS FOR USE WITH Xpert® FLU ASSAY:

- Open the cartridge lid. Vortex NATtrol™ sample for 5-10s and using a clean transfer pipette (supplied with Xpert® Flu), transfer 300 µl to the 'S' chamber of the cartridge.
- Add Binding Reagent into cartridge chamber 1. Squeeze the ampoule until entire contents are added to the cartridge.
- Close cartridge lid and follow manufacturer's instructions.

For all other assays follow manufacturer's Instructions.

EXPECTED RESULTS:

Catalog Number	Organism	Xpert® FLU Expected Result
NATFLUA/B-6MC	Influenza A/NewCaledonia/20/99 Influenza B/Florida/02/06	Flu A Positive 2009 H1N1 Not Detected Flu B Positive
NATFLUAH1N1-6MC	Influenza A/NY/02/09	Flu A Positive 2009 H1N1 Detected Flu B Negative
NATCXVA9-6MC	Coxsackie virus A9	Flu A Negative 2009 H1N1 Not Detected Flu B Negative

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.

This product was manufactured in a facility whose Quality Management System is certified as being in compliance with ISO 9001:2008 and ISO 13485:2003 standards

ZeptoMetrix Corporation
878 Main Street
Buffalo, New York 14202
Phone: 716-882-0920
Fax: 716-882-0959
Customer Service: 800-274-5487
www.zeptometrix.com

PSNATFLUA/B-6MC
PSNATFLUAH1N1-6MC
PSNATCXVA9-6MC
Rev.: 10/2011
For Research Use Only