NATtrol™ Influenza External Run Controls

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

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 contains 6 x 0.5 mL vials of NATtrol™ Influenza A/B or Influenza A H1N1 (2009) or Coxsackie virus A9. These controls are supplied in a purified protein matrix that mimics the composition of a true clinical specimen.

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

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 virus stocks used to formulate each control. The inactivation was verified by the absence of virus growth in a validated tissue culture based infectivity assay.
- 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.

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:

- Mix NATtrol™ sample by vortexing for 5-10s or by inverting the tube 5 times. Follow manufacturer's instructions.

EXPECTED RESULTS:

Catalog Number	Organism	Expected Result
NATFLUA/B-6MC	Influenza A/Brisbane/59/07 Influenza B/Florida/02/06	Flu A Positive Flu B Positive
NATFLUAH1N1-6MC	Influenza A/NY/02/09**	Flu A Positive 2009 H1N1 Positive
NATCXVA9-6MC	Coxsackie virus A9	Flu A Negative Flu B Negative

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

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.

Please note that although similar in nomenclature, **this is a 2009 H1N1 pandemic Influenza strain and does NOT correlate with the seasonal 2009 Influenza strains found in the Fludb.org database. For reference, the NCBI Taxon IDs for the seasonal Influenza strains listed in the Fludb.org database are: A/New York/01/2009 (H1N1) - 666252; B/New York/01/2009 - 664512; A/New York/02/2009 (H1N1) - 666298; and A/New York/03/2009 (H3N2) - 659637.

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

REF	Catalog Number		Temperature Limitation
LOT	Lot Number		Expiration Date
RUO	For Research Use Only		Biological Risk

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PINATFLUA/B-6MC
PINATFLUAH1N1-6MC
PINATCXVA9-6MC
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