NATtrol™ Influenza Verification Panel

Catalog #: NATFVP-C

PRODUCT DESCRIPTION:

NATtrol™ Influenza Verification Panel (NATFVP-C) is formulated with purified, intact virus and bacterial particles that have been chemically modified to render them non-infectious and refrigerator stable*. NATFVP-C panel contains 16 x 1.0 mL vials each containing virus and bacterial NATtrol™ targets listed in the Expected Results. 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 Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of viral and bacterial nucleic acids. NATFVP-C can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATFVP-C contains 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 member in the panel. The inactivation was verified by the absence of viral growth in validated tissue culture based infectivity assays and absence of bacterial growth in a validated growth protocol.
- 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 NATFVP-C contains inactivated organisms, it should be handled as if potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ Influenza Verification Panel 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:

Panel Member	Strain	Xpert® FLU Expected Result
Influenza A H1	A/NewCaledonia/20/99	Flu A Positive 2009 H1N1 Not Detected Flu B Negative
Influenza A H1	A/Brisbane/59/07	Flu A Positive 2009 H1N1 Not Detected Flu B Negative
Influenza A H3	A/Brisbane/10/07	Flu A Positive 2009 H1N1 Not Detected Flu B Negative
Influenza A H3	A/Wisconsin/67/05	Flu A Positive 2009 H1N1 Not Detected Flu B Negative
Influenza A 2009 H1N1	Canada/6294/09	Flu A Positive 2009 H1N1 Detected Flu B Negative
Influenza A 2009 H1N1	NY/02/09	Flu A Positive 2009 H1N1 Detected Flu B Negative
Influenza B	B/Florida/02/06	Flu A Negative 2009 H1N1 Not Detected Flu B Positive
Influenza B	B/Malaysia/2506/04	Flu A Negative 2009 H1N1 Not Detected Flu B Positive
Respiratory Syncytial Virus A	NA	Flu A Negative 2009 H1N1 Not Detected Flu B Negative
Respiratory Syncytial Virus B	CH93(18)-18	Flu A Negative 2009 H1N1 Not Detected Flu B Negative
Rhinovirus 1A	NA	Flu A Negative 2009 H1N1 Not Detected Flu B Negative
Parainfluenza virus Type 1	NA	Flu A Negative 2009 H1N1 Not Detected Flu B Negative
Echovirus Type 30	NA	Flu A Negative 2009 H1N1 Not Detected Flu B Negative
Coxsackievirus type A9	NA	Flu A Negative 2009 H1N1 Not Detected Flu B Negative
Mycoplasma. pneumoniae	M129	Flu A Negative 2009 H1N1 Not Detected Flu B Negative
Neisseria. Meningitides Serogroup A	NA	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

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