NATtrol™ Influenza Verification Panel

Catalog Number: NATFVP(XP)-C

PRODUCT DESCRIPTION:

NATtrol™ Influenza Verification Panel (P/N NATFVP(XP)-C) is formulated with purified, intact virus particles that have been chemically modified to render them non-infectious and refrigerator stable*. NATFVP(XP)-C panel contains 18 x 0.5 mL vials each containing viral NATtrol™ targets listed in the Expected Results table. The panel contains 3 tubes each of the Influenza A H1 and Influenza A H3 positive members, 6 tubes of the Influenza B positive member, and 6 tubes of Coxsackievirus A9 negative member. The panel members 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 Verification Panel is designed to evaluate the performance of nucleic acid tests for determination of the presence of viral nucleic acids. NATFVP(XP)-C can also be used for verification of clinical assays, development of diagnostic tests and training of laboratory personnel.
- NATFVP(XP)-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.
- 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 NATFVP(XP)-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® Xpress Flu ASSAY:

- Vortex NATtrol™ sample for 5-10 seconds.
- Open the cartridge lid. Using a clean 300 µL transfer pipette, transfer 300 µL (one draw) of the NATtrol™ sample to the sample chamber with large opening in the cartridge.
- Close cartridge lid and follow manufacturer's instructions.

For all other assays follow manufacturer's Instructions.

EXPECTED RESULTS:

Panel Member	Strain	Expected Result
Influenza A H1	A/New Caledonia/20/99	Flu A POSITIVE Flu B NEGATIVE
Influenza A H3	A/Brisbane/10/07	Flu A POSITIVE Flu B NEGATIVE
Influenza B	B/Florida/02/06	Flu A NEGATIVE Flu B POSITIVE
Coxsackievirus Type A9	NA	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.

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
	Biological Risk		

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