NATtrol™ Flu Verification Panel

Catalog Number:
NATFVP-NNS

PRODUCT DESCRIPTION:

NATtrol™ Flu Verification Panel* (qualitative) is formulated with purified, intact viral particles. The microorganisms have been chemically modified to render them non-infectious and refrigerator stable. NATFVP-NNS contains 6 x 0.5 mL vials of viral NATtrol™ and 1 x 0.5 mL of negative (matrix only) as listed in Table 1. The panel members are supplied in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ Flu Verification Panel can be used to develop procedures for verification of performance of molecular assays that detect the presence of viral nucleic acids (listed in Table 1). The panel can also be used for training and evaluation of operator proficiency.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on virus stocks used to formulate the panel members. The inactivation was verified in a standard microbiological growth protocol.
- This panel contains inactivated microorganisms and materials of human and animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin that have been tested and found to be 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 Fetal Bovine Serum 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.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ Flu Verification Panel should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix vial vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

LIMITATION:

- **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES**
- Use in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the assay.

EXPECTED RESULTS:

- Each laboratory must evaluate the product and establish their own performance criteria.
- The table shown below is for informational purposes only.

TABLE 1: PANEL MEMBERS

Panel Member	Strain
Negative	N/A
Influenza AH1	A/New Caledonia/20/99
Influenza AH3	A/Brisbane/10/07
Influenza A H1N1pdm	A/NY/02/09[1]
Influenza B	B/Florida/02/06
Respiratory Syncytial Virus A	N/A
Respiratory Syncytial Virus B	CH93(18)-18

[1]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.

REF	Catalog Number		Temperature Limitation
LOT	Batch Code		Expiration Date
RUO	For Research Use Only		Biological Risk
	Manufacturer		

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