NATtrol™ Influenza Verification Panel

Catalog Number:
NATFVP(XP)-C

PRODUCT DESCRIPTION:

NATtrol™ Influenza Verification Panel* (qualitative) is formulated with purified, intact viral particles that have been chemically modified to render them non-infectious and refrigerator stable. NATFVP(XP)-C contains 18 x 0.5 mL vials of viral NATtrol™ as listed in Table 1 (3 x 0.5 mL vials each of Influenza A H1 and Influenza A H3, 6 x 0.5 mL vials of Influenza B and 6 x 0.5 mL vials of the Coxsackievirus A9 negative control). The panel members are supplied in a proprietary matrix.

*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 (from organisms listed in Table 1). NATtrol™ Influenza Verification Panel can also be used for validation of clinical assays, development of diagnostic tests and training of laboratory personnel.

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™ Influenza 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**
- Quality control materials should be used 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:

- Qualitative results are shown in Table 1 below.
- Each laboratory must evaluate the product and establish their own acceptance criteria.
- The table shown below is for informational purposes only.

TABLE 1: PANEL MEMBERS

Panel Member	Strain	Expected Result
Influenza A H1	A/New Caledonia/20/99	Flu A is positive
Influenza A H3	A/Brisbane/10/07	Flu A is positive
Influenza B	B/Florida/02/06	Flu B is positive
Coxsackievirus Type A9	N/A	Flu A is negative Flu B is negative

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

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