NATtrol™ Influenza A H1N1pdm Stock

Catalog Number: NATFLUAH1(2009)-STQ

PRODUCT DESCRIPTION:

NATtrol™ Influenza A H1N1pdm Stock* is formulated with purified, intact viral particles that have been chemically modified to render them non-infectious and refrigerator stable. Each vial contains 1.0 mL of NATtrol™ Influenza A H1N1pdm Stock in a proprietary matrix at the target concentration listed in Table 1.

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

INTENDED USE:

- NATtrol™ Influenza A H1N1pdm stock is designed to evaluate the performance of nucleic acid tests for determination of the presence of NATtrol™ Influenza A H1N1pdm nucleic acid. NATtrol™ Influenza A H1N1pdm stock enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, and can provide assistance in identifying random or systemic error.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on Influenza A H1N1pdm stock used to formulate the product. The inactivation was verified in a standard microbiological growth protocol.
- This product 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 has 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 meets 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 A H1N1pdm Stock 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:

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

TABLE 1:

Catalog Number	Strain	Target Concentration (copies/mL)**
NATFLUAH1(2009)-STQ	A/NY/02/09	1.00E+06

****Quantitation based on in-house real time PCR assay targeting the Influenza A matrix protein 2 (M2) gene region.**

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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