NATtrol™ Influenza A H1N1pdm External Run Controls

Catalog Numbers:
NATFLUAH1N1-ERCL
NATFLUAH1N1-ERCM

PRODUCT DESCRIPTION:

NATtrol™ Influenza A H1N1pdm External Run Controls (NATFLUAH1N1-ERCL and NATFLUAH1N1-ERCM)* are formulated with purified, intact viral particles. The cells have been chemically modified to render them non-infectious and refrigerator stable. Each control pack contains 6 X 1.0mL of NATtrol™ Influenza A H1N1pdm. These controls are provided in a proprietary matrix.

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

INTENDED USE:

- NATtrol™ Influenza A H1N1pdm external run controls are designed to evaluate the performance of nucleic acid tests for determination of the presence of Influenza A H1N1pdm nucleic acid. NATFLUAH1N1-ERCL and NATFLUAH1N1-ERCM enable 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 stocks used to formulate the controls. 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 External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tube 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:

Catalog Number	Strain[1]	Target Concentration (Ct Range)[2]
NATFLUAH1N1-ERCL	A/NY/02/2009	28-31
NATFLUAH1N1-ERCM	A/NY/02/2009	25-28

[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.

[2]Cycle threshold (Ct) range based on in-house real time PCR assay targeting the Influenza A matrix protein 2 (M2) gene region.

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

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