MICROBIX

Product Information Sheet

***Product Name*:** Influenza A (H3N2) Antigen

***Catalogue Number*:** EL-13-03

***Storage*:** Store this antigen preparation frozen at - 70 °C to – 100 °C. Repeated freezing and thawing should be avoided.

***Hazards*:** The product has been inactivated. No test method guarantees a product to be non-infectious. All products should be handled as if potentially infectious. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

Strain: H3N2 Subtype

Cultured In: Embryonated chicken eggs.

Buffer: PBS

Agent Description: Influenza virus is an enveloped, single stranded RNA virus with a segmented genome. Virions are spherical to pleomorphic or filamentous, 80-120 nm diameter and 200-300 nm long. Surface features are distinctive spikes primarily of the hemagglutinin interposed irregularly with clusters of the neuraminidase protein. Influenza causes an acute viral disease of the upper respiratory tract characterized by fever, chills, headache, myalgia, weakness, runny nose and mild sore throat; cough can be severe; nausea and vomiting are uncommon; fatality is usually low, except in those with chronic lung or heart conditions.

Preparation: Eggs are infected by injection into the allantoic chamber, incubated for 48-72 hours, and refrigerated overnight prior to harvest. Allantoic fluids are harvested from live eggs and pooled.

Inactivation: Gamma radiation inactivation.

Description: This preparation contains a high concentration of viral antigens as well as some egg proteins (allantoic fluid).

Recommendations for Use: A precipitate may form upon thawing, due to high product concentration. Dilute prior to clarification or other manipulation.

Quality Control Information

Product Name: Influenza A, subtype H3N2, grade 2 Antigen *Lot Number:* 13XXXXX

Microbix performs quality control tests to ensure each batch meets in-house specifications. Test results are provided with each lot of antigen shipped. Antigen users require this information for a number of reasons:

- to maintain a record for good manufacturing purposes,
- to correlate user results with Microbix results and
- for use as a starting point for those just starting with either a new antigen or developing a new assay.

It is important that users perform titrations of antigen in their own assay, since results vary with the assay format and the use of specific reagents. Often, the use of an antigen may be optimized by making adjustments to concentrations of other assay reagents, such as immunoconjugates. Such assay optimization will ensure cost effective use of the antigen and best assay performance.

Tests:

Identity: Identity of the viral strain is assessed by sequencing of regions from within the hemagglutinin and neuraminidase genes
Result: Sequence matches Influenza A/Texas/1/1977 (H3N2)

Titre: Hemaglutination Endpoint Assay
Result: XXX Units/mL

Protein:
Result: XXX mg/mL

Inactivation Assay: The effectiveness of inactivation is determined when no detection of growth in two blind passages under optimal culture conditions. No live virus detected by either CPE or HA Assay.

Result: No growth detected

Quality Assurance Signature: Date:

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Assistance: If you have any questions regarding the production, testing or use of this antigen, please send them by email to customer.service@microbix.com or fax 905-361-8911, with any relevant data, to Microbix Technical Services. Your complete satisfaction with the performance of this product is important to us.