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Product Name:

Influenza A H1N1 Antigen (Reassortant Vaccine Strain)

Catalogue Number:* EL-001

**As specifications are not yet assigned to this product this is an interim catalogue number for record keeping purposes and may be revised.*

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

Hazards: We are aware of no specific hazards associated with this product. The reagent has been inactivated and should contain no infectious material. The viral strain used is an attenuated reassortant vaccine candidate strain of reduced pathogenicity relative to the wild type A/California/4/2009 virus, according to data published by the World Health Organization. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

Virus Strain: A/CALIFORNIA/7/2009 NYMC X-179A (H1N1)_v

Cultured In: Embryonated chicken eggs

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. Strains of influenza A are by convention described by geographic origin, strain number, year of isolation and hemagglutinin (H) and neuraminidase (N) sub-types.

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.

This particular influenza strain is a reassortant virus that includes genetic components of the H1N1 influenza pandemic swine flu in a culture-adapted virus that has been selected for its qualities as a vaccine-producing strain. The live reassortant virus has passed safety testing in ferrets, in which it is attenuated for pathogenicity relative to wild-type A/California/4/2009 virus. Because A/California/4/2009 is identified as a variant strain of a pandemic virus, live derivatives must be handled under BSL2⁺ facilities and procedures.

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

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.

Quality Control Information

Product Name: Influenza A reassortant pandemic H1N1 grade 2 Antigen

Lot Number: FLU12.6.20

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 each user perform titrations of antigen using their own assay as each assay format and serum release panel makes different performance demands on the antigen. Often, use of an antigen may be optimized by making adjustments to concentrations of other assay reagents such as conjugate. Once this is complete the result is cost effective use of the antigen and optimal assay performance.

Test:

Titre: Hemagglutination Endpoint Assay 7973 HA Units / ml

Protein: 0.92 mg/ml

Inactivation Assay: The effectiveness of inactivation is shown when there is no detection of growth in two blind passages under standard cell culture conditions (MDCK cells). No live virus is detected by either CPE or HA Assay.

Result: No growth detected



Quality Assurance Signature

25-April, 2011