

Anti-influenza monoclonal antibodies to hemagglutinin (HA) that are suitable for identification and quantification of seasonal influenza vaccines

Technology Summary

Human influenza virus is responsible for frequent seasonal epidemics, as well as pandemics. The virus can infect any age group, with children and the elderly most at risk of severe morbidity and mortality. Vaccination is the most effective method to control seasonal infections and the most important strategy to prepare for a possible pandemic. The hemagglutinin (HA) protein is the most abundant envelope glycoprotein on the influenza virion that enables the virus to enter and spread between cells. HA is also a major target for neutralizing antibodies. Monoclonal antibodies (mAbs) that target specific strains and subtypes of influenza HA can be used to develop new diagnostic tools for detection and prevention, and to improve quality control during vaccine production.

The invention available for licensing includes mAbs to seasonal and pandemic influenza HA, and hybridoma cell lines capable of expressing these mAbs. Multiple panels of mAbs to influenza HA, both subtype- and strain-specific mAbs, were developed for use in evaluating and in quantifying the potency of inactivated influenza vaccines. These mAbs may also be useful for influenza research or the development of diagnostic tools.

HA strain-specific and subtype-specific mAbs and hybridoma cell lines are available and include: 1) Seasonal influenza strains H1N1, (H1N1pdm09), H3N2 (Subclades 3C.3A and 3C.2a); 2) Influenza B (Influenza B Yamagata lineage and Influenza B Victoria lineage); 3) Potential pandemic influenza strains; 4) H5 (Clades 1, 2.1.3.2, 2.3.2.1a, 2.3.4, 2.3.4.4); 5) H7; 6) H2; and H9.

Potential Commercial Applications

- A diagnostic test to detect influenza virus infection.
- A reagent to measure the potency of HA in influenza virus vaccines during manufacture.
- A multiplexed immunoassay for determination of influenza potency

Development Stage: in vitro data

Inventors: Jerry P. Weir

Publications:

- Weir, J.P., et al. Neutralizing and protective epitopes of the 2009 pandemic influenza H1N1 hemagglutinin. Influenza Other Respi. Viruses. 2013 May;7(3):480-90. PMID: <u>23122228</u>
- Weir, J.P., et al. A monoclonal antibody-based immunoassay for measuring the potency of 2009 pandemic influenza H1H1 vaccines. Influenza Other Respi. Viruses. 2014 Sep;8(5):587-95. PMID: 25087462

Intellectual Property: Research Tool - no patent protection was pursued for this technology

Product Area: influenza, hemagglutinin, antibodies

FDA Reference No: E-2016-004

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Competitive Advantages

- Can provide an alternative assay to the single radial immunodiffusion test (SRID) for flu vaccine potency determinations
- The anti-influenza antibodies bind current circulating influenza strains