

DIAGNOSTIC TARGETS AND POTENTIAL VACCINE AGAINST H5N1 AVIAN INFLUENZA

Technology Summary

Highly pathogenic avian H5N1 influenza A virus is responsible for influenza outbreaks in poultry and migratory birds worldwide. Transmission of highly pathogenic avian H5N1 viruses from poultry to humans have raised concern of an impending influenza pandemic. The influenza virus encodes eight genes, of which immunity against the surface glycoproteins hemagglutinin (HA) and neuraminidase (NA) play a central role in protection against influenza. During a pandemic, influenza vaccines are typically developed against the target antigens, HA and NA.

FDA researchers used epitope mapping of the Influenza virus A proteome (H5N1-A/VIETNAM/1203/2004) to identify polypeptides that can bind antibodies from a subject infected with and/or vaccinated against H5N1 influenza. In particular, an H5N1 HA influenza polypeptide was isolated that can be used as a serodiagnostic surveillance tool to rapidly distinguish between exposure to human influenza or bird influenza, infection versus vaccination, and to predict likelihood of a vaccine's protective efficacy against H5N1 infection. The patented H5N1 HA influenza polypeptide can also be used as part of a vaccine to prevent bird influenza in humans and animals.

Potential Commercial Applications

- Diagnostics for detection of influenza virus infection, or prior vaccination
- Generation of influenza virus specific antibodies
- Vaccine candidates against influenza virus infection

Competitive Advantages

- Peptides can be expressed in multiple different expression systems; and
- Peptides were identified based on the specificity of antibodies derived from human and avian influenza virus infected individuals

Development Stage: *in vivo* studies

Inventors: Hana Golding, Surender Khurana

Publications:

"Antigenic fingerprinting of H5N1 avian influenza using convalescent sera and monoclonal antibodies reveals potential vaccine and diagnostic targets." *PLoS Med.* 2009 Apr 21; 6(4) e1000049, PMID [19381279](https://pubmed.ncbi.nlm.nih.gov/19381279/)

Intellectual Property:

United States patent: US [8,778,847](https://www.uspto.gov/patent/publications/details/8778847) B2, issued 07.15.2014

Product Area: Serodiagnostic for bird influenza; vaccine candidate; infectious disease therapy

FDA Reference No: E-2007-026

Licensing Contact:

William Ronnenberg, JD, MIP, MS

Technology Transfer Specialist

Email: FDAlnventionlicensing@fda.hhs.gov

Phone: 240-402-4561