

# REASSORTANT INFLUENZA VIRUSES EXPRESSING NEURAMINIDASE (NA) AND A MISMATCHED HEMAGGLUTININ (HA) PROTEIN USEFUL FOR DETERMINING ANTIBODY TITERS OF FUNCTIONAL NA-SPECIFIC ANTIBODIES

# **Technology Summary**

These reassortant influenza (flu) viruses can be used to determine neuraminidase inhibition (NI) antibody titers to assess the immunogenicity of candidate influenza vaccines. NI antibody titers are not routinely measured during vaccine trials because antibodies against hemagglutinin (HA) interfere with NI antibody titer assays conducted using wild type viruses. Reassortant viruses that contain the trial vaccine NA subtype and an HA subtype not contained in the trial vaccine virus are suitable for measuring NI antibody titers. For example, two reassortant viruses available for licensing are H6N1 and H6N2 influenza viruses. These reassortant viruses are useful for determining NI titers from subjects vaccinated or infected with H1N1 or H3N2 viruses. Other reassortant viruses available for licensing include: H6N1 influenza viruses with a NA that originates from H5N1 viruses and H6N9 influenza viruses with a NA that originates from H5N1 viruses may also be available.

The reassortant viruses have been used in a miniaturized colorimetric assay for detecting neuraminidaseinhibiting antibodies (PMID: 21462400) or an enzyme-linked lectin assay (ELLA) to measure neuraminidase inhibition (NI) titers (PMID: 24899442; 25233882).

## **Potential Commercial Applications**

- Can be used in a variety of assays (thiobarbituric acid assay, enzyme-linked lectin assay, ELISA etc.).
- Provides a source of antigen for accurate measurement of functional neuraminidase-specific antibodies.
- A readily-accessible reagent that overcomes the need for lengthy development and qualification of reassortant viruses.
- Useful for the development of influenza vaccines.

#### Development Stage: Research reagent

## **Competitive Advantages**

- Assessment of neuraminidase inhibition titers for influenza vaccine clinical trials.
- Evaluation of antigenic differences between neuraminidases from different viruses.
- Evaluation of breadth of reactivity of neuraminidase-specific antibodies.

Inventors: Maryna Eichelberger, Jin Gao, Matthew Sandbulte, Hongquan Wan

### **Publications:**

"An optimized enzyme-linked lectin assay to measure influenza A virus neuraminidase inhibition antibody titers in human sera." *J Virol Methods*. 2014 Dec 15;210:7-14. PMID: <u>25233882</u>

"Analyzing swine sera for functional antibody titers against influenza A neuraminidase proteins using an enzyme-linked lectin assay (ELLA). *Methods Mol Biol.* 2014;1161:337-45. PMID: <u>24899442</u>

"A miniaturized assay for influenza neuraminidase-inhibiting antibodies utilizing reverse genetics-derived antigens. Methods Mol Biol." *Influenza Other Respir Viruses*. 2009;Sep;3(5):233-40. PMID: <u>21462400</u>

Product Area: Bioassay, diagnostics, vaccine

### FDA Reference No: E-2017-022

#### **Licensing Contact:**

Bill Ronnenberg, MS, JD/MIP FDA Technology Transfer Program Email: <u>FDAInventionlicensing@fda.hhs.gov</u> Phone: 240-402-4561