REAL-TIME DETECTION OF INFLUENZA VIRUS

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 11/746,535, filed on May 9, 2007 now U.S Pat. No. 8,007,999, which claims the benefit of U.S. Provisional Patent Application No. 60/799,442, filed May 10, 2006 and U.S. Provisional Patent Application No. 60/800,939, filed May 16, 2006, each of which is incorporated herein by reference in their entirety for all purposes. This application is related to application Ser. No. 11/389,409, filed on Mar. 24, 2006, which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

Influenza ("flu") is an infectious disease capable of inflicting upon a wide variety of hosts, including birds and mammals. Flu is caused by an RNA virus of the orthomyxoviridae family (that generally comprises the type A, B, and C influenza viruses). Avian flu is caused by a virus of this family adapted to birds, thus it is also named bird flu, avian influenza, or bird influenza. A current pandemic threat stems from an unprecedented outbreak of the H5N1 strain of the influenza A virus in Asia and Europe. This strain has an ability to mutate and adapt itself to a wide range of hosts, including birds and humans. The Homeland Security Council issued the "National Strategy for Pandemic Influenza" ("The Strategy") in November of 2005 in response to the current pandemic threat. A critical part of that initiative focuses on the rapid identification of Avian Flu in patients and birds. The strategy seeks to improve the surveillance and detection of the Avian Flu.

As of November 2005, the virus causing the Avian Flu pandemic threat was known to have infected 121 people in four countries, resulting in 62 deaths over the past two years. Those infected with H5N1 had, in almost all cases, extensive physical contact with infected birds. Although the virus has not yet shown an ability to transmit efficiently between humans, as is seen with the annual human influenza virus epidemic, it raises a serious concern that it will acquire this capability through genetic mutation or exchange of genetic material with a human influenza virus.

Influenza causes approximately 36,000 deaths and more than 200,000 hospitalizations each year in the U.S. alone, and costs the U.S. over $10 billion annually. In addition, the last three pandemics, in 1918, 1957, and 1968, killed approximately 40 million, 2 million, and 1 million people worldwide, respectively.

There remains a pressing need for devices and methods that can accurately and rapidly detect the presence of Avian Flu to provide an early warning of a pandemic in order to contain the spread of the disease. An ideal system would (1) allow for retrieval, transmission, and analysis of data from such devices; and (2) provide a real-time warning system to health and government officials. The present invention satisfies this need and provides related advantages.

SUMMARY OF INVENTION

The present invention provides a system for detecting an analyte indicative of an influenza viral infection in a bodily fluid from a subject. The system typically comprises a) a fluidic device, said fluidic device comprising a sample collection unit and an assay assembly, wherein said sample collection unit allows a sample of bodily fluid suspected to

contain said analyte to react with reactants contained within said assay assembly to yield a detectable signal indicative of the presence of said analyte; b) a reader assembly comprising a detection assembly for detecting said detectable signal; and c) a communication assembly for transmitting said detected signal to said external device. The system is capable of detecting an influenza type A, B, and/or C viral infection. In general, the analyte may comprise a surface glycoprotein of an influenza virus, which can be hemagglutinin (e.g., H1, H2, H3, H4, H5, H6, H7, H8, H9, H10, H11, H12, H13, H14, H15, and H16) and/or neuraminidase (e.g., N1, N2, N3, N4, and N5). The bodily fluid can be drawn from a subject selected from the group consisting of human, poultry and wild birds.

The present invention also provides a system for detecting a plurality of analytes, at least two of which are indicative of an influenza viral infection in a bodily fluid from a subject. The system typically comprises a) a fluidic device, said fluidic device comprising a sample collection unit and an assay assembly, wherein said sample collection unit allows a sample of bodily fluid suspected to contain said plurality of analytes to react with reactants contained within said assay assembly to yield one or more detectable signals indicative of the presence of said at least two analytes; b) a reader assembly comprising a detection assembly for detecting said one or more detectable signals; and c) a communication assembly for transmitting said detected signal to said external device.

The present invention further provides a method of using the subject systems. In one aspect, the present invention provides a method for detecting an analyte indicative of an influenza infection in a bodily fluid of a subject. The method involves the steps of a) providing a subject system; b) allowing a sample of bodily fluid to react with the reactants contained within said assay assembly to yield a detectable signal indicative of the presence of said analyte; and c) detecting said detectable signal. In another aspect, the method comprises the steps of a) providing a fluidic device comprising at least one sample collection unit, an immunoassay assembly containing immunoassay reagents, a plurality of channels in fluid communication with said sample collection unit and/or said immunoassay assembly; b) actuating said fluidic device and directing said immunoassay reagents within said fluidic device; c) allowing a sample of bodily fluid suspected to contain said analyte to react with said immunoassay reagents contained within said assay immunoassay assembly to yield a detectable signal indicative of the presence of said analyte indicative of an influenza viral infection in said sample; and d) detecting said detectable signal generated from said analyte collected in said sample of bodily fluid. Where desired, the sample of bodily fluid used for such detection is less than about 500 microliters. A variety of influenza viral infections can be detected. They include but are not limited to influenza type A, B, and C viral infection.

The present invention further provides a method of detecting a plurality of analytes, at least two of which are indicative of an influenza viral infection in a bodily fluid from a subject. The method comprise the steps of a) providing a fluidic device comprising at least one sample collection unit, an immunoassay assembly containing immunoassay reagents, a plurality of channels in fluid communication with said sample collection unit and/or said immunoassay assembly; b) actuating said fluidic device and directing said immunoassay reagents within said fluidic device; c) allowing a sample of bodily fluid suspected to contain said plurality of analytes to react with said immunoassay reagents contained within said assay immunoassay assembly to yield one or more detectable signals indicative of the presence of said at least two analytes