



## Press Release

For Immediate Release  
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Contact: [FDA Press Office](#) (301)827-6242 ext. 301  
[CDC Division of Media Relations](#) (404) 639-3286

### **New CDC Test to Detect Human Infections with the 2009 H1N1 Influenza Virus Authorized for Use by FDA**

A test developed by the [U.S. Centers for Disease Control and Prevention](#) to diagnose human infections with the 2009 H1N1 influenza virus (formerly known as swine flu or pandemic H1N1 flu) was authorized for use today by the U.S. Food and Drug Administration.

“The development of this test exemplifies our dedication to improving public health surveillance for the 2009 H1N1 virus and other influenza viruses in the United States and abroad,” said Dr. Nancy Cox, director of CDC’s Influenza Division.

The test, called the “CDC Influenza 2009 A (H1N1)pdm Real-Time RT-PCR Panel (IVD),” will help ensure the accuracy of influenza testing results among the different qualified laboratories that conduct influenza subtype testing in the United States and abroad. It uses a molecular biology technique to detect influenza A viruses and specifically the [2009 H1N1 virus](#). The new test will replace the previous real-time RT-PCR diagnostic test used during the 2009 H1N1 pandemic, called the “Swine Influenza Virus Real-time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel),” which received an emergency use authorization by the FDA in April 2009.

“This clearance represents several months of close collaboration between the FDA and the CDC,” said Jeffrey Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health. “This test is the second diagnostic cleared in recent weeks by the FDA for the 2009 H1N1 influenza virus.”

The earlier test was developed based on the limited number of 2009 H1N1 specimens available at the start of the 2009 H1N1 pandemic in April 2009. The new test has been optimized using the vast amount of 2009 H1N1 genetic information CDC received throughout the pandemic. As a result, the new PCR diagnostic test can detect human infections with 2009 H1N1 virus with sensitivity and specificity greater than 96 percent for upper respiratory specimens.

The test is used to isolate and amplify viral genetic material present in secretions taken from a patient’s upper or lower respiratory tract. Upper respiratory specimens are easily obtainable in a doctor’s office, and lower respiratory specimens are typically obtained from severely ill patients in a hospital setting. Amplified viral genetic material generates a fluorescent signal, which is then detected and analyzed by a diagnostic instrument called the Applied Biosystems 7500 Fast DX Realtime PCR Instrument. The test panel and diagnostic system can provide results within four hours, and multiple samples can be tested at the same time.

The test will be available soon to CDC-qualified laboratories for detecting 2009 H1N1 influenza.

For more information, please visit [www.cdc.gov](http://www.cdc.gov).

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