4-Hour Flu Detection Test Gains FDA Approval

BY LORINDA BULLOCK
Associate Editor

The Food and Drug Administration approved a new test that can diagnose human influenza infections, including the highly pathogenic influenza A (H5N1) virus, and produce results within 4 hours.

The device, known as the Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel), was developed by the Centers for Disease Control and Prevention. It is able to detect and identify the most commonly circulating human influenza viruses using a molecular biology technique that can "differentiate between seasonal and novel influenza," according to a written statement released jointly by the FDA and CDC.

The ability to distinguish those differences facilitates speedier diagnoses, Dr. Frank Torti, FDA principal deputy commissioner and chief scientist said in the statement. "It will also provide qualified laboratories with a means to rapidly detect new influenza viruses that have not been identified yet and that could pose a pandemic risk."

Dr. Julie Gerberding, director of the CDC, emphasized the value of having a tool that can test multiple samples at the same time and produce results faster.

The FDA and CDC said the device isolates and amplifies viral genetic material present in secretions taken from a patient's nose or throat. That material is analyzed by another device approved simultaneously with the rRT-PCR Flu Panel, called the Applied Biosystems 7500 Fast Dx.

The test will be available to CDC-qualified laboratories as soon as this fall, and some labs will be able to receive free of charge reagents to aid in the testing process. The CDC, Applied Biosystems Inc., and the Association of Public Health Laboratories collaborated on the development of the new test. ■