

# 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. ■

## IMPORTANT SAFETY INFORMATION

### Risk of Serious Infections

Infections, including serious infections leading to hospitalization or death, have been observed in patients treated with ENBREL. Infections have included bacterial sepsis and tuberculosis. Patients should be educated about the symptoms of infection and closely monitored for signs and symptoms of infection during and after treatment with ENBREL. Patients who develop an infection should be evaluated for appropriate antimicrobial treatment and, in patients who develop a serious infection, ENBREL should be discontinued.

Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation) has been observed in patients receiving TNF-blocking agents, including ENBREL. Tuberculosis may be due to reactivation of latent tuberculosis infection or to new infection. Data from clinical trials and preclinical studies suggest that the risk of reactivation of latent tuberculosis infection is lower with ENBREL than with TNF-blocking monoclonal antibodies. Nonetheless, postmarketing cases of tuberculosis reactivation have been reported for TNF blockers, including ENBREL. Patients should be evaluated for tuberculosis risk factors and be tested for latent tuberculosis infection prior to initiating ENBREL and during treatment. Treatment of latent tuberculosis infection should be initiated prior to therapy with ENBREL. Treatment of latent tuberculosis in patients with a reactive tuberculin test reduces the risk of tuberculosis reactivation in patients receiving TNF blockers. Some patients who tested negative for latent tuberculosis prior to receiving ENBREL have developed active tuberculosis. Physicians should monitor patients receiving ENBREL for signs and symptoms of active tuberculosis, including patients who tested negative for latent tuberculosis infection.

Many of these serious infections occurred in patients predisposed to infection because of concomitant immunosuppressive therapy and/or their underlying disease. Do not start ENBREL in the presence of sepsis, active infections (including chronic or localized), or allergy to ENBREL or its components. Use caution in patients predisposed to infection, such as those with advanced or poorly controlled diabetes.

### Neurologic Events

TNF inhibitors, including ENBREL, have been associated with rare cases of new onset or exacerbation of CNS demyelinating disorders (some presenting with mental status changes and some associated with permanent disability). Transverse myelitis, optic neuritis, multiple sclerosis, and cases of new onset or exacerbation of seizure disorders have been observed in association with ENBREL therapy. The causal relationship to ENBREL therapy remains unclear. Exercise caution when considering ENBREL for patients with these disorders.

### Hematologic Events

Rare cases of pancytopenia, including aplastic anemia, some fatal, have been reported. The causal relationship to ENBREL therapy is unclear. Exercise caution in patients who have a previous history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs or symptoms of blood dyscrasias or infection. Consider discontinuing ENBREL if significant hematologic abnormalities are confirmed.

### Malignancies

In clinical trials of all TNF inhibitors, more cases of lymphoma were seen compared to control patients. The risk of lymphoma may be up to several-fold higher in RA and psoriasis patients; the role of TNF inhibitors in the development of malignancies is unknown. In clinical trials, the incidence of malignancies other than lymphoma has not increased with exposure to ENBREL and is similar to what would be expected in the general population.

### Hepatitis B Reactivation

TNF inhibitors, including ENBREL, have been associated with reactivation of hepatitis B virus (HBV) in chronic carriers of this virus. The majority of these reports occurred in patients on concomitant immunosuppressive agents, which may also contribute to HBV reactivation. Prescribers should exercise caution in prescribing TNF blockers for patients identified as carriers of HBV.

### Adverse Events

The most commonly reported adverse events in RA clinical trials were injection site reaction, infection, and headache. In clinical trials of all other adult indications, adverse events were similar to those reported in RA clinical trials.

*Please see brief summary  
of Prescribing Information  
on adjacent pages.*

