November News and Events

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United States Food and Drug Administration Approves Distribution of 10-Minute Flu Test to All Doctors

Quidel Corporation (San Diego) announced on 12 October 2000 that the US Food and Drug Administration (FDA) waived the Clinical Laboratory Improvement Amendments (CLIA) requirement for the company’s QuickVue Influenza Test, which detects influenza types A and B within 10 min. The product will now be available to most doctors’ offices. The 1988 CLIA established national quality standards for laboratories performing tests on human specimens. Diagnostic test systems are classified into CLIA regulatory categories on the basis of their potential risk to public health. CLIA-waived tests are the lowest-regulated diagnostic test systems and are those most often used in doctors’ offices.

In the 17 December 1999 issue of the Medical Letter on Drugs and Therapeutics, new FDA-approved influenza rapid diagnostic tests that detect both influenza A and B were assessed, including Quidel’s QuickVue (sensitivity, 73%–81%; specificity, 95%–99%), Flu OIA by Biostar (sensitivity, 77%; specificity, 93%), and Zstatflu by ZymeTx (sensitivity, 65% [for influenza A] and 57% [for influenza B]; specificity, 95%–100%) [1]. The authors concluded that, of the 3 tests, “the QuickVue appears to be the easiest and fastest, but no direct comparisons have been reported. With all three, negative tests do not exclude influenza.” Also mentioned in the article, but not included in the comparison, was Becton Dickinson’s Directigen Flu A test, which detects only influenza A and which has been on the market for several years.

With the availability of antiviral drugs that must be started within 48 h after the onset of symptoms, the ability to make a rapid, specific diagnosis is important, said influenza expert Robert B. Couch, MD, professor of medicine at Baylor College of Medicine in Houston. Couch said that rapid diagnostic tests also can help health care providers identify an epidemic period. “Once the physician knows the epidemic is here, then I think it is still important that individuals who may have influenza and are sick enough to be admitted to the hospital have a rapid diagnostic test performed.” Test results can guide the physician to use an antiviral agent and not use unnecessary antibiotics, he said.

During the epidemic period, if a patient with classic influenza symptoms is not sick enough to be hospitalized, administering a test isn’t necessarily required in order to start antiviral therapy, Couch suggested. However, physicians may feel more confident about their diagnosis if they use a test, he said.

According to recommendations issued on 14 April by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices, rapid tests for influenza can aid clinical judgment and help guide treatment decisions, but traditional tests still should be used.

“Despite the availability of rapid diagnostic tests, the collection of clinical specimens for viral culture is important because only culture isolates can provide specific information on circulating influenza subtypes and strains,” the recommendations say. “This information is needed to compare current circulating influenza strains with vaccine strains, to guide decisions about influenza treatment and prophylaxis, and to formulate vaccine for the coming year. Virus isolates also are needed to monitor the emergence of antiviral resistance.”


For more information, see also the articles “Defining the preventive role of antivirals given a possible influenza vaccine shortage” (17 August 2000) and “The role of the new antiviral drugs in treating influenza: an interview with Robert B. Couch, MD” (12 October 2000), which are published online in the Diseases and Organisms: Influenza section of icanNEWS, available from icanPREVENT (http://www.icanprevent.com).

Reference


Nabi Corporation Stages Presentation of StaphVAX Data at the Interscience Conference on Antimicrobial Agents and Chemotherapy, Despite Lack of Abstract Submission

Officials from the American Society for Microbiology (ASM) confronted Steven Black, MD, and Henry Shinefield, MD, co-