



food and drug administration Clears Rapid Test for Meningitis

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March 16, 2007, The U.S. Food and Drug Administration (FDA) today cleared for marketing a test that uses molecular biology to quickly detect the presence of viral meningitis.

The Xpert EV test, when used in combination with other laboratory tests, will help physicians distinguish between viral meningitis and the less-common, but more severe, version of meningitis caused by bacteria.

Meningitis is an infection of the cerebrospinal fluid surrounding a person's spinal cord and brain, causing inflammation of the tissues in these areas. The illness is diagnosed by testing the fluid obtained from a patient during a spinal tap. Typically, diagnostic tests for meningitis can take up to a week to get results. But results from the Xpert EV test are available in two and one-half hours.

"Because this test is significantly faster than existing methods for diagnosing meningitis, it could minimize delays in treating patients. Swift recognition of the cause and appropriate treatment is critical to patient recovery," said Daniel Schultz, M.D., director of the Center for Devices and Radiological Health. "Since bacterial meningitis can be deadly within as little as two days, patients who have viral meningitis are frequently treated with antibiotics as a safeguard against the more dangerous bacterial meningitis. This test should help physicians manage patients appropriately and prevent unnecessary treatment with antibiotics."

Knowing whether the meningitis is viral or bacterial is imperative to early effective treatment. But distinguishing between the two types of infection is difficult because of similar symptoms. Patients with viral meningitis usually recover within two weeks without any medical intervention. Bacterial meningitis, however, can lead to brain damage, hearing loss and even death if not treated properly.

For patients over two years of age, symptoms of meningitis include fever, severe headache, stiff neck, nausea, sleepiness, confusion, and sensitivity to bright lights or seizures. These symptoms may be absent or difficult to detect in newborns and small infants who may only appear slow or inactive, or be irritable, have vomiting or feed poorly.

The Xpert EV test is the first fully-automated medical diagnostic test that isolates and amplifies viral genetic material present in a patient's cerebrospinal fluid by a process called reverse transcription-polymerase chain reaction. The test identifies infection resulting from a class of viruses known as Enterovirus, which are responsible for approximately 90 percent of all viral meningitis cases.

The Xpert EV test is performed by adding the sample directly to a disposable, single-use cartridge. The cartridge is loaded into the Gene Xpert DX instrument which then conducts all the necessary laboratory procedures in a one-step, easy-to-use format that helps minimize errors.

The accuracy of the Xpert EV test was confirmed in a multi-site study at six institutions. A total of 255 patient samples were tested and demonstrated that 96 percent of patients who tested positive did have viral meningitis, and that 97 percent of patients who tested negative did not have viral meningitis.

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