FDA Approves First Rapid MRSA Blood Test

BY ROBERT FINN
San Francisco Bureau

The Food and Drug Administration has approved the first rapid blood test for methicillin-resistant *Staphylococcus aureus*.

The test, called the BD GeneOhm Staph SR, can detect both methicillin-resistant *S. aureus* (MRSA) and more common and less dangerous strains of the staph bacterium in just 2 hours. Manufactured by BD Diagnostics, a subsidiary of BD of Franklin Lakes, N.J., the test uses polymerase chain reaction techniques to detect a gene sequence unique to the drug-resistant strain of *S. aureus*. Traditional microbiology-based cultures require 24-72 hours to return results.

In 2005, BD received approval for a similar test, the BD GeneOhm MRSA Assay, which detects MRSA in nasal specimens. That test is used primarily to screen patients about to enter the hospital for the presence of asymptomatic MRSA so preventive measures can be taken.

The new blood test will be used primarily to choose among treatment options for patients already suspected of having an invasive staph infection.

According to BD spokesperson Barbara Kalavik, the company plans to begin marketing the BD GeneOhm Staph SR as soon as next week in the United States. Marketing began in Europe in late December 2007.

Both versions of the test require the use of a specialized instrument, called a PCR-thermocycler, which costs about $35,000. Not counting the capital cost of this equipment, the new BD GeneOhm Staph SR blood test is expected to cost about $35 per patient, compared with about $25 for the older BD GeneOhm MRSA Assay.

The approval was based on the results of a multicenter clinical trial that demonstrated that the BD GeneOhm Staph SR correctly identified 100% of the MRSA-positive specimens and more than 98% of other staph infections.

According to the FDA, "In order to preserve the integrity of positive test results, this test should be used only in patients suspected of a staph infection. The test should not be used to monitor treatment for staph infections because it cannot quantify a patient's response to treatment."

In addition, the FDA warned that test results should not be used as the sole basis for diagnosis, since positive results may reflect the bacteria's presence in patients who have already been successfully treated for staph infections. Furthermore, the agency cautioned, the test will not rule out other complicating conditions or infections. ■

Antibiotics Resolve Some Appendicitis

MONTREAL — Antibiotic therapy is largely successful for treating acute, nonperforated appendicitis, but unlike surgery, it carries a risk of recurrence, according to long-term follow-up on the first randomized comparison of both treatments, Dr. Staffan Eriksson said at a meeting sponsored by the International Society of Surgery.

"This is a treatment with quite a high number of recurrences, but the treatment may have some advantages. It can be used in patients who do not want surgery, or in patients who are not fit for surgery," said Dr. Eriksson of Uppsala (Sweden) University. It might also be useful for postponing night surgery until the next day, as has been shown in children, he said.

The multicenter study randomized 252 men, aged 15-50 years, from six Swedish centers, to surgery (124 patients) or antibiotic therapy (128 patients). Excluded from the study were patients in whom there was a high suspicion of perforation.

Patients in the antibiotic group received 2 days of intravenous therapy consisting of cefotaxime 2 g twice daily and tinidazole 0.8 g once daily. This was followed by 10 days of oral antibiotic therapy consisting of ofloxacin 0.2 g twice daily and tinidazole 0.5 g twice daily, he said.

In the surgery group, there was a 5% perforation rate and a 14% complication rate, mainly from wound infection.

The same rate of perforation was noted in the antibiotic group, in which 15 patients were treated surgically, 7 of whom had perforations. The remainder of patients in the antibiotic group (88%) recovered without surgery, Dr. Eriksson said. However, there was a 24% rate of recurrence within the 5-year follow-up.

—Kate Johnson