ICU MANAGEMENT & PRACTICE

FDA Clears Test to Help Manage Antibiotic Treatment For Lower Respiratory Tract Infections & Sepsis

ThermoFisher SCIENTIFIC

The U.S. Food and Drug Administration today cleared the expanded use of the Vidas Brahms PCT Assay to help health care providers determine if antibiotic treatment should be started or stopped in patients with lower respiratory tract infections, such as community-acquired pneumonia, and stopped in patients with sepsis. This is the first test to use procalcitonin (PCT), a protein associated with the body's response to a bacterial infection, as a biomarker to help make antibiotic management decisions in patients with these conditions.

"Unnecessary antibiotic use may contribute to the rise in antibiotic-resistant infections," said Alberto Gutierrez, Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health at the FDA's Center for Devices and Radiological Health. "This test may help clinicians make antibiotic treatment decisions."

The test works by measuring PCT. High levels of PCT suggest a bacterial infection, while low levels suggest a viral infection or non-infectious causes. Clinicians may be able to use PCT and other information to safely withhold or stop antibiotics. Because PCT may indicate the presence of a variety of bacterial infections, it does not detect the exact cause of a patient's symptoms.

Sepsis can be part of the body's response to an infection and can lead to tissue damage, organ failure, and death. Lower respiratory tract infections include community-acquired pneumonia, acute bronchitis, and acute exacerbations of chronic obstructive pulmonary disease (COPD). Bacteria often cause sepsis and lower respiratory tract infections, but viruses (particularly for lower respiratory tract infections) and non-infectious diseases can cause similar symptoms.

The Vidas Brahms test was cleared through the 510(k) pathway, a regulatory pathway for certain medical devices that are substantially equivalent to a legally marketed predicate device. The FDA first cleared this test to help clinicians better predict a patient's risk of dying or becoming sicker due to sepsis.

Data supporting the test's expanded use included clinical trial findings from published literature that compared PCT-guided therapy to standard therapy. Data from these prospective, randomized studies showed a significant decrease in antibiotic use for patients who had received PCT-guided therapy, without significantly affecting safety.

The Vidas Brahms test is intended to be used in the hospital or emergency room. Risks associated with use of the test may include false positive results, which may lead to unnecessary treatment with antibiotics, and false negative results, which may lead to a delay in the selection of appropriate therapy. Health care providers should not rely solely on PCT test results when making treatment decisions, but should interpret test results in the context of a patient's clinical status and other laboratory results. Health care providers and laboratorians should review the test's package insert for complete information regarding appropriate clinical use and test performance.

The Vidas Brahms test is manufactured by bioMérieux Inc. in Marcy l'Etoile, France.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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