

FOR IMMEDIATE RELEASE

BioFire Receives FDA Clearance for the FilmArray® Blood Culture Identification Panel

Test reduces time required to identify pathogens from days to about an hour

SALT LAKE CITY, Utah, (June 25, 2013) – BioFire Diagnostics, Inc., announced today the FDA clearance of its FilmArray Blood Culture Identification (BCID) Panel. To date, the 27-target panel is the most comprehensive test to be approved by the FDA.

The FilmArray BCID Panel provides results from positive blood cultures, and can identify more than 100 blood pathogens known to cause sepsis. For each hour that severe sepsis goes untreated, the average mortality rate increases by 7.6 percent, making timely diagnosis and administration of appropriate therapy imperative for positive patient outcomes.

The BCID Panel is designed to help hospitals identify bloodstream infection-causing organisms more rapidly than conventional identification methods. Rapid identification of pathogens in positive blood cultures has been shown to reduce mortality rates, shorten hospital stays and lower overall costs due to sepsis.

“We have made it a top priority this year to significantly reduce deaths caused by sepsis, and we plan to use diagnostic tools to help us achieve this goal,” said Paul Schreckenberger, Director of the Clinical Microbiology Laboratory at Loyola University Medical Center. “The faster we get test results, the faster we will be able to apply an optimized treatment plan, thus improving overall patient outcomes including reduced deaths, costs and the length of patient hospital stays.”

With an easy procedure requiring only two minutes of hands-on time, the BCID Panel can identify a pathogen in nine out of 10 positive blood cultures in about an hour, and is the only test that provides results for gram-positive bacteria, gram-negative bacteria and yeast that cause bloodstream infections.

In addition, the panel includes the first FDA cleared diagnostic test for the *bla*_{KPC} gene, which is linked to carbapenem resistance in *Klebsiella pneumoniae*, *Acinetobacter* spp and Carbapenem-resistant Enterobacteriaceae (CRE). Bloodstream infections with CREs are reported to kill up to 50 percent of infected patients. The BCID Panel also tests for common antimicrobial resistance genes associated with Methicillin-resistant *Staphylococcus aureus* (MRSA) and Vancomycin-resistant Enterococci (VRE).

“Customer feedback on the BCID Panel has been extremely positive. There is a lot of excitement for this product among our clinical hospital laboratory customers and anticipation for the effect it will likely have on antibiotic stewardship, patient care and cost reduction,” said Kirk Ririe, CEO of BioFire Diagnostics. “We expect an immediate increase in revenues since existing FilmArray customers have indicated that they intend to adopt the BCID Panel.”


About BioFire Diagnostics, Inc.

BioFire Diagnostics, Inc., formerly Idaho Technology, Inc., is a privately held clinical diagnostics company based in Salt Lake City, Utah. The company manufactures and distributes the user-friendly FilmArray System to hospital-based clinical laboratories across the U.S. and EU. BioFire currently offers the FilmArray Respiratory (RP) Panel and the Blood Culture Identification (BCID) Panel, both

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FDA-cleared and CE IVD marked. The FilmArray System is a significant advancement in user-friendliness and multiplex infectious disease testing capability for hospital clinical labs. Requiring only two minutes of hands-on time, the FilmArray System has about a 1-hour turnaround time, and each panel simultaneously tests for 20+ pathogens.

BioFire holds more than 85 patents related to polymerase chain reaction (PCR), and has used its extensive patent portfolio to successfully market nearly 200 products to the clinical, research and military markets. BioFire customers include the Department of Health and Human Services, the Department of Defense, state and local law enforcement, researchers and medical technicians across a spectrum of fields and industries.

For further information, please visit www.BioFireDx.com.

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