

BioFire Submits 510(k) Application to FDA for FilmArray® Blood Culture Identification Test

SALT LAKE CITY, Utah, (April 16, 2013) – BioFire Diagnostics, Inc. today announced that it has submitted the FilmArray Blood Culture Identification (BCID) Panel to the U.S. Food and Drug Administration (FDA) for 510(k) clearance.

The submission comes after the successful completion of clinical trials for the FilmArray BCID Panel. The panel provides automatic results for the most common infectious causes of sepsis, a significant cause of mortality and morbidity in adults, children and infants. BioFire anticipates commercial release of the panel in summer 2013, pending FDA clearance.

Using an easy procedure requiring only 2-3 minutes of hands-on time, the BCID Panel simultaneously tests positive blood cultures for approximately 90 percent of the gram-positive bacteria, gram-negative bacteria and yeast microbes that cause bloodstream infections.

In addition, the BCID Panel tests for common antimicrobial resistance genes associated with MRSA (Methicillin-Resistant *Staphylococcus aureus*), VRE (Vancomycin-Resistant Enterococci) and the newly emerging CRE (Carbapenem-Resistant Enterobacteriaceae).

Timely diagnosis and administration of effective treatments can significantly reduce mortality rates, duration of hospital stays and overall costs due to sepsis. The rapid and accurate FilmArray BCID Panel is designed to help hospitals identify bloodstream infections more quickly than commonly used methods in practice today.

“Our submission of the BCID Panel to the FDA marks another significant milestone in our efforts to expand the menu of tests for our FilmArray platform,” said Kirk Ririe, CEO of BioFire Diagnostics. “We believe the availability of the BCID Panel, the FDA-cleared Respiratory Panel and our future Gastrointestinal and Meningitis Panels will continue to increase the utility of the FilmArray in the hospital clinical laboratory.”

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 FDA-cleared and CE IVD marked FilmArray Respiratory Panel. The company continues to broaden its FilmArray test menu with the regulatory application for the Blood Culture ID Panel and ongoing development of a Gastrointestinal Panel and a Meningitis Panel.

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 and researchers and medical technicians across a spectrum of fields and industries.

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

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