FOR IMMEDIATE RELEASE

BioFire Submits 510(k) Application to FDA for FilmArray® Gastrointestinal Panel

SALT LAKE CITY, Utah, (February 18, 2014) – BioFire Diagnostics, LLC today announced that it has submitted the FilmArray Gastrointestinal (GI) Panel to the U.S. Food and Drug Administration (FDA) for 510(k) clearance. The comprehensive FilmArray GI Panel tests for over 20 common bacteria, viruses and parasites that cause infectious diarrhea.

The submission of the FilmArray GI Panel comes after the successful completion of a clinical study that included more than 1,500 prospective samples. The study was conducted at several hospital-based clinical laboratories in the US. BioFire anticipates commercial release of the FilmArray GI Panel in early summer 2014, pending FDA clearance. Concurrently, the FilmArray GI Panel will receive CE marking.

Despite advances in food safety, sanitation and medical treatment, infectious gastroenteritis remains a significant problem in industrialized countries among all age groups. In the United States, around 76 million cases of foodborne disease – resulting in 325,000 hospitalizations and 5,000 deaths – are estimated to occur each year. [1, 2]

Current diagnostic practice requires choosing amongst multiple tests that can be laborious to perform and do not cover the breadth of pathogens that cause gastrointestinal illness. These tests are often carried out in a stepwise fashion and the process can take too long to aid in timely pathogen-specific treatment decisions. Unlike open-platform testing that leaves labs vulnerable to cross-contamination, the FilmArray is a closed-system that integrates sample preparation, amplification and detection. With a run-time of about an hour and only two minutes of hands-on time, the FilmArray GI Panel is a comprehensive 23-target test that is performed directly from stool in transport media.

“We are thrilled to submit our GI Panel to the FDA and believe that this panel will deliver the rapid, comprehensive results that our customers need to aid in timely diagnosis of infectious diarrhea,” said Randy Rasmussen, CEO of BioFire Diagnostics. “This submission highlights our continued work to expand the menu of tests for our FilmArray platform.”

Additionally, BioFire has initiated studies for its Meningitis Panel, with FDA submission expected in 2015.

About BioFire Diagnostics, LLC

BioFire Diagnostics, LLC, a wholly owned subsidiary of bioMérieux, Inc., 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 and FilmArray Blood Culture Identification Panel. The company continues to broaden its FilmArray test menu with regulatory applications for the GI Panel and ongoing development of novel panels.

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.

1. Herikstad, H. *et al.* A population-based estimate of the burden of diarrheal illness in the United States: FoodNet, 1996–7. *Epidemiology and Infection* **129,** 9–17 (2002).

2. Mead, P. S. *et al.* Food-related illness and death in the United States. *Emerging infectious diseases* **5,** 607 (1999).

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