## BioFire Receives FDA Clearance for Updated FilmArray<sup>®</sup> Respiratory Panel Improving Sensitivity and Reactivity of Adenovirus Detection

**SALT LAKE CITY, Utah,** (February 20, 2013) – BioFire Diagnostics, Inc., announced today the FDA clearance of its updated FilmArray Respiratory Panel. The purpose of the updated panel is to improve the detection of Adenovirus. Studies performed to support the clearance of the modified panel demonstrated a 73% increase in the detection of Adenovirus and a 3-fold improvement in the limit of detection when compared to the original panel.

All existing assays for the 20 viral and bacterial targets in the original Respiratory Panel are unchanged. The updated panel includes an additional assay designed to increase sensitivity and reactivity for the detection of Adenovirus. BioFire plans to make the updated panel available to its customers in April.

Kirk Ririe, Chief Executive Officer of BioFire Diagnostics, said, "We are pleased that the updated FilmArray RP has received FDA clearance. BioFire continually strives to increase the quality of its products. The increased sensitivity and reactivity of the Adenovirus assay shows our commitment to customers and to providing accurate test results. With an improved Adenovirus assay, hospitals will be better prepared to identify the underlying pathogens causing upper respiratory tract infections."

## About FilmArray RP

FilmArray RP is BioFire's first clinical diagnostic test designed to run on the Company's novel FilmArray system, which represents a significant advancement in user-friendliness and multiplex infectious disease testing capability for hospital clinical labs. FilmArray RP rapidly detects nucleic acids in nasopharyngeal swabs obtained from individuals suspected of respiratory tract infections. Requiring only two minutes of hands-on time, FilmArray RP has about a 1-hour turnaround time, and simultaneously tests for the following panel of respiratory pathogens: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1 2009, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus, *Bordetella pertussis, Chlamydophila pneumoniae,* and *Mycoplasma pneumoniae*. FilmArray RP has received FDA clearance for twenty targets and is available for use by hospital and clinical laboratory professionals in the United States. In addition, the FilmArray RP is CE IVD marked. BioFire is continuing to develop a broader test menu for its FilmArray system, including a Blood Culture ID Panel, Gastrointestinal Panel, and a Meningitis 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 FilmArray RP, which operates on the user-friendly, patented FilmArray system, to hospital-based clinical laboratories across the U.S. and EU. With the FilmArray RP, BioFire provides the only FDA-cleared clinical diagnostic test for eight of the 20 organisms in its panel. In addition, BioFire continues to broaden its FilmArray test menu, and is currently developing a blood culture ID panel, a gastrointestinal panel, and a meningitis panel.

BioFire holds more than 85 patents related to polymerase chain reaction (PCR), and it has used its extensive patent portfolio to successfully market nearly 200 products to the clinical, research, and

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military markets. BioFire customers include the Department of Health and Human Services, the Department of Defense, state and local law enforcement, clinical laboratories, and research institutions across a spectrum of fields and industries around the world.

For further information, please visit <u>www.BioFireDx.com</u>.

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