



Press release

BioFire's FilmArray[®] Gastrointestinal Panel Receives FDA Clearance

Marcy l'Etoile, France - May 5, 2014 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that BioFire, its new molecular biology affiliate, received U.S. Food and Drug Administration (FDA) 510(k) clearance for the FilmArray[®] Gastrointestinal (GI) Panel¹. The 22-target FilmArray[®] GI Panel allows a syndromic approach² to the diagnosis of infectious diarrhea as it includes bacteria, viruses and parasites in one test. It is the most comprehensive gastrointestinal test to be cleared by the FDA and contains several pathogens receiving FDA clearance for the first time.

Current diagnostic practice requires choosing among 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. In addition, the FilmArray[®] GI Panel is performed directly from stool in Cary Blair transport media, takes only two minutes to set up, and produces results in about an hour. The FilmArray[®] GI Panel is a user-friendly alternative to the time-consuming, labor intensive, costly and technically complex testing methods used today and improves accuracy, timeliness and diagnostic yield for all 3 pathogen types.

"The excitement about this panel from the medical community has been astounding" said Randy Rasmussen, bioMérieux Corporate Vice-President Molecular Biology & CEO of BioFire Diagnostics. "We view this panel as a game-changer in the diagnosis of infectious diarrhea, delivering accurate and timely results. The breadth of pathogens on our GI Panel provides physicians with the underlying causes of gastrointestinal infectious disease, which aids with treatment decisions for their patients."

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, between 200 and 375 million episodes of diarrheal illness are estimated to occur each year, resulting in 73 million physician visits, 1.8 million hospitalizations, 3,100 deaths and \$6 billion in medical care and lost productivity. Early diagnosis facilitates timely and appropriate therapeutic interventions that can alleviate symptoms and prevent secondary infections³. In addition, rapid determination of the exact cause will assist in managing contacts and stopping the transmission of the pathogens which are contagious, thereby contributing to improved Public Health.

As of today, the FilmArray[®] menu comprises three panels, the Respiratory Panel and the Blood Culture Identification Panel (both of which are CE-marked and FDA-cleared) and the GI panel which is FDA-cleared. The latter clearance has been received in less than three months. BioFire anticipates CE IVD marking of the FilmArray[®] GI Panel in late spring of 2014.

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

ABOUT BIOMERIEUX

Pioneering diagnostics

A world leader in the field of *in vitro* diagnostics for 50 years, bioMérieux is present in more than 150 countries through 41 subsidiaries and a large network of distributors. In 2013, revenues reached €1,588 million with 87% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are used for diagnosing infectious diseases and providing high medical value results for cancer screening and monitoring and cardiovascular emergencies. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the NYSE Euronext Paris market. (Symbol: BIM - ISIN: FR0010096479).
Corporate website: www.biomerieux.com - Investor website: www.biomerieux-finance.com.

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

¹ A test panel is a predetermined group of medical tests used as an aid in the diagnosis and treatment of diseases

² The syndromic approach is based on analyzing a syndrome (i.e. a set of symptoms) and, with a single reagent, identifying the disease-causing organisms responsible for this syndrome, whether they are viruses, bacteria or parasites

³ Guerrant. *Clin Infect Disease*. 2001; 32:334-351

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