



BioFire Defense, a bioMérieux company, receives Emergency Use Assessment and Listing for FilmArray® Ebola Test by the World Health Organization

Marcy l'Etoile (France) – September 24, 2015 – BioFire Defense, LLC of Salt Lake City, UT announces that its FilmArray® Ebola test (BioThreat-E test¹) has received Emergency Use Assessment and Listing (EUAL) by the World Health Organization (WHO) allowing the test to be eligible for WHO procurement. The FilmArray® BioThreat-E test is intended for use on patients with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors. This follows the FilmArray® BioThreat-E test Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (US FDA) in October 2014.

In view of the unprecedented outbreak of Ebola virus raging in West and Central Africa since summer 2014, the WHO introduced an emergency mechanism to assess *in vitro* diagnostics that will be used to diagnose Ebola virus disease. As a result, the FilmArray® BioThreat-E test, which enables a simple, fast and reliable diagnosis of the Zaire Ebola virus involved in the current epidemic was evaluated by the WHO and received this EUAL.

The FilmArray® BioThreat-E test uses a nucleic acid amplification assay (PCR) to detect viral RNA, and is run on the BioFire FilmArray® system, a highly accurate, fast, automated and easy-to-use diagnostic instrument which is CE-marked and FDA cleared. The system delivers test results in about one hour, significantly reducing testing time and allowing health professionals to more rapidly diagnose Ebola infections, implement infection control precautions and make treatment decisions. As part of post-crisis surveillance, the FilmArray® BioThreat-E test can also be used to detect in due time new emergence or re-emergence of this virus.

“We are very pleased that our FilmArray® BioThreat-E test is now available for procurement by the WHO. This authorization fits our mission to help improve public health through a facilitated access to quality diagnostics. The rapid turnaround time, reliability and ease-of-use of FilmArray® will certainly be a great help to healthcare professionals for the diagnosis of Ebola in this unprecedented outbreak,” said Kirk Ririe, CEO of BioFire Defense.

In February 2015, BioFire Defense received the prestigious Global New Product Innovation Award for the FilmArray® Ebola test. Conferred annually by Frost & Sullivan, this award is given to companies that make the most active contribution to address a global need and serve the public interest. More recently, in the setting of the Interscience Conference of Antimicrobial Agents and

¹ This test has not been FDA cleared or approved.

This test has been authorized by FDA under an Emergency Use Authorization for use by CLIA* Moderate and High Complexity Laboratories only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) and not for any other viruses or pathogens.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola Zaire virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

* Clinical Laboratory Improvement Amendments

PRESS RELEASE

Chemotherapy (ICAAC), the clinical performance study of the FilmArray® Ebola test has been selected by the American Society for Microbiology to receive an ICAAC Program Committee Award in the area of Clinical Microbiology and Diagnosis. This award recognizes the outstanding presentation related to the African-based study entitled "Clinical Performance of the FilmArray® BioThreat-E Test for the Diagnosis of Ebola Virus Disease "in the Field" in Guinea".

ABOUT BIOFIRE DEFENSE

BioFire Defense, LLC, is a subsidiary of bioMérieux Inc. (Durham, NC) and is based in Salt Lake City, Utah. BioFire Defense is focused on technology innovation and product development of pathogen identification applications. It has developed and provided products for defense, food testing, clinical diagnostics, and the life sciences since 1990.

BioFire Diagnostics, LLC, its sister subsidiary, continues delivering and expanding the clinical applications of the FilmArray System to hospital-based clinical laboratories across the world.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2014, revenues reached €1,698 million with 88% 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 stock market (Symbol: BIM – ISIN: FR0010096479).

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