

**Date:** October 25, 2014

**Communication:** Press Release

**RE:** BioFire Defense receives emergency use authorization of FilmArray Ebola Tests

BioFire Defense, LLC of Salt Lake City, UT announced today that it has received Emergency Use Authorization by the U.S. Food and Drug Administration for its commercial FilmArray Ebola test (BioThreat-E test) as well as a second Ebola test to be used by laboratories designated by the Department of Defense. The FilmArray BioThreat-E is the first commercial Ebola test to be authorized for emergency use on patients with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

The BioFire FilmArray system is a highly accurate, fast, and easy to use clinical molecular biology (PCR) diagnostic device. The BioFire FilmArray system, which has previously been cleared by FDA, is capable of identifying hundreds of the most prevalent viruses, fungi, bacteria, and parasites associated with common patient infectious disease syndromes in one hour allowing health professionals to make treatment decisions faster. “The FilmArray system is in routine use in over 300 hospitals. The rapid authorization of emergency use of the FilmArray Ebola test by FDA instantly creates an extensive Ebola testing network in the United States.” said Randy Rasmussen, CEO of BioFire Diagnostics.

“We believe that a fast, easy-to-use and accurate Ebola test will help in the fight against this horrible virus. We are pleased that years of collaboration with the Department of Defense, FDA and other federal agencies have helped make this possible.” said Kirk Ririe, CEO of BioFire Defense.


The commercial BioThreat-E test is available to high and moderate complexity clinical laboratories in the US and can be run on any existing BioFire FilmArray system.

- This test has not been FDA cleared or approved;
- This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) and not for any other viruses or pathogens; and
- 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.

#### **ABOUT BIOFIRE DEFENSE**

BioFire Defense, LLC, formerly Idaho Technology, Inc., is a subsidiary of bioMerieux Inc. (Durham, NC) and is based in Salt Lake City, Utah. BioFire Defense is focused on technology innovation and product development of pathogen identification and the life science applications. It has developed and provided products for defense, food testing, 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 BIOMERIEUX**

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](http://www.biomerieux.com) - Investor website: [www.biomerieux-finance.com](http://www.biomerieux-finance.com).

