November 12, 2019

Cynthia Philips, Ph.D.
V.P. of Regulatory and Clinical Affairs
BioFire Defense, LLC
79 West 4500 South Suite 14
Salt Lake City, Utah 84107, US

Re: EUA140010/A003
Trade/Device Name: FilmArray Biothreat-E
Dated: June 4, 2019
Received: June 13, 2019

Dear Dr. Philips:

This letter is to notify you that your request to modify the authorized Instructions for Use of the FilmArray Biothreat-E test to include additional data on analytical exclusivity wet-testing and inclusion of associated limitations has been granted. In addition, the updates requested by the US Food and Drug Administration (FDA) to the (1) Instructions for Use, including wording in the intended use, to improve the overall clarity and accuracy of the document, and (2) Healthcare Provider and Patient Fact Sheets, have been granted.

Upon review, we concur that the data submitted in EUA140010/A003 supports the addition of the aforementioned data to the Instructions for Use. By submitting this amendment for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the FilmArray Biothreat-E test issued on October 25, 2014.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health