March 8, 2023

David Rabiger, PhD
Associate Director of Regulatory and Clinical Affairs
BioFire Defense, LLC
79 W 4500 S, Suite 14
Salt Lake City, Utah 84107

Re: Revocation of EUA140009

Dear Dr. Rabiger:

This letter is in response to the request from BioFire Defense, LLC, received via email on February 24, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the FilmArray NGDS BT-E Assay issued on October 25, 2014, amended on November 22,2014, and December 2, 2015, and reissued on March 2, 2015. BioFire Defense, LLC indicated that they are obsolescing the FilmArray NGDS BT-E Assay, that it is no longer commercially available, and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there is no viable FilmArray NGDS BT-E Assay reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because BioFire Defense, LLC has requested FDA withdraw the EUA for the FilmArray NGDS BT-E Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA140009 for the FilmArray NGDS BT-E Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the FilmArray NGDS BT-E Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration