



March 17, 2021

Kristen Kanack, Ph.D.
SVP, Regulatory and Clinical Affairs
BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108

Re: Revocation of EUA200521

Dear Dr. Kanack:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA200521) for emergency use of BioFire Diagnostics, LLC's BioFire Respiratory Panel 2.1 (RP2.1), issued on May 1, 2020, and amended on December 22, 2020.

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 revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the Act, an EUA may be issued only if FDA concludes there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition. FDA issued a De Novo classification order for the BioFire Respiratory Panel 2.1 (RP2.1) as a Class II (Special Controls) device under the generic name "*Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test.*" (to be codified in 21 CFR 866.3981) on March 17, 2021, (https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf). FDA has concluded that this is an adequate, approved, and available alternative to BioFire Diagnostics, LLC's BioFire Respiratory Panel 2.1 (RP2.1) EUA product (EUA200521) for detection and/or diagnosis of the virus that causes COVID-19.

Accordingly, FDA revokes EUA200521 pursuant to section 564(g)(2) of the Act. As of the date of this letter, the BioFire Respiratory Panel 2.1 (RP2.1) that was authorized by FDA for emergency use under EUA200521 is no longer authorized by FDA.

As discussed, FDA does not have concerns with the use of any remaining inventory of the BioFire Respiratory Panel 2.1 (RP2.1) that was distributed prior to revocation of the EUA, when such product is used in conjunction with the BioFire Respiratory Panel 2.1 (RP2.1) package insert/manufacturer instructions for use associated with the De Novo order issued March 17, 2021. FDA encourages the relabeling of any product already manufactured but not distributed prior to the revocation of the EUA with the BioFire Respiratory Panel 2.1 (RP2.1) package insert/manufacturer instructions for use associated with the De Novo request granted March 17, 2021. Importantly, the BioFire Respiratory Panel 2.1 (RP2.1) product for which FDA had issued an EUA and the product for which FDA has granted De Novo classification are manufactured under the same quality system with the same lot release criteria. BioFire Diagnostics, LLC should instruct customers who have remaining BioFire Respiratory Panel 2.1 (RP2.1) EUA product inventory that they may use their EUA product in combination with the package insert/manufacturer instructions for use labeling associated with the De Novo request granted March 17, 2021. FDA encourages BioFire Diagnostics, LLC to use all appropriate means (e.g., mail, email, or website link) to notify affected customers of this EUA revocation and provide access to the package insert/manufacturer instructions for use labeling associated with the De Novo order issued March 17, 2021.

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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration