April 27, 2021

Kevin Bourzac Ph.D.,
VP of Regulatory and Clinical Affairs
BioFire Diagnostics, LLC
515 Colorow Drive,
Salt Lake City, UT 84108

Re: EUA202392/S003
Trade/Device Name: BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)
Dated: March 25, 2021
Received: March 26, 2021

Dear Dr. Bourzac:

This is to notify you that your request to update the Instructions for Use (IFU) of the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) to; (1) align with the IFU of the de novo for the BioFire Respiratory Panel 2.1 (RP2.1) including performance data, (2) addition of saline (up to 3 mL) as an acceptable transport medium for collection of nasopharyngeal swabs, and (3) update the *in silico* inclusivity analysis, is granted. FDA also made minor updates to the IFU, Quick Guide, Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect more recent authorizations. By submitting these revisions for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the BioFire Respiratory Panel 2.1 (RP2.1) issued on October 2, 2020.

Sincerely yours,

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