December 22, 2020

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

Re: EUA200521/S002
Trade/Device Name: BioFire Respiratory Panel 2.1 (RP2.1)
Dated: November 19, 2020
Received: November 20, 2020

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 (RP2.1) to include the results of the FDA SARS-CoV-2 Reference Panel testing, is granted. We also concur with the minor updates made to the Fact Sheet for Healthcare Providers and Fact Sheet for Patients. FDA made updates to the IFU to reflect more recent authorizations and reporting requirements for SARS-CoV-2. FDA also updated the Fact Sheet for Healthcare Providers and the 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 May 1, 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