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: EUA202392/S001
Trade/Device Name: BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)
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-EZ (RP2.1-EZ) to include the results of the FDA SARS-CoV-2 Reference Panel testing and fic some errors in the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) Quick Guide, is granted. We also concur with the minor updates made to the Fact Sheet for Healthcare Providers and Fact Sheet for Patients. FDA made minor updates to the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) IFU and Quick Guide 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,

Uwe Scherf -S

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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