April 26, 2022

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

Re: EUA202392/S005
Trade/Device Name: BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)
Dated: April 14, 2022
Received: April 14, 2022

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 results from your recent *in silico* inclusivity analysis and some other minor revisions, is granted. By submitting this revision 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) re-issued on August 30, 2021.

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

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