June 05, 2023

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

Re: EUA202392/S006
Trade/Device Name: BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)
Dated: May 18, 2023
Received: May 18, 2023

Dear Dr. Bourzac:

This is to notify you that your request to extend the shelf-life expiration date of the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) to 18 months when stored at the recommended conditions in the authorized labeling, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA202392/S006 supports the requested updates for use with the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ). FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the reissued letter authorizing the emergency use of the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ) 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health