May 31, 2022

Cynthia Phillips, Ph.D.
VP Regulatory, Quality and Clinical Affairs
BioFire Defense, LLC
4900 S 79 W, Suite 14
Salt Lake City UT 84107

Re: EUA200044/S011
Trade/Device Name: BioFire COVID-19 Test
Dated: May 24, 2022
Received: May 24, 2022

Dear Dr. Phillips:

This is to notify you that your request to update the authorized labeling for BioFire COVID-19 Test to include revisions that were agreed upon during interactive review of EUA200044/S009/A001 but not reflected in some of the May 24, 2022, authorized labeling, is granted. Upon review, we concur that the information submitted in EUA200044/S011 supports the requested updates for use with the BioFire COVID-19 Test. 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 letter authorizing the emergency use of the BioFire COVID-19 Test re-issued on May 24, 2022.

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