April 30, 2020

Cynthia Phillips, Ph.D.
VP of Regulatory, Quality, and Clinical Affairs
BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, Utah 84107

Re: EUA200044/A001
Trade/Device Name: BioFire COVID-19 Test
Dated: April 22, 2020
Received: April 22, 2020

Dear Dr. Phillips:

This is to notify you that your request to update the Instructions for Use (IFU) labeling for the BioFire COVID-19 Test to; (1) add a summary of additional clinical testing performed on archived nasopharyngeal swab (NPS) specimens that have been previously tested positive for SARS-CoV-2 virus RNA, (2) revise the clinical contrived testing summary to improve clarity, (3) add concentration values in TCID50/mL units to the Limit of Detection section, and (4) make minor edits to formatting, is granted. Upon review, we concur that the data and information submitted in EUA200044/A001 supports the requested updates for the BioFire COVID-19 Test. We also concur with the minor formatting update to the BioFire COVID-19 Test Verification Guidelines. By submitting this amendment 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 issued on March 23, 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