



March 7, 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/S010
Trade/Device Name: BioFire COVID-19 Test
Dated: March 1, 2022
Received: March 1, 2022

Dear Dr. Phillips:

This is to notify you that your request to update the BioFire COVID-19 Test to extend the shelf-life expiration date for version v1.1 to 15 months, when stored at the recommended storage temperature (18-30°C), based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA200044/S010 supports the requested updates for use with version v1.1 of 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 August 24, 2021.

Sincerely yours,

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