November 15, 2022

Aarthi Srinivasan
Regulatory Affairs
Verily Life Sciences
269 E Grand Ave.
South San Francisco, CA 94080

Re: EUA202054/S005 & S006
Trade/Device Name: Verily COVID-19 RT-PCR Test
Dated: September 28, 2021, and May 15, 2022
Received: October 4, 2021, and May 16, 2022

Dear Aarthi Srinivasan:

This is to notify you that your request is granted to update the authorized labeling of the Verily COVID-19 RT-PCR Test to; (1) address Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (2) update the EUA Summary with the results of the additional pooling performance evaluation done to fulfill Condition of Authorization U. in the November 8, 2021 Letter of Authorization, and (3) include minor updates to the laboratory standard operating procedures that are clarifying in nature. Upon review, we concur that the data and information submitted in EUA202054/S005 & S006 supports the requested updates for use with the Verily COVID-19 RT-PCR Test and fulfills Condition of Authorization U. in the November 8, 2021, letter and Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021. FDA have updated the Healthcare Provider and Patient Fact Sheets to reflect 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 letter authorizing the emergency use of the Verily COVID-19 RT-PCR Test re-issued on November 8, 2021, and the Viral Mutation Revision Letter issued on September 23, 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