U.S. FOOD & DRUG ADMINISTRATION

September 21, 2020

Michelle L. Neff, J.D.
Research Advisor
Global Regulatory Affairs, Drug Delivery & Digital Health
Eli Lilly and Company
Lilly Corporate Center 98A/3C
Indianapolis, IN 46285

Re: EUA200041/S001
Trade/Device Name: Lilly SARS-CoV-2 Assay
Dated: August 17, 2020
Received: August 17, 2020

Dear Ms. Neff:

This is to notify you that your request to update the authorized labeling of the Lilly SARS-CoV-2 Assay to include the results of a post-authorization clinical evaluation preformed to address Condition of Authorization S, is granted. Upon review, we concur that the data and information submitted in EUA200041/S001 supports the requested update to the Lilly SARS-CoV-2 Assay authorized labeling. FDA also requested a minor update to the intended use to reflect more recent reporting recommendations. 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 Lilly SARS-CoV-2 Assay issued on July 27, 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