June 2, 2021

Michelle Ortiz, Chief Operating Officer
Synergy Diagnostic Laboratory, Inc.
DBA SynergyDx
4081 SW 47th Avenue, Suite 1-4
Davie, FL 33314

Re: EUA210195/S001
Trade/Device Name: SynergyDx SARS-CoV-2 RNA Test
Dated: May 10, 2021
Received: May 13, 2021

Dear Michelle Ortiz:

This is to notify you that your request to update the EUA Summary of the SynergyDx SARS-CoV-2 RNA Test to include the results of a post-authorization clinical study in individuals without symptoms or other reasons to suspect COVID-19, performed to fulfill Condition of Authorization O. in the April 16, 2021 letter of authorization, is granted. Upon review, we concur that the data and information submitted in EUA210195/S001 supports the requested updates for use with the SynergyDx SARS-CoV-2 RNA Test. FDA have also updated the Fact Sheet for Healthcare Providers to update some of the webpage links. 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 SynergyDx SARS-CoV-2 RNA Test issued on April 16, 2021.

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