June 15, 2020

Kenneth Butz
Associate Director, Regulatory Affairs
PPD, LLC
Representing: Fulgent Therapeutics, LLC
3900 Paramount Parkway
Morrisville, NC 27560

Re: EUA200156/A001
Trade/Device Name: Fulgent COVID-19 by RT-PCR Test
Dated: May 22, 2020
Received: May 22, 2020

Dear Mr. Butz:

This is to notify you that your request to update the authorized labeling of the Fulgent COVID-19 by RT-PCR Test to include use of nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using the Picture COVID-19 Home Collection Kit, as an authorized home collection kit, when determined to be appropriate by a healthcare provider, is granted. Upon review, we concur that the data, additional labeling, and information submitted in EUA200156/A001 supports use of the Picture COVID-19 Home Collection Kit with the Fulgent COVID-19 by RT-PCR Test. 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 Fulgent COVID-19 by RT-PCR Test issued on May 15, 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