July 8, 2022

Marcia Eisenberg, PhD
Senior Vice President & Chief Scientific Officer
Laboratory Corporation of America
531 S. Spring Street
Burlington, NC 27215

Re: EUA203057/S004
Trade/Device Name: Pixel by Labcorp COVID-19 Test Home Collection Kit
Dated: April 28, 2022
Received: April 28, 2022

Dear Dr. Eisenberg:

This is to notify you that your request is granted to (1) update the EUA Summary to extend the winter sample stability claim for anterior nasal swab specimens collected using the Pixel by Labcorp COVID-19 Test Home Collection Kit to 56 hours, and (2) provide for the record the updated "Accessioning of the Labcorp COVID-19 Home Collection Kits" Standard Operating Procedure (SOP) that is common across Labcorp COVID-19 EUA submissions. Upon review, we concur that the data and information submitted in EUA203057/S004 supports the requested updates for use with the Pixel by Labcorp COVID-19 Test Home Collection Kit. 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 reissued letter authorizing the emergency use of the Pixel by Labcorp COVID-19 Test Home Collection Kit re-issued on May 11, 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