November 1, 2022

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

Re: EUA203057/S005
Trade/Device Name: Pixel by Labcorp COVID-19 Test Home Collection Kit
Dated: September 1, 2022
Received: September 1, 2022

Dear Dr. Eisenberg:

This is to notify you that your request is granted to; (1) offer additional online ordering options through authorized distributors for the Pixel by Labcorp COVID-19 Test Home Collection Kit to increase community access to testing, and (2) update the Pixel by Labcorp COVID-19 Test Home Collection Kit box label to reflect the authorized device name and update the location of the Universal Product Code (UPC) sticker. Upon review, we concur that the information submitted in EUA203057/S005 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