



April 1, 2022

Jeffrey Albrecht, Ph.D.
Associate Vice President
Laboratory Corporation of America (“Labcorp”)
1447 York Court
Burlington, NC, 27215

Re: EUA203057/S003
Trade/Device Name: Pixel by Labcorp COVID-19 Test Home Collection Kit
Dated: December 15, 2021
Received: December 16, 2021

Dear Dr. Albrecht:

This is to notify you that your request to update the shelf-life of the Pixel by Labcorp COVID-19 Test Home Collection Kit from 1 to 2 years total, is granted. Upon review, we concur that the data and information submitted in EUA203057/S003 supports the requested updates for use with the Pixel by Labcorp COVID-19 Test Home Collection Kit. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Individuals to reflect language used in more recent authorizations. 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 issued on May 11, 2021.

Sincerely yours,

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