May 11, 2021

Brian Krueger
Associate Vice President, Research and Development
Laboratory Corporation of America
1447 York Court
Burlington, NC 27215

Re: EUA200011/S010
Trade/Device Name: COVID-19 RT-PCR Test
Dated: April 30, 2021
Received: April 30, 2021

Dear Dr. Krueger:

This is to notify you that your request to update the authorized labeling of the COVID-19 RT-PCR Test to extend the shipping summer sample stability claim of anterior nasal swab specimens collected at home using the Labcorp At Home COVID-19 Test Home Collection Kit from 2 to 4 days, is granted. Upon review, we concur that the data and information submitted in EUA200011/S010 supports the requested update for use with the COVID-19 RT-PCR Test. 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 COVID-19 RT-PCR Test re-issued on April 28, 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