July 1, 2020

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

Re: EUA200011/A003
Trade/Device Name: COVID-19 RT-PCR Test
Dated: May 1, 2020
Received: May 1, 2020

Dear Dr. Krueger:

This is to notify you that your request to update the authorized labeling of the COVID-19 RT-PCR Test to; (1) add the LabCorp At Home COVID-19 Test Home Collection Kit as an authorized home collection kit for nasal specimens, that will not be administered through the Pixel platform, and associated authorized labeling, (2) update the intended use to include that the test is also for use with "*the LabCorp At Home COVID-19 test home collection kit to self-collect nasal swab specimens at home when directly ordered by a healthcare provider*", (3) update the current home collection kit cotton swab to a foam swab going forward, (4) update the Pixel by LabCorp COVID-19 test home collection kit patient instructions, and (5) update the extraction protocol for the ThermoFisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit on the Thermo Fisher KingFisher Flex Instrument to reduce the sample and therefore reagent volumes to preserve extraction reagents due to current shortages, is granted. Upon review, we concur that the data and information submitted in EUA200011/A003 supports the requested updates for use with the COVID-19 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 COVID-19 RT-PCR Test re-issued on April 20, 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