April 14, 2020

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

Re: EUA200011/A002
Trade/Device Name: COVID-19 RT-PCR Test
Dated: April 9, 2020
Received: April 9, 2020

Dear Dr. Krueger:

This is to notify you that your request to update the Instructions for Use (IFU) of the COVID-19 RT-PCR Test to; (1) add multiplex testing format using the N1, N2 and RP primer/probes to increase the throughput of the LabCorp EUA assay, (2) add an automated Hamilton Microlab Star liquid handler for the multiplex assay and, (3) add a second extraction method, the Thermo Fisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit on the Thermo Fisher KingFisher Flex Instrument to the multiplex assay, is granted. Upon review, we concur that the data submitted in EUA200011/A002 supports the multiplex testing primer-probe target combination format for the COVID-19 RT-PCR Test. We also concur with the related changes to the Instructions for Use that reflect the requested updates and in addition FDAs request to include nasal swabs as an additional specimen type to the intended use, along with the associated update to the Healthcare Provider Fact Sheet for 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 issued on March 16, 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