April 7, 2022

Marcia Eisenberg
Sr Vice President and Chief Scientific Officer
Laboratory Corporation of America
1447 York Court
Burlington, NC 27215

Re: EUA200011/S011
Trade/Device Name: COVID-19 RT-PCR Test
Dated: December 17, 2021
Received: December 17, 2021

Dear Ms. Eisenberg:

This is to notify you that your request to update the Standard Operating Procedures (SOPs) of the COVID-19 RT-PCR Test to; (1) add DC Health's Test Yourself DC At-Home COVID-19 Collection Kit to the "Accessioning of the LabCorp COVID-19 Home Test Kits" SOP, and (2) clarify in the "SARS-CoV-2 Detection by Nucleic Acid Amplification (LabCorp EUA – 384 Well Multiplex)" SOP that an "Invalid" result is reported to patients and to DC Health as "Specimen Unsatisfactory for Evaluation", is granted. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients 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 COVID-19 RT-PCR Test 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