July 21, 2021

Brandi Limbago, Ph.D.
EOC Laboratory and Testing Task Force Lead
CDC COVID-19 Response
Centers for Disease Control and Prevention
1600 Clifton Rd. NE, MS H24-8
Atlanta, GA 30333

Re: EUA200001/S010
Trade/Device Name: CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel
Dated: July 6, 2021
Received: July 7, 2021

Dear Dr. Limbago:

This is to notify you that your request to update the Instructions for Use (IFU) of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel to update of in silico inclusivity analysis summary, is granted. Upon review, we concur that the data and information submitted in EUA200001/S010 supports the requested update for use with the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. In addition, the Food and Drug Administration (FDA) has updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect more recent authorizations. By submitting this EUA revision for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel re-issued on December 1, 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