March 15, 2020

Kirsten St. George, MAppSc, Ph.D.,
Chief, Laboratory of Viral Diseases
Wadsworth Center, NYSDOH
Empire State Plaza, Coring Tower
Albany, NY 12237

Re: EUA200003/A002
Trade/Device Name: New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel
Dated: March 14, 2020
Received: March 15, 2020

Dear Dr. St. George:

This is to notify you that your request to update the intended use of the New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel to change "presumptive positive" to "positive" has been granted. The New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel instructions for use, Healthcare Provider and Patient Fact Sheets have been updated to reflect this change and also some additional edits to update information. 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 New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel issued on March 10, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health