November 13, 2020

Michael J. Wagner, Esq.
Senior Corporate Counsel
Quest Diagnostics Infectious Disease, Inc.
33608 Ortega Highway Bldg B-West Wing
San Juan Capistrano, CA 92675

Re: EUA200015/S006
Trade/Device Name: SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR
Dated: September 4, 2020
Received: September 4, 2020

Dear Mr. Wagner:

This is to notify you that your request to update the Instructions for Use (IFU) of the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR to; (1) change the language in the pooling disclosure to patients, (2) update the pooling monitoring plan to be consistent with more recent authorizations, and (3) modify the limitation statement regarding the lack of RNaseP specimen adequacy control, is granted. Upon review, we concur that the information submitted in EUA200015/S006 supports the requested updates for use with the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR and have updated the Fact Sheet for Healthcare Providers accordingly. FDA has made updates to the Intended Use statement and IFU to reflect recent policy. 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 re-issued letter authorizing the emergency use of the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR issued on August 7, 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
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