March 26, 2020

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

Re: EUA200015/A001
Trade/Device Name: SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR
Dated: March 24, 2020
Received: March 24, 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 SARS-CoV-2 primer-probes target combination from N1+N2 (separate wells) to N1+N3 (same well) in order to double testing capacity, and (2) temporarily allow use of a DNA-based internal process control in situations where supply chain issues limit the availability of the RNA-based internal process control, is granted. Upon review, we concur that the data submitted in EUA200015/A001 supports the change in the SARS-CoV-2 primer-probe target combination for the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR. We also concur with the related updates of the Instructions for Use for the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR the reflect the requested updates. 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 SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR issued on March 17, 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