



July 28, 2020

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

Re: EUA200015/A004  
Trade/Device Name: SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR  
Dated: July 20, 2020  
Received: July 20, 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 add use of the Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek, Cat. M6219-2304) with the Hamilton MagEx STAR ("Omega Method") as an additional extraction method, and the associated updated instructions and performance data, is granted. Upon review, we concur that the data submitted in EUA200015/A004 supports the requested updates for the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR. We also concur with the minor updates and clarifications made to the Instructions for Use for the SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR. By submitting this EUA revision request 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 re-issued on July 18, 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