July 7, 2022

Michael J. Wagner Esq.
Senior Corporate Counsel
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675

Re: EUA220010/S001
Trade/Device Name: Quest COVID-19 PCR Test Home Collection Kit
Dated: May 20, 2022
Received: May 20, 2022

Dear Mr. Wagner:

This is to notify you that your request to update the Quest COVID-19 PCR Test Home Collection Kit; (1) EUA Summary and Retail Collection kit Workflow to remove use of UTM as an option for anterior nasal swab specimen transport media, and (2) update the EUA Summary with the results of the additional specimen stability study performed to fulfil Condition of Authorization Q. in the March 21, 2022 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA220010/S001 supports the requested updates for use with the Quest COVID-19 PCR Test Home Collection Kit and fulfills Condition of Authorization Q. from the March 21, 2022 letter. 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 letter authorizing the emergency use of the Quest COVID-19 PCR Test Home Collection Kit issued on March 21, 2022.

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