



October 6, 2022

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

Re: EUA220033/S002/A001
Trade/Device Name: Quest COVID-19 PCR DTC
Dated: September 2, 2022 and September 14, 2022
Received: September 2, 2022 and September 14, 2022

Dear Mr. Wagner:

This is to notify you that your request to update the EUA Summary of the Quest COVID-19 PCR DTC to include results of the additional asymptomatic screening performance evaluation conducted to fulfill Condition of Authorization N. from the March 21, 2022 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA220033/S002/A001 supports the requested updates for use with the Quest COVID-19 PCR DTC and fulfills Condition of Authorization N. from the March 21, 2022, letter of authorization. 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 DTC issued on March 21, 2022.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health