U.S. FOOD & DRUG ADMINISTRATION

September 16, 2022

Ronald H. Lollar
VP, Clinical and Regulatory Affairs – Infectious Disease
Quidel Corporation
9975 Summers Ridge Road
San Diego, CA 92121

Re: EUA200016/S005
Trade/Device Name: Lyra SARS-CoV-2 Assay
Dated: July 11, 2022
Received: July 11, 2022

Dear Mr. Lollar:

This is to notify you that your request to update the Instructions for Use of the Lyra SARS-CoV-2 Assay to; (1) add new clinical performance data using anterior nasal swab specimens, (2) add Quidel Transport Media (QTM) as a compatible media type and include acceptable storage conditions for specimens in QTM, (3) add a new limitation to limit the number of freeze/thaw cycles for specimens to one prior to testing, (4) modify the limitation section to reflect the new anterior nasal swab specimen data provided and reflect language used in more recent authorizations, and (5) provide minor modifications to the warning section consistent with more recent authorizations, is granted. Upon review, we concur that the data and information submitted in EUA200016/S005 supports the requested updates for use with the Lyra SARS-CoV-2 Assay. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations. 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 Lyra SARS-CoV-2 Assay issued on March 17, 2020.

Sincerely yours,

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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health