April 21, 2021

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

Re: EUA200016/S004
Trade/Device Name: Lyra SARS-CoV-2 Assay
Dated: April 14, 2021
Received: April 14, 2021

Dear Mr. Lollar:

This is to notify you that your request to update the Instructions for Use (IFU) of the Lyra SARS-CoV-2 Assay to; (1) update to the workflow for specimens that when initially tested generate a Ct value between 0 and 5 to allow review of the amplification curves and an additional dilution step and retest for such specimens prior to final result interpretation, (2) update the *in silico* analysis for inclusivity, (3) include a qualification protocol and Emergency Use Only (EUO) labeling for Research Use Only (RUO) instruments used by the product, and (4) other minor updates and clarifications to reflect more recent authorizations, is granted. Upon review, we concur that the data and information submitted in EUA200016/S004 supports the requested updates for use with the Lyra SARS-CoV-2 Assay. In addition, FDA have updated the Fact Sheet for Healthcare Provider and Fact Sheet for Patients to reflect 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,

_____

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