May 25, 2021

Ronald Lollar
Senior Director, Clinical and Regulatory Affairs
Quidel Corporation
9975 Summers Ridge Road
San Diego, CA 92121

Re: EUA200423/S003
Trade/Device Name: Lyra Direct 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 Direct 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 and include a limitation around SARS-CoV-2 variants, and (3) other minor updates and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200423/S003 supports the requested updates for use with the Lyra Direct 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 Direct SARS-CoV-2 Assay isued on May 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