January 26, 2021

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

Re: EUA200423/S002
Trade/Device Name: Lyra Direct SARS-CoV-2 Assay
Dated: October 19, 2020
Received: October 20, 2020

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 the storage claim for lysed specimens, (2) include results of the prospective post-authorization clinical study, (3) update inclusivity data, and (4) include an RUO instrument qualification protocol, is granted. Upon review, we concur that the data and information submitted in EUA200423/S002 supports the requested updates for use with the Lyra Direct SARS-CoV-2 Assay. 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