



April 17, 2023

Selena Liu
Senior Regulatory Specialist
Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701

Re: EUA200016/S008
Trade/Device Name: Lyra SARS-CoV-2 Assay
Dated: April 03, 2023
Received: April 03, 2023

Dear Ms. Liu:

This is to notify you that your request to update the Instructions for Use of the Lyra SARS-CoV-2 Assay to; (1) add the EMAG nucleic acid extraction system for use with the Lyra SARS-CoV-2 Assay, (2) include materials, limitations, and instructions relating to the use of the EMAG system for nucleic acid extraction, and (3) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA200016/S008 supports the requested updates for use with the Lyra 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 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health