April 8, 2020

Ronald H. Lollar,
Senior Director Clinical and Regulatory Affairs
Quidel Corporation
2005 East State Street, Suite 100,
Athens, OH 45701 US

Re: EUA200016/A002
Trade/Device Name: Lyra SARS-CoV-2 Assay
Dated: March 24, 2020
Received: March 31, 2020

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 "nasal" swab specimens to the intended use , (2) add the CDC Viral Transport Medium and Molecular Transport Media (MTM) to the list of acceptable transport media, (3) to allow the use of the Bio-Rad CFX96 Touch and Thermofisher QuantStudio 7 Pro real-time PCR instruments for amplification and detection of the SARS-CoV-2 RNA, and (4) to make various clarifying and organizational edits to the Instructions for Use, has been granted. Upon review, we concur that the data submitted in EUA200016/A002 supports the requested updates for use with the Lyra SARS-CoV-2 Assay. We also concur with the related changes to the Lyra SARS-CoV-2 Assay instructions for Use that reflect the requested updates and have also updated the Healthcare Provider Fact Sheet for the Lyra SARS-CoV-2 Assay accordingly. By submitting this amendment 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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Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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