March 23, 2020

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

Re: EUA200016/A001
Trade/Device Name: Lyra SARS-CoV-2 Assay
Dated: March 20, 2020
Received: March 20, 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) include use of additional real-time PCR instruments, Applied Biosystems 7500 Standard, Roche LightCycler 480, or Qiagen Rotor-Gene Q, and (2) extend the storage claim for nucleic acid extracts at 2°C to 8°C from 8 to 24 hours has been granted. In addition, the Lyra SARS-CoV-2 Assay – Verification Requirements protocol as requested has been included as part of the FDA posted Manufacturer Instructions/Package Insert. 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,

_____

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health