March 25, 2021

Ronald H. Lollar
VP, Clinical and Regulatory Affairs – Infectious Disease
Quidel Corporation
9975 Summers Ridge Road
San Diego, CA 92121

Re: EUA203087/S002
Trade/Device Name: Solana SARS-CoV-2 Assay
Dated: March 1, 2021
Received: March 3, 2021

Dear Mr. Lollar:

This is to notify you that your request to update the Instructions for Use (IFU) of the Solana SARS-CoV-2 Assay to include the Remel M4RT and Quidel QTM as acceptable transport media, is granted. Upon review, we concur that the data and information submitted in EUA203087/S002 supports the requested updates for use with the Solana SARS-CoV-2. In addition, FDA has updated the Fact Sheet for Healthcare Providers and the 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 Solana SARS-CoV-2 Assay issued on December 23, 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