May 5, 2022

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

Re: EUA203087/S004
Trade/Device Name: Solana SARS-CoV-2 Assay
Dated: February 1, 2022
Received: February 1, 2022

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; (1) replace the frozen master mix with a lyophilized version of the same primer/probe master mix, (2) add a bridging clinical study to the Clinical Performance section to support the use of the lyophilized reagents, (3) include additional data using lyophilized reagents to the Limit of Detection study, (4) update Limitation language regarding variants in accordance with the September 23, 2021 Viral Mutation Revision Letter, (5) update the *in silico* inclusivity analysis, and (6) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA203087/S004 supports the requested updates for use with the Solana SARS-CoV-2 Assay. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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