July 17, 2020

Ron H. Lollar
Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701

Re: EUA200742/A002
Trade/Device Name: Sofia 2 SARS Antigen FIA
Dated: June 29, 2020
Received: June 29, 2020

Dear Mr. Lollar:

This is to notify you that your request to update the Instructions for Use (IFU) and the Quick Reference Instructions (QRI) of the Sofia 2 SARS Antigen FIA to; (1) claim use of only direct nasopharyngeal (NP) and nasal (NS) swab specimens and remove the use of viral transport media (VTM) in the intended use and associated updated to the IFU, (2) update the clinical performance section in the IFU to include direct nasal performance and remove studies relating to spiked swabs and frozen VTM, (3) include in the intended use testing of individuals "*within the first five days of the onset of symptoms*", and (4) other minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200742/A002 supports the requested updates for use with the Sofia SARS Antigen FIA, the Healthcare Provider and Patient Fact Sheets have also been updated, 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 Sofia SARS Antigen FIA (formerly Sofia 2 SARS Antigen FIA) issued on May 8, 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