June 9, 2020

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

Re: EUA200742/A001
Trade/Device Name: Sofia 2 SARS Antigen FIA
Dated: May 20, 2020
Received: June 4, 2020

Dear Mr. Lollar:

This is to notify you that your request to update the Instructions for Use (IFU) of the Sofia 2 SARS Antigen FIA to; (1) specify in the Intended Use specific transport media, either Copan UTM or the CDC's formulation of VTM, for use with the test, (2) add the Sofia Instrument in addition to the Sofia 2 Instrument and include the additional performance testing, (3) update the name of the test from "Sofia 2 SARS Antigen FIA" to the "Sofia SARS Antigen FIA", (4) add results of cross-reactivity, endogenous interference substances, and some additional clinical data requested as part of the conditions of authorization, and (5) other minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200742/A001 supports the requested updates for use with the Sofia SARS Antigen FIA, and we have also updated the Healthcare Provider and Patient Fact Sheets, 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