November 19, 2021

Sunyoung Park
General Manager
Sugentech, Inc.
721-26, Jeongjungyeonje-ro, Osong-eup, Heungdeok-gu,
Cheongju-si
Chungcheonbuk-do, 28161
Republic of Korea

Re: EUA202243/S004
Trade/Device Name: SGTi-flex COVID-19 IgG
Dated: November 10, 2021
Received: November 10, 2021

Dear Sunyoung Park:

This is to notify you that your request to modify the cassette design of the SGTi-flex COVID-19 IgG is granted. Upon review, we concur that the information provided in EUA202243/S004 supports the requested updates for the SGTi-flex COVID-19 IgG. By submitting this supplement 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 SGTi-flex COVID-19 IgG reissued on August 11, 2021.

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