



November 02, 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/S003
Trade/Device Name: SGTi-flex COVID-19 IgG
Dated: October 05, 2021
Received: October 06, 2021

Dear Sunyoung Park:

This is to notify you that your request to (1) extend the SGTi-flex COVID-19 IgG shelf-life stability to 12 months when stored at 2-30°C, and (2) update the Instructions for Use (IFU) to indicate stability of test through the printed expiration date is granted. Upon review, we concur the information provided in EUA202243/S003 supports the requested updates for use with the SGTi-flex COVID-19 IgG. FDA also requested minor updates to the Quick Reference Instructions (QRI) and Controls IFU for clarity. 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 issued on August 11, 2021.

Sincerely yours,

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