



December 11, 2023

Kelli Turner
Senior Program Manager
Representing:
SD Biosensor, Inc.
C-4th & 5th, 16, Deogyong-Daero,
1556beon-Gil, Yeongtong-Gu,
Suwon-si, Gyeonggi-Do,
Republic of Korea 16690

Re: EUA210661/S016
Trade/Device Name: Pilot COVID-19 At-Home Test
Dated: October 15, 2023
Received: October 15, 2023

Dear Kelli Turner:

This is to notify you that your request to update the Pilot COVID-19 At-Home Test to extend the shelf-life expiration date to 16 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210661/S016 support the requested update for the Pilot COVID-19 At-Home Test. 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 Pilot COVID-19 At-Home Test re-issued on May 5, 2023.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health