



October 14, 2022

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/S012  
Trade/Device Name: Pilot COVID-19 At-Home Test  
Dated: August 24, 2022  
Received: August 24, 2022

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 12 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/S012 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 April 4, 2022.

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