March 7, 2022

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

Re: EUA210661/S003
Trade/Device Name: COVID-19 At-Home Test
Dated: February 17, 2022
Received: February 17, 2022

Dear Kelli Turner:

This is to notify you that your request to update the COVID-19 At-Home Test to support the product's stability after exposure to conditions that may be encountered during shipping, based on the results of your transport stability study, is granted. Upon review, we concur that the data and information submitted in EUA210661/S003 support the requested update for the 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 COVID-19 At-Home Test re-issued on January 5, 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

cc: SunYoung Jeong, SD Biosensor, Inc.