



January 22, 2022

Sung Jang
Manager, Regulatory Affairs Division
Access Bio, Inc.
65 Clyde Road, Suite A,
Somerset, NJ 08873

Re: EUA210314/S003
Trade/Device Name: *CareStart* COVID-19 Antigen Home Test
Dated: December 1, 2021
Received: December 1, 2021

Dear Sung Jang:

This is to notify you that your request to update the shelf-life expiration date of the *CareStart* COVID-19 Antigen Home Test to 9 months when stored at 1–30°C based on the results of your ongoing stability studies is granted. Upon review, we concur that the information submitted in EUA210314/S003 supports the requested update for use with the *CareStart* COVID-19 Antigen 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 *CareStart* COVID-19 Antigen Home Test re-issued on November 22, 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

Cc: Sang Joon Han, Associate Principal Scientist, Division of R&D, Access Bio, Inc.