



February 01, 2023

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

Re: EUA210314/S015
Trade/Device Name: *CareStart* COVID-19 Antigen Home Test
Dated: November 2, 2022
Received: November 2, 2022

Dear Sung Jang:

This is to notify you that your request to update the *CareStart* COVID-19 Antigen Home Test to extend the shelf-life expiration date to 21 months when stored at 1°C – 30°C, based on the results of your on-going stability studies, is granted. Upon review, we concur that the data and information submitted in EUA210314/S015 support the requested update for 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
Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health