June 7, 2022

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

Re: EUA210314/S007
Trade/Device Name: *CareStart* COVID-19 Antigen Home Test
Dated: December 17, 2021
Received: December 20, 2021

Dear Sung Jang:

This is to notify you that your request to; (1) fulfil Condition of Authorization S. in the November 22, 2021 Letter of Authorization, and (2) modify the dimensions of the 2-tests outer box for the *CareStart* COVID-19 Antigen Home Test and update some of the statements on the outer box, is granted. During interactive review, updates to the Instructions for Use and Quick Reference Instructions were made to harmonize with other authorized over the counter (OTC) antigen tests. Upon review, we concur that the data and information submitted in EUA210314/S007 support the requested updates for the *CareStart* COVID-19 Antigen Home Test and fulfil Condition of Authorization S. in the November 22, 2021 letter. 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,

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For: 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