August 23, 2021

Sang Joon Han
Associate Principal Scientist, Division of R&D
Access Bio, Inc.
65 Clyde Road, Suite A,
Somerset, NJ 08873

Re: EUA210314/S001
Trade/Device Name: *CareStart* COVID-19 Antigen Home Test
Dated: July 12, 2021
Received: July 13, 2021

Dear Sang Joon Han:

This is to notify you that your request to update the authorized labeling for the *CareStart* COVID-19 Antigen Home Test with various edits and clarifications, including a new QR code used to access the On/Go Mobile Application and to make those same edits to the authorized brand name labeling, On/Go COVID-19 Antigen Self-Test, is granted. Upon review, we concur that the information submitted in EUA210314/S001 supports the requested updates 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 issued on August 2, 2021.

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