January 17, 2023

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

Re: EUA202625/S007
Trade/Device Name: *CareStart* COVID-19 Antigen
Dated: November 15, 2022
Received: November 15, 2022

Dear Sung Jang:

This is to notify you that your request to update authorized labeling of the *CareStart* COVID-19 Antigen; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A of the letter, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include with results of additional reactivity studies, is granted. Upon review, we concur that the data and information submitted in EUA202625/S007 supports the requested updates for use with the *CareStart* COVID-19 Antigen and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the *CareStart* COVID-19 Antigen issued on April 12, 2021.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health