



December 2, 2021

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

Re: EUA202625/S006  
Trade/Device Name: *CareStart* COVID-19 Antigen  
Dated: October 20, 2021  
Received: October 20, 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 test to 16 months at 1–30°C based on the results of your real-time stability study, is granted. Upon review, we concur that the data and information submitted in EUA202625/S006 supports the requested update. 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 re-issued on April 12, 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