



March 15, 2021

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

Re: EUA202625/S003
Trade/Device Name: *CareStart* COVID-19 Antigen
Dated: March 8, 2021
Received: March 10, 2021

Dear Sang Joon Han:

This is to notify you that your request to update the shelf-life expiration date of the *CareStart* COVID-19 Antigen test to nine 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/S003 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 February 1, 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

Technical Correction: April 15, 2021

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov