



March 19, 2021

Jun Yong Ha, Ph.D.
Director of Research & Development
Access Bio, Inc.
65 Clyde Road, Suite A.
Somerset, NJ 08873 USA

Re: EUA201309/S004 and EUA201309/S005
Trade/Device Name: CareStart COVID-19 IgM/IgG Kit
Dated: EUA201309/S004 – January 18, 2021
EUA201309/S005 – February 9, 2021
Received: EUA201309/S004 – January 19, 2021
EUA201309/S005 – February 12, 2021

Dear Dr Ha:

This is to notify you that your request to (1) to add an additional authorized distributor of the CareStart COVID-19 IgM/IgG test (EUA201309) to be distributed under the brand name KarmaCare SARS-CoV-2 IgM/IgG, and (2) to extend the CareStart COVID-19 IgM/IgG Kit shelf-life stability to 8 months when stored at 1 – 30 °C is granted. Upon review, we concur that the information submitted in EUA201309/S004 and EUA201309/S005 and subsequent interactive review supports the requested updates for use with the CareStart COVID-19 IgM/IgG Kit. FDA also made minor updates to the IFU, Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients to reflect more recent authorizations.

By submitting these revisions 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 SARS-CoV-2 IgM/IgG Antibody Test issued on July 24, 2020.

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



-----INTERNAL ONLY – DELETE PRIOR TO SIGNING LETTER-----

Final Amendment Package Review and Concurrence Table	
DMD EUA Team	03/16/2021 – Patricia S. Conville (DMD/OHT7-OIR/OPEQ/CDRH): Reviewed the supplement package prior to final review.
Branch Review/Concurrence	N/A
Division Review Review/Concurrence	03/19/2021 – Uwe Scherf (DMD/OHT7-OIR/OPEQ/CDRH): Reviewed, concurred and granted supplement 4 and 5.
Office of Counter Terrorism and Emerging Threats (OCET)/OCS/OC Review/Concurrence	N/A