



February 9, 2021

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

Re: EUA200407/S005
Trade/Device Name: CareStart COVID-19 MDx RT-PCR
Dated: January 18, 2021
Received: January 19, 2021

Dear Sung Jang:

This is to notify you that your request to add an authorized distributor, KPC Biotech, to distribute the CareStart COVID-19 MDx RT-PCR under the brand name, KarmaCare COVID-19 MDx RT-PCR, is granted. Upon review, we concur that the information submitted in EUA200407/S005 supports the requested updates for use with the CareStart COVID-19 MDx RT-PCR. FDA has generated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients for the additional distributor. 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 MDx RT-PCR issued on July 7, 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