October 31, 2020

Jun Yong Ha
Head of Research and Development
Access Bio, Inc.
65 Clyde Road, Suite A.
Somerset, NJ 08873 USA

Re: EUA201309/S001
Trade/Device Name: *CareStart* COVID-19 IgM/IgG
Distributor Device Name: Rapid Response COVID-19 IgM/IgG
Authorization Date: July 24, 2020
Supplement Received: August 18, 2020

Dear Mr. Ha:

This is to notify you that your request to revise the name of your assay for one distributor, BTNX, Inc., from Rapid Response COVID-19 IgM/IgG to Rapid Response Liberty COVID-19 IgG/IgM is granted. Further, your request to add external controls for use with your device with separate labeling, per Condition "T" of the July 24, 2020 Letter of Authorization, is also granted. Upon review, we concur that the data and information submitted in EUA201309/S001 supports the requested updates for use with the *CareStart* COVID-19 IgM/IgG. FDA also made minor updates to the CareStart COVID-19 IgM/IgG and Rapid Response Liberty COVID-19 IgM/IgG Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients and the CareStart COVID-19 IgM/IgG Instructions for Use 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* COVID-19 IgM/IgG issued on July 24, 2020.

Sincerely yours,

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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