



## Acknowledgment Letter

5/20/2020

Jinsu Kim  
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UNITED STATES

Dear Jinsu Kim:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA201309  
Received: 5/16/2020  
Applicant: Access Bio, Inc.  
Device: CareStart™ COVID-19 IgM/IgG

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Sincerely yours,

Center for Devices and Radiological Health