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COVID-19 Variant Brief

Date: December 01, 2021

RE: Access Bio *CareStart*™ Antigen Home Test (EUA210314) and authorized distributor brand name On/GoTM COVID-19 Antigen Self-Test Efficacy in New SARS-CoV-2 Variant Omicron

To Whom It May Concern:

The FDA has issued the Emergency Use Authorization (EUA) for the Access Bio *CareStart*™ COVID-19 Antigen Test. Since then, however, the SARS-CoV-2 variants with mutations have emerged and public health communities are concerned if the COVID-19 antigen tests on the market may have negative impacts on new mutations.

Based on the internal studies, the mutated Omicron variant of SARS-CoV-2 should not affect the performance of the *CareStart*™ Covid-19 Antigen Home Test and On/GoTM COVID-19 Antigen Self-Test. Our tests detect the nucleocapsid protein antigen ("N-Protein") of the virus, which are not affected by variant strain that mainly mutate in the virus' spike proteins ("S-Protein"). We will continue to monitor and analyze variants of SARS-CoV-2 and, based on the design of our test, it is highly likely that our test will continue to detect all variants of SARS-CoV-2.

We are actively monitoring and participating with agencies (e.g. FDA) and organizations to ensure our test will continue to be efficacious against mutating strains. In order to provide our customers with up-to-date information, we will continue to assess our test's performance as new mutations are found and work closely with the FDA to provide transparency on our product's accuracy.

If you have any further concerns, please feel to contact Seungiae Baek (sjbaek@accessbio.net)

Thank you and best

Seungjae Baek

Senior Managing Director

Customer Service

Access Bio, Inc.