

## Access Bio's coronavirus test kit nears approval for FDA's emergency-use authorization

Access Bio (KOSDAQ: 950130) announced on March 31st that it has submitted an emergency-use authorization (EUA) application for its coronavirus diagnostic test to the U.S. Food and Drug Administration (FDA) after successfully completing a FDA's pre-submission process, a preliminary review procedure prior to application for EUA.

US FDA issued EUA of a diagnostic test for COVID-19 in order to meet a surging need for test devices for the novel coronavirus and thus to contain a spiraling spread of the virus. Also, FDA has currently relaxed its regulations to allow states to regulate diagnostics for COVID-19.

Access Bio's coronavirus test kit *CareStart*<sup>™</sup> COVID-19 MDx RT-PCR is to detect SARS-CoV-2 (the virus responsible for COVID-19) via nasopharyngeal and oropharyngeal swab samples. The device is designed to amplify a total of two unique target genes of SARS-CoV-2 to improved sensitivity and with its high sensitivity, the test kit can deliver results within two hours in a single reaction.

Upon outbreak of the novel coronavirus, Access Bio co-developed coronavirus test device (*CareStart*<sup>™</sup> N-CoV RT-PCR Kit) with its Korean subsidiary Wells Bio and currently, it has been planning to expand its supply of coronavirus test devices globally in collaboration with Wells Bio and the largest shareholder Wooridulpharm.

"Access Bio has already obtained export approvals for its COVID-19 test kits in many countries and not before long, it is expected to supply its test kits globally in large volume", said an official at Access Bio.

In Korea, Access Bio's subsidiary Wells Bio acquired the European CE mark for its *careGENE*<sup>™</sup> N-CoV RT-PCR Kit in early March and successfully received an approval for exports from Korea's Ministry of Food and Drug Safety (MFDS) on March 18<sup>th</sup> by demonstrating a relatively higher sensitivity than other test kits in clinical tests.

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### About Access Bio

Headquartered in Somerset, New Jersey, Access Bio is a manufacturer of in vitro diagnostic tests with the manufacturing facilities in the U.S., Ethiopia, and South Korea. The company (KOSDAQ: 950130) is dedicated to the prevention and early diagnosis of infectious diseases. Access Bio has a comprehensive line of diagnostic

platforms, including rapid immunoassays, biosensors, and molecular tests. Of note, the company is the leading global supplier of malaria rapid tests, annually making more than 130 million tests. In the global health arena, Access Bio's mission is to make high-quality diagnostic tests accessible and affordable for its customers, particularly the ones in low- and middle-income countries (LMICs), through its expertise in innovative manufacturing. [www.accessbio.net](http://www.accessbio.net)