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Seegene receives FDA EUA for Allplex 2019-nCoV assay

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To enable laboratories in the United States to run the Seegene's test immediately for high-volume testing



South Korean firm Seegene, Inc. has announced that U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for its Allplex™ 2019-nCoV Assay, a Real-time RT-PCR test for SARS-CoV-2, the novel coronavirus responsible for the COVID-19 disease.

Seegene's Allplex 2019-nCoV Assay, already sold over 10 million tests globally in over 60 countries and being used as a standard SARS-CoV-2 assay, has a unique feature that identifies 3 different target genes (E, RdRP and N genes) in a single reaction tube, which allows for highly accurate results and maximizes the throughput for high volume testing.

Using its exclusive AI-based assay design platform, Seegene was able to rapidly develop the assay shortly after the COVID-19 outbreak started in China. Seegene's proprietary high multiplex chemistry, technology combined with its unique automated solution, has played a pivotal role in South Korea's rapid response to the COVID 19 outbreak.

"Our automated system, with its advanced analysis software, has proven to be extremely useful due to its convenience and scalability, especially in such a pandemic situation where thousands of tests may be required to be performed in a day at every location," said Dr. Jong-Yoon Chun, CEO of Seegene.

Seegene anticipates that the FDA EUA approval will now enable laboratories in the United States to run the Seegene's test immediately for high-volume testing.