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Seegene launches KFDA approved COVID-19 Assay

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Korea Centers for Disease Control & Prevention notified Seegene Inc. that Korea Ministry of Food and Drug Safety has approved its novel coronavirus (COIVD-19) Real-time PCR assay for the Emergency Use, following the recent CE-IVD Mark.

It will now begin offering the assays in Korea and across the globe.

As the global concern is growing over the rapid spread of COVID-19, the market is demanding more accurate and prompt diagnostic solution to reduce the global prevalence of this unprecedented virus.

Seegene launched a single-tube assay, Allplex™ 2019-nCoV Assay that identifies the 3 different target genes (E gene, RdRP gene and Ngene) designed based on the international recommended protocols posted by World Health Organization (WHO). The capability of a simultaneous test in a single-tube, compared to the existing multi-tube assays, greatly improves the efficiency in workflow, maximizing the throughput for a high volume test and minimizing the test cost.

Seegene's automated system with its auto analysis software, Seegene viewer, is extremely useful especially in such an epidemic situation where thousands of tests may be required to be performed in a day, providing test results in 4 hours.

Also, when used together with Seegene's other high multiplex respiratory assay portfolio that screens and identifies 19 respiratory viruses and 7 pneumonia bacteria with similar symptoms, it is able to diagnose the cause accurately and promptly.

According to Dr. Jong-Yoon Chun, CEO and Founder of Seegene said, "It is meaningful that our molecular diagnostic technology and product can contribute to the international community in need of this new virus." He also added, "We are pleased to report KFDA approval of our COIVD-19 assay and are ready to support global healthcare organizations in need of our diagnostic solution."

Seegene is capable of manufacturing 100,000 COVID-19 tests a day in order to meet the demands from the market and international society.