

Seegene receives expanded EUA for COVID-19 diagnostic assay

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Seegene's Allplex 2019-nCoV Assay has a unique feature that identifies 3 different target genes

South Korean firm Seegene, Inc. has announced that U.S. Food and Drug Administration (FDA) has further expanded the 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 initially received EUA on April 21, 2020 and this expansion greatly increases the number of nucleic acid extraction/isolation systems and extraction kits as well as PCR instruments.

Laboratories can now utilize Seegene STARlet, Seegene NIMBUS, Microlab STARlet IVD and Microlab NIMBUS IVD all with Seegene STARMag RNA/DNA extraction kits, AdvanSure E3 System with AdvanSure NA EX Kits, GeneAll Ribospin vRD (Viral RNA/DNA Extraction Kit) (all six available through Seegene Technologies in San Francisco Bay Area), QIAamp DSP Viral RNA Mini kits, MagNA Pure 96 System, KingFisher Flex System with MagMAX Viral/Pathogen Nucleic Acid Isolation Kits. For PCR instruments, laboratories can use Bio-Rad CFX96 and CFX96 Touch systems or Applied Biosystems 7500 and 7500 Fast Dx real-time PCR detection systems.

Seegene's Allplex 2019-nCoV Assay has a unique feature that identifies 3 different target genes (E, RdRP and N genes) simultaneously in a single reaction tube/well, which allows for highly accurate results and maximizes the throughput for high volume testing. Allplex 2019-nCoV Assay has been independently validated by the Foundation for Innovative New Diagnostics, a global non-profit organization that is a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation. Using its exclusive AI-based assay design platform and proprietary high multiplex chemistry technologies, and combining that with its high throughput, automated instrument and software solutions, Seegene offers unparalleled capacity at the most competitive pricing available on the market.