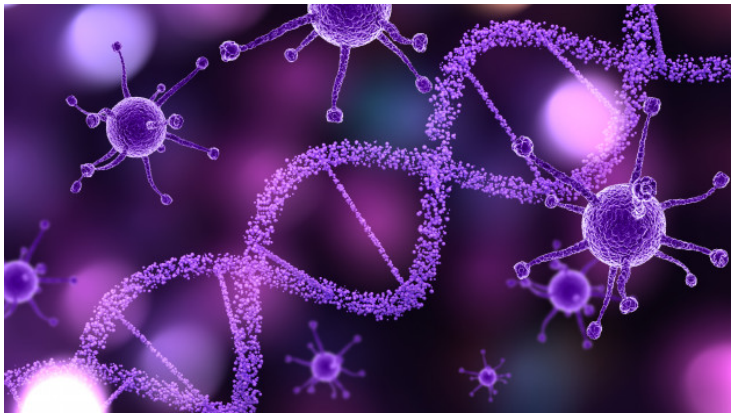
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

FDA issues EUA to first next gen sequence test for COVID-19

15 June 2020 | News

FDA authorized the Illumina COVIDSeq Test for the qualitative detection of SARS-CoV-2 RNA from the specimen of COVID-19 suspect



FDA has issued an emergency use authorization (EUA) to American company Illumina, Inc., for the first COVID-19 diagnostic test utilizing next-generation sequence technology.

The FDA authorized the Illumina COVIDSeq Test for the qualitative detection of SARS-CoV-2 RNA from respiratory specimens collected from individuals suspected of COVID-19. Illumina, Inc. is paving the way for large-scale, next-generation sequencing-based (NGS) COVID-19 testing.

COVIDSeq™ Test is a high-throughput, sequencing-based, in vitro diagnostic (IVD) workflow enabling the detection of SARS-CoV-2. The end-to-end workflow extends the options available for labs to scale diagnostic testing.

COVIDSeq uses upper respiratory specimens, including a nasopharyngeal or oropharyngeal swab, and delivers sample receipt to result in 24 hours using the NovaSeq™ 6000 Sequencing System. The differentiated diagnostic design includes 98 amplicons that target the full SARS-CoV-2 genome, creating accurate detection and high sensitivity. COVIDSeq is currently available to a limited number of early access sites and is expected to be more broadly available this summer.

The workflow accommodates up to 3,072 samples per NovaSeq run leveraging the S4 flow cell and includes steps for viral RNA extraction, RNA-to-CDNA conversion, PCR, library preparation, sequencing and report generation. The key components leveraged include the NovaSeq 6000, coupled with Illumina Tagmentation library preparation technology, and the DRAGEN™ COVIDSeq Test Pipeline for rapid reporting.

COVIDSeq is only authorized for use in laboratories in the U.S., certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests. Outside the U.S., COVIDSeq will be labelled either as Research Use Only (RUO) or with labelling aligned with local regulations