Illumina receives EUA for sequencing-based COVID-19 dx

June 12, 2020—Illumina announced that the FDA issued an emergency use authorization for the Illumina COVIDSeq test, a high-throughput, sequencing-based, in vitro diagnostic workflow enabling the detection of SARS-CoV-2.

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.

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. Components include the NovaSeq 6000 coupled with Illumina Tagmentation library preparation technology and the Dragen COVIDSeq Test Pipeline for rapid reporting.

COVIDSeq is available to a limited number of early access sites, the company reports, and is expected to be more broadly available this summer.