NeuMoDx gets emergency use authorization for SARS-CoV2 test

April 2, 2020—NeuMoDx Molecular announced that the FDA has issued an emergency use authorization for the NeuMoDx SARS-CoV-2 Assay implemented on NeuMoDx molecular systems.

The NeuMoDx SARS-CoV-2 Assay is a rapid, automated in vitro real-time RT-PCR diagnostic test for the direct detection of SARS-CoV-2 coronavirus RNA from nasopharyngeal, oropharyngeal, and nasal swab specimens in transport medium from patients with signs and symptoms of infection of COVID-19. The multiplexed assay detects highly conserved regions of two SARS-Cov-2 genes, the Nsp2 gene and N gene, and uses different fluorophores for reporting each target. The assay is available to CLIA-certified hospitals and reference laboratories with experience performing high-complexity tests.

The NeuMoDx 288 and 96 molecular systems can provide the first test results in about 80 minutes from primary collection or daughter tubes. The NeuMoDx systems allow laboratories to validate their own SARS-Cov-2 laboratory-developed tests, including those provided by the World Health Organization and Centers for Disease Control and Prevention.