FDA issues EUA for Roche Cobas SARS-CoV-2 test

March 13, 2020—The FDA has issued an emergency use authorization for the Roche Cobas SARS-CoV-2. The single-well dual target assay includes specific detection of SARS-CoV-2 and pan-sarbecovirus detection for the sarbecovirus subgenus family that includes SARS-CoV-2. It is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients who meet the CDC SARS-CoV-2 clinical criteria. The test runs on the Cobas 6800/8800 systems and has a full-process negative control, positive control, and internal control.

“Providing quality, high-volume testing capabilities will allow us to respond effectively to what the World Health Organization has characterized as a pandemic. It is important to quickly and reliably detect whether a patient is infected with SARS-CoV-2,” Thomas Schinecker, CEO of Roche Diagnostics, said in a press release. “Over the last weeks, our emergency response teams have been working hard to bring this test to the patients. CE-mark certification and the FDA’s granting of EUA supports our commitment to give more patients access to reliable diagnostics which are crucial to combat this serious disease.”

Test results are available in three and half hours; throughput is up to 96 results in about three hours and a total of 1,440 results for the Cobas 6800 and 4,128 results for the Cobas 8800 in 24 hours. The company says it will, upon authorization, have millions of tests a month available for use on the Cobas 6800 and 8800 systems.