Roche’s COVID-19 antibody test receives EUA

May 4, 2020—Roche announced that the FDA has issued an emergency use authorization for its Elecsys Anti-SARS-CoV-2 antibody test.

The Elecsys Anti-SARS-CoV-2 is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to SARS-CoV-2 in human serum and plasma. Through a blood sample, the test, which is based on an in-solution double-antigen sandwich format, can detect antibodies to the coronavirus causing COVID-19. Based on the measurement of a total of 5,272 samples, the assay has 99.81 percent specificity and 100 percent sensitivity in samples taken 14 days after a PCR-confirmed infection.

Hospitals and reference laboratories can run the test on Roche’s Cobas e analyzers, which provide SARS-CoV-2 test results in about 18 minutes for one test, with a test throughput of up to 300 tests per hour, depending on the analyzer.

Roche has started shipping the new antibody test to leading laboratories worldwide and will ramp up production capacity to high double-digit millions per month, the company reported, to serve health care systems in countries accepting the CE mark as well as the United States.