Bio-Rad SARS-CoV-2 serology, ddPCR tests granted EUAs

May 6, 2020—Bio-Rad Laboratories announced it was granted FDA emergency use authorization for the company's SARS-CoV-2 Total Ab test, a blood-based immunoassay that aims to help clinicians identify if an individual has developed antibodies against SARS-CoV-2. The test has also met the CE mark requirements for Europe.

Clinical evaluation of the SARS-CoV-2 Total Ab test has demonstrated diagnostic specificity of more than 99 percent and diagnostic sensitivity of 98 percent. Cross-reactivity testing demonstrated specificity of 100 percent with no reactivity against other interfering specimens including non-CoV-2 coronaviruses, the company reports.

The SARS-CoV-2 Total Ab test can be used manually or on an automated immunoassay platform, such as Bio-Rad's Evolis system, which offers high-throughput processing and sample traceability.

In a separate release, the company announced its SARS-CoV-2 Droplet Digital PCR test kit has been granted emergency use authorization.

"The high sensitivity of the test makes it well suited to screening upper respiratory samples in patients with a low viral load," the company said in a press release, "including individuals in the early stages of infection as compared to classical quantitative PCR tests. The test can also play an important role in surveillance by detecting minimal residual disease in people recovering from COVID-19 informing them if they are negative for the virus."

The SARS-CoV-2 ddPCR test runs on Bio-Rad's QX200 and QXDx ddPCR systems.