Luminex submits EUA request for COVID-19 antibody test

July 6, 2020—Luminex Corp. has submitted an emergency use authorization request to the FDA for its xMAP SARS-CoV-2 Multi-Antigen IgG assay. The assay was developed to provide additional capacity to detect antibodies in patients who may have been exposed to or infected by SARS-CoV-2. It delivers results for up to 96 samples in less than three hours and is designed to be run on all xMAP platforms.

“By expanding our COVID-19 testing offerings into serology testing with our first multi-antigen IgG assay, Luminex is taking another important step to support laboratories and research institutions that are working to meet the continued high demand for a range of testing solutions,” said Nachum “Homi” Shamir, president and CEO of Luminex, said in a press release. “Serology testing is essential because it uniquely detects prior exposure to a pathogen, as well as possible immunity. Our xMAP technology is ideally suited for serology testing because of its proven ability to deliver extremely high specificity and sensitivity on a high-throughput, gold-standard multiplex platform.”

The assay uses multiplexing to simultaneously detect antibodies to three SARS-CoV-2 antigens and includes multiple internal controls. The company plans to launch the test for research use only.