

BioWorld

Roche snags FDA nod for COVID-19 antibody test



Elecsys Anti-SARS-CoV-2 antibody test. Credit: Roche Holding AG

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By [Meg Bryant](#)

[Roche Holding AG](#), of Basel, Switzerland, has garnered U.S. FDA authorization for emergency use of a test to determine whether people have been infected with the novel coronavirus fueling the COVID-19 pandemic.

The Swiss health care giant, which also makes molecular tests to detect active COVID-19 infection, claims its Elecsys Anti-SARS-CoV-2 antibody test accurately identifies COVID-19 antibodies in the blood 100% of the time, 14 days post-infection. Specificity is also high, at more than 99.8%.

Shipments of the new serology test are already heading to laboratories across the globe, and Roche expects to quickly scale production to high double-digit millions per month to meet demand in the U.S. and CE mark countries.

“Thanks to the enormous efforts of our dedicated colleagues, we are now able to deliver a high-quality antibody test in high quantities,” said Severin Schwan, Roche Group CEO. “I am particularly pleased about the high specificity and sensitivity of our test, which is crucial to support health care systems around the world with a reliable tool to better manage the COVID-19 health crisis.”

Push for more widespread antibody testing

With no vaccine or proven treatment for COVID-19, countries have looked to antibody testing as a way to gauge a community’s resistance to future infection and signal the safe return to work, school and travel. Since April 1, the FDA has granted emergency use authorization for about a dozen COVID-19 antibody tests, but there are dozens of others that do not have EUA approval and many of those are inferior and inaccurate. “I particularly worry about people having a test result that tells them that they do not have COVID, but they actually do, and so they are still spreading it in their

household or community,” Julie Swann, head of the Department of Industrial and Systems Engineering at North Carolina State University and advisor to the CDC’s response on the 2009 H1N1 flu pandemic, told *BioWorld*.

Meanwhile, the World Health Organization has downplayed the idea that individuals with antibodies to SARS-CoV-2 could receive an “immunity passport,” [warning](#) there is no evidence that antibodies protect people from a subsequent infection.

The Elecsys Anti-SARS-CoV-2 immunoassay detects IgM and IgG antibodies in human serum and plasma. Its high specificity – 99.81% – means it can reduce the likelihood of false positives by ruling out antibodies to the four human coronaviruses responsible for the common cold.

Assay validation

Roche used 5,272 samples from routine diagnostics, blood donors, a common cold panel and a coronavirus panel to establish clinical specificity of its test. The cold and coronavirus panels comprised 40 samples each, for potential cross-reactivity with past infection from the HKU1, NL64, 229E or OC43 coronaviruses. Additionally, there was no reactivity to antibodies for HIV, hepatitis C and several other common viruses.

To determine sensitivity, Roche tested its assay on 204 samples from 69 symptomatic patients with a PCR-confirmed SARS-CoV-2 infection. Sensitivity increased from 66% between zero and six days, to 88% at seven to 13 days and 100% 14 days post-infection and longer.

The test, which is based on an in-solution double-antigen sandwich format, is designed to run on Roche’s fully automated Cobas E immunoassay analyzers, which are in wide use many hospitals and laboratories around the world. Depending on the system, results are available in about 18 minutes for a single test, with an hourly throughput of up to 300 tests.

“Our best scientists have worked 24/7 over the last few weeks and months to develop a highly reliable antibody test to help fight this pandemic,” said Thomas Schinecker, CEO of Roche Diagnostics. “Roche is committed to helping laboratories deliver fast, accurate and reliable results to health care professionals and their patients.”

During a first quarter earning call last month, Thomas Schinecker, CEO of Roche Diagnostics, said more than 40,000 cobas systems are in place worldwide. “We have a very broad installed base on which we can support the world in fighting this pandemic,” he added.

U.K. Health Secretary Matt Hancock is reportedly in talks with Roche about antibody testing.

Roche received the FDA greenlight for its Cobas SARS-CoV-2 antigen test on March 13. The oro- and nasopharyngeal swab-based diagnostic runs on Cobas 6800 and Cobas 8800 systems. Both Cobas SARS-CoV-2 and Elecsys Anti-SARS-CoV-2 have CE-IVD certification.

Separately, on May 4, the FDA [granted](#) an EUA to Euroimmun US Inc., a Perkinelmer company based in Mountain Lakes, N.J., for its Anti-SARS-CoV-2 ELISA test. The assay is intended for the detection of IgG antibodies against the virus in human serum and plasma.

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