

[Siemens COVID-19 total antibody, molecular tests](#)

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June 2020—Siemens Healthineers announced it is shipping worldwide its CE-marked, laboratory-based total antibody test to detect the presence of SARS-CoV-2 IgM and IgG antibodies in blood. The test has demonstrated 100 percent sensitivity and 99.8 percent specificity and is available on the Atellica Solution immunoassay analyzer and the Advia Centaur XP and XPT analyzers.

The test detects antibodies to a spike protein on the surface of the SARS-CoV-2 virus. “Studies indicate that certain (neutralizing) antibodies to the spike protein can disarm SARS-CoV-2, presumably by interfering with the ability of the virus to bind, penetrate, and infect human cells,” according to a press release from the company. “Multiple potential vaccines in development for SARS-CoV-2 include the spike protein within their focus.”

Siemens also announced that its CE-marked molecular PCR Fast Track Diagnostics SARS-CoV-2 Assay test kit received FDA emergency use authorization on May 5. In method comparison studies, the test has shown 100 percent positive agreement and 100 percent negative agreement. It evaluates two targets in one test tube, detecting two genes with less test preparation. Sample-to-answer time, including extraction and generating the result, takes two to three hours, depending on the molecular system and lab resources employed. The test is compatible with many lab platforms and may be run simultaneously with Siemens FTD Respiratory Pathogens 218 and FTD FLU/HRSV8 molecular syndromic testing panels.

The company plans to ship more than 2.5 million tests per month worldwide as production capacity increases.

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