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Siemens Healthineers Now Shipping Worldwide

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Siemens Healthineers Now Shipping Worldwide Total Antibody Test and Molecular Test Kit for COVID-19 with Expanded Capacity



Siemens Healthineers announced that it is now shipping worldwide its laboratory- based total antibody test1 to detect the presence of SARS-CoV-2 IgM and IgG antibodies in blood. The test received the CE mark and data has demonstrated 100 percent sensitivity2 and 99.8 percent specificity. The total antibody test allows for identification of patients who have developed an adaptive immune response, which indicates recent infection or prior exposure.

The company is prepared to ramp up production as the pandemic evolves with capacity exceeding 50 million tests per month across its platforms starting in June. Siemens Healthineers is poised to increase production at the company's Walpole (Walpole, Mass.) and Glasgow (Newark, Del.) facilities.

The antibody test is now available on the largest installed base in the U.S. and one of the largest in the world with 20,000 Siemens Healthineers systems installed worldwide. This includes the Atellica® Solution immunoassay analyzer, which can run up to 440 tests per hour4 and enables a result in just 10 minutes. By detecting both IgM and IgG antibodies, the test provides a clearer clinical picture over a longer period of time as the disease progresses. Importantly, the test detects antibodies to a key protein on the surface of the SARS-CoV-2 virus—a spike protein, which binds the virus to cells with a distinct human receptor found in lungs, heart, multiple organs and blood vessels. 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. Multiple potential vaccines in development for SARS-CoV-2 include the spike protein within their focus.

"Not all antibody tests are created equal. A high-quality test that targets the right protein and is highly scalable is essential for antibody testing to help ensure we effectively manage the threat of COVID-19," said Deepak Nath, PhD, President, Laboratory Diagnostics, Siemens Healthineers. "Siemens Healthineers sought to provide a highly accurate antibody test that could reach millions of people to address the current need for identifying immune response, and also for delivering long-term value as we look toward immunity and vaccination."

The total antibody test also is available on the company's expansive installed base of ADVIA Centaur® XP and XPT analyzers, which can test up to 240 samples per hour, with a result in 18 minutes. Comparable tests for Siemens Healthineers Dimension Vista® and Dimension® EXL systems also are being pursued,5 with a view to realize clinical reach. The company intends to develop an IgG test to provide flexibility for testing needs as the pandemic evolves.