Siemens Healthineers to Expand SARS-CoV-2 Testing to Include a Total Antibody Test to Aid in the COVID-19 Pandemic

- With a demonstrated sensitivity and specificity of more than 99 percent, the test is expected to exceed the stringent FDA quality guidelines.
- The test is expected to be available by late May on the company’s multiple laboratory-based high throughput analyzers with time to first result as short as 14 minutes.
- Planned expanded manufacturing production will accommodate more than 25 million tests per month in June and beyond.

TARRYTOWN, N.Y., April 23, 2020 - Siemens Healthineers announced today it is expanding its infectious disease testing capabilities to aid in the COVID-19 pandemic. Recognizing the critical need for accurate diagnostic testing to manage COVID-19, the company has developed a laboratory-based total antibody test\(^1\) to detect the presence of SARS-CoV-2 antibodies in blood. The test, which detects both IgM and IgG, has demonstrated specificity and sensitivity of greater than 99 percent. This total antibody test will provide a clear view of a patient’s disease progression by identifying individuals infected with the virus who have developed an immune response to the virus, even if they were asymptomatic or never diagnosed with the disease.

The test will be available on the Atellica\(^\text{®}\) Solution immunoassay analyzer, which can run up to 440 tests per hour\(^2\) and will enable a result in just 14 minutes. In addition, the serology test also is expected to be available on the company’s expansive installed base of ADVIA Centaur\(^\text{®}\) XP and XPT analyzers, which deliver up to 240 tests per hour, with a result in 18 minutes. Availability of this test on these industry leading platforms ensures more patients are tested in a shorter time.

"Siemens Healthineers is working diligently to address the need for high-quality tests in the fight against COVID-19. This test is being designed with the precision and controls, sensitivity and specificity that laboratories have come to expect from our immunoassay

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\(^{1}\text{Atellica Solution immunoassay analyzer.}\)

\(^{2}\text{ADVIA Centaur XP and XPT analyzers.}\)
tests,” said Deepak Nath, PhD, President, Laboratory Diagnostics, Siemens Healthineers. “I am especially proud of the dedication of our colleagues involved in development of this test—many of whom are based at the epicenter of the pandemic.”

Siemens Healthineers anticipates availability of the total antibody test by late May 2020. Planned expanded production in the company’s Walpole, Massachusetts manufacturing facility will accommodate more than 25 million tests per month in June and beyond. The company is pursuing Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) as well as the CE Mark. Comparable tests for Siemens Healthineers Dimension Vista® and Dimension® EXL systems are being pursued in the coming weeks with a view to further expand clinical reach. In addition, the company intends to develop an IgG test to provide flexibility for testing needs as the pandemic evolves.

The test will join a robust diagnostics portfolio from Siemens Healthineers currently aiding in the prognosis, treatment and follow up of COVID-19 patients. For example, the molecular Fast Track Diagnostics (FTD) SARS-CoV-2 test kit is used to aid in the diagnosis of infection by the SARS-CoV-2 virus that causes the COVID-19 disease. Additionally, the company’s imaging, blood gas, and broad and differentiated menu of tests, including D-Dimer, provide actionable results that aid in the care of acute infected patients.

1 Under development. Not available for sale. Future availability cannot be guaranteed.
2 Dependent upon test mix.
3 Not available for sale in the U.S.

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Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of Healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company’s foundation in in-vitro diagnostic, image-guided therapy, and in-vivo diagnostics. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers’ ability to provide high-quality, efficient care to patients. In fiscal 2019, which ended on September 30, 2019, Siemens Healthineers, which has approximately 52,000 employees worldwide, generated revenue of €14.5 billion and adjusted profit of €2.5 billion. Further information is available at www.siemens-healthineers.com.