SIEMENS Healthineers

Press

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Siemens Healthineers Receives FDA Emergency Use Authorization for its SARS-CoV-2 Total Antibody Test that Delivers Superior Clinical Performance

- **Total antibody test has demonstrated 100 percent sensitivity and 99.8 percent specificity in identifying SARS-CoV-2 antibodies.**
- **The test detects the antibodies believed to neutralize the SARS-CoV-2 virus; specifically targeting antibodies that attach to a spike protein on the surface of the virus.**
- **The test is available on the company's high-throughput analyzers that can deliver up to 440 tests/hour[1] and report results in as few as 10 minutes.**
- **The company has production capacity for more than 50 million tests per month as the pandemic evolves to address the largest installed base in the U.S.**

TARRYTOWN, N.Y., June 1, 2020 – Siemens Healthineers announced today the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for its laboratory-based total antibody test to detect the presence of SARS-CoV-2 antibodies including IgM and IgG in blood. Test data demonstrated 100 percent sensitivity[2] 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. Testing can begin immediately with more than one million tests already shipped to health systems and laboratories.

A spike protein on the surface of the SARS-CoV-2 virus enables the virus to penetrate and infect human cells found in multiple organs and blood vessels. The Siemens Healthineers Total Antibody COV2T assay was thoughtfully designed to detect antibodies to the spike protein. These antibodies are believed to neutralize the SARS-CoV-2 virus and therefore prevent infection. Multiple potential vaccines in development for SARS-CoV-2 include the spike protein within their focus.

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"As a leader in laboratory diagnostics, Siemens Healthineers designed a high-quality, highly accurate antibody test with the capacity and reach necessary to help address a critical societal need," said Deepak Nath, PhD, President, Laboratory Diagnostics, Siemens Healthineers. "The test targets both IgM and IgG antibodies, which allows for early identification of individuals infected with the virus who have developed an immune response, even if they were asymptomatic or never diagnosed with the disease."

About Antibody Test Specificity

Tests with high level of specificity yield low false positive rates, which is highly desirable especially when prevalence of disease is low. For example, a test with 99.8 percent specificity, in populations with low disease prevalence (e.g., 5 percent), will yield a positive predictive value (PPV) of 96.5 percent. In other words, 96.5 people in 100 testing positive will truly have antibodies. This number only goes up as the disease prevalence increases; for example, in communities with 10 percent of disease prevalence, this test would yield a PPV of 98.3 percent, meaning that 98.3 people in 100 people with positive tests results have antibodies. High-quality antibody testing is vital to accurately assess the prevalence of disease, which varies across the U.S.

"As one of the leading specialized laboratories, we recognized the critical need of our customers to have rapid and accurate testing to manage COVID-19 among their patients and staff," said Paul F. Beyer, CEO of Ascend Clinical. "The Siemens Healthineers total antibody test enables us to confidently deliver fast, reliable results that will be extremely valuable in the surveillance of the disease."

The total antibody test SARS-CoV-2 Total (COV2T)[3] is available on the largest installed base of high-throughput analyzers, including the Atellica® IM immunoassay analyzers, which can run up to 440 tests per hour[1] and enables a result in just 10 minutes. The 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 antibody tests[4] for Siemens Healthineers Dimension Vista® and Dimension® EXL systems started shipping on May 29, further extending clinical reach across the company's 20,000 systems installed worldwide.

The tests were developed in the epicenter of the pandemic, are manufactured in Walpole, Mass. and Newark, Del., and are distributed from Plainfield, Indiana. 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.

About Siemens Healthineers Commitment to COVID-19 Testing

In addition to antibody and molecular SARS-CoV-2 tests, Siemens Healthineers offers a broad diagnostics portfolio to aid in the prognosis, treatment and follow up of COVID-19 patients. The company's broad and differentiated menu includes hematology, coagulation, cardiac, respiratory, inflammation and infectious disease panels. Blood gas and imaging solutions from Siemens Healthineers deliver actionable results that aid clinicians in caring for COVID-19 patients.

For further information please see https://www.siemens-healthineers.com/laboratory-diagnostics.

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1 Dependent upon test mix and configuration for Atellica IA Immunoassay analyzer.

2 ≥14 days post-PCR test

3 This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Product availability may vary by country and is subject to varying regulatory requirements.

4 CE-marked for sale in the EU. This test has not been reviewed by the FDA. In the US, use of this test is limited to laboratories that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity testing. Product availability may vary by country and is subject to regulatory requirements.

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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.