SIEMENS Healthineers

# Press

Erlangen, May 26, 2020

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

- **Siemens Healthineers started shipping its total antibody tests globally, including to the largest analyzer installed base in the U.S.**
- **The company has a total of 20,000 systems worldwide and will ramp up its production capacity to more than 50 million antibody tests per month as the pandemic evolves.**
- **The total antibody test has demonstrated 100 percent sensitivity and 99.8 percent specificity in identifying SARS-CoV-2 antibodies in as few as 10 minutes.**
- **The SARS-CoV-2 total antibody test is CE marked and the company is pursuing FDA Emergency Use Authorization (EUA).**
- **FDA authorized EUA for the company's real-time PCR molecular SARS-CoV-2 detection test kit, which demonstrates 100 percent positive percent agreement and 100 percent negative percent agreement. The company plans to ship more than 2.5 million molecular PCR tests per month worldwide as production capacity increases.**

Siemens Healthineers announced today that it is now shipping worldwide its laboratory-based total antibody test[1] 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 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.[3]

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.

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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 hour[4] 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.[5]

**About the Siemens Healthineers SARS-CoV-2 Molecular Test**

Siemens Healthineers also announced that the FDA issued an EUA on May 5 for its molecular PCR Fast Track Diagnostics (FTD) SARS-CoV-2 Assay[6] test kit, which can detect the

virus that causes COVID-19. The FTD SARS-CoV-2 Assay also is CE marked for diagnostic use in the EU since April 24. In method comparison studies, the real-time PCR test has shown 100 percent positive percentage agreement and 100 percent negative percentage agreement[7]. The molecular test, of which more than 500,000 have already been sold in Europe, is compatible with many lab platforms and 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 2-3 hours, depending on the molecular system and lab resources employed.

"I'm proud of our team who saw the societal need and mobilized very quickly to bring this high-quality, diagnostic test to the U.S. market," said Deepak Nath. "Siemens Healthineers now offers the broadest portfolio of high-quality tests for SARS-CoV-2 to help address the global pandemic. Our tests arm healthcare professionals with the information they need to accurately detect SARS-CoV-2, assess disease severity and therapeutic response, and aid care management for patients with comorbidities or complications such as escalated immune response or sudden development of coagulation disorders. These tests will assist clinicians with more timely interventions that can result in better patient outcomes."

To meet demand, the company plans to ship more than 2.5 million molecular PCR tests per month worldwide as production capacity increases in May and June. The FTD SARS-CoV-2 Assay can be run on equipment widely used in laboratories worldwide and may be run simultaneously with Siemens Healthineers FTD Respiratory Pathogens 21[8] and FTD FLU/HRSV[8] molecular syndromic testing panels that identify a wide range of pathogens that can cause acute respiratory infections.

**About Siemens Healthineers Commitment to COVID-19 Testing**

In addition to the antibody and molecular 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.

[1] 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.

[2] ≥ 14 days post-PCR positive test

[3] Product claims, including intended use, are applicable to the CE-marked assay. These claims have not been authorized by FDA.

[4] Dependent upon test mix.

[5] Under development. Not available for sale. Future availability cannot be guaranteed.

[6] CE-marked for sale in the EU. 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 the detection of nucleic acid from 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 regulatory requirements.

[7] In method comparison studies, FTD SARS-CoV-2 has shown Positive Percent Agreement: 100% (91.8-100, 95% CI) and Negative Percent Agreement: 100% (88.7-100, 95% CI) when tested in Copan eSwab nasopharyngeal and oropharyngeal swabs.

[8] CE-marked for sale in the EU. Research Use Only (RUO) in the U.S.

This press release and a press picture is available at https://www.siemens-healthineers.com/press-room/press-releases/serology-pcr-coronavirus-covid-19.html.

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

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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.