SIEMENS Healthineers

Press

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Siemens Healthineers lab-based antigen test available on high-throughput analyzers to support COVID-19 testing

- **The Siemens Healthineers SARS-CoV-2 Antigen Assay (CoV2Ag) offers an accurate, high-capacity testing solution to diagnose COVID-19.**
- **CoV2Ag offers testing for current infection worldwide on a widely available installed base of automated immunoassay analyzers.**
- **The fast time-to-result includes a pretreatment process to inactivate the virus as a safeguard for laboratory staff handling the samples.**

Siemens Healthineers announced today the company's laboratory-based SARS-CoV-2 Antigen Assay (CoV2Ag)[1] obtained CE Mark and is now offered for the Atellica® Solution and ADVIA Centaur® analyzers, widely available in laboratories worldwide. The test has been submitted to the FDA for Emergency Use Authorization. The antigen test detects the nucleocapsid antigen and has been designed with five monoclonal antibodies with the objective to maximize its sensitivity to both current and future SARS-CoV-2 variants. It also offers a leading time-to-result for lab-based antigen tests, making it an ideal tool to test large quantities of patient samples quickly. Additionally, the test helps protect laboratory staff from the virus with a pretreatment process, which inactivates the virus without compromising the quality or validity of patient test results.

The Siemens Healthineers' CoV2Ag test shows strong alignment to molecular RT-PCR methods with sensitivity exceeding 94% and specificity at 100% for the Atellica COVAg test.[2] While molecular RT-PCR diagnostic testing is the gold standard in accuracy, it lacks the high throughput capability of a lab-based, automated antigen test. With availability of CoV2Ag on the Atellica IM Analyzer, laboratories can significantly increase the SARS-CoV-2 testing capacity with a platform that can run up to 440 tests per hour.[3]

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Other benefits of lab-based, automated antigen testing include simplified pre-analytics and a more economical cost per test compared with RT-PCR testing, making this a cost effective solution to detect infection when high throughput is critical. Such testing could be deployed at on-site collection centers for hospital staff, patients and visitors, remote collection facilities for large scale testing of local populations or in dedicated, pop-up labs at airports or large universities.

"SARS-CoV-2 antigen testing is a critical tool to help support the fight against COVID-19 and identify infected individuals, including those who are asymptomatic," said Deepak Nath, PhD, President of Laboratory Diagnostics at Siemens Healthineers. "High-throughput SARS-CoV-2 antigen testing can help laboratories rapidly scale their SARS-CoV-2 diagnostic testing capacity. The Siemens Healthineers' antigen test offers fast pretreatment time and time to results."

The CoV2Ag assay is for in vitro diagnostic use in the qualitative detection of SARS-CoV-2 in nasopharyngeal swab and nasal swab specimens within the first seven days of symptom onset, or from asymptomatic individuals, using the Atellica IM Analyzer or ADVIA Centaur XP and ADVIA Centaur XPT immunoassay Systems.

Siemens Healthineers has distinguished itself as a provider of quality assays to aid the COVID-19 pandemic. In addition to antibody, antigen, 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.

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[1] 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 from country to country and is subject to varying regulatory requirements.

[2] Based on PCR results obtained from symptomatic and asymptomatic patients with the FTD SARS-CoV-2 PCR method. Percent positive agreement with PCR Ct<30 samples (relative sensitivity) was 96.07%, and percent negative agreement with PCR negative samples (relative specificity) was 100%.

[3] Dependent upon text mix.

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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 diagnostics, 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 2020, which ended on September 30, 2020, Siemens Healthineers, which has approximately 54,000 employees worldwide, generated revenue of €14.5 billion and adjusted EBIT of €2.2 billion. Further information is available at www.siemens-healthineers.com