

Siemens Healthineers Launches Rapid Antigen Test for the Detection of SARS-CoV-2

- **The CLINITEST Rapid COVID-19 Antigen Test helps identify infected individuals in 15 minutes so they can isolate sooner and avoid spreading COVID-19**
- **Easy-to-use test, which doesn't require specialized laboratory personnel or instruments, offers flexibility to test in locations that benefit from immediate results**
- **Test to be launched in CE mark countries; plans to submit to FDA for Emergency Use Authorization**

As society continues to navigate through the COVID-19 pandemic, there is a critical public health need to get ahead of the spread with a fast and simple testing for all. To address this need Siemens Healthineers is launching a rapid and easy-to-use antigen test for the detection of SARS-CoV-2, the virus that causes COVID-19. The CLINITEST Rapid COVID-19 Antigen Test¹ is a point-of-care cassette test that does not require laboratory instruments or specialized lab personnel to administer, and it delivers results in 15 minutes.

The CE marked test which has been developed and tested by a Siemens Healthineers partner demonstrated 96.72 % sensitivity and 99.22 % specificity based on a clinical study of 317 subjects. The study was performed using operators with varied credentials at six diverse sites including a hospital, a community clinic, a college campus, and an oncology unit. Siemens Healthineers intends to meet such testing demand as the pandemic evolves. There are plans to submit the test for FDA Emergency Use Authorization.

“There is a great public need for reliable tests that can quickly identify contagious individuals and help to minimize the spread of COVID-19, especially in high-traffic areas and where people commonly congregate,” said Christoph Pedain, PhD, Head of Point of Care Diagnostics at Siemens Healthineers. “With quality at the forefront of decision makers’ criteria to determine test reliability, it was critical the clinical study for this test assesses

variable clinical conditions that can be expected when implementing a rapid antigen test. This rapid antigen test makes testing available to more people across a wider variety of settings—particularly in locations that need to test people quickly such as airports or that have limited access to laboratory resources such as schools.”

The CLINITEST Rapid COVID-19 Antigen Test is easy to administer for healthcare professionals and delivers results quickly using the nasopharyngeal swab method. Once a sample is collected, the swab is inserted into a tube with special liquid to extract the target molecule. This liquid is then dispensed onto a test cassette and, in 15 minutes, a positive or negative result is clearly indicated.

In addition to the CLINITEST Rapid COVID-19 Antigen Test, Siemens Healthineers offers an extensive diagnostics portfolio to aid in the prognosis, treatment and follow up of COVID-19 patients. This test adds to the 15 critical assays Siemens Healthineers offers to detect severe symptoms and better manage critical COVID-19 patients. The company’s broad and differentiated menu includes antibody and molecular SARS-CoV-2 tests, and 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 Product availability varies by country.

This press release and a press picture are available at <https://www.siemens-healthineers.com/press-room/press-releases/covid-19-poc-rapid-antigentest.html>.

For further information please see <https://www.siemens-healthineers.com/press-room/press-features/pf-covid-19.html>.

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Further information is available at www.siemens-healthineers.com.