HealthManagement
Promoting Management and Leadership

COVID-19 Antigen Test Achieved CE Mark For Easier Specimen Collection From The Frontal Part Of Nose

- The CLINITEST Rapid COVID-19 Antigen Test, distributed by Siemens Healthineers, can now be used with swabs from the frontal (anterior) part of the nose, in addition to the nasopharyngeal swab method.
- The new anterior method offers 97.3% sensitivity and 100% specificity.
- This new sampling method can be used with existing test kits in the field, allowing for simplified application and thus broader utility in professional settings.

Siemens Healthineers announced today CE mark has been achieved to use anterior nose swab sampling for the CLINITEST Rapid COVID-19 Antigen test. This sampling method can be less cumbersome and time consuming for both the provider and the patient. 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 test first became available under CE Mark in October 2020 using the nasopharyngeal swab method.

"The CLINITEST Rapid COVID-19 Antigen Test offers providers and patients flexibility regarding how to test without compromising on the quality of patients' results and without having to obtain a different test kit," said Christoph Pedain, PhD, Head of Point of Care Diagnostics at Siemens Healthineers. "With the test values achieved, the rapid antigen test now represents an essential pillar in the fight against Covid-19, in addition to vaccination," Pedain adds.

To evaluate clinical performance using the anterior nose swab sampling method, a study was conducted in the United States with 237 subjects, 109 of which were confirmed to be positive with a PCR test. The study results confirmed 97.3% sensitivity and 100% specificity when compared with the results of a U.S. FDA Emergency Use Authorized rt-PCR assay—the latter with samples obtained from the nasopharynx.

The dataset complies with the latest requirements of most major regulatory authorities, which mandate that the number of positive tested must exceed 100 as a minimum criterion for clinical evidence to enable market access. As an example, the Paul-Ehrlich Institute, an agency of the German Federal Ministry of Health has set this requirement.

The anterior nose swab sampling method can be deployed easily, and an updated Instructions For Use document is available to download from the following Siemens Healthineers website CLINITEST® Rapid COVID-19 Antigen Test (siemens-healthineers.com).

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. 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 testing, for example the RAPIDPoint® and epoc® systems, as well as imaging solutions from Siemens Healthineers deliver actionable results that aid clinicians in caring for COVID-19 patients.

Published on : Tue, 12 Jan 2021