

## Siemens Healthineers Announces CE-Mark for CLINITEST Rapid COVID-19 Antigen Self-Test for Unsupervised Self Testing

- **The CLINITEST Rapid COVID-19 Antigen Self-Test can be used by laypersons 12 and older, with or without symptoms, to detect the SARS-CoV-2 virus.**
- **Rapid antigen testing provides individuals with results in just 15 minutes in any setting, including the comfort of their homes. This information can help reduce the risk of exposure for families, schools, and communities.**
- **Siemens Healthineers is among the first to supply a high-quality CE-marked COVID-19 test for home use.**

Siemens Healthineers announced today the CLINITEST Rapid COVID-19 Antigen Self-Test<sup>1</sup> received CE Mark certification for unsupervised self-testing by laypersons 12 and older, including at-home testing. The nasal swab test can be used for symptomatic or asymptomatic self-testing. For children younger than 12 years, the samples must be collected by or under supervision of an adult. The CLINITEST Rapid COVID-19 Antigen Self-Test is available in packs of one test, five tests, and 20 tests. Additionally, two configurations of the five and 20 test packages are available: a multi-use test buffer bottle, or tubes pre-filled with the test buffer solution for added convenience depending on the environment in which the test will be used.

"The CLINITEST Rapid COVID-19 Antigen Self-Test is the among the first CE-marked tests for home use, making information about a possible infection with COVID-19 more widely available without long wait times. Siemens Healthineers has been able to offer a variety of high-quality tests to address all COVID-19 testing needs and this option makes testing even more convenient for a greater number of people," said Christoph Pedain, Head of Point of Care Diagnostics at Siemens Healthineers.

The CLINITEST Rapid COVID-19 Antigen Self-Test has a sensitivity of 97.25 percent and a specificity of 100 percent (compared to a PCR, or nucleic acid-detection method) and provides results in 15 minutes. The simple process for collecting a nasal swab and obtaining a result are included in the Instructions for Use. A nasal swab is collected from both nostrils and then the swab is washed in a buffer to reveal a specific protein inside the SARS-CoV-2 virus. The sample is then dispensed onto the test cassette and after 15 minutes the result is visible. The position and number of lines clearly indicate whether the test is positive or negative.

<sup>1</sup> Product availability varies by country. Distributed by Siemens Healthineers.

This press release and a press picture is available at <https://www.corporate.siemens-healthineers.com/press/releases/antigen-selftest-ce>

For further information on please see [CLINITEST® Rapid COVID-19 Self-Test \(siemens-healthineers.com\)](https://www.corporate.siemens-healthineers.com/press/releases/antigen-selftest-ce).

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