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Siemens Healthineers receives FDA EUA for CLINITEST rapid COVID-19 antigen self-test

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The product is highly accurate, with sensitivity of 86.5% and a specificity of 99.3%

Siemens Healthineers has announced that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for the CLINITEST Rapid COVID-19 Antigen Self-Test, providing nationwide access to a new at-home or over-the-counter self-test as COVID-19 testing needs continue to grow for individuals, families, and businesses.

The easy-to-use nasal swab test is intended to aid in the rapid detection of SARS-CoV-2 (the virus that causes COVID-19) and provides visually read test results in just 15 minutes.

It is authorized for self-testing use by individuals age 14 and older or adult-collected samples from individuals ages 2 to 13 years. The test is expected to be available starting in January. Siemens Healthineers has secured dedicated production capacity for U.S. bound product in the tens of millions per month.