

Scalable COVID-19 Antigen Testing in 15 Minutes

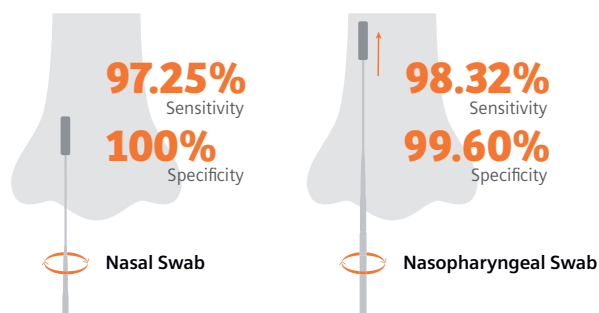
The clinical accuracy you need for results you can trust

siemens-healthineers.com/clinitest-covid-antigen



CLINITEST Rapid COVID-19 Antigen Test

The lateral flow CLINITEST® Rapid COVID-19 Antigen Test, distributed by Siemens Healthineers, is so easy to use that any trained professional can administer it in virtually any setting, without special equipment, at a fraction of the cost of laboratory PCR testing. When used as part of a comprehensive strategy, the CLINITEST Rapid COVID-19 Antigen Test can help communities stay ahead of the spread of COVID-19, even in the face of emerging variants.



Rapid testing, reliable results

Accurate results in only 15 minutes.



Accessible and Scalable testing for effective population health management

Test individuals with or without COVID-19 symptoms, wherever you need it most.



Eliminates traditional barriers to access

No lab personnel or equipment needed; nasal specimens can be collected by a layperson under the direct supervision of a healthcare professional.



Consistent performance in an evolving crisis

Consistent and accurate results with the confirmed detection of alpha, beta, gamma and delta variants of concern.

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Product Specifications

Test time to result: 15 minutes

Sample type: Nasopharyngeal swab or anterior nasal swab

Storage: Room temperature or refrigerated (2–30°C)

Shelf life: 24 months from date of manufacture

Antigen detected: Nucleocapsid

CLINITEST COVID-19 Antigen Controls

Kit contents: 5 negative control swabs (blue) and 5 positive control swabs (red), each individually wrapped

Storage: Room temperature or refrigerated (2–30°C)

Shelf life: 24 months from date of manufacture

Additional Product Information

Clinical performance of the CLINITEST Rapid COVID-19 Antigen Test was evaluated at seven sites within the U.S. where patients were enrolled and tested. Testing was conducted across several different sites, clinical environments, and operators. The resulting datasets for both nasopharyngeal and anterior nasal sampling comply with the latest requirements of most major regulatory authorities and demonstrate high-quality performance.

Nasopharyngeal Swab Performance

Method	PCR (Nasopharyngeal Swab)			Total Results
	Results	Positive	Negative	
CLINITEST Rapid COVID-19 Antigen Test (Nasopharyngeal Swab)	Positive	117	3	120
	Negative	2	743	745
Total		119	746	865

Relative Sensitivity: 98.32% (95% CI: * 94.06% to 99.80%)

Relative Specificity: 99.60% (95% CI: * 98.83% to 99.92%)

Accuracy: 99.42% (95% CI: * 98.66% to 99.81%)

*Confidence interval

Nasal Swab Performance

Method	PCR (Nasopharyngeal Swab)			Total Results
	Results	Positive	Negative	
CLINITEST Rapid COVID-19 Antigen Test (Nasal Swab)	Positive	106	0	106
	Negative	3	128	131
Total		109	128	237

Relative Sensitivity: 97.25% (95% CI: * 92.17% to 99.43%)

Relative Specificity: 100% (95% CI: * 97.16% to 100%)

Accuracy: 98.73% (95% CI: * 96.35% to 99.74%)

*Confidence interval

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Not available for sale in the U.S. Product availability may vary by country. Distributed by Siemens Healthineers. Please contact your local representative for availability. For additional specifications and performance data, please refer to the instructions for use.

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