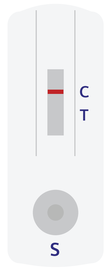
The road to reopening safely

From laboratory testing at scale to testing near the patient, multiple options for high-quality COVID-19 tests will get us to what's next

Detection of current infection

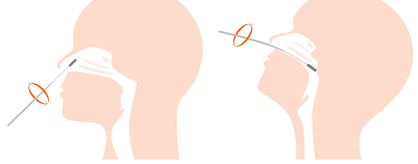
Near-patient testing

Rapid antigen testing is used to identify and isolate infected people quickly, with no lab equipment required.



CLINITEST® Rapid COVID-19 Antigen Test[1]

15 min
to result[2]



Anterior Nasal Swab | Nasopharyngeal Swab

Rapid antigen testing can be performed anywhere that fast results are needed, **for patients with or without COVID-19 symptoms**. **No laboratory personnel or equipment** are required. **Nasal specimens** can be collected by a healthcare provider or **self-collected** under the supervision of a healthcare professional.

97.3%	100.0%
sensitivity[3]	specificity[3]

Large-scale testing and diagnosis

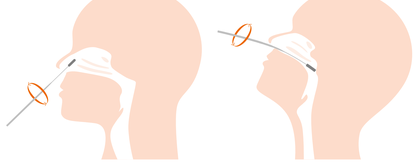
Clinicians use diagnostic tests to determine if people have current COVID-19 infections, enabling patient management decisions.

Laboratory antigen tests

Used to identify currently infected people quickly. Enables community testing with fast, high-volume lab equipment and results delivered through automated reporting.

SARS-CoV-2 Antigen Assay[4]

26 min
time to first result[2]



Anterior Nasal Swab[5] | Nasopharyngeal Swab

The laboratory antigen test has high testing capacity, with clinical reach of **>9,000 analyzers worldwide.**[6] This test features antibodies that maximize **variant detection.** It can **quickly detect positive cases,** allowing timely protective measures and appropriate follow up.

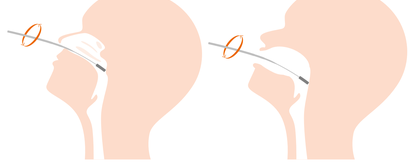
98.0%	100.0%
sensitivity[7]	specificity

Molecular PCR tests

Gold standard for accurate and early detection of infection.[8]

FTD SARS-CoV-2 Assay[9]

<3 hr for 24 tests[10] | <7 hr for 96 tests[10]



Nasopharyngeal Swab | Oropharyngeal Swab[11]

The FTD SARS-CoV-2 Assay was **ranked in the top 5** for analytical sensitivity in an FDA comparative study.[12] The test likely detects the **major SARS-CoV-2 variants of concern** at a rate of 100%.[13]

100.0%	100.0%
sensitivity	specificity

Past infection/vaccination

Community immunosurveillance, patient monitoring and management

Systematic, ongoing testing is critical to determine the full scope of the disease, combat the pandemic, and rebuild public confidence.

Total antibody tests

Measure immune response with a "yes" or "no" answer.

10 min
time to first result[2]

SARS-CoV-2 Total Assay[9] | Blood Draw or Fingerstick[15]

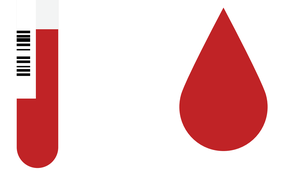
Antibody tests **monitor the long-term duration of the immune response** after natural infection and vaccination. The Siemens Healthineers SARS-CoV-2 Total Assay was recognized by **PHE as a top-performing antibody assay.**[14] Siemens Healthineers is the first major company with an assay to detect **neutralizing antibodies**.[15] The SARS-CoV-2 IgG Assay generates **quantitative results**[15] to assess and track antibodies over time. Its ability to detect neutralizing antibodies positions it as a valuable tool for assessing and monitoring vaccine effectiveness. The assay runs on a large installed base of **~20,000 analyzers worldwide.**[16]

100.0%	99.8%
sensitivity[17]	specificity

IgG antibody tests

Measure persistence of immune response over time with a quantitative result.[15]

24 min
time to first result[2]



SARS-CoV-2 IgG Assay[9] | Blood Draw or Fingerstick[15]

96.4%	99.9%
sensitivity[17]	specificity

What are sensitivity and specificity?

Sensitivity and specificity are terms that indicate a test's ability to correctly classify a person as having or not having a disease. Sensitivity is a test's ability to designate an individual with disease as positive. A highly sensitive test produces fewer false-negative results; therefore, fewer cases of disease are missed. A test's specificity is the ability to designate an individual who does not have a disease as negative. A highly specific test produces fewer false-positive results.

1. Distributed by Siemens Healthineers. CLINITEST Rapid COVID-19 Antigen Test: Not available for sale in the U.S. Product availability may vary by country.
2. Analytical time: time to generate a result on the cartridge or analytical device.
3. For anterior nasal samples.
4. This test has not been reviewed by the FDA. In the U.S., use of this test is limited to laboratories that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high-complexity testing.
5. Anterior nasal swab only available in the U.S. Product availability may vary by country and is subject to regulatory requirements.
6. Installed base of ADVIA Centaur XP, ADVIA Centaur XPT, and Atellica Solution analyzers.
7. Evaluated with PCR-positive results of symptomatic and asymptomatic individuals categorized by cycle threshold <29 (Ct) values of a comparative PCR method. Tested with the Atellica® IM SARS-CoV2Ag Assay using the Atellica® IM Analyzer.
8. IFCC interim guidelines on molecular testing of SARS-CoV-2 infection. https://doi.org/10.1515/cclm-2020-1412, September 18, 2020.
9. The SARS-CoV-2 molecular and antibody tests have not been FDA-cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories. The molecular test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The antibody test has been authorized only for detecting the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Product availability may vary from country to country and is subject to varying regulatory requirements.
10. Turnaround times are calculated based on theoretical analysis with one NUCLISENS EASYMAG and one Thermo Fisher ABI7500; not based on real workflow study. Using more instruments would decrease the total turnaround time.
11. FTD SARS-CoV-2 Assay (CE-IVD) Instructions for Use 11416283_en Rev. B, 2020-12 and FTD SARS-CoV-2 Assay (EUA) Instructions for Use 11416299_en Rev. C, 2021-01.
12. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data. Accessed on March 2, 2021.
13. Data on file at Fast Track Diagnostics, A Siemens Healthineers Company, Luxembourg.
14. Evaluation of sensitivity and specificity of four commercially available SARS-CoV-2 antibody immunoassays. Public Health England. 2020 Jul. GW-1386
15. Some claims are not available in all countries. The SARS-CoV-2 IgG assays are for semiquantitative use in the U.S. The semiquantitation claim for the SARS-CoV-2 Total assays is not available. The fingerstick claim is not available in the U.S. Claims for detection of neutralizing antibodies and correlation to PRNT are not available in the U.S. and are under development for the COV2T assays. Not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements.
16. Installed base of ADVIA Centaur XP, ADVIA Centaur XPT, ADVIA Centaur CP, Atellica Solution, Dimension Vista®, and Dimension® EXL™ analyzers.
17. For samples collected ≥21 days after positive PCR result, using the Atellica Solution.

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