COVID-19

Overview of Testing for SARS-CoV-2

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WHAT TO KNOW

This overview describes current information on the types of tests used to detect SARS-CoV-2 infection and their intended uses. This information is intended for use by healthcare providers, public health professionals, and those organizing and implementing testing in non-healthcare settings.

Test types

Resource

Information for the general public on COVID-19 testing is also available.

Viral tests, including nucleic acid amplification tests (NAATs) and PCR tests, as well as antigen tests, are used as diagnostic tests to **detect current infection** with SARS-CoV-2, determine the need for prevention measures, and inform a person's medical care.

Viral tests

- Nucleic acid amplification tests (NAATs) are highly sensitive and highly specific tests that detect one or more viral ribonucleic acid (RNA) genes. PCR tests are the most common type of NAAT used for COVID-19 testing. Viral RNA may stay in a person's body for up to 90 days after they test positive. Therefore, NAATs should not be used to test someone who has tested positive in the last 90 days. Most NAATs need to be performed in a laboratory, although some are performed at the point-of-care. Most NAATs produce qualitative (positive/negative) results.
- Antigen tests are immunoassays that detect the presence of specific viral proteins, called antigens. A positive test indicates current infection. Antigen tests generally have high specificity, similar to NAATs, but are less sensitive than most NAATs. Because antigen tests have lower sensitivity, FDA recommends that negative antigen tests be repeated up to three times, with each test 48 hours apart to confirm a negative result. Most antigen tests are less expensive than NAATs and can provide results in minutes. Antigen tests are available for at-home testing (self-testing), at the point of care, or in a laboratory.
  - As noted in the labeling for authorized over-the-counter antigen tests: Negative results should be treated as presumptive (meaning that they are preliminary results). Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Please see FDA guidance on the use of at-home COVID-19 antigen tests.
- Other diagnostic tests may be used to detect SARS-CoV-2 from non-traditional respiratory specimens, such as breath. These tests' results may be presumptive and require confirmation by NAAT. Please refer to each test's Instructions for Use (IFU) for specific interpretation.

Positive viral test results indicate current infection and the person with COVID-19 should take steps to prevent spreading COVID-19 to others.

Negative viral test results mean the test did not detect the virus, but this doesn't rule out that the person could have an infection. These results represent a snapshot of the time around specimen collection and could change if the same test was performed again in one or more days. Negative antigen test results should be repeated following FDA guidance.

Antibody (or serology) tests are used to **test for the presence of antibodies** from previous infection or vaccination and can aid in fulfilling the case definition for multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A).[1] Antibody testing does not diagnose current infection. Antibody testing is primarily used for public health surveillance and epidemiologic purposes. Antibody tests detect specific antibodies that target different parts (nucleocapsid or spike protein) of the virus. Detection of anti-nucleocapsid antibody indicates SARS-CoV-2 infection, while anti-spike protein antibody may be induced by COVID-19 vaccination or by SARS-CoV-2 infection. This should be considered when choosing whether to test for antibodies originating from past infection versus those from vaccination.

COVID-19 Test Monitoring

FDA continually monitors the accuracy of COVID-19 tests. Their website provides up-to-date information on the impact of viral mutations on COVID-19 tests. See FDA's list of In Vitro Diagnostics Emergency Use Authorizations for more information about the performance and interpretation of specific authorized tests.

Diagnostic testing

Testing individuals with signs or symptoms consistent with COVID-19

Positive test results using a viral test (NAAT, antigen or other tests) in individuals with signs or symptoms consistent with COVID-19 indicate that the person has COVID-19. A negative antigen test in individuals with signs or symptoms of COVID-19 should be repeated following FDA recommendations or confirmed by NAAT.

Additionally, consider other illnesses with similar symptoms that may require testing. For many diseases, including flu, early diagnosis and prompt treatment can be important for preventing severe illness.

Anyone who tests positive should take steps to prevent spreading COVID-19 to others or, if in a healthcare setting, be placed on appropriate precautions. Some people should receive treatment. Most people with COVID-19 have mild illness and can recover at home.

Vaccination and SARS-CoV-2 testing

Vaccination does not affect the results of someone's SARS-CoV-2 NAAT, antigen, or other diagnostic tests.

The main effect of vaccination on SARS-CoV-2 testing is related to antibody testing. Because mRNA COVID-19 vaccines use the SARS-CoV-2 spike protein to generate an immune response, a positive serologic (antibody) test for spike protein IgM/IgG could indicate either previous infection or vaccination.

Antibody testing is not currently recommended to assess a person's protection against SARS-CoV-2 infection or severe COVID-19 following COVID-19 vaccination or prior infection, or to assess the need for vaccination in an unvaccinated person. Antibody testing can be used in the diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) or Multisystem Inflammatory Syndrome in Adults (MIS-A).

To evaluate for evidence of previous infection in a vaccinated individual, use an antibody test specifically evaluating IgM/IgG to the nucleocapsid protein. For example, specific antibody tests can be used for public health surveillance.

Table 1. NAAT and Antigen Test* Differences

	NAATs	Antigen Tests*
Intended Use	Diagnose *current* infection	Diagnose *current* infection
Analyte Detected	Viral ribonucleic acid (RNA)	Viral antigens
Specimen Type(s)	Nasal, nasopharyngeal, oropharyngeal, sputum, saliva	Nasal, nasopharyngeal
Sensitivity	Varies by test, but generally high for laboratory-based tests and moderate-to-high for point-of-care (POC) tests	Less sensitive than NAATs. Varies by test and depending on the course of infection+*
Specificity	High	High
Test Complexity	Varies by test	Relatively easy to use
Authorized for Use at the Point of Care	Most are not, some are	Most are, some are not
Turnaround Time	Most 1–3 days; some are rapid with results in 15 minutes	Ranges from 15 minutes to 30 minutes
Cost/Test	~$75-$100/test	~$5-$50/test
Advantages	• Most sensitive test method available • Short turnaround time for NAAT POC tests, but few available • Usually does not need to be repeated to confirm results	• Short turnaround time (approximately 15 minutes) ◊ • Cost-effective • Some can be performed at home, or anywhere else
Disadvantages	• Longer turnaround time for lab-based tests (1–3 days) • Higher cost per test • After an infection has ended, and the risk of transmission has passed, people may have detectable RNA and test positive for up to 90 days	• Negative tests should be confirmed by NAAT or repeated as recommended by FDA • Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people and with some variants

Notice

* As noted in the labeling for authorized over-the-counter antigen tests: negative results should be treated as presumptive (meaning that they are preliminary results). Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Please see FDA guidance on the use of at-home COVID-19 antigen tests.

† The decreased sensitivity of antigen tests might be offset if the POC antigen tests are repeated more frequently.

◊ Refers to point-of-care antigen tests only.

Health Equity in SARS-CoV-2 testing

- Social determinants of health may influence access to testing. For example, travel time may limit access to, and use of, testing services for those who have limited access to transportation and who live in areas with fewer public transit services and schedules. Racial and ethnic disparities in test site distribution have been found[2]. Other factors that may affect both access to, and use of, testing services include:
- Lack of health insurance
- Concern about the costs or co-pays
- Occupational factors such as not being able to take time off work and lack of paid leave
- Lack of accessible options for people with disabilities, and
- Distrust of the government and healthcare systems[3,4,5,6]

Delays in testing may also delay seeking care and treatment (when sick) as well as delays in prevention measures that could reduce the spread of the virus to others.

One component to move toward greater health equity is ensuring availability of resources, including access to testing for populations who have experienced longstanding, systemic health and social inequities. All population groups, including racial and ethnic minority groups, should have equal access to affordable, quality, and timely SARS-CoV-2 testing—with fast turnaround time for results. Efforts should be made to address barriers that might overtly or inadvertently create inequalities in testing.

In addition, completeness of race and ethnicity data is an important factor in understanding the impact the virus has on racial and ethnic minority populations. When possible, healthcare providers and public health professionals should ask and record race and ethnicity for anyone receiving a reportable test result and ensure these data are reported with the person's test results to facilitate understanding the impact of COVID-19 on racial and ethnic minority populations.

Some strategies to achieve health equity in testing access and availability include:

- Use a social vulnerability index to assist in selecting testing sites.
- Increase the availability of free testing sites in communities. Employers, community-based, and faith-based organizations can be important partners to increase the number of free, community-based testing sites. This expansion ensures that wait times both for testing and reporting of results are decreased.
- Increase accessible and culturally appropriate public messaging about the importance of testing and communicate these messages in multiple accessible formats, languages, and venues, particularly in communities at higher risk and disproportionately impacted by the virus.

Additional information

- Infection Prevention and Control Recommendations for Healthcare Personnel
- COVID-19 Testing: What You Need to Know (for the public)
- Laboratory Resources

References

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2. Dalva-Baird NP, Alobuia WM, Bendavid E, Bhattacharya J. Racial and ethnic inequities in the early distribution of U.S. COVID-19 testing sites and mortality. *Eur J Clin Invest.* 2021;51(11):e13669. doi:10.1111/eci.13669
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5. Institute of Medicine (US) Committee on the Consequences of Uninsurance. Care Without Coverage: Too Little, Too Late. Washington (DC): National Academies Press (US); 2002.

6. Institute of Medicine (US) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Smedley BD, Stith AY, Nelson AR, eds. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Washington (DC): National Academies Press (US); 2003.

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Coronavirus and Other Respiratory Viruses Division