COVID-19

Overview of Testing for SARS-CoV-2, the virus that causes COVID-19

Updated Aug. 25, 2022

Key Points

- People who have symptoms of COVID-19 or who have had known exposure to someone with COVID-19 should be tested for COVID-19.
- A person's vaccination status does not affect the results of their viral test for SARS-CoV-2.
- Screening testing can provide important information to limit transmission and outbreaks in high-risk congregate settings.

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, such as schools, workplaces, and congregate housing. Information for the general public on SARS-CoV-2 testing is also available.

Considerations When Testing

People undergoing testing should receive clear information on

- The purpose of the test
- Who will pay for the test
- How the test will be performed
- How and when they will receive test results
- How to understand what the results mean
- What actions need to happen after someone has a negative or positive result
- The performance specifications and any limitations associated with the test
- The difference between diagnostic testing and screening testing
- Who will receive the results and how they may be used
- Any consequences for declining to be tested
- The manufacturer, name, and type of the test

Individuals tested are required to receive patient fact sheets as part of the test's Emergency Use Authorization (EUA).

Testing for SARS-CoV-2 Infection

Many types of tests are used to detect SARS-CoV-2,[1] and their performance characteristics vary.

- Some tests provide results rapidly (within minutes); others require 1-3 days for processing.

- Some must be performed in a laboratory by trained personnel, some can be performed at the point of care, and others can be performed at home or anywhere.
- Tests vary in their sensitivity (i.e., few false-negative results or few missed detections of SARS-CoV-2) and specificity (i.e., few false-positive results or few tests incorrectly identifying SARS-CoV-2 when the virus is not present).
- Some tests may be able to be performed frequently because they are less expensive and easier to use than other tests, and supplies are readily available.
- Some tests may need to be repeated, if initial test is negative; see FDA guidance .

Test Types

Viral tests, including Nucleic Acid Amplification Tests (NAATs, such as Reverse Transcription – Polymerase Chain Reaction), antigen tests and other tests (such as breath tests) are used as diagnostic tests to **detect current infection** with SARS-CoV-2 and to inform an individual's medical care. Viral tests can also be used as screening tests to reduce the transmission of SARS-CoV-2 by identifying infected persons who need to isolate from others.

Viral Tests include:

- Nucleic Acid Amplification Tests (NAATs) are highly sensitive and highly specific tests that detect one or more viral ribonucleic acid (RNA) genes and indicate a current infection. 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, however some are performed at the point-of-care. Most NAATs produce qualitative (positive/negative) results.
- Antigen tests are immunoassays that detect the presence of a specific viral antigen. Antigen tests generally have similar specificity, but are less sensitive than most NAATs. Most are less expensive than NAATs and can provide results in minutes. There are antigen tests 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 tests' Instructions for Use (IFU) for specific interpretation.

Positive viral test results allow for identification and isolation of infected persons.

Negative viral test results suggest no current evidence of 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.

Antibody (or serology) tests are used to **detect previous infection** with SARS-CoV-2 and can aid in the diagnosis of multisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A)[2]. Antibody testing does not diagnose current infection. Antibody testing is being used for public health surveillance and epidemiologic purposes. Antibody tests detect specific antibodies that target different parts (nucleocapsid or spike protein) of the virus. This should be considered when choosing whether to test for antibodies originating from past infection versus those from vaccination. For more information about COVID-19 vaccines and antibody test results, refer to Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

See FDA's list of In Vitro Diagnostics Emergency Use Authorizations for more information about the performance and interpretation of specific authorized tests.

Overview of Testing Scenarios

Diagnostic testing is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or is asymptomatic, but has recent known or suspected exposure to someone with suspected or confirmed SARS-CoV-2 infection.

Screening testing is intended to identify people with COVID-19 who are asymptomatic or do not have any known, suspected, or reported exposure to SARS-CoV-2. Screening helps to identify unknown cases so that steps can be taken to prevent further transmission.

Public health surveillance testing is intended to monitor population-level burden of disease, or to characterize the incidence and prevalence of disease. Surveillance testing is primarily used to gain information at a population level, rather than an individual level, and generally involves testing of de-identified specimens. Surveillance testing results are not reported back to the individual. As such, surveillance testing cannot be used for an individual's healthcare decision-making or individual public health actions, such as isolation. An example of surveillance testing is wastewater surveillance.

NOTE: For guidance on using tests to determine which mitigations are recommended as someone recovers from COVID-19, see the Isolation and Precautions for People with COVID-19.

Choosing a Test

When choosing which test to use, it is important to understand the purpose of the testing (diagnostic or screening), test performance in context of COVID-19 incidence, need for rapid results, and other considerations (See Table 1). Use of a laboratory-based NAAT in areas where COVID-19 Community Level and testing demand is high may result in diagnostic delays due to processing time and time to return results. Positive and negative predictive values of NAAT and antigen tests vary depending upon the pretest probability. Pretest probability considers both the COVID-19 Community Level as well as the clinical context of the individual being tested. Additional information is available on sensitivity, specificity, positive and negative predictive values for antigen tests and antibody tests, and the relationship between pretest probability and the likelihood of positive and negative predictive values [458 KB, 1 Page].

Table 1 summarizes some characteristics of NAATs and antigen tests to consider for a testing program. FDA has provided additional information for healthcare providers who are using diagnostic tests in screening asymptomatic individuals , and the Centers for Medicare & Medicaid Services has exercised enforcement discretion under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to enable the use of antigen tests that are not currently authorized for use in asymptomatic individuals for the duration of the COVID-19 public health emergency. Laboratories that perform screening or diagnostic testing for SARS-CoV-2 must have a CLIA certificate and meet regulatory requirements. Tests that have received an EUA from FDA for point-of-care (POC) use can be performed with a CLIA certificate of waiver.

> **Need additional help?** Use the Viral Testing Tool to get personalized recommendations and resources.

Vaccination and SARS-CoV-2 Testing

If a person has received one or more COVID-19 vaccinations, it does not affect the results of their SARS-CoV-2 diagnostic or screening tests (nucleic acid amplification tests [NAAT], antigen or other diagnostic tests).

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 infection or severe COVID-19 following COVID-19 vaccination or prior infection, or to assess the need for vaccination in an unvaccinated person. To evaluate for evidence of previous infection in a vaccinated individual, an antibody test specifically evaluating IgM/IgG to the nucleocapsid protein should be used (e.g., for public health surveillance or the diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) or Multisystem Inflammatory Syndrome in Adults (MIS-A)).

Table 1. NAAT and Antigen Test Differences to Consider When Planning for Diagnostic or Screening Use

	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 POC tests	Varies 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 could be rapid in 15 minutes	Ranges from 15 minutes to 30 minutes
Cost/Test§	Moderate (~$75-$100/test)	Low (~$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) ◊ When performed at or near POC, allows for rapid identification of infected people, thus preventing further virus transmission.
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 repeated per FDA guidance May need confirmatory testing Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people and with some variants

* 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.
§ Costs for NAATs
◊ 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.[3] 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.[4, 5, 6, 7]

Delays in testing may also delay seeking care when sick as well as delays in self-isolation that could reduce the spread of the virus to others.

CDC's COVID-19 Response Health Equity Strategy outlines a plan to reduce the disproportionate burden of COVID-19 among racial and ethnic minority populations and other population groups (e.g., essential and frontline workers, people living in rural or frontier areas) who have experienced a disproportionate burden of COVID-19. One component to move towards 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—for diagnosis and screening. 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. The U.S. Department of Health and Human Services has required laboratories and testing facilities to report race and ethnicity data to health departments, in addition to other data elements, for individuals tested for SARS-CoV-2 or diagnosed with COVID-19. Healthcare providers and public health professionals need to 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 in order 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.
- The Centers for Disease Control and Prevention's (CDC) Operation Expanded Testing (OpET) program increases access to testing nationwide, especially for communities that have been disproportionately affected by the COVID-19 pandemic. Assess the capacity of these sites to expand diagnostic and screening testing to meet the demand for impacted areas. This includes assessing the availability of free testing, wait times for testing and for results, and categories of available test (NAAT vs. antigen), as well as identifying and removing barriers to testing (e.g., alternatives to drive-through testing for a community where many do not have cars; availability of testing on evenings and weekends).
- 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, helping limit the spread of SARS-CoV-2.
- Increase public messaging about the importance of testing and communicate these messages in multiple languages and venues, particularly in communities at higher risk and disproportionately impacted by the virus.

Considerations for testing in different scenarios

Diagnostic testing

Testing persons with signs or symptoms consistent with COVID-19

Positive test results using a viral test (NAAT, antigen or other tests) in persons with signs or symptoms consistent with COVID-19 indicate that the person has COVID-19, independent of vaccination status of the person. A negative antigen test in persons with signs or symptoms of COVID-19 should be confirmed by NAAT, a more sensitive test. For more information, see the Antigen Test Algorithm.

All persons (independent of vaccination status) with positive results should isolate at home 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 without medical care. For more information, see CDC's COVID-19 isolation guidance.

Please update the text in the link as shown below.

Testing asymptomatic persons who have had recent known or suspected exposure to SARS-CoV-2

Viral testing is recommended for individuals who have been exposed to persons with COVID-19. People who have had an exposure with someone known or suspected of having COVID-19 should be tested at least 5 days after the exposure. If symptoms develop before 5 days, they should get tested immediately.

In instances of higher pretest probability, such as high incidence of infection in the community, or a person with household or continuous contact with a person with COVID-19, clinical judgement should determine if a positive antigen result for an asymptomatic person should be followed by a laboratory-based confirmatory NAAT. Results from NAATs are considered the definitive result when there is a discrepancy between the antigen and NAAT test. For more information, see the antigen test algorithm.

Persons with positive results should follow CDC's COVID-19 isolation guidance.

Testing persons who have recently tested positive, and recovered from COVID-19

If someone has had exposure to someone with COVID-19 and is asymptomatic, but has had COVID-19 within the past 30 days,* testing to identify a new infection is generally not recommended. If someone has become newly symptomatic after having had COVID-19 within the past 30 days,* antigen tests should be used to identify a new infection. If they test negative, the antigen test should be repeated per FDA guidance .

If someone had exposure to another person with COVID-19, but the exposed individual has had COVID-19 within the past 30-90 days,* consider using antigen tests (rather than an NAAT, such as a PCR test) to identify a new infection. They should not test until at least 5 days after their exposure. Whether they are symptomatic or asymptomatic, if they test negative with an antigen test, they should repeat the antigen test as recommended by FDA guidance.

*The clock starts from the day of your first positive test result or your original onset of symptoms, whichever came first.

Some adults with severe illness may produce replication-competent virus beyond 10 days that may warrant extending duration of isolation and precautions. A test-based strategy for ending isolation may be considered in consultation with infectious disease experts for persons with severe illness or who are severely immunocompromised. For more information, including on retesting persons previously infected with SARS-CoV-2, visit Ending Isolation and Precautions for People with COVID-19: Interim Guidance.

Screening Testing

Testing asymptomatic persons without recent known or suspected exposure to SARS-CoV-2 for early identification, isolation, and disease prevention

Screening testing allows early identification and isolation of persons who are asymptomatic or pre-symptomatic and who might be unknowingly transmitting virus. Screening testing may be most valuable in certain settings where early identification is essential to reducing transmission and mitigating risk for severe disease among populations at high risk. CDC's COVID-19 Community Levels recommendations include implementing screening testing in high-risk settings at the medium and high levels.

Examples of screening testing include:

- Point-in-time screening testing
  - This is screening testing that happens on a situational basis, for example, testing yourself before you visit an older relative who is at high risk of getting very sick from COVID-19.
- Serial screening testing
  - This is screening testing that is repeated at different points in time within a group, such as testing every 3 days for everyone in a particular setting or facility.

How to conduct screening testing

When screening testing is used, it should be applied to participants regardless of vaccination status.

People without symptoms and without known exposure to COVID-19 do not need to take any special actions while awaiting screening test results. If a person tests positive on a screening test and is referred for a confirmatory test, they should isolate until they receive the results of their confirmatory test.

Settings to prioritize for screening testing

Settings that should be prioritized for screening testing include facilities and situations where transmission risk is high and the population served is at high risk of severe outcomes from COVID-19 or there is limited access to healthcare, including:

- High-risk congregate settings, such as assisted living facilities, correctional facilities, and homeless shelters, that have demonstrated high potential for rapid and widespread virus transmission to people at high risk for severe illness.
- Settings that involve close quarters and that are isolated from healthcare resources (e.g., fishing vessels, wildland firefighter camps, or offshore oil platforms).

Serial screening testing is less effective at reducing COVID-19's impacts in settings where disease rates are lower, risk of spread is lower, and risk of severe illness is lower. Because of this, CDC does not recommend serial screening testing in most lower risk settings.

Public Health Surveillance Testing for SARS-CoV-2

Public health surveillance testing may sample a certain percentage of a specific population to monitor for increasing or decreasing infection rate or to determine the population effect from community interventions. An example of public health surveillance testing is when a state public health department samples a random percentage of all people in a city on a rolling basis to assess local infection rates and trends.

CDC is working with state, local, territorial, academic, and commercial partners to conduct surveillance testing to better understand COVID-19 in the United States.

For more on surveillance conducted by CDC:

- Cases, Data, and Surveillance
  - COVID-19-Associated Hospitalization Surveillance Network (COVID-NET)
  - COVID-19 Serology Surveillance
  - National Wastewater Surveillance System (NWSS)
  - FAQ: COVID-19 Data & Surveillance
- Surveillance and Data Analytics
- CDC's Diagnostic Multiple Assay for Flu and COVID-19 at Public Health Laboratories and Supplies
- Emerging SARS-CoV-2 Variants (SARS-CoV-2 Strain Surveillance)

Setting-specific Testing Guidance

Testing in Healthcare Settings
Nursing Homes
Acute Care Facilities
Infection Prevention and Control Recommendations for Healthcare Personnel

Testing in Communities, Schools and Workplaces
K-12 Schools
Non-Healthcare Workplaces
Homeless Shelters
Correctional and Detention Facilities

Testing Information for the Public
Testing Guidance for the Public
Frequently Asked Questions: Testing

Other Testing Resources
Antigen Testing Algorithm
Interim Guidelines for COVID-19 Antibody Testing
Pooled Procedures for Testing
Laboratory Resources

Previous Updates

Updates from Previous Content

Updates as of May 27, 2022

- Added Health Equity language for access of testing
- Added information about other diagnostic tests for SARS-CoV-2

As of January 21, 2022

- Revised to align with CDC's updated recommendations on isolation and quarantine.
- Revised to align with CDC recommendations for people who are up to date with their vaccines.

As of October 22, 2021

- Based on evolving evidence, CDC recommends fully vaccinated people get tested 5-7 days after close contact with a person with suspected or confirmed COVID-19.

As of August 2, 2021

- Revised to align with CDC recommendations for fully vaccinated individuals

As of July 1, 2021

- Revised to align with CDC recommendations for fully vaccinated individuals

As of June 14, 2021

- Expansion on the description of categories of tests, choosing a test, and addition of intended uses of testing
- Addition of health equity considerations related to testing, including discussion on ensuring equitable testing access and availability

- Discussion on expanded availability to, and use of, screening tests to reduce asymptomatic spread
- Discussion on testing of vaccinated individuals and interpretation of test results
- Inclusion of links to setting-specific testing guidance

As of September 18, 2020

- Due to the significance of asymptomatic and pre-symptomatic transmission, this guidance further reinforces the need to test asymptomatic persons, including close contacts of a person with documented SARS-CoV-2 infection.

As of August 24, 2020

- Diagnostic testing categories have been edited to focus on testing considerations and actions to be taken by individuals undergoing testing

As of July 17, 2020

- Except for rare situations, a test-based strategy is no longer recommended to determine when an individual with a SARS-CoV-2 infection is no longer infectious (i.e., to discontinue Transmission-Based Precautions or home isolation)

As of July 2, 2020

- Added screening to possible testing types
- Removed examples – please refer to setting specific guidance

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Last Updated Aug. 25, 2022