Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community

Updated Mar. 4, 2022

CDC is in the process of updating this page to align with the new COVID-19 Community Levels. Updates will be posted here when available.

Summary of Recent Changes

Updates as of March 3, 2022

- Updated information on when to consider confirmatory testing in symptomatic and asymptomatic individuals
- Updated antigen testing algorithm figure
- Removed general guidance for congregate settings and added links to setting-specific guidance
- Removed general guidance for processing and handling SARS-CoV-2 clinical specimens and added links to guidance on quality assurance procedures

Key Points

- This guidance is intended for healthcare providers who order antigen tests, receive antigen test results, or perform point-of-care testing, as well as for laboratory and testing professionals and public health practitioners who perform antigen testing and reporting in a laboratory setting or at the point-of-care.
- The purpose of this technical guidance is to support effective clinical and public health use of antigen tests for different testing situations.
- This guidance incorporates considerations for people who are up to date with their vaccines and should be used in conjunction with CDC's Stay Up to Date with Your Vaccines | CDC
- This guidance focuses on the use of antigen tests to diagnose new infections. See CDC's guidance on Quarantine and Isolation for testing to end isolation.
- Guidance for individuals who are performing antigen self-tests can be found on CDC's Self-Testing webpage

Antigen Testing for SARS-CoV-2

General Guidance

Antigen tests are commonly used in the diagnosis of other respiratory pathogens, including influenza viruses and respiratory syncytial virus (RSV). The U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2. See FDA's list of In Vitro Diagnostics EUAs .

Antigen tests are immunoassays that detect the presence of a specific viral antigen, which indicates current viral infection. Antigen tests are currently authorized to be performed on nasopharyngeal, nasal swab, or saliva specimens placed directly into the assay's extraction buffer or reagent. The currently authorized antigen tests include point–of care, laboratory-based, and self-tests. Certain tests have age limitations; refer to FDA's website for more details. See Table 1 for additional information about antigen tests.

Antigen tests produce results quickly (within approximately 15–30 minutes), and most can be used at the point of care. Antigen tests for SARS-CoV-2 are generally less sensitive than real-time reverse transcription polymerase chain reaction (RT-PCR) and other nucleic acid amplification tests (NAATs), which detect and amplify the presence of viral nucleic acid. However, NAATs may remain positive for weeks to months after initial infection and can detect levels of viral nucleic acid even when virus cannot be cultured, suggesting that the presence of viral nucleic acid may not always indicate contagiousness.

Antigen tests and NAATs (when indicated) require proper interpretation for both accurate clinical management of people with suspected COVID-19, and for identification of people with infection when used for screening.

The clinical performance of diagnostic tests largely depends on the circumstances in which they are used. Both antigen tests and NAATs perform best if the person is tested when they are symptomatic. Although antigen tests generally have lower sensitivity compared to NAATs, they can also be used to test for infection with specific attention to the context in which they are used, described below.

Antigen test performance data have helped guide the use of these tests as screening tests in asymptomatic people to detect or exclude SARS-CoV-2 infection. See FDA's recommendations for healthcare providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19 . Also see information from the Centers for Medicare & Medicaid Services (CMS) on the Updated CLIA SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion .

Antigen tests have been used for screening testing for COVID-19 in congregate settings such as nursing homes, dormitories, homeless shelters, and correctional facilities. Screening testing has quickly identified people with COVID-19, informing infection prevention and control measures, thus preventing transmission. In this case, and where rapid test turnaround time is critical, there is value in providing immediate results with antigen tests.

Healthcare providers and public health practitioners should understand test performance characteristics for interpretation of results, to recognize potentially false negative or false positive test results, and to guide additional confirmatory testing and management of the person tested. Laboratory and testing professionals who perform antigen tests should understand the factors that affect the accuracy of antigen testing, as described in this guidance. Healthcare providers, laboratory and testing professionals, and public health practitioners should also understand the differences among diagnostic, screening, and surveillance testing. See FDA's FAQs on Testing for SARS-CoV-2 .

This guidance supplements and is consistent with CDC's Overview of Testing for SARS-CoV-2 and SARS-CoV-2 Point-of-Care and Rapid Testing guidance. CDC has also published guidance on SARS-CoV-2 Antigen Testing in Long Term Care Facilities, Interim Guidance for SARS-CoV-2 Testing in Correctional and Detention Facilities, Interim Guidance for SARS-CoV-2 Testing in Homeless Shelters and Encampments, and Guidance for COVID-19 Prevention in K-12 Schools.

Regulatory Requirements for Using Antigen Tests for SARS-CoV-2

FDA regulates in vitro diagnostic devices and has provided recommendations and information regarding EUA requests for COVID-19 diagnostic tests in the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) ("Policy for COVID-19 Tests") and the EUA templates referenced in that policy. COVID-19 tests and test systems used for diagnostic or screening testing, including those for antigen testing, must have received an EUA from FDA or be offered under the policies in FDA's Policy for COVID-19 Tests . Every antigen test for SARS-CoV-2 authorized for use by FDA is included on

FDA's list of In Vitro Diagnostics EUAs . The intended use of each test, available in the Instructions for Use and in the Letter of Authorization, defines the population in which the test is intended to be used, the acceptable specimen types, and how the results should be used.

Laboratory and testing professionals who conduct diagnostic or screening testing for SARS-CoV-2 with antigen tests must also comply with Clinical Laboratory Improvement Amendments (CLIA) regulations. Any laboratory or testing site that intends to report patient-specific test results to a person or healthcare provider must first obtain a CLIA certificate and meet all requirements to perform that testing. For more information, see CMS' How to Obtain a CLIA Certificate . CMS has provided additional information on enforcement discretion for the use of SARS-CoV-2 point-of-care testing on asymptomatic individuals.pdf

Performance of Antigen Tests for SARS-CoV-2

It is important for healthcare providers and testing professionals to understand the performance characteristics, including sensitivity, specificity, and positive and negative predictive values, of the antigen test being used, and to follow the manufacturer's instructions for use, which summarize performance characteristics. See FDA's In Vitro Diagnostics EUA for detailed information about specific authorized tests.

The "gold standard" for clinical diagnostic detection of SARS-CoV-2 remains laboratory-based (moderate- and high-complexity) NAATs. Thus, providers may choose to confirm an antigen test result with a laboratory-based NAAT, especially if the result of the antigen test is inconsistent with the clinical context. Table 1 summarizes some of the differences between NAATs and antigen tests. Clinical performance of NAATs and antigen tests may differ from clinical utility when considering issues of test availability, quality of specimen collection and transport, and turnaround times of results. Based on their instructions for use, some point-of-care NAATs may not be used for confirmatory testing. NAATs that generate presumptive results are not appropriate for use in confirmatory testing.

The antigen level in specimens collected either before symptom onset, or late in the course of infection, may be below the tests' limit of detection, resulting in a false negative antigen test result, while a more sensitive test, such as most NAATs, may return a positive result. Studies have shown that antigen tests have comparable sensitivity to laboratory-based NAATs when viral load in the specimen is high and the person is likely to be most contagious.

The specificity of antigen tests is comparable to NAATs, which means that false positive test results are unlikely when an antigen test is used according to the manufacturer's instructions. Despite the high specificity of antigen tests, false positive results can occur, especially when used in situations where the pre-test probability or prevalence of infection is low – a circumstance that is true for all in vitro diagnostic tests. In general, for all diagnostic tests, the lower the prevalence of infection in the community, the higher the proportion of false positive test results.

Positive and negative predictive values of all in vitro diagnostic tests (e.g., NAAT and antigen tests) vary depending upon the pretest probability. Pretest probability considers both the prevalence of the target infection in the population that is being tested as well as the clinical context of the individual being tested. If the prevalence of infection in the community is high, the person being tested is symptomatic, and the likelihood of alternative diagnoses is low, then the pretest probability is generally considered high. If the prevalence of infection in the community is low, and the person being tested is asymptomatic and has not had close contact to a person with COVID-19, then the pretest probability is generally considered low. State health departments generally publish COVID-19 data on case rates for their communities. See CDC's Interpreting Results of Diagnostic Tests for additional information on the relationship between pretest probability and the likelihood of positive and negative predictive values.

Processing of Antigen Tests for SARS-CoV-2

The Conditions of Authorization in the antigen EUAs specify that CLIA-certified laboratories and testing sites are to follow the manufacturer's instructions for use, typically found in the package insert, when performing the test and reading test results. The authorized instructions for use for each test, including when and how to read each test, can also be found at FDA's In Vitro Diagnostics EUA . Also see FDA's, At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions . All testing for SARS-CoV-2, including antigen testing, depends on the integrity of the specimen, which is affected by procedures for both specimen collection and handling. See CDC's Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing.

Quality assurance procedures should be followed to prevent cross-contamination and inaccurate test results. For more information on proper specimen processing and handling for COVID-19 testing, including point-of-care tests, see CDC's guidance on Point-of-Care Testing, and Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).

Interpreting the Results of Antigen Testing for SARS-CoV-2

Interpreting the results of an antigen test for SARS-CoV-2 depends primarily on the clinical and epidemiological context of the person who has been tested (e.g., symptoms, close contact to others with COVID-19, setting in which they live, likelihood of alternative diagnoses, or disease prevalence in their geographic location). For additional details on testing recommendations see CDC's Overview of Testing for SARS-CoV-2. When evaluating the results of an antigen test for SARS-CoV-2 the performance characteristics (e.g., sensitivity, specificity) and the instructions for use of the FDA-authorized test, and the prevalence of SARS-CoV-2 infection in that community (number of cases in the community relative to the population size) should be considered.

The evaluation of an antigen test result should also consider whether the person has experienced symptoms, and if so for how long. Generally, healthcare providers can rely upon a positive antigen test result for a symptomatic patient because the specificity of current FDA-authorized antigen tests is high.

The sensitivity of current FDA-authorized antigen tests varies, and thus negative diagnostic testing results should be handled depending on the circumstances. In most circumstances, the manufacturers' instructions for use of antigen tests indicate that negative test results should be considered "presumptive," meaning that they are preliminary results. See FDA's In Vitro Diagnostics EUA .

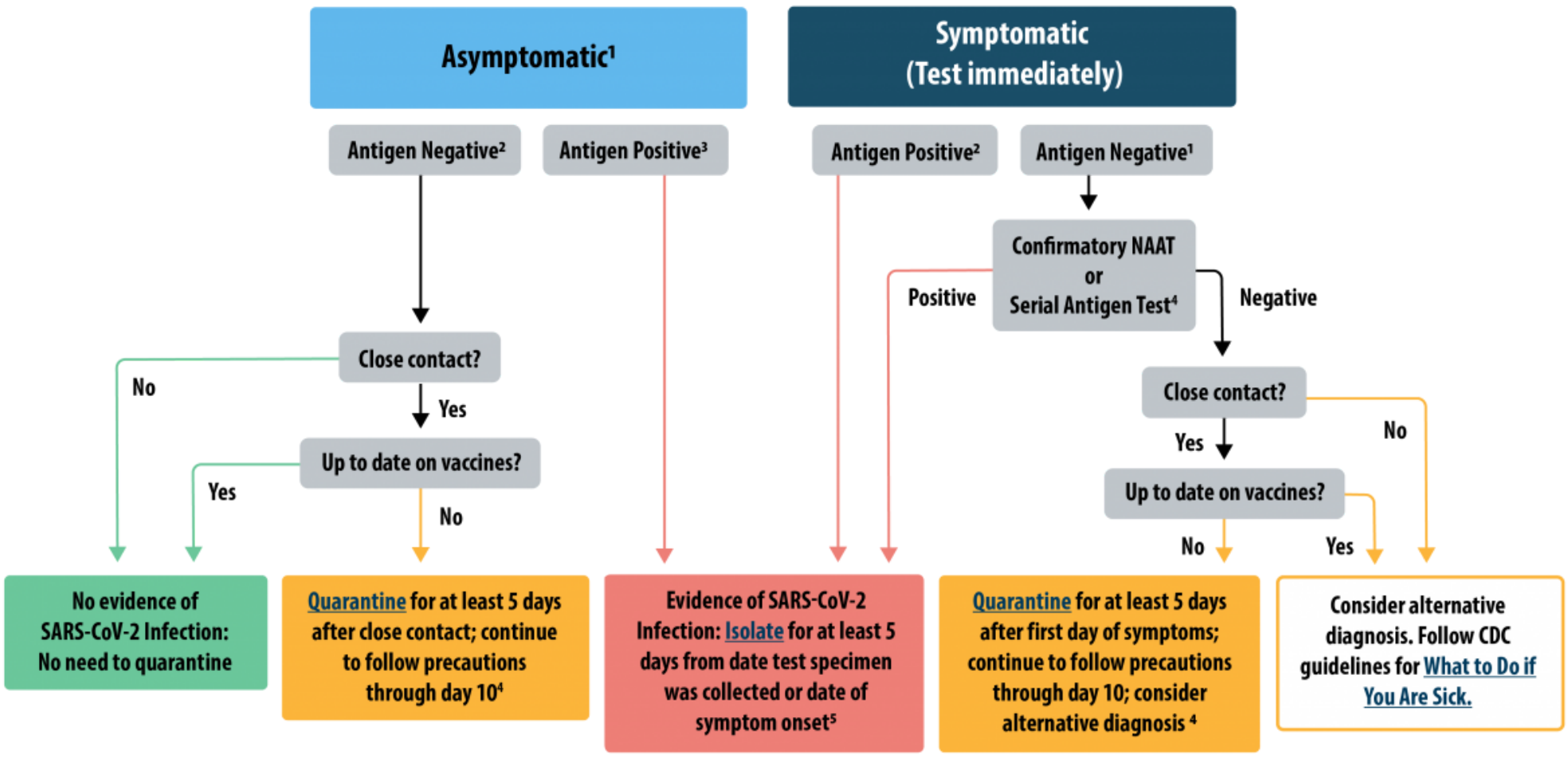
It may be appropriate to confirm antigen test results with a laboratory-based NAAT, as described below. For confirmatory testing, CDC recommends using a laboratory-based NAAT that has been evaluated against the FDA reference panel for analytical sensitivity. See FDA's SARS-CoV-2 Reference Panel Comparative Data . **NAATs that generate presumptive results are not appropriate for use in confirmatory testing.**

CDC has developed an algorithm for community testing for people who do not live in congregate settings. The primary objective of this testing is to reduce the transmission of SARS-CoV-2 in the community, where there are concerns for introduction and widespread transmission, by quickly identifying and isolating people who are infected. See Figure 1, also available as a PDF.

Additional guidance has been developed for those who live in congregate settings. In these settings, correct case identification is particularly important because of the need to group isolated people together or in close proximity, so false positive test results can have significant consequences. See additional guidance for these settings: long-term care facilities, correctional and detention facilities, homeless shelters and other group shelters, and higher education shared housing settings.

Using Antigen Tests for SARS-CoV-2 in Community Settings

Figure 1. Antigen Test Algorithm for Community Settings



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Technical Notes

[1] If testing after a suspected exposure, test 5 days after last close contact with a person with COVID-19. For those who are traveling or have recently traveled, please refer to CDC's guidance for domestic and international travel during the COVID-19 pandemic. Take precautions while traveling.

[2] Consider confirmatory testing with a NAAT or serial antigen testing for a negative antigen test result if the person has a higher likelihood of SARS-CoV-2 infection (e.g., in an area where the COVID-19 Community Level is high or the person has had close contact with or suspected exposure to someone infected with SARS-CoV-2) or if the person has symptoms of COVID-19.

[3] A positive antigen test result generally does not require confirmatory testing; however, it could be considered when the person has a lower likelihood of infection (e.g., in an area where the COVID-19 Community Level is low and no known close contact with someone infected with SARS-CoV-2).

[4] Confirmatory NAAT testing should take place as soon as possible after the antigen test, and not longer than 48 hours after the initial antigen testing. If the results are discordant, the confirmatory test result should be interpreted as definitive for the purposes of clinical diagnosis. If performing serial antigen testing, wait 24-48 hours between tests. See CDC's guidance on Quarantine and Isolation.

[5] See CDC's guidance on treatments for COVID-19, particularly if individual is at high-risk of severe disease from COVID-19. Also see CDC's guidance on Quarantine and Isolation.

Testing a symptomatic person in a community setting

In a community setting, when testing a person who has symptoms compatible with COVID-19, the healthcare provider generally can interpret a positive antigen test to indicate that the person is infected with SARS-CoV-2; this person should follow CDC's guidance for isolation.

A positive antigen test result for a symptomatic person generally does not require confirmatory testing; however, it could be considered if the person has a lower likelihood of SARS-CoV-2 infection. Factors that might indicate a lower likelihood of infection include, living in an area where the COVID-19 Community Level is low **and** no known close contact with someone infected with SARS-CoV-2.

A negative antigen test result for a symptomatic person should generally be confirmed with a laboratory-based NAAT. In this case, serial antigen testing that is performed every 2-3 days while symptomatic may be used as an alternative to confirmatory NAAT testing. A negative antigen result for a symptomatic person may not need confirmatory testing if the person has a lower likelihood of SARS-CoV-2 infection (see above).

A symptomatic person who has received a negative antigen test result and then a positive confirmatory NAAT should follow CDC's guidance for isolation from the date of the first test. A symptomatic person who has received a negative antigen test result and then a negative confirmatory NAAT should be considered for alternative diagnoses and avoid close contact with others to prevent spreading illness.

Testing an asymptomatic person in a community setting

When testing an asymptomatic person in a community setting for COVID-19, the healthcare provider generally can interpret a positive antigen test to indicate that the person is infected with SARS-CoV-2; this person should follow CDC's guidance for isolation. A positive antigen test result from an asymptomatic person may need confirmatory testing if the person has a low likelihood of SARS-CoV-2 infection. For example, a low likelihood of SARS-CoV-2 infection would be a person who has had no close contact to a person with COVID-19 **and** resides in a community where the COVID-19 Community Level is low.

When testing an asymptomatic person for COVID-19, the healthcare provider can generally interpret a negative antigen test result to indicate that the SARS-CoV-2 virus was not detected. However, a negative antigen test result may need confirmatory testing with a laboratory-based NAAT if that asymptomatic person has a higher likelihood of SARS-CoV-2 infection. For example, a higher likelihood of SARS-CoV-2 infection would be a person who has had close contact or suspected exposure to a person with COVID-19.

An asymptomatic person who has received a negative antigen test result should follow CDC's guidance for quarantine if they have had close contact or suspected exposure to a person with COVID-19 and are not up to date on their vaccines.

Confirmatory Testing When Using Antigen Tests for SARS-CoV-2

As the antigen testing algorithms indicate, confirmatory testing may be needed regardless of the symptom or exposure status of the person being tested. Confirmatory testing should take place as soon as possible after the antigen test, and not longer than 48 hours after the initial antigen testing. If more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a laboratory-based NAAT should be considered a separate test – not a confirmation of the earlier test. If the results are discordant between the antigen test and the confirmatory NAAT, in general the confirmatory test result should be interpreted as definitive for the purpose of clinical diagnosis.

CDC recommends laboratory-based NAATs for confirmatory testing. CDC does not recommend NAATs that use oral specimens (e.g., saliva) for confirmatory testing and instead suggests the use of specimens that are considered optimal for detection, such as nasopharyngeal, nasal mid-turbinate, and anterior nasal swabs. See CDC's guidance for Nucleic Acid Amplification Tests (NAATs).

Several studies have documented persistent or intermittent detection of virus using RT-PCR after recovery; in these cases, the people did not seem to be infectious to others. Thus, if the person being tested has recently had COVID-19 and completed their period of isolation, it is possible for that person to receive a negative antigen test result and a positive confirmatory NAAT, potentially indicating a persistent detection of SARS-CoV-2 after recovery from COVID-19. For this reason, repeat testing after the initial diagnostic test is not recommended during the period of isolation or as a test of cure. See CDC's Clinical Questions about COVID-19: Questions and Answers.

If confirmatory testing is not available, clinical discretion can determine whether to recommend that the patient isolate or quarantine. See CDC's guidance on Testing in Nursing Homes, Quarantine and Isolation, Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings, Discontinuation of Transmission-Based Precautions of Patients in Healthcare Settings, Return to Work for Healthcare Personnel, Recommendations for Quarantine Duration in Correctional and Detention Facilities, and Guidance for COVID-19 Prevention in K-12 Schools.

Serial Testing When Using Antigen Tests

Depending on the circumstances and setting, it may be useful to implement serial antigen testing for persons who receive a negative antigen test result. There is evidence that serial antigen testing every few days can identify SARS-CoV-2 during early stages of infection, and thus reduce disease transmission. Serial antigen testing within a congregate living setting, such as a long-term care facility or a correctional or detention facility, could quickly identify someone with a SARS-CoV-2 infection and help to prevent further transmission. It may not be necessary to perform confirmatory testing with a NAAT when conducting serial antigen testing on those who have received a negative antigen test result.

Reporting Antigen Test Results for SARS-CoV-2 to Health Departments and Patients

A CLIA-certified laboratory or testing site must report antigen diagnostic test results to the local, state, tribal, or territory health department in accordance with Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The CARES Act requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results of each such test. Antigen test results that are reported to public health departments must be clearly distinguished from other COVID-19 tests, such as NAATs and antibody tests.

On January 8, 2021, the U.S. Department of Health and Human Services updated its published guidance on COVID-19 Pandemic Response, Laboratory Data Reporting that specifies what additional data should be collected and electronically reported to health departments along with COVID-19 diagnostic or screening test results. Laboratory and testing professionals should collect and report complete patient demographic information and ensure that they report antigen test results using the proper LOINC code for their particular FDA-authorized tests. Facilities should refer to CDC's LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests.

A CLIA-certified laboratory or testing site must report antigen test results to the individual or the individual's healthcare provider according to the instructions for use of the FDA-authorized SARS-CoV-2 in vitro diagnostic device that was used. Depending on the stipulations of the FDA authorization, the laboratory or testing site may be required to report negative test results to patients as "presumptive negative."

For long-term care facilities that are enrolled in CDC's National Healthcare Safety Network (NHSN), the preferred method for reporting point-of-care SARS-CoV-2 testing data, including antigen test results, is through the NHSN.

Summary Table

Table 1. Summary of Some Differences Between Nucleic Acid Amplification Tests (NAATs) and Antigen Tests

	NAATs	Antigen Tests
Intended Use	Detect *current* infection	Detect *current* infection
Analyte Detected	Viral Ribonucleic Acid (RNA)	Viral Antigens
Specimen Type(s)	Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva	Nasal, Nasopharyngeal, Saliva
Sensitivity	Varies by test, but generally high for laboratory-based tests and moderate-to-high for POC tests	Varies depending on the course of infections, but generally moderate-to-high at times of peak viral load*
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 15 minutes	Ranges from 15 minutes–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 in the community, workplace, etc. Comparable performance to NAATs in symptomatic persons and/or if culturable virus present, when the person is presumed to be infectious
Disadvantages	Longer turnaround time for lab-based tests (1–3 days) Higher cost per test A positive NAAT diagnostic test should not be repeated within 90 days, since people may continue to have detectable RNA after risk of transmission has passed	May need confirmatory testing Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people

*The decreased sensitivity of antigen tests might be offset if the point-of-care antigen tests are repeated more frequently (i.e., serial testing at least weekly).

^Costs for: NAATs , Antibody tests

[+]Refers to point-of-care antigen tests only.

Previous Updates

Updates from Previous Content

As of September 9, 2021

- Updated footnotes for the Antigen Test Algorithm for Congregate Living Settings.

As of May 13, 2021

- Updated guidance based on new published studies on antigen test performance.

- Clarification about which nucleic acid amplification tests (NAATs) should be used for confirmatory testing.
- Considerations for people who have had previous SARS-CoV-2 infections and those who have been fully vaccinated.
- Two new antigen testing algorithms, one for congregate living settings, and one for community settings.
- Updates to testing suggestions for fully vaccinated, asymptomatic people.

As of December 5, 2020

- The word “rapid” has been deleted because FDA has authorized laboratory-based antigen tests.
- New section on processing of antigen tests, reflecting what has been learned on how to minimize the risk of false results.
- Revised section on evaluating the results of antigen tests, introducing a new testing algorithm, and reflecting what has been learned about the performance of antigen tests and the need to implement confirmatory testing.

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