

Testing for COVID-19

Partners In Health United States
December 2021

Context for these materials

This deck is intended to provide guidance for trusted messengers and community leaders to conduct community-based conversations around the COVID-19 diagnostic testing. The goal of this deck is to share accurate, science-based evidence and engage in discussion that enables individuals to make informed decisions about their own health. This slide deck guides a short, 15-minute presentation and is intended to prompt a more comprehensive Q&A session.

Supplementing this deck with up-to-date local information (on testing availability, eligibility criteria, and registration procedures) is critical.

The ideas and testing methods presented in this deck reflect the latest public health thinking and scientific evidence as of December 2021. You are advised that the COVID-19 testing landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-to-date information available.

Partners In Health does not provide medical advice, diagnosis or treatment in the United States. The information, including but not limited to, text, graphics, images and other material contained in this slide deck, are intended for informational purposes only.

Overview

Overview of test types

Choosing a test type

Population-based testing strategies

Rapid antigen testing; uses and challenges

Addressing inequities in testing

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There are 2 general categories of COVID-19 tests: **Diagnostic** and **Antibody**

Diagnostic Test

- Detects active COVID-19 infection and indicates the necessity of quarantine or isolation from others, especially with ongoing symptoms.
- Currently two types of diagnostic tests which directly detect the virus (see next slide):
 1. Molecular tests, such as RT-PCR tests, that detect the virus's genetic material
 2. Antigen tests that detect specific proteins on the surface of the virus
- Samples are generally collected with a nasal or throat swab, or saliva collected by spitting into a tube.

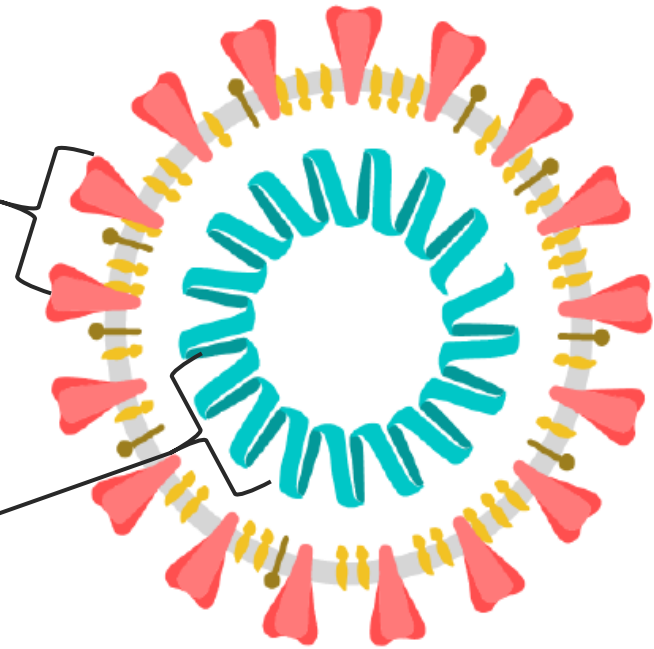
Antibody Test

- Looks for antibodies in the blood that are made by the immune system in response to the virus to help fight infections.
- Antibody tests should not be used to diagnose an active COVID-19 infection. Antibodies can take several days or weeks to develop after the onset of infection and may stay in the serum for weeks/months or more after recovery.
- Samples are generally collected from a finger stick or blood draw.

Diagnostic tests can be further classified into antigen or nucleic acid tests

Antigen tests detect physical components of the virus, such as the surface proteins on the outer layer, or nucleocapsids inside the virus

Nucleic Acid tests, such as RT-PCR, detect the genetic material of the virus – often RNA – and therefore require “breaking open” the virus to obtain the genetic material inside



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Choice of test may depend on the reason for testing...

1

Diagnosis

- **Aims to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.**
- Examples of diagnostic testing include testing symptomatic persons regardless of vaccination status, testing persons identified through contact tracing efforts, and testing persons who indicate they were exposed to someone with a confirmed or suspected case of COVID-19.

2

Screening

- **Aims to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening tests are recommended for unvaccinated people to identify those who are asymptomatic and do not have known or suspected exposure to SARS-CoV-2.**
- May identify persons who are contagious so that measures can be taken to prevent further transmission.
- Examples of screening include workplace testing for employees, school testing its students, faculty, and staff, testing before or after travel, or home testing for someone without symptoms who has no known exposures.

3

Surveillance

- **Aims to monitor population-level infection and disease, or to characterize the incidence and prevalence of disease.**
- Performed on de-identified specimens, and thus results are not linked to individuals; results of surveillance testing are only returned in aggregate. Thus, surveillance testing is not used for individual decision making, but rather population interventions.
- An example of surveillance testing is [wastewater surveillance](https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html).

...with different tests better suited for different purposes

Key elements of a test needed:

Test type suggestions:

1

Diagnosis

- Accuracy (Sensitivity & Specificity)
- Speed

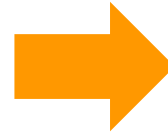


- Prioritize molecular tests for clinical accuracy
- If speed becomes a barrier to taking clinical or epidemiological actions, consider expanding to antigen testing

2

Screening

- Accuracy (Sensitivity & Specificity)
- Speed
- Scale/Volume/Cost



- Antigen testing if done at high frequency
- Prioritize point-of-care rapid tests for screening events to reduce loss-to-follow up and prevent spread (e.g. rapid antigen tests, or rapid molecular tests like IDnow)

3

Surveillance

- Scale/Volume/Cost
- Logistical convenience



- Antigen testing for surveillance of active cases
- Antibody testing for seroprevalence studies; dried blood spot sample collection eases sample collection/transport

High volume population-level screening is distinct from lower volume screening/testing -- and requires a new set of considerations

Screening Criteria

Broad sampling of asymptomatic people generally where they work or live and not in testing facilities

Technology

Requirement for high throughput, high accuracy, and low-cost testing.
See pooled testing options in appendix.

Payment

Screening should be free to the individual and paid for by employers, schools, or government

Logistics

End to end reliability and data transfer is critical to ensuring data integrity and efficiency of screening program

Procedure

Since screening may be frequent, self-administered saliva, anterior nares, or oral swabs would be preferred. Dried blood spot for antibody testing.

Supply Chain

Reliable raw material supply and manufacturing capacity to meet enormous global demand

What to look for when evaluating a test

- **Pretest probability** is the chance that the patient has the disease, estimated before the test result is known based on the probability of the suspected disease in that person given their symptoms and level of transmission in the community.
 - At the population level, the pretest probability is also known as the **prevalence**: the number of known cases of the disease in a population at a given time.
- **Post-test probability** tells us a person's chance of having a disease after a test is performed, and more important for clinical use to decide whether to accept a diagnosis of disease, rule one out or order more testing.
- **Sensitivity** is the ability of a test to correctly identify the disease in the population of people who have the disease.
 - *The closer to 100% sensitivity, the better the test is at detecting the virus (fewer false negatives).*
- **Specificity** is the proportion of people who test negative for the disease among those who do not have the disease.
 - *The closer to 100% specificity, the less likely the test is to have false positives.*

Test Result	Patient has disease	Patient does not have disease
Positive	True Positive	False Positive
Negative	False Negative	True Negative

Click [here](#) to visit the source document and read more information here with examples.
Click [here](#) to practice calculating these values with an online calculation tool.

Keep in mind the impact of viral mutations on test effectiveness

Variations are the result of mutations and can change the characteristics of a virus—all viruses mutate and change naturally. Just like other viruses, SARS CoV-2, the virus that causes COVID-19, is constantly mutating. A new variant, known as the Omicron variant, was identified in November 2021. Scientists are studying the effect of this new variant on transmissibility, disease severity, immune evasion, and effectiveness of existing prevention measures.

Testing may also be impacted by viral mutations. Different types of test are affected differently due to the inherent design differences of each test.

- **PCR testing appears to be an effective tool to identify the Omicron variant.**
 - **Preliminary evidence suggests that rapid antigen tests also effectively detect infections, including those cause by the Omicron variant.**
 - **Certain EUA-authorized molecular tests may be impacted by mutations in the Omicron variant; negative results should be considered with clinical observations, patient history, and epidemiological information. Consider repeat testing with an alternative test type.**
- **[The FDA has identified tests for which performance may be impacted by COVID-19 variants](#), including Omicron— this information will be updated as new data become available.**

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Testing strategies should match the population risk level

Population

Symptomatic people

Exposed contacts

Healthcare workers

Nursing home residents and staff

Congregate living settings

Service sector/essential workers

Students and teachers

Public housing/Senior buildings

Asymptomatic unvaccinated people

Return to work/employees

Asymptomatic vaccinated people

We will discuss recommendations for these populations in three main categories:

1) High risk

2) Medium risk

3) Lower risk

All testing should be complemented with essential community mitigation strategies:

- Vaccination
- Daily or day-of symptom screening
- Mask wearing
- Hand washing
- Social distancing

Testing recommendations – high risk groups

Risk Level	High
Populations	<ul style="list-style-type: none">• Symptomatic people (regardless of vaccination status)• Exposed contacts
Current Testing Strategy	<ul style="list-style-type: none">• Molecular (mostly PCR) diagnostic testing available through community testing locations, physician's offices, hospitals, pharmacies, etc.• All exposed contacts referred for immediate testing via contact tracing team• Vaccinated people, with or without symptoms should get tested 3-5 days after exposure• People who are not fully vaccinated should be tested immediately and if negative, tested against 5-7 days after last exposure or immediately if symptoms develop during quarantine
Strategic Improvements	<ul style="list-style-type: none">• Continue to prioritize molecular (PCR) diagnostic testing for high sensitivity/specificity• Improve turnaround time for results in under 24 hours
Considerations	<ul style="list-style-type: none">• To achieve faster TAT, consider:<ul style="list-style-type: none">○ Amending current lab contracts to require turnaround time metrics/data reporting○ Engaging new vendors with extra capacity/faster TAT○ Procuring molecular tests with faster TAT (e.g., Abbot IDnow, CRISPR)

Testing recommendations – medium risk groups

Risk Level	Medium
Populations	<ul style="list-style-type: none">Healthcare workers, nursing home residents/staff, those living in congregate settings, service sector/essential workers, students and teachers, public housing/senior building residents, asymptomatic unvaccinated people, return to work employment/office-based populations
Current Testing Strategy	<ul style="list-style-type: none">Return to work testing for employees/stay in school testing for students and staffNursing home testing through state and local health departmentsTesting events at public housing locations/senior buildings/shelters/etc.
Strategic Improvements	<ul style="list-style-type: none">Introduce weekly screening tests targeting random samples of each populationEmphasis on immediate/same day TAT of results to isolate and contact tracing any positives → Introduce rapid antigen testing as "entrance" tests
Considerations	<ul style="list-style-type: none">FDA EUA restrictions on rapid antigen testing of asymptomatic individualsPrioritize tests with easy sample collection (saliva, oral, nasal self-swabs)Pooled sampling could be leveraged to increase overall test capacityPolicy shaping at the state level to determine what tests are covered by insurance, so asymptomatic contacts and other asymptomatic individuals qualify for testing

Testing recommendations – lower risk groups

Risk Level	Low
Populations	<ul style="list-style-type: none">• Asymptomatic vaccinated people
Current Testing Strategy	<ul style="list-style-type: none">• Return to work testing for some public sector employees• Molecular (mostly PCR) diagnostic testing available through community testing locations, PCPs, hospitals, pharmacies, etc.• Home-based testing
Strategic Improvements	<ul style="list-style-type: none">• Broad testing and outbreak surveillance, e.g., waste-water testing• Not priority for additional testing interventions if asymptomatic• Improve reporting capacity and infrastructure for home-based testing
Considerations	<ul style="list-style-type: none">• Reduce pre-test prevalence as much as possible (symptom screening, sanitation practices) to reduce false negative rate if using lower sensitivity tests, e.g., antigen tests• Need to ensure access to testing for the general/asymptomatic population is maintained at community testing sites, regardless of insurance or immigration status

Considerations for vaccinated & unvaccinated people in different testing scenarios

Test if/for:	Vaccinated	Unvaccinated
Close contact w/known or suspected COVID-19 positive person	✓	✓
Experiencing COVID-19 Signs and/or symptoms	✓	✓
Entering the U.S. from abroad	✓	✓
Leaving the U.S. for international travel*		✓
Before or after domestic travel		✓
Routine screening testing programs (work, school, etc.)		✓

*Testing may be required at destination regardless of vaccination status



- Vaccinated people, with or without symptoms, should get tested 3-5 days after having close contact with someone with COVID-19
- Federal, state, local, and tribal laws, rules, & regulations may require testing, even for fully vaccinated people
- It is recommended fully vaccinated people be exempt from routine screening & testing, if feasible

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Widely available rapid testing is one effective tool to fight COVID-19, but the availability of fast, low-cost antigen testing is limited in the U.S.

Most tests in the U.S. are PCR, which offer high sensitivity but slow turnaround for results (24-48+ hours)-- time that a person can spread COVID-19 to others.

- Recent analysis suggests that test frequency matters more for reducing COVID-19 cases than test sensitivity.
- Broad uptake of frequent and sustained use of rapid testing may have potential to slow spread of COVID-19.
- Vaccine mandates (including employment- and school-based) with test alternatives further necessitate low-cost test availability.

The Biden administration plans to rapidly scale up access to rapid tests with \$1B investment to quadruple availability of at-home tests by end of 2021, for distribution to target testing settings and wholesalers to sell **at cost**, and to expand free pharmacy testing.

Where Are the Tests?

Other countries are awash in Covid tests. The U.S. is not.

Test sensitivity is secondary to frequency and turnaround time for COVID-19 screening

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SCIENCE ADVANCES • 1 Jan 2021 • Vol 7, Issue 1 • DOI: 10.1126/sciadv.abd5393

A Cheap, Simple Way to Control the Coronavirus

With easy-to-use tests, everyone can check themselves every day.

By Laurence J. Kotlikoff and Michael Mina

Sources: <https://www.nytimes.com/2021/09/21/briefing/rapid-testing-covid-us.html>
<https://www.npr.org/sections/coronavirus-live-updates/2021/09/14/1037077480/an-epidemiologist-says-at-home-testing-is-key-to-stopping-covid>; <https://www.science.org/doi/10.1126/sciadv.abd5393>

Even if the sensitivity is low in real world use, rapid antigen testing can still effectively rule out disease

Specificity 99%, sensitivity estimated at **80%**. 500 people screened.

Test Result	Positive	Negative
Test Positive	40	4.5
Test Negative	10	445.5
10% Prevalence	50	450

With high prevalence, there will be 10 people with the disease out of 500 who tested negative with a 2% false negative rate

Test Result	Positive	Negative
Test Positive	8	4.9
Test Negative	2	485.1
2% Prevalence	10	490

With low prevalence, there will be 2 people with the disease out of 500 who tested negative with a 0.4% false negative rate

Home-based tests (many of them antigen) can make access to testing significantly more equitable

TYPES OF HOME-BASED TESTING



Self-collection

Sample collection (nasal swab or saliva) is performed at home, often under remote supervision. Sample processing occurs outside of the home, and a third-party provider delivers results (“swab and send” model). Most often molecular tests (appropriate for diagnosis in a clinical setting, detecting individuals at the post-infectious stage).



Self-testing

Sample collection (nasal swab or saliva) AND sample processing are performed in the home. Results are delivered within 15-30 minutes within the home setting, with the user interpreting based on instructions. Self-tests are also referred to as “home tests” or “at-home tests”. Mostly rapid antigen tests, and one molecular test (Lucira), can be completed entirely at home.

The FDA has granted Emergency Use Authorization (EUA) to an increasing number of sample collection devices. [As of early December 2021](#), EUA has been granted to:

- 89 molecular tests (4 with self-testing capabilities; 1 prescription and 3 OTC)
- **14 antigen tests (all with self-testing capabilities; 3 prescription and 11 OTC)**

For real-time information on FDA EUA for home-based testing, visit the FDA's [website](#) and search for “home” in both the antigen and the molecular test databases.

Specific challenges with rapid antigen testing

Issues

- **VARIABLE ACCURACY DEPENDING ON CONTEXT:**
 - Have been authorized by the FDA for diagnostic use in symptomatic patients, but providers should confirm negative results by PCR if the pretest probability of infection is high.
 - May be useful for screening if performed on a regular and frequent basis, e.g., every few days. This is to correspond to the 5-day period when viral shedding is highest (between Days 3 and 8 of infection) and thus when tests are most effective.
- **OPERATOR ERROR** may contribute to reports of false positives in some settings.
- **REPORTING:** Rapid testing results are more challenging to integrate into local or state health reporting systems.
- **COST:** Waivers for non-medically necessary tests are expiring.

Public Health Considerations

- Health departments may discourage use of antigen tests for one-time screenings given low positive predictive value.
- Consider advising facilities against moving nursing home patients to COVID-19 wards until an antigen screening test is confirmed.
- In communities where transmission rates are low and mitigation efforts are effective, PCR testing may be a more reliable approach to screening due to false positive and negative rates.
- Training of personnel is critical to reduce false positives.
- Effectiveness against spread of COVID-19 is dependent on widespread use of antigen tests and associated quarantine and isolation behaviors. Health departments may offer guidance and social supports to encourage these behaviors.

White House COVID-19 Action Plan



On September 9, 2021 President Biden announced a six-pronged national strategy to combat COVID-19. Several parts will directly affect the rapid testing landscape.

1

Vaccinating the Unvaccinated

2

Further Protecting the Vaccinated

3

Keeping Schools Safely Open

4

Increasing Testing & Requiring Masking

5

Protecting Our Economic Recovery

6

Improving Care for those with COVID-19

Vaccine mandates have indirectly prompted renewed attention to testing, as an alternative or interim measure to satisfying vaccine requirements.

Return to school and commitment to economic recovery have also placed added emphasis on testing and corresponding federal investment.

White House COVID-19 Action Plan: Mandates and their effect on testing

➤ The six-pronged national strategy to combat COVID-19 includes **new vaccine (and testing) mandates and expanded access to testing, prompting emphasis on widely available testing options.**

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Mandates for Workers

- All federal workers and all employees of federal contractors must receive a COVID-19 vaccination with no testing option.
- All federal employees must be fully vaccinated by November 22, 2021.
- Employers with 100+ employees must ensure workers are vaccinated or tested weekly. This mandate impacts ~80M private sector workers nationally.
- Employers are required to give paid time off for vaccination and post-vaccination recovery.
- Vaccinations are required for workers in healthcare settings that receive Medicare or Medicaid reimbursements. This mandate will cover ~17M HCWs.

White House COVID-19 Action Plan: Increased demand for testing



The six-pronged national strategy to combat COVID-19 includes **new vaccine (and testing) mandates and expanded access to testing, prompting emphasis on widely available testing options.**

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Increased Demand for and Access to Testing

- Increased manufacturing of rapid COVID-19 tests, including at-home tests
- Improved access to rapid tests for consumers at easy-to-access locations and at low prices
- Support for COVID-19 testing in K-12 schools to ensure schools can remain safe and open
- Encouragement for venues where large numbers of people gather to institute vaccination/testing requirements for entry

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There are significant disparities in access to testing

Barriers

- Cost and/or insurance status
- Immigration status and fear of ICE
- Distrust of government and/or health systems
- Communication and language barriers
- Transportation and access barriers
- Lack of ability to safely isolate after a positive test due to employment insecurity or personal/family obligations
- Fear of getting a test because of risk of losing work/income



Mitigation Strategies

- Universal testing paid for by government, regardless of insurance or immigration status
- Eliminate police presence at testing sites + ensure no information is shared with non-health personnel
- Hire test site staff directly from the community
- Ensure testing locations and resources are located within the community, in easy-to-access places via public transportation, with flexible hours of operation (use [SVI](#) data and/or [equity mapping](#) to assist with site placement)
- Provide resources to support isolation and quarantine
- Encourage paid time off and sick leave for employees waiting for test results, quarantining, and isolating

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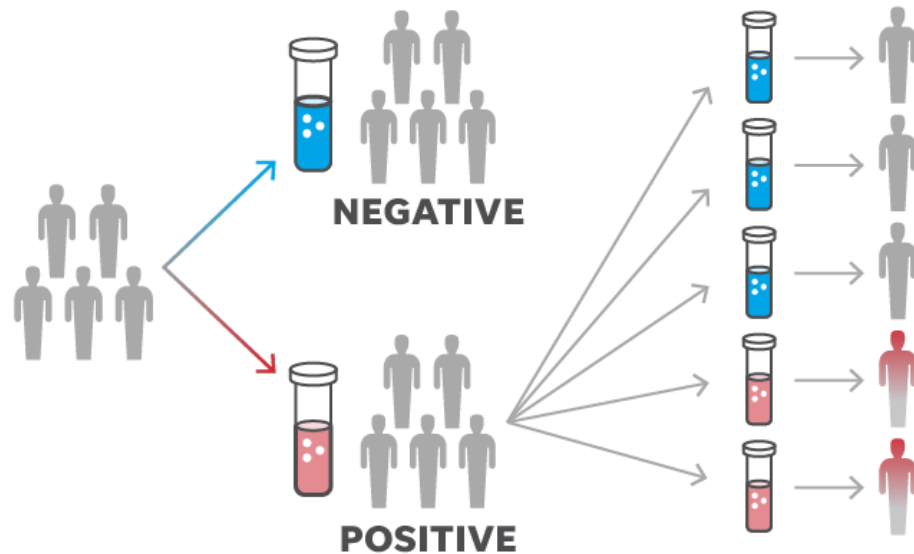
CLIA regulations pertain to diagnostic and screening tests depending on the level of test complexity

Term	Definition	Implication
CLIA	Clinical Laboratory Improvements Amendments. CMS oversight body regulating all tests that result to a patient	Almost all testing is included except for research and forensics
CLIA – waived tests	Any laboratory test deemed by the FDA to be simple enough that there is an insignificant risk of an erroneous result. These tests are exempt from CLIA rules if following the manufacturer's instructions	Deemed so simple that they do not require licensure to conduct, interpret, or report
CLIA certificate of waiver	A waiver obtained by a laboratory to allow conducting of testing, their interpretation, and delivery to a patient	A "laboratory" refers to any group of people if there is designated lab director. Easily obtainable
Moderate and High complexity lab tests	More complex tests that require specific regulations for persons performing and interpreting the tests with corresponding responsibilities for each position	PCR testing generally falls under this designation except for POC NAA tests
Certificate of compliance (COC) / accreditation (COA)	Denote higher levels of laboratory certification required to perform medium to high complexity lab tests	Many state and county laboratories fit this more advanced designation

Pooled testing allows for increased testing capacity in surveillance

How pooled testing works

- 1** People are broken up into groups and a group is tested together.
- 2** A combined sample from the group either tests negative or positive.
- 3** If positive, people are tested individually to find the positive cases.



SOURCE USA TODAY research
Karl Gelles/USA TODAY

Pooled testing is useful in populations where prevalence is expected to be low (if all pool samples test positive, no resources have been saved)

Most useful when routine, repeat testing is needed in congregate living areas such as skilled nursing facilities, dormitories, or school classrooms

Samples can be pooled at the point of collection or later at the lab before the test is run

Side-by-side comparison of testing technologies

	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Also known as...	Diagnostic test, viral test, molecular test, nucleic acid amplification test (NAAT), RT-PCR test, LAMP test	Diagnostic test, viral test, rapid test	Serological test, serology, blood test, serology test
How the sample is taken...	Nasal swabs, either shallow or deep (most tests). Saliva (some tests)	Nasal or nasopharyngeal swab (most tests)	Blood from a fingerstick or vein
How long it takes to get results...	Less than an hour (at-home tests and some point-of-care locations), same day (some point-of-care locations) or 1-3 days (tests sent to a lab for processing). Some tests may take longer in some locations, depending on testing capacity.	Some may be very fast (15-30 minutes), depending on the test	Same day (some point-of-care locations) or 1-3 days (tests sent to a laboratory for processing)
Is another test needed...	Not usually. This type of test is typically highly accurate and usually does not need to be repeated. Some may indicate the need to re-test in certain circumstances.	Maybe. Positive results are usually highly accurate, but false positives can happen, especially in areas where very few people have the virus. Negative results may need to be confirmed with a molecular test.	Sometimes a second antibody test is needed for accurate results.
What it shows...	Diagnoses active COVID-19 infection. (Some tests may also diagnose influenza or other respiratory viruses)	Diagnoses active COVID-19 infection. (Some tests may also diagnose influenza or other respiratory viruses)	Shows if you've been infected by the virus that causes COVID-19 in the past
What it can't do...	It cannot show if you ever had COVID-19 or were infected with the virus that causes COVID-19 in the past	It may not detect an early COVID-19 infection. Your health care provider may order a molecular test if your antigen test shows a negative result, but you have symptoms of COVID-19. It also cannot show if you ever had COVID-19 or were	It cannot diagnose COVID-19 at the time of the test or show that you do not have COVID-19



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