At-Home COVID-19 Test Kit

FDA Emergency Use Authorization (EUA) in the USA

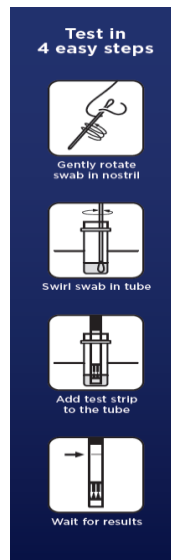# Frequently Asked Questions

About the Test

What is the Walgreens At-Home COVID-19 Test Kit?
The Walgreens At-Home COVID-19 Test Kit is a type of test called a rapid antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19, in anterior nasal swabs.

How does the Walgreens At-Home COVID-19 Test Kit work?
The test uses a gentle nasal swab sample to determine a positive or negative COVID-19 result. The swab is swirled in a tube of reagent solution, then removed, before a test strip is inserted. After ten minutes, you can take the strip out of the tube and see your results.

General steps for conducting the test are:

Before you begin the test, it's important to first read and closely follow the detailed user instructions included in the package.

How accurate is this At-Home COVID-19 test?
Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU) that can be found on this web page.
The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

How long does it take to get at-home test results?
Results are available in as little as 10 minutes in the privacy of your own home.

Will this test detect COVID-19 variants?
The manufacturer of this test continuously monitors the evolution and activity of COVID-19 variants in circulation and will continue to be vigilant in evaluating the tests with real-world virus samples to assure you of the product's efficacy. The manufacturer has completed testing on several variant strains and the test was able to detect the mutations. Since the test detects a part of the virus that is less susceptible to mutation, the likelihood of detecting new or emerging variants is high. The manufacturer monitors the variants closely and will inform the FDA promptly, should any issues be detected.

Is this test acceptable for travel? Can it be used for proof of a negative COVID-19 test?
There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

What are the differences between antigen tests and other COVID-19 tests?
There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection.

What is the difference between an antigen test and PCR or molecular tests?
There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Walgreens At-Home COVID-19 Test Kit, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

Is the solution in the tube harmful?
The solution in the tube contains small amounts of hazardous ingredients as listed in the User Instructions. If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice at https://www.poison.org/contact-us or **1.800.222.1222**.

What is the age range for this COVID-19 test?
This test is authorized for nonprescription home use with self-collected (unobserved) direct anterior nasal (NS) swab specimens from individuals aged 14 years and older or with adult-collected anterior NS samples from individuals aged 2 years or older.

Will this COVID-19 test hurt?
No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

Will the test work if I don't have symptoms?
The test is intended for the individuals with or without symptoms or other epidemiological reasons to suspect COVID-19.

What are the known and potential risks and benefits of this COVID-19 test?
Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Results section).

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

How many times should I use this test kit?
Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals, and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

What is Emergency Use Authorization (EUA)?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

How many COVID-19 tests come in a kit?
The test kit comes with two tests intended to be used for the same patient.

Should people who are vaccinated use this test?
Individuals with or without symptoms can still utilize this test, as needed, regardless of vaccination status.
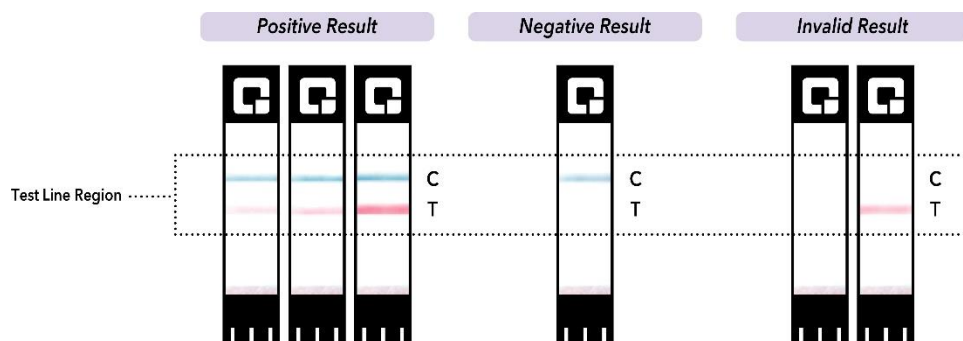
Is a prescription required to perform this test?
You do not need a doctor's prescription to purchase and perform this test.

Using the Test

I see a pink line, but it's not in the same spot as in the User Instructions. Is this a positive result?
Only a pink line about a half of a centimeter below the blue control line in the Test Line Region should be considered a positive result. Pink lines in any other area of the test strip should not be called a positive result.

If I see pink shading on the strip bordering the black label(s), is this a positive result?
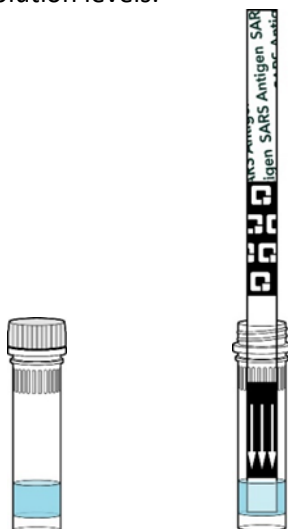Only a pink line about half of a centimeter below the blue control line should be considered a positive result. A pink line bordering the black label with the arrows, a vertical pink line, or a faint grey line next to the blue control line is not considered a positive test line and should not be called a positive result.
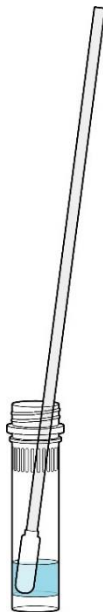

How much liquid should be in the tube?
The tube contains a small amount of liquid that only fills the bottom, as illustrated below. The amount of liquid may not look exactly like the photo in the User Instructions. The liquid in the tube should cover the bottom of the swab and test strip when immersed. The entire swab tip and arrows on the test strip do not need to be completely covered by the liquid. Please ensure to stir the swab 3-4 times in the liquid before the 1-minute incubation step. Examples of tubes and expected liquid solution levels:

Should the liquid in the tube cover the whole swab head when it's immersed?
The amount of liquid should cover approximately ¾ of the swab when it is immersed. It is important to follow the User Instructions and stir the swab 3-4 times once immersed in the tube. After the 1-minute incubation in the solution, remove the swab from the TUBE by rubbing the swab head against the inside wall of the tube to squeeze out as much liquid as possible.

Is it alright if my COVID-19 test kit if it was exposed to temperatures outside of the storage temperature range printed on the box during shipping?
The Walgreens At-Home COVID-19 Test Kit should always be stored upon receipt according to the temperature printed on the kit box (59°F to 86°F or 15°C to 30°C). The manufacturer of the test, has performed studies that demonstrate the product performs as expected under different temperature conditions (i.e., heated and frozen conditions) encountered during shipping.

The FDA also posted guidance to consumers on their website here:
- https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-covid-19-diagnostic-tests-frequently-asked-questions

Where can I find the kit expiration date?
The expiration date is labeled on the back of the kit box after "EXP." The date listed next to "MFG" is the date of manufacture.

What is the storage temperature?
The Walgreens At-Home COVID-19 Test Kit should always be stored upon receipt according to the temperature printed on the kit box (59°F to 86°F or 15°C to 30°C).

The kit components look different than the User Instructions. Is this normal or did I receive a defective kit?

The kit components may look slightly different than the User Instructions. You may observe the following kit differences:

- A different sized tube
- A different color cap on the tube (e.g., an orange or purple cap)
- Different brands of swabs
- A different tray and tube holder
- A white or clear tray

Can I swab my throat instead of my nose? Is this accurate?

The test is only authorized for use with nasal swab specimens and the accuracy and performance of throat swab specimens have not been evaluated. Throat swabs are not recommended and may not produce accurate results.

My test was negative at the 10-minute read time, but 1 hour later I noticed a faint pink line. Is this a positive result?

The test is intended to be read only at 10 minutes. If the test is read more than 5 minutes after the indicated read time, the result may be inaccurate and should not be used.

Is the test reusable?

No. Each test is designed for single use by one individual. We recommend keeping the User Instructions and tube holder until the second test is completed.

Results

Where can I obtain documentation of a negative test for travel purposes?
The Walgreens At-Home COVID-19 Test Kit does not provide documentation of a test result. Please visit the website for your airline or airport to view the latest requirements on the type of documentation required for your travel destination.

Where can I obtain documentation of my result?
The Walgreens At-Home COVID-19 Test Kit provides an immediate actionable result. The current test does not have the ability to provide a document of your result.

What do I do if I test positive?
Individuals who test positive with the Walgreens At-Home COVID-19 Test Kit should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

If I am positive after the first test, do I have to take another test?
If you test positive with the Walgreens At-Home COVID-19 Test Kit you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) your medical history, and your symptoms.

What does it mean if I have a positive test result?
A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What does it mean if I have a negative test result?
A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARSCoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does it mean if I have an Invalid Test result?
An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

Where do I report my positive result?
Please follow the latest CDC guidelines and communicate your results to your healthcare provider. Healthcare providers are responsible for reporting COVID-19 test results to the appropriate authorities.

Reimbursement Programs

Is this test covered by insurance?
Coverage varies based on the health insurance plan. Please check with your plan for details.

How can I get reimbursed for this test?
After the end of the PHE in May 2023, mandatory coverage for over-the-counter and laboratory-based COVID-19 tests ended. Coverage will vary depending on the health insurance plan. Details regarding coverage can be found in the following links:

- https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency
- Coverage for COVID-19 Tests (cms.gov)

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