QUIDEL

QuickVue® At-Home OTC COVID-19 Test

FDA Emergency Use Authorization (EUA) in the USA

Frequently Asked Questions

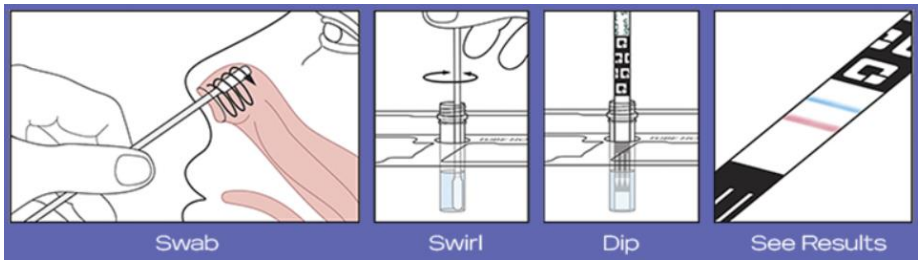
About the Test

What is the QuickVue At-Home OTC COVID-19 Test?
The QuickVue At-Home OTC COVID-19 Test 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 QuickVue At-Home OTC COVID-19 Test 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.

For a demonstration on how the test works, watch the instructional video:
https://quickvueathome.com/#video_testkit-2

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 the test?
Based on the interim results of a clinical study where the QuickVue At-Home OTC COVID-19 Test was compared to an FDA authorized molecular SARS-CoV-2 test, QuickVue At-Home OTC COVID-19 Test correctly identified 83.5% of positive specimens and 99.2% of negative specimens.

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 results?
Results are available in as little as 10 minutes in the privacy of your own home.

Where can I purchase the QuickVue At-Home OTC COVID-19 Test?
Please visit quickvueathome.com and select Where to Buy to view the list of retailers.

Will this test detect COVID-19 variants?
At Quidel, we continuously monitor the evolution and activity of COVID-19 variants in circulation and will continue to be vigilant in evaluating our tests with real-world virus samples to assure you of our product's efficacy. Quidel has completed testing on several variant strains and the test was able to detect the mutations. Because the test detects a part of the virus that is less susceptible to mutation, the likelihood of detecting new or emerging variants is high. Quidel 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?
The type of testing and documentation required for air travel may differ based on travel destination, airline, and state/country requirements. We encourage you to visit the CDC/TSA website as well as the airport, airline, and health department's website for the latest requirements on the type of acceptable testing and documentation for your travel destination.

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?
An antigen test, such as the QuickVue At-Home OTC COVID-19 Test, detects proteins from the virus. Molecular tests detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

Is the solution in the tube harmful?
The solution in the tube contains small amounts of hazardous ingredients (see table on page 5 of the User Instructions here). 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 the 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 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 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.

What is serial testing?
COVID-19 serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

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 tests come in a kit?
The test kit comes with two tests intended to be used for the same patient. A 25-test kit is also available.

Should people who are vaccinated use this test?
Individuals with or without symptoms can still utilize this test, as needed, regardless of vaccination status.

How long should I wait between the first and second test?
The QuickVue At-Home OTC COVID-19 Test is intended to be used for serial testing or used twice by the same individual over two or three days with at least 24 hours (and no more than 48 hours) hours between tests.

Is a prescription required to perform this test?
You do not need a doctor's prescription to purchase and perform this test.

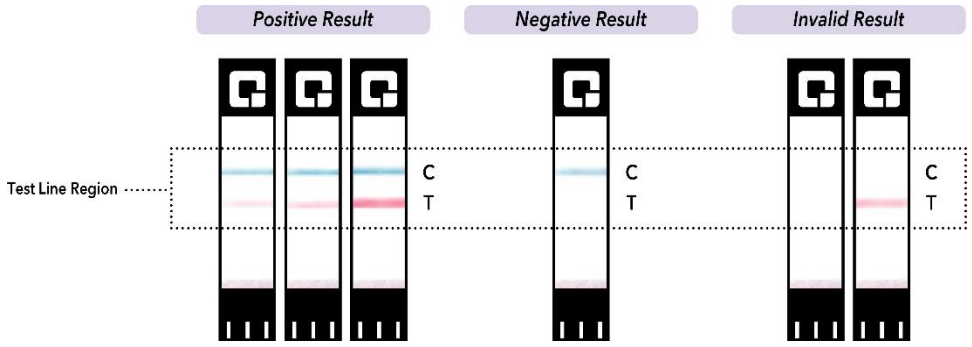
Where can I get information about the Say Yes! COVID Test campaign?
Please visit the Say Yes! COVID Test website for more information. The FAQ can be found here:

- https://sayyescovidhometest.org/faq.html

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?

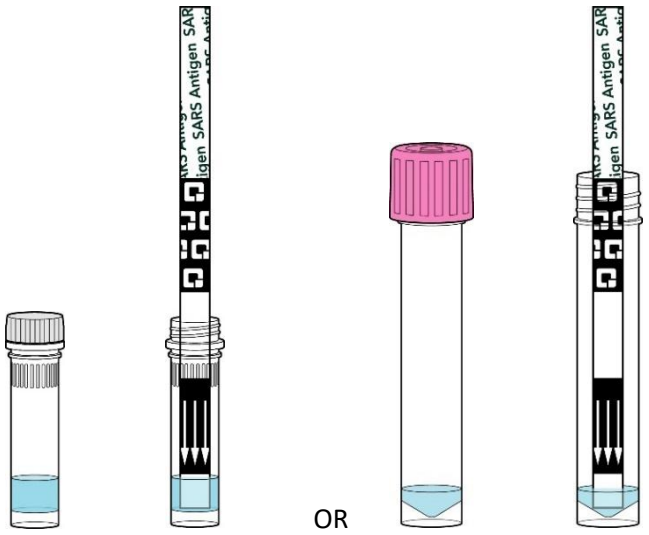
Only a pink line about a half of a centimeter below the blue control line in the Test Line Region should be considered a positive result. Pink lines in any other area of the test strip should not be called a positive result.



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.

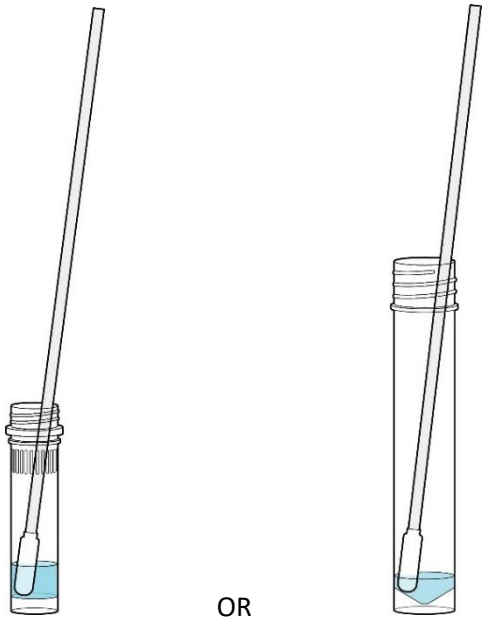
How much liquid should be in the tube?
The tube contains a small amount of liquid that only fills the bottom, as illustrated below. The amount of liquid may not look exactly like the photo in the User Instructions. The liquid in the tube should cover the bottom of the swab and test strip when immersed. 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.



OR

Is it alright if my test kit if it was exposed to temperatures outside of the storage temperature range printed on the box during shipping?

The QuickVue At-Home OTC COVID-19 Test 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). Quidel has performed studies that demonstrate the product performs as expected under different temperature conditions (i.e., heated and frozen conditions) encountered during shipping. If you have any concerns about the shipping conditions of your test kit, please contact the retailer where you purchased the test.

The FDA also posted guidance to consumers on their website here:

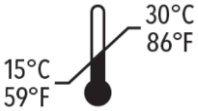
- https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-covid-19-diagnostic-tests-frequently-asked-questions

Where can I find the kit expiration date?

The expiration date is labeled on the outside of the kit box, under the lot number, next to the hourglass symbol. There is also a date printed next to the symbol of a building with a chimney and this is the date of manufacture.

What is the storage temperature?

The QuickVue At-Home OTC COVID-19 Test 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.

Why are the instructions in my test kit different than the instructions on the website? Which one do I use?
Quidel recently updated the kit instructions to clarify the best timeframe to use the test. Please refer to the User Instructions on Quidel.com for the most up-to-date instructions.

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.

What do the symbols mean?

REF	LOT
Catalogue number	Batch code
	
Use-by date	Manufacturer
	
Temperature limit	Consult instructions for use

IVD

In vitro diagnostic medical device

Results

Where can I obtain documentation of a negative test for travel purposes?
The QuickVue At-Home OTC COVID-19 Test 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 QuickVue At-Home OTC COVID-19 Test 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 QuickVue At-Home OTC COVID-19 Test 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 QuickVue At-Home COVID-19 Test 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) along with your medical history, and your symptoms.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive with the QuickVue At-Home OTC COVID-19 Test 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) along with your medical history, and your symptoms

What does it mean if I have a negative test result?
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay. If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Do I always need to perform two tests?
The QuickVue At-Home OTC COVID-19 Test is intended to be used for serial testing of asymptomatic individuals or used twice by the same individual over two or three days with at least 24 hours (and no more than 48 hours) between tests or once by symptomatic individuals within the first six days of symptom onset. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

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?
The test is available for at-home use without a prescription. Effective January 15, 2022, most people with a health plan can go online, to a pharmacy or store to purchase an at-home over-the-counter COVID-19 diagnostic test authorized by the FDA at no cost, either through reimbursement or free of charge through their insurance. Insurance companies and health plans are required to cover 8 free over-the-counter at-home tests per covered individual per month. For more details, please visit How to get your At-Home Over-The-Counter COVID-19 Test for Free | CMS.

How can I get reimbursed for this test?
Effective January 15, 2022, individuals with private health coverage or covered by a group health plan who purchase OTC COVID-19 test that are authorized, cleared, or approved by FDA can get OTC COVID-19 tests free of charge. Reimbursement and free of charge tests are not provided by Quidel. Details regarding the coverage details can be found in the following links:

- The Centers for Medicare and Medicaid (CMS) Press Release
- The CMS FAQ
- The Department of Labor/HHS/Treasury FAQ

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