QUIDEL | QuickVue At-Home OTC COVID-19 Test

Take 10 Minutes. Take Charge.

Introducing the QuickVue® At-Home OTC COVID-19 Test

Fast. Easy. Ready When You Are.

QuickVue At-Home OTC COVID-19 Test lets you get rapid results, in the privacy of your own home. Available over-the-counter, everything you need is in the package and taking the test is simple.

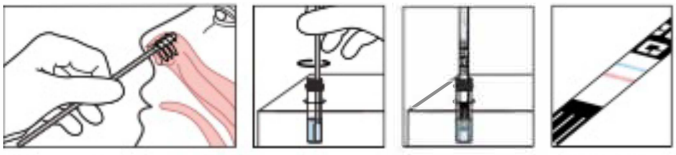
The test is authorized for home use with self-collected anterior nasal (nares) swab samples in individuals aged 2 and older. This test is also authorized for home use for individuals aged 2 through 14 with an adult performing the test. The test is intended to be used twice over two to three days, with at least 24 hours and no more than 36 hours between tests.

For use under FDA Emergency Use Authorization (EUA) only.
Available in the U.S. For In Vitro Diagnostic (IVD) Use.

RAPID RESULTS IN 10 MINS

How Does the QuickVue At-Home OTC COVID-19 Test Work?

The test uses a gentle self-collected anterior nasal (nares) 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.



Frequently Asked Questions

Who is Quidel Corporation?

Quidel Corporation (Nasdaq: QDEL) is a leading manufacturer of diagnostic solutions at the point of care delivering a continuum of rapid testing technologies that further improve the quality of healthcare throughout the globe. An innovator for over 40 years in the medical device industry, Quidel pioneered the first point-of-care test for influenza in 1999 and was the first to market a rapid SARS-CoV-2 antigen test in the U.S. Under trusted brand names Sofia®, Solana®, Lyra®, Triage® and QuickVue®, Quidel's comprehensive product portfolio includes tests for a wide range of infectious diseases, cardiac and autoimmune biomarkers, as well as a host of products to detect COVID-19. Quidel's mission is to provide patients with immediate and frequent access to highly accurate, affordable testing for the good of our families, our communities and the world.

What is the history of the QuickVue® brand?

The QuickVue® brand launched in 1986 with visually read rapid diagnostics focusing on women's health and respiratory diseases. In 1999, QuickVue® Influenza A+B was the first visually read rapid test approved by the FDA for professional use. QuickVue® At-Home OTC COVID-19 Test utilizes the same technology used for decades by healthcare professionals and by the QuickVue® SARS Antigen Test used in professional settings, receiving emergency use authorization (EUA) by the FDA in December 2020.

What is the accuracy of the test?

In a clinical study, the QuickVue® At-Home OTC COVID-19 Test identified positive cases 83.5% of the time, and identified negative cases 99.2% of the time (83.5% PPA, and 99.2% NPA, respectively), when compared to PCR.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY.

The QuickVue At-Home OTC COVID-19 Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 36 hours between tests. This home test is authorized for nonprescription home use with self-collected (unobserved) direct anterior nasal swab (NS) specimens from individuals aged 14 years and older or with adult-collected anterior NS samples from individuals aged 2 years or older.

This home test has not been FDA cleared or approved, but has been authorized by the FDA under an Emergency Use Authorization (EUA) for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This home test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless authorization is terminated or revoked sooner.

QUIDEL

QuickVue At-Home OTC COVID-19 Test

FDA Emergency Use Authorization (EUA) in the USA

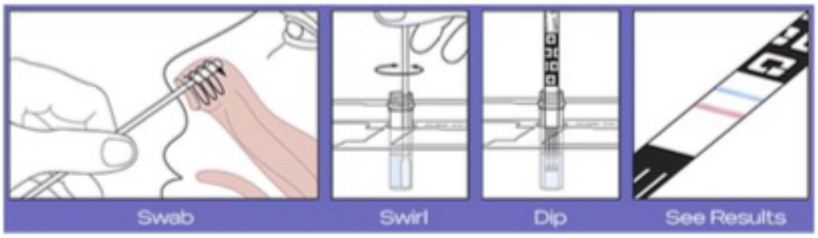
Frequently Asked Questions

What is the QuickVue At-Home OTC COVID-19 Test?
The QuickVue At-Home OTC COVID-19 Test is a type of test called an 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 long does it take to get results?
Results are available in as little as 10 minutes in the privacy of your own home.

Do I always need to perform two tests?
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 or no more than 36 hours between tests. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

BLVD MEDICAL

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.

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.

If I see pink shading on the strip bordering the black label, 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.

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 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.

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 requirements. We encourage you to visit the CDC/TSA website as well as your local airport and health department's website for the latest requirements on the type of acceptable testing and documentation for your travel destination.

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.

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.

- 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-9 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.

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 or no more than 36 hours between tests.

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.

Is this test covered by insurance?

The test is available for at-home use without a prescription. Please consult with your specific health insurance to make sure your test will be covered.

Is a prescription required to perform this test?

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

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 COVID19 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.

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?
Quidel has completed testing on recombinant several variant strains and the QuickVue At-Home OTC COVID-19 Test was able to detect the mutations. We are confident that the performance of the QuickVue At-Home OTC COVID-19 Test remains unaffected by the known variants. Quidel monitors the variants closely and will inform the FDA promptly, should any issues be detected.

Where is the test made?
The test is made in San Diego, California.