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.

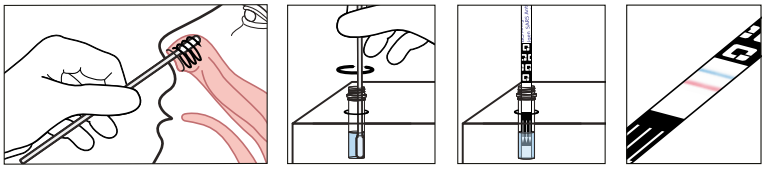
For use under FDA Emergency Use Authorization (EUA) only.

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 health care 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 (NS) swab 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.

For more information about Quidel, or the QuickVue At-Home OTC COVID-19 Test, please contact:

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Or visit: QuickVueAtHome.com