QUIDEL | QuickVue®

SARS Antigen Test

Frequently Asked Questions

Summary
On December 18, 2020, Quidel received FDA Emergency Use Authorization for the QuickVue SARS Antigen for qualitative detection of nucleocapsid protein from SARS-CoV-2 in nasopharyngeal and nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

How does the assay work?
The test employs lateral flow immunoassay technology to detect nucleocapsid protein from SARS-CoV and SARS-CoV-2 virus in anterior nares specimens.

Does the test come with everything needed to perform the assay?
The test comes with all the materials necessary to perform the test with an anterior nares swab (Cat. #20387.)

Does the test come with swabs?
Yes. Kit Cat. #20387 comes with swabs.

Where is the test performed?
Testing is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests, or at the Point of Care (POC) in patient care settings operating under a CLIA Certificate of Waiver.

Where is the test made?
The test was designed and is manufactured in San Diego, California.

How fast is the test?
The test includes approximately 1 minute of extraction with a 10-minute run time.

How many tests can you supply?
Quidel is currently able to manufacture just under 1 million tests per week.

How will Quidel determine who gets the test kits?
Quidel is doing everything possible to produce as many tests as we can during this developing situation with the understanding that during a global health emergency demand may exceed supply at times. The need for testing remains unchanged with exceptional demand. We continue to do our best to position products to the accounts that are best situated to address this global pandemic with our tests. We also support strategic research partnerships in order to learn more about this life altering disease.

Where can patients get a test?
Anyone with symptoms consistent with COVID-19 should contact a medical professional for evaluation. The test can be ordered by a medical professional if the patient meets the criteria for COVID-19 testing.

Medical professionals may order these tests through their select distributor representative.

What is the sensitivity of the assay?
The performance data in the Package Insert for QuickVue SARS Antigen test has a percent positive agreement (PPA) of 96.6%* with RT-PCR using direct anterior nares swabs. The clinical samples were all collected from patients with symptom onset of 5 days or less.

Can viral transport media (VTM) be used with this assay?
Because of the clinical benefit of employing the most sensitive method during the critical 0-5 day window, Quidel is not supporting the use of transport media with the QuickVue SARS Antigen test.

Are these tests available outside of the U.S.?
We are currently focused on the North American professional segment, providing our COVID products preferentially to laboratories that are addressing the testing needs of hospital health care providers and first responders.

What CPT code should be used?
The recommended CPT code for QuickVue SARS Antigen is 87811QW** and is for infectious agent antigen detection by immunoassay by direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]).*** For reimbursement inquiries, please contact CodeMap® at quidel@codemap.com or 312.291.8408. You may also visit https://www.codemap.com/quidel.

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.

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 SARS Antigen 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.

What is serial testing?
COVID-19 serial testing is when a patient is tested 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 signs or symptoms. QuickVue SARS Antigen is authorized for serial testing when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Can people who are vaccinated use this test?
This test is intended for use on patients with or without symptoms, as needed, regardless of vaccination status.

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.

*For fresh and frozen specimens combined.
**"QW" modifier is added to report use of CLIA-Waived test system(s) for Medicare/Medicaid claims.
***This information is being provided as a reference, for informational purposes only, with no expressed or implied warranty and does not purport to provide legal or certified coding advice. Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service. Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their contracted payers to determine appropriate coding and charge or payment levels prior to submitting claims.

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