QUIDEL

QuickVue® SARS Antigen TEST

For Emergency Use Authorization (EUA) only
For *in vitro* diagnostic use

℞ ONLY

QUICK REFERENCE INSTRUCTIONS

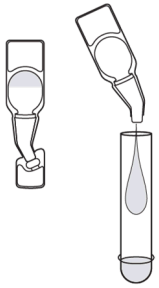
Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.

All clinical specimens must be at room temperature before beginning the assay.
Performing the assay outside the time and temperature ranges provided may produce invalid results.
Assays not performed within the established time and temperature ranges must be repeated.
Expiration date: Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

Test Procedure

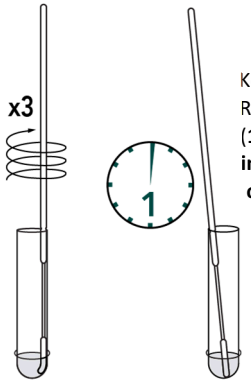
1

Dispense all of the Reagent Solution into the Reagent Tube. Gently swirl the Reagent Tube to dissolve its contents. NOTE: The Reagent Tube should remain in the tube holder for the entirety of the testing.



2

Immediately place the patient anterior nasal swab sample into the Reagent Tube. Roll the swab a minimum of three (3) times while pressing the head against the bottom and side of the Reagent Tube.



Keep the Swab in the Reagent Tube for **one (1) minute**. **Incorrect or invalid results may occur if the incubation time is too short or too long.**

3

Express all liquid from the swab head by rolling the swab a minimum of three (3) times as the swab is being removed. Discard the swab in accordance with your biohazard waste disposal protocol.

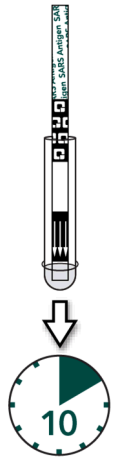
4

Place the Test Strip into the Reagent Tube with the arrows pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.

At **10 minutes**, remove the Test Strip and read result within five (5) minutes according to the Interpretation of Results section on the other side of this card.

Test Strips should be read between 10 -15 minutes after placing into the Reagent Tube.

False positive, false negative, or invalid results may occur if the strip is read beyond the recommended time period.



Quality Control

Built-in Control Features

The QuickVue SARS Antigen Test contains built-in procedural control features. The manufacturer's recommendation for daily control is to document these built-in procedural controls for the first sample tested each day.

The two-color result format provides a simple interpretation for positive and negative results. The appearance of a blue procedural Control Line provides positive control by demonstrating sufficient flow has occurred and the functional integrity of the Test Strip was maintained. If a blue procedural Control Line does not develop within 10 minutes on the Test Strip, then the test result is invalid.

A built-in negative control is provided by the clearing of red background color, verifying that the test has been performed correctly. Within 10 minutes, the result area should be white to light pink and allow the clear interpretation of the test result. If background color remains and interferes with interpretation of the test result, then the test result is invalid. Should this occur, review the procedure and repeat the test with a new patient sample and a new Test Strip. Patient samples or reagents cannot be reused.

External Quality Control

External Controls may also be used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits — provided that each different lot received in the shipment is tested — and as deemed additionally necessary by your internal quality control procedures, and in accordance with local, state and federal regulations or accreditation requirements.

The Test Procedure described in the Package Insert should be used when testing the external controls.

If the controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens.

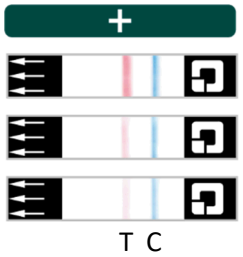
Interpretation of Results

When the test is complete, the test strip will yield results that are reviewed visually. If used on asymptomatic individuals for serial testing, test at least three times over five days with at least 48 hours between tests.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Positive Result:
At ten (10) minutes, the appearance of **ANY shade of a pink-to-red Test Line AND** the appearance of a blue procedural Control Line indicates a positive result for the presence of SARS antigen. Results will remain stable for five (5) minutes after the recommended read time. Do not read the result beyond the five minutes. False positive, false negative, or invalid results may occur if the strip is read outside of the recommended time period.



A positive result does not rule out co-infections with other pathogens.

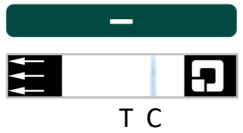
***Look closely!** Even if you see a very faint, pink Test Line and a blue Control Line, you must report the result as POSITIVE.

C = Control Line
T = Test Line

Repeat testing does not need to be performed if patients have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the QuickVue SARS Antigen Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Negative Result:
At ten (10) minutes, the appearance of **ONLY the blue procedural Control Line** indicates SARS antigen was not detected. Results will remain stable for five (5) minutes after the recommended read time. False positive, false negative, or invalid results may occur if the strip is read outside of the recommended time period.



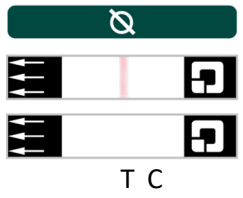
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

***Note: All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.*

Invalid Result:
If at ten (10) minutes, the blue procedural Control Line does not appear, even if any shade of a pink-to-red Test Line appears, the result is invalid.
If at ten (10) minutes, the background color does not clear and it interferes with the reading of the test, the result is also invalid.
If the result is invalid, a new test should be performed with a new swab and a new Test Strip.



INTENDED USE

The QuickVue SARS Antigen Test is a lateral flow immunoassay that allows for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The QuickVue SARS Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection, and should not be used as the sole basis for treatment or patient management decisions, including infection measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The QuickVue SARS Antigen test is intended for use by medical professionals or operators who are proficient in performing tests in a point of care setting. The QuickVue SARS Antigen Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA-cleared or approved.

Refer to the Package Insert for *Warnings and Precautions, Specimen Collection and Handling,* and *Quality Control*.

EMERGENCY USE AUTHORIZATION – WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization for use by authorized laboratories; and use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product 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 the declaration is terminated or authorization is revoked sooner.

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.

If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support Number 800.874.1517 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S., contact your local distributor or technicalsupport@quidel.com. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; http://www.fda.gov/medwatch).

Study the Package Insert thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

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