QUIDEL

QuickVue® SARS Antigen TEST

For use under the Emergency Use Authorization (EUA) only
For *in vitro* diagnostic use
Rx Only

QUICK REFERENCE INSTRUCTIONS

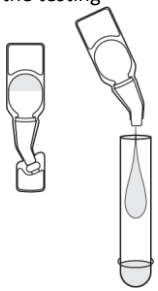
Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.

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

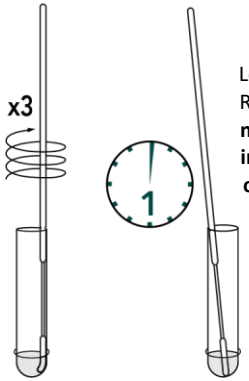
1

Dispense all of the Reagent Solution into the Reagent Tube. 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

Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.



Leave the Swab in the Reagent Tube for **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.

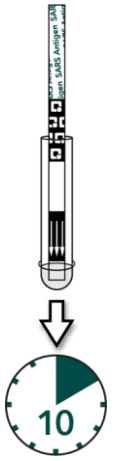
4

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. 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

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.

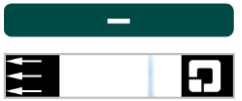
**A positive result does not rule out co-infections with other pathogens.*

***Look closely!** This is a positive result. 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

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.



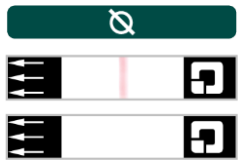
*** Note: Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as a close contract with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection..*

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 patient sample 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 anterior nares (NS) swab specimens directly from individuals who are suspected of COVID19 by their healthcare provider within the first five days of the onset of symptoms or from individuals 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. 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 test 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.

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Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior 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 definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive, 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. 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, and confirmed with a molecular assay, if necessary, for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

The QuickVue SARS Antigen test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings. The QuickVue SARS Antigen test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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

EMERGENCY USE AUTHORIZATION – WARNING AND PRECAUTIONS

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; 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. In the USA, - 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.

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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