

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

Rx ONLY



QUIDEL

QuickVue[®]
SARS Antigen TEST

For *in vitro* diagnostic use only.



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 COVID-19 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 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. 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 as 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.

SUMMARY AND EXPLANATION

SARS-CoV-2, also known as the COVID-19 virus, was first identified in Wuhan, Hubei Province, China in December 2019. This virus, as with the novel coronavirus SARS-1 and MERS, is thought to have originated in bats, however the SARS-CoV-2 may have had an intermediary host such as pangolins, pigs or civets.¹ The WHO declared that COVID-19 was a pandemic on March 11, 2020, and human infection has spread globally, with hundreds of thousands of confirmed infections and deaths.² The median incubation time is estimated to be 5.1 days with symptoms expected to be present within 12 days of infection.³ The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough and shortness of breath.⁴

PRINCIPLE OF THE PROCEDURE

The QuickVue SARS Antigen test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV and SARS-CoV-2 in respiratory specimens taken from patients with signs and symptoms who are suspected of COVID-19, or taken from asymptomatic individuals being tested serially, as described in the authorized intended use. This test allows for the detection of SARS-CoV and SARS-CoV-2 but does not differentiate between the two viruses.

To begin the test, a lyophilized reagent must be rehydrated in the Reagent Tube. This reagent facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The Reagent is first rehydrated with the provided Reagent Solution, and the swab specimen is then inserted into the Reagent Tube. This Reagent interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The Test Strip is added to the Reagent Tube now containing the specimen and Reagent Solution.

If the extracted specimen contains SARS-CoV or SARS-CoV-2 antigens, a pink-to-red Test Line, along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. If SARS-CoV or SARS-CoV-2 is not present, or is present at very low levels, only a blue procedural Control Line will appear.

REAGENTS AND MATERIALS SUPPLIED

25-Test Kit:

- Individually Packaged Test Strips (25): Monoclonal anti-SARS antibodies
- Reagent Tubes (25): Lyophilized buffer with detergents and reducing agents
- Reagent Solution (25): Vials with 340 µL salt solution
- Sterile Nasal Swabs (Kit #20387) (25)
- SARS Positive Control Swab (1): Swab is coated with non-infectious recombinant SARS antigens
- Negative Control Swab (1): Swab is coated with heat-inactivated, non-infectious Streptococcus C antigen
- Package Insert (1)
- Procedure Card (1)

MATERIALS NOT SUPPLIED

- Timer or watch
- QuickVue SARS Antigen Control Swab Set for additional QC (20389)
- Dry transport tube (SKU # 20385) (25). Store at room temperature.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use
- For prescription use only
- This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under the CLIA 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.
- 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.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Wear suitable protective clothing, gloves (nitrile or latex), and eye/face protection when handling patient samples or used kit components.
- The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
- Do not reuse the used Test Strip, Reagent Tubes, solutions, or Control Swabs.
- The Test Strip must remain sealed in the protective foil pouch until use. The user should never open the foil pouch of the Test Strip exposing it to the ambient environment until the Test Strip is ready for immediate use. If the test strip is open for an hour or longer, invalid test result may occur.
- The QuickVue SARS Antigen Test must only be used with the lyophilized buffer and reagent solution provided in the kit.
- Proper specimen collection, storage, and transport are critical to the performance of this test. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.^{5,6,7,8}
- When collecting a nasal swab sample, use the nasal swab provided in the kit (Kit #20387)
- Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- To obtain accurate results, you must follow the Package Insert instructions.
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wash hands thoroughly after handling.
- For additional information on safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

KIT STORAGE AND STABILITY

Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

SPECIMEN COLLECTION AND HANDLING

Proper specimen collection and handling is critical to the performance of this test.^{5,6,7,8}

Specimen Collection

Nasal Swab Sample:

Use the nasal swab supplied in the kit.

Prior to collecting the nasal swab, the patient should be instructed to blow their nose. To collect a nasal swab sample, insert the entire absorbent tip of the swab (usually ½ to ¾ of an inch (1 to 1.5 cm) inside the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. Take approximately 15 seconds to collect the sample. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostrils with same swab.

Sample Transport and Storage

Samples should be tested as soon as possible after collection. Based on data generated with the QuickVue SARS Antigen Test, nasal swabs are stable for up to 120-hours at room temperature or 2° to 8°C in a clean, dry transport tube.

QUALITY CONTROL

There are two primary types of Quality Control for this device: the built-in control features defined below and the external controls.

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. It is necessary to collect another patient specimen; patient swabs 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.

Additional Control Swabs may be obtained separately by contacting Quidel's Customer Support Services at (800) 874.1517 (toll-free in the U.S.A.) or (858) 552.1100.

TEST PROCEDURE

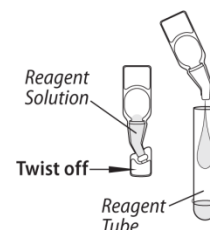
Test materials and clinical specimens must be at room temperature before beginning the assay.

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.*

Nasal Swab Test Procedure

1. Add the Reagent Solution to the Reagent Tube. Gently swirl the 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 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 swab in the 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.



5. At ten (10) minutes, remove the Test Strip, and read result within five (5) minutes according to the Interpretation of Results section.

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.

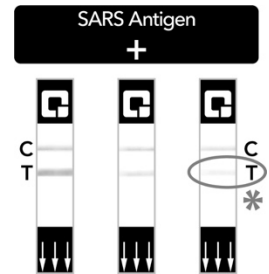


INTERPRETATION OF RESULTS

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 more than fifteen minutes after placing into the Reagent Tube.

**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.

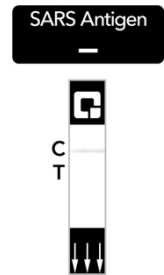
C = Control Line

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. Do not read the result more than fifteen minutes after placing into the Reagent Tube.

*** 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 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.*

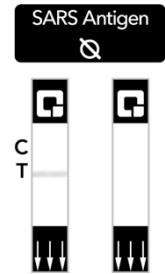


Invalid Result:

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.



LIMITATIONS

- The test is intended for direct swab specimens only. Viral Transport Media (VTM) should not be used with this test as it may cause false results.
- The contents of this kit are to be used only for the qualitative detection of SARS antigens from anterior nares nasal swab specimens.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Failure to follow the Test Procedure and Interpretation of Results may adversely affect test performance and/or invalidate the Test Results.
- Test Results must be evaluated in conjunction with other clinical data available to the physician.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Positive test results do not rule out co-infections with other pathogens.
- Negative results should be treated as presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time. The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS

The QuickVue SARS Antigen Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>.

However, to assist clinical laboratories using the QuickVue SARS Antigen Test (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:

- Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the “QuickVue SARS Antigen Assay” Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Quidel (via email: QDL.COVID2.test.event.report@quidel.com, or via phone by contacting Quidel Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Quidel Corporation, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

CLINICAL PERFORMANCE

The QuickVue SARS Antigen Test was compared to a Reference Extracted EUA SARS-CoV-2 RT-PCR Assay using frozen and fresh matched anterior nares swab specimens.

One hundred fifty-six (156) matched anterior nares swab specimens from patients suspected of having COVID-19 within five days of symptom onset were obtained from three US collection sites between August 2020 and December 2020. The specimens were sent on cold packs to the Quidel laboratory in Athens, Ohio. The Reference Extracted SARS-CoV-2 RT-PCR Assay testing was performed on one of the matching swabs according to the device’s instructions for use. Fifty-six (56) of the remaining swabs were frozen at -70°C prior to testing with the QuickVue SARS Antigen Test. On the day of QuickVue testing the swabs were thawed and tested with the QuickVue SARS Antigen Test. One hundred (100) swabs were tested fresh, within 24-hours of collection, with the QuickVue SARS Antigen Test.

* The letter of authorization refers to “authorized laboratories” as “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, 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.”

Thirty-eight (38) matched anterior nares swab specimens from patients suspected of having COVID-19 within five days of symptom onset were obtained from an on-going prospective clinical study at three (3) POC sites, with two (2) minimally trained operators per POC site. One swab was tested at the POC site with the QuickVue SARS Antigen Test by six minimally trained operators on the day of collection. The Operators were provided only the test instructions and quick reference guide. The matching swabs were sent on cold packs to the Quidel laboratory in Athens, Ohio for SARS-CoV-2 RT-PCR testing. The Reference Extracted SARS-CoV-2 RT-PCR Assay testing was performed on the matching swabs according to the device's instructions for use. As with all antigen tests, performance may decrease as days since symptom onset increases due to lower viral loads later in the patient's disease course. Similarly, the inability to synchronize asymptomatic individuals with onset of infection may impact performance as specimens may be tested when viral loads are below the assay's limit of detection. Clinical studies in asymptomatic patients undergoing serial testing are ongoing to establish the clinical performance.

The table below summarizes the data from the fresh (138) and frozen (56) specimens:

Comparison of QuickVue SARS Antigen Test and an authorized EUA Molecular comparator assay with matched anterior nares swabs									
Specimen Type	Number Tested	True Positive	False Positive	True Negative	False Negative	PPA%	NPA%	PPA 95% CI	NPA 95% CI
Fresh Specimens	138	30	1	106	1	96.8	99.1	83.8 to 99.4	94.9 to 99.8
Frozen Specimens	56	26	0	29	1	96.3	100	81.7 to 99.3	88.3 to 100
Combined Specimens	194	56	1	135	2	96.6	99.3	88.3 to 99.0	96.0 to 99.9

The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection or for serial screening applications, and performance may differ in these populations.

ANALYTICAL PERFORMANCE

Limit of Detection

The Limit of Detection (LoD) of the QuickVue SARS Antigen Test was determined using limiting dilutions of heat-inactivated SARS-CoV-2 (ZeptoMetrix 0810587CFHI). The ZeptoMetrix material is a preparation of SARS-Related Coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020, that has been inactivated by heating at 65°C for 30-minutes. The material was supplied frozen at a concentration of 1.15×10^7 TCID₅₀/mL.

The study to determine the QuickVue SARS Antigen Test LoD was designed to reflect the assay when using direct swabs. In this study a NP swab was spiked with approximately 50-µL of the virus dilution in saline. The spiked swab was added to the QuickVue SARS Antigen Test extractant concurrently to a NP swab containing NP matrix. The swabs were processed concurrently according to the package insert.

The LoD was determined in three steps:

1. LoD Screening
10-fold dilutions of the heat inactivated virus were made in saline and processed for each study as described above. These dilutions were tested in triplicate. The lowest concentration demonstrating 3

of 3 positives was chosen for LoD range finding. Based on this testing, the concentration chosen was TCID₅₀ of 1.51 x10⁴.

2. LoD Range Finding

Three (3) doubling dilutions were made of the 1.51 x10⁴ concentration in saline processed for the study as described above. These dilutions were tested in triplicate. The lowest concentration demonstrating 3 of 3 positives was chosen for LoD confirmation. Based on this testing the concentration chosen was 7.57 x10³.

3. LoD Confirmation

The concentration 7.57 x10³ dilution was tested twenty (20) times. Twenty (20) of twenty (20) results were positive. Based on this testing the concentration was confirmed as TCID₅₀ of 7.57 x10³.

Analytical Reactivity/Inclusivity

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the QuickVue SARS Antigen Test were evaluated with a currently available SAR-CoV-2 strain (see table below).

2019-nCoV Strain/Isolate	Source/Sample Type	Concentration
USA-WA1/2020	ZeptoMetrix0810587CFHI	1.15 x10 ⁷ TCID ₅₀ /mL

Cross-Reactivity

Cross-reactivity of the monoclonal antibodies used for the detection of SARS-CoV-2 was evaluated by testing various microorganisms (12) and viruses (16) that may potentially cross-react with the QuickVue SARS Antigen Test. Each organism and virus were tested in triplicate. The final concentration of the organisms and viruses are documented in the table below:

Cross-Reactivity/Interference of QuickVue SARS Antigen Test					
Virus/Bacteria/Parasite	Strain	Source/ Sample type	Concentration	Cross-Reactivity Results*	Interference Results*
Adenovirus	Type 1	Isolate	1 x 10 ^{5.53} U/mL	No Cross-Reactivity	No Interference
Coronavirus	229e	Isolate	1 x 10 ^{5.10} U/mL	No Cross-Reactivity	No Interference
Coronavirus	OC43	Isolate	9.55 x 10 ⁵ TCID ₅₀ /mL	No Cross-Reactivity	No Interference
Coronavirus	NL63	Isolate	5 x 10 ^{3.67} U/mL	No Cross-Reactivity	No Interference
MERS-CoV (heat-inactivated)	Florida/USA-2_Saudi Arabia_2014	Isolate	1.17 x 10 ⁵ TCID ₅₀ /mL	No Cross-Reactivity	No Interference
<i>Mycoplasma pneumoniae</i>	M129	Isolate	3 x 10 ⁶ CCU/mL**	No Cross-Reactivity	No Interference
<i>Streptococcus pyogenes</i>	Z018	Isolate	3.8 x 10 ⁶ cfu/mL	No Cross-Reactivity	No Interference
Influenza A H3N2	Brisbane/10/07	Isolate	1 x 10 ^{5.07} U/mL	No Cross-Reactivity	No Interference
Influenza A H1N1	New Caledonia/20/99	Isolate	1 x 10 ^{5.66} U/mL	No Cross-Reactivity	No Interference

Cross-Reactivity/Interference of QuickVue SARS Antigen Test					
Virus/Bacteria/Parasite	Strain	Source/ Sample type	Concentration	Cross-Reactivity Results*	Interference Results*
Influenza B	Brisbane/33/08	Isolate	1 x 10 ^{5.15} U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 1	Isolate	1 x 10 ^{5.01} U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 2	Isolate	1 x 10 ^{5.34} U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 3	Isolate	8.5 x 10 ⁵ TCID ₅₀ /mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 4b	Isolate	1 x 10 ^{5.53} U/mL	No Cross-Reactivity	No Interference
Enterovirus	Type 68	Isolate	1 x 10 ^{5.5} U/mL	No Cross-Reactivity	No Interference
Human Metapneumovirus	A1 (IA10-s003)	Isolate	1 x 10 ^{5.55} U/mL	No Cross-Reactivity	No Interference
Respiratory Syncytial Virus	Type A (3/2015 Isolate #3)	Isolate	1 x 10 ^{5.62} U/mL	No Cross-Reactivity	No Interference
Human Rhinovirus	N/A	Inactivated virus	Not available***	No Cross-Reactivity	No Interference
<i>Chlamydomphila pneumoniae</i>	AR-39	Isolate	2.9 x 10 ⁶ IFU/mL****	No Cross-Reactivity	No Interference
<i>Haemophilus influenzae</i>	Type b; Eagan	Isolate	7.87 x 10 ⁶ cfu/mL	No Cross-Reactivity	No Interference
<i>Legionella pneumophila</i>	Philadelphia	Isolate	6.82 x 10 ⁶ cfu/mL	No Cross-Reactivity	No Interference
<i>Streptococcus pneumoniae</i>	Z022; 19f	Isolate	2.26 x 10 ⁶ cfu/mL	No Cross-Reactivity	No Interference
<i>Bordetella pertussis</i>	A639	Isolate	6.37 x 10 ⁶ cfu/mL	No Cross-Reactivity	No Interference
<i>Pneumocystis jirovecii</i> - <i>S. cerevisiae</i> Recombinant	W303-Pjj	Isolate	1.56 x 10 ⁶ cfu/mL	No Cross-Reactivity	No Interference
<i>Mycobacterium tuberculosis</i>	H37Ra-1	Isolate	6.86 x 10 ⁷ cfu/mL	No Cross-Reactivity	No Interference
<i>Staphylococcus epidermidis</i>	MRSE; RP62A	Isolate	1.21 x 10 ¹⁰ cfu/mL	No Cross-Reactivity	No Interference
<i>Staphylococcus aureus</i> MSSA	NCTC 8325	Isolate	5.5 x 10 ⁹ cfu/mL	No Cross-Reactivity	No Interference
<i>Staphylococcus aureus</i> MRSA	0801638	Isolate	1.38 x 10 ¹⁰ cfu/mL	No Cross-Reactivity	No Interference
Coronavirus HKU1 was not tested for cross-reactivity due to lack of availability. 19 specimens containing Coronavirus HKU1 were tested and all resulted as negative, additional cross-reactivity wet testing was not required.					

* Testing was performed in triplicate

**CCU/mL is Color Changing Units as calculated according to a modified Reed-Muench method based on dilutions which produced a color change in the broth.

*** The stock is inactivated virus with no quantitation provided.

**** IFU/mL is infectious units per milliliter

Hook Effect:

As part of the LoD study the highest concentration of heat-inactivated SARS-CoV-2 stock available (TCID₅₀ of 3.40x10⁵ per mL) was tested. There was no Hook effect detected.

Endogenous Interference Substances Studies:

A study was performed to demonstrate that twenty (20) potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the QuickVue SARS Antigen Test.

Potentially Interfering Substances for QuickVue SARS Antigen Test				
Substance	Active Ingredient	Concentration	Cross-Reactivity Results*	Interference Results*
Afrin – nasal spray	Oxymetazoline	5%	No Cross-Reactivity	No Interference
Homeopathic (Alkalol)	Galphimia glauca, Luffa operculate, Sabadilla	10X	No Cross-Reactivity	No Interference
Blood (human)	Blood	5%	No Cross-Reactivity	No Interference
Chloraseptic, Cepacol	Benzocaine, Menthol	0.7 g/mL	No Cross-Reactivity	No Interference
CVS throat spray	Phenol	1.4%		
Flonase	Fluticasone	5%	No Cross-Reactivity	No Interference
Halls Relief Cherry Flavor	Menthol	0.8 g/mL	No Cross-Reactivity	No Interference
Mupirocin Ointment	Mupirocin	2% w/w	No Cross-Reactivity	No Interference
Nasocort Allergy 24 hour	Triamcinolone	5.00%	No Cross-Reactivity	No Interference
NasalCrom Spray	Cromolyn Sodium	5.2mg	No Cross-Reactivity	No Interference
NeilMed SinuFlow Ready Rinse	Sodium chloride, Sodium bicarbonate	Not available**	No Cross-Reactivity	No Interference
NeilMed SinuFrin Plus	Oxymetazoline HCl	0.05%	No Cross-Reactivity	No Interference
Neo-Synephrine	Phenylephrine hydrochloride	5%	No Cross-Reactivity	No Interference
Oseltamivir	Oseltamivir	2.2 µg/mL	No Cross-Reactivity	No Interference
Purified mucin protein	Mucin protein	2.5 mg/mL	No Cross-Reactivity	No Interference
Rhinocort	Budesonide (Glucocorticoid)	5%	No Cross-Reactivity	No Interference
Saline nasal spray	Saline	15%	No Cross-Reactivity	No Interference
Tobramycin	Tobramycin	1.25 mg/mL	No Cross-Reactivity	No Interference
Zanamivir	Zanamivir	282.0 ng/mL	No Cross-Reactivity	No Interference
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5%	No Cross-Reactivity	No Interference

* Testing was performed in triplicate

** No concentration was provided in the product labeling

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>).

REFERENCES

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2. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen>
3. Clinical and Laboratory Standards Institute. Viral Culture; Approved Guidelines. CLSI document M41-A [ISBN 1562386239] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2006.
4. Lauer, S.A., et. al. The incubation period of Coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: estimation and application, Ann Intern Med. 2020
5. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (2007).
6. Henretig F.M. MD, King C. MD. Textbook of Pediatric Procedures, Chapter 123 – Obtaining Biologic Specimens Williams and Williams (April 1997).
7. The Clinical Virology Laboratory, Department of Laboratory Medicine at Yale: <http://info.med.yale.edu/labmed/virology/booklet.html>.
8. Australian Management Plan for Pandemic Influenza – Section 5 Annex 5: Laboratory Guidelines.

REF

20387 – QuickVue SARS Antigen 25 Test Kit (Nasal Swab)

IVD



EC

REP

MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany



Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701 USA
quidel.com

XXXXXXXXEN00 (11/21)

GLOSSARY

REF

Catalogue number



CE mark of conformity

EC REP

Authorized Representative
in the European Community

LOT

Batch code



Use by



Manufacturer



Temperature limitation



Intended use

R_x ONLY

Prescription use only



Consult instructions for use

IVD

For *In Vitro* diagnostic use



Contains sufficient for 25 determinations

CONT

Contents/Contains

CONTROL +

Positive control

CONTROL -

Negative control



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.

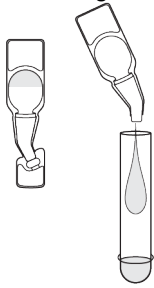
Assays not performed within the established time and temperature ranges must be repeated.

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

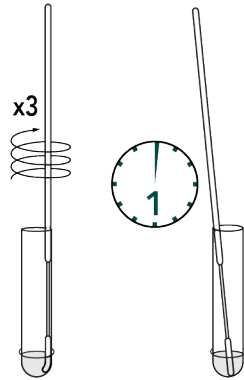
1

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.



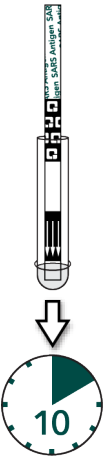
4

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.

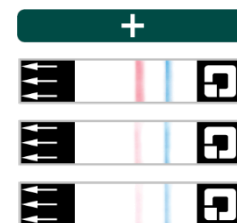
The Test Procedure described in the Package Insert should be used when testing the external controls.

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.



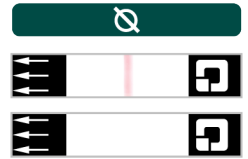
**** Note:** Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as a close 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.

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 COVID-19 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 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.

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. 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 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. 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.



Quidel Corporation
San Diego, CA 92121 USA
quidel.com

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