QUIDEL

QuickVue®
SARS Antigen TEST

For the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares swab specimens

For *in vitro* diagnostic use only.

A symbols glossary can be found on quidel.com/glossary.

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 infection. The test is intended for serial testing of symptomatic individuals for use at least twice with 48 hours between tests, or for serial testing of asymptomatic individuals for use at least three times with 48 hours between tests.

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 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 are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 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.

The QuickVue SARS Antigen test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

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. 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 #20396) (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)
- Quick Reference Instructions (1)

MATERIALS NOT SUPPLIED

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

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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 #20396)
- 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 (5-days) 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.**

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.

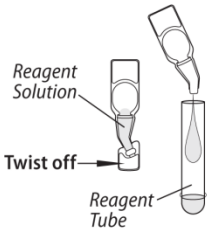
Additional Control Swabs may be obtained separately by contacting Quidel's Customer Support Services at (800) 874.1517 (toll-free in the U.S.A.) or (858) 552.1100.

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) 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

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

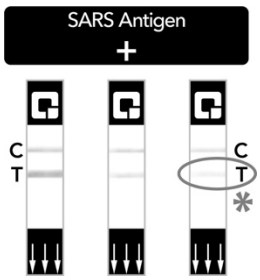
Status on First Day of Testing	First Result Day 2	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

N/A = not applicable

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.

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.



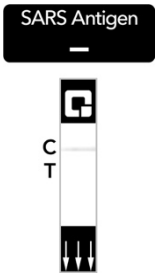
**A positive result does not rule out co-infections with other pathogens.*
Repeat testing does not need to be performed if the patient has a positive result at any time.

***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.



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

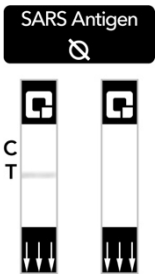
- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

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.

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 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 device has not been assessed in a population vaccinated against COVID-19.
- 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; performance may differ in these populations.

Serial Testing (Repeat Testing) Information and Limitations

- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
- A negative result should be followed up with repeat, or serial testing at least twice over three days with at least 48 hours between tests for symptomatic individuals and/or at least three times over five days with at least 48 hours between tests for asymptomatic individuals. A self-test may be used for this additional testing.

- Serial testing recommendations are supported by the study conducted by the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.

CLINICAL PERFORMANCE

This clinical performance data reflects the accuracy of the test when testing once. The serial testing recommendations are supported by the study conducted by the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

Single-testing 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 (3) US collection sites. 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.

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.

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.

Serial-testing clinical performance

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at

least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test (Ag) with serial testing in individuals is described in Table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive/PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Test	3 Test	1 Test	2 Test	3 Test
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

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 x10^7 $TCID_{50}$/mL.

The study to determine the QuickVue SARS Antigen Test LoD was designed to reflect the assay when using direct swabs. In this study an anterior nares 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 NS swab containing NS 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 $TCID_{50}$ of 1.51 $x10^4$.

2. LoD Range Finding
   Three (3) doubling dilutions were made of the 1.51 $x10^4$ 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 $x10^3$.

3. LoD Confirmation

   The concentration 7.57 $x10^3$ dilution was tested twenty (20) times. Twenty (20) of twenty (20) results were positive. Based on this testing the concentration was confirmed as $TCID_{50}$ of 7.57 $x10^3$.

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	ZeptoMetrix 0810587CFHI	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

Cross-Reactivity/Interference of QuickVue SARS Antigen Test					
Virus/Bacteria/Parasite*	Strain	Source/ Sample type	Concentration	Cross-Reactivity Results*	Interference Results*
Mycoplasma pneumoniae	M129	Isolate	3 x 10^6 CCU/mL	No Cross-Reactivity	No Interference
Streptococcus pyogenes	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
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
Chlamydophila pneumoniae	AR-39	Isolate	2.9 x 10^6 IFU/mL	No Cross-Reactivity	No Interference
Haemophilus influenzae	Type b; Eagan	Isolate	7.87 x 10^6 cfu/mL	No Cross-Reactivity	No Interference
Legionella pneumophila	Philadelphia	Isolate	6.82 x 10^6 cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	Z022; 19f	Isolate	2.26 x 10^6 cfu/mL	No Cross-Reactivity	No Interference
Bordetella pertussis	A639	Isolate	6.37 x 10^6 cfu/mL	No Cross-Reactivity	No Interference
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	1.56 x 10^6 cfu/mL	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	H37Ra-1	Isolate	6.86 x 10^7 cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	MRSE; RP62A	Isolate	1.21 x 10^{10} cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MSSA	NCTC 8325	Isolate	5.5 x 10^9 cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus 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 (9.08 x10^5 $TCID_{50}$ /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%	No Cross-Reactivity	No Interference
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	Oyxmetazoline 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 or to report a product problem, 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.

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INTELLECTUAL PROPERTY

REF 20396 – QuickVue SARS Antigen Test, 25 Test Kit (Nasal Swab)

IVD

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Revision Changes:

- Updated Intended Use statement to indicate serial testing parameters.
- Updated Interpretation of Results to describe and clarify serial testing sequence.
- Updated Limitations section to add subsection titled “Serial Testing (Repeat Testing) Information and Limitations”
- Updated Clinical Performance to add section for “Serial-testing clinical performance” with description of the study conducted by the National Institutes of Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

GLOSSARY

REF Catalogue number	LOT Batch code
 Use-by date	 Manufacturer
 Temperature limit	 Consult instructions for use
IVD *In vitro* diagnostic medical device	 Keep away from direct sunlight
 Contains sufficient for <n> tests	CONTROL + Positive control
CONTROL − Negative control	