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

℞ ONLY

QUIDEL

QuickVue®
SARS Antigen TEST

For *in vitro* diagnostic use.

INTENDED USE

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

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

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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

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

cleared or approved.

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 SARS-CoV-2 may have passed through an intermediary host such as pangolins, pigs, or civets.[1] The WHO declared the COVID-19 pandemic on March 11, 2020, and human infection has spread globally, with hundreds of millions of reported infections and millions of reported 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 those of 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 tested serially from patients with signs and symptoms who are suspected of COVID-19, or tested serially from asymptomatic individuals, 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 anterior nasal (nares) 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 (SKU # 20389)
- Dry transport tube (SKU # 20385) (25). Store at room temperature.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For prescription use only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- 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, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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.
- The test has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under the CLIA 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If the individual has had symptoms longer than 5 days you should consider testing them at least three times over five days with at least 48 hours between tests.
- Do not use the kit past its expiration date.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not touch the swab tip.
- 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. Once opened, the test strip should be used within 60 minutes.
- 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.
- **Do not read test results before 10 minutes or after 15 minutes. Results read before 10 minutes or after 15 minutes may lead to a false positive, false negative, or invalid result.**
- 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.
- Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components.
- The Reagent Solution contains harmful chemicals (see table below). If the solution contacts the skin, eyes, nose, or mouth, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name / CAS	Concentration
Tris Base / 77-86-1	0.135%
EDTA / 10378-23-1	1.103%
TCEP / 51805-45-9	0.038%
Mouse IgG	0.002%
Empigen BB / 66455-29-6	0.006%

- For additional information on safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at https://www.quidel.com
- For more information on EUAs please visit: https://www.fda.gov/emergency- preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency- use-authorization
- For the most up to date information on COVID-19, please visit: https://www.cdc.gov/COVID19

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

Anterior Nasal Swab Sample:

Use the nasal swab supplied in the kit.

Prior to collecting the anterior nasal swab, the patient should be instructed to blow their nose. To collect an anterior 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, anterior 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.

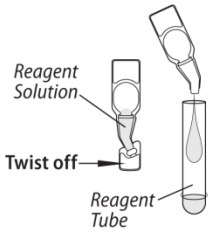
Additional Control Swabs may be obtained separately by contacting Quidel's Customer Support Services at (800) 874.1517 (toll-free in the U.S.A.) or (858) 552.1100.

TEST PROCEDURE

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

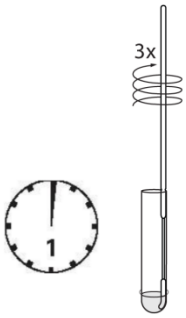
Expiration date: Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

Anterior Nasal Swab Test Procedure



1. Dispense all of the Reagent Solution into the Reagent Tube. Gently swirl the Reagent Tube to dissolve its contents.

   NOTE: The Reagent Tube should remain in the tube holder for the entirety of the testing.



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

   Keep the swab in the Reagent Tube for one (1) minute.

   Incorrect or invalid results may occur if the incubation time is too short or too long.

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

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

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.

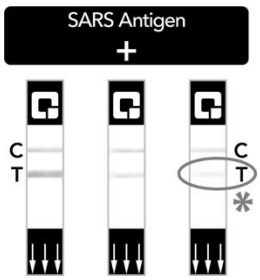
INTERPRETATION OF RESULTS

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

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

Positive Result:

At ten (10) minutes, the appearance of **ANY shade of a pink-to-red Test Line AND** the appearance of a blue procedural Control Line indicates a positive result for the presence of SARS antigen. Results will remain stable for five (5) minutes after the recommended read time. Do not read the result more than fifteen (15) minutes after placing into the Reagent Tube.



C = Control Line
T = Test Line

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

∗**Look closely!** Even if you see a very faint, pink Test Line (as circled in the depiction, right) and a blue Control Line you must report the result as POSITIVE.

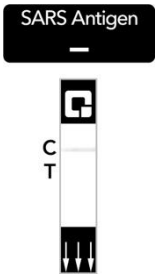
Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self- isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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

Negative Result:

At ten (10) minutes, the appearance of **ONLY the blue procedural Control Line** indicates SARS antigen was not detected. Results will remain stable for five (5) minutes after the recommended read time. Do not read the result more than fifteen (15) minutes after placing into the Reagent Tube.



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

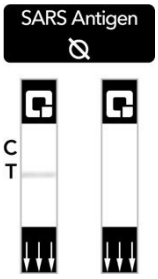
- **Test again in 48 hours if the individual has symptoms on the first day of testing**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing**

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 swab and a new Test Strip.

LIMITATIONS

- The test is intended for direct anterior nasal 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 nasal (nares) 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 SARS clinical specimens collected between August 2020 and December 2020. The clinical performance has not been established for 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

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 authorized labeling. 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.

[*] 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."

- 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 Corporation (via email: QDL.COV2.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.

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. Performance may decrease as days since symptom onset increases due to lower viral loads later in the patient's disease course.

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

Serial Screening

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 with serial testing in individuals is described in the 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	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
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 1.15×10^7 $TCID_{50}$/mL.

The study to determine the QuickVue SARS Antigen Test LoD was designed to reflect the assay when using direct swabs. In this study a nasal 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 nasal swab containing nasal 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 1.51×10^4.

2. LoD Range Finding
   Three (3) doubling dilutions were made of the 1.51×10^4 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 $TCID_{50}$ of 7.57×10^3.

3. LoD Confirmation

   The concentration 7.57 x 10^3 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 x 10^3. The LoD of 7.57 x 10^3 $TCID_{50}$/mL equates to 3.79 x 10^2 $TCID_{50}$/swab.

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 SARS-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

Omicron Performance

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx team using clinical pooled samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, this test detected 100% of live virus Omicron samples at a Ct-value of 26.0 (n=5). Testing was also compared to two additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 26.0) were not detected by this test in this study.

Omicron Pool 1 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	QuickVue SARS Antigen Test Percent Positive (n=5)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)
Dilution 1	**20.6**	100	100	100
Dilution 2	**21.5**	100	100	100
Dilution 3	**22.7**	100	100	100
Dilution 4	**24.0**	100	100	100
Dilution 5	**25.3**	100	100	100
Dilution 6	**26.0**	100	100	100
Dilution 7	**27.3**	0	0	60
Dilution 8	**28.8**	0	0	0
Dilution 9	**29.2**	0	0	0
Dilution 10	**30.6**	0	0	0
Dilution 11	**31.7**	0	0	0
Dilution 12	**32.6**	0	0	0

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	$1 \times 10^{5.53}$ U/mL	No Cross-Reactivity	No Interference
Coronavirus	229e	Isolate	$1 \times 10^{5.10}$ U/mL	No Cross-Reactivity	No Interference
Coronavirus	OC43	Isolate	9.55×10^{5} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Coronavirus	NL63	Isolate	$5 \times 10^{3.67}$ U/mL	No Cross-Reactivity	No Interference
MERS-CoV (heat-inactivated)	Florida/USA-2_Saudi Arabia_2014	Isolate	1.17×10^{5} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Mycoplasma pneumoniae	M129	Isolate	3×10^{6} CCU/mL**	No Cross-Reactivity	No Interference
Streptococcus pyogenes	Z018	Isolate	3.8×10^{6} cfu/mL	No Cross-Reactivity	No Interference
Influenza A H3N2	Brisbane/10/07	Isolate	$1 \times 10^{5.07}$ U/mL	No Cross-Reactivity	No Interference
Influenza A H1N1	New Caledonia/20/99	Isolate	$1 \times 10^{5.66}$ U/mL	No Cross-Reactivity	No Interference
Influenza B	Brisbane/33/08	Isolate	$1 \times 10^{5.15}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 1	Isolate	$1 \times 10^{5.01}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 2	Isolate	$1 \times 10^{5.34}$ U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 3	Isolate	8.5×10^{5} $TCID_{50}$/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 4b	Isolate	$1 \times 10^{5.53}$ U/mL	No Cross-Reactivity	No Interference
Enterovirus	Type 68	Isolate	$1 \times 10^{5.5}$ U/mL	No Cross-Reactivity	No Interference
Human Metapneumovirus	A1 (IA10-s003)	Isolate	$1 \times 10^{5.55}$ U/mL	No Cross-Reactivity	No Interference
Respiratory Syncytial Virus	Type A (3/2015 Isolate #3)	Isolate	$1 \times 10^{5.62}$ 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	2.9×10^{6} IFU/mL****	No Cross-Reactivity	No Interference
Haemophilus influenzae	Type b; Eagan	Isolate	7.87×10^{6} cfu/mL	No Cross-Reactivity	No Interference
Legionella pneumophila	Philadelphia	Isolate	6.82×10^{6} cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	Z022; 19f	Isolate	2.26×10^{6} cfu/mL	No Cross-Reactivity	No Interference
Bordetella pertussis	A639	Isolate	6.37×10^{6} cfu/mL	No Cross-Reactivity	No Interference
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	1.56×10^{6} cfu/mL	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	H37Ra-1	Isolate	6.86×10^{7} cfu/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***
Staphylococcus epidermidis	MRSE; RP62A	Isolate	1.21×10^{10} cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MSSA	NCTC 8325	Isolate	5.5×10^{9} cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MRSA	0801638	Isolate	1.38×10^{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 ($TCID_{50}$ of 3.40×10^{5} 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	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, please call Quidel's Technical Support Number at 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).

INTELLECTUAL PROPERTY

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

IVD

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GLOSSARY

REF Catalogue number	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx 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	