QuidelOrtho™

QuickVue®
COVID-19 Test

INSTRUCTIONS FOR USE

For *In Vitro* Diagnostic Use
Store at Room Temperature, 59°F to 86°F (15°C to 30°C)

Intended Use

The QuickVue COVID-19 Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19 within the first 5 days from symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

The QuickVue COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from January 2021 to February 2024 when COVID-19 variants Alpha, Delta, and Omicron were dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Summary and Explanation

SARS-CoV-2, the strain of coronavirus which causes COVID-19, was first identified in Wuhan, Hubei Province, China in December 2019. The World Health Organization (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.[1]

The average incubation period of ancestral SARS-CoV-2 is estimated to be between 4.6 and 6.4 days, with comparatively shorter incubation periods to be estimated for the Delta and Omicron BA.1 variants of concern.[2] The symptoms of COVID-19, generally expected to be present within 14 days of infection, are similar to those of other viral respiratory diseases and include fever, cough, and shortness of breath.[3]

Principle of the Procedure

The QuickVue COVID-19 Test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV-2 as described in the intended use.

To begin the test, a self-and/or adult-collected anterior nasal swab sample is inserted into the Reagent Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the Test Strip is inserted into the Reagent Tube now containing the extracted specimen.

If the extracted specimen contains 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-2 antigens are not present or are present at very low levels, only a blue procedural Control Line will appear.

Reagents and Materials Supplied

Name	Quantity (2-Test Kit)	Quantity (4-Test Kit)	Quantity (25-Test Kit)
Swab	2	4	25
COVID-19 Test Strip	2	4	25
Pre-filled Reagent Tube	2	4	25
Strip Placement Card	2	2	2
User Instructions	1	1	1

Materials Not Supplied

- Timer or watch
- Safety mask or other face covering
- Gloves
- Optional QVue® mobile app (must be downloaded from Apple App Store or Google Play Store)
- iPhone or Android phone for using the optional mobile app (Requires iOS 13.0 or later, Android 9.0 or later)

Warnings and Precautions

- For *in vitro* diagnostic use.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- **Serial testing should be performed on symptomatic individuals with negative results at least twice over three days (with 48 hours between tests). You may need to purchase additional tests to perform this serial (repeat) testing.**
- **False positive test results are more likely when prevalence of SARS-CoV-2 is low in the community.**
- **This test is not a substitute for consultation with a healthcare provider and should not be used to determine any treatments without provider supervision. Healthcare providers will consider additional information such as the patient's personal medical history and symptoms, current disease prevalence in the community, and additional test results if applicable, to help determine what steps are best for diagnosis and treatment if needed.**
- Swab specimens should not be collected from children under 2 years of age.
- You should not use this test if you have no symptoms.
- If symptoms persist or worsen, discuss the test results with a healthcare provider.
- Persons with condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results); or persons performing this test on behalf of a person who has any of these conditions should discuss the test results with a healthcare provider.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are necessary.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Do not use if any of the test kit contents or packaging is damaged.
- Testing should be performed in an area with adequate ventilation.
- All test components are for single-use only. Do not reuse any previously used Test Strips, Reagent Tubes, Reagent Solution, or Swabs.
- The user should not open the foil pouch of the Test Strip, thus exposing it to the ambient environment, until the Test Strip is ready for immediate use. If the Test Strip is open for 120 minutes (2 hours) or longer, invalid test results may occur.
- Inadequate or inappropriate sample collection, storage, or transport may yield false test results.

- This test is intended to be used with direct anterior nasal swabs and is not validated for use with viral transport media.
- When collecting a nasal swab sample, use only the Nasal Swab supplied in the kit.
- Do not touch the swab tip.
- Wash hands thoroughly after handling.
- Discard and do not use any damaged or dropped Test Strip or material. Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- For additional information on safety, handling, and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at www.quidelortho.com
- The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin or eyes, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Hazardous Ingredients for Reagent Solution		
Chemical Name/CAS	**Harms (GHS Code) for Each Ingredient**	**Concentration**
Sodium Phosphate Monobasic Monohydrate/10049-21-5	Causes skin irritation (H315) Causes serious eye irritation (H319) May cause respiratory irritation (H335)	0.7%
Sodium Phosphate Dibasic Anhydrous/7558-79-4	Causes serious eye damage (H318) Causes serious eye irritation (H319)	0.7%
C12-14-Alkyldimethyl-betaines/66455-29-6	Causes severe skin burns and eye damage (H314) Causes serious eye damage (H318) Causes skin irritation (H315) Causes serious eye irritation (H319)	0.03%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.03%
EDTA Tetrasodium Salt/64-02-8	Harmful if swallowed (H302) Causes serious eye damage (H318) Causes serious eye irritation (H319) Harmful if inhaled (H332) May cause respiratory irritation (H335) May cause damage to organs (H371), single exposure	0.2%

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.

Quality Control

Built-in Control Features

The QuickVue COVID-19 Test contains built-in procedural control features.

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

A built-in negative control is provided by the clearing of the red background color, verifying that the test has operated correctly. Within 10 minutes, the result area should be white to light pink in color, allowing for a clear interpretation of the test result. **If the background color remains and interferes with the interpretation of the test result, then the test result is considered invalid.** Should this occur, review the procedure and repeat the test with a new patient sample, a new Reagent Tube, and a new Test Strip. Patient samples, Reagent Tubes, and Test Strips may not be reused.

Specimen Collection and Handling

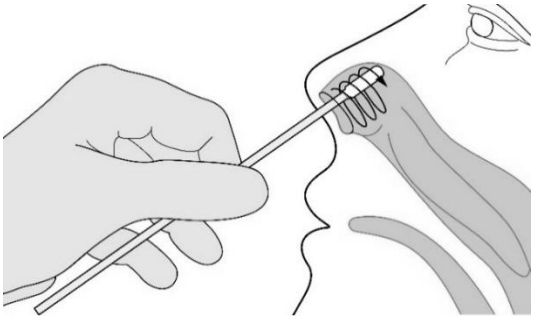
Specimen Collection

Nasal Swab Sample:

Use only the nasal swab supplied in the kit.

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 four (4) times. Take approximately fifteen (15) seconds to collect the sample.

Be sure to collect any nasal drainage that may be present on the swab. **Sample both nostrils with the same swab.**



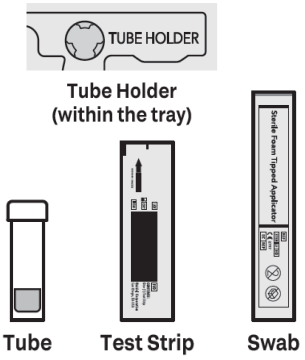
Test Procedure

Test materials and clinical specimens must be at room temperature prior to operating 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 listed on the label.

Test Procedure

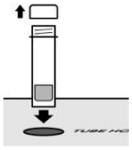
1. **Wash your hands**
   Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.



2. **Check your test kit**
   Check the expiration date on the outside of the box located next to the Lot number.
   Do not use the kit past its expiration date.
   Find the kit components.

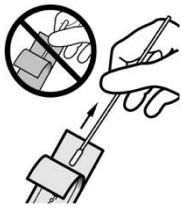
   Materials required but not provided:
   A watch or timer.

   Recommended materials: Disposable gloves, mask if swabbing others.



3. **Place tube in the tube holder**
   Remove the cap from one pre-filled Reagent Tube and place the tube in the tube holder.

4. **Swab the nostrils**
   Remove the swab from its wrapper, being careful not to touch the swab head.



   Gently insert the swab ½ to ¾ of an inch into the nostril, depending on the size of the person's nose. Firmly rub the swab in a circular motion around the inside wall of EACH NOSTRIL at least 4 times.

   Be sure to rub BOTH nostrils with the SAME SWAB.

   NOTE: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

   NOTE: Failure to swab properly may cause false negative results.

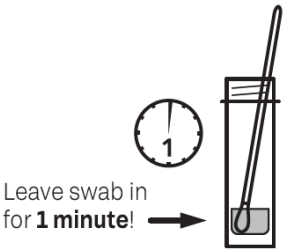
5. **Place swab in the tube**

   Immediately place the swab into the liquid inside the tube, and ensure it is touching the bottom.

   Stir 3-4 times.

   Leave the swab in the solution for ONE MINUTE.

   NOTE: If the swab is in the solution for more than 10 minutes, it should not be used.

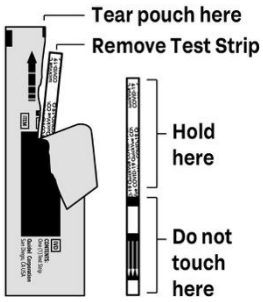


6. **Remove swab from the tube**
   After **ONE MINUTE**, remove the swab from the tube by rubbing the swab head against the inside wall of the tube in order to squeeze out as much liquid as possible.

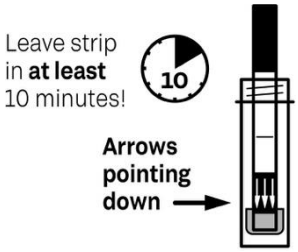
   Dispose of swab in the trash.

7. **Open the test strip**
   Hold the test strip pouch with the arrow pointing up. Locate the notch in the middle of the pouch and tear straight down.

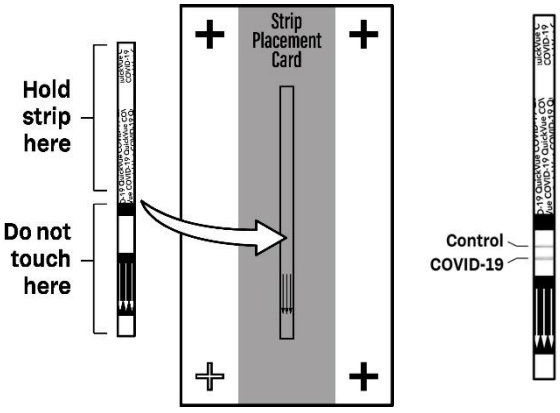
   Hold the test strip as indicated with arrows pointing down.



8. **Place test strip in the tube**
   Place the Test Strip into the tube with the arrows pointing down. Leave the strip in the tube for a **FULL TEN MINUTES** – do not handle or remove during this timeframe.



9. **Remove test strip from the tube**
   At **TEN MINUTES**, remove the test strip from the **TUBE**. Place the test strip exactly over the strip outline on the strip placement card included in the kit on a flat surface in good lighting before reviewing the results.



NOTE: Read the test strip right away! Do not read after 15 minutes. If the results are read after 15 minutes, the results may be inaccurate and the test should be repeated.

10. Check your results

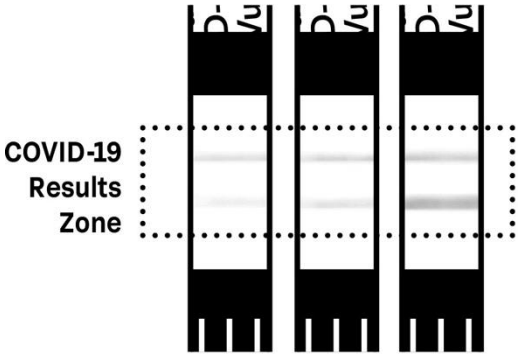
REPEAT TESTING is needed to improve accuracy. Please follow the table below when interpreting test results for COVID-19. Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Interpretation
With Symptoms	Positive	N/A	Positive for COVID-19
	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative for COVID-19

11. Check for a Positive Result

A **POSITIVE** result must show **BOTH** a **BLUE** line and a **PINK** line next to the **BLUE** line in the results zone.

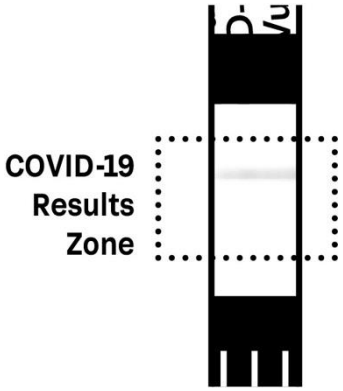
Look closely! Even a very faint, pink Test line and a blue Control line is a POSITIVE result. Pink shading or a line near the labels on the strip is not considered a positive result. You do not need to perform repeat testing if you have a positive result at any time.



12. Check for a Negative Result

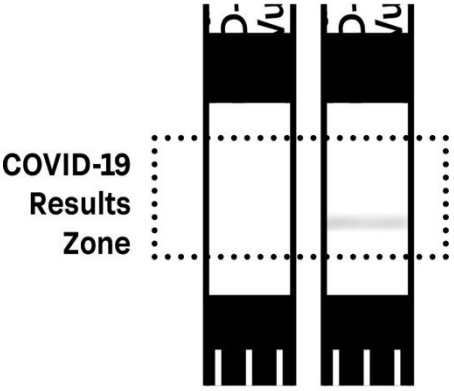
A **NEGATIVE** result will show a **BLUE** line but **NO PINK** line in the results zone.

To increase the chance that the negative result for COVID-19 is accurate, you should:
● Test again in 48 hours if you have symptoms on the first day of testing.



13. Check for an Invalid Result

If there is **NO LINE**, or if there is **ONLY** a **PINK** line in the results zone, the test is INVALID and you should repeat the steps starting at the beginning using a new **TUBE, SWAB**, and **TEST STRIP**



14. Understanding your Results

Positive Result: A positive test result means that the virus that causes COVID-19 was detected in the sample and it is very likely the patient has COVID-19 and is contagious. The patient should contact their doctor/primary care physician or local health authority immediately and 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 definitive cause of disease. Individuals who test positive with the QuickVue COVID-19 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: A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result is presumptive, meaning it is not certain that the patient has COVID-19. The patient may still have COVID-19 and be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If the patient tests negative and continues to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) the patient should seek follow-up care with their healthcare 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 10 minutes the blue Control Line does not appear, the result is invalid, whether or not any shade of pink or red Test Line appears.

If the test result is invalid, a new swab should be collected and the test should be performed again with a new pre-filled tube and test strip.

If the second QuickVue COVID-19 Test is also invalid, call 833-QUICKVUE (833-784-2588) for assistance.

After the test is completed, dispose of all used test components in the waste and wash your hands.

Limitations

- The performance of this test was established based on the evaluation of a limited number of SARS-CoV-2 clinical specimens collected from 2021 through 2024. The clinical performance has not been established for all circulating variants, but it is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Due to the propensity of the virus to mutate, new strains emerge over time which may potentially affect the performance of this device and have serious public health implications. Additional testing with a molecular test and/or sequencing should be considered in situations where a new virus strain or variant is suspected.
- This test is only for use with individuals who show symptoms of COVID-19 within 5 days of symptom onset.
- 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 SARS-CoV-2 infection as compared to a molecular test, especially in samples with low viral load.
- Test performance depends on the amount of virus (antigen) in the sample. 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 or transported improperly.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19.

- 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 detects both viable (live) and non-viable SARS-CoV-2 virus.
- This test does not differentiate between SARS-CoV and SARS-CoV-2.
- Test results should be interpreted in conjunction with other clinical and laboratory information available to the healthcare provider.
- Failure to follow the Test Procedure may adversely affect test performance and lead to incorrect test results. Accurate results are dependent on adequate specimen collection, transport, storage, and processing (as applicable).
- Positive test results do not rule out co-infections with other pathogens.
- All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision-such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).This test has not been validated for use by those with color-impaired vision.
- There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates).
- Based on in vitro testing, the presence of Rheumatoid Factor at higher than 1.12 IU/mL concentrations in nasal samples may result in false positive results. However, it is unclear if such concentrations are clinically relevant.
- If infection with a novel SARS-CoV-2 virus variant is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions and sent to state or local health departments for testing.

Clinical Performance

Prospective Clinical Study

The performance of the QuickVue COVID-19 Test was compared to a high-sensitivity SARS-CoV-2 RT-PCR assay in a prospective clinical study from January 2021 to February 2024. Eight (8) clinical sites participated in the study. Samples were collected by lay users from themselves or collected from a household member. A total of 878 subjects were enrolled in this study, 39.6% male and 60.4% female. In symptomatic individuals tested within 5 days post symptom onset, the QuickVue COVID-19 Test detected SARS-CoV-2 with Positive Percent Agreement (PPA) of 82.0% and Negative Percent Agreement (NPA) of 99.1% when compared to the result from a high-sensitivity SARS-CoV-2 RT-PCR assay. Results are provided in Table 1 and Table 2.

Table 1. QuickVue COVID-19 Test Performance Compared to a **SARS-CoV-2 RT-PCR Assay**

	SARS-CoV-2 RT-PCR		
	Pos	Neg	Total
QuickVue Pos	164	5	169
QuickVue Neg	36	575	611
Total	200	580	780

PPA =	82.0% (164/200) 95% CI: 76.1% - 86.7%
NPA =	99.1% (575/580) 95% CI: 98.0% - 99.6%
Positivity Rate by QuickVue Assay =	21.7% (169/780) 95% CI: 18.9% - 24.7%
Positivity Rate by Comparator Assay=	25.6% (200/780) 95% CI: 22.7% - 28.8%

Table 2. PPA results by DPSO

Days Since Symptom Onset	# Specimens Tested	# Positive by QuickVue	# Positive by RT-PCR	PPA
0	61	14	16	87.5%
1	203	45	53	81.1%
2	248	52	63	79.4%
3	148	27	28	92.9%
4	74	21	28	75.0%
5	46	10	12	83.3%

Serial Testing

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative of the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, covering a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic for at least 14 days prior to enrollment in the study, and did not have a history of SARS-CoV-2 infection within three months prior to enrollment. Participants were assigned to one of three different Emergency Use Authorized SARS-CoV-2 over-the-counter rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result was 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-PCR test methods. If results of the first two molecular tests 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 status of symptoms throughout the study using the MyDataHelps mobile application. Two-day serial antigen testing is defined as performing two antigen tests 36 to 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.

Performance of the antigen test utilizing serial testing is described in Table 3.

Table 3. PPA of COVID-19 Antigen Serial Testing Compared to Molecular Comparator Single Day Testing

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	Ag Positive / PCR Positive (Antigen Test Performance % PPA) SYMPTOMATIC ON FIRST DAY OF TESTING		
	1 Test	2 Tests	3 Tests
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)

6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	

Analytical Performance

Limit of Detection

The Limit of Detection (LoD) of the QuickVue COVID-19 Test was determined using limiting dilutions of heat-inactivated SARS-CoV-2 (WA1/2020 and Omicron BA.5).

The study to determine the LoD of the QuickVue COVID-19 Test was designed to reflect the assay when using direct swabs. Individual foam swabs were placed into reagent tubes containing 50 µL of the virus dilution in negative nasal matrix (NNM). The swabs were then processed according to the QuickVue COVID-19 Test Package Insert. The results were recorded for each swab in the study.

The limit of detection for each strain is listed below in Table 4.

Table 4. LoD Concentration

Analyte Strain	LoD Concentration ($TCID_{50}$/mL)	LoD Concentration ($TCID_{50}$/Swab)
SARS-CoV-2 WA1/2020 / Alpha	3.03E+04	1.52E+03
SARS-CoV-2 Omicron / BA.5	2.48E+04	1.24E+03

WHO SARS-CoV-2 Standard Limit of Detection

A study was performed to determine the Limit of Detection (LoD) for QuickVue COVID-19 Test with different dilutions of the WHO International Standard for SARS-CoV-2 antigen (NIBSC code: 21/368). The Limit of Detection for the WHO International Standard Antigen was determined to be 1.00E+04 IU/mL and 5.00E+02 IU/swab as shown in Table 5.

Table 5. WHO Standard LoD

Analyte Virus	Analyte Strain/ Lineage	LoD Concentration (IU/mL)	LoD Concentration (IU/swab)
SARS-CoV-2	WHO International Standard Antigen NIBSC code: 21/368	1.00E+04	5.00E+02

Analytical Reactivity

The analytical reactivity of the QuickVue COVID-19 Test was demonstrated using viral strains/isolates SARS-CoV-2 Omicron BA.1 and SARS-CoV-2 Delta. The minimum detectable concentrations are listed below in Table 6.

Table 6. Minimum Detectable Concentrations

Strain	Lineage	Minimum Detectable Concentration
Heat Inactivated SARS-CoV-2, Omicron BA.1	BA.1.18	7.08+04 $TCID_{50}$/mL

Strain	Lineage	Minimum Detectable Concentration
Heat Inactivated SARS-CoV-2, Delta	B.1.617.2	3.00E+04 $TCID_{50}$/mL

Cross-Reactivity

Cross-reactivity and potential interference of thirty-nine (39) viruses and twenty-one (21) microorganisms with the QuickVue COVID-19 Test were evaluated, in the presence and absence of SARS-CoV-2. QuickVue COVID-19 Test did not cross-react or interfere with any of the organisms and viruses tested except for SARS-Coronavirus. Cross-reactivity was observed on SARS-Coronavirus sample as expected. Cross Reactivity and Microbial Interference Study Results are provided in Table 7.

Table 7. Cross-Reactivity/Microbial Interference Study Results

Virus/Bacteria/Parasite	Strain/ID	Concentration	Units	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Adenovirus	Type 1	1.41E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 2	1.04E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 3	1.05E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 4	1.78E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 5	1.58E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 7	1.90E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 11	1.47E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 14	1.06E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 22	2.50E+06	$TCID_{50}$/mL	No	No
Adenovirus	Type 31	1.06E+05	$TCID_{50}$/mL	No	No
Adenovirus	Type 35	4.00E+05	$TCID_{50}$/mL	No	No
Coronavirus	229e	1.26E+05	$TCID_{50}$/mL	No	No
Coronavirus	NL63	1.06E+05	$TCID_{50}$/mL	No	No
Coronavirus	OC43	1.28E+05	$TCID_{50}$/mL	No	No
MERS-CoV	None Specified	1.04E+05	$TCID_{50}$/mL	No	No
SARS-Coronavirus (SARS-CoV)	None Specified	1.05E+05	$TCID_{50}$/mL	Yes	No
Cytomegalovirus	None Specified	1.13E+05	$TCID_{50}$/mL	No	No
Enterovirus	Coxsackie	1.04E+05	$TCID_{50}$/mL	No	No
Enterovirus	Echovirus	1.41E+05	$TCID_{50}$/mL	No	No
Enterovirus	EV68	1.28E+05	$TCID_{50}$/mL	No	No
Epstein Barr Virus	None Specified	1.96E+05	$TCID_{50}$/mL	No	No

Virus/Bacteria/Parasite	Strain/ID	Concentration	Units	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Influenza A	H1N1	1.04E+05	$TCID_{50}$/mL	No	No
Influenza A	pH1N1	1.21E+05	$TCID_{50}$/mL	No	No
Influenza A	H3N2	1.05E+05	$TCID_{50}$/mL	No	No
Influenza B	Victoria	1.51E+05	$TCID_{50}$/mL	No	No
Influenza B	Yamagata	1.06E+05	$TCID_{50}$/mL	No	No
Measles	None Specified	1.04E+05	$TCID_{50}$/mL	No	No
Human Metapneumovirus	A1	1.19E+05	$TCID_{50}$/mL	No	No
Mumps virus	None Specified	1.19E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 1	1.27E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 2	1.26E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 3	1.15E+05	$TCID_{50}$/mL	No	No
Parainfluenza	Type 4	1.19E+05	$TCID_{50}$/mL	No	No
Respiratory Syncytial Virus	Type A	1.26E+05	$TCID_{50}$/mL	No	No
Respiratory Syncytial Virus	Type B	1.14E+05	$TCID_{50}$/mL	No	No
Human Rhinovirus	Type A	1.06E+05	$TCID_{50}$/mL	No	No
Human Rhinovirus	Type B	1.55E+05	$TCID_{50}$/mL	No	No
Herpes Simplex Virus	Type 1	1.58E+05	$TCID_{50}$/mL	No	No
Varicella-zoster virus	None Specified	1.21E+05	$TCID_{50}$/mL	No	No
Bordetella pertussis	A639	1.00E+06	CFU/mL	No	No
Candida albicans	None Specified	1.83E+06	CFU/mL	No	No
Chlamydia pneumoniae	None Specified	1.45E+06	IFU/mL	No	No
Corynebacterium sp.	None Specified	1.00E+06	CFU/mL	No	No
Escherichia coli	None Specified	1.72E+06	CFU/mL	No	No
Haemophilus influenzae	None Specified	1.52E+06	CFU/mL	No	No
Lactobacillus sp.	None Specified	1.58E+06	CFU/mL	No	No
Legionella pneumophila	None Specified	1.00E+06	CFU/mL	No	No
Moraxella catarrhalis	None Specified	1.04E+06	CFU/mL	No	No
Mycoplasma pneumoniae	None Specified	1.35E+06	CCU/mL	No	No
Neisseria meningitides	None Specified	1.68E+06	CFU/mL	No	No

Virus/Bacteria/Parasite	Strain/ID	Concentration	Units	Cross-Reactivity (Yes/No)	Interference (Yes/No)
Neisseria sp.	None Specified	1.23E+06	CFU/mL	No	No
Pseudomonas aeruginosa	None Specified	1.16E+06	CFU/mL	No	No
Pooled human nasal wash – representative of normal respiratory microbial flora (Wet-testing)	None Specified	N/A	N/A	No	No
Staphylococcus aureus	Type Not Specified	1.67E+06	CFU/mL	No	No
Staphylococcus epidermidis	None Specified	1.53E+06	CFU/mL	No	No
Streptococcus pneumoniae	None Specified	1.06E+06	CFU/mL	No	No
Streptococcus pyogenes	None Specified	1.07E+06	CFU/mL	No	No
Streptococcus salivarius	None Specified	1.05E+06	CFU/mL	No	No
Mycobacterium tuberculosis avirulent	None Specified	1.16E+06	CFU/mL	No	No
Methicillin-resistant Staphylococcus aureus (MRSA)	None Specified	3.30E+06	CFU/mL	No	No
Methicillin-susceptible Staphylococcus aureus (MSSA)	None Specified	3.67E+06	CFU/mL	No	No

Nineteen (19) specimens containing Coronavirus HKU1 were also tested with an EUA version of this test (EUA203086) and all resulted as negative.

Hook Effect

The effect of high concentration (1.09E+06 $TCID_{50}$/mL) of heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020) on the QuickVue COVID-19 Test was tested. No high dose hook effect was observed for any of the levels evaluated from very high to moderate positive inactivated virus concentrations at 1.09E+06 to 9.09E+04 TCID50/mL (40x to 3x LoD).

Interference Substances Study

A study was performed to verify if endogenous and exogenous substances that may be present in respiratory specimens cross react or interfere with the QuickVue COVID-19 Test. Interference was observed with Rheumatoid Factor when tested at 112 IU/mL and 11.2 IU/mL in NNM with no SARS-CoV-2 present. There was no interference observed at these test concentrations with the positive sample (analyte present). Rheumatoid Factor did not cross react at the final testing concentration of 1.12 IU/mL in NNM. Twenty-four (24) of the substances tested did not interfere with the performance of the QuickVue COVID-19 Test at the concentration listed below in Table 8.

Table 8. Non-Interfering Substances

Substances	Active Ingredients	Concentration
Throat lozenges, oral anesthetic and analgesic	Menthol	700 mg/mL
Sore throat spray	Phenol	15% w/v

Substances	Active Ingredients	Concentration
Mucin bovine submaxillary gland, type I-S or pooled mucous	Purified mucin protein	2.5mg/mL
Whole Blood (human)	Whole blood	4% v/v
Leukocytes	Leukocytes	5.00E+06 cells/mL
Zinc (common ingredient in many nasal sprays) or Zicam as noted below.	Zinc	15% v/v
Nasal sprays or drops	Cromolyn Oxymetazoline,	15% v/v
Nasal corticosteroids	Fluticasone	15% v/v
Nasal gel	Luffa opperculata, sulfur, Sodium Hyaluronate	5% w/v
Homeopathic allergy relief, or nasal wash	Alkalol	15% v/v
Anti-viral drugs	Molnupiravir (broad-spectrum antiviral)	2.5 mg/mL
Anti-viral drugs	Oseltamivir Phosphate (TamiFlu)	2.5 mg/mL
Anti-viral drugs	Ribavirin	2.5 mg/mL
Antibiotic, nasal ointment	Mupirocin	10mg/mL
Hand sanitizer	Isopropyl alcohol	15% v/v
Lotion	Not specified	15% w/v
Hand Soap	Not specified	15% v/v
Rheumatoid Factor	Rheumatoid Factor	1.12 IU/mL
Homeopathic Alkalol	Thymol; Eucalyptol; Manitol; Camphor; Benzoin; Potassium Alum; Potassium Chlorate; Sodium Bicarbonate; Sodium Chloride; Oils of: Sweet Birch; Spearmint; Pine; Cinnamon	1:10 dilution
Cough syrup	Dextromethorphan	5%v/v
Nicotine or Tobacco	Nicotine	0.03 mg/mL
Analgesic ointment (Vicks®, VapoRub®)	Camphor, eucalyptus oil, menthol	1% w/v
Petroleum Jelly (Vaseline®)	White petroleum	1% w/v
Systemic antibiotic	Tobramycin	4 µg/mL

Precision

Lot-to-Lot precision of the QuickVue COVID-19 Test was evaluated by using three (3) product lots. A series of coded, contrived samples were prepared as negative, low positive (1×LoD), and moderate positive (4×LoD) using heat-inactivated SARS-CoV-2 (isolate USA-WA1/2020). Each sample was tested in duplicate in two (2) events per day over twenty (20) days with two (2) operators. The negative sample produced results with a lower 95% confidence interval limit of ≥95% negative agreement. The low positive sample (1×LoD) produced results with a lower 95% confidence interval limit of ≥95% positive agreement. The

moderate positive sample (4×LoD) produced results with a lower 95% confidence interval limit of ≥95% positive agreement. Results of the within-laboratory precision study are summarized in Table 9.

Table 9. Precision Study Results

Lot	Negative*		Low Positive** (1×LoD)		Moderate Positive** (4×LoD)	
	Reader 1	**Reader 2**	**Reader 1**	**Reader 2**	**Reader 1**	**Reader 2**
1	80/80	80/80	78/80	78/80	80/80	80/80
2	80/80	80/80	80/80	80/80	80/80	80/80
3	80/80	80/80	80/80	80/80	80/80	80/80
Total	240/240	240/240	238/240	238/240	240/240	240/240
% Agreement (95% CI)	**100% (98.4% - 100.0%)**	**100% (98.4% - 100.0%)**	**99.2% (97.0% - 99.8%)**	**99.2% (97.0% - 99.8%)**	**100% (98.4% - 100.0%)**	**100% (98.4% - 100.0%)**

*Virus not detected/total; **Virus detected/total

Assistance

If you have any questions regarding the use of this product, please call 833-QUICKVUE (833-784-2588) for assistance.Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 1.800.FDA.1088; fax: 1.800.FDA.0178; http://www.fda.gov/medwatch).

Intellectual Property

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Patents: https://www.quidelortho.com/us/en/patents

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20451 – QuickVue COVID-19, 2 Test Kit

REF 20464 – QuickVue COVID-19, 4 Test Kit

20398 – QuickVue COVID-19, 25 Test Kit

IVD

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1562400EN00 (07/24)

Glossary

 Catalog number	 Batch code
 Use by	 Manufacturer
 Temperature limitation	 Do not re-use
 For *In Vitro* diagnostic use	 Consult instructions for use
 Positive control	 Negative control
 Contains sufficient for n tests	