QUIDEL

QuickVue® At-Home OTC COVID-19 Test

Healthcare Provider Instructions for Use

For use with direct anterior nasal swab specimens

For *In Vitro* Diagnostic Use Only

INTENDED USE

The QuickVue At-Home OTC COVID-19 Test is a lateral flow immunoassay that allows for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. 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. This test is authorized for home use with self-collected (unobserved) direct anterior nasal (NS) swab specimens from individuals aged 14 years and older or with adult-collected anterior NS samples from individuals aged 2 years or older.

The QuickVue At-Home OTC COVID-19 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 nasal specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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 and the agent detected may not be the definite cause of disease. Individuals who test positive with the QuickVue At-Home OTC COVID-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the

authorized product to relevant public health authorities in accordance with local, state, and federal requirements.
The QuickVue At-Home OTC COVID-19 Test is authorized for self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.

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 At-Home OTC COVID-19 Test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV-2 through serial testing, from individuals with and without signs and symptoms of infection who are being tested serially, as described in the intended use. This test does not differentiate between SARS-CoV and SARS-CoV-2.

To begin the test, a self-collected anterior nasal swab samples in individuals aged 14 and older or individuals between the age of 2 to 14 a swab collected by a parent or guardian is 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 is added to the Reagent Tube now containing the specimen and Reagent Solution.

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 is not present, or is present at very low levels, only a blue procedural Control Line will appear.

MATERIALS SUPPLIED WITH the QuickVue At-Home OTC COVID-19 Test Kit

- Swabs – individually wrapped sterile foam swabs
- Test Strips – individually packaged, single-use strips
- Pre-filled Tubes
- Tube Holder
- Instruction Sheet
- Fact Sheet for Individuals

NOTE: This test comes in a 2 test, 5 test, 25 test quantity. The number of items supplied in the kit will vary depending on which kit was purchased.

MATERIALS NOT SUPPLIED WITH the QuickVue At-Home OTC COVID-19 Test Kit

- Clock, Timer, or Stopwatch
- Hand soap and water or hand sanitizer for cleaning your hands
- Safety mask or other face covering
- Gloves
- Household waste basket

WARNINGS and PRECAUTIONS

- For *in vitro* diagnostic use.

- Read the written instructions fully before starting the procedure.
- If uncertain how to proceed, contact Technical Assistance (see below).
- Keep testing kit and kit components out of the reach of children and pets before and after use.
- Wear safety mask or other face covering when collecting anterior nasal swab specimen from child or another individual.
- Use of gloves is recommended when conducting testing.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The QuickVue At-Home OTC COVID-19 Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms. A second test should be obtained with at least 48 hours between tests.
- Do not open the test material until ready for use.
- Do not reuse the used Test Strip, Reagent Tubes, or 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.
- Do not touch swab tip when handling the swab.
- When collecting an anterior nasal swab sample, only use the nasal swab(s) provided in the kit.
- Inadequate or inappropriate specimen collection, may yield false negative test results.
- To obtain accurate results, you must follow the Package Insert instructions.
- Testing should be performed in an area with adequate ventilation.
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- Dispose of all materials in household waste.
- Do not use the QuickVue At-Home OTC COVID-19 Test Kit after its expiration date.
- Wash hands thoroughly or use hand sanitizer after handling.
- The Reagent Solution contains harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222

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

You can store the testing kit at room temperature in a place out of direct sunlight and out of reach of children until its expiration date. After that date the kit should be discarded in household waste.

PLANNING

If you are performing the test for more than one person complete all of the steps for one person's test before starting the next collection. This will help avoid possible mix-ups of specimens and test results. Take time to review the product information, quick reference instructions and training material prior to testing.

If the test is being used for testing individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection, testing should be scheduled at least three times with 48 hours between tests.

BEFORE STARTING

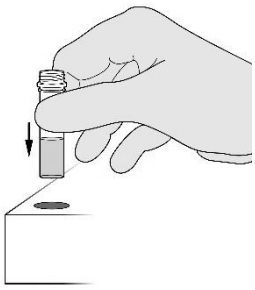
- Read these instructions carefully.
- Complete the steps in order.
- Gather all kit components required for running the test.
- If collecting a sample or performing the test on another individual, a face covering and gloves should be worn
- Before starting the test, wash your hands with soap and water or use hand sanitizer.

TEST PROCEDURE

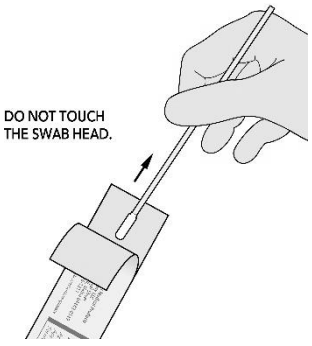
Test materials and clinical specimens must be at room temperature before beginning the assay. Use of gloves is recommended when conducting testing.

1. Remove and identify kit components and instructions.

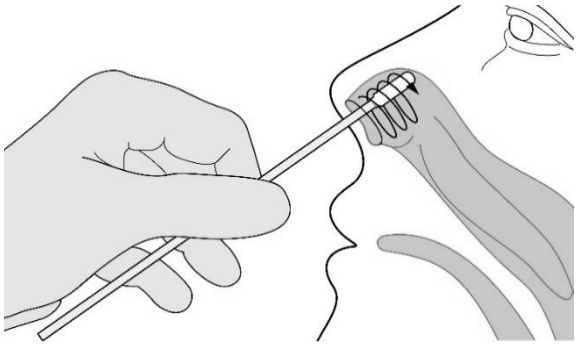
2. Remove cap from one pre-filled tube and place back in the tube holder.



3. Peel open the wrapper from the anterior nasal swab. Note: Do not touch the swab head or remove the anterior nasal swab until ready for sample collection.



COLLECTING A SAMPLE



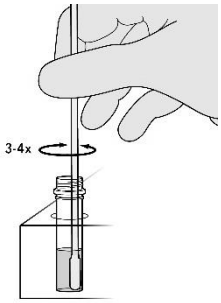
1. Hold the swab approximately halfway up the handle and gently insert the swab ½ to ¾ of an inch into the nostril, depending on the size of the person's nose.
2. Rub the swab around the inside wall of each nostril at least 4 times. Take approximately 15 seconds to collect the sample. This is done with the same swab.

   Note: Please wear a face covering if collecting specimen from an individual aged 2 years or older. With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch and you may need to have a second person to hold the child's head while collecting. Samples should be processed as soon as possible after collection.

   Note: Inadequate or inappropriate specimen collection, may yield false negative test results

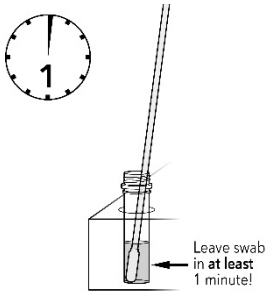
PERFORMING THE TEST

1. Immediately place the swab into the open pre-filled tube. Be sure the swab is touching the bottom of the tube. Stir or twirl swab 3 or 4 times.

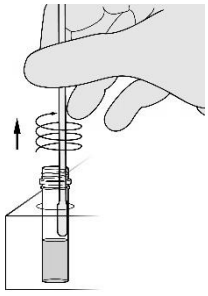


2. After stirring or twirling, leave the swab in the tube for at least one minute (use a timer or watch). **Note: this step is very important, do not remove the swab prior to one minute.**

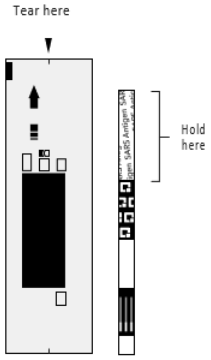
   Note: Incorrect or invalid results may occur if the incubation time is too short or too long.



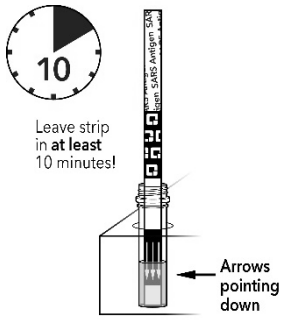
3. After one minute, carefully remove the swab from the tube. As you remove the swab, rub the swab head against the wall of the tube to squeeze out as much liquid as possible. Do not touch the swab head. Immediately discard the swab into the garbage.



4. Prepare the Test Strip by opening the strip pouch carefully at the tear here mark. Remove the Test Strip carefully and only hold the top portion of the strip.



5. Place the Test Strip into the open pre-filled tube with the arrows pointing down. Leave the strip in the tube for 10 minutes. Do not handle or move the strip until the 10 minutes is complete.



6. After 10 minutes, remove the Test Strip from the pre-filled tube and place on a flat surface with good lighting. Inspect the strip for test results. **The Test Strip must be read within 5 minutes after being removed from the pre-filled tube to avoid inaccurate results.** Wash hands with soap and water or use hand sanitizer when complete.

   Note: 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.

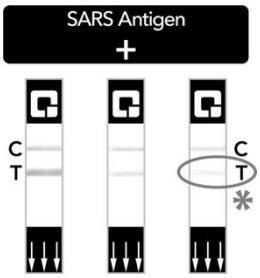
Status on First Day of Testing	First Result Day 2	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	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 10 minutes, the appearance of **ANY shade of pink-to-red Test Line AND** the appearance of a blue procedural Control Line indicates a positive Test Result for the presence of SARS-CoV-2 antigen. Results can only be read for an additional five (5) minutes after being remove from the tube at the 10-minute read time. Do not read the Test Strip more than fifteen minutes after placing into pre-filled tube.



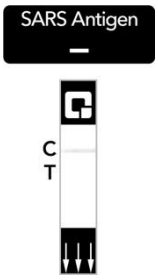
**A positive result does not rule out co-infections with other pathogens*
Repeat testing does not need to be performed if the patient has a positive result at any time.

Look closely! The test strip on the far right is a positive result. Even if you see a very faint, pink Test Line and a blue Control Line, this is a POSITIVE Test Result.

C = Control Line
T = Test Line

Negative Result:**

At 10 minutes, the appearance of **ONLY the blue procedural Control Line** indicates SARS antigen was note detected. Results can only be read for an additional five (5) minutes after the 10-minute read time. Do not read the Test Strip more than fifteen minutes after placing into pre-filled tube.



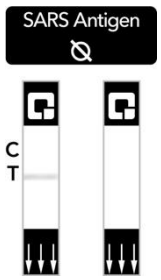
For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high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

A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR.

** *A negative result does 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 treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.*
If you receive a negative test, follow the instructions below:

- *If you have **COVID-19 symptoms**, test again 48 hours after the first negative test, for a total of at least two tests.*
- *If you **do not have COVID-19 symptoms** and believe you have been exposed to COVID-19, test again 48 hours after the first negative test, then 48 hours after the second negative test, for a total of at least three tests.*
- *If any of the repeat tests are positive, you most likely have COVID-19 and should follow current Public Health measures.*
- *If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.*

Invalid Result:
If at 10 minutes, the blue Control Line does not appear, even if any shade of pink-to-red Test Line appears, the result is invalid.



If at 10 minutes, the background color does not clear and it interferes with the reading of the test, the result is also invalid.

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.

LIMITATIONS

- The test is intended for direct anterior nasal swab specimens only. Using another sample collection device or method may cause false results.
- The contents of this kit are to be used only for the qualitative detection of SARS-CoV-2 antigens from anterior nasal swab specimens.
- A negative tests 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-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 Performing the Test and Interpretation of Results may adversely affect test performance and/or invalidate the Test Results.
- Positive Test Results do not rule out co-infections with other pathogens.
- Negative results should be treated as presumptive, and confirmation with another SARS-COV-2 assay, if necessary, should be done.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required. Please discuss with your healthcare provider.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January, 2021 and March, 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.

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, to assess serial testing in patients. The QuickVue At-Home OTC COVID-19 Test was one of the COVID-19 antigen self-tests that was clinically validated during this study.

- 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.

The QuickVue At-Home OTC COVID-19 Test correctly identified 81.3% of positive specimens and 99.3% of negative specimens in that clinical study. The study was based on testing only once. **However, clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results.**

Single-testing clinical performance

The QuickVue At-Home OTC COVID-19 Test was compared to a Reference Extracted EUA SARS-CoV-2 RT-PCR Assay using fresh self-collected or parent/guardian collected anterior nasal swab specimens and healthcare provider collected anterior nasal swab specimens. Symptomatic subjects were enrolled within six days of the onset of symptoms from a multi-site prospective clinical study. The subjects included in the study were provided a Quick Reference Instruction (QRI) and the test kit. No additional training or instructions were provided. Testing occurred in subjects' home, a private, home-like environment within an outpatient clinic, or in subjects' cars.

Five hundred forty-five (545) patients (489 symptomatic, 56 asymptomatic) were enrolled in the on-going prospective clinical study at six (6) collection sites. The healthcare collected swabs were sent on cold packs to the Quidel laboratory in Athens, Ohio for EUA SARS-CoV-2 RT-PCR testing. The Reference Extracted SARS-CoV-2 RT-PCR Assay testing was performed on the swabs according to the device's instructions for use.

The table below summarizes the data from the five hundred and forty-five (545) specimens:

Patient Demographics

Patient demographics (age, elapsed time from date of on-set) for the combined data are provided below.

The specimen positivity breakdown based on age of the patient:

	QuickVue At-Home OTC COVID-19 Test (N=545)		
Age	Total #	Total Positive	Prevalence
≤ 5 years	25	1	4.0%
6 to 21 years	154	16	9.6%
22 to 59 years	349	81	23.2%
≥ 60 years	17	5	29.4%

The specimen positivity breakdown based on days post onset:

Days Post Symptom Onset	QuickVue At-Home OTC COVID-19 Test		
	# Specimens Tested	# Positive Specimens	% Positive
0	48	11	22.9%
1	113	12	10.6%
2	135	22	16.3%
3	81	16	19.8%
4	39	14	35.9%
5	37	8	21.6%
6	17	6	35.3%
>6	19	4	21.1%
Asymptomatic	56	10	17.9%

Comparison of QuickVue At-Home OTC COVID-19 Test and an authorized EUA Molecular comparator assay with anterior nasal swabs								
Number Tested	True Positive	False Positive	True Negative	False Negative	PPA%	NPA%	PPA 95% CI	NPA 95% CI
545	100	3	419	23	81.3	99.3	73.5 to 87.2	97.9 to 99.8

** 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 At-Home OTC COVID-19 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 9.55 x10^6 $TCID_{50}$/mL.

The study to determine the QuickVue At-Home OTC COVID-19 Test LoD was designed to reflect the assay when using direct swabs. Individual foam swabs (the same swab that is provided with the kit) were placed into the limiting dilutions. The swabs were then processed according to the QuickVue At Home COVID-19 Test. The results were recorded for each swab in the study.

The LoD was determined in three steps:

1. LoD Screening
   10-fold dilutions of the heat inactivated virus were made in negative nasal matrix 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 $TCID_{50}$ per mL of 9.55 x10^4.

2. LoD Range Finding
   A 1:3 and 1:5 dilution was made of the 9.55× 10^4 $TCID_{50}$ per mL dilution from the previous study yielding concentrations of 3.18× 10^4 $TCID_{50}$ per mL and 1.91× 10^4 $TCID_{50}$ per mL, respectively. (Note: 9.55× 10^3 $TCID_{50}$ per mL was previously determined to be negative (0/3).

3. LoD Confirmation

The concentration 1.91 x10^4 dilution was tested twenty (20) times. Twenty (20) of twenty (20) results were positive. Based on this testing the concentration was confirmed as $TCID_{50}$ per mL of 1.91 x10^4.

Analytical Reactivity/Inclusivity

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the QuickVue At-Home OTC COVID-19 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	9.55 x10^6 $TCID_{50}$/mL

Cross-Reactivity

Cross-reactivity of the monoclonal antibodies used for the detection of SARS-CoV-2 was evaluated by testing various microorganisms (15) and viruses (16) that may potentially cross-react with the QuickVue At-Home OTC COVID-19 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 At-Home OTC COVID-19 Test					
Virus/Bacteria/Parasite	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Adenovirus	Type 1	Isolate	4.57e^6 U/mL	No Cross-Reactivity	No Interference
Coronavirus	229e	Isolate	1.17e^5 U/mL	No Cross-Reactivity	No Interference
Coronavirus	OC43	Isolate	9.55e^6 U /mL	No Cross-Reactivity	No Interference
Coronavirus	NL63	Isolate	1.41e^5 U/mL	No Cross-Reactivity	No Interference
MERS-CoV (heat-inactivated)	Florida/USA-2_Saudi Arabia_2014	Isolate	3.55e^5 U /mL	No Cross-Reactivity	No Interference
Mycoplasma pneumoniae	M129	Isolate	3.16 x 10^6 CCU/mL	No Cross-Reactivity	No Interference
Streptococcus pyogenes	Z018	Isolate	4.30e^6 cfu/mL	No Cross-Reactivity	No Interference
Influenza A H3N2	Hong Kong/8/68	Isolate	1.17e^5 U/mL	No Cross-Reactivity	No Interference
Influenza A H1N1	New Caledonia/20/99	Isolate	3.55e^5 U/mL	No Cross-Reactivity	No Interference
Influenza B	Brisbane/33/08	Isolate	1.17e^6 U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 1	Isolate	5.01e^5 U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 2	Isolate	2.19e^6 U/mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 3	Isolate	2.82e^6 U /mL	No Cross-Reactivity	No Interference
Parainfluenza	Type 4b	Isolate	2.30e^6 U/mL	No Cross-Reactivity	No Interference
Enterovirus	Type 68	Isolate	1.26e^6 U/mL	No Cross-Reactivity	No Interference
Human Metapneumovirus	A1 (IA10-2003)	Isolate	3.80e^6 U/mL	No Cross-Reactivity	No Interference
Respiratory Syncytial Virus	Type A (3/2015 Isolate #3)	Isolate	4.17e^5 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	2.8 x 10^6 IFU/mL	No Cross-Reactivity	No Interference
Haemophilus influenzae	Type b; Eagan	Isolate	4.54e^6 cfu/mL	No Cross-Reactivity	No Interference
Legionella pneumophila	Philadelphia	Isolate	3.76e^6 cfu/mL	No Cross-Reactivity	No Interference
Streptococcus pneumoniae	Z022; 19f	Isolate	4.52e^6 cfu/mL	No Cross-Reactivity	No Interference

Cross-Reactivity/Interference of QuickVue At-Home OTC COVID-19 Test					
Virus/Bacteria/Parasite	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Bordetella pertussis	A639	Isolate	$3.82e^6$ cfu/mL	No Cross-Reactivity	No Interference
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	$3.12e^6$ cfu/mL	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	H37Ra-1	Isolate	$6.86e^6$ cfu/mL	No Cross-Reactivity	No Interference
Streptococcous salivarius	Z127	Isolate	$4.19e^6$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	MRSE; RP62A	Isolate	$9.27e^6$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MRSA	NCTC 8325	Isolate	$5.50e^6$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MRSA *mecA*	0801648	Isolate	$2.76e^6$ cfu/mL	No Cross-Reactivity	No Interference
Candida albicans	Z006	Isolate	$6.27e^6$ cfu/mL	No Cross-Reactivity	No Interference
Pseudomonas aeruginosa	Z139; VIM-1	Isolate	$7.48e^6$ cfu/mL	No Cross-Reactivity	No Interference
Pooled human nasal wash	Not applicable	Nasal wash	NA	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 ($TCID_{50}$ per mL of 9.55×10^6) was tested. There was no Hook effect detected.

Endogenous Interference Substances Studies:

A study was performed to demonstrate that twenty-one (21) 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 At-Home OTC COVID-19 Test.

Potentially Interfering Substances for QuickVue At-Home OTC COVID-19 Test				
Substance	**Active Ingredient**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Afrin – nasal spray	Oxymetazoline	15% v/v	No Cross-Reactivity	No Interference
Alkalol (Homeopathic)	Alkalol	15% v/v	No Cross-Reactivity	No Interference
Biotin	Biotin	1200 ng/mL	No Cross-Reactivity	No Interference
Biotin + Blood	Biotin	1200 ng/mL (Biotin), 15% v/v (Blood)	No Cross-Reactivity	No Interference
Blood (whole, human)	N/A	15% v/v	No Cross-Reactivity	No Interference
Chloraseptic, Cepacol	Benzocaine, Menthol	15% v/v	No Cross-Reactivity	No Interference
CVS throat spray	Phenol	15% v/v	No Cross-Reactivity	No Interference
Flonase	Fluticasone	15% v/v	No Cross-Reactivity	No Interference
Halls Relief Cherry Flavor	Menthol	15% v/v	No Cross-Reactivity	No Interference
Mupirocin Ointment	Mupirocin	15% v/v	No Cross-Reactivity	No Interference

Potentially Interfering Substances for QuickVue At-Home OTC COVID-19 Test				
Nasocort Allergy 24 hour	Triamcinolone	15% v/v	No Cross-Reactivity	No Interference
NasalCrom Spray	Cromolyn Sodium	15% v/v	No Cross-Reactivity	No Interference
NeilMed SinuFlow Ready Rinse	Sodium chloride, Sodium bicarbonate	15% v/v	No Cross-Reactivity	No Interference
NeilMed SinuFrin Plus	Hexymetazoline HCl	15% v/v	No Cross-Reactivity	No Interference
Neo-Synephrine	Phenylephrine hydrochloride	15% v/v	No Cross-Reactivity	No Interference
Oseltamivir	Oseltamivir	2.5 mg/mL	No Cross-Reactivity	No Interference
Purified mucin protein	Mucin	2.5 mg/mL	No Cross-Reactivity	No Interference
Rhinocort	Budesonide (Glucocorticoid)	15% v/v	No Cross-Reactivity	No Interference
Saline nasal spray	Saline	15% v/v	No Cross-Reactivity	No Interference
Tobramycin	Tobramycin	4.4 µg/mL	No Cross-Reactivity	No Interference
Zanamivir	Zanamivir	282.0 ng/mL	No Cross-Reactivity	No Interference
Zicam Allery Spray	Galphimia glauca, Luffa operculata, Histaninum hydrochloricum, Sulphur	15% v/v	No Cross-Reactivity	No Interference
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	15% v/v	No Cross-Reactivity	No Interference

* Testing was performed in triplicate

ASSISTANCE

If the test does not perform as expected, please contact Quidel Technical Support at 833-QUICKVUE (833-784-2588) if within the U.S. or Canada. If outside the U.S. and Canada, please contact your local distributor or visit www.quickvueathome.com

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REF 20410 – QuickVue At-Home COVID-19 Test, 2 Test Kit
20436 – QuickVue At-Home OTC COVID-19 Test, 5-Test Kit
20411 – QuickVue At-Home COVID-19 Test, 25 Test Kit

IVD

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Revision Changes:

- Corrected $TCID_{50}$ value in Hook Effect and Cross-Reactivity/Interference sections to match master reports.
- Updated Cross-Reactivity/Interference section table to add biotin testing.
- 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	 Manufacturer
 Temperature limitation	 Consult instructions for use
IVD For *In Vitro* diagnostic use	 Contains sufficient for <n> tests
 Do not reuse	 Self-test