QUIDEL

QuickVue® At-Home OTC COVID-19 Test

Healthcare Provider Instructions for Use
For Use Under an Emergency Use Authorization (EUA) Only
For use with direct anterior nasal (nares) swab specimens
For *In Vitro* Diagnostic Use Only

INTENDED USE

The QuickVue At-Home OTC COVID-19 Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older or adult-collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first six days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for 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. 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, 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 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. 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.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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 an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

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 and to receive appropriate medical care. 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 using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The QuickVue At-Home OTC COVID-19 Test is intended for non-prescription self-use and/or, as applicable an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The QuickVue At-Home

OTC COVID-19 Test is only for 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 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 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 Strip 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

NOTE: This test comes in a 2 test, 10 test, and 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
- 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)
- Compatible computer to access the web-based instructions on **QuickVueAtHome.com**

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.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **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 you have had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use the used Test Strip, Reagent Tubes, or swabs.
- Do not use the QuickVue At-Home OTC COVID-19 Test Kit after its expiration date.
- Do not touch swab tip when handling the swab.
- Do not open the test material until ready for use. Once opened, the test strip should be used within 60 minutes
- 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.
- **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 results and the test should be repeated.**
- 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.
- Wash hands thoroughly or use hand sanitizer after handling.
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, and eyes. Do not ingest any kit components. 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 more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization
- 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

You can store the testing kit at room temperature, 59°F to 86°F (15°C to 30°C), 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. For the most current expiration dates of this test, please refer to: http://www.fda.gov/covid-tests.

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.

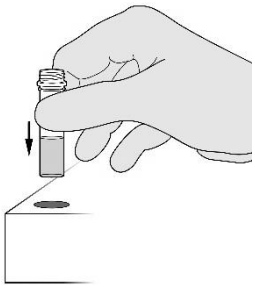
If the test is being used for testing individuals without symptoms or other epidemiological reasons to suspect COVID-19, testing should be scheduled twice over two (or three) days with at least 24 hours (and no more than 48 hours) between tests.

BEFORE STARTING

- Read these instructions carefully
- Complete the steps in order
- Gather all kit components required for running the test
- Check expiration date printed on test. Do not use kit past its expiration date. For the most current expiration dates of this test, please refer to: http://www.fda.gov/covid-tests
- 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

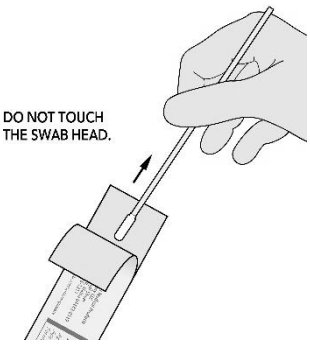
Test materials and clinical specimens must be at room temperature, 59°F to 86°F (15°C to 30°C), before beginning the assay.
Before you start testing, wash your hands or use hand sanitizer. The use of gloves is recommended when conducting testing.



1. Check the expiration date printed on the test kit. Do not use the kit past its expiration date.
   For the most current expiration dates of this test, please refer to: http://www.fda.gov/covid-tests.

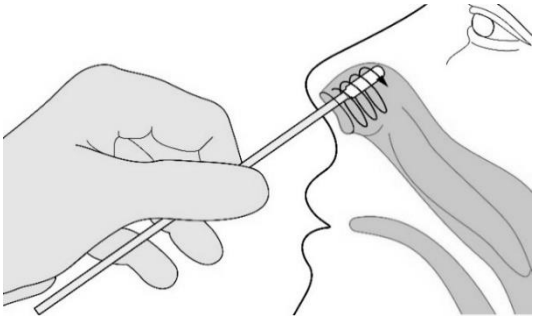
2. Remove and identify kit components and instructions.

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



4. 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

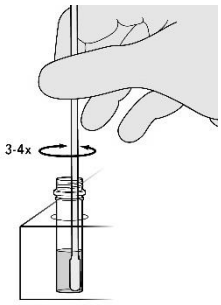


1. Hold the swab approximately halfway up the handle and gently insert the swab ½ to ¾ of an inch into the nostril, depending on the size of the person's nose.
2. Firmly rub the swab in a circular motion around the inside wall of each nostril at least 4 times.
   Be sure to rub BOTH nostrils with the 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. Failure to swab properly may cause false negative results.

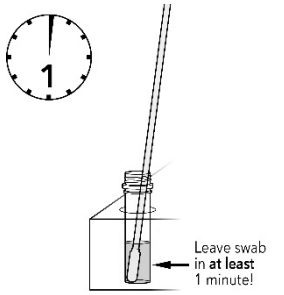
PERFORMING THE TEST

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 to 4 times.

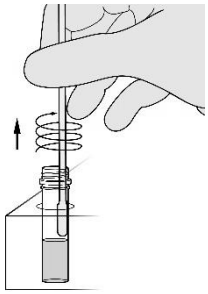


2. After stirring or twirling, leave the swab in the tube for at least one minute (use a timer or watch). **Note: this step is very important, do not remove the swab prior to one minute.**

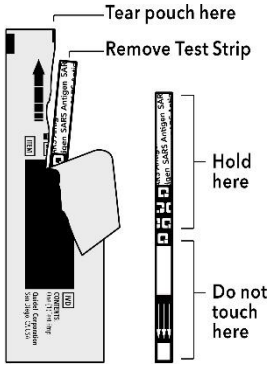
   Note: If the swab is in the solution for more than 10 minutes it should not be used.



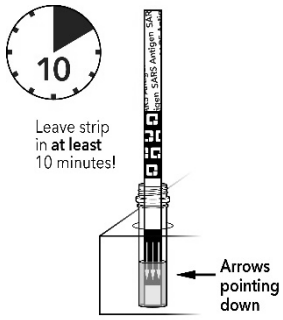
3. After one minute, carefully remove the swab from the tube. As you remove the swab, rub the swab head against the wall of the tube to squeeze out as much liquid as possible. Do not touch the swab head. Immediately discard the swab into the garbage.



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 a full 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: The test is intended to be read at 10 minutes. If the test is read before this or is read more than 5 minutes after the indicated read time, results may be inaccurate (false negative, false positive, or invalid) and the test should be repeated.

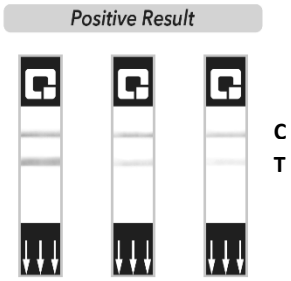
INTERPRETATION OF RESULTS

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	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 10 minutes, the appearance of ANY shade of pink-to-red Test Line (T) AND the appearance of a blue procedural Control Line (C) 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*

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

C = Control Line
T = Test Line

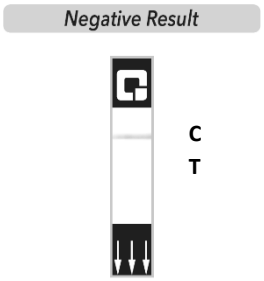
Repeat testing does not need to be performed if patients have a positive result at any time.

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 At-Home OTC 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:**

At 10 minutes, the appearance of ONLY the blue procedural Control Line (C) indicates SARS antigen was not 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.



*** A negative result does not exclude SARS-CoV-2 infection. Negative results should be treated as presumptive and may need to be confirmed by a molecular assay.*

C = Control Line
T = Test Line

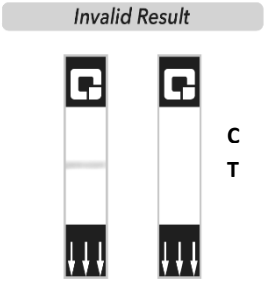
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **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, the individual should 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 10 minutes, the blue Control Line (C) does not appear, even if any shade of pink-to-red Test Line (T) 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.

C = Control Line
T = Test Line

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

LIMITATIONS

- Testing for asymptomatic individuals should be performed at least three times over five days, with at least 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- 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 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.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- 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.
- 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.

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.

Three hundred fifty (350) patients (306 symptomatic, 44 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 one hundred and sixty-one 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:

Age	QuickVue At-Home OTC COVID-19 Test (N=350)		
	Total #	Total Positive	Prevalence
≤ 5 years	6	0	0%
6 to 21 years	84	9	10.7%
22 to 59 years	249	70	28.1%
≥ 60 years	11	4	36.4%

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	32	9	28.1%
1	71	5	7.0%
2	86	21	24.4%
3	49	15	30.6%
4	31	14	45.2%
5	18	5	27.8%
6	9	5	55.6%
>6	10	2	20.0%
Asymptomatic	44	7	15.9%

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
350	81	2	251	16	83.5	99.2	74.9 to 89.6	97.2 to 99.8

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 SARSCoV-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 RTPCR, 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	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	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 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 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

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, the QuickVue At-Home OTC COVID-19 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 the QuickVue At-Home OTC COVID-19 Test in this study.

Omicron Pool 1 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	QuickVue At-Home OTC COVID-19 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 (13) and viruses (16) that may potentially cross-react with the QuickVue At-Home 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	3.16×10^6 CCU/mL	No Cross-Reactivity	No Interference
Streptococcus pyogenes	Z018	Isolate	$4.30e^6$ cfu/mL	No Cross-Reactivity	No Interference
Influenza A H3N2	Brisbane/10/07	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

Cross-Reactivity/Interference of QuickVue At-Home OTC COVID-19 Test					
Virus/Bacteria/Parasite	**Strain**	**Source/ Sample type**	**Concentration**	**Cross-Reactivity Results***	**Interference Results***
Enterovirus	Type 68	Isolate	$1.26e^6$ U/mL	No Cross-Reactivity	No Interference
Human Metapneumovirus	A1 (IA10-s003)	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	2.8×10^6 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
Bordetella pertussis	A639	Isolate	$3.82e^6$ cfu/mL	No Cross-Reactivity	No Interference
Pneumocystis jirovecii-S. cerevisiae Recombinant	W303-Pji	Isolate	$6.86e^6$ cfu/mL	No Cross-Reactivity	No Interference
Mycobacterium tuberculosis	H37Ra-1	Isolate	$3.12e^6$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus epidermidis	MRSE; RP62A	Isolate	$9.27e^6$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MSSA	NCTC 8325	Isolate	$5.50e^6$ cfu/mL	No Cross-Reactivity	No Interference
Staphylococcus aureus MRSA	0801638	Isolate	$2.76e^6$ cfu/mL	No Cross-Reactivity	No Interference
Candida albicans	Z0006	Isolate	$6.27e^6$ 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 ($TCID_{50}$ 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 (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 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
Homeopathic (Alkalol)	Alhahol	15% v/v	No Cross-Reactivity	No Interference

Potentially Interfering Substances for QuickVue At-Home OTC COVID-19 Test				
Blood (human)	Blood	15% v/v	No Cross-Reactivity	No Interference
Chloraseptic®, Cepacol®	Benzocaine, Menthol	1.5 mg/mL	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	10 mg/mL	No Cross-Reactivity	No Interference
Nasacort® 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 SinuFlo® Ready Rinse	Sodium chloride, Sodium bicarbonate	15% v/v	No Cross-Reactivity	No Interference
NeilMed SinuFrin® Plus	Oxymetazoline 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 protein	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® Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	15% v/v	No Cross-Reactivity	No Interference

* Testing was performed in triplicate

ASSISTANCE

If you have any questions regarding the use of this product, please call QuickVue at Home product support 833-QUICKVUE (833-784-2588). 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).

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REF 20402 – QuickVue At-Home OTC COVID-19, 2 Test Kit
20427 – QuickVue At-Home OTC COVID-19, 10 Test Kit
20398 – QuickVue At-Home OTC COVID-19, 25 Test Kit

IVD

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1500204EN00 (01/23)

GLOSSARY

	
Catalogue number	Batch code
	
Use-by date	Manufacturer
	
Temperature limit	Consult instructions for use
	
In vitro diagnostic medical device	