



# QuickVue<sup>®</sup> At-Home OTC COVID-19 Test

## USER INSTRUCTIONS

*In vitro* diagnostic use only.



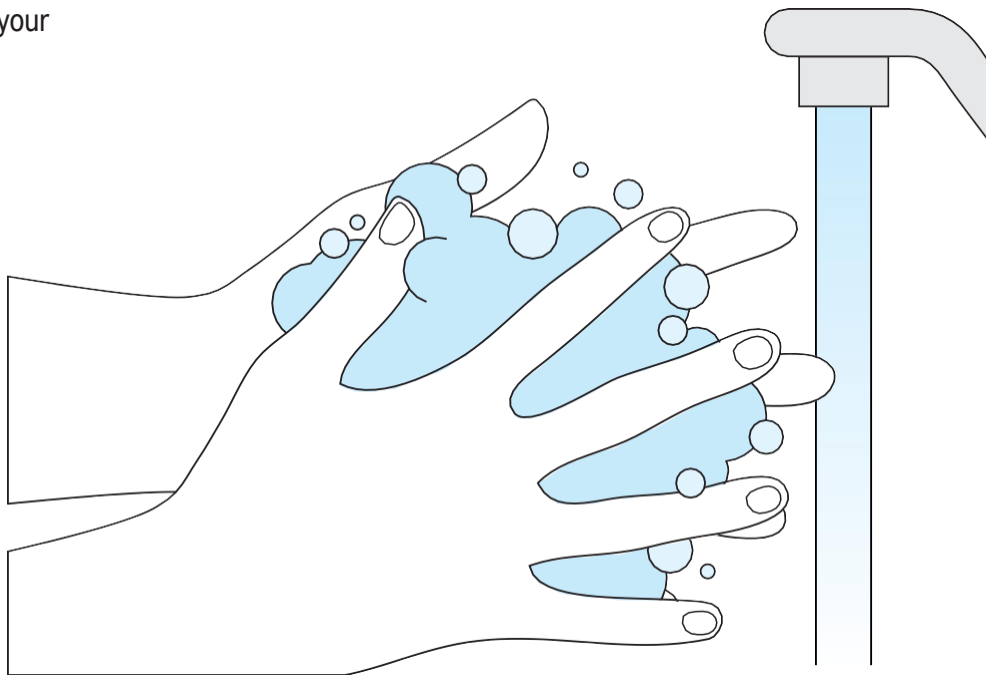
RAPID RESULTS IN



# Wash Your Hands

Before you start testing, wash your hands or use hand sanitizer.

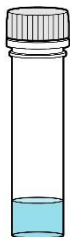
Make sure your hands are dry before starting.



# STEP 1: Check Your Test Kit

Locate the kit components:

It is recommended gloves  
(not provided) also be used  
during testing.



**Tubes**



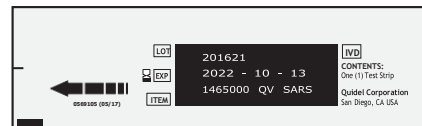
**Tube Holder**



**Swabs**



**Watch or Timer**  
(not included)

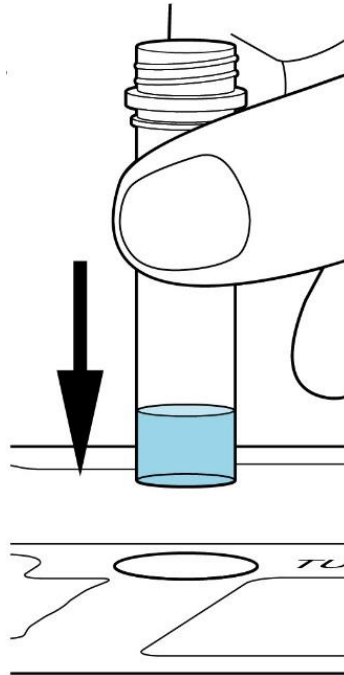


**Test Strips**

## STEP 2: Place Tube in the Tube Holder

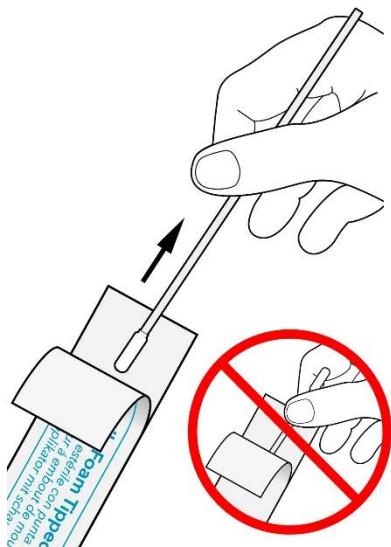
Remove cap from one **TUBE** and place it in the **TUBE HOLDER**.

**NOTE:** Use of gloves is recommended.



## STEP 3: Swab the Nostrils

- A** Remove the **SWAB** from its wrapper, being careful not to touch the **SWAB** head.

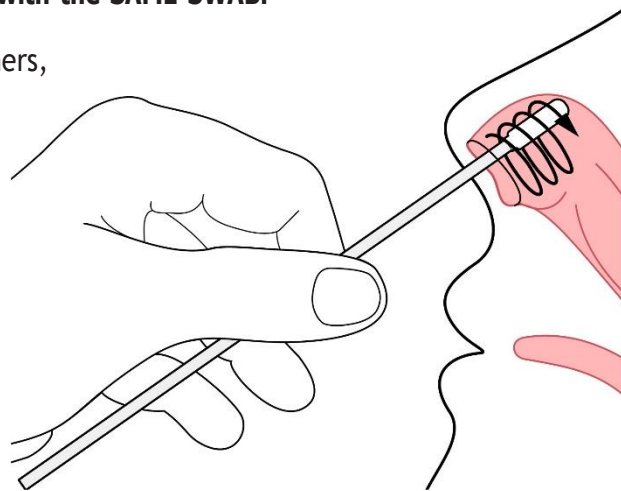


- B** Gently insert the **SWAB**  $\frac{1}{2}$  to  $\frac{3}{4}$  of an inch into the nostril, depending on the size of the person's nose. Firmly rub the **SWAB** in a circular motion around the inside wall of **EACH NOSTRIL at least 4 times**.

**Be sure to rub BOTH nostrils with the SAME SWAB.**

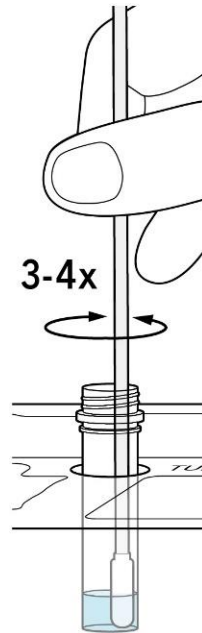
**NOTE:** If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

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



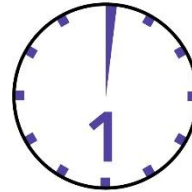
## STEP 4: Place Swab in the Tube

- A** Immediately place the **SWAB** into the liquid inside the **TUBE**, and ensure it is touching the bottom. Stir 3-4 times.

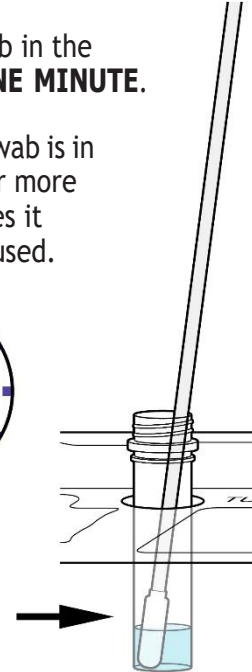


- B** Leave the swab in the solution for **ONE MINUTE**.

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

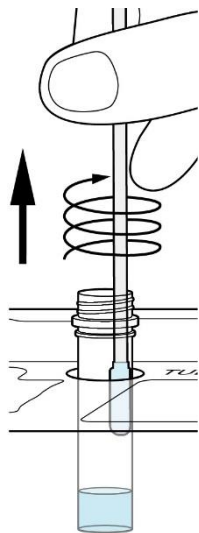


Leave swab  
in at least  
1 minute!

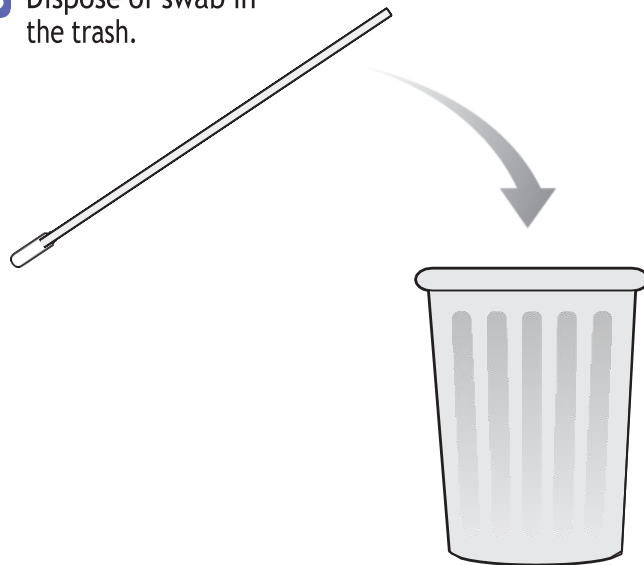


## STEP 5: Remove Swab from the Tube

- A** After **ONE MINUTE**, remove the swab from the **TUBE** by rubbing the swab head against the inside wall of the tube to squeeze out as much liquid as possible.

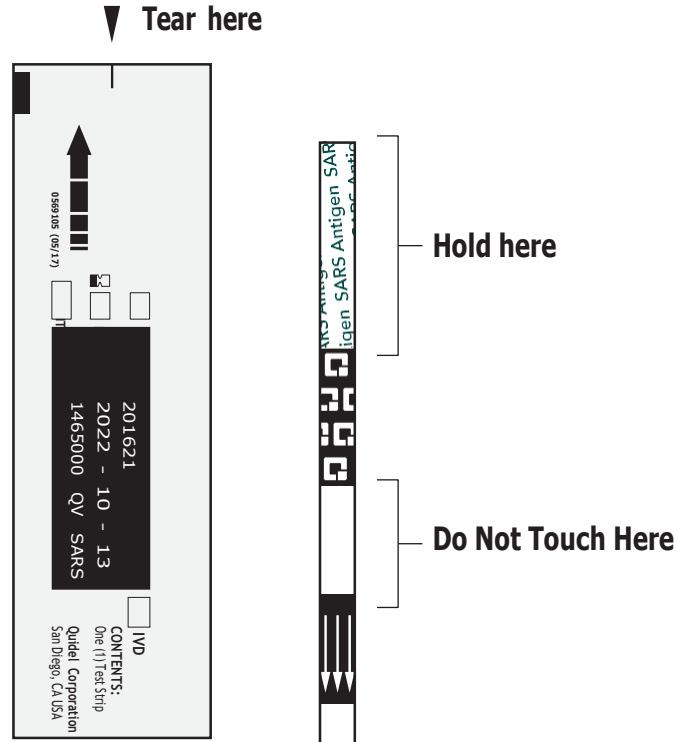


- B** Dispose of swab in the trash.



## STEP 6: Open the Test Strip

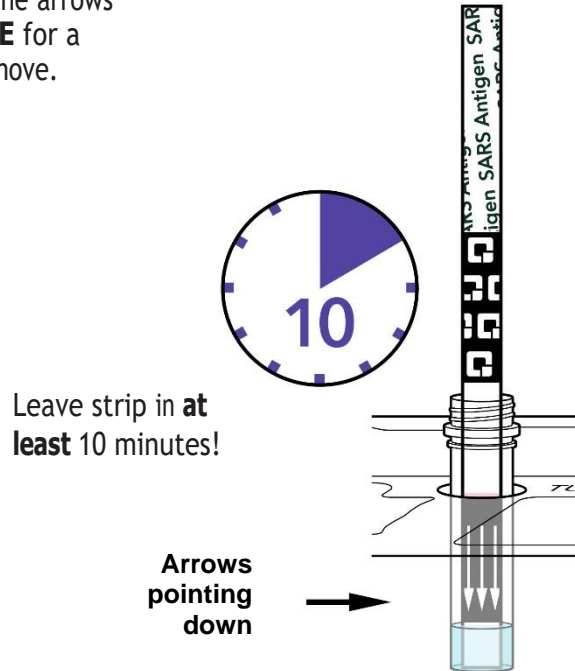
Open the **TEST STRIP** pouch carefully at the slit and hold the **TEST STRIP** as indicated.





## STEP 7: Place Test Strip in the Tube

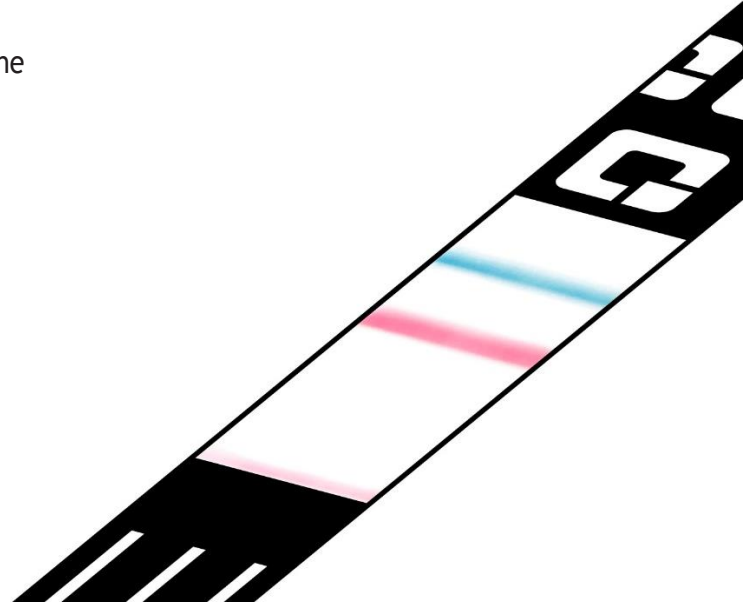
Place the **TEST STRIP** into the **TUBE** with the arrows pointing down. Leave the strip in the **TUBE** for a **FULL TEN MINUTES** - do not handle or remove.



## STEP 8: Remove Test Strip from the Tube

At **TEN MINUTES**, remove the **TEST STRIP** from the **TUBE** and place on the test strip outline in Steps 10-12. Ensure the **TEST STRIP** is on a flat surface in good lighting.

**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.



## STEP 9: Check Your Results

There are three type of results possible.

- 1. Check for a Positive Result**
- 2. Check for a Negative Result**
- 3. Check for an Invalid Result**

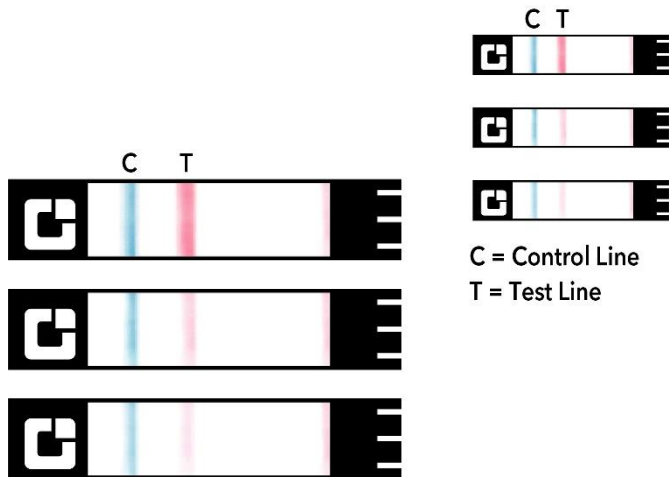
**Interpretation of Results:** Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results. (N/A = not applicable)

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

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.

## STEP 10: Check for a Positive COVID-19 Result

Place the **TEST STRIP** on the test strip outline below and compare with test result examples shown.



Results shown at 2x.

### Positive Result

A **POSITIVE** result must show **BOTH** a **BLUE** line and a **PINK** line just below the **BLUE** line.

**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.**

\*Repeat testing does not need to be performed if the patient has a positive result at anytime.

## Positive COVID-19 Result

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A positive test result means that proteins from the virus that causes COVID-19 were found in your sample and it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give you a positive test result that is wrong (false positive). If you test positive with the QuickVue At-Home OTC COVID-19 Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result along with your medical history, and your symptoms.

## STEP 11: Check for a Negative COVID-19 Result

Place the **TEST STRIP** on the test strip outline below and compare with test result examples shown.



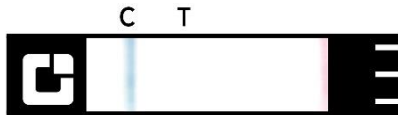
C = Control Line  
T = Test Line

### *Negative Result*

A **NEGATIVE** result will show a **BLUE** line (C) but **NO PINK** line (T).

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.



Results shown at 2x.

## Negative COVID-19 Result

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.

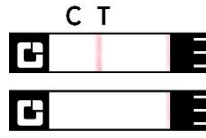
It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

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. 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.

## STEP 12: Check for an Invalid COVID-19 Result

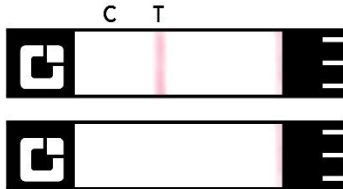
Place the **TEST STRIP** on the test strip outline below and compare with test result examples shown.



C = Control Line  
T = Test Line

### *Invalid Result*

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



Results shown at 2x.



## Invalid COVID-19 Result

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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 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.

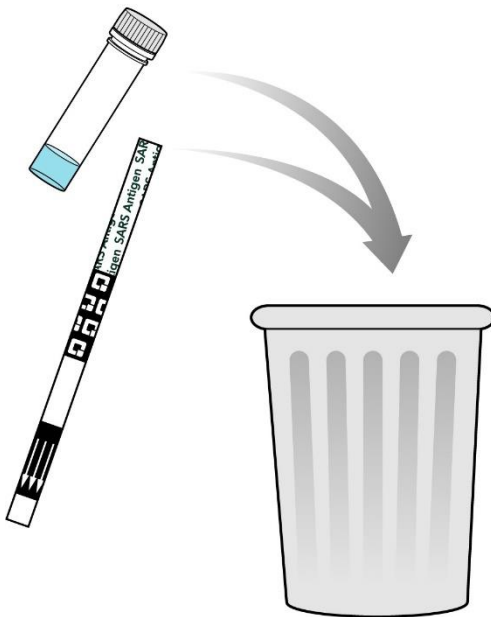
If the second QuickVue At-Home OTC COVID-19 Test is also INVALID, call for assistance.

If within the U.S. or Canada, call 833-QUICKVUE (833-784-2588).

If outside the U.S. and Canada, please contact your local distributor or visit [www.quickvueathome.com](http://www.quickvueathome.com).

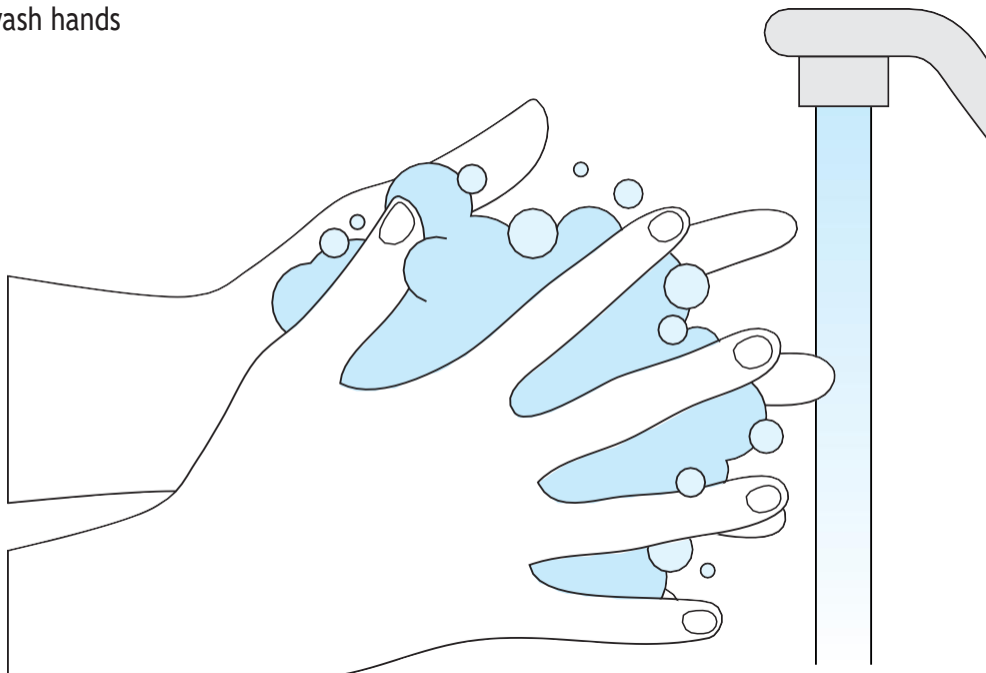
## STEP 13: Dispose Used Test in the Trash

All used test components should be disposed of in your household waste.



## Wash Your hands

After completing all steps, wash hands  
or use hand sanitizer.



## The QuickVue At-Home OTC COVID-19 Test is for *In Vitro* Diagnostic (IVD) Use Only.

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- 20410 - QuickVue At-Home OTC COVID-19 Test - 2 Test  
20436 - QuickVue At-Home OTC COVID-19 Test - 5 Test  
20411 - QuickVue At-Home OTC COVID-19 Test - 25 Test
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- For the most up to date information on COVID-19, please visit: [www.cdc.gov/COVID19](http://www.cdc.gov/COVID19)
- For detailed instructions, please visit [www.quickvueathome.com](http://www.quickvueathome.com)

# Warnings, Precautions and Safety Information

- 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 of 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.
- 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.
- Read the written instructions fully before starting the test procedure.
- To ensure correct results, you must follow the instructions.
- Keep test kit and materials out of the reach of children and pets before and after use.
- Wear safety mask or other face covering when collecting swabs from children or others.
- Use of personal protection materials such as gloves are recommended.
- Do not open the materials until ready for use. If the test strip is open for an hour or longer, invalid test results may occur.
- Improper swab collection may result in incorrectly negative (false negative) results.
- 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, and the test should be repeated.
- Do not use a test kit that is expired.
- Do not touch the swab head when handling the swab.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.

## Hazardous Ingredients for Liquid Reagent

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 <sup>®</sup> 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%

- The solution in the tube contains hazardous ingredients (see table above). If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. 1.800.451.8346 (Verisk 3E)

## What do I need to know about Results from Serial Testing?

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**If your first or second test is positive, then proteins from the virus that causes COVID-19 has been found in your sample and you likely have COVID-19.** If you test positive with the QuickVue At-Home COVID-19 Test, you should self-isolate and seek follow-up care with your healthcare provider to determine the next steps you should take. You may need additional testing, depending on your personal health history and other factors.

**If your first test is negative, you should test again in 48 hours. If both your first and second tests are negative, you may not have COVID-19, however, you should follow-up with your healthcare provider if you are at high risk for COVID-19 infection.** If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

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.

### 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 (Revise as applicable to the intended use of your device). A self-test may be used for this additional testing.
- Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the 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.



## Intended Use

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

# Frequently Asked Questions

## Will this test hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a healthcare provider.

## What are the known and potential risks and benefits of this test?

### Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Results section).

### Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

## What is Serial Testing?

COVID-19 Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

## What is the difference between an antigen and molecular test?

An antigen test, such as the QuickVue At-Home OTC COVID-19 Test, detects proteins from the virus. Molecular tests detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home.

## How Accurate is this Test?

Based on the interim results of a clinical study where the QuickVue At-Home OTC COVID-19 Test was compared to an FDA authorized molecular SARS-CoV-2 test, QuickVue At-Home OTC COVID-19 Test correctly identified 83.5% of positive specimens and 99.2% of negative specimens.



QuickVue<sup>®</sup>  
At-Home  
OTC COVID-19 Test

# USER INSTRUCTIONS

A second test should be obtained with at least 48 hours between tests.

Please notify your Healthcare provider of the results of your QuickVue At-Home OTC COVID-19 Test.

## 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](http://www.quickvueathome.com).



**Quidel Corporation**  
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[quidel.com](http://quidel.com)

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