



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

## USER INSTRUCTIONS

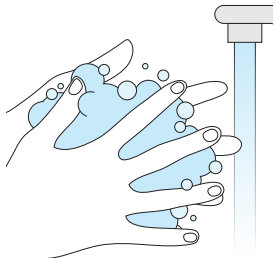
For Emergency Use  
Authorization (EUA) only.  
*In vitro* diagnostic use only.



Scan QR Code with phone camera to learn  
more or visit [quickvueathome.com](https://quickvueathome.com).

### Wash Your Hands

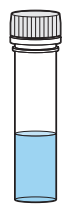
Before you start testing,  
wash your hands or use  
hand sanitizer.  
Make sure your hands are  
dry before starting.



### 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)



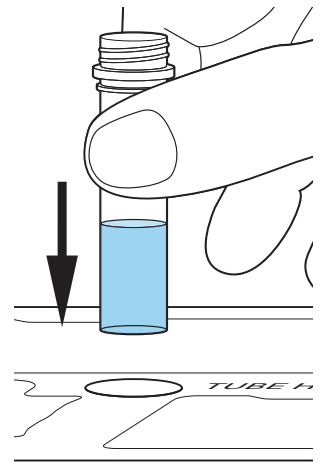
Test Strips

### 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.

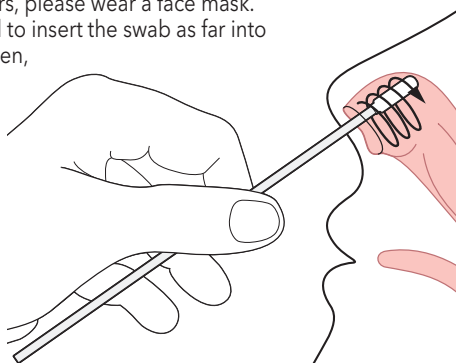


**B** Gently insert the **SWAB** ½ to ¾ of an inch into the nostril, depending on the  
size of the person's nose. Firmly rub the **SWAB** in a circular motion around  
the inside wall of **EACH NOSTRIL** at least **4** times.

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

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

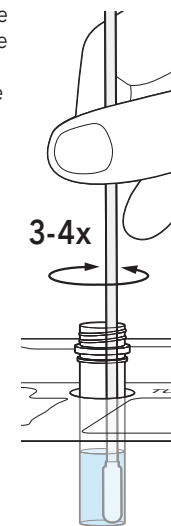
**NOTE:** Failure to swab  
properly may cause  
false negative results.



### 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.

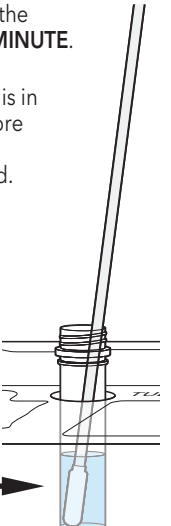


**B** Leave the swab in the  
solution for **ONE MINUTE**.

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



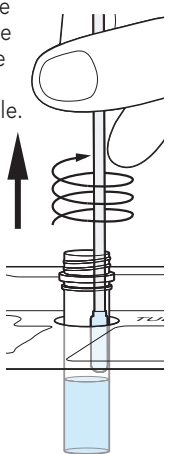
Leave swab  
in **at least**  
1 minute!



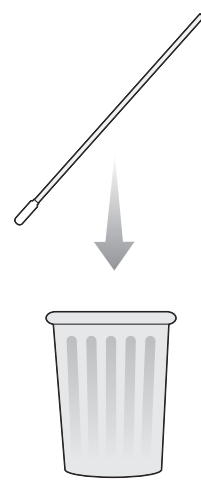
### STEP 5

#### 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.



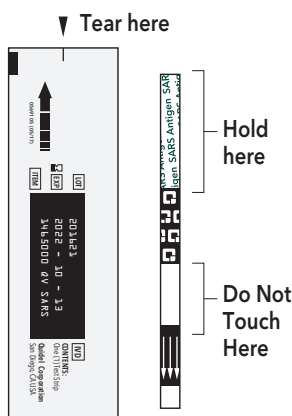
**B** Dispose of swab  
in the trash.



### STEP 6

#### Open the Test Strip

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



### STEP 7

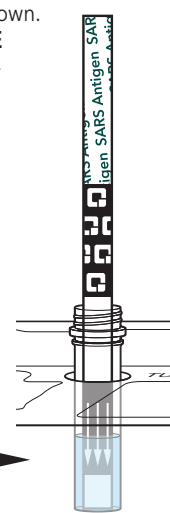
#### Place Test Strip in the Tube

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.



Leave strip  
in **at least**  
10 minutes!

Arrows  
pointing  
down

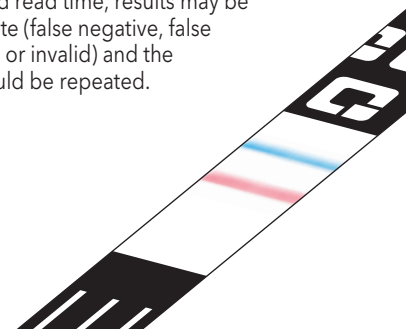


### STEP 8

#### Remove Test Strip from the Tube

At **TEN MINUTES**, remove the **TEST STRIP** from  
the **TUBE**. Next, place the **TEST STRIP** on the  
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

### 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.



#### 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.



Results shown at 2x.



#### Positive COVID-19 Result

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.

Continued on other side



# QuickVue<sup>®</sup>

## At-Home

### OTC COVID-19 Test

# USER INSTRUCTIONS

For Emergency Use Authorization (EUA) only.  
*In vitro* diagnostic use only.

Continued from other side

### 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.

**Negative Result**

A **NEGATIVE** result will show a **BLUE** line but **NO PINK** line.

#### 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.

### 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.

**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**.

#### Invalid COVID-19 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 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 833-QUICKVUE (833-784-2588) for assistance.

### STEP 13

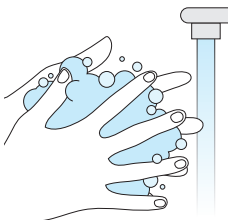
#### Dispose Used Test in the Trash

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.



**Please notify your healthcare provider of the results of your QuickVue At-Home OTC COVID-19 Test.**  
A second test should be obtained with at least 24 hours (and no more than 48 hours) between tests.

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

- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- 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 IVDs 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.
- For more information on EUAs go here: <https://www.fda.gov/emergency-preparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- 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 within 6-days of symptom onset or individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.
- 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-Alkyltrimethyl-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%

- 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. <https://www.poisson.org/contact-us> or 1-800-222-1222

### Intended Use

The QuickVue At-Home OTC COVID-19 Test is a lateral flow assay 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 with symptoms of COVID-19 within the first six days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first six days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 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. 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 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.

Persons 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.

All results should be provided to a healthcare provider for public health reporting.

The QuickVue At-Home OTC COVID-19 Test is intended 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. The QuickVue At-Home OTC COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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

**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 OTC 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 24-48 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.

### 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. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

#### 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. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

#### 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.

*The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.*

### Assistance

If the test does not perform as expected, call 833-QUICKVUE (833-784-2588).



Quidel Corporation  
10165 McKellar Court, San Diego, CA 92121 USA  
[quidel.com](http://quidel.com)



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

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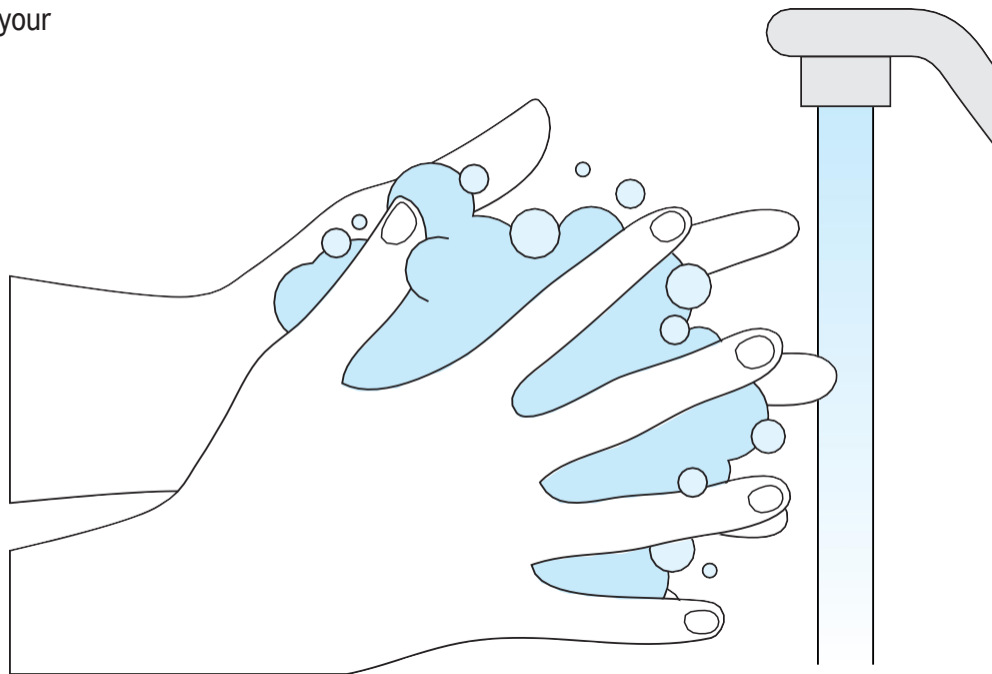
RAPID RESULTS IN



## 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**



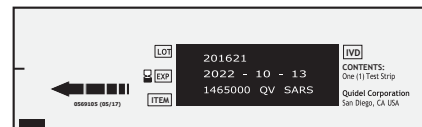
**Tube Holder**



**Swabs**



**Watch or Timer**  
(not included)

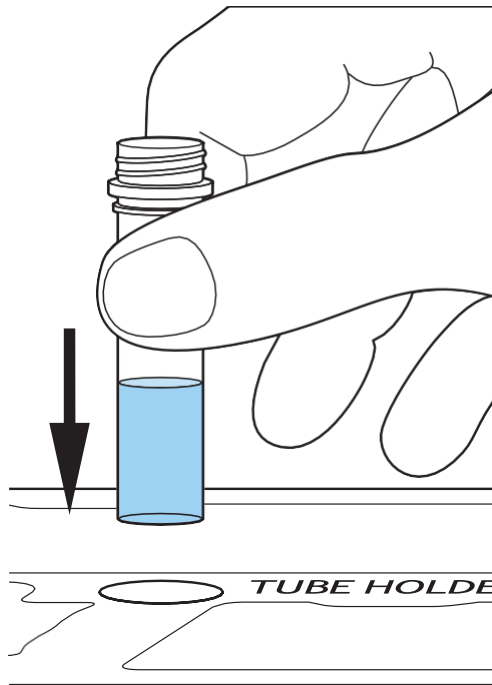


**Test Strips**

## STEP 2: Place Tube in the Tube Holder

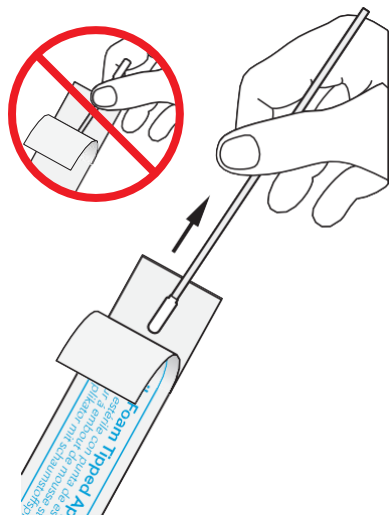
Remove cap from one **TUBE** and place it in the **TUBE HOLDER**.

**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.

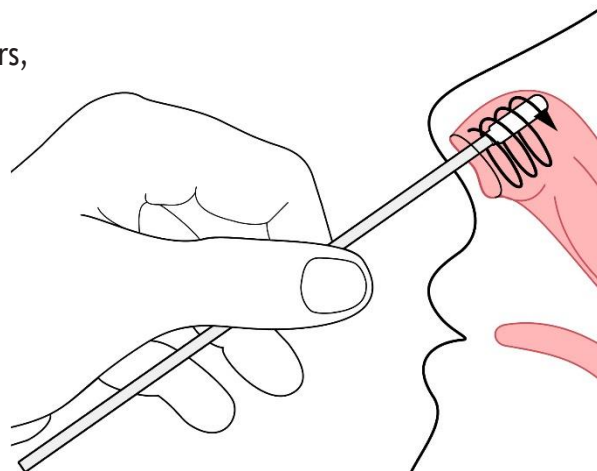


- B** Gently insert the **SWAB**  $\frac{1}{2}$  to  $\frac{3}{4}$  of an inch into the nostril, depending on the size of the person's nose. Firmly rub the **SWAB** in a circular motion around the inside wall of **EACH NOSTRIL at least 4 times**.

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

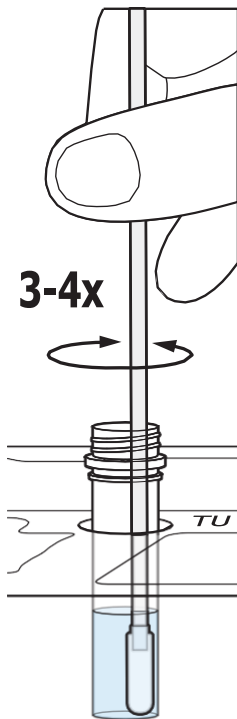
**NOTE:** If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

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



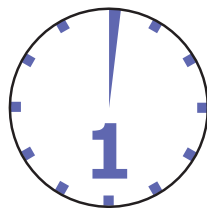
## STEP 4: Place Swab in the Tube

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

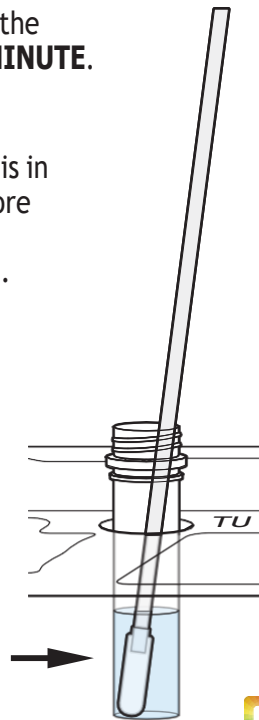


- B** Leave the swab in the solution for **ONE MINUTE**.

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



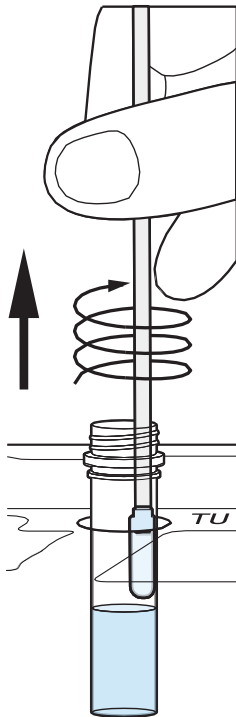
Leave swab in  
at least 1 minute!



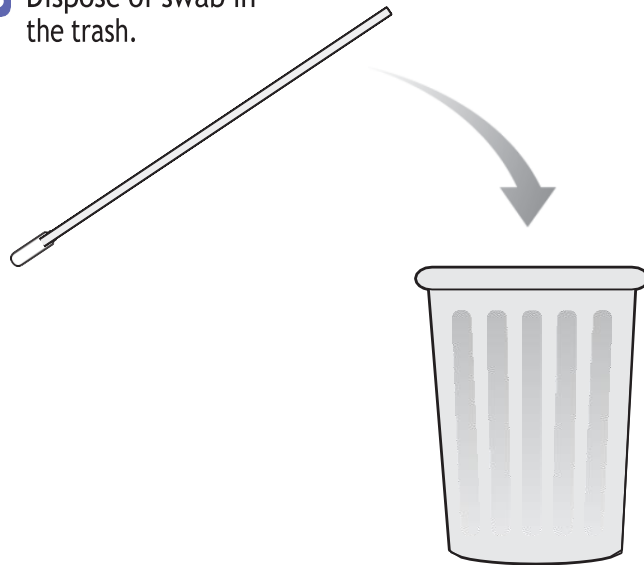


## STEP 5: Remove Swab from the Tube

- 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.

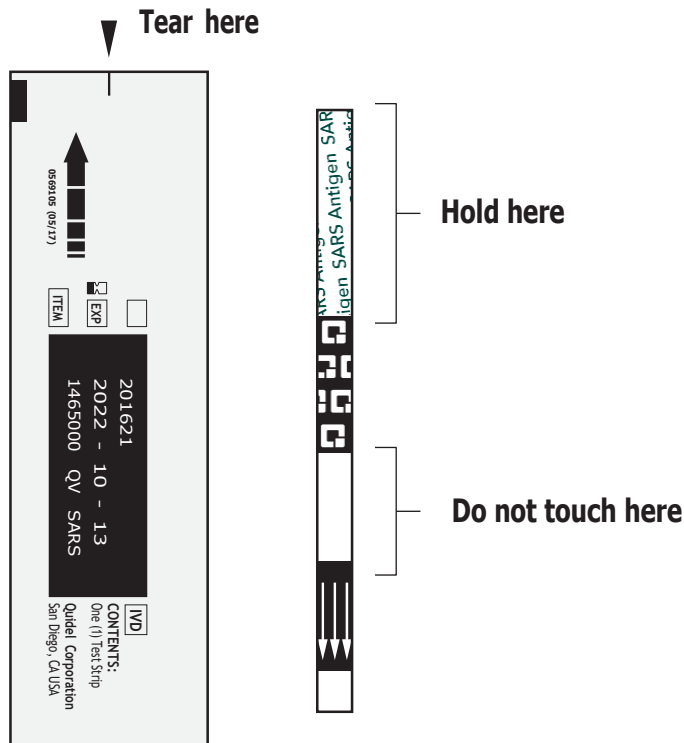


- B** Dispose of swab in the trash.



## STEP 6: Open the Test Strip

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



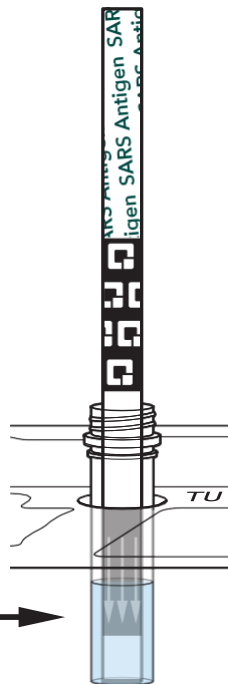
## STEP 7: Place Test Strip in the Tube

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.



Leave strip  
in **at least**  
10 minutes!

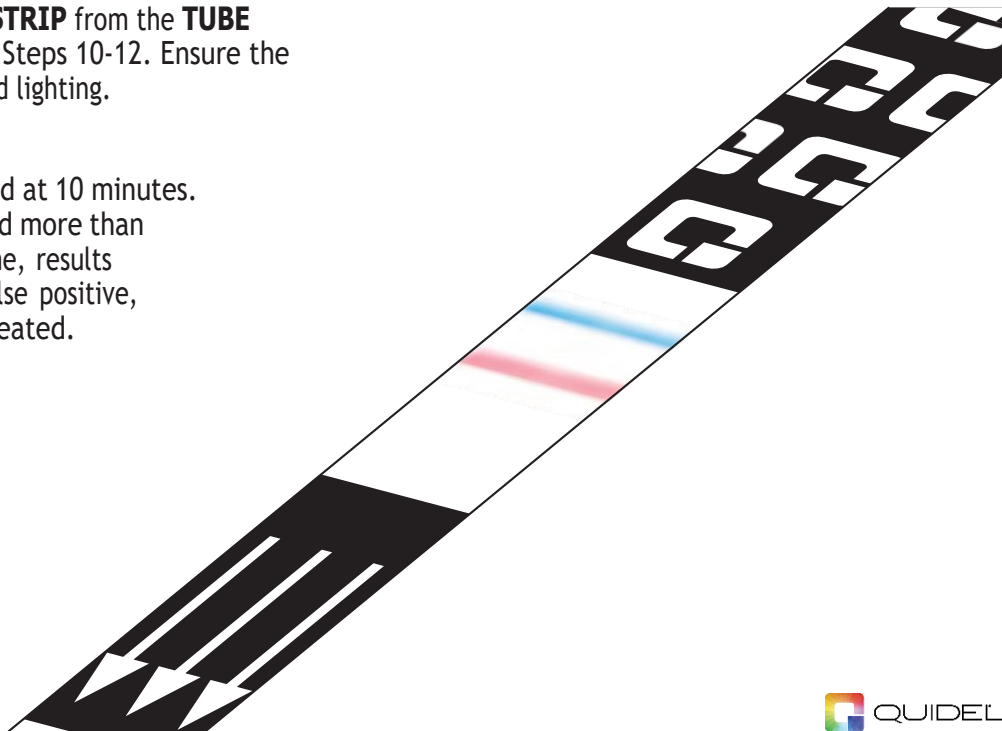
Arrows pointing down →



## 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

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There are three types of results possible.

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

## 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.

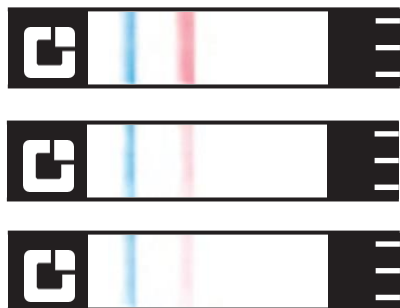


### *Positive Result*

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.**

Results shown at 2x.



## 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.



*Negative Result*

A **NEGATIVE** result will show a **BLUE** line but **NO PINK** line.

Results shown at 2x.





## Negative COVID-19 Result

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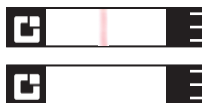
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.

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.

## 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.



### *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

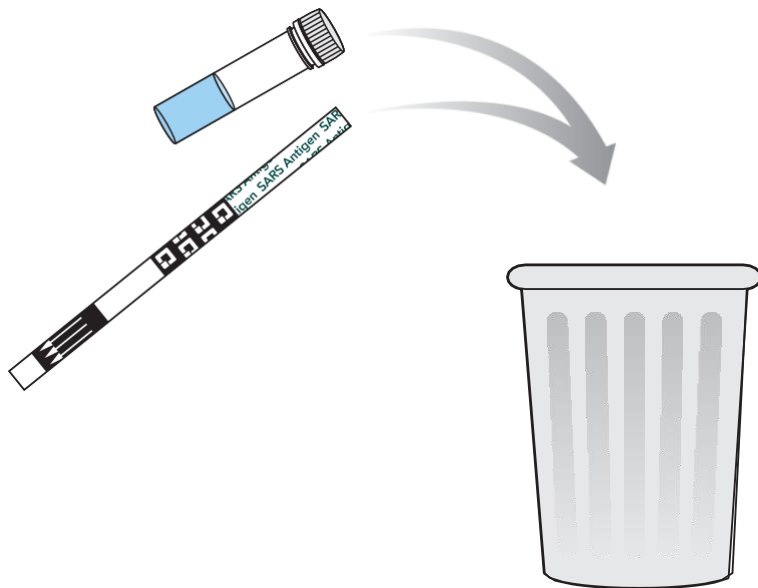
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If at 10 minutes, the blue Control Line does not appear, even if any shade of pink to-red Test Line appears, the result is invalid. If the Test Result is invalid, a new swab should be collected, and the test should be performed again with a new pre-filled tube and Test Strip.

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

## STEP 13: Dispose Used Test in the Trash

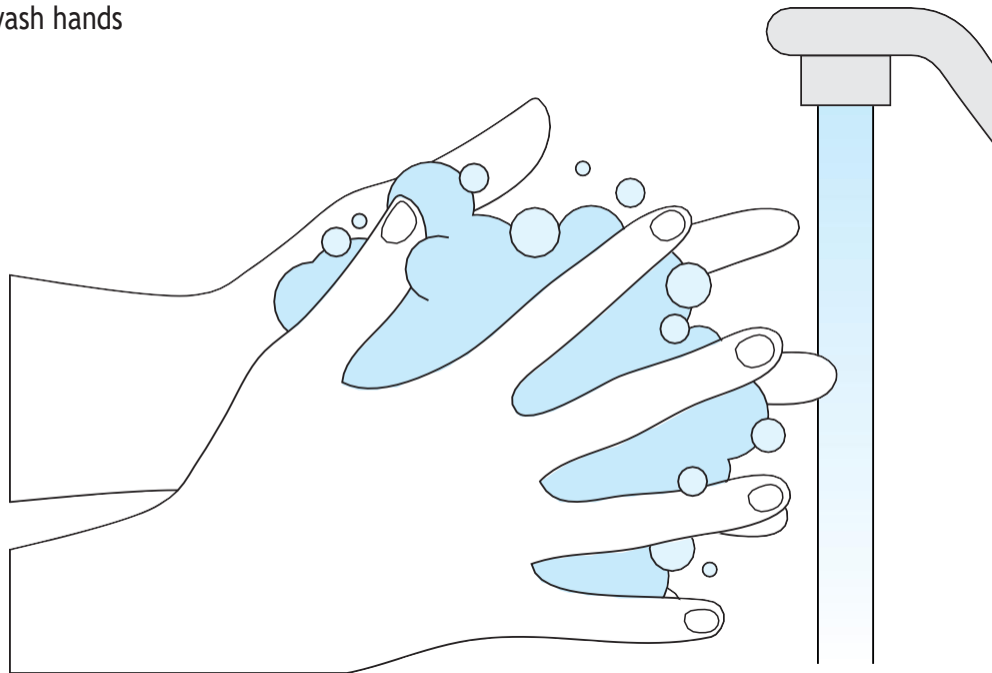
All used test components should be disposed of in your household waste.





## Wash Your hands

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



# The QuickVue At-Home OTC COVID-19 Test is for FDA Emergency Use Authorization (EUA) Only

## For *In Vitro* Diagnostic (IVD) Use.

- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- 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 IVDs 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.
- For more information on EUAs go here:  
*<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>*
- For the most up to date information on COVID-19, please visit: [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

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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 within 6-days of symptom onset or individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

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® 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. <https://www.poison.org/contact-us> or 1-800-222-1222

The QuickVue At-Home OTC COVID-19 Test is a lateral flow assay 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 with symptoms of COVID-19 within the first six days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first six days of symptom onset. This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 24 hours (and no more than 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. 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.

Persons 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.

All results should be provided to a healthcare provider for public health reporting.

The QuickVue At-Home OTC COVID-19 Test is intended 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. The QuickVue At-Home OTC COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

## 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 OTC 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 24-48 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.

# 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. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

## 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. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.

## 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.

*The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations*



# QuickVue<sup>®</sup>

## At-Home

### OTC COVID-19 Test

# USER INSTRUCTIONS

A second test should be obtained with at least 24 hours  
(and no more than 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,  
call 833-QUICKVUE (833-784-2588).

RAPID RESULTS IN



**Quidel Corporation**  
10165 McKellar Court, San Diego, CA 92121 USA  
**quidel.com**

1479704EN00 (04/22)





QuickVue®  
At-Home  
OTC COVID-19 Test

RAPID RESULTS IN  
10 MINS



FAST. EASY. READY WHEN YOU ARE.

1  
TEST



QuickVue®  
At-Home  
OTC COVID-19 Test

- One (1) test with simple instructions
  - You may need to purchase additional tests to perform this serial (repeat) testing.
- .....
- Uno (1) prueba con instrucciones sencillas
  - Es posible que deba comprar pruebas adicionales para realizar esta prueba en serie (repetición).

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

RAPID RESULTS IN  
10 MINS

FOR USE UNDER EMERGENCY  
USE AUTHORIZATION



Quidel Corporation  
10165 McKellar Court,  
San Diego, CA 92121 USA  
quidel.com

REF 20431

IVD

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OTC COVID-19 Test



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OTC COVID-19 Test

FAST. EASY. READY WHEN YOU ARE.

1  
TEST



QuickVue®  
At-Home  
OTC COVID-19 Test



RAPID RESULTS IN  
10 MINS

Creamos la prueba QuickVue At-Home OTC COVID-19 Test para que pueda obtener resultados rápidos y fáciles de entender en casa, sin procedimientos complicados ni capacitación extensa. Todo lo que necesita está en este paquete.

Contiene una (1) hisopo nasal, una (1) tira reactiva, una (1) hoja informativa para individuos, para tubos, una (1) instrucciones para el usuario y una (1) tubo pre-llenado para analizar la muestra anterior de la nariz.

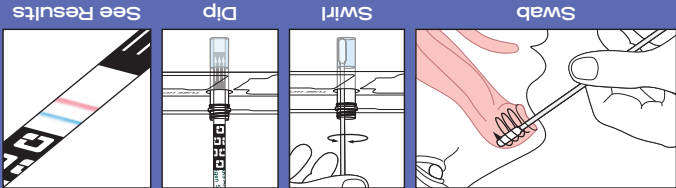
Para mayores de 2 años. Para las edades de 2 a 14, un adulto debe recolectar y analizar la muestra anterior de la nariz.

Este producto no ha sido autorizado o aprobado por la FDA, pero ha sido autorizado por la FDA bajo autorización de uso de emergencia (EUA) para la detección de proteínas de SARS-CoV-2, no para otros virus o patógenos. Este producto solo está autorizado por la duración de la declaración que existen circunstancias que justifiquen la autorización del uso de esta autorización de emergencia de COVID-19 bajo la Sección 564 (b) (1) de la Ley Federal de Alimentos, Medicamentos y Ley de Cosméticos, 21 U.S.C. § 360bb-3 (b) (1), a menos que la autorización sea cancelada o revocada antes.

Manufactured by Quidel, trusted maker of medical diagnostic tests for over 40 years.

For more information, call 833-QUICKVUE (833-784-2588) or visit us at QuickVueAtHome.com

Para obtener más información, llame al 833-QUICKVUE (833-784-2588) o visitemos en QuickVueAtHome.com



Scan QR code with phone camera to learn more.

Escanee el código QR con la cámara del teléfono para obtener más información.



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We created the QuickVue At-Home OTC COVID-19 Test so you can get fast, easy-to-understand results at home, without complicated procedures or extensive training. Everything you need is in this package.

Contains one (1) nasal swab, one (1) test strip, one (1) pre-filled tube, one (1) tube holder, one (1) user instructions and one (1) fact sheet for individuals.

For ages 2 and up. For ages 2 to 14, an adult must collect and test the anterior nares specimen.

This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). 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. § 360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



QuickVue®  
At-Home  
OTC COVID-19 Test

RAPID RESULTS IN  
**10**  
MINS



FAST. EASY. READY WHEN YOU ARE.

**2**  
TESTS



# QuickVue® At-Home OTC COVID-19 Test

- Two (2) tests with simple instructions
- The test is intended to be used twice over two to three days, with at least 24 hours and no more than 48 hours between tests.

- Dos (2) pruebas con instrucciones sencillas
- La prueba está diseñada para usarse dos veces durante dos o tres días, con al menos 24 horas y no más de 48 horas entre pruebas.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

RAPID RESULTS IN  
**10**  
MINS

FOR USE UNDER EMERGENCY  
USE AUTHORIZATION



Quidel Corporation  
10165 McKellar Court,  
San Diego, CA 92121 USA  
quidel.com

REF 20402

IVD

QuickVue®  
At-Home  
OTC COVID-19 Test



QuickVue®  
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OTC COVID-19 Test

FAST. EASY. READY WHEN YOU ARE.

**2**  
TESTS

1490702 (10/21)



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At-Home  
OTC COVID-19 Test



Creamos la prueba QuickVue At-Home OTC COVID-19 Test para que pueda obtener resultados rápidos y fáciles de entender en casa, sin procedimientos complicados ni capacitación extensa. Todo lo que necesita está en este paquete.

Contiene dos (2) hisopos nasales, dos (2) tiras reactivas, dos (2) tubos precargados, un (1) soporte para tubos, una (1) instrucciones para el usuario y una (1) hoja informativa para individuos.

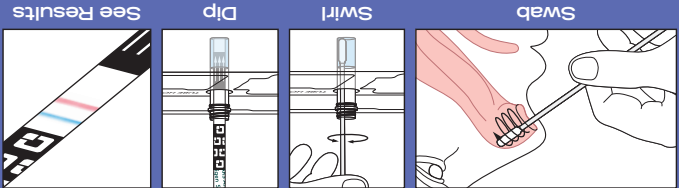
Para mayores de 2 años. Para las edades de 2 a 14, un adulto debe recolectar y analizar la muestra anterior de la nariz.

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Manufactured by Quidel, trusted maker of medical diagnostic tests for over 40 years.

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Scan QR code with phone  
camera to learn more.

Escanee el código QR con la cámara del  
teléfono para obtener más información.



Keep testing kit and kit components out of  
the reach of children before and after use.

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We created the QuickVue At-Home OTC COVID-19 Test so you can get fast, easy-to-understand results at home, without complicated procedures or extensive training. Everything you need is in this package.

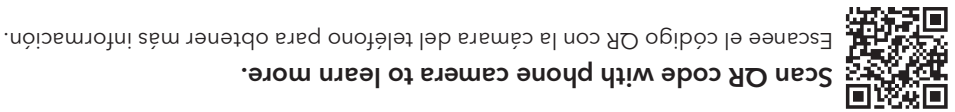
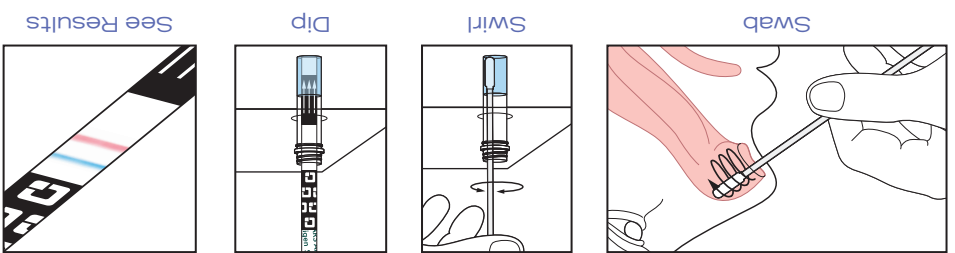
Contains two (2) nasal swabs, two (2) test strips, two (2) pre-filled tubes, one (1) tube holder, one (1) user instructions and one (1) fact sheet for individuals.

For ages 2 and up. For ages 2 to 14, an adult must collect and test the anterior nares specimen.



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QuickVue<sup>®</sup>



FAST. EASY. READY WHEN YOU ARE.

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

RAPID RESULTS IN  
10  
MINS



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

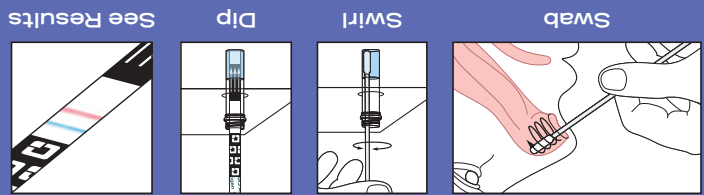
RAPID RESULTS IN  
10  
MINS

- Ten (10) tests with simple instructions
  - The test is intended to be used twice over two to three days, with at least 24 hours and no more than 48 hours between tests.
- Diez (10) pruebas con instrucciones sencillas
- La prueba está diseñada para usarse dos veces durante dos o tres días, con al menos 24 horas y no más de 48 horas entre pruebas.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests (multiple separate tests may need to be used). Do not use tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

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QUIDEL



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For more information, call 833-QUICKVUE (833-784-2588) or visit us at QuickVueAtHome.com.  
Para obtener más información, llame al 833-QUICKVUE (833-784-2588) o visítanos en QuickVueAtHome.com.



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FOR USE UNDER EMERGENCY USE AUTHORIZATION

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FAST. EASY. READY WHEN YOU ARE.

10  
TESTS

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

RAPID RESULTS IN  
10  
MINS

Be prepared whenever testing is required

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

Keep testing kit and kit components out of the reach of children before and after use.

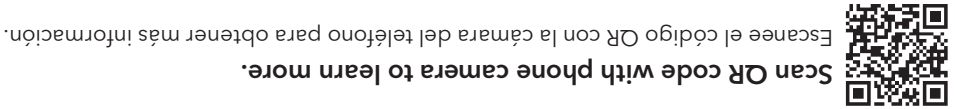
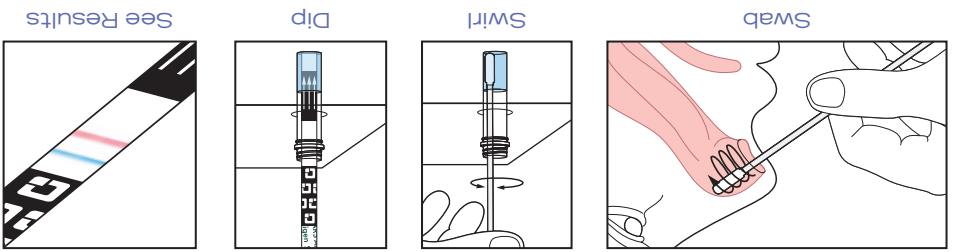
1515901 (10/21)

Contains ten (10) nasal swabs, ten (10) test strips, ten (10) pre-filled tubes, one (1) tube holder, one (1) user instructions and one (1) fact sheet for individuals.  
Contiene diez (10) hisopos nasales, diez (10) tiras reactivas, diez (10) tubos precargados, un (1) soporte para tubos, una (1) hoja informativa para individuos.  
Para mayores de 2 años. Para las edades de 2 a 14, un adulto debe recolectar y analizar la muestra anterior de la nariz.  
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QuickVue<sup>®</sup>



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At-Home  
OTC COVID-19 Test

RAPID RESULTS IN  
10 MINS



FAST. EASY. READY WHEN YOU ARE.

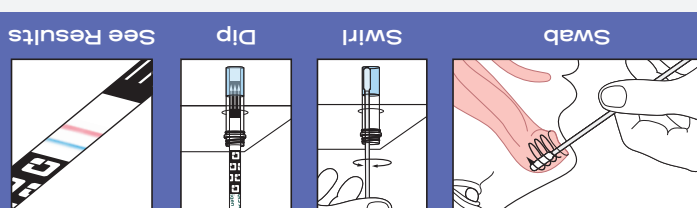
25  
TESTS

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

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Escanee el código QR con la cámara del teléfono para obtener más información.

QUIDEL<sup>®</sup>



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FOR USE UNDER EMERGENCY USE AUTHORIZATION

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

15°C  
98°F  
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QUIDEL<sup>®</sup>

FAST. EASY. READY WHEN YOU ARE.

25  
TESTS

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

RAPID RESULTS IN  
10 MINS

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

Be prepared whenever testing is required

Keep testing kit and kit components out of the reach of children before and after use.

1486502 (10/21)

This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of protein from SARS-CoV-2, not for any other disease or diagnosis. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use in the detection, diagnosis, and/or treatment of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 (b)(1), and the declaration of the Secretary of Health and Human Services under the authority of the President of the United States.