QUIDEL

QuickVue® At-Home OTC COVID-19 Test

USER INSTRUCTIONS

For Emergency Use Authorization (EUA) only.
***In vitro* diagnostic use only.**
Store at Room Temperature,
59°F to 86°F (15°C to 30°C)

RAPID RESULTS IN 10 MINS

QuickVue At-Home OTC COVID-19 Test

Using our mobile app (optional)

For a stress-free testing experience download the QVue™ mobile app

QVue helps you **INTERPRET**, **SAVE**, and **SHARE** your **RESULTS**.

1. Visual step-by-step instructions to perform the test
2. Guided test result interpretation steps
3. Save, share, and send your result

IMPORTANT: Timing is essential for accurate test results. Therefore, we suggest using EITHER the guided app experience OR these printed instructions to perform the entire test procedure. The QVue app has convenient built-in
timers, but you cannot skip the countdown once initiated.

(Requires iOS 13.0 or later, Android 9.0 or later)

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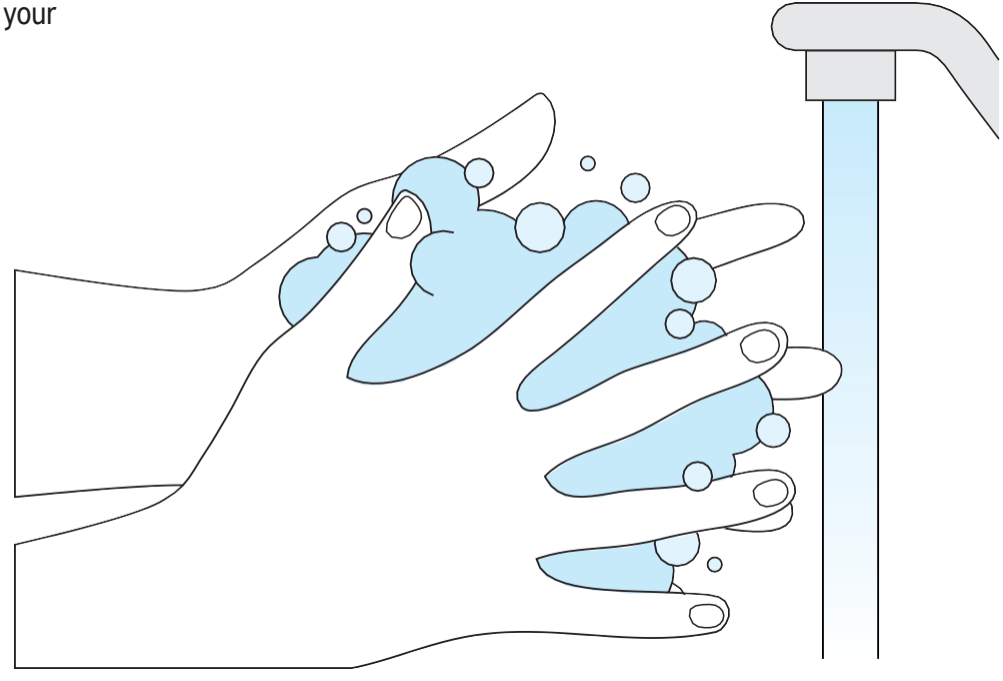
Wash Your hands

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

Make sure your hands are dry before starting.



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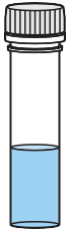
STEP 1:
Check Your Test Kit

Locate the kit components:

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

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

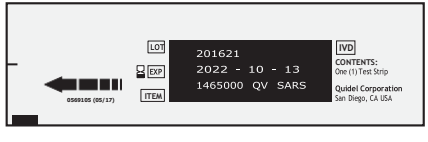


Tubes

Tube Holder

Swabs

Watch or Timer
(not included)



Test Strips

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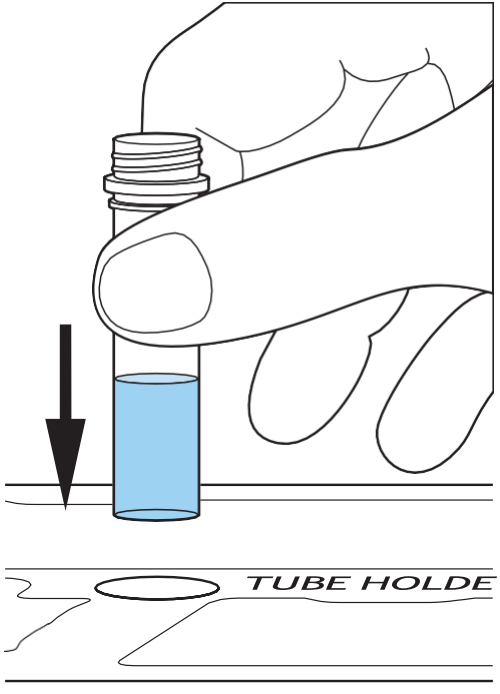
STEP 2:
Place Tube in the Tube Holder

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

NOTE: Use of gloves is recommended.



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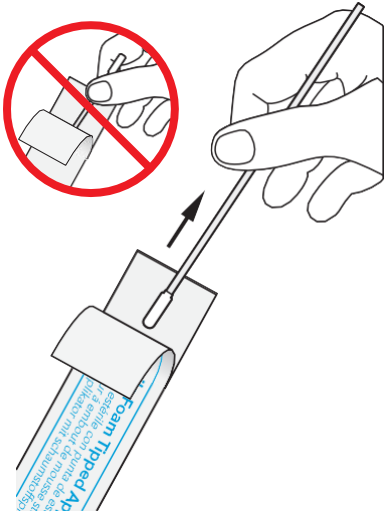
STEP 3:
Swab the Nostrils

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

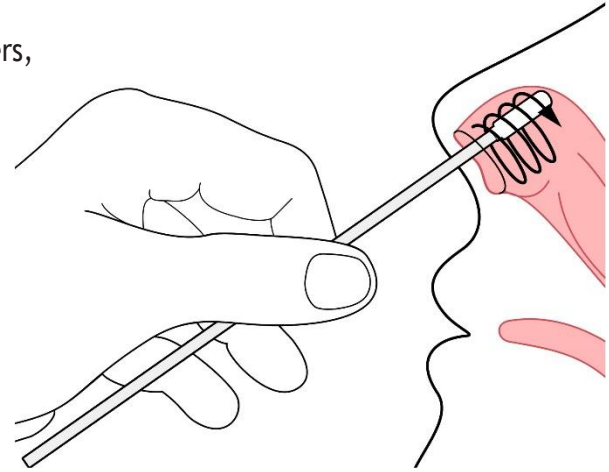


B Gently insert the **SWAB** ½ to ¾ of an inch into the nostril, depending on the size of the person's nose. Firmly rub the **SWAB** in a circular motion around the inside wall of **EACH NOSTRIL at least 4 times**.

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.



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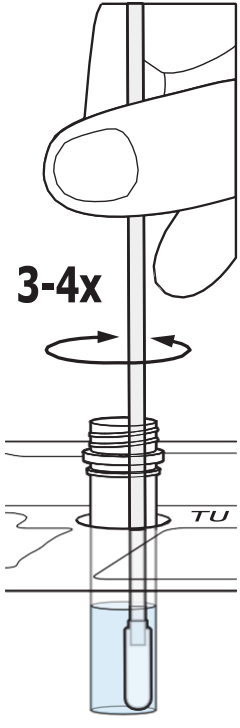
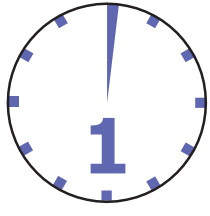
STEP 4:
Place Swab in the Tube

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

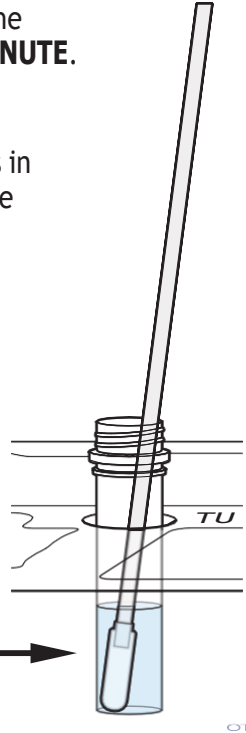


B Leave the swab in the solution for **ONE MINUTE**.

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!



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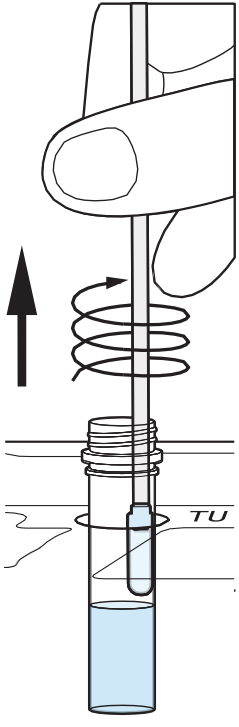
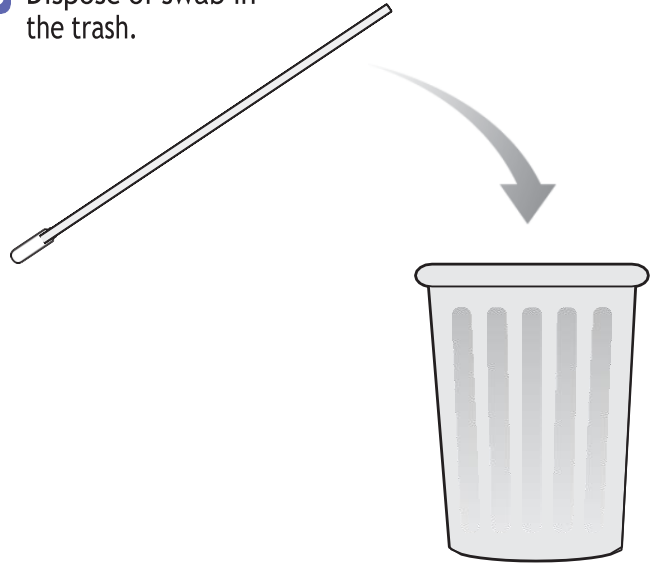
STEP 5:
Remove Swab from the Tube

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.



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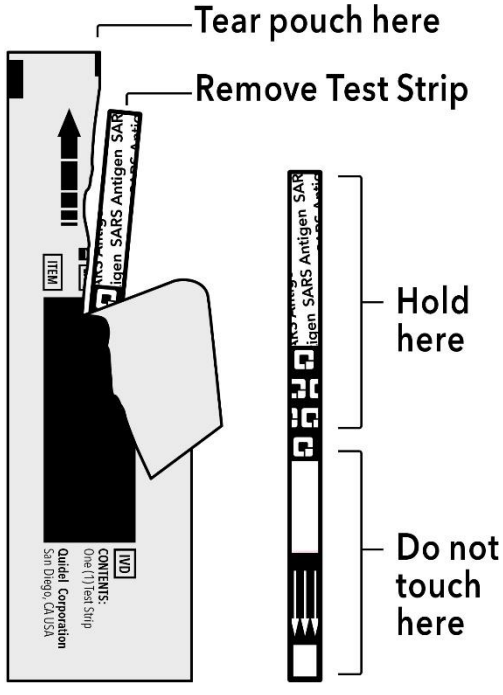
STEP 6:
Open the Test Strip

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



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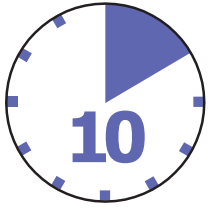
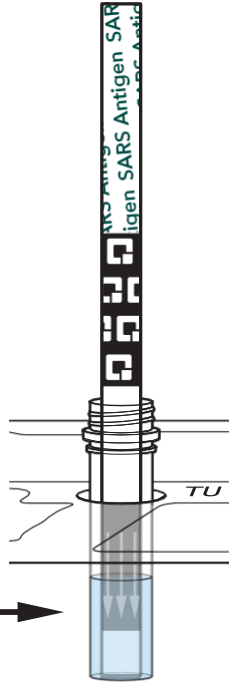
STEP 7:
Place Test Strip in the Tube

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 →

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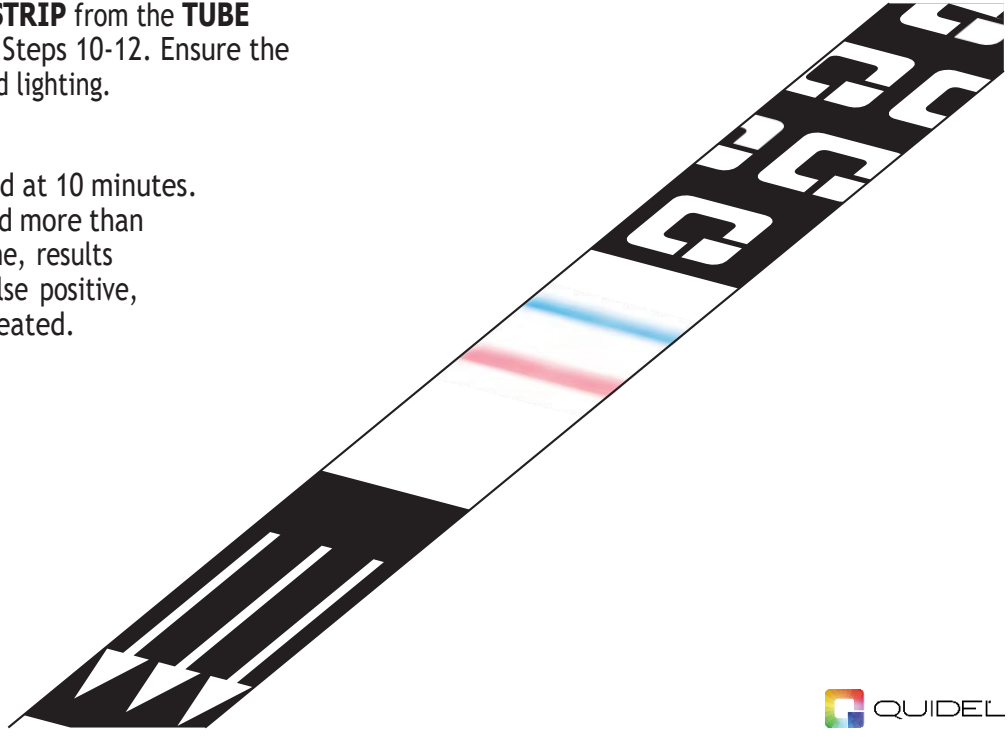
STEP 8:
Remove Test Strip from the Tube

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.



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STEP 9:
Check Your Results

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**

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STEP 9:
Check Your Results

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

Status on First Day of Testing	First Result Day 1	Second Result Day 3	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

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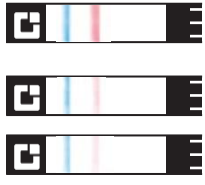
STEP 10:
Check for a Positive COVID-19 Result

Place the **TEST STRIP** on the test strip outline below and compare it with the 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 Lineand a blue Control Line is a POSITIVE result. Pink shading or a line near the labels on the strip is not considered a positive result.

You do not need to perform repeat testing if you have a positive result at any time.

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Positive COVID-19 Result

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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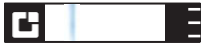
STEP 11:
Check for a Negative COVID-19 Result

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.

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

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

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Negative COVID-19 Result

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. 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 you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow-up care with your healthcare provider.

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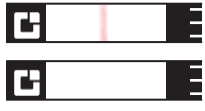
STEP 12:
Check for an Invalid COVID-19 Result

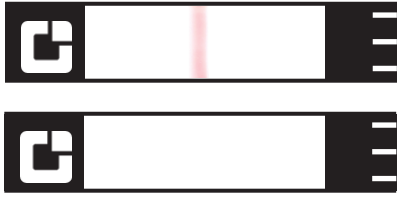
Place the **TEST STRIP** on the test strip outline below and compare with test result examples shown.



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.



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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.

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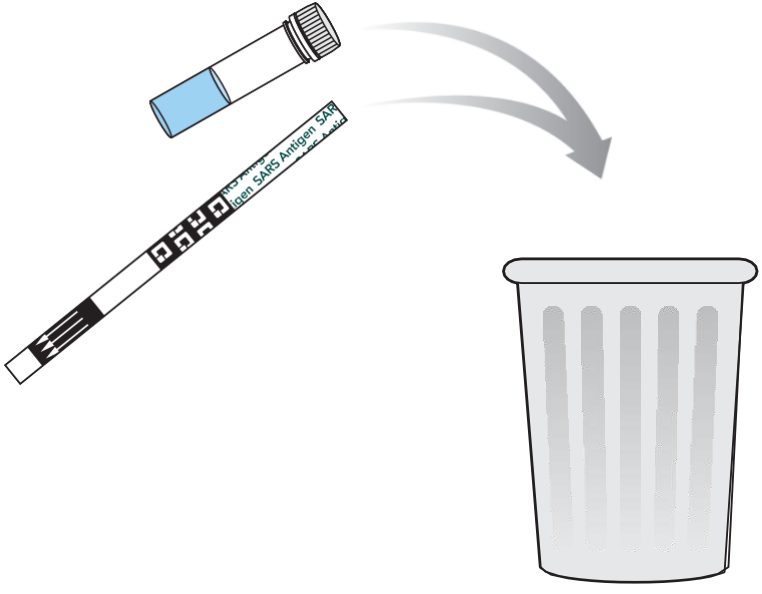
STEP 13:
Dispose Used Test in the Trash

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



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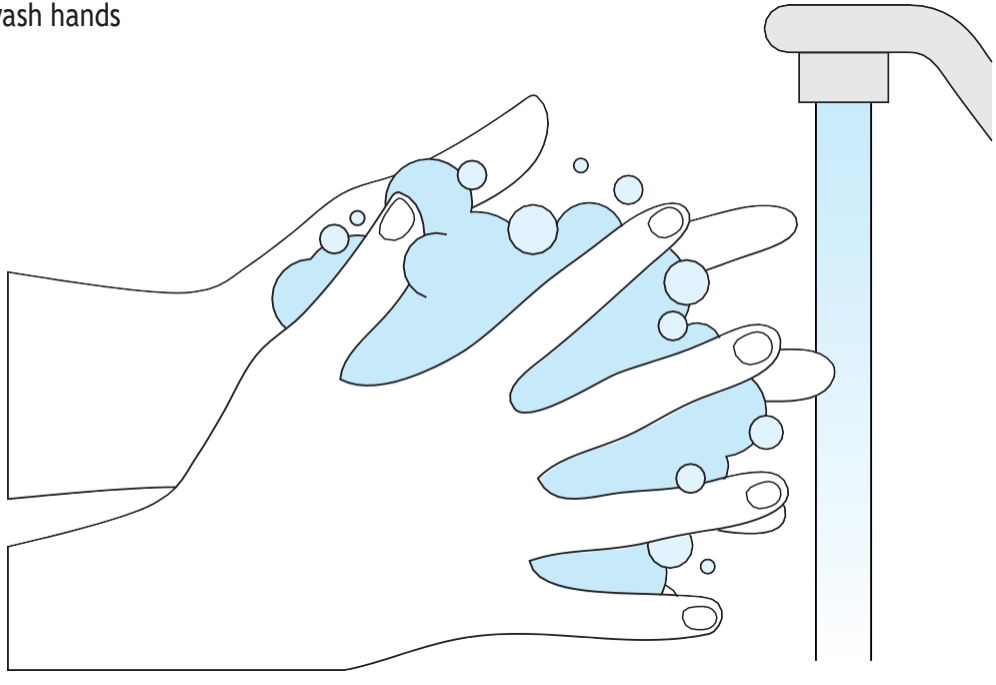
Wash Your hands

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



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How To Use This Test

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but 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 your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

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Warnings, Precautions and Safety Information

- Read the written instructions fully before starting the test procedure. Failure to follow the instructions may result in inaccurate 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 14 years and older. Children aged 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.

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Warnings, Precautions and Safety Information

- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test strip must be used within 60 minutes.
- 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
- Do not read test results before 10 minutes. Results read before 10 minutes or after 15 minutes may lead to false positive, false negative, or invalid results.
- Keep testing kit and kit components away from children and pets before and after use.
- Avoid contact with your skin, or eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see Hazardous Ingredients for Liquid Reagent 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: https://www.cdc.gov/COVID19
- For detailed instructions, please visit https://www.quickvueathome.com.

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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%

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Limitations

- 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.
- 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 SARSCoV-2 and their prevalence, which change over time.
- 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.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have 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.

QuickVue At-Home OTC COVID-19 Test

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. 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.

QuickVue At-Home OTC COVID-19 Test

Frequently Asked Questions

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 Warnings and Results Interpretation sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcareprovider 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.

  For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the QuickVue At-Home OTC COVID-19 Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

How Accurate is this Test?

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. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.quickvueathome.com .

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Frequently Asked Questions

What if I have a Positive Test Result?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a Negative Test Result?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARSCoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an Invalid Test result mean?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

QUIDEL

QUIDEL

QuickVue® At-Home OTC COVID-19 Test

USER INSTRUCTIONS

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 10 MINS

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

1479705EN00 (01/23)

QuickVue® At-Home OTC COVID-19 Test

USER INSTRUCTIONS

For Emergency Use Authorization (EUA) only.

***In vitro* diagnostic use only.**

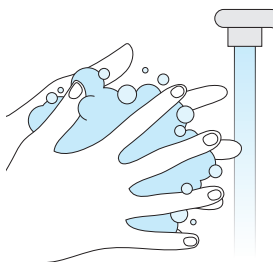
Take your test, lose the stress.
Scan the QR code to download QVue,™ the optional mobile app that makes your testing experience easier than ever.
(Requires iOS 13.0 or later, Android 9.0 or later)

Store at Room Temperature, 59°F to 86°F (15°C to 30°C)

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

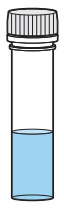
Locate the kit components:

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

Check 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*

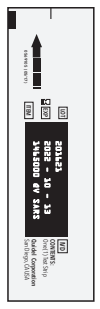
Tube Holder



Tubes

Swabs

Watch or Timer (not included)



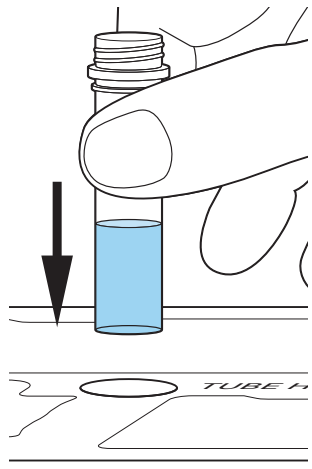
Test Strips

STEP 2

Place Tube in the Tube Holder

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

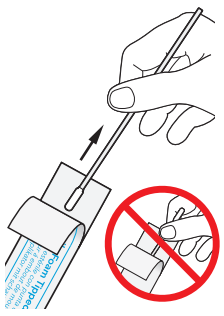
NOTE: Use of gloves is recommended.



STEP 3

Swab the Nostrils

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

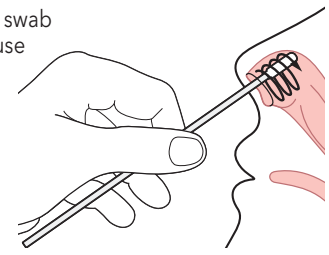


B Gently insert the **SWAB** ½ to ¾ of an inch into the nostril, depending on the size of the person's nose. Firmly rub the **SWAB** in a circular motion around the inside wall of **EACH NOSTRIL at least 4 times**.

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.

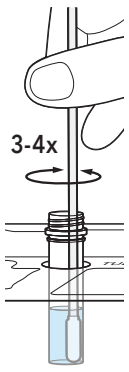
NOTE: Failure to swab properly may cause false negative results.



STEP 4

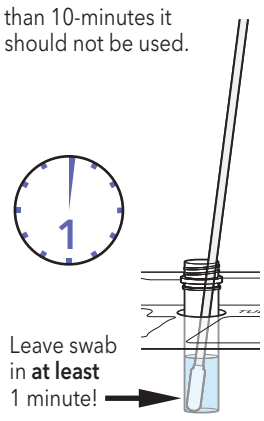
Place Swab in the Tube

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**.

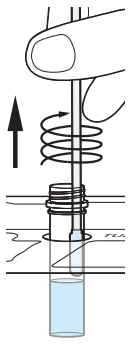
NOTE: If the swab is in the solution for more than 10-minutes it should not be used.



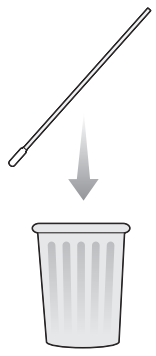
STEP 5

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.



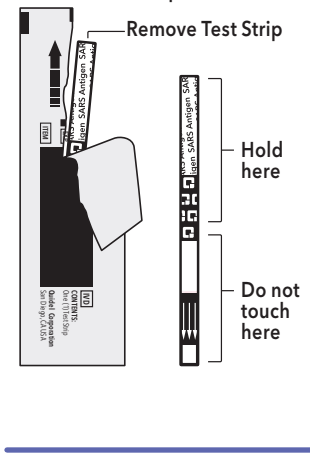
B Dispose of swab in the trash.



STEP 6

Open the Test Strip

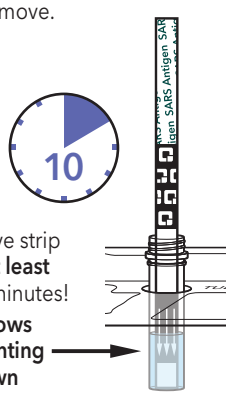
Open the **TEST STRIP** pouch carefully at the slit and hold the **TEST STRIP** as indicated.



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.

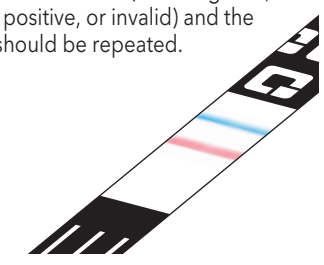


STEP 8

Remove Test Strip from the Tube

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

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

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.

You do not need to perform repeat testing if you have a positive result at any time.

Results shown at 2x.

Positive COVID-19 Result

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Continued on other side

QuickVue® 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.

To increase the chance that the negative result for COVID-19 is accurate, you should:
- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

Negative COVID-19 Result

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. 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 you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow-up care with your healthcare provider.

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.

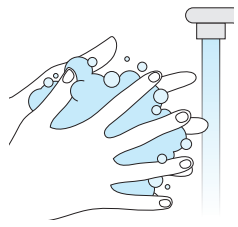
STEP 13

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.

How To Use This Test

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but 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 your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Warnings, Precautions and Safety Information

- Read the written instructions fully before starting the test procedure. Failure to follow the instructions may result in inaccurate 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 14 years and older. Children aged 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear 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.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test strip must be used within 60 minutes.
- 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
- Do not read test results before 10 minutes. Results read before 10 minutes or after 15 minutes may lead to false positive, false negative, or invalid results.
- Keep testing kit and kit components away from children and pets before and after use
- Avoid contact with your skin, or eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see Hazardous Ingredients for Liquid Reagent 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
- For detailed instructions, please visit www.quickvueathome.com.

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%

Limitations

- 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.
- 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 SARSCoV-2 and their prevalence, which change over time.
- 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.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have 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.

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.

Frequently Asked Questions

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 Warnings and Results Interpretation sections for more information).

Potential benefits include:
- The results, along with other information, can help you and 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. For more information on EUAs go here: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization*

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

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the QuickVue At-Home OTC COVID-19 Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

How Accurate is this Test?

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. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.quickvueathome.com.

What if I have a Positive Test Result?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a Negative Test Result?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARSCoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an Invalid Test result mean?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

Assistance

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

Manufactured by:
Quidel Corporation10165 McKellar Court, San Diego, CA 92121 USA, **quidel.com**

QUIDEL | QuickVue® At-Home OTC COVID-19 Test

RAPID RESULTS IN 10 MINS

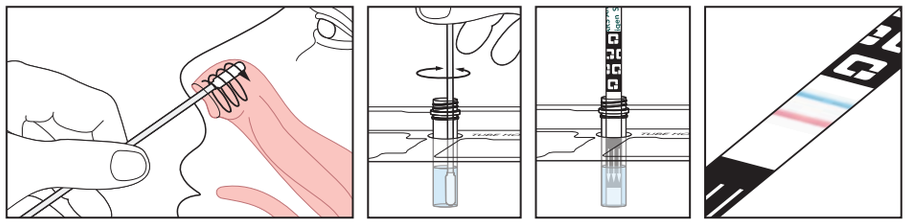
We created the QuickVue At-Home OTC COVID-19 Test so you can get fast, easy-to-understand results at home, without complicated procedures or extensive training. Everything you need is in this package.

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

Items necessary to use the test but not provided: Watch or Timer

Para instrucciones en Español, visite QuickVueAtHome.com.

For ages 2 and up. For ages 2 to 14, an adult must collect and test the anterior nares specimen. Keep testing kit and kit components out of the reach of children before and after use.



Swab | Swirl | Dip | See Results

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. Individuals with negative results who have symptoms of COVID-19, should test twice over three days with at least 48 hours between tests. Individuals with negative results who do not have symptoms of COVID-19, should test at least three times over five days with at least 48 hours between tests. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

In the USA, 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 *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.

For the most current expiration dates of this test, please refer to: *http://www.fda.gov/covid-tests*

LOT ######

EXP YYYY-MM-DD MFG YYYY-MM-DD

QUIDEL® | QuickVue® At-Home OTC COVID-19 Test

QUIDEL® | QuickVue® At-Home OTC COVID-19 Test

0 14613 33972 3

1490703 (02/23)

Manufactured by Quidel Corporation, trusted maker of medical diagnostic tests for over 40 years.
10165 McKellar Court, San Diego, CA 92121 USA
quidel.com

2 TESTS

For Emergency Use Authorization (EUA) only

Catalog Number 20402

Store between 59°–86°F (15°–30°C)

For *in vitro* diagnostic use

RAPID RESULTS IN 10 MINS

Includes two (2) tests with simple instructions

QuickVue® At-Home OTC COVID-19 Test

FAST. EASY. READY WHEN YOU ARE.

2 TESTS

QUIDEL® | QuickVue® At-Home OTC COVID-19 Test

Scan to download QVue,™ the optional mobile app that makes your testing experience easier than ever.
(Requires iOS 13.0 or later, Android 9.0 or later)
For more information, call 833-QUICKVUE (833-784-2588)
or visit us at QuickVueAtHome.com

QUIDEL® | QuickVue® At-Home OTC COVID-19 Test

QUIDEL

QuickVue® At-Home OTC COVID-19 Test

2 TESTS

FAST. EASY. READY WHEN YOU ARE.

Includes two (2) tests with simple instructions

RAPID RESULTS IN 10 MINS

Manufactured by Quidel Corporation, trusted maker of medical diagnostic tests for over 40 years.
10165 McKellar Court, San Diego, CA 92121 USA
quidel.com

For Emergency Use Authorization (EUA) only

Catalog Number 20451

Store between
59°–86°F (15°–30°C)

For in vitro diagnostic use

154260O (02/23)

0 14613 34017 0

QUIDEL

QuickVue® At-Home OTC COVID-19 Test

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or visit us at QuickVueAtHome.com

QUIDEL

QuickVue® At-Home OTC COVID-19 Test

RAPID RESULTS IN 10 MINS

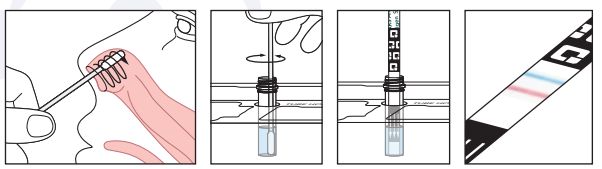
We created the QuickVue At-Home OTC COVID-19 Test so you can get fast, easy-to-understand results at home, without complicated procedures or extensive training. Everything you need is in this package.

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

Items necessary to use the test but not provided: Watch or Timer

Para instrucciones en Español, visite QuickVueAtHome.com.

For ages 2 and up. For ages 2 to 14, an adult must collect and test the anterior nares specimen. Keep testing kit and kit components out of the reach of children before and after use.



Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. Individuals with negative results who have symptoms of COVID-19, should test twice over three days with at least 48 hours between tests. Individuals with negative results who do not have symptoms of COVID-19, should test at least three times over five days with at least 48 hours between tests. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

In the USA, 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 *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.

For the most current expiration dates of this test, please refer to:
http://www.fda.gov/covid-tests

QUIDEL

QuickVue® At-Home OTC COVID-19 Test

QUIDEL

QuickVue®
At-Home
OTC COVID-19 Test

RAPID RESULTS IN 10 MINS

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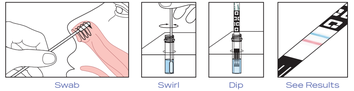

RAPID RESULTS IN 10 MINS

Includes ten (10) tests with simple instructions

QuickVue®
At-Home
OTC COVID-19 Test

FAST. EASY. READY WHEN YOU ARE.

10 TESTS

QUIDEL

QUIDEL

QuickVue®
At-Home
OTC COVID-19 Test

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 ten (10) nasal swabs, ten (10) test strips, one (1) tube rack containing ten (10) pre-filled tubes and one (1) user instructions.

Items necessary to use the test but not provided: Watch or Timer

Para instrucciones en Español, visite QuickVueAtHome.com.

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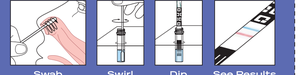

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quidel.com

0 14613 33996 8

For Emergency Use Authorization (EUA) only

Catalog Number 20427

Store between 59°-86°F (15°-30°C)

For *in vitro* diagnostic use

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FAST. EASY. READY WHEN YOU ARE.

10 TESTS

Be prepared whenever testing is required

RAPID RESULTS IN 10 MINS

QuickVue®
At-Home
OTC COVID-19 Test

1515902 (02/23)

QUIDEL

QuickVue®
At-Home
OTC COVID-19 Test

RAPID RESULTS IN 10 MINS

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. Individuals with negative results who have symptoms of COVID-19, should test twice over three days with at least 48 hours between tests. Individuals with negative results who do not have symptoms of COVID-19, should test at least three times over five days with at least 48 hours between tests. 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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For the most current expiration dates of this test, please refer to: *http://www.fda.gov/covid-tests*

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QuickVue®
At-Home
OTC COVID-19 Test

RAPID RESULTS IN 10 MINS

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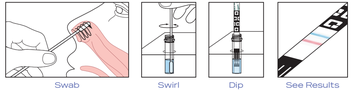

RAPID RESULTS IN 10 MINS

Includes twenty-five (25) tests with simple instructions

QuickVue®
At-Home
OTC COVID-19 Test

FAST. EASY. READY WHEN YOU ARE.

25 TESTS

QUIDEL

QUIDEL

QuickVue®
At-Home
OTC COVID-19 Test

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 twenty-five (25) nasal swabs, twenty-five (25) test strips, one (1) tube rack containing twenty-five (25) pre-filled tubes and one (1) user instructions.
Items necessary to use the test but not provided: Watch or Timer
Para instrucciones en Español, visite QuickVueAtHome.com.
For ages 2 and up. For ages 2 to 14, an adult must collect and test the anterior nares specimen.
Keep testing kit and kit components out of the reach of children before and after use.

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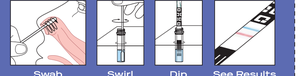

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For Emergency Use Authorization (EUA) only

Catalog Number 20398

Store between 59°-86°F (15°-30°C)

For *in vitro* diagnostic use

QUIDEL

FAST. EASY. READY WHEN YOU ARE. 25 TESTS

Be prepared whenever testing is required

RAPID RESULTS IN 10 MINS

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OTC COVID-19 Test

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1486502 (02/23)