

COVID-19 Test User Instructions

For *in vitro* diagnostic use.

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

Using Our Mobile App (Optional)

Scan QR code to get digital instructions and to download the QVue® mobile app for a stress-free testing experience.

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



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.

WARNING: Failure to follow the instructions may result in inaccurate test results.

Step 1: Wash Your Hands

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



Step 2: Check Your Test Kit

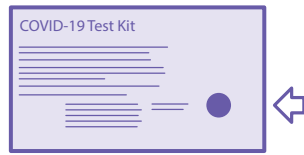
Check the expiration date at the back of the box in the bottom right corner with EXP next to it.

WARNING: Do not use the kit past its expiration date.

Find the kit components.

Materials required but not provided: A watch or timer.

Recommended materials: Disposable gloves, mask if swabbing others.



Tube Holder (back of box)



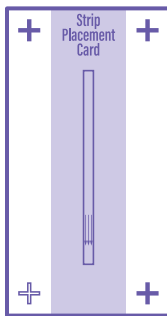
Tube



Test Strip



Swab



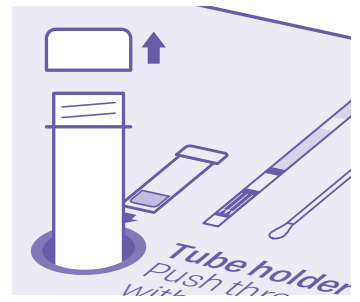
Strip Placement Card

Step 3: Place Tube in the Tube Holder

Locate the hole for the tube holder at the back of the box.

Gently push the tube through the hole.

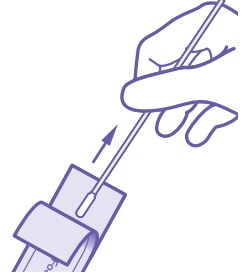
Then remove the cap from the tube.



Step 4: Swab the Nostrils

A Remove the swab from its wrapper.

WARNING: Be careful not to touch the swab head.

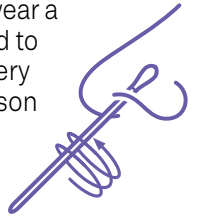


B Gently insert the swab ½ to ¾ of an inch into the nostril, depending on the size of the person's nose.

Firmly rub the swab in a circular motion around the inside wall of **EACH NOSTRIL** at least 4 times.

STOP: 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.



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

Step 5: Place Swab in the Tube

A Immediately place the swab into the liquid inside the tube.

Ensure it is touching the bottom.

Stir 3-4 times.



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

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

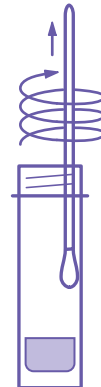


Leave swab in **at least** 1 minute!

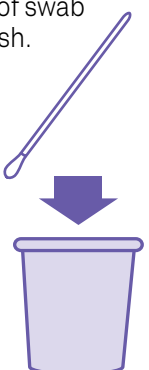


Step 6: Remove Swab from the Tube

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.

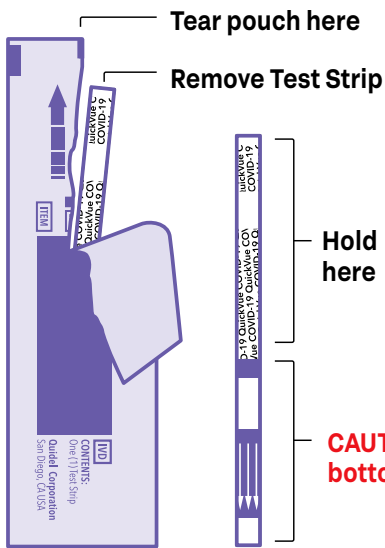


B Dispose of swab in the trash.



Step 7: Open the Test Strip

Hold the test strip pouch with the arrow pointing up. Locate the notch in the middle of the pouch and tear straight down. Hold the test strip as indicated with arrows pointing down.



CAUTION: Do not touch the bottom half of the test strip

Step 8: 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**.

WARNING: DO NOT disturb or remove the strip during this timeframe.

Inaccurate results can occur if the strip is disturbed or removed.

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



Arrows pointing down



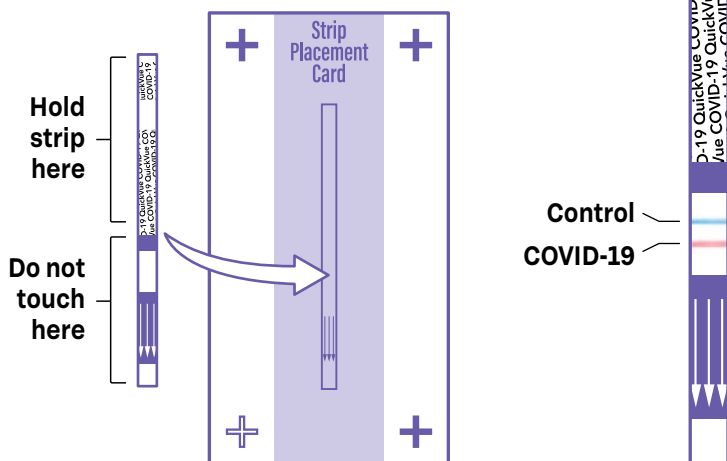
Step 9: Remove Test Strip from the Tube

At **TEN MINUTES**, remove the test strip from the TUBE.

Place the test strip exactly over the strip outline on the strip placement card included in the kit on a flat surface in good lighting before reviewing the results.

WARNING: Read the test strip right away! Do not read after 15 minutes.

If the results are read after 15 minutes, the results may be inaccurate and the test should be repeated.



Step 10: 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

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.

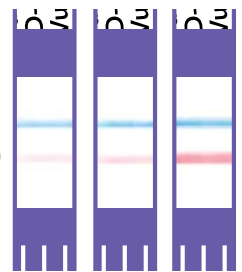
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19

Step 11: Check for a Positive Result

A **POSITIVE** result must show **BOTH** a **BLUE** line and a **PINK** line next to the **BLUE** line.

Look closely! Even a **VERY FAINT, PINK** COVID-19 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.

Control COVID-19



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

Step 12: Check for a Negative Result

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

STOP: To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours.

Control COVID-19

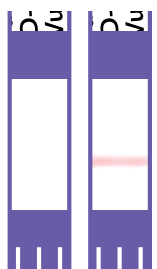


Step 13: Check for an Invalid Result

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**.

STOP: If the second test is also invalid, call 833-QUICKVUE (833-784-2588) for assistance.

Control COVID-19



After the test is completed, dispose of all used test components in your household waste and wash your hands.

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This is not a complete Package Insert. Refer to the Package Insert at [quidelortho.com/quickvue](https://www.quidelortho.com/quickvue) for complete instructions.

Serial Testing Information

- If your first test result is negative, you should test again in 48 hours.
- 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.
- All negative results with this test 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.

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.
- The test is not a substitute for consultation with a healthcare provider and should not be used to determine treatments without provider supervision. Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and followup with a healthcare provider, who will advise if additional testing or treatment are necessary.
- 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 reuse.
- Do not use kit past its expiration date.
- Do not open the materials until ready for use.
- Once opened, the test strip must be used within 120 minutes (2 hours). If the test strip is open for 2 hours or longer, invalid test results may occur.
- Do not touch the swab tip.
- 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 the most up-to-date information on COVID-19, please visit: www.cdc.gov/COVID19.
- For detailed instructions, please visit [quidelortho.com/quickvue](https://www.quidelortho.com/quickvue).

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 from 2021 through 2024. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- 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.
- Based on *in vitro* testing, the presence of Rheumatoid Factor at higher than 1.12 IU/mL concentrations in nasal samples may result in false positive results. However, it is unclear if such concentrations are clinically relevant.
- 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. Individuals with impaired vision or color impaired vision should ensure help in interpretation of their test results.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

Intended Use

The QuickVue COVID-19 Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19 within the first 5 days from symptom onset. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

The QuickVue COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from January 2021 to February 2024 when COVID-19 variants Alpha, Delta and Omicron were dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

Understanding Your Results

Positive 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).

Negative 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.

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

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 test is also invalid, call 833-QUICKVUE (833-784-2588) for assistance.

Frequently Asked Questions

What does this test do and not do?

The Quick-View COVID-19 Test is a lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus. This test is intended to be used as an aid in the clinical diagnosis of active COVID-19. Do not use this test as the only guide to manage your illness. Please consult a healthcare professional to discuss your results and if any additional testing is required.

Who should and should not use this test?

The Quick-View COVID-19 Test is authorized for use with self-collected anterior nasal (nares) swab samples from individuals 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. Do not use this test on anyone under 2 years of age or who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.

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. However, due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would. 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 quidelortho.com/quickvue.

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 have a negative result, it does not rule out SARS-CoV-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.

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-Alkyldimethylbetaines/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%

Please notify your Healthcare provider of the results of your QuickVue COVID-19 Test if you test positive or negative and continue to have symptoms suggestive of COVID-19.

Assistance

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

QuickVue COVID-19 Test Kit Catalog Numbers:

20451 – 2 Test Kit
20464 – 4 Test Kit
20398 – 25 Test Kit

Manufactured by:

Ortho-Clinical Diagnostics, Inc.
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quidelortho.com