

COVID-19 Antigen Home Test

QUICK REFERENCE INSTRUCTIONS

For *in vitro* diagnostic use.
For Over The Counter (OTC) use.
For use with anterior nasal swab specimens.

Please read these Quick Reference Instructions carefully before starting the test procedure.
Refer to the Instructions for Use (IFU) for more complete information at <https://wondfousa.com/>.

STEP BY STEP INSTRUCTIONS

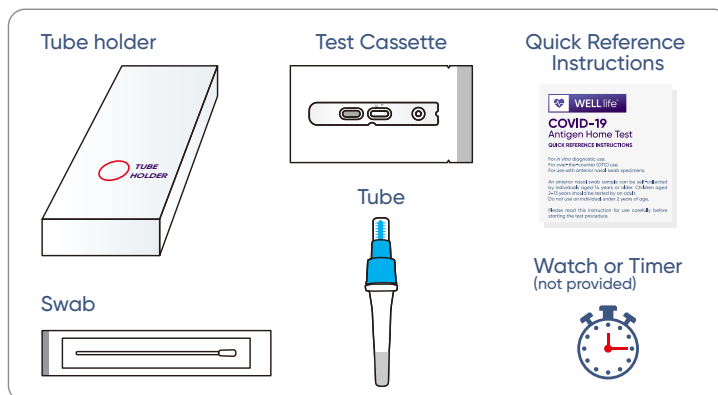
Before Starting

- 1 Wash and dry hands before you begin to perform the test.



Prepare Materials

- 2 Ensure you have all required testing components. Place the kit components on a flat surface.
NOTE: Ensure all test components are at room temperature (15-30°C/59-86°F) before use.



- 3 Check the expiration date of the test kit before use.

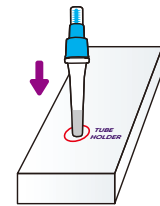


WARNING: The test must not be used beyond the expiration date listed on the packaging. Use of expired tests can lead to incorrect results.

- 4 Remove the large blue cap from the **TUBE**.

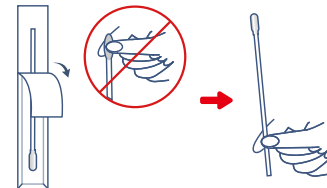


- 5 Place **TUBE** in the **Tube Holder** (round opening in kit box).



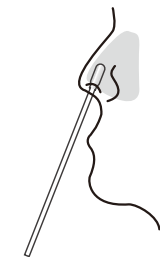
Collect Sample

- 6 Remove the **SWAB** from its wrapper.



WARNING: Do not touch the tip of the swab.

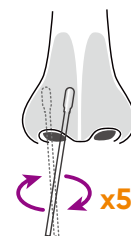
- 7 Gently insert the entire absorbent tip of the swab (3/4 of an inch) into the nostril.



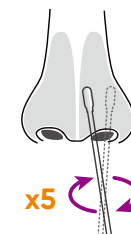
WARNING: Do not insert the swab any further if you feel any resistance.

- 8 Firmly and slowly brush against the nasal wall in a circular motion **at least 5 times**. Take **at least 15 seconds** to collect the specimen and be sure to collect any nasal drainage on the swab.

Right Nostril



Left Nostril

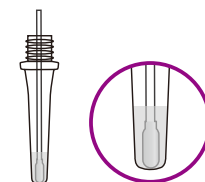


WARNING: Be sure to rub **BOTH** nostrils with the same **SWAB**.

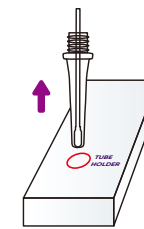
NOTE: With children, you may not need to insert the swab as far into the nostril and you may need another person to steady the child's head while swabbing. Wear safety mask or other face covering when collecting swabs from children or others.
NOTE: Failure to swab properly may cause false negative results.

Process the Sample

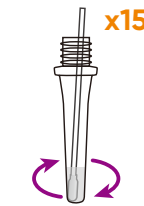
- 9 Immediately place the **SWAB** into the liquid inside the **TUBE**, and ensure it is touching the bottom of the **TUBE**.



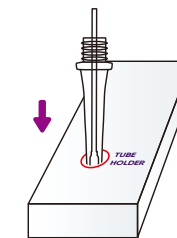
- 10 Remove the **TUBE** from the tube holder.



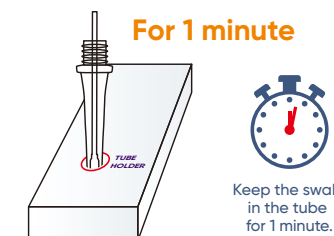
- 11 Stir the swab vigorously **at least 15 times**.



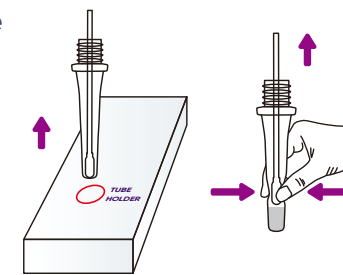
- 12 Place the tube back into the tube holder. Keep the swab inside of the tube for 1 minute.



- 13 Start timer for 1 minute.

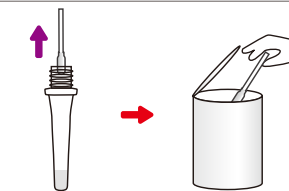


- 14 After 1 minute, take the tube out of the tube holder. **Remove the swab while squeezing the sides of the tube** to express as much liquid as possible from the swab.

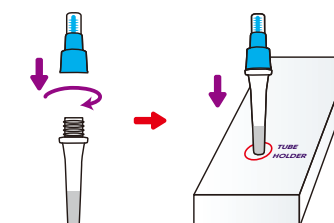


WARNING: Be sure to squeeze the tube while removing the swab.

- 15 Dispose the **SWAB** in the trash.

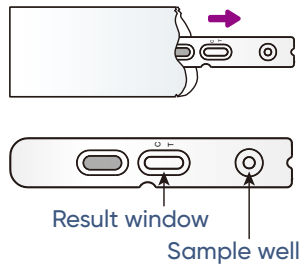


- 16 Screw the large blue cap back onto the **TUBE**. Place **TUBE** in the Tube Holder.

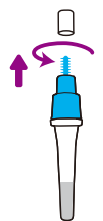


Add Sample to the Test Cassette

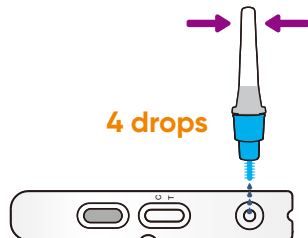
- 17 Remove the **TEST CASSETTE** from the sealed pouch and lay it flat.



- 18 Twist to open the small white cap at the top of the **TUBE**.



- 19 Add **4 drops** of sample into the sample well of the **TEST CASSETTE**.



Wait and Read Test Results

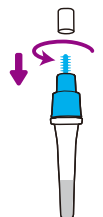
- 20 Wait **10 minutes**. And then read the result at 10 minutes as described in the next section **INTERPRETING YOUR RESULTS**.



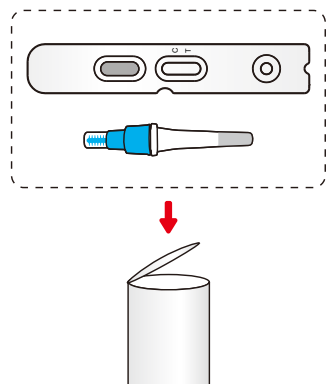
WARNING: Do not read the result before 10 minutes or after 20 minutes.

Dispose the Test Kit

- 21 Screw back the small white cap.



- 22 After the test is completed, dispose of the kit and its components in the trash.



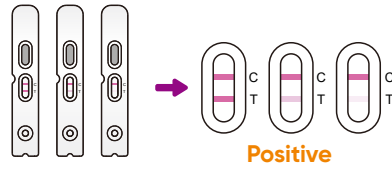
INTERPRETING YOUR RESULTS

For help in understanding your results, please refer to Frequently Asked Questions at the end of this Result Interpretation section.

WARNING: Do not read the result before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may result in false or invalid results.

Look carefully for a C line for a valid test result. For positive result, look carefully for a T line.

Positive Result

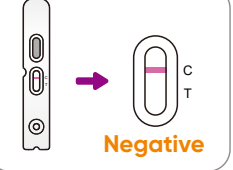


Look closely!
The T line may be very faint. Any pink/purple line visible is a Positive Result.

If the Control (C) line and the Test (T) line are visible, the test result is Positive. Any faint visible pink or purple test (T) line with the control (C) line should be read as positive.

Consult your healthcare provider to discuss your positive test result. Self-isolate at home per CDC recommendations to stop spreading virus to others.

Negative Result



If the Control(C) line is visible, but the Test(T) line is not visible, the test is negative.
To increase the chance that the negative test result for COVID-19 is accurate, you should test again in 48 hours if you have symptoms on the first day of testing.

If you still have COVID-19 symptoms, you should seek follow up care with your healthcare provider.

Invalid Result



If a Control (C) line is NOT visible, DO NOT CONTINUE reading the results. It means that your test result is INVALID.

An invalid test result means that the test is unable to determine if you are infected with SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new kit and sample.

FREQUENTLY ASKED QUESTIONS

Q1: WHAT DOES AN INVALID TEST RESULT MEAN?
A: If the control line (C) is not visible on the test strip, the test is invalid, even if the test line is visible. An invalid test result means that the test is unable to determine if you are infected with SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new kit and sample.

Q2: WHAT DOES A NEGATIVE RESULT MEAN?
A: A negative test result means that the virus that causes COVID-19 virus was not detected in the sample. A negative result is presumptive because despite a negative result you may still have SARS-CoV-2 infection. This is because the amount of virus in your sample may be too low for the test to detect it, which is called a 'false negative result'. False negative results can occur if you read your test result before the 10 minutes have passed or when your sample has only a low amount of virus in it. Low amount of virus can occur if you take your sample at a time when your symptoms just started appearing, or when you already started to feel better at the end of your infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19 symptoms, you should therefore

seek follow-up care with your healthcare provider who will determine the best course of action. Your healthcare provider can also determine if confirmation of your test result with a molecular assay is necessary.

Q3: WHAT DOES A POSITIVE RESULT MEAN?
A: A positive test result means that SARS-CoV-2 virus was detected by this test were also detected in your sample. It is very likely that you have COVID-19 and are contagious. You should self-isolate following local guidelines. Please contact your physician or healthcare provider to discuss your tests results and follow-up care. In rare instances, individuals may also have co-infections with other bacteria or viruses that this test is not designed to detect. This means that the virus detected by this test may not be the definitive or the only cause of your disease. There is a very small chance that this test can give you a positive result that is incorrect (a false positive). You do not need to perform repeat testing if you have a positive result at any time.

Q4. WHAT IS SERIAL TESTING?
A: Serial testing is when a single person is tested for COVID-19 MORE THAN ONCE. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify individuals with COVID-19 more reliably than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. You may need to purchase additional tests to perform this serial (repeat) testing.

Q5. WHAT IF I AM UNCERTAIN HOW TO INTERPRET MY RESULTS?
A: If uncertain how to proceed, contact Technical Assistance at +1(888)444-3657 (9:00 a.m. to 5:30 p.m. CDT M-F) or wondfo@wondfousa.com.

Q6. DO I HAVE TO REPORT MY RESULTS? (OPTIONAL)
A: Report your test result(s) at MakeMyTestCount.org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

Q7. WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: The WELLlife™ COVID-19 Antigen Home Test is an antigen test which 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.

Q8: HOW ACCURATE IS THIS TEST?
A: The WELLlife™ COVID-19 Antigen Home Test was compared to an FDA-authorized high sensitivity SARS-CoV-2 PCR test. 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 Instructions for Use (IFU), available at <https://wondfousa.com/>.

INTENDED USE

The WELLlife™ COVID-19 Antigen Home Test is a visually read lateral flow immunoassay test intended for the qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19. 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. 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 rule out 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 April 2023 to February 2024 when SARS-CoV-2 Omicron was 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.

WARNINGS AND PRECAUTIONS

- Do not use this test when you have symptoms for more than 5 days or if you have no symptoms.
- Do not use on individuals under 2 years of age.
- Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.
- Check the test's expiration date. Do not use kit past its expiration date. Use of expired tests can lead to incorrect results.
- Do not reuse the test cassette, processing solution, or swab.
- Not for use with viral transport media (VTM).
- When collecting a sample, only use the swab provided in the kit.
- Inadequate or inappropriate sample collection, test storage, or test transport may yield false test results.
- Testing should be performed in an area with good lighting.
- Keep test kit and materials out of the reach of children and pets before and after use. Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the reagent solution contacts the skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice. <https://www.poisonhelp.org> or 1-800-222-1222.

Chemical name	Harms (GHS Code) for each ingredient	Concentration
ProClin 300	Causes serious eye irritation (H319) Causes mild skin irritation (H316)	0.02%
Tris-HCl	Causes eye irritation (H320) Causes skin irritation (H315)	1.2%
Tween 20	Causes eye irritation (H319) Causes skin irritation (H315)	0.5%

LIMITATION

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between April, 2023 and February, 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. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19 but you you should follow-up with a healthcare provider.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision – such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test

- has not been validated for use by those with color-impaired vision.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample.
 - This test does not distinguish between SARS-CoV and SARS-CoV-2.
 - 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 follow-up with a healthcare provider, who will advise if additional testing or treatment is necessary.
 - It is important to discuss your test results with a healthcare provider if you or the person on behalf of whom you perform the test have/has persisting or worsening symptoms, a high risk for severe illness based on age or a preexisting medical condition, or a condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results). who will consider additional information such as personal medical history and symptoms, current disease prevalence in the community, and additional test results, if applicable, to help determine what steps are best for diagnosis and treatment (if needed).

HOW TO USE THE 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. 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.











STORAGE AND STABILITY

- The test kit should be stored in a dry place between 2-30°C (36-86°F).
- The test kit is stable until the expiration date on kit box and pouch.
- Do not use beyond the expiration date.

ASSISTANCE

If the test does not perform as expected, please call 1-888-444-3657.

INDEX OF SYMBOLS

	Keep away from sunlight		Temperature limit 20°C / 66°F 2°C / 36°F		Keep dry
	Do not re-use		Catalogue number		Batch code
	Use-by date		In Vitro diagnostic medical device		Consult instructions for use
	Do not use if package is damaged				

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890 Remington Blvd
Bolingbrook, IL 60440
+1 (630) 468-2199
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