

COVID-19/Influenza A&B Home Test QUICK REFERENCE INSTRUCTIONS

For use under Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use.
For over-the-counter (OTC) use
For use with anterior nasal swab specimens.

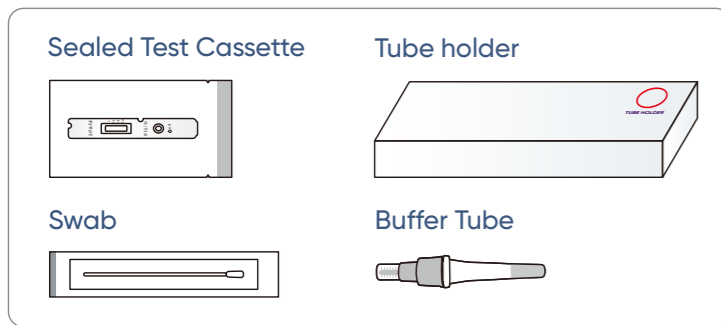


Scan here to visit our product website

Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate test results. Refer to the Instruction for Use (IFU) for more complete information at <https://wondfousa.com/>.

An anterior nasal swab sample can be self-collected by individuals aged 14 years or older. Children aged 2-13 years should be tested by an adult.

Materials Provided



Materials required but not provided: Timer or watch.

Preparing for the Test

NOTE: Do not open the test materials until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.

1 Check the expiration date of the test printed on the right side of the outer box.

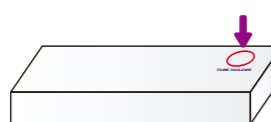
For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit <http://www.fda.gov/covid-tests>.



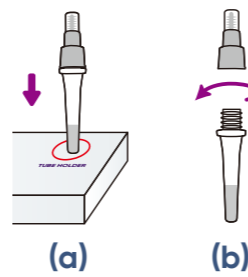
2 WASH your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.



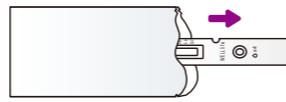
3 LOCATE the tube holder on the box (look for the red circle on the kit's box).



- 4**
- INSERT the buffer tube into the tube holder. Ensure that the buffer tube is stable and upright.
 - REMOVE the large cap from the buffer tube and set it aside for later use.

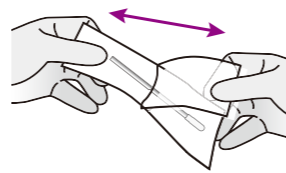


- 5** REMOVE test cassette from sealed pouch and lay it on a flat surface.



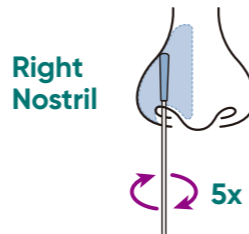
Sample Collection

- 6** REMOVE the swab from the pouch.



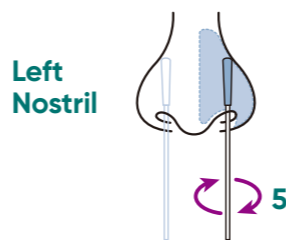
- ⚠️** Be careful not to touch the swab tip (soft end) with hand.

- 7**
- CAREFULLY INSERT the swab no more than 3/4 inch (1.5 cm) into the nostril. Slowly rotate the swab at least 5 times against the nostril wall.



- ⚠️** Do not insert the swab any further if you feel any resistance.

- REMOVE the swab and REPEAT in the other nostril using the same swab.

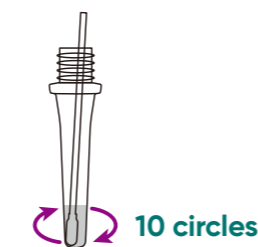


Check: Did you swab BOTH nostrils?

NOTE: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than 1/2 to 3/4 of an inch, and you may require another adult to hold the child's head while swabbing.

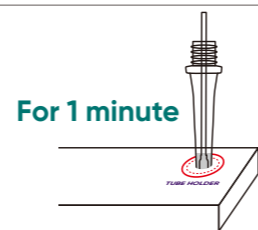
Running the Test

- 8** IMMERSE the swab into the buffer tube and SWIRL the swab in the buffer. Ensure the sample is mixed thoroughly by making at least 10 circles.

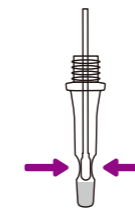


- ⚠️** Sample must be adequately mixed into the buffer, otherwise, incorrect results may occur.

- 9** LEAVE the swab in the buffer tube for 1 minute. A timer is recommended for this step.

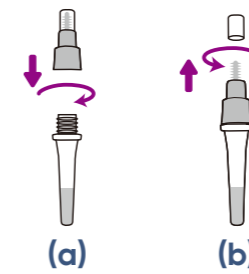


- 10** After 1 minute, PINCH the tip of the swab from the outside of the tube to remove any excess liquid from the swab.

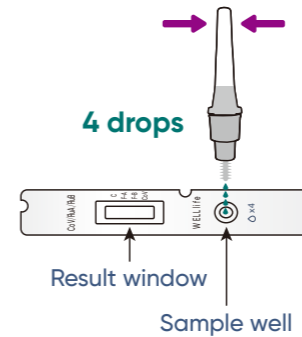


REMOVE and DISCARD the swab.

- 11**
- HOLD the buffer tube upright and SCREW the large cap back onto the tube. Ensure a tight fit to prevent leaking.
 - TWIST to open the small cap at the top of the tube.



- 12** INVERT the buffer tube and SQUEEZE 4 drops of test sample into the sample well on the test cassette. Then DISCARD the buffer tube.



NOTE: Incorrect results may be observed if <4 drops of sample are added.

- ⚠️** Sample must be applied to the test cassette within one hour of completing step 8.

- 13** START timer. Read results at 10 minutes.



- ⚠️** Do not interpret results before 10 minutes or after 20 minutes. Inaccurate test interpretations may occur.

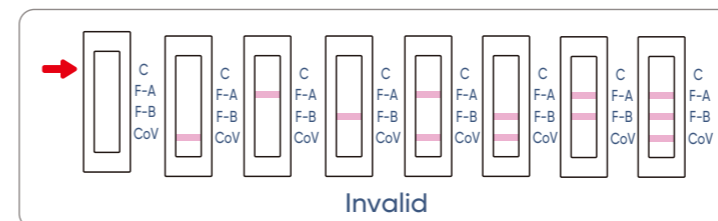
Interpreting Your Results

LOOK for lines next to 'C' (Control), 'F-A', 'F-B' and 'CoV'.

C = Control Line
F-A = Flu A Test Line
F-B = Flu B Test Line
CoV = COVID-19 Test Line

A red line should always appear at the 'C' position; this is a control line and signals that the test is working properly.

Invalid Result



Check to see if a pink to red line is visible at the control line 'C' in the results window. If a line is not visible at "C", even if any other line is visible in the results window, the result is considered invalid.

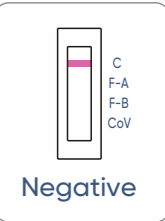
- STOP** If you do not see a C line, DO NOT CONTINUE reading the results. It means your test is invalid. Repeat the test with a new sample and new test kit materials.

Negative Result

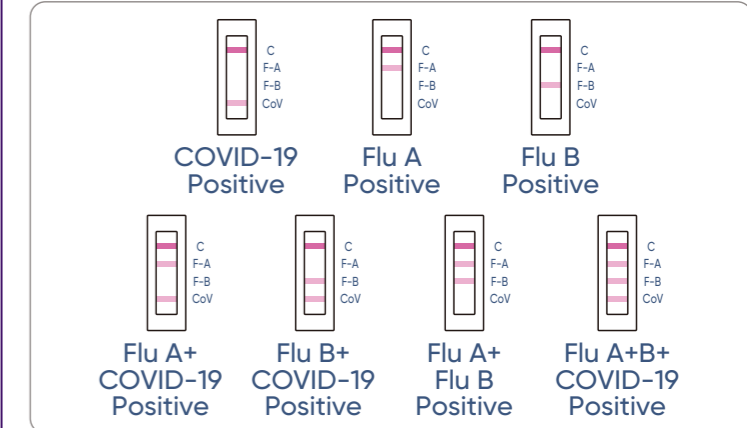
If a control 'C' line is visible and you do not see a line at 'F-A', 'F-B' or 'CoV', it means the test is negative. The Flu A, Flu B or COVID-19 virus have not been detected.

To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours after the first day of testing.

If respiratory symptoms persist, you seek follow-up care with healthcare provider.



Positive Result



If the control line at "C" is visible and any other line or multiple lines on 'F-A', 'F-B' and/or 'CoV' are visible, the test is positive for that virus.

NOTE: Any pink to red test line, no matter how faint, should be considered a positive result when the control line is also present.

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

Serial Testing

Repeat Testing is needed for all samples that are negative for SARS-CoV-2 on the first day of testing, even if they are positive for influenza A and/or B. Repeat testing is needed to improve test accuracy for SARS-CoV-2. Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing: With Symptoms			
Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Interpretation
SARS-CoV-2 (+), Influenza A and B (-)	NO	Not needed	Positive for COVID-19, Presumptive negative for Influenza
SARS-CoV-2 (+), Influenza A and/or B (+)	NO	Not needed	Positive for COVID-19, Positive for Influenza A and/or B
SARS-CoV-2 (-), Influenza A and/or B (-)	YES	SARS-CoV-2 (+), Influenza A and/or B (-)	Positive for COVID-19, Presumptive Negative for Influenza
SARS-CoV-2 (-), Influenza A and/or B (+)	YES	SARS-CoV-2 (+), Influenza A and/or B (+)	Positive for COVID-19, Positive for Influenza A and/or B
SARS-CoV-2 (-), Influenza A and/or B (-)	YES	SARS-CoV-2 (-), Influenza A and/or B (+)	Presumptive Negative for COVID-19, Positive for Influenza A and/or B
SARS-CoV-2 (-), Influenza A and/or B (-)	YES	SARS-CoV-2 (-), Influenza A and/or B (-)	Presumptive Negative for COVID-19, Presumptive Negative for Influenza
SARS-CoV-2 (-), Influenza A and/or B (+)	YES	SARS-CoV-2 (+), Influenza A and/or B (+)	Positive for COVID-19, Positive for Influenza A and/or B
SARS-CoV-2 (-), Influenza A and/or B (+)	YES	SARS-CoV-2 (-), Influenza A and/or B (-)	Presumptive Negative for COVID-19, Positive for Influenza A and/or B
SARS-CoV-2 (-), Influenza A and/or B (+)	YES	SARS-CoV-2 (-), Influenza A and/or B (+)	Presumptive Negative for COVID-19, Positive for Influenza A and/or B
SARS-CoV-2 (-), Influenza A and/or B (+)	YES	SARS-CoV-2 (+), Influenza A and/or B (+)	Positive for COVID-19, Positive for Influenza A and/or B

Understanding your Results

Invalid Result: The test could not tell whether or not you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

Negative Result: The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean it is certain that you do not have COVID-19, Flu A and/or Flu B 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, Flu A and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider.

Positive Result: The COVID-19, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

Results Reporting

Report your test result(s) at [MakeMyTestCountOrg](https://www.wondfousa.com/MakeMyTestCountOrg)—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.

Intended Use

The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A and influenza B proteins antigens.

This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals aged two (2) years or older. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

Results are for the simultaneous identification of SARS-CoV-2, influenza A virus and influenza B virus protein antigens, but do not differentiate between SARS-CoV and SARS-CoV-2 viruses and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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 definitive cause of disease. Individuals who test positive with the WELLlife™ COVID-19 / Influenza A&B Home 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, influenza A, and influenza B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions 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 SARS-CoV-2, influenza A, and influenza B infection.

Individuals who test negative and continue to experience SARS-CoV-2 and/or influenza-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 and/or influenza infection and should seek follow up care with their physician or healthcare provider.

The WELLlife™ COVID-19 / Influenza A&B Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

How to Use this Test

Serial testing should be performed in all individuals with SARS-CoV-2 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 SARS-CoV-2 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 SARS-CoV-2 positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Warnings and Precautions

- Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate test 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, influenza A, and influenza B, 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 SARS-CoV-2 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.**
- Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.**
- An anterior nasal swab sample can be self-collected by individuals aged 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.
- This test may only be used in symptomatic individuals.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not re-use the test strip, buffer liquid, or swab.
- If any liquid spills from the buffer tube, discard test components and re-start test using new test components.
- Do not read test results before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.**
- If uncertain how to proceed, contact Technical Assistance at 1-888-444-3657.
- Do not touch swab tip when handling the swab.
- To ensure accurate test results, avoid contamination with liquid gel hand soap, hand sanitizer cream lotion, and fast-crying 80% ethanol hand sanitizer.
- Do not open the test contents until ready for use, if the test cassette is open for an hour or longer, false test results may occur.
- Testing should be performed in an area with good lighting.
- Do not use the test kit after its expiration date.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your 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 skin irritation (H315) Causes eye irritation (H320)	0.05%

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

For the most up-to-date information on COVID-19, please visit: www.cdc.gov/COVID19.

Storage and Stability

- Store the test kit between 36–86°F (2–30°C) in a place out of direct sunlight.

- Reagents and devices must be used at room temperature (59–86°F/15–30°C).
- The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening. The expiration date is on the package.

Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between December 2023 and March 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.
- 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 negative results SARS-CoV-2 or influenza are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19 or influenza and both your first and second tests are negative, you may not have COVID-19 or influenza, 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 and the individual likely has respiratory infection with COVID-19 or influenza.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- Based on sequence and epitope analyses, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exist. Wet testing with HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.

Frequently Asked Questions

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

- A: Potential risks include:
- Possible discomfort during sample collection.
 - Possible incorrect test result (see Warnings and Result 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 and flu to the family of the tested individual and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

- A: There are different kinds of tests for the viruses that cause COVID-19 and the flu. Molecular tests detect genetic material from the virus. Antigen tests, such as the WELLlife™ COVID-19 / Influenza A&B Home 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.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?

- A: A positive result means that it is very likely you have COVID-19 or influenza 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.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?

- A: A negative test result indicates that antigens from the virus that causes COVID-19 or influenza 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 or influenza 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.

Q: HOW ACCURATE IS THIS TEST?












- A: 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: <https://wondfousa.com/>.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

- A: An invalid result means something with the test did not work properly. 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.

Index of Symbols

	Keep away from sunlight		Temperature limit		Keep dry
	Do not re-use		Manufacturer		Do not use if package is damaged
	Catalogue number		Batch code		Use-by date
	In vitro diagnostic medical device		Consult instructions for use		

Support

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact Wondfo Product Support at +1 (888) 444-3657 or Wondfo USA Co., Ltd. Product Support website: <https://wondfousa.com/>.

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