WELLlife™

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

Scan here to visit our product website

**Catalogue numbers:**
CWV01P0001-1
CWV01P0001-2
CWV01P0001-5
CWV01P0001-10
CWV01P0001-25

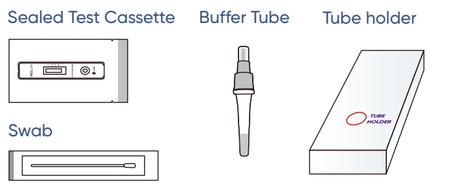
For *in vitro* diagnostic use.
For over-the-counter (OTC) use
For use with anterior nasal swab specimens.

This test is intended for symptomatic individuals within 5 days of symptom onset.

**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 must be tested by an adult.**
**Do not use on anyone under 2 years of age.**

## Materials Provided




**Materials required but not provided:** Timer or watch.

## Preparing for the Test

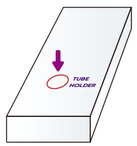
**NOTE:** Do not open the test materials until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.

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


**2** Ensure all test components are at room temperature (15-30°C/59-86°F) before use.

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

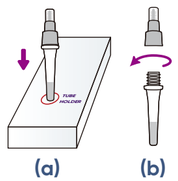
**4** **LOCATE** the tube holder on the box (look for the red circle on the kit's box).



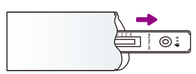

**5**

a) **INSERT** the buffer tube into the tube holder. Ensure that the buffer tube is stable and upright.

b) **REMOVE** the large cap from the buffer tube and set it aside for later use.



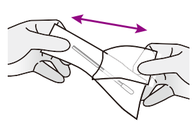

**6** **REMOVE** test cassette from sealed pouch and lay it on a flat surface.



## Sample Collection

**7** **REMOVE** the swab from the pouch.

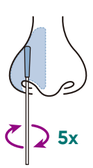
⚠ **Be careful not to touch the swab tip (soft end) with hand.**



**8**

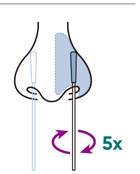
a) **CAREFULLY INSERT** the swab no more than 3/4 inch (1.5 cm) into the nostril. Slowly rotate the swab at least 5 times against the nostril wall.

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




b) **REMOVE** the swab and repeat in the other nostril using the same swab.

⚠ **Check: Did you swab BOTH nostrils?**

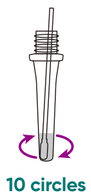



**NOTE: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.**
**NOTE: Failure to swab properly may cause false negative results.**

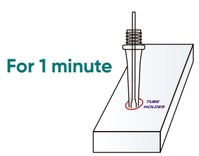
## Running the Test

**9** **IMMERSE** the swab into the buffer tube, and ensure it is touching the bottom of the 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.**

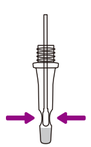



**10** **LEAVE** the swab in the buffer tube for 1 minute. A timer is recommended for this step.




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

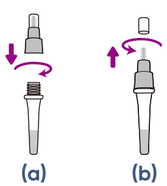
**REMOVE** and **DISCARD** the swab.



**12**

a) **HOLD** the buffer tube upright and **SCREW** the large cap back onto the tube. Ensure a tight fit to prevent leaking.

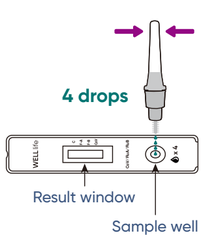
b) **TWIST** to open the small cap at the top of the tube.




**13** **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 9.**




## Interpreting Your Results

**14** **START** timer. Read results at 10 minutes.

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

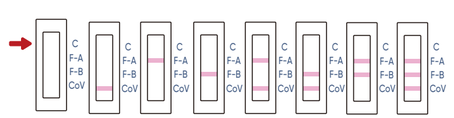

## Interpreting Your Results

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.

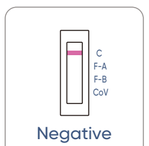
## Invalid Result




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

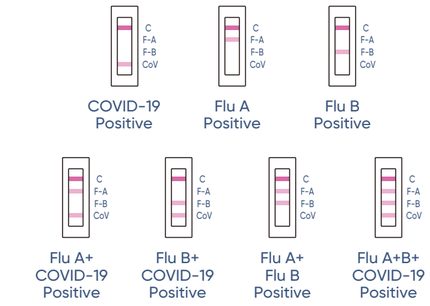



If a control '**C**' line is visible and you do not see a line at '**F-A**' , '**F-B**' or '**CoV**', it means the test is negative. The Flu A, Flu B or COVID-19 virus have not been detected.

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

If respiratory symptoms persist, you should seek follow-up care with your 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, as instructed by your local health authority, 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.
All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary. Negative results do not rule out SARS-CoV-2, Flu A, and/or Flu B infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
**Positive Result:** The SARS-CoV-2, 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 self-isolate at home, as instructed by your local health authority, to stop spreading virus to others. There is a small chance that this test can give you a positive result that is incorrect (a false positive).
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.

## Intended Use

The WELLlife™ COVID-19 / Influenza A&B Home Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection within five (5) days of symptom onset. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar.
This test is intended for 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 and confirmation with a licensed molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2, or other pathogens.
Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare providers.
Positive results do not rule out co-infection with other respiratory pathogens, and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

## 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

- **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.**
- **Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.**
- Do not use on anyone under 2 years of age.
- Do not use if any of the test kit contents or packaging is damaged or open.
- When collecting a sample, only use the swab provided in the kit.
- All test components are single-use. Do not reuse the test cassette, processing solution, or swab.
- Testing should be performed in an area with good lighting.
- Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use this test if you have been vaccinated with the FluMist/FluMist quadrivalent live intranasal influenza virus vaccine within the last two weeks.
- Do not conduct this test if prone to nose bleeds or have a nose injury.
- Do not use this test if you are using anti-viral drugs or having a nasal wash.
- Do not use this test if you are using nasal corticosteroids.
- Do not use this test if you are using zinc-based throat sprays.
- Remove any piercings from nose before starting the test.
- **Keep testing kit and kit components away from children and pets before and after use.**
- **Eyewear protection is recommended.**
- **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://infopoison.ca/for-professionals/ or 1-844-764-7669 (please call 1-800-463-5060 for residents of Quebec only).**

| Chemical name | Harms (GHS Code) for each ingredient | Concentration |
|---|---|---|
| ProClin 300 | Causes skin irritation (H315)<br>Causes eye irritation (H320) | 0.05% |

- 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. Do not use beyond the expiration date.

## 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.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected or handled improperly.
- Performance of this test on individuals using anti-viral drugs, having a nasal wash, and individuals having undergone craniofacial injury or surgery within the previous 6 months is not established.
- 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 and influenza as compared to a molecular test, especially in samples with low viral load.
- False positive test results are more likely when the prevalence of SARS-CoV-2, influenza A, and/or influenza B is low in the community.
- False negatives may be observed in the event of a co-infection.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., young children, elderly individuals, chronic lung disease, heart disease, compromised immune system, diabetes, and other conditions) should contact a healthcare provider; users should also contact a healthcare provider if symptoms persist or worsen.
- 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 device is a qualitative test and cannot provide information on the amount of virus present in the specimen.
- This test detects both viable (live) and non-viable influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the sample.
- Hand soap and hand sanitizers may cause false negative results with this test.
- FluMist/FluMist quadrivalent live intranasal influenza virus vaccine may cause false positive influenza A and B results with this test.
- Zinc-based throat sprays may cause false positive influenza A results with this test.
- Nasal corticosteroids may cause false negative results with this test.
- This test does not distinguish between SARS-CoV and SARS-CoV-2.

## 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, FluA or FluB 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 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 providers.**

## Index of Symbols

| | | |
|---|---|---|
| Keep away from sunlight | Store at 36–86°F/2–30°C | Keep dry |
| Do not re-use | Do not use if package is damaged | REF Catalogue number |
| LOT Batch code | Use-by date | IVD *In vitro* diagnostic medical device |
| Consult instructions for use | Manufacturer | |

## 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 (9:00 a.m. to 5:30 p.m. CDT M-F) or Wondfo USA Co., Ltd. Product Support website: https://wondfousa.com/.

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Made in China

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