WELL life™

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

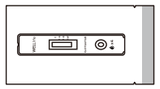
Scan here to visit our product website

For *in vitro* diagnostic use.
For professional use.
For use with anterior nasal swab specimens.

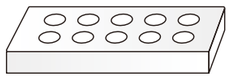
Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate test results. Refer to the Instructions for Use (IFU) for more complete information.

Materials Provided

Sealed Test Cassette



Tube holder



Swab

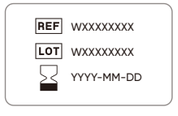
Buffer Tube

Materials required but not provided:
- Timer or watch,
- Optional: WELLlife™ COVID-19 / Influenza A&B Antigen Test Control Kit (Catalog number: WCOVFLU-CON-5)

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.

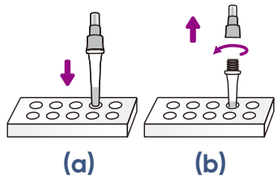
3 **WASH** your hands with soap and water for 20 seconds or use hand sanitizer and dry them thoroughly.

4 **ASSEMBLE** the tube holder in the kit.

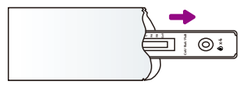
5

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.



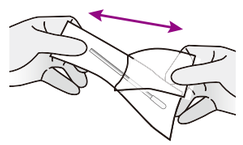
6 **REMOVE** test cassette from sealed pouch and lay it on a flat surface.



Sample Collection

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

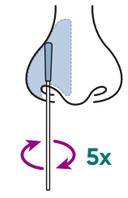
⚠ **Be careful not to touch the swab tip (soft end) with hand.**



8

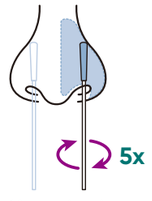
a) **CAREFULLY INSERT** the swab no more than 3/4 inch (1.5 cm) into the nostril. Slowly rotate the swab at least 5 times against the nostril wall.

⚠ **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.

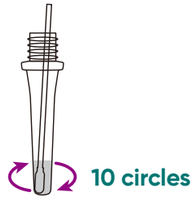
Check: Did you swab BOTH nostrils?



NOTE: 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.

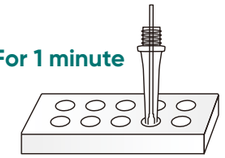
Running the Test

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**.



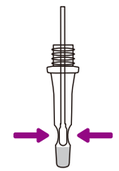
⚠ **Sample must be adequately mixed into the buffer, otherwise, incorrect results may occur.**

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.

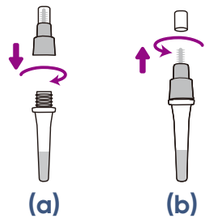
REMOVE and **DISCARD** the swab.



12

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

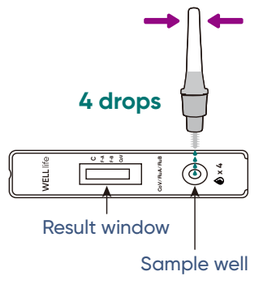
b) **TWIST** to open the small cap at the top of the tube.



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.**



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

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

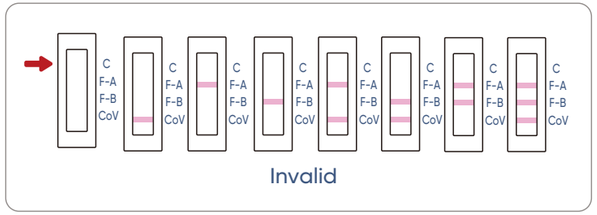
Interpreting Your Results

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.

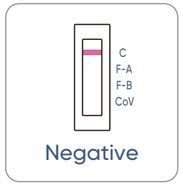
Invalid Result



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

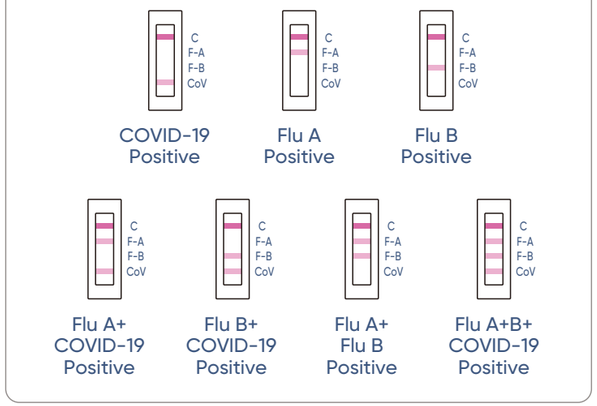


If a control '**C**' line is visible and you do not see a line at '**F-A**' , '**F-B**' or '**CoV**', it means the test is negative. The Flu A, Flu B or COVID-19 virus have not been detected.

If respiratory symptoms persist, 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



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.

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 Antigen 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. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared 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.

Test results should not be used as the sole basis for treatment or other patient management decisions.

Warnings and Precautions

- **Do not use the test if individuals have had symptoms for more than 4 days or no symptoms at all.**
- 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 individuals 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 individuals are using nasal corticosteroids.
- Do not use this test if individuals 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. 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 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.

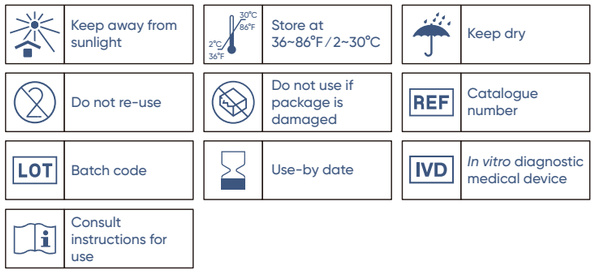
Limitations

- 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.
- 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.
- 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.

External Quality Control Procedure

To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab. Wondfo USA Co., Ltd. recommends that the positive and negative controls be run once for each untrained operator, once for each new shipment of kits –provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.

Index of Symbols



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 USA 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/.

Manufactured for Wondfo USA Co., Ltd.
6720 Cobra Way,
San Diego, CA 92121
Made in China

Rev. A1 Rel.: 2025/02/10