WELL life™

Influenza A&B Test

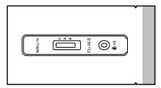
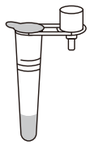
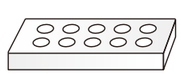
QUICK REFERENCE INSTRUCTIONS

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.

Materials Provided

Sealed Test Cassette | Buffer Tube | Tube holder

Swab

Materials required but not provided: Timer or watch.

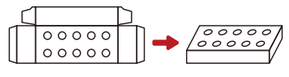
Preparing for the Test

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.

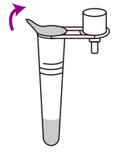
1 **CHECK** the expiration date of the test printed on the outer box.

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

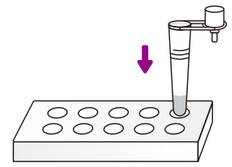
2 **ASSEMBLE** the tube holder in the kit.



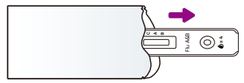
3 **REMOVE** the sealed foil seal from the buffer tube.



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

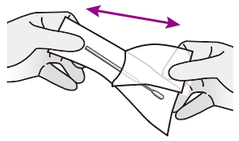


5 **REMOVE** test cassette from sealed pouch and lay it on a flat surface.



Sample Collection

6 **REMOVE** the swab from the pouch.

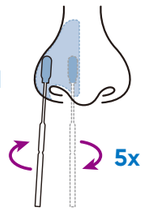


⚠ **Do not touch the swab tip (soft end) with hand.**

7

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

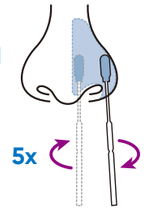
Right Nostril



⚠ **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.

Left Nostril



Check: Did you swab BOTH nostrils?

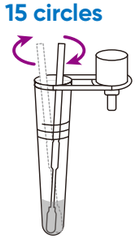
Note: With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

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

Running the Test

8 **IMMERSE** the swab into the buffer tube until it touches the bottom and **SWIRL** the swab in the buffer. Ensure the sample is mixed thoroughly by making **at least 15 circles**.

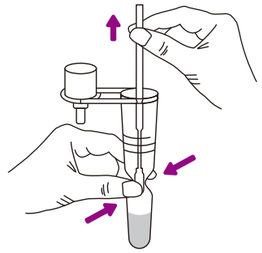
15 circles



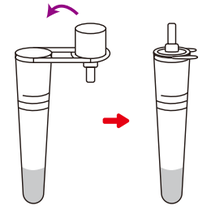
⚠ **Sample must be adequately mixed into the buffer, otherwise, incorrect results may occur.**

9 **REMOVE** the swab while **SEQUEEZING** the tip of the swab from the outside of the tube to remove any excess liquid from the swab.

DISCARD the swab.

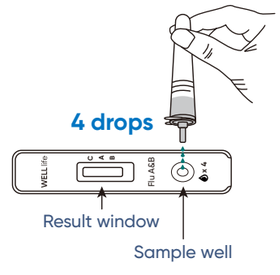


10 **CLOSE** the dropper cap firmly that is attached to the buffer tube.



11 **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 immediately.**

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

10 minutes

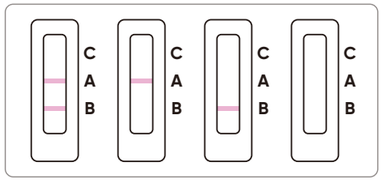
⚠ **Do not read the result before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may result in false or invalid results.**

Results Interpretation

Look for lines next to '**C**'(Control), '**A**' and '**B**'.
C = Control Line
A = Flu A Test Line
B = Flu B 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.

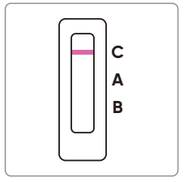
Invalid Result



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.

NOTE: 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

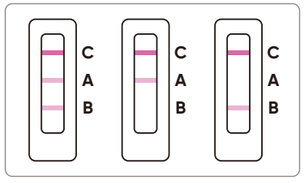


If a control '**C**' line is visible, but the line at '**A**' and '**B**' is not visible, the test is **NEGATIVE**. The Flu A or Flu B virus was not detected in the sample.

If respiratory symptoms persist, individuals should seek follow-up care with their healthcare provider.

NOTE: All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary. Negative results do not rule out 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 '**A**' and/or '**B**' 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™ Influenza A&B Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. This test is for use by individuals aged 14 years or older testing themselves, or adults testing other individuals 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 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%

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)
- 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 clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2025 and March 2025. 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 influenza virus 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 influenza A or B as compared to a molecular test, especially in samples with low viral load.
- False positive test results are more likely when the prevalence of 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 and influenza B. 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.

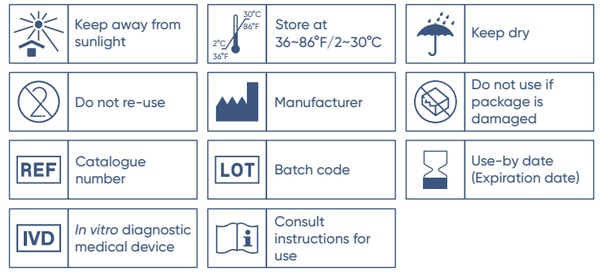
Quality Control

The WELLlife™ Influenza A&B Test Control Kit (Catalog number: WFLUAB-CON-5) is sold separately and may be used with the WELLlife™ Influenza A&B Test. To perform a positive or negative control test, complete the steps in the Running the Test section, treating the control swab in the same manner as a patient swab.

It is recommended 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.

If external controls do not perform as expected, testing of individuals should not be performed. Repeat the test or contact Wondfo via email at wondfo@wondfousa.com or call 1-888-444-3657.

Index of Symbols



Index of Symbols

If the test does not perform as expected, please email at wondfo@wondfousa.com or call 1-888-444-3657 (9:00 a.m. to 5:30 p.m. CDT M-F).

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