WELLlife™

# Influenza A&B Test
## INSTRUCTIONS FOR USE

For *In Vitro* Diagnostic Use.
For Professional Use.
For use with anterior nasal swab specimens.

IVD

**Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate test results.**

### 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.

### SUMMARY AND EXPLANATION

The WELLlife™ Influenza A&B Test is an antigen test that can provide rapid detection of influenza A and influenza B viral proteins from symptomatic patients.
Influenza A&B are highly contagious respiratory viruses causing acute upper respiratory infections with very similar symptoms such as headache, chills, dry cough, body aches, and fever. There are two main seasonal influenza viruses, influenza A and influenza B; Influenza A virus is typically more common. Influenza affects 5%-20% of the United States population annually, resulting in more than 200,000 hospitalizations and 36,000 deaths. [1] Diagnosis of these viruses is difficult because all respiratory viruses cause similar initial symptoms. Accurate diagnosis may allow prompt treatment of patients and can have a positive effect on public health.

### PRINCIPLE OF PROCEDURE

The WELLlife™ Influenza A&B Test consists of a test cassette that separately detects influenza A and influenza B antigens. The test procedure requires an anterior nasal swab specimen to be inserted into the prefilled extraction buffer tube to elute the sample material for testing and disrupt the virus particles in the specimen. The eluted sample extract is then dropped into the sample well of the test cassette, and the swab is discarded.
If influenza A and/or influenza B antigens are present in the specimen, they will react with influenza A/B antibodies, all coupled to dye particles. They then migrate through the membrane as antigen-antibody-dye complexes, bind to the immobilized capture antibody on the membrane's test line(s), and generate a colored pink to red line in the specific test line position. The rest of the sample and rabbit-antibody-dye-particle complexes continue to migrate to the Control line position (C), where immobilized goat anti-rabbit antibodies will capture the rabbit-antibody-dye-particle complexes and form the Control line. Formation of the pink to red Control line serves as an internal control to demonstrate that test reagents are functional, antibody-dye conjugates in the dye pad have been hydrated and released and that sufficient sample has been applied to allow for migration through the Test and Control lines. If the Control line does not appear within the designated incubation time, the result is invalid, and the test should be repeated using a new test device and specimen.
If the antigen level is equal to or above the detection limit, a visible colored band appears at the test region. Absence of this pink to red colored band in the test region of test strip and only a visible control line will appear, suggests a negative result.
WELLlife™ Influenza A&B Test has two Test lines, one for influenza A and one for influenza B. The two Test lines allow for the separate and differential identification of influenza A and/or B from a single specimen. If any Test line appears in the test result window, together with the Control line, the test result is positive for influenza A and/or B.
Results can be interpreted between 10 and 20 minutes after adding the extracted sample into the sample well.

### REAGENTS AND MATERIALS

The WELLlife™ Influenza A&B Test kit configurations are indicated below:

| Components | 25 Tests/kit |
|---|---|
| Sealed Test Cassettes | 25 |
| Buffer Tubes | 25 |
| Swabs | 25 |
| Tube Holder | 1 |
| Instructions for Use (IFU) | 1 |
| Quick Reference Instructions (QRI) | 1 |

**Materials Required but Not Provided**
- Timer or watch
- WELLlife™ Influenza A&B Test Control Kit (Catalogue No.: WFLUAB-CON-5)

### 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)<br>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.

### QUALITY CONTROL

**INTERNAL QUALITY CONTROL**
Each WELLlife™ Influenza A&B Test has a built-in internal procedural control. The red line appearing at the "C" position verifies proper assembly and capillary flow of the test strip. A distinct red Control Line should always appear if the test has been performed correctly. If the Control Line does not appear, the test result is invalid, and a new test should be performed using a new swab and new test kit.

**EXTERNAL QUALITY CONTROL PROCEDURE**
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. The controls are specifically formulated and manufactured to ensure performance of the test and are used to verify an operator's ability to properly perform the test and interpret the results. The external controls should be processed and tested in accordance with the nasal swab test procedure provided in the Instructions for Use or in the Quick Reference Instructions (QRI). Use of Kit Control reagents manufactured by any other source may not produce the expected results, and therefore, will not meet the requirements for an adequate quality assurance program for the WELLlife™ Influenza A&B Test.
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.

### 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.**



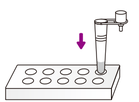

2. **ASSEMBLE** the tube holder in the kit.



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.



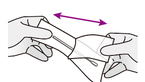
5. **REMOVE** test cassette from sealed pouch and lay it on a flat surface.



### SAMPLE COLLECTION

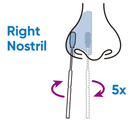
6. **REMOVE** the swab from the pouch.

⚠ **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.

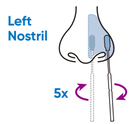
⚠ **Do not insert the swab any further if you feel any resistance.**




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

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

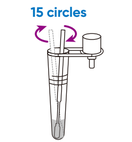
**Note: With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing. Note: Failure to swab properly may cause false negative results.**



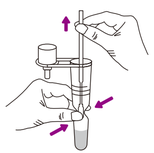

### RUNNING THE TEST

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**.

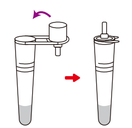
⚠ **Sample must be adequately mixed into the buffer, otherwise, incorrect results may occur.**




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.



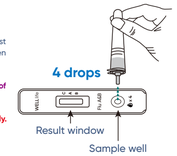
10. **CLOSE** the dropper cap firmly that is attached to the buffer tube.



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.

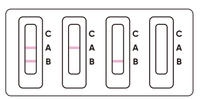
⚠ **Do not read the result before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may result in false or invalid results.**




### 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.

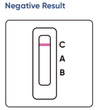
**Invalid Result**




**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.**

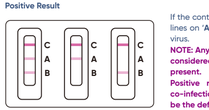
**Negative Result**




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.**

### 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.

### PERFORMANCE CHARACTERISTICS

**ANALYTICAL PERFORMANCE**
**Lot-to-Lot Precision**
A single-site lot-to-lot precision study was conducted internally to measure repeatability using three levels of contrived samples. A panel of four samples was tested: a negative sample prepared in pooled negative swab matrix (PNSM), low positive sample (0.5x co-spiked LoD of Flu A and Flu B), weak positive sample (1x co-spiked LoD of Flu A and Flu B), moderate positive sample (3x co-spiked LoD of Flu A and Flu B). The strains used for testing were live influenza A H1N1 and live influenza B Yamagata. Two replicates per sample type was tested per run, per operator, and per lot across 5 days with two test runs per day for a total of 180 results per sample type (3 lots x 3 operators x 2 replicates per run x 2 runs per day x 5 days). Repeatability was determined by comparing test results to expected results across cll lots, operators, and days. Results are shown in the table below.

**Lot-to-Lot Reproducibility Study Results**

| Sample | Analyte | % Positive (# positive/replicates) | | | |
|---|---|---|---|---|---|
| | | Lot 1 | Lot 2 | Lot 3 | Total |
| Negative sample (PNSM only) | Flu A | 0% (0/60) | 0% (0/60) | 0% (0/60) | 0% (0/180) (0%-2.1%) |
| | Flu B | 0% (0/60) | 0% (0/60) | 0% (0/60) | 0% (0/180) (0%-2.1%) |
| Low positive sample (0.5x co-spiked LoD of Flu A and Flu B) | Flu A | 46.7% (28/60) | 55.0% (33/60) | 53.3% (32/60) | 51.7% (93/180) (44.4%-58.9%) |
| | Flu B | 53.3% (32/60) | 58.3% (35/60) | 63.3% (38/60) | 58.3% (105/180) (51.0%-65.3%) |
| Weak positive sample (1x co-spiked LoD of Flu A and Flu B) | Flu A | 100% (60/60) | 100% (60/60) | 100% (60/60) | 100% (180/180) (97.9%-100%) |
| | Flu B | 100% (60/60) | 100% (60/60) | 100% (60/60) | 100% (180/180) (97.9%-100%) |
| Moderate positive sample (3x co-spiked LoD of Flu A and Flu B) | Flu A | 100% (60/60) | 100% (60/60) | 100% (60/60) | 100% (180/180) (97.9%-100%) |
| | Flu B | 100% (60/60) | 100% (60/60) | 100% (60/60) | 100% (180/180) (97.9%-100%) |

**Site-to-Site Reproducibility**
The reproducibility of WELLlife™ Influenza A&B Test was evaluated at three external sites with three operators per site (a total of nine operators) over five days. The nine-member panel described above was

tested in this study. The summary of results is presented in Table below.

**Site-to-Site Reproducibility Study Result**

| Sample | % Positive (# positive/replicates) | | | | |
|---|---|---|---|---|---|
| | Site A | Site B | Site C | Total | 95%CI |
| Negative Sample | 0% (0/45) | 0% (0/45) | 0% (0/45) | 0% (0/135) | 0% - 2.8% |
| Flu A High Negative (0.1x LoD) | 2.2% (1/45) | 0% (0/45) | 0% (0/45) | 0.7% (1/135) | 0.1% - 4.1% |
| Flu A Low Positive (0.8x LoD) | 75.6% (34/45) | 84.4% (38/45) | 86.7% (39/45) | 82.2% (111/135) | 74.9% - 87.8% |
| Flu A Weak Positive (1x LoD) | 95.6% (43/45) | 97.8% (44/45) | 97.8% (44/45) | 97.0% (131/135) | 92.6% - 98.8% |
| Flu A Moderate Positive (3 x LoD) | 100% (45/45) | 100% (45/45) | 100% (45/45) | 100% (135/135) | 97.2% - 100% |
| Flu B High Negative (0.1x LoD) | 0% (0/45) | 0% (0/45) | 2.2% (1/45) | 0.7% (1/135) | 0.1% - 4.1% |
| Flu B Low Positive (0.8x LoD) | 91.1% (41/45) | 88.9% (40/45) | 88.9% (40/45) | 89.6% (121/135) | 83.3% - 93.7% |
| Flu B Weak Positive (1x LoD) | 97.8% (44/45) | 100% (45/45) | 100% (45/45) | 99.3% (134/135) | 95.9% - 99.9% |
| Flu B Moderate Positive (3x LoD) | 100% (45/45) | 100% (45/45) | 100% (45/45) | 100% (135/135) | 97.2% - 100% |

**Limit of Detection (Analytical Sensitivity)**

Limit of detection (LoD) for influenza A and B in WELLLife® Influenza A&B Test was determined by evaluating different concentrations of live influenza A and B viruses. The viruses were diluted in PNSM to generate virus dilutions for testing. Anterior nasal swab samples were prepared by adding 50µL of each virus dilution onto the sterile swab. The swab samples were tested according to the test procedure in package insert. Range-finding testing was conducted with three replicates at various dilutions and confirmatory testing was conducted with 20 replicates. The lowest concentration that generated ≥95% positive detection rate was set as the LoD concentration.

**Limit of Detection (LoD) Study Results**

| Virus Strains | | Stock Concentration ($TCID_{50}$/mL) | LoD ($TCID_{50}$/mL) | LoD ($TCID_{50}$/Swab) |
|---|---|---|---|---|
| Influenza A | A/California/07/2009 pdm (H1N1) | $7.29 \times 10^6$ | $7.29 \times 10^2$ | $3.65 \times 10^1$ |
| | A/Victoria/4897/2022 (H1N1) | $3.89 \times 10^6$ | $3.89 \times 10^2$ | $1.95 \times 10^{-1}$ |
| | A/Darwin/6/2021 (H3N2) | $4.17 \times 10^5$ | $4.17 \times 10^1$ | $2.09 \times 10^0$ |
| | A/Perth/16/09 (H3N2) | $3.89 \times 10^6$ | $3.89 \times 10^2$ | $1.95 \times 10^1$ |
| Influenza B | B/Washington/02/2019 (Victoria) | $3.16 \times 10^6$ | $1.05 \times 10^3$ | $5.25 \times 10^1$ |
| | B/Malaysia/2506/2004 (Victoria) | $3.16 \times 10^6$ | $1.05 \times 10^2$ | $5.25 \times 10^0$ |
| | B/Florida/4/2006 (Yamagata) | $1.17 \times 10^5$ | $1.17 \times 10^1$ | $5.85 \times 10^{-1}$ |
| | B/Utah/9/14 (Yamagata) | $4.17 \times 10^5$ | $4.17 \times 10^1$ | $2.09 \times 10^0$ |

**Analytical Reactivity**

The analytical reactivity of the antibodies targeting Influenza A and influenza B in WELLLife® Influenza A&B Test was evaluated with the currently available strains. A selection of temporally, geographically, and genetically diverse influenza strains were tested for analytical reactivity. A series of ten-fold dilutions of each virus was spiked into PNSM and tested in triplicate. Once the ten-fold LoD range was established for each strain, an additional three two-fold dilution series of the lowest positive ten-fold dilution for each virus was tested in triplicate to demonstrate analytical reactivity. Based on this dilution series, the minimum detectable concentration was defined as the lowest concentration for which all three replicates were detected. Results are summarized in the following table.

**Analytical Reactivity Study Results**

| Target Analyte | Strain | Minimum Detectable Concentration |
|---|---|---|
| Influenza A H1N1 | A/Victoria/2570/19 pdm | $2.34 \times 10^2$ $TCID_{50}$/mL |
| | A/Taiwan/42/06 | $2.26 \times 10^2$ $TCID_{50}$/mL |
| | A/Solomon Islands/03/06 | $2.81 \times 10^2$ $TCID_{50}$/mL |
| | A/NY/02/09 pdm | $2.37 \times 10^2$ $TCID_{50}$/mL |
| | A/Brisbane/02/18 | $2.21 \times 10^2$ $TCID_{50}$/mL |
| | A/Michigan/45/15 pdm | $8.10 \times 10^2$ $TCID_{50}$/mL |
| | A/Wisconsin/67/22 | $4.21 \times 10^1$ $TCID_{50}$/mL |
| | A/Singapore/63/04 | $7.55 \times 10^1$ $TCID_{50}$/mL |
| Influenza A H3N2 | A/Wisconsin/588/19 | $6.30 \times 10^1$ $TCID_{50}$/mL |
| | A/Guangdong-Maonan/SWL1536/19 pdm | $5.85 \times 10^1$ $TCID_{50}$/mL |
| | A/California/04/2009* | $2.80 \times 10^3$ $TCID_{50}$/mL |
| | A/Indiana/02/2020* | $9.70 \times 10^4$ $CEID_{50}$/mL |
| | A/Hawaii/66/2019* | $1.85 \times 10^2$ $CEID_{50}$/mL |
| | A/Tasmania/503/20 | $1.41 \times 10^3$ $TCID_{50}$/mL |
| | A/Cambodia/E0826360/20 | $1.17 \times 10^3$ $TCID_{50}$/mL |
| | A/Michigan/173/20 | $5.25 \times 10^3$ $TCID_{50}$/mL |
| | A/Hong Kong/4801/14 | $8.88 \times 10^2$ $TCID_{50}$/mL |
| | A/Kansas/14/17 | $7.55 \times 10^2$ $TCID_{50}$/mL |
| | A/Singapore/INFIMH-16-0019/16 | $7.85 \times 10^1$ $TCID_{50}$/mL |
| | A/South Australia/55/14 | $3.15 \times 10^3$ $TCID_{50}$/mL |
| | A/Switzerland/9715293/13 | $3.80 \times 10^3$ $TCID_{50}$/mL |
| | A/Hong Kong/2671/19 | $1.26 \times 10^3$ $TCID_{50}$/mL |
| | A/Wisconsin/67/05 | $4.18 \times 10^3$ $TCID_{50}$/mL |
| | A/New York/21/2020* | $2.60 \times 10^4$ $FFU$/mL |
| | A/Alaska/01/2021* | $3.75 \times 10^4$ $FFU$/mL |
| | A/Indiana/08/2011* | $8.10 \times 10^3$ $TCID_{50}$/mL |
| Influenza A H3N8 | A/blue-winged teal/Iowa/10OS2411/2010 | $1.40 \times 10^4$ $CEID_{50}$/mL |
| Influenza A H1N1 | A/Ohio/09/2015* | $7.00 \times 10^2$ $CEID_{50}$/mL |
| Influenza A H1N2 | A/Minnesota/19/2011* | $4.00 \times 10^4$ $CEID_{50}$/mL |
| Influenza A H5N1 | A/mallard/Wisconsin/2576/2009 | $2.0 \times 10^4$ $CEID_{50}$/mL |
| Influenza A H5N6 | A/duck/Guangxi/S10888/2024* | $6.76 \times 10^5$ $EID_{50}$/mL |
| Influenza A H5N8 | A/goose/Liaoning/S1266/2021* | $6.76 \times 10^5$ $EID_{50}$/mL |
| Influenza A H7N3 | A/northern pintail/Illinois/10OS3959/2010 | $1.6 \times 10^4$ $CEID_{50}$/mL |
| Influenza B Victoria | B/Michigan/01/21 | $1.16 \times 10^3$ $TCID_{50}$/mL |
| | B/Austria/1359417/21 | $2.82 \times 10^3$ $TCID_{50}$/mL |
| | B/Singapore/WUH4618/21 | $2.93 \times 10^2$ $TCID_{50}$/mL |
| | B/Hong Kong/574/19 | $1.25 \times 10^3$ $TCID_{50}$/mL |
| | B/Brisbane/35/18 | $5.75 \times 10^2$ $TCID_{50}$/mL |
| | B/Wisconsin/1/2010 | $7.00 \times 10^3$ $CEID_{50}$/mL |
| Influenza B Yamagata | B/Phuket/3073/13 | $9.30 \times 10^3$ $TCID_{50}$/mL |
| | B/Brisbane/9/14 | $3.15 \times 10^3$ $TCID_{50}$/mL |
| | B/Texas/6/11 | $9.50 \times 10^3$ $TCID_{50}$/mL |
| | B/Brisbane/36/12 | $3.55 \times 10^3$ $TCID_{50}$/mL |
| | B/Lee/40 | $1.90 \times 10^2$ $TCID_{50}$/mL |

*These viruses were tested with the WELLLife COVID-19/Influenza A&B Antigen Test

**Analytical Specificity: Cross-Reactivity and Microbial Interference**

Cross-reactivity of the WELLLife® Influenza A&B Test was evaluated by testing a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens and could potentially cross-react with the WELLLife® Influenza A&B Test including twenty-two (22) bacteria, twenty-three (23) viruses and one (1) negative matrix. Each organism and virus were tested in triplicate the absence (cross-reactivity) or presence (interference) of live influenza A or influenza B virus at 3 x LoD contraction. No cross-reactivity was observed with the listed microorganisms when tested at the concentration presented in the table below. No interference was observed with the listed microorganisms when tested at the concentration presented in the table below in the presence of the target analytes.

**Cross-Reactivity and Microbial Interference Study Results**

| Microorganism/ Virus | Concentration Tested | Cross-reactivity (# pos / total) | | Microbial Interference (# pos / total) | |
|---|---|---|---|---|---|
| | | Flu A | Flu B | Flu A | Flu B |
| Pooled Negative Swab Matrix (PNSM) | NA | 0/3 | 0/3 | 3/3 | 3/3 |
| Adenovirus Type 1 | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Adenovirus Type 7A | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Human coronavirus OC43 | $1.70 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Human coronavirus 229E | $1.29 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Human coronavirus NL63 | $5.62 \times 10^2$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Human coronavirus HKU1* | Ct =22.0 Ct = 20.5 | 0/3 | 0/3 | 3/3 | 3/3 |
| MERS-coronavirus | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Cytomegalovirus | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Enterovirus Type 68 | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Epstein Barr Virus | $2.00 \times 10^5$ cp/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Parainfluenza virus Type 1 | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Parainfluenza virus Type 2 | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Parainfluenza virus Type 3 | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Parainfluenza virus Type 4A | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Measles Virus | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Human Metapneumovirus (hMPV-5) | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Mumps virus | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Respiratory syncytial virus Type A | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Respiratory syncytial virus Type B | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Rhinovirus | $5.62 \times 10^4$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Coxsackievirus Type A16 | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| SARS-CoV-2 USA-WA1/2020 | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| SARS-CoV-2 Omicron Variant | $2.00 \times 10^3$ $TCID_{50}$/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Bordetella pertussis* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Candida albicans* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Chlamydia pneumoniae* | $2.00 \times 10^5$ IFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Corynebacterium diphtheriae* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Escherichia coli* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Haemophilus influenzae* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Lactobacillus acidophilus* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Legionella pneumophila Philadelphia* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Moraxella catarrhalis* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Mycobacterium tuberculosis* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Mycoplasma pneumoniae* | $2.00 \times 10^6$ CCU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Neisseria meningitidis* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Neisseria gonorrhoeae* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Pseudomonas aeruginosa* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Staphylococcus aureus* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Staphylococcus epidermidis* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Streptococcus pneumoniae* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Streptococcus pyogenes* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Streptococcus salivarius* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Pneumocystis jirovecii - S.cerevisiae* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Neisseria subflava biovar flava* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| *Streptococcus mutans* | $2.00 \times 10^6$ CFU/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Mucin (Bovine submaxillary glands Type I-S or pooled mucous) | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Benzocaine | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Zinc* | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Menthol | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Luffa oppercculata | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Sulfur | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Galphimia glauca | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Histanium hydrocitricum | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Phenylephrine | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Oxymetazoline | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Cromolyn | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Sodium chloride with preservatives | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Zicam | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Alkalol | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Phenol | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Fluticasone* | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Budesonide | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Flunisolide | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Dexamethasone | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Beclomethasone | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Triamcinolone | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Mometasone | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Tamiflu (Oseltamivir Phosphate) | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Tobramycin | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Mupiricin | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| FluMist/ FluMist Quadrivalent Live intranasal influenza virus vaccine | 15% v/v | 3/3 | 3/3 | 3/3** | 3/3*** |
| | 6% v/v | 3/3 | 0/3 | NT | 3/3 |
| | 3% v/v | 3/3 | 0/3 | NT | 3/3 |
| | 1.5% v/v | 3/3 | 0/3 | NT | NT |
| | 0.75% v/v | 3/3 | 0/3 | NT | NT |
| | 0.375% v/v | 0/3 | 0/3 | 3/3 | NT |
| | 0.188% v/v | 0/3 | 0/3 | 3/3 | NT |
| Zanamivir | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Remdesivir | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Molmupiravir | 10 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Biotin | 3,500 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Aspirin | 15 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Motrin (Ibuprofen) | 50 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Naproxen | 20 mg/mL | 0/3 | 0/3 | 3/3 | 3/3 |
| Bleach | 0.01% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Dish soap | 1% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Laundry detergent (liquid) | 1% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Multi surface cleaner | 1% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Hand soap | 1% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Laundry detergent (solid) | 1% w/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Bar soap | 1% w/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Multipurpose cleaner | 1% w/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Hand sanitizer | 1% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Disinfectant spray-Lysol | 1% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Body & Hand Lotion | 0.5% w/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Hand Lotion | 5% w/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Hand Sanitizer with Aloe, 62% ethyl alcohol | 5% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Hand Sanitizer cream lotion | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Body Lotion, with 1.2% dimethicone | 0.5% w/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Hand soap liquid gel* | 10% w/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Hand Sanitizer, 80% ethanol, fast drying * | 15% v/v | 0/3 | 0/3 | 3/3 | 3/3 |

*Two different clinical samples were tested in replicates of three.

**Endogenous Interfering Substances**

The potential interference of endogenous substances with the antibodies used for the detection of influenza A and B was examined by testing fifty-one (51) substances in a negative clinical matrix in triplicate, in the absence or presence of influenza A(H1N1) or influenza B(Yamagata) virus at 3 x LoD concentration. The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the WELLLife® Influenza A&B Test.

At 15% (v/v) and when diluted down to 0.75% (v/v), FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine yielded false positive results for Influenza A and at a dilution of 0.375% (v/v), the results were negative for influenza A. At 15% (v/v), FluMist Quadrivalent Live Intranasal Influenza Virus Vaccine yielded false positive results for influenza B. And at a dilution of 6% (v/v), the results were negative for influenza B. No interference was observed with the listed substances when tested at the concentration presented in the table below in the presence or absence of the target analytes.

**Endogenous/Exogenous Interfering Substances Study Results**

| Potential Interferent | Concentration | Without analytes (# pos / total) | | With analytes (3x LoD) (# pos / total) | |
|---|---|---|---|---|---|
| | | Flu A | Flu B | Flu A | Flu B |
| Whole Blood | 5 % v/v | 0/3 | 0/3 | 3/3 | 3/3 |
| Leukocytes | $1 \times 10^6$ cells/mL | 0/3 | 0/3 | 3/3 | 3/3 |

NT: Not tested.

* These substances showed interference with the WELLLife COVID-19/Influenza A&B Antigen Test at the same concentrations tested.

**When Flu A was in the sample, a false positive for Flu B was detected.

***When Flu B was in the sample, a false positive for Flu A was detected.

**High Dose Hook Effect**

A high-dose hook effect was not observed in WELLLife® Influenza A&B Test for the influenza A and B viral strains at the concentration listed below.

**High Dose Hook Effect Study Results**

| Subtype | Strain | Concentration ($TCID_{50}$/mL) | Positive Results / Total Results All Lots | |
|---|---|---|---|---|
| | | | Influenza A | Influenza B |
| Influenza A | A/California/07/2009 pdm | $7.29 \times 10^5$ | 9/9 | 0/9 |
| | A/Victoria/4897/22 | $3.89 \times 10^6$ | 9/9 | 0/9 |
| | A/Darwin/6/21 | $4.17 \times 10^5$ | 9/9 | 0/9 |
| | A/Perth/16/09 | $3.89 \times 10^6$ | 9/9 | 0/9 |
| Influenza B | B/Washington/02/19 | $3.16 \times 10^6$ | 0/9 | 9/9 |
| | B/Malaysia/2506/2004 | $3.16 \times 10^6$ | 0/9 | 9/9 |
| | B/Florida/04/06 | $1.17 \times 10^5$ | 0/9 | 9/9 |
| | B/Utah/9/14 | $4.17 \times 10^5$ | 0/9 | 9/9 |

**Competitive Interference**

The study was performed to evaluate if the WELLLife® Influenza A&B Test assay can detect low levels of influenza A in the presence of high levels of influenza B and vice versa. Four influenza strains were used in this study: influenza A/Victoria/4897/2022, influenza A/Perth/16/2009, influenza B/Washington/02/2019, and influenza B/Florida/04/2006. Testing was performed with different combinations of low (2 x LoD) and high concentrations (exceeding 104 TCID50/mL, >1000 x LoD) of Influenza A and Influenza B. Using a pipette, 50µL of each influenza sample was applied to a swab. The swabs were tested in triplicate. Low and high concentrations of the influenza strains used in this study are presented in Table below.

**Results of Competitive Interference Study Results**

| Influenza A strain | Influenza B strain | Influenza A Positive Replicates | Influenza B Positive Replicates |
|---|---|---|---|
| A/Victoria/4897/2022 Low concentration | B/Washington/02/2019 High Concentration | 9/9 (100%) | 9/9 (100%) |
| A/Victoria/4897/2022 Low concentration | B/Florida/04/2006 High Concentration | 9/9 (100%) | 9/9 (100%) |
| A/Perth/16/2009 Low Concentration | B/Washington/02/2019 High Concentration | 9/9 (100%) | 9/9 (100%) |
| A/Perth/16/2009 Low Concentration | B/Florida/04/2006 High Concentration | 9/9 (100%) | 9/9 (100%) |
| A/Victoria/4897/2022 High Concentration | B/Washington/02/2019 Low concentration | 9/9 (100%) | 9/9 (100%) |
| A/Victoria/4897/2022 High Concentration | B/Florida/04/2006 Low Concentration | 9/9 (100%) | 9/9 (100%) |
| A/Perth/16/2009 High Concentration | B/Washington/02/2019 Low Concentration | 9/9 (100%) | 9/9 (100%) |
| A/Perth/16/2009 High Concentration | B/Florida/04/2006 Low Concentration | 9/9 (100%) | 9/9 (100%) |

**CLINICAL PERFORMANCE**

A prospective study was performed in which seven hundred sixty (766) subjects were sequentially enrolled (between January 2025 and March 2025) and tested fresh. Anterior nasal swab (ANS) samples were collected from symptomatic patients suspected of infection with respiratory symptoms, at six (6) clinical sites. To be enrolled in the study, patients had to present at the participating study site with signs and symptoms of respiratory infection generally observed from influenza A and/or influenza B, during the study period. Two anterior nasal swab specimens were collected from each patient: one swab was collected by a healthcare professional and sent for testing using an FDA-cleared molecular comparator method, and the other swab was self-collected and tested immediately with the WELLLife® Influenza A&B Test per the test procedure. The collection order for the investigational and the comparator tests' ANS swab was randomized. Subjects performed testing on self-collected swab samples in age groups 14 and older, and adult collected samples for other individuals, in a simulated at-home environment. Out of 766 enrolled subjects, there were 680 evaluable subjects and 86 enrolled subjects were excluded.

**Subjects Demographic**

| Characteristics | Number | Percent of Subjects |
|---|---|---|
| **Age (years)** | | |
| 2 to 13 years | 167 | 24.6% |
| 14 to 21 years | 78 | 11.5% |
| 22 to 59 years | 346 | 50.9% |
| ≥60 years | 89 | 13.1% |
| Total | 680 | 100.0% |
| **Sex** | | |
| Male | 295 | 43.4% |
| Female | 385 | 56.6% |
| Total | 680 | 100.0% |
| **Ethnicity** | | |
| Hispanic/Latino | 260 | 38.2% |
| Not Hispanic/Latino | 420 | 61.8% |
| Total | 680 | 100.0% |

**Influenza A Performance**

**Clinical Performance for Flu A**

| Influenza A | Comparator Positives | Comparator Negatives | Total |
|---|---|---|---|
| **Candidate Positives** | 146 | 0 | 146 |
| **Candidate Negatives** | 12 | 522 | 534 |
| **Total** | 158 | 522 | 680 |
| Positive Percent Agreement (PPA): 92.4% (95% CI: 87.2%-95.6%) | | | |
| Negative Percent Agreement (NPA): 100% (95% CI: 99.3%-100%) | | | |

**Influenza B Performance**

**Clinical Performance for Flu B**

| Influenza B | Comparator Positives | Comparator Negatives | Total |
|---|---|---|---|
| **Candidate Positives** | 32 | 0 | 32 |
| **Candidate Negatives** | 3 | 645 | 648 |
| **Total** | 35 | 645 | 680 |
| Positive Percent Agreement (PPA): 91.4% (95% CI: 77.6%-97.0%) | | | |
| Negative Percent Agreement (NPA): 100.0% (95% CI: 99.4%-100%) | | | |

## ASSISTANCE

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).

## REFERENCES


1. US Department of Health and Human Services. National Institutes of Health. Influenza [Fact Sheet]. January 2011.


## INDEX OF SYMBOLS

Keep away from sunlight

Store at 36-86°F/2-30°C

Keep dry

Do not re-use

REF Catalogue number

LOT Batch code

Use-by date (Expiration date)

IVD *In vitro* diagnostic medical device

Consult instructions for use

Do not use if package is damaged


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

Rev. A1
Rel.: 2025/08/27