WELLlife™

COVID-19 / Influenza A&B Test

QUICK REFERENCE INSTRUCTIONS

REF WV01P0002 IVD ℞ONLY

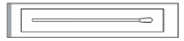
For use under Emergency Use Authorization (EUA) only
For *in vitro* diagnostic use.
For use with anterior nasal swab specimens.

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

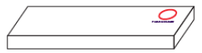
Sealed Test Cassette

Swab



Buffer Tube

Tube Holder



Required but not provided: Timer or clock.

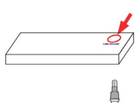
PREPARING FOR THE TEST

NOTE: 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.

1. **Check the test's expiration date printed on the outer test packaging.** For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

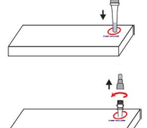
2. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer

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

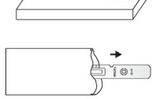


4. **a)** Insert the buffer tube into the tube holder. Ensure that the buffer tube is stable and upright.

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

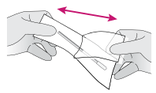


5. Remove test cassette from sealed pouch and lay it on a flat surface.



SAMPLE COLLECTION

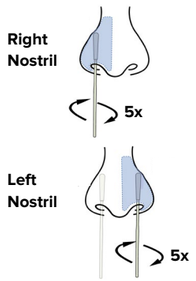
6 Remove the swab from the pouch.



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

7 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.

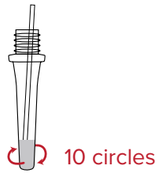
b) Remove the swab and repeat in the other nostril using the same swab.



Check: Did you swab both nostrils?

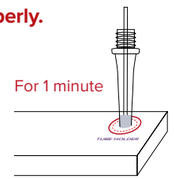
RUNNING THE TEST

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



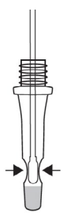
Sample must be adequately mixed into the buffer or the test will not work properly.

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



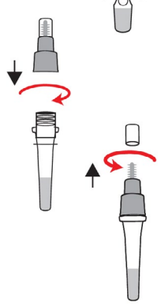
10 After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess liquid from the swab.

Remove and discard the swab.



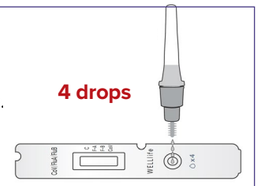
11 a) Hold the buffer tube upright and screw the large cap back onto the tube. Ensure a tight fit to prevent leaking.

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



RUNNING THE TEST CONT'D

12 Invert the buffer tube and sque 4 drops of test sample into the sample well on the test cassette. Then discard the buffer tube



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

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

13 Start timer. Read results at 10 minutes

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

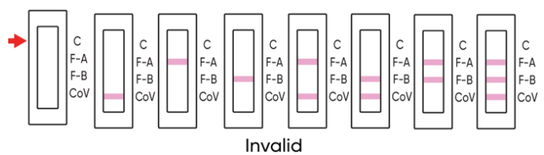
INTERPRETING TEST RESULTS

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 singals that the test is working properly.

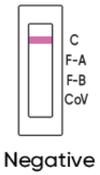
INVALID TEST RESULT



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.

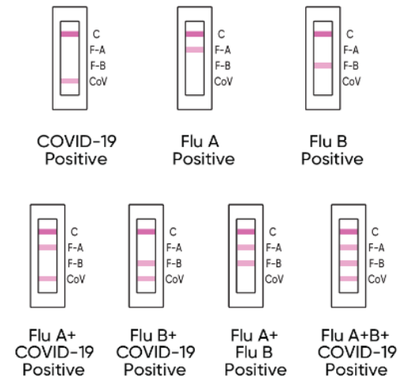
If you do not see a C line, DO NOT CONTINUE reading the results. It means the test is invalid. Repeat the test with a new sample and new test kit materials.

NEGATIVE TEST RESULT



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

POSITIVE TEST RESULT



If the control line at "C" is visible and any other line or multiple lines at 'F-A', 'F-B" and/or 'CoV' appear, 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.

It is possible to have more than one positive Test Line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2, the virus that causes COVID-19. If more than one positive Test Line is observed, retest with a new patient sample, Extraction Buffer vial, and Test Stick. A differing result should be followed by confirmatory testing with another test method, such as PCR.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

COVID-19 / Influenza A&B Test

INTENDED USE

The WELLLife™ COVID-19 / Influenza A&B Test is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests.

This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

These viral antigens are generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of the disease.

All negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out influenza or SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with each respiratory infection.

The WELLLife™ COVID-19 / Influenza A&B Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Carefully read all instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.
- Do not use after the expiration date printed on the outside of the box.
- Ensure that there is sufficient lighting for testing and interpretation.
- **In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/ or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.**
- **Serial testing should be performed in individuals with 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.**
- This test may only be used in symptomatic individuals.
- **Do not read test results before 10 minutes or after 20 minutes. Results read before 10 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.**

SERIAL TESTING

Repeat Testing is needed for all samples that are negative for SARSCoV- 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

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.

ASSISTANCE

If the test does not perform as expected, please email at wondfo@wondfousa.com or call 1-888-444-3657.

INDEX OF SYMBOLS

	Consult instructions for use		Manufacturer		Use-by date
	Do not reuse		Store between 2-30°C (35.6°F-86°F)	LOT	Batch code
REF	Catalog number		Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control		Contains sufficient for <n> Tests
IVD	For in vitro diagnostic use	℞ONLY	Prescription Use Only		

Wondfo USA Co., Ltd.
6720 Cobra Way,
San Diego, CA 92121

Manufacturing Site
Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City
Huangpu District, 510663
Guangzhou, P.R. China
Made in China

Distributed by Wondfo USA Co., Ltd.
545 Willowbrook Centre Parkway, Unit B
Willowbrook, IL 60527
+1 (630) 468-2199
www.wondfousa.com

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