Covid-19 / Influenza A&B Home Test

Quick Reference Instructions

For use under Emergency Use Authorization (EUA) only

For in vitro diagnostic use.

For the over-the-counter (OTC) 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 Instruction for Use (IFU) for more complete information at https://www.fda.gov/covid-tests.

An anterior nasal swab sample can be self-collected by individuals aged 14 years or older. Children aged 2-13 years should be tested by an adult.

Materials Provided

Sealed Test Cassette

Swab

Buffer Tube

Materials required but not provided: Timer or watch.

Preparation for the Test

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

1. Check the expiration date of the test printed on the outer box. 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. Insert the buffer tube into the tube holder. Ensure that the buffer tube is stable and upright.

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

6. Remove the swab from the pouch. Be careful not to touch the swab tip (soft end) with hand.

7. 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.

8. Immersely swab the inside of the tube and swab the swab in the buffer. Ensure the sample is mixed thoroughly by making at least 10 circles.

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

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

Sample Collection

If the control line “C” is visible and you do not see a line at “A”, “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 is accurate, you should test again in 48 hours after the first day of testing. If respiratory symptoms persist, you seek follow-up care with health care provider.

If the control line “C” is visible and you do not see a line at “A”, “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 is accurate, you should test again in 48 hours after the first day of testing. If respiratory symptoms persist, you seek follow-up care with health care provider.

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

Running the Test

Start timer. Read results at 10 minutes.

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

Running the Test Cont’d

Look for lines next to “C” (Control), “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 signifies that the test is working properly.

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.

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.

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 “A”, “B” or “CoV”, it means the test is positive. The Flu A, Flu B or COVID-19 virus have not been detected.

To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours after the first day of testing. If respiratory symptoms persist, you seek follow-up care with health care provider.

Positive Result

If the control line “C” is visible and you do not see a line at “A”, “B” or “CoV”, it means 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 per CDC recommendations 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.

<table>
<thead>
<tr>
<th>Status on First Day of Testing: With Symptoms</th>
<th>day 1</th>
<th>day 2</th>
<th>Interpretaiton</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 (-)</td>
<td>No needed</td>
<td>SARS-CoV-2 (+) or INFLUENZA A and/or B (+)</td>
<td>Positive for COVID-19, Presumptive negative for Influenza</td>
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</tr>
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</table>

Your results:

Your test results are positive for COVID-19.

Follow-up care with healthcare provider.
Results

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, kit and test will be followed-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

If the test is negative, it is important to carefully perform the procedure. Failure to follow the instructions may result in inaccurate test results. If you test positive, it means you have evidence that you have COVID-19, and are infectious. A healthcare provider or public health authorities will follow local guidelines for self-isolation. There is a small chance that this test can give you a positive result that is incorrect (a false positive).

RESULTS REPORTING

Report your test result(s) at StikyTextCount.org, this voluntary and anonymous reporting helps public health workers understand COVID-19 spread in your area and across the country and informs public health decisions.

INTENDED USE

THE WELLIe COVID-19 / Influenza A & B Home Test is a lateral flow immunassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A and influenza B proteins antigens. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals aged 2 (years or older. This test is indicated for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first 5–10 days of symptom onset at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral disease due to SARS-CoV-2 and influenza can be similar.

Results are for the simultaneous identification of SARS-CoV-2, influenza A virus and influenza B virus protein antigens, but do not differentiate between SARS-CoV-2 and SARS-CoV-1 and are not intended to detect influenza C antigens.

The viral antigens targeted by this test are generally detectable from specimens collected using nasal swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other clinical 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 disease. Individuals testing positive with the WELLIe™ COVID-19 / Influenza A & B Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as testing may cause nausea.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection. Influenza A, and influenza B 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 do not indicate the absence of the virus in an individual’s recent exposures, history, and the presence of clinical signs and symptoms consistent with SARS-CoV-2, influenza A, and influenza B infection.

Individuals who test negative and continue to experience SARS-CoV-2 and/or influenza-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 and other co-infections and should seek follow-up care with their physician or healthcare provider.

The WELLIe™ COVID-19 / Influenza A & B Home Test is only intended for use under Food and Drug Administration’s Emergency Use Authorization.

HOW TO USE THIS TEST

The test 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, kit and test will be followed-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.

STORAGE AND STABILITY

Store the test kit between 36-85°F (-2°C to 32°C) in a place out of direct sunlight.

Results: The test cassette contains an assay pad, a control line (C), a test line (T), and a test control line (C). A test control line is used to verify that the test works properly. If the test control line does not appear, the test result cannot be interpreted.

For the most up-to-date information on COVID-19, please visit www.cdc.gov/covid19

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 circumstances.

• Do not perform this test 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. You may test negative and currently infected. In this case, the test for SARS-CoV-2 or influenza infection may be still 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.

• CAUTION: Test results are presumptive and confirmatory with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out COVID-19 when taken multiple times across several days. Repeat testing may improve 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 Healthcare Provider Instructions for Use (FPF), available at: https://wondofusa.com/

• Q: WHAT Does AN INVALID TEST RESULT MEAN? A: An invalid result means something is with 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 you have not been infected by the virus that causes COVID-19. It may be a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

• All negative results SARS-CoV-2 or influenza or are presumptive and confirmatory with a molecular assay may be necessary. If you continue to have symptoms of COVID-19 or influenza and both your first and second tests are negative, you may not have COVID-19 or influenza, however, you should follow up with a healthcare provider.

• If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19 and the individual likely has respiratory infection with COVID-19 or influenza.

• Inconce test results may occur if a specimen is incorrectly collected or handled.

Q: HOW ACCURATE IS THIS TEST? A: Clinical studies have shown that antigen tests are more accurate than SARS-CoV-2 or influenza virus. However, these tests are not as sensitive for detecting COVID-19 as molecular tests. If you test negative and you have symptoms of COVID-19, you should self test again in 48 hours since the first test may be a false negative result.

If you are uncertain how to proceed, consult Technical Assistance at +1-888-444-3657. If you want to report a problem with this product, please contact Wondofusa Product Support at +1 (888) 444-3657 or Wondofusa Co., Ltd. Product Support website: https://wondofusa.com/

A: What are the known and potential risks and benefits of the test?

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 results (see Warnings and Result Interpretation sections for more information).

• Potentially harmful substances:

The results of the test may improve test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results.

If you have questions regarding the use of this product, or if you want to report a problem with this test, please contact Wondofusa Product Support at +1 (888) 444-3657 or Wondofusa Co., Ltd. Product Support website: https://wondofusa.com/
COVID-19 / Influenza A&B Home Test

Do not use if you've had symptoms longer than 5 days or no symptoms at all.

• The WELLlife™ COVID-19 / Influenza A&B Home Test is authorized for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older or adult collected anterior nasal swab samples from individuals aged 2 years or older.

• This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A virus and influenza B virus, not for any other viruses or pathogens.

• Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

• In the USA, this product has not been FDA cleared or approved; but has been authorized for use by FDA under an EUA.

• This product does NOT determine if you had COVID-19 or influenza A or influenza B in the past or if you have immunity.

• 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.

• Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

For use under Emergency Use Authorization (EUA) only. For in vitro diagnostic use. For use with anterior nasal swab specimens. For over-the-counter (OTC) use. Store sealed at 36°F-86°F/2°C-30°C

CONTENTS:
• 1 Sealed Test Cassette
• 1 Buffer Tube
• 1 Swab
• 1 Tube holder (Top right corner on Box)
• 1 Quick Reference Instructions (QRI)

Materials required but not provided: Timer or watch

For information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/covid-tests

Rev. A1   Rel.: 2024/05/08

For use with anterior nasal swab specimens.
COVID-19 / Influenza A&B Home Test

Results in just 10 Mins

An Easy Nasal Swab Test

For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.
For use with anterior nasal swab specimens.
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Store sealed at 36°F-86°F/2°C-30°C

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GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Huangpu District, 510663
Guangzhou, P.R. China
Made in China

• Do not use if you’ve had symptoms longer than 5 days or no symptoms at all.
• This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A virus and influenza B virus, not for any other viruses or pathogens.
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• Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

For use in antigen detection. The results of this test may be different from the results of a laboratory test performed in a laboratory.

For use with anterior nasal swab samples from individuals aged 2 years or older.

CONTENTS:
• 2 Sealed Test Cassettes
• 2 Buffer Tubes
• 2 Swabs
• 1 Tube Holder (Top right corner on Box)
• 1 Quick Reference Instructions (QRI)

Materials required but not provided: Timer or watch

2 Tests
Results in just 10 Mins
An Easy Nasal Swab Test

COVID-19 ⁄ Influenza A&B Home Test

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For information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/covid-tests

For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.
For use with anterior nasal swab specimens.
For over-the-counter (OTC) use.
Store sealed at 36°F-86°F/2°C-30°C

CONTENTS:
• 5 Sealed Test Cassettes
• 5 Buffer Tubes
• 5 Swabs
• 1 Tube holder (Top right corner on Box)
• 1 Quick Reference Instructions (QRI)

Materials required but not provided: Timer or watch
COVID-19 ⁄ Influenza A&B Home Test

Results in just 10 Mins
An Easy Nasal Swab Test

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CONTENTS:
- 10 Sealed Test Cassettes
- 10 Buffer Tubes
- 10 Swabs
- 1 Tubing Holder (Top right corner on Box)
- 1 Quick Reference Instructions (QRI)

Materials required but not provided: Timer or watch.

COVID-19 ⁄ Influenza A&B
Home Test

Up to 400g
150x90x62mm
UVM

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

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

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www.wondfousa.com

Made in China

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For use under Emergency Use Authorization (EUA) only.
For in vitro diagnostic use.
For use with anterior nasal swab specimens.
For use with children 5 years of age and over.
Store sealed at 36°F-86°F / 2°C-30°C

Specifications (LOGO+):
- 10 Sealed Test Cassettes
- 10 Buffer Tubes
- 10 Swabs
- 1 Tubing Holder (Top right corner on Box)
- 1 Quick Reference Instructions (QRI)

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COVID-19 ⁄ Influenza A&B Home Test
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- Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

CONTENTS:
- 25 Sealed Test Cassettes
- 25 Buffer Tubes
- 25 Swabs
- 1 Tube holder (Top right corner on Box)
- 1 Quick Reference Instructions (QRI)

For information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/covid-tests

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