
FAQs on Testing for COVID-19 / Influenza A&B Test

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Part I: Basic questions on COVID-19 / Influenza A&B Test

Q1: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: Please see the below follow:

Antigen Test: This test detects specific proteins on the surface of the virus, known as antigens. It is generally less sensitive than a molecular test but can provide results more quickly, often within minutes. Antigen tests are often used for rapid screening and are less expensive and easier to administer than molecular tests. However, they may not detect the virus if the viral load is low, such as in the early stages of infection or in asymptomatic individuals.

Molecular Test (PCR Test): This test detects the genetic material of the virus. It is highly sensitive and can detect even small amounts of the virus, making it more accurate for confirming an active infection. Molecular tests require specialized equipment and trained personnel to process the samples, which typically involves a nasal or throat swab. The results usually take longer to obtain, often 24 to 48 hours or more, compared to antigen tests.

Q2: WHAT TYPE OF SPECIMEN DOES IT USE?

A: The test uses the anterior nasal swab specimen.

Q3: HOW TO COLLECT THE ANTERIOR NASAL SWAB SPECIMEN?

A: The sample collection process is very simple. 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.

Q4: IF THERE IS THICK MUCUS ON THE SWAB, WILL IT AFFECT THE TEST RESULTS?

A: Yes, it can. Thick mucus, which is a type of nasal secretion, can interfere with the sampling process and potentially lead to inaccurate results. This is because the viscous nature of the mucus can cause difficulties in obtaining a proper sample. Before testing, you can gently wipe your nose with a tissue to clear away any thick mucus, and then use a nasal swab for sampling and testing.

Q5: HOW LONG DOES A SINGLE TEST TAKE?

A: It takes 10 minutes, and DO NOT read the result after 20 minutes.

Q6: HOW LONG CAN THE TEST BE KEPT AFTER OPENING?

A: The reagent kit should be used within its expiration date! The test card should be used immediately upon opening, and the test should be conducted within 1 hour after opening. If the reagent card is opened for more than 1 hour, it is recommended to discard it and use a new test for testing.

Q7: CAN I USE THE TEST AFTER THE EXPIRATION DATE?

A: No, do not use the test kit after its expiration date. To confirm the expiration date, please check the side of the outer box or the pouch label. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit <http://www.fda.gov/covid-tests>.

Q8: HOW TO INTERPRET THE TESTING RESULT?

A: Look for lines next to 'C' (Control), 'F-A', 'F-B' and 'CoV'.

C = Control Line

F-A = Flu A Test Line

F-B = Flu B Test Line

CoV = COVID-19 Test Line

A red line should always appear at the 'C' position; this is a control line and signals that the test is working properly.

Please see below picture

POSITIVE RESULT



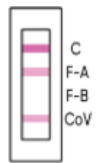
COVID-19 Positive



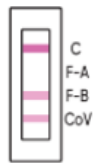
Flu A Positive



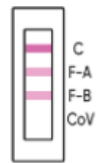
Flu B Positive



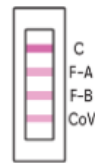
Flu A+ COVID-19 Positive



Flu B+ COVID-19 Positive



Flu A+ Flu B Positive

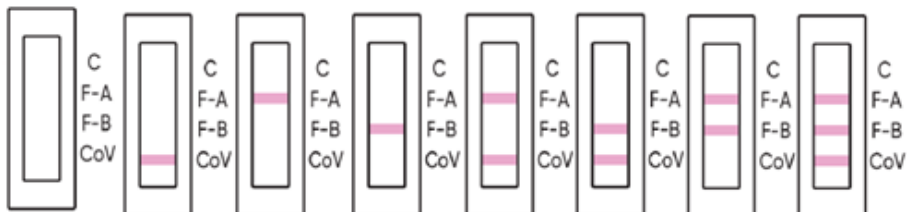


Flu A+B+ COVID-19 Positive

NEGATIVE RESULT



INVALID RESULT





Wondfo USA Co., Ltd.

545 Willowbrook Centre Parkway - Unit B, Willowbrook, IL 60527
Ph: 630-468-2199 Fax: 866-769-0168
<http://www.wondfousa.com>

Q9: HOW SOON CAN I TEST WITH SYMPTOMS

A: This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the **first four (4)** days of symptom onset when tested at least twice over three days with at least 48 hours between tests.

Q10: CAN I USE THIS TEST FOR CHILD WITH SYMPTOMS

A: 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 two (2) years or older. An anterior nasal swab sample can be self-collected by individuals aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

Q11: WHAT IF I HAVE A POSITIVE TEST RESULT?

A: A positive result means that it is very likely you have COVID-19 or influenza because proteins from the virus that causes COVID-19 were found in your sample. You should self isolate from others and contact a healthcare provider for medical advice about your positive result.

Q12: WHAT IF I HAVE A NEGATIVE TEST RESULT?

A: A negative test result indicates that antigens from the virus that causes COVID-19 or influenza were not detected in your sample. However, 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. If you have a negative result, it does not rule out SARS-CoV-2 or influenza infection; you may still be 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.

Q13: WHAT DOES AN INVALID TEST RESULT MEAN?

A: An invalid result means something with the test did not work properly. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

Q14: HOW ACCURATE IS THIS TEST?

A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves 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 (IFU), available at: <https://wondfousa.com/>.

Part II: further questions on COVID-19 / Influenza A&B Test

Q1: WHY DO I GET WRONG RESULTS?

- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- Based on sequence and epitope analyses, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exist. Wet testing

with HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

Q2: WHAT SHOULD I DO IF SMALL BUBBLES APPEAR IN THE SAMPLE WELL WHILE ADDING THE DILUENT?

A: If small bubbles appear, gently puncture them with the tip of a tube. This should not interfere with the continuation of the sample addition or the flow of the liquid.

Q3: IF WATER, JUICE, BEVERAGES, CONDIMENTS, ETC. ARE TESTED, WHAT RESULTS WOULD APPEAR?

A: Liquids such as water, fruit juice, beverages, and condiments have complex compositions and varying pH levels. When they are directly or mixed with an extraction solution and dropped onto a test card, it may have already compromised the optimal reaction conditions for the product. Additionally, it may cause staining of the biological materials on the test card or directly induce a reaction, leading to meaningless test outcomes such as false negatives, false positives, and invalid results.

Q4: WHAT DO I HAVE TO PAY ATTENTION TO IN ORDER TO GET THE MOST EXACT TEST RESULT POSSIBLE?

A: Always follow the instructions for use exactly. Perform the test immediately after collecting the sample. Put the drops from the buffer tube only into the designated well of the test cassette. Dispense four drops from the buffer tube. Too many or too few drops can lead to an incorrect or invalid test result.

Q5: WHAT SHOULD I DO IF I ACCIDENTALLY INGEST THE SAMPLE EXTRACTION FLUID, OR IF THE SAMPLE EXTRACTION FLUID ENTERS THE EYES OR COMES INTO CONTACT WITH THE SKIN?

A: The sample extraction fluid that comes with the reagent kit contains a small amount of preservatives, which may cause irritation to the skin and eyes. If you accidentally ingest it, drink a large amount of water or milk immediately. If there is significant discomfort, seek medical attention promptly.

If the solution comes into contact with the skin or eyes, rinse with clean water. If discomfort persists, seek medical attention promptly.

It is recommended to store the reagent kit properly, such as in a place that is not easily accessible to children, to prevent children from coming into contact with the reagents and its accessories.

Q6: IF I NEED TO TAKE A SECOND TEST, HOW LONG SHOULD I WAIT BETWEEN THEM?

You should wait at least 15 minutes between tests. Taking tests closer together might result in a false negative due to potentially low viral loads.

A: If the same individual requires two tests, a minimum of 15 minutes must elapse between them. Testing within a 15-minute interval may yield a false negative due to potentially low viral loads.

IMPORTANT: Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.