

# COVID-19 & Influenza A&B Test FAQs

# **Table of Contents**

Content	Page
Q1: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND A MOLECULAR TEST?	2
Q2: WHAT TYPE OF SPECIMEN DOES THE TEST USE?	2
Q3: HOW TO COLLECT AN ANTERIOR NASAL SWAB SPECIMEN?	2
Q4: HOW LONG DOES IT TAKE TO GET A RESULT?	2
Q5: HOW LONG CAN THE TEST BE KEPT FOR AFTER OPENING?	2
Q6: CAN I USE THE TEST AFTER THE EXPIRATION DATE?	2
Q7: WILL SECRETIONS FROM THE NASAL CAVITY COLLECTED BY THE SWAB AFFECT THE TEST RESULT?	2
Q8: HOW TO INTERPRET THE TEST RESULT?	3
Q9: HOW SOON CAN I TEST WITH SYMPTOMS?	4
Q10: CAN I USE THIS TEST ON A CHILD WITH SYMPTOMS?	4
Q11: WHAT IF THE TEST RESULT IS POSITIVE?	4
Q12: WHAT IF THE TEST RESULT IS NEGATIVE?	4
Q13: WHAT DOES AN INVALID TEST RESULT MEAN?	4
Q14: HOW ACCURATE IS THIS TEST?	4
Q15: IF WATER, JUICE, BEVERAGES, CONDIMENTS, ETC. COME INTO CONTACT WITH THE TEST, WHAT IS THE RESULT?	4
Q16: WHY WOULD I GET AN INCORRECT TEST RESULT?	5
Q17: WHAT DO I HAVE TO PAY ATTENTION TO IN ORDER TO GET THE MOST EXACT TEST RESULT POSSIBLE?	5
Q18: WHAT IS SERIAL (REPEAT) TESTING?	5
Q19: 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?	5





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

- 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, typically 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 THE TEST USE?

A: The test uses an anterior nasal swab specimen.

## Q3: HOW TO COLLECT AN 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. Remove the swab from one nostril and repeat the process in the other nostril with the same swab.

#### Q4: HOW LONG DOES IT TAKE TO GET A RESULT?

A: The result will be available within 10 minutes. It should not be read after 20 minutes.

#### Q5: HOW LONG CAN THE TEST BE KEPT FOR 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 sample should be run within 1 hour after opening. If the reagent card is opened for more than 1 hour, it is recommended to discard it and start the process again with a new test.

# Q6: 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 www.fda.gov/covid-tests

# Q7: WILL SECRETIONS FROM THE NASAL CAVITY COLLECTED BY THE SWAB AFFECT THE TEST RESULT?

A: The secretions in the nasal cavity have a varied composition and, can make obtaining a suitable sample more difficult. This can lead to false negative or invalid results. Before taking the sample the nose can be wiped to remove mucus before inserting the swab.





# **Q8: HOW TO INTERPRET THE TEST 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 indicates that the test is working properly.

Please see below pictures

# **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**





















#### Q9: HOW SOON CAN I TEST WITH SYMPTOMS?

A: The test is validated for use in individuals with symptoms of respiratory infection consistent with COVID-19 or Influenza A/B within the first five days of symptom onset. Tests should be carried out at least twice over three days with a 48 hour gap between tests.

## Q10: CAN I USE THIS TEST ON A CHILD WITH SYMPTOMS?

A: This test is authorized for at home (over-the-counter) 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. An anterior nasal swab sample can be self-collected by individuals aged 14 years and older. Children aged 2 to 13 years should have their test sample collected by an adult.

# Q11: WHAT IF THE TEST RESULT IS POSITIVE?

A: A positive result against any or all of the tests indicates that it is very likely you have COVID-19 and/or influenza A/B because proteins from one or more of the viruses 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 THE TEST RESULT IS NEGATIVE?

A: A negative test result indicates that antigens from the viruses that cause COVID-19 or influenza A/B were not detected in your sample. However, if you have symptoms of respiratory infection, and your first test is negative, you should test again 48 hours later since antigen tests are not as sensitive as molecular tests. If you have a negative result, it does not rule out COVID-19 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 the test did not perform as expected. If the test is invalid, a new swab should be used to collect another nasal specimen and you should test again with a new kit.

# Q14: HOW ACCURATE IS THIS TEST?

A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the viruses that cause COVID-19 or Influenza A/B 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 Package Insert, available at www.wondfousa.com

# Q15: IF WATER, JUICE, BEVERAGES, CONDIMENTS, ETC. COME INTO CONTACT WITH THE TEST, WHAT IS THE RESULT?

A: Liquids such as water, fruit juice, beverages, and condiments have complex compositions and varying pH levels. When they enter the sample testing well, they can compromise the test leading to invalid or false results. Liquids, other than the test extraction buffer should be kept clear of the test and the test area.



#### Q16: WHY WOULD I GET AN INCORRECT TEST RESULT?

- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Individuals who recently received a nasally administered influenza A or influenza B vaccine may produce a false positive test result.
- There is the potential to produce a positive result for COVID-19 when infected with HKU1 coronavirus. If you suspect you have been infected with HKU1 coronavirus consult your healthcare professional for further advice.
- 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 the 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.

## Q17: WHAT DO I HAVE TO PAY ATTENTION TO IN ORDER TO GET THE MOST EXACT TEST RESULT POSSIBLE?

A: Always follow the instructions in the Package Insert exactly. Perform the test immediately after collecting the sample. Drop only the sample from the buffer tube into the test well. Dispense four drops from the buffer tube. Too many or too few drops can lead to an incorrect or invalid test result.

# Q18: WHAT IS SERIAL (REPEAT) TESTING?

A: Serial (repeat) testing is when a test is performed over a series of days, for example, every 48 hours. By testing more frequently it is possible to detect COVID-19 / Influenza A&B more quickly and reduce the spread of infection. Please see the WARNINGS AND PRECAUTIONS, and SERIAL TESTING sections of the Package Insert for the recommended testing frequency for symptomatic individuals that are negative for COVID-19 on the first day of testing, even if they are positive for influenza A and/or B. Serial (repeat) testing is needed to improve test accuracy for COVID-19.

# Q19: 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, flush with large amounts of water immediately. If irritation persists, seek medical advice: www.poisonhelp.org or 1 (800) 222-1222 and refer to the Package Insert for chemical information. It is recommended to store the reagent kit in a secure location, inaccessible to children.

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 share all results obtained by using this product with their healthcare provider.