Distributed by: WATMIND

SpeedySwab™

Rapid **COVID-19** + **FLU A&B** Antigen Self-Test

QUICK REFERENCE INSTRUCTIONS

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

Carefully read the instructions below before performing the test. Failure to follow the instructions may result in inaccurate test results.

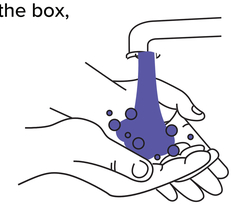
STORAGE AND STABILITY

Store kit between 60-86°F (15-30°C). Ensure all test components are at room temperature before use.
Please refer to the Instructions for Use (IFU) for more information.

BEFORE GETTING STARTED

1.
Check expiration date on the outside of the box, Do not use beyond the expiration date.

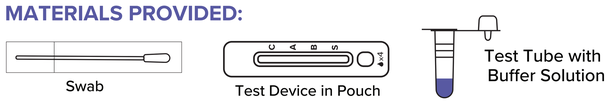
2.
Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.



3.
Clean the tabletop on which the test will be performed. Before testing, read the User Instructions carefully.

PREPARE THE MATERIALS

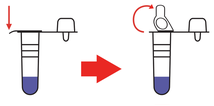
MATERIALS PROVIDED:



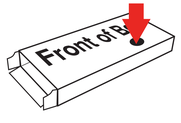
Materials required but not provided: A clock or timer;
Recommended materials: Disposable gloves and mask, if swabbing others

4.
Arrange the materials on a clean, dry, flat surface.
Use only one of each of the materials provided for each test

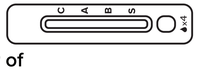
5.
Pick up the Test Tube and remove the sealing foil of the tube.



6.
Locate the tube holder on the front of box labeled "Push Tube Here" and insert the buffer tube into the tube holder.



7.
Remove the Test Device from its foil pouch.

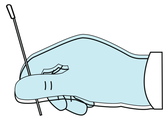


NOTE: Use the Test Device within one hour of opening the test pouch.

PERFORMING THE TEST

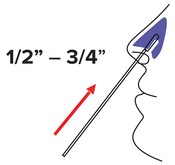
8.
Open swab package from its stick end and remove the swab from this end.

DO NOT touch the swab head or lay the swab on any surface.



9.
Gently insert the swab 1/2 to 3/4 inch into a nostril.

DO NOT insert the swab any farther if you feel any resistance.



Using medium pressure, rub and rotate the swab against the inside walls of the nostril, making **at least 5 circles** for **at least 15 seconds**.

REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB

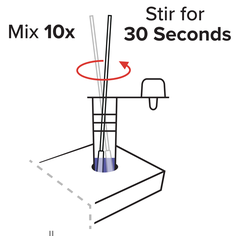
5x for 15 seconds, each nostril

NOTE: With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.

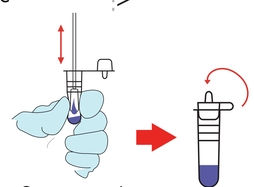
10.
Place the swab into the buffer solution as soon as possible after collection and completely immerse the swab head in the sample.

Swirl the swab in the solution by rotating the swab forcefully against the side of the tube **at least 10 times** for **30 seconds**, keeping the swab tip submerged in the buffer solution the entire time.

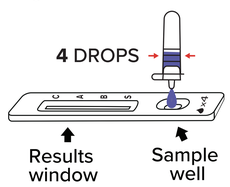


11.
Squeeze the tube **5 times** with your fingers to ensure that the sample on the swab is fully mixed into the buffer solution.

Attached the dropper cap to the test tube.



12.
Squeeze only **4 DROPS** of the Buffer Solution into the sample well of the Test Device.



DO NOT squeeze more than 4 drops from the tube. Additional sample volume may yield inaccurate results.

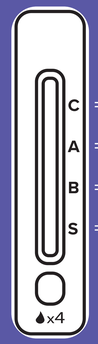
13.
Set a timer and read the test result at 15 minutes.

DO NOT disturb the device during this time. Inaccurate results can occur if the device is disturbed.

TEST RESULT INTERPRETATION

Test results are read and interpreted visually. Read result at 15 minutes with good lighting.

WARNING: Do not read the result before 15 minutes or after 20 minutes. Inaccurate test interpretations may occur.



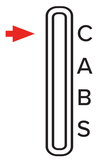
C = Control Line
A = Influenza A Line
B = Influenza B Line
S = COVID-19 (SARS-CoV 2)

Look for lines next to 'C' (Control), 'A', 'B' and 'S'.

INVALID RESULTS

If a pink or red control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, THE TEST HAS FAILED and is considered **invalid.**

STOP: If the control (C) line is not visible, the test is invalid. Do not continue reading the results. Re-test with a new swab and new test device.



Invalid

NEGATIVE RESULTS

At 15 minutes, the appearance of ONLY the Control Line indicates that Influenza A, Influenza B, or SARS-CoV-2 has 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.

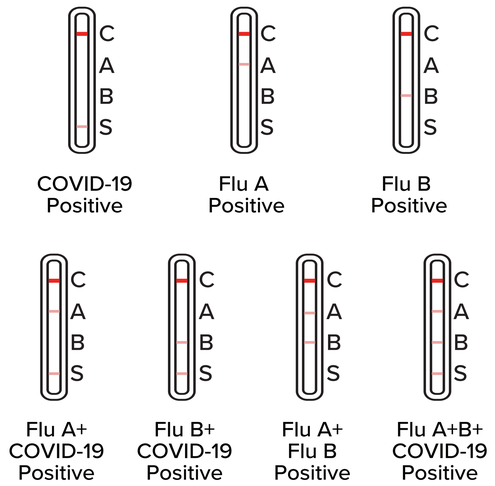
If respiratory symptoms persist, you should seek follow up care with your healthcare provider.

Negative

POSITIVE RESULTS

If the control line at "C" is visible and any other line or multiple lines on 'A', 'B' and/or 'S' appear, the test is **positive for that or those viruses.**

NOTE: Any pink to red line, no matter how faint, should be considered an Indication of 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.

UNDERSTANDING YOUR RESULTS

INVALID RESULT:
This test did not work. The result should not be used. The test cannot determine if you have COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

NEGATIVE RESULT:
The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean that you do not have COVID-19, Flu A and/or Flu B infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If you tested negative and continue to experience COVID-19, Flu A and/or Flu B-like symptoms, you should seek follow-up care with your healthcare provider.

POSITIVE RESULT:
The COVID-19, Flu A and/or Flu B virus(es) were detected in your sample. It is very likely that you have the respective infection(s) and are contagious. Please contact your healthcare provider or your local health authorities and 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).

AFTER TEST IS COMPLETED, DISPOSE OF USED MATERIALS IN HOUSEHOLD TRASH.

HOW TO USE THIS TEST

Serial testing 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. Please follow the table below for serial 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 COVID19, however you should follow-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.

Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Final 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

RESULTS REPORTING

Report your test result(s) at MakeMyTestCount.Org–this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

INTENDED USE

The Speedy Swab Rapid COVID-19 + Flu A&B Antigen Self-Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein 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 two (2) years or older. This test is only authorized for 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.

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 and SARS-CoV-2 viruses 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 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. Individuals who test positive with the Speedy Swab Rapid COVID-19 + Flu A&B Antigen Self-Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

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, 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 should be considered in the context of 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/or influenza infection and should seek follow up care with their physician or healthcare provider.

The Speedy Swab Rapid COVID-19 + Flu A&B Antigen Self-Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

WARNINGS AND PRECAUTIONS

1 Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

2 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.

3 Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) or symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

4 Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B on the initial test but test negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for co-infection with SARS-CoV-2 infection.

5 This test may only be used in symptomatic individuals.

6 An anterior nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

7 Do not use on anyone under 2 years of age.

8 Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.

9 Do not use if any of the test kit contents or packaging is opened or damaged.

10 Test components are for single use. Do not re-use the test strip, buffer liquid, or swab.

11 If any liquid spills from the buffer tube, discard test components and re-start test using new test components.

12 Do not use kit past its expiration date.

13 Only use the nasal swabs provided in the kit. Do not touch the swab head prior to testing.

14 Exposure to hand sanitizer may cause false positive results with this test.

15 The Buffer vial contains only enough liquid for one test. Do not use the same Buffer vial with an additional test as invalid or incorrect results may occur.

16 Do not interchange or mix components from different kit lots.

17 Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

18 Once opened, the test device should be used within 60 minutes.

19 Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.

20 Ensure that there is sufficient lighting for testing and interpretation.

21 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	GHS Code for each Ingredient	Concentrations
Proclin 300	H317, allergic skin reaction	0.1%
Trimethylsilyl acetamide	H316, mild skin irritation	0.03%

22 For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization

23 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 June 2023 and March 2024. 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 SARS-CoV-2 and their prevalence, which change over time.
- 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 there is a higher chance this test will give a false negative result, especially in samples with low viral load.
- All COVID-19 and influenza A&B antigen test negative results are presumptive and confirmation with 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.
- If the test is positive, then proteins from the virus that causes COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with SARS-CoV-2 or influenza.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Based on sequence analysis, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exists. Wet testing for HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact Watmind USA at +1 866-928-6463 or technicalsupport@watmindusa.com

FREQUENTLY ASKED QUESTIONS

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Warnings and Result Interpretation sections for more information).

A: Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 and flu to the family of the tested individual and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the viruses that cause COVID-19 and the flu. Molecular tests detect genetic material from the virus. Antigen tests, such as the SpeedySwab Rapid COVID-19+ FLU A&B Antigen Self-Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

Q: 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 or influenza were found in 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 antigens from the virus that causes COVID-19 or influenza were not detected in your sample. However, if you have symptoms of COVID-19 or influenza, 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.

Q: 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 fda.gov.

Q: WHAT DOES AN INVALID TEST RESULT MEAN? A: An invalid result means the test was not able to tell if you have COVID-19 and influenza infection or not. 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.

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.

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture
Σ	Contains sufficient for <n> tests	REF	Catalogue number
	Temperature limit	EXP	Use-by date
2	Do not reuse	LOT	Batch code

Distribution by :
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