



Flu A&B/COVID-19 Rapid Test

QUICK REFERENCE INSTRUCTIONS

For over the counter use.

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.

For more complete information, please refer to the full Instructions for Use (IFU) available at <https://support.ihealthlabs.com/3-in-1-IFU>

STORAGE AND STABILITY

Store kit between 36-86 °F (2-30 °C). Ensure all test components are at room temperature (65-86 °F/18-30 °C) before use.

- Ensure all kit components are at room temperature before use.

- Once removed from the pouch, the Test Card should be used immediately.

- DO NOT** read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.

- Make sure there is sufficient light for testing. For best results, read test in a well-lit area.

- Keep the test device on a flat surface during the testing.

- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a sample.

- Do not use this test if you have recently received a nasally administered influenza A or B vaccine.

- Remove any piercings from nose before starting the test.

- Do not conduct this test if prone to nosebleeds or if you have a nose injury.

- Keep testing kit and kit components away from children and pets before and after use.**

- Do not ingest any kit components.**

- The extraction solution contains harmful chemicals (see table in the next column). Avoid contact with your skin, eyes, nose, or mouth. If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If you have a known skin allergy or are sensitive to the use of aminoglycosides, we recommend the use of gloves while performing the test. If irritation persists, seek medical advice: <https://www.poisohelp.org> or 1-800-222-1222.**

Chemical Name	GHS Code for Each Ingredient	Concentrations
Triton X-100	Harmful if swallowed (H302) Causes skin irritation (H315) Causes serious eye damage (H318)	0.40%
Proclin 300	Causes skin irritation (H315) Causes eye irritation (H320)	0.10%
Gentamicin Sulfate	Causes allergy or asthma symptoms or breathing difficulties if inhaled (H334) Causes an allergic skin reaction (H317)	0.25%

VIDEO INSTRUCTIONS



Scan the QR code to access the video tutorial.

BEFORE GETTING STARTED

Do not open the test contents until ready for use. Once opened, the test device should be used immediately.

1.

Check expiration date on the outside of the box. Do not use beyond the expiration date. Do not use if any of the test kit contents or packaging is damaged.



2.

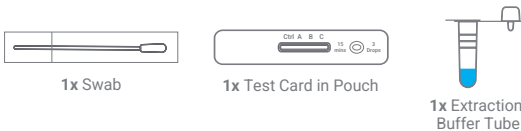
Wash hands thoroughly for at least 20 seconds before testing.

3.

Clean the surface on which the test will be performed. Before testing, read instructions carefully. The test kit must be at room temperature (65-86 °F) for testing.

PREPARE THE MATERIALS

MATERIALS PROVIDED:



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



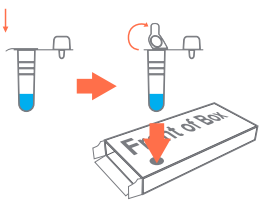
4.

Arrange the materials on a clean, dry, flat surface. Your box may contain more than one test kit. Use only one of each of the materials provided for each test.

DO NOT open the individual pouches until instructed to do so.

5.

Pick up the Extraction Buffer Tube and remove the sealing foil of the tube.



6.

Push the Extraction Buffer Tube into the perforated tube holder located on the front of the box and insert the Extraction Buffer Tube into the front of box where labeled "Insert tube here".

7.

Remove the Test Card from its foil pouch.



DO NOT remove the Test Card until you are ready to begin the test. The unsealed test card is valid for 60 minutes.

PERFORMING THE TEST

8.

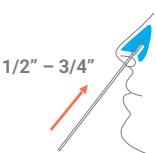
Open the package from the swab's stick end and take out the swab by holding the stick.



DO NOT touch the swab head (soft end).

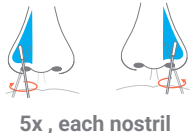
9.

Gently insert the swab 1/2 to 3/4 inch into a nostril. **For young children, the swab should not be inserted more than 1/2 inch.**



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.**



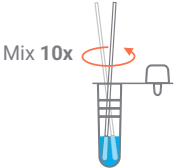
REPEAT IN THE OTHER NOSTRIL USING THE SAME SWAB.

NOTE: If you are swabbing others, please wear a face mask. 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 extraction solution making sure the swab head is completely immersed.

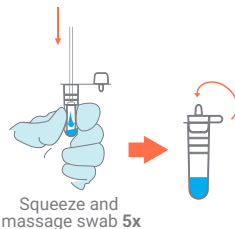


Swirl the swab in the solution by rotating the swab forcefully against the side of the Extraction Buffer Tube **at least 10 times**, keeping the swab tip submerged in the extraction solution the entire time.

NOTE: Failure to rotate the swab 10 times may lead to false negative results.

11.

Squeeze the swab within the Extraction Buffer Tube **5 times** with your fingers to ensure that the sample on the swab is fully mixed into the extraction solution.



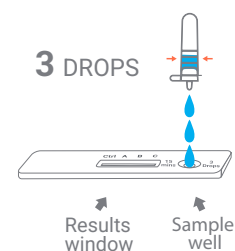
Discard swab.

Close the dropper cap that is attached to the Extraction Buffer Tube.

NOTE: Failure to squeeze the swab within the extraction buffer tube may lead to false negative results.

12.

Holding the dropper **VERTICALLY** over the sample well on the test card, squeeze out exactly **3 DROPS** of the solution.



DO NOT squeeze more than 3 drops from the Extraction Buffer Tube. Additional sample volume may yield inaccurate results.

13.

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



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



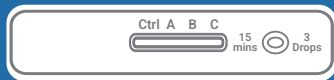
Note: DO NOT read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.



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 30 minutes. Inaccurate test interpretation may occur.

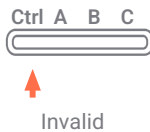


Ctrl = Control Line
A = Influenza A Line
B = Influenza B Line
C = COVID-19 (SARS-CoV-2)

Look for lines next to 'Ctrl', 'A', 'B', and 'C'.
FOR EASE OF USE, HOLD TEST CARD NEXT TO THE IMAGES IN THE FOLLOWING 3 SECTIONS.

INVALID RESULTS

If a control line is **not** visible at "Ctrl" after 15 minutes, even if any other line is visible in the results window, **the result is considered INVALID.**

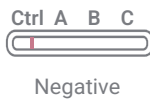


STOP: If the test is invalid, repeat the test procedure using a new kit and sample.

NOTE: The image displayed above is one example only; additional invalid outcomes are possible. For a complete set of invalid results to go to <https://support.ihealthlabs.com/3-in-1-results>.

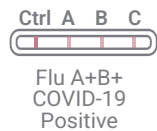
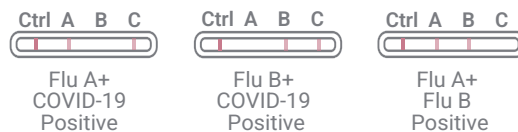
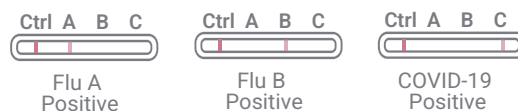
NEGATIVE RESULTS

If the control line at "Ctrl" is visible and you do not see a line at 'A', 'B', or 'C', it means the test is **negative.**



POSITIVE RESULTS

If the control line at "Ctrl" is visible and any other single line **or** multiple lines on 'A', 'B', and/or 'C' appear, the test is **positive.**



NOTE: Any pink line in the correct indicated locations, no matter how faint, should be considered an indication of a positive result.

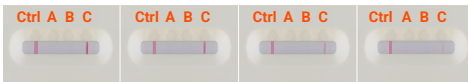
Flu A Positive:



Flu B Positive:



COVID-19 Positive:



UNDERSTANDING YOUR RESULTS

INVALID RESULT:

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

NEGATIVE RESULT:

A negative test result indicates that the virus that causes Flu A, Flu B, and/or COVID-19 was not detected in the sample. A negative result does not mean that you do not have Flu A, Flu B, and/or COVID-19 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 Flu A, Flu B, and/or COVID-19-like symptoms, you should seek follow-up care with your healthcare provider.

POSITIVE RESULT:

A positive test result means that the virus that causes influenza or COVID-19 infection was 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 AND WASH HANDS.



INTENDED USE

The iHealth Flu A&B/COVID-19 Rapid Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid protein directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza, SARS-CoV-2 or other pathogens.

Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough and/or shortness of breath, should seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

STORAGE AND STABILITY

Store the iHealth Flu A&B/COVID-19 Rapid Test at room temperature 36-86 °F (2-30 °C) in the original packaging, away from direct sunlight. Ensure all test components are at room temperature (65-86 °F/ 18-30 °C) before use. It is stable until the expiration date marked on the packaging.

- DO NOT FREEZE.

- Do not use Test Cards or Extraction Buffer Tubes after expiration date.

- Test Cards that have been outside of the pouch for more than one hour should be discarded.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2024 and March 2025. 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 influenza and COVID-19 and their prevalence, which change over time. Additional testing with a laboratory-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled or transported improperly.

- 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 influenza and COVID-19 as compared to a molecular test, especially in samples with low viral load.

- Positive results do not rule out co-infection with other respiratory pathogens.

- False positive test results are more likely when the prevalence of Flu A/B, and SARS-CoV-2 is low in the community.

- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision. Because test lines can be very faint, users with conditions affecting their vision, such as far-sightedness, glaucoma, or color blindness, are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).

- Influenza A and influenza B false positive results were observed with this test when tested with intranasal FluMist Vaccine.

- Hand Sanitizer cream lotion and Hand Sanitizer(80% ethanol, fast drying) may cause false negative results with this test.

- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions) should contact a healthcare provider.

- This test does not differentiate between SARS-CoV and SARS-CoV-2 and does not detect influenza C.

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).

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 iHealth Flu A&B/COVID-19 Rapid 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, Flu A and/or Flu B because proteins from the virus that causes COVID-19, Flu A and/or Flu B were detected 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, Flu A and/or Flu B were not detected in your sample. If you have a negative result, it does not rule out SARS-CoV-2, Flu A and/or Flu B 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: WHAT DOES AN INVALID TEST RESULT MEAN?

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

Q: HOW ACCURATE IS THIS TEST?

A: 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://support.ihealthlabs.com/3-in-1-IFU>.

Q: WHAT IF I AM UNCERTAIN HOW TO INTERPRET MY RESULTS?

A: If uncertain how to proceed, contact Technical Assistance at (855) 816-7705 or support@ihealthlabs.com.

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.

SYMBOLS

	Manufacturer		In vitro diagnostic medical device		Date of manufacture
	Consult instructions for use		Catalogue number		Use-by Date
	Temperature limit		Batch code		Do not re-use
	Do not use if package is damaged		Contains sufficient for <n> tests		Over-the-Counter

SUPPORT

If you have questions regarding the use of this product, or if you want to report a problem with the test, please contact iHealth Labs Inc. at (855) 816-7705 or support@ihealthlabs.com.

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