iHealth®

Flu A&B/COVID-19/RSV 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. Refer to the Instructions for Use (IFU) for more complete information.

STORAGE AND STABILITY
Store iHealth Flu A&B/COVID-19/RSV Rapid Test in a dry location between 36-86 °F (2-30 °C) out of direct sunlight. Ensure all test components are at room temperature (65-86 °F/18-30 °C) before use.

WARNINGS AND PRECAUTIONS

- **Do not use the test if you have had symptoms for more than 6 days or no symptoms at all.**
- **Do not use the test on anyone under 6 months of age.**
- **It is recommended that at least two adults are present to appropriately perform sample collection for ages Users aged 6 – 24 months.**
- **All viruses tested by this test can cause severe disease, especially RSV in infants and young children.**
- **Certain people should not use this test. These people could get much sicker very quickly or even die if they don't get medical help right away: persons showing signs or symptoms of ongoing severe disease, [e.g., short and shallow breathing, flaring of the nostrils or straining (retractions) of the chest or stomach while breathing, or turning blue around the lips and fingertips advance disease] infants born prematurely (birth before 29 weeks of gestation), certain types of congenital chronic lung or heart disease, neurologic or neuromuscular conditions especially those who have difficulty swallowing or clearing mucus secretions. If you or your child have any of these conditions, see a healthcare provider right away instead of using this test.**
- Infants and young children can get hurt more easily when collecting the nose swab sample. If the swab is not used the right way, it could hurt the inside of the nose, causing nosebleeds. It could also mean not getting enough sample to test properly, which might provide the wrong test results.
- If your infant has received monoclonal antibodies (e.g., Clesrovimab-cfor), you may need a healthcare provider to interpret test results.
- This product is used only for the detection and differentiation of protein antigens from influenza A, influenza B, SARS-CoV-2 and respiratory syncytial virus (RSV), not for any other viruses or pathogens. This product does not detect influenza C.
- Test components are single use. Do not re-use the test card, extraction buffer tube, or swab.
- Do not touch the swab tip prior to testing. Accidental contamination can lead to inaccurate results. Repeat sample collection with a new test kit if swab head touches another surface.
- Wash hands thoroughly with water to remove all traces of soap. Exposure to liquid soap may cause false negative results with this test.
- 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 nasal sample.
- Do not use this test if you have recently received a nasally administered influenza A or B vaccine.
- Do not use this test if you have recently used nasal fluticasone propionate.
- Do not conduct this test if prone to nose bleeds or have a nose injury.
- Remove any piercings from nose before starting the test.
- If you continue to have symptoms consistent with influenza, COVID-19, and RSV, you may not have influenza, COVID-19, or RSV, however, you should follow-up with a healthcare provider.
- All users should contact a healthcare provider if symptoms worsen.
- **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.poison-help.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

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 your hands with soap and water for 20 seconds and dry them thoroughly before testing or use hand sanitizer.

PREPARE THE MATERIALS

MATERIALS PROVIDED:

1x Swab

1x Test Card in Pouch

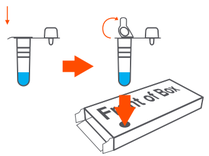
1x Extraction Buffer Tube

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

DO NOT open the test contents until ready for use.

3.

Pick up the Extraction Buffer Tube and remove the sealing foil of the tube. Insert the Extraction Buffer Tube in the front of box labeled "Insert tube here".



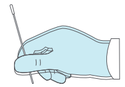
4.

Remove the Test Card from its foil pouch. **The unsealed test card is valid for 60 minutes.**

PERFORMING THE TEST

5.

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



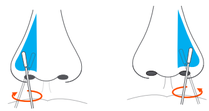
DO NOT touch the swab head (soft end).

6.

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.



5x , each nostril

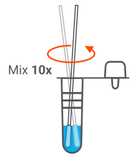
Did you swab BOTH nostrils?
Inaccurate test results may occur if the nasal sample is not properly collected.

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.

7.

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.

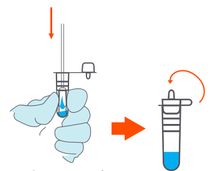


NOTE: Failure to rotate the swab 10 times may lead to false negative results.

8.

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.

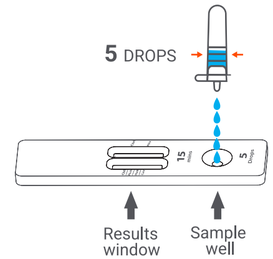
Close the dropper cap that is attached to the Extraction Buffer Tube.



NOTE: Failure to squeeze the swab within the Extraction Buffer Tube may lead to false negative results.

9.

Holding the dropper **VERTICALLY** over the sample well on the test card, squeeze out exactly **5 DROPS** of the solution.

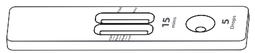


NOTE: DO NOT squeeze more than 5 drops from the Extraction Buffer Tube. Additional sample volume may yield inaccurate results.

10.

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

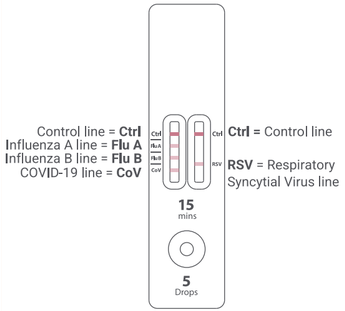
DO NOT disturb the card during this time. Inaccurate results can occur if the card is disturbed.



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

TEST RESULT INTERPRETATION

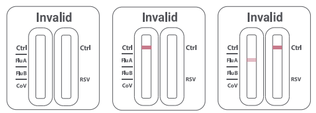
Test results are read and interpreted visually. Read result at 15 minutes with good lighting.



Look for lines next to 'Ctrl', 'Flu A', 'Flu B', 'CoV', and 'RSV'. Make sure there is a **visible line** next to **'Ctrl' in both** result windows.

INVALID RESULTS

Missing 'Ctrl' line on ONE or BOTH strips



Check to see if a line is **visible** at the control line **'Ctrl'** on both strips. **I**f one or both **'Ctrl'** lines are **missing,** even if any test line is visible in the result window, the result is **invalid.**

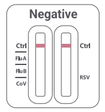
UNDERSTANDING YOUR RESULTS:

The test could not tell whether or not you have influenza A (Flu A), influenza B (Flu B), COVID-19, or Respiratory Syncytial Virus (RSV). The test needs to be repeated with a new kit and sample.

NOTE: The 3 images displayed above are examples only; additional invalid outcomes are possible. For a complete set of invalid results, please go to https://support.ihealthlabs.com/4-in-1-results.

NEGATIVE RESULTS

Both 'Ctrl' lines only



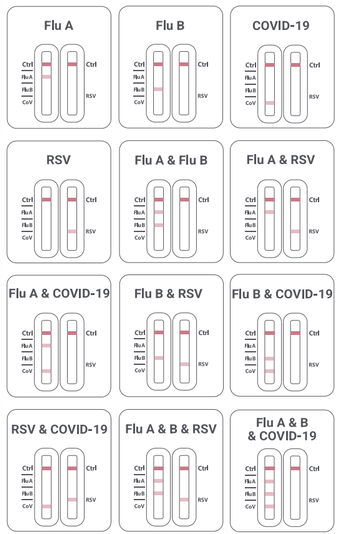
If the control lines at **'Ctrl'** are **visible** and you **do not see** a line at **'Flu A'**, **'Flu B'**, **'CoV'**, or **'RSV'**, it means the test is **negative**.

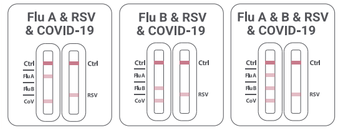
UNDERSTANDING YOUR RESULTS:

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

POSITIVE RESULTS

Both 'Ctrl' lines must be PRESENT





If the control lines at **'Ctrl'** are **visible** and any other single line **or** multiple lines on **'Flu A'**, **'Flu B'**, **'CoV'**, and/or **'RSV' 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.

For example, the images displayed below should all be considered Flu A positive.

UNDERSTANDING YOUR RESULTS:

The Flu A, Flu B, COVID-19, and/or RSV virus(es) were detected in your sample. **I**t 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).

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.

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

INTENDED USE

The iHealth Flu A&B/COVID-19/RSV Rapid Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, influenza B, SARS-CoV-2, and respiratory syncytial virus (RSV) protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to influenza, SARS-CoV-2, and RSV 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 six (6) months 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, RSV, or other pathogens.

Individuals who test negative and/or experience continued or worsening 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 iHealth Flu A&B/COVID-19/RSV Rapid Test in a dry location between 36-86 °F (2-30 °C) out of direct sunlight.
- Ensure all test components are at room temperature (65-86 °F/18-30 °C) before use. **I**t is stable until the expiration date marked on the packaging.
- The unsealed test card is valid for one hour. **I**t is recommended to use the test kit immediately after opening.
- DO NOT FREEZE.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2024 and November 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, COVID-19, and RSV 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, COVID-19, or RSV 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.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., infants and young children, elderly individuals, chronic lung disease, heart disease, compromised immune system, diabetes and other conditions) should contact a healthcare provider; users should also contact a healthcare provider if symptoms persist or worsen, (specially for individuals 6 to 24 months of age), independently of test results, or if you have any concerns.
- False positive test results are more likely when the prevalence of RSV, 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).
- FluMist/FluMist quadrivalent live intranasal influenza virus vaccine may cause false positive influenza A and B results with this test.
- Fluticasone propionate at concentrations >10% v/v may interfere with SARS-CoV-2, Flu B, and RSV results.
- Hand Sanitizer (80% ethanol, fast drying) may cause false negative results with this test.
- This test does not differentiate between SARS-CoV and SARS-CoV-2 and does not detect influenza C.
- The performance of this test was evaluated with a limited number of RSV positive samples from individuals aged 60 years and older.

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 **I**nterpretation 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 Flu, COVID-19, and RSV 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 Flu, COVID-19, and RSV. Molecular tests detect genetic material from the virus. Antigen tests, such as the iHealth Flu A&B/COVID-19/RSV 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 Flu, COVID-19, and RSV than a molecular test would.

Q: WHAT ARE THE SYMPTOMS OF RSV IN CHILDREN?
A: Most infants are unable to communicate some of the typical signs and symptoms of infection, and some of these may be different from symptoms in older children and adults, and may be subtle such as: irritability, decreased activity, breathing difficulties (apnea episodes), eating or drinking less. For individuals aged 2 years or older, symptoms may include fever, chills, cough, sneezing, wheezing, fatigue, decrease in appetite, unusual tiredness, congestion or runny nose, nausea, vomiting, or diarrhea. Many infants will not have a fever with RSV infection.

Q: WHAT ARE SIGNS AND SYMPTOMS OF SEVERE DISEASE?
A: These symptoms usually appear in stages and not all at once. Short and shallow breathing, flaring of the nostrils or straining (retractions) of the chest or stomach while breathing, or turning blue around the lips and fingertips advance disease are some of the signs of possible severe viral infection (bronchiolitis, pneumonia and possible progression to respiratory failure). **I**f you or your child currently have signs and symptoms of severe disease do not use this test. Delayed or avoided medical care to infants or patients having these conditions might get much sicker quickly or even die.

Q: WHEN TO SEEK EMERGENCY CARE?
A: Respiratory infections (specially RSV) can be serious for infants, some young children, and adults who are older or have certain risk factors. Persons with risk factors for severe disease from respiratory pathogens (e.g., infants and young children, elderly individuals, chronic lung or heart disease, compromised immune system, diabetes, and other conditions), should contact a healthcare provider. Users should also contact a healthcare provider if symptoms persist (not improving) or worsen (specially for infants and young children, independently of (positive or negative) test results, or if you have any concerns.

Q: WHAT TO DO IF YOUR INFANT HAS RECEIVED A MONOCLONAL ANTIBODY?
A: Test results may be affected if your infant has received monoclonal antibodies. Talk to your health care professional to help interpreting your test results.

Q: WHAT DOES A POSTIVE RESULT MEAN?
A: A positive test result means that any one, or multiple, of the viruses detected by this test were also detected in your sample. It is very likely that you have the respective RSV, COVID-19, or influenza infection(s) and are contagious. **You should self-isolate following local guidelines. Please contact your physician or healthcare provider to discuss your tests results and follow-up care. I**n rare instances, individuals may also have co-infections with other bacteria or viruses that this test is not designed to detect. This means that the virus detected by this test may not be the definitive or the only cause of your disease. There is a very small chance that this test can give you a positive result that is incorrect (a false positive).

Q:WHAT DOES A NEGATIVE RESULT MEAN?
A: A negative test result means that RSV, COVID-19, Flu A, and/or Flu B viruses were not detected in the sample. A negative result is presumptive because despite a negative result you may still have RSV, COVID-19, Flu A, and/or Flu B infection. This is because the amount of virus in your sample may be too low for the test to detect it, which is called a 'false negative result'. False negative results can occur if you read your test result before the 15 minutes have passed or when your sample has only a low amount of virus in it. Low amount of virus can occur if you take your sample at a time when your symptoms just started appearing, or when you already started to feel better at the end of your infection. **If an adult or child tested negative and continues to experience RSV, COVID-19, Flu A, and/or Flu B-like symptoms, you should therefore seek follow-up care with a healthcare provider who will determine the best course of action. The healthcare provider can also determine if confirmation of your test result with a molecular assay is necessary.**

Q: WHAT SHOULD I DO IF I RECEIVE A POSITIVE TEST RESULT FOR RSV?
A: Because there is no specific treatment for RSV, the CDC recommends managing symptoms with over-the-counter medications. Most RSV infections are resolved within 1-2 weeks. For adults and children, especially infants aged 6-23 months, immediately talk to your healthcare provider for emergency care if you are having difficulty breathing, not drinking enough fluids, or experiencing worsening conditions.

Q: HOW ACCURATE IS THIS TEST?
A: The iHealth Flu A&B/COVID-19/RSV Rapid Test was compared to highly sensitive PCR tests. Antigen tests, such as the iHealth Flu A&B/COVID-19/RSV Rapid Test detect proteins from the virus, while a molecular test (e.g., PCR) detects the virus's genetic material and is generally more sensitive. For more information on the performance of the test and how it may apply to you, please refer to the performance data in the **I**nstructions for Use (**I**FU) available at https://support.iHealthlabs.com/4-in-1-IFU

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

SYMBOLS

	Manufacturer	IVD	In vitro diagnostic medical device		Date of manufacture
	Consult instructions for use	REF	Catalogue number		Use-by Date
	Temperature limit	LOT	Batch code		Do not re-use
	Do not use if package is damaged		Contains sufficient for <n> tests	OTC	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 **I**nc. at (855) 816-7705 or support@ihealthlabs.com.

iHealth

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Revision Date: 12/11/2025