Flowflex® PLUS

RSV + Flu A/B + COVID Home Test Quick Reference Instructions

REF L03A-R1445	REF L03A-R1545	REF L03A-R1645	REF L03A-R1745	English

For in vitro diagnostics use. For Over-the-Counter 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 results. A full IFU can be found at flowflexcovid.com.**

An anterior nasal swab sample can be self-collected by an individual aged 14 years or older. Children aged 6 months-13 years should be tested by adults.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- **Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.**
- **Do not use the test on anyone under 6 months of age.**
- **Users aged 6 – 23 months must use swab guard during collection to reduce risk of injury.**
- **Users aged 6 – 23 months must have at least two adults present to appropriately perform sample collection.**
- 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 respiratory syncytial virus (RSV), influenza A, influenza B, and SARS-CoV-2, not for any other viruses or pathogens. This product does not detect influenza C.
- Do not use the test after the expiration date shown on the test cassette pouch or if the test kit contents are damaged or opened.
- Do not touch the nasal swab head during sample collection. Accidental contamination can lead to inaccurate results. Repeat sample collection with a new test kit if swab head touches another surface.
- The swab specimen should be processed and tested immediately after collection.
- Once opened, the test cassette 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.**
- Test components are single-use. Do not re-use the test cassette, buffer, guard, or swab.
- Testing should be performed in an area with good lighting.
- 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.
- **Keep testing kit and components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, and mouth. Do not ingest any kit components as the reagent solution contains harmful chemicals (see Hazardous Ingredients for the Reagent Solution Table).**
- **If the reagent solution contacts the 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**

Hazardous Ingredients for the Reagent Solution

Hazard Category (mixture)	GHS Hazard Statement for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)
2	Skin irritation	Causes skin irritation (H315)	• Proclin 300/ 0.1% • Tris/ 1%
2	Eye irritation	Causes eye irritation (H320)	• Proclin 300/ 0.1% • Tris/ 1%

KIT CONTENTS

Test Cassette (in pouch) | Extraction Buffer Tube (in pouch) | Sterile Nasal Swab and Pediatric Swab Guard | Tube Holder (only for 25 test quantity) | Quick Reference Instructions | Timer (Not included)

Check your kit contents and make sure you have everything.

PREPARATION

1. Wash or sanitize hands. Dry hands before testing.
2. Remove the test cassette from pouch and lay on a clean, flat surface. Locate the Result Window and Sample Well on the cassette.
3. Remove buffer tube from pouch. Remove the foil from tube.
4. Punch through perforation on box to form a tube holder. Place tube in holder.

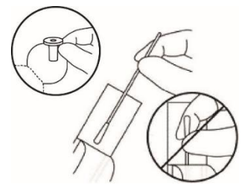
RESULTS REPORTING

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

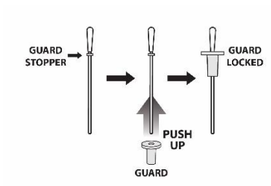
Flow*flex* QR Code

Scan to learn more about FAQs, downloadable resources, and where to buy the test

TEST PROCEDURE FOR INFANTS (6 MONTHS - 23 MONTHS)

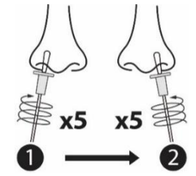


1. Open swab package at stick end. Take out swab. Open swab guard package. Take out swab guard. **Do not touch the swab tip.**

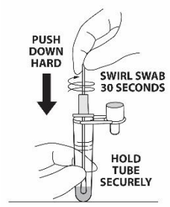


2. Slide the guard into the nasal swab through the guard opening from the stick end. **Push guard to the top of the swab until guard clicks into place at the bottom of the foam head.**

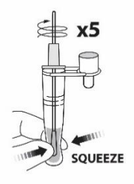
3. Position the child comfortably on the adult's lap. The adult should cross one arm over the child's body to hold their arms securely. Place the other hand on the child's forehead, tilting head backwards slightly.



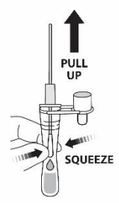
4. Another adult gently inserts swab into one nostril until the guard touches the nose. **If resistance is felt, do not attempt to insert swab deeper**. Rub swab in circular motion against the inside of the wall of nostril **5 times** (15 sec.) Repeat this in the other nostril. Please use a face mask when swabbing others.



5. Place nasal swab into the extraction buffer tube. **Forcefully**, push swab into the bottom of the buffer tube to remove guard from top of nasal swab. Swirl swab in tube for **30 seconds**.



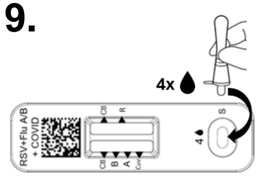
6. Rotate swab **5 times while squeezing the swab head** in the bottom of the tube. Incorrect results may be observed if the swab is not swirled for 30 seconds or rotated 5 times.



7. Remove swab while **squeezing tube** and swab head. Discard nasal swab and guard.

Note: The swab should be tested no more than 30 minutes after adding to the tube.

8. Attach dropper tip and mix by swirling or flicking tube.



9. Gently squeeze and put **4 drops** into the sample well. Discard tube.

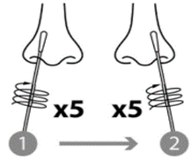
Note: An invalid result may occur if less than 2 drops are added to the Sample Well.

10. Set timer and read result after 15 minutes. Do not read after 30 minutes. Discard test cassette.

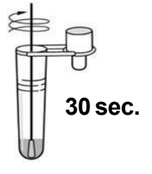
Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

TEST PROCEDURE FOR 2 YEARS AND OLDER

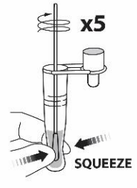
1. Open swab package at stick end. Take out swab. **Do not use swab guard. Do not touch the swab tip.**



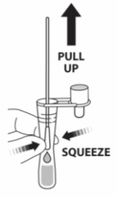
2. Gently insert tip of swab into 1 nostril (½ to ¾ of an inch). **With children, insert swab less than ¾ of an inch. You may need to have a second person to hold the child's head while swabbing. Firmly rub swab** in a circular motion against the inside wall of nostril **5 times** (15 sec.). Repeat this in the other nostril using the same swab. Please use a face mask when swabbing others.



3. Remove the swab from nostril and immediately place into buffer tube. Swirl swab in buffer tube for 30 seconds.

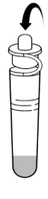


4. Rotate swab 5 times while **squeezing tube**. Incorrect results may be observed if the swab is not swirled for 30 seconds or rotated 5 times.

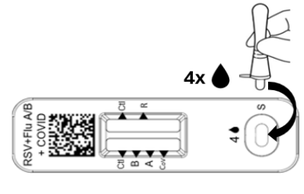


5. Remove swab while **squeezing tube**. Discard swab.

Note: Swab with collected sample should be tested no more than 30 minutes after adding to the tube.



6. Attach dropper tip and mix by swirling or flicking tube.



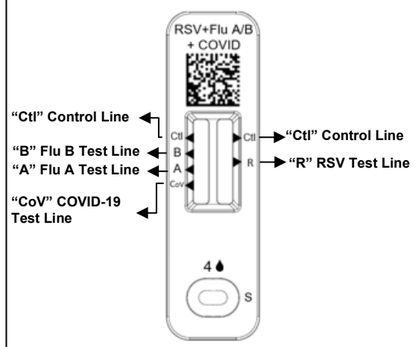
7. Invert buffer tube and gently squeeze **4 drops** of sample into the Sample Well**.** Discard tube.

Note: An invalid result may occur if less than 2 drops are added to the Sample Well.

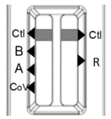
8. Set timer and read result after 15 minutes. Do not read after 30 minutes. Discard test cassette.

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

RESULT GUIDE

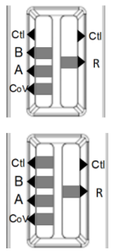


NEGATIVE



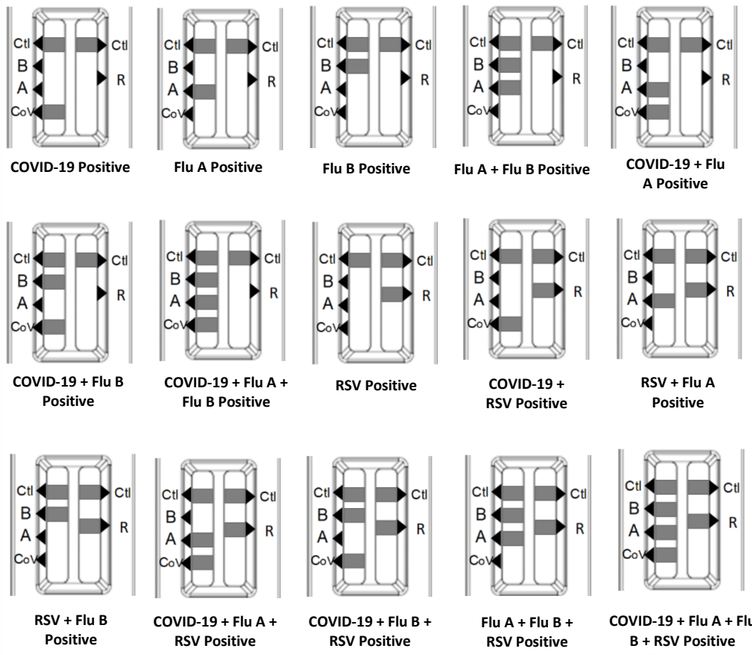
If both Control (Ctl) lines are visible, but the Test (R/A/B/CoV) line(s) is not visible, the test is negative. The RSV, Flu A, Flu B, or COVID-19 virus have not been detected.
If respiratory symptoms persist, seek follow-up care with a healthcare provider.

INVALID



If the Control (Ctl) line is not visible on either or both test strips, even if any test line is visible in the result window, the test is invalid. Re-test with a new test kit and sample.
If the problem persists, call (800) 838-9502 for assistance.

POSITIVE



If the Control (Ctl) line is visible on both strips and any line or multiple lines, no matter how faint, at "R", "A" "B" and/or "CoV" appear, the test is positive for that virus. **Any visible faint red or pink line in the Test line regions (R/A/B/CoV) should be read as positive for that virus.** Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation.

Please refer to the "Frequently Asked Questions" section for further instructions on interpreting your test result.

INTENDED USE

The Flow*flex* Plus RSV + Flu A/B + COVID Home Test is a lateral flow immunoassay intended for the rapid, simultaneous qualitative detection and differentiation of respiratory syncytial virus (RSV), influenza A, influenza B, and SARS-CoV-2 protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory tract infections due to RSV, influenza, and SARS-CoV-2 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 RSV, influenza, SARS-CoV-2 or other pathogens.

Individuals who test negative and/or experience continued or worsening symptoms, such as fever, cough and/or shortness of breath should therefore 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 HANDLING

- The kit should be stored at temperatures between 36-86°F (2- 30°C) out of direct sunlight.
- The test must remain in the sealed pouch until use and should be run at temperatures between 59-86°F (15-30°C).
- The test is stable until the expiration date printed on the sealed pouch.
- DO NOT FREEZE.

LIMITATIONS

1) The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October 2024 and April 2025. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of RSV, influenza, and COVID-19 emerge. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of RSV, 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.

2) 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.

3) 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 RSV, Flu A/B, or COVID-19 as compared to a molecular test, especially in samples with a low viral load.

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

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

6) 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, (specifically for individuals 6 to 23 months of age), independently of test results or if you have concerns.

7) This device is a qualitative test and cannot provide information on the amount of virus present in the specimen.

8) This test detects both viable (live) and non-viable RSV, influenza A, influenza B, and SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the sample.

9) FluMist/FluMist quadrivalent live intranasal influenza virus vaccine may cause false positive influenza A and B results with this test.

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

11) The performance of this test was evaluated with a limited number of RSV positive samples from individuals aged 60 years and older.

12) This test is read visually. Because test lines can be 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. This test has not been validated for use by those with color-impaired vision.

FREQUENTLY ASKED QUESTIONS

Q: WHAT IS THE DIFFERENCE BETWEEN ANTIGEN & MOLECULAR TEST?

A: There are different kinds of tests for the viruses that cause COVID-19, influenza, and RSV. Molecular tests detect genetic material from the virus. Antigen tests, such as the Flow*flex* Plus RSV + Flu A&B + COVID Home Test detect proteins from the virus.

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). If 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 (especially 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: WHEN TO USE A SWAB GUARD?

A: All children under 24 months of age should use the swab guard included with this test. A second adult is needed to help hold the child, and/or collect the sample.

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 interpret your test results.

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 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.** In 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 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 Flow*flex* Plus RSV + Flu A/B + COVID Home Test was compared to highly sensitive PCR tests. Antigen tests, such as the Flow*flex* Plus RSV + Flu A&B + COVID Home 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 Healthcare Provider Instructions for Use (IFU), available at flowflexcovid.com

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: If the Control line (Ctl) is not visible on either or both the test strips, even if any test line is visible in the result window, the test is invalid. An invalid test result means that the test is unable to determine if you are infected with RSV, influenza or SARS-CoV-2 or not. The test needs to be repeated with a new test kit and sample.

Q I need more help. Where else can I get it?

A: If uncertain how to proceed, contact Customer Support at flowflexcovid.com or 1-800-838-9502 (Monday - Sunday: 5 a.m.- 5 p.m. PST).

Index of Symbols

	Manufacturer		Date of manufacture
Σ	Contains sufficient for <*n*> tests	REF	Catalogue number
IVD	*In vitro* diagnostic medical device		Use by date
	Consult instructions for use	LOT	Batch code
	Temperature limit		Do not reuse

ACON®

flowflexcovid.com

***ACON* Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego, CA 92121, USA
Customer Support: 1-800-838-9502
Part Number: 1150003291
Effective Date: 2025-11-21