Flowflex® PLUS

COVID-19 + Flu A/B Home Test

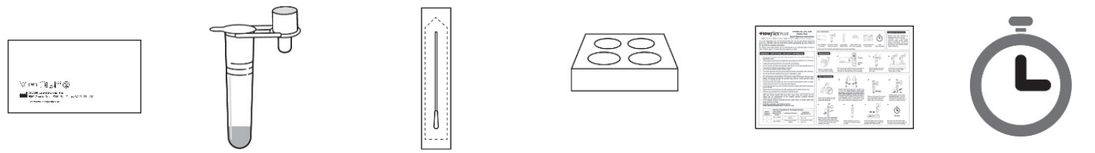
Quick Reference Instructions

REF L03A-R0645 | REF L03A-R0745 | REF L03A-R0845 | REF L03A-R0945 | 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. Refer to the full Instructions for use (IFU) for complete information.***

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

KIT CONTENTS



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

Check your kit contents and make sure you have everything.

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.

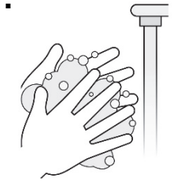
WARNINGS , PRECAUTIONS, AND SAFETY INFORMATION

- **Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.**
- This product is used only for the detection of proteins from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens.
- 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 use on anyone under 2 years of age.
- The swab specimen should be processed and tested immediately after collection.
- Do not use the test cassette if the pouch is damaged or open.
- 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, or swab.
- Testing should be done in an area with good lighting.
- Do not use this test if you have recently received a nasally administered influenza A or B vaccine.
- Please ensure that hands are dry after washing prior to performing the test.
- 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 table below).**
- **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%

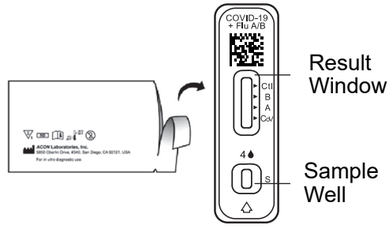
PREPARATION

1.



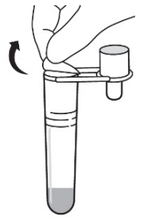
Wash or sanitize hands. Dry hands before testing.

2.



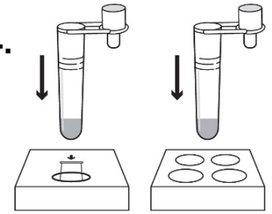
Remove the test cassette from pouch and lay on a clean, flat surface. Locate the Result Window and Sample Well on the cassette.

3.



Remove buffer tube from pouch. Remove the foil from tube.

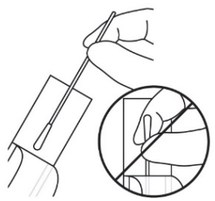
4.



Punch through perforation on box to form a tube holder. Place tube in holder.

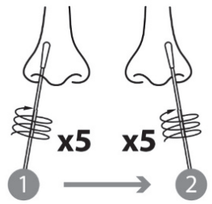
TEST PROCEDURE

1.



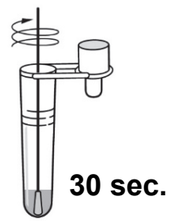
Open swab package at stick end. Take out swab. **Do not touch the swab tip.**

2.



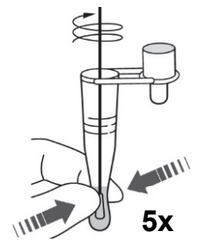
Gently insert tip of swab into 1 nostril (½ to ¾ of an inch). **With children, insert swab less than ¾ of an inch. You may need to have a second person to hold the child's head while swabbing. Firmly rub swab** in a circular motion against the inside wall of nostril **5 times** (15 sec.). Repeat this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

3.



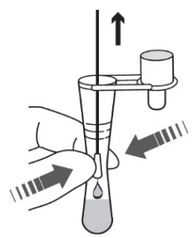
Remove the swab from nostril and immediately place into buffer tube. Swirl swab in buffer tube for 30 seconds.

4.



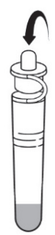
Rotate swab 5 times while **squeezing tube**. Incorrect results may be observed if the swab is not swirled for 30 seconds or rotated 5 times.

5.



Remove swab while **squeezing tube**. Discard swab. 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 bottom of tube.

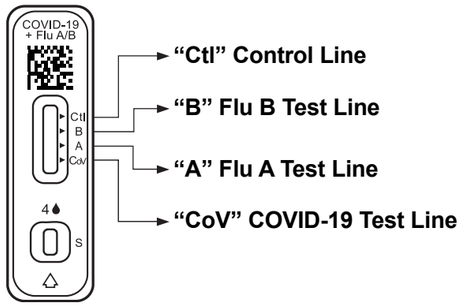
7.

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

8.

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

RESULT INTERPRETATION

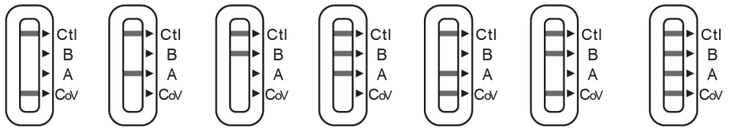


Flow*flex* QR Code

Scan to learn more about the test

Note: Any visible faint red or pink line in the Test line region (CoV/A/B) should be read as positive. If there is no colored line in the Test line region (CoV, A, and/or B) and a colored line in the Control line (Ctl) region, then that test line (CoV, A, and/or B) should be read as negative.

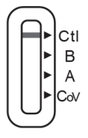
POSITIVE



COVID-19 Positive | **Flu A Positive** | **Flu B Positive** | **Flu A + Flu B Positive** | **COVID-19 + Flu A Positive** | **COVID-19 + Flu B Positive** | **COVID-19, Flu A + Flu B Positive**

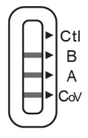
If the Control (Ctl) line is visible and any other line or multiple lines, no matter how faint, at "CoV", "A" and/or "B" appear, the test is positive for that virus. Please contact your healthcare provider or your local health authorities and follow local guidelines for self-isolation.

NEGATIVE



If the Control (Ctl) line is visible, but the Test (CoV/A/B) line is not visible, the test is negative. The COVID-19, Flu A, or Flu B 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, even if any other line is visible in the result window, the test is not valid. Re-test with a new test kit and sample. If the problem persists, call (800) 838-9502 for assistance.

INTENDED USE

The Flow*flex* Plus COVID-19 + Flu A/B Home Test is a lateral flow immunoassay intended for the qualitative detection and differentiation of SARS-CoV-2, influenza A, and influenza B protein antigens 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 with self-collected anterior nares 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.

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 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

- Store Flow*flex* Plus COVID-19 + Flu A/B Home Test between 36-86°F (2-30°C) out of direct sunlight until use. The test should be performed in an environment between 59-86°F (15-30°C).
- Kit contents are stable until the expiration date printed on the outer packaging and should not be used beyond the expiration date.

LIMITATIONS

1. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between December 2022 and March 2024. 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 COVID-19 and influenza emerge. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of COVID-19 and influenza 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 COVID-19 and influenza as compared to a molecular test, especially in samples with low viral load.
4. False positive test results are more likely when the prevalence of SARS-CoV-2, Flu A/B 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., 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.
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 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 is read visually. 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). This test has not been validated for use by those with color-impaired vision.

FREQUENTLY ASKED QUESTIONS

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 Flow*flex* Plus COVID-19 + Flu A/B Home Test, detect proteins from the virus.

Q: WHAT DOES A NEGATIVE RESULT MEAN?

A: A negative test result means that 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 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.

IMPORTANT: If you tested negative and continue to experience COVID-19, Flu A, and/or Flu B-like symptoms, you should therefore seek follow-up care with your healthcare provider who will determine the best course of action. Your 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 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: HOW ACCURATE IS THIS TEST?

A: The Flow*flex* Plus COVID-19 + Flu A/B Home Test was compared to highly sensitive PCR tests. 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 flowflexcovid.com

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: If the control line (Ctl) is not visible on the test strip, the test is invalid, even if any test line is visible. An invalid test result means that the test is unable to determine if you are infected with influenza or SARS-CoV-2 (COVID-19) or not. The test needs to be repeated with a new test kit and sample.

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

A: If uncertain how to proceed, contact Customer Support at flowflexcovid.com or 1-800-838-9502 (Monday to 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
	Do not use if package is damaged		

flowflexcovid.com

***ACON* Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego, CA 92121, USA
Customer Support: 1-800-838-9502

Number: 1151623103
Effective Date: 2026-03-26