Frequently Asked Questions

Flowflex Plus COVID-19 and Flu A/B Home Test

1. What is the Flowflex Plus COVID-19 and Flu A/B Home Test?

The Flow*flex* Plus COVID-19 and 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.

2. What is serial testing? Do I have to serial test with the Flow*flex* Plus COVID-19 and Flu A/B Home Test?

Serial testing is when you test yourself multiple times for COVID-19 on a routing basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce the spread of infection. Serial testing should be performed in symptomatic individuals with SARS-CoV-2 negative results at least twice over three days (with 48 hours between tests). You may need to purchase additional tests to perform this serial (repeat) testing. Consistent with serial testing recommendations for SARS-CoV-2, for multianalyte 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.

3. Does the Flow*flex* Plus COVID-19 and Flu A/B Home Test work for new variants?

We are continuously monitoring the arrival of new COVID-19 variants, and we promptly evaluate our test's performance against any new variants, as clinical samples containing the new variants become available to us. This process takes time, but as soon as the results are in, we issue a Press Release on our website to keep consumers informed in a timely manner.

Please check the website for updates at www.flowflexcovid.com in the news section towards the bottom of the page.

Alternatively, www.aconlabs.com in the News/Tradeshow section.

4. What is the age range for this test?

This test is authorized 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.

5. How many tests come with the test package?

This test is available in 1-test, 2-test, 5-test, and 25-test packages.

6. Can I swab my throat/ear instead of my nose?

Please do not swab your throat / ear. Please only swab your nose to collect sample and follow procedures on the Quick Reference Instructions.

7. I lost my swab; can I use a Q-tip instead of the swab?

Please only use the swab that is provided with the test. Contact customer service at (800) 838-9502 for assistance. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

8. How deep should I insert the swab into my nose?

Insert the swab ½ to ¾ inches inside your nostril. With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person hold the child's head while swabbing.

Note: A false-negative result may occur if the nasal swab specimen is not properly collected.

9. Should I swab my left or right nostril?

Please use the swab to collect specimens from both of your nostrils to ensure sufficient sample collection to generate an accurate result.

10. For how long do I have to swab my nostril?

Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Repeat this in the other nostril.

11. My Flow*flex* Plus COVID-19 and Flu A/B Home Test did not include any English instructions, what should I do?

Please fill out the Contact Us form (Contact Us - Flowflexcovid.com) and provide the Lot number and location where the product was purchased. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

12. The test cassette, extraction buffer tube, nasal swab, or tube holder is missing from the test package. What should I do?

Please contact customer service at (800) 838-9502. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

13. What color should the solution be inside the extraction buffer tube?

The solution should be clear and colorless. If you receive a solution that has a yellow color, do not use this test kit. Please contact customer service at (800) 838-9502 for assistance. Customer Service hours are 8 a.m. – 8 p.m. (EST), 7 days a week.

14. I spilled some of the extraction buffer. What should I do now?

Do not use the test and contact customer service at (800) 838-9502. Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.

15. After nasal specimen collection, how long do I need to swirl the nasal swab in the buffer tube?

Place the swab into the buffer tube and swirl for 30 seconds. Rotate the swab 5 times while squeezing the tube. Remove the swab while squeezing the tube to extract as much liquid as possible. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube. Then gently squeeze the tube and dispense 4 drops of solution into the Sample Well.

16. How many drops should I put in the cassette well? Can I put in all the buffer solution?

You should dispense 4 drops of solution into the cassette sample well. Please do not overuse the buffer solution.

17. Where should I dispense the solution on the cassette?

You should dispense 4 drops of solution into the cassette Sample Well marked with an “S”.

18. The liquid in the little tube seems low, how can I tell if I have enough liquid to perform the test?

If the little tube contains approximately 0.28 inch or 7 mm of buffer solution or more, there is enough buffer solution to perform the test.

19. I just put my swab into the little tube, but I am concerned because the liquid does not cover the entire swab tip. Is this okay?

If the little tube contains approximately 0.28 inch or 7 mm of buffer solution or more, there is enough buffer solution to perform the test, even if the entire swab tip is not covered.

20. I ran my test and applied 4 drops of the liquid to the test cassette, but I am concerned because the liquid did not cover the entire swab tip when I prepared the sample. Is this okay?

If you were able to apply 4 drops of liquid unto the test cassette sample well marked “S”, and you followed all the instructions on the product insert, then it is fine. The entire swab tip does not need to be covered.

21. I performed the test according to the instructions, but when I tried to squeeze 4 drops out of the little liquid bottle, there was just enough liquid for 3 drops. Is my test result valid?

For the test to provide an accurate result, you must apply 4 drops of liquid unto the test cassette sample well, the one marked with an “S”. If your tube contained only enough liquid for 3 drops, you must repeat the test with a new cassette and a newly collected specimen sample.

22. How long does it take to obtain results?

Results are available in 15 minutes.

23. Will this test cause any pain?

No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

24. Are there any limitations as to who can use this test?

Do not use this test on children under two years of age. Do not use this test on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.

25. What are the known and potential risks and benefits of this test?

Potential **risks** include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation section 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.

26. Is the test result still valid if I see a pinkish color on the test strip after applying the sample to the test cassette sample well?

A pinkish background color on the test strip will not affect the result of your test.

27. What is the difference between Antigen, Molecular, and Antibody tests?

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 and Flu A/B Home 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.

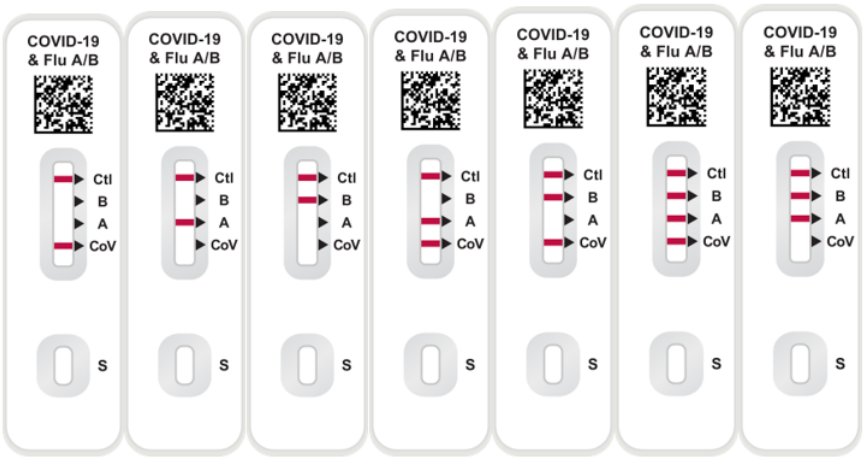
Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been produced by your immune system in response to a previous COVID-19 infection or vaccination. Antibody tests are not suitable for diagnosing an active COVID-19 infection.

For more information on the different kinds of COVID-19 tests, please visit:
https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics

28. What do the red lines on the cassette mean after I complete the test?

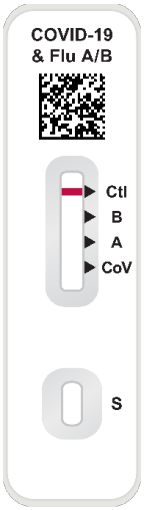
If the control (Ctl) line is visible and any other line or multiple lines, no matter how faint, at “CoV”, “A” and/or “B” appear, the test is positive for that virus. Please refer to the Quick Reference Instructions for more information.

29. What does it mean if I have a positive test 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 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).

30. What does it mean if I have a negative test result?

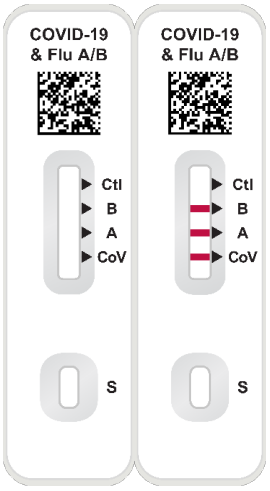


If the Control (Ctl) line is visible, but the Test (CoV/A/B) line is not visible, the test is negative. The COVID-19, Flu A, or Flu B virus have not been detected.

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, seek follow-up care with a healthcare provider.

31. What if I have an invalid result?



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 swab and a new test cassette. If the problem persists, call (800) 838-9502 for assistance.

32. What is a false-positive and a false-negative test result?

A false positive is a test result that indicates a person has a specific disease or condition when the person actually does not have the disease or condition. A false-negative test result indicates a person does not have a specific disease or condition when the person actually does have the disease or condition. Incorrect specimen collection and sample preparation can result in false-negative and false-positive test results. Therefore, before you begin the test, it is very important to read the Quick Reference Instructions provided in the test package and follow the instructions.

33. How accurate is this test?

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 flowflexcovid.com.

34. What is EUA? How does that affect this test?

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.

35. Do I need insurance to perform this test?

No, you do not need insurance to use this test. The Flow*flex* Plus COVID-19 and Flu A/B Home Test is for over-the-counter (OTC) use.

36. Do I need a prescription to use this test?

No, you do not need a prescription to use this test. The Flow*flex* Plus COVID-19 and Flu A/B Home Test is for over-the-counter (OTC) use.

37. Is this test eligible for Flexible Spending Accounts (FSAs)?

Yes, this test is an eligible expense that can be reimbursed under FSAs.

38. Is this test reusable?

No, the Flow*flex* Plus COVID-19 and Flu A/B Home Test is a single-use test and cannot be reused.

39. What is the Flow*flex* Plus COVID-19 and Flu A/B Home Test CPT code to bill insurance?

The CPT Code for COVID-19 is: 87811QW

- Short Descriptor: SARS-COV-2 COVID19 W/OPTIC
- Medium Descriptor: IAADIADOO SEVERE AQT RESPIR SYND CORONAVIRUS
- Long Descriptor: Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

The CPT code for Flu A is: 87804QW

Descriptor: INFECTIOUS AGENT ANTIGEN DETECTION BY IMMUNOASSAY WITH DIRECT OPTICAL (IE, VISUAL) OBSERVATION; INFLUENZA

QW: CLIA WAIVED TEST

The CPT code for Flu B is: 87804QW-59

Descriptor: INFECTIOUS AGENT ANTIGEN DETECTION BY IMMUNOASSAY WITH DIRECT OPTICAL (IE, VISUAL) OBSERVATION; INFLUENZA

QW – 59: CLIA WAIVED TEST, INFLUENZA B

The CPT code for COVID-19 and Flu A/B is: 87428

- Short Descriptor: SARSCOV & INF VIR A&B AG IA
- Medium Descriptor: IAAD IA SARSCOV & INFLUENZA VIRUS TYPES A&B
- Long Descriptor: Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA] qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]) and influenza virus types A and B.

40. What is the Flow*flex* Plus COVID-19 and Flu A/B Home Test NDC code?

The Flow*flex* Plus COVID-19 and Flu A/B Home Test NDC codes are provided below:

Kit Configuration	UPC	NDC
1T	810107290019	10107-0290-01
2T	810107290026	10107-0290-02
5T	810107290033	10107-0290-03
25T	810107290040	10107-0290-04

41. What is the Flow*flex* Plus COVID-19 and Flu A/B Home Test LOINC code?

The LOINC code is 97099-6

• Description: Influenza virus A and B and SARS-CoV-2 (COVID-19) Ag panel - Upper respiratory specimen by Rapid immunoassay

42. What is the nasal swab made of, is it sterile, how is it sterilized, are chemical residues on the swab?

The tip of the nasal swab is made of polyurethane foam and is sterile and safe to use. The swab is sterilized using Ethylene Oxide before aeration to remove any residual components. After the aeration process, no chemicals should be left on the swabs.

43. Is the yellowish color on the tip of my nasal swab normal?

Yes, discoloration of the swab tip is normal and due to UV exposure. The swab is safe to use and will have no impact on test performance.

44. The package containing my Flow*flex* Plus COVID-19 and Flu A/B Home Tests was left outside in freezing temperatures for a few hours – below the storage temperature listed on the kit box. Will it affect the tests' performance, and should I throw the tests away?

Our R&D Dept. has checked and confirmed that the Flow*flex* Plus COVID-19 and Flu A/B Home Test kits that were frozen are still working. Make sure the entire kit is back to room temperature and that the extraction buffer is thawed and back to liquid solution form before the kit is used for the testing.

45. The package containing my Flow*flex* Plus COVID-19 and Flu A/B Home Tests was left outside in very high temperatures for a few hours – above the storage temperature listed on the kit box. Will it affect the tests' performance, and should I throw the tests away?

Our R&D Dept. has checked and confirmed that the Flow*flex* Plus COVID-19 and Flu A/B Home Test kits that were exposed to temperatures above average (up to 65 °C / 150 °F) for a few hours are still working.

Make sure the entire kit is cooled back to room temperature and there is still a least 1/3 of an inch of buffer in the tube before the kit is used for the testing.

46. If your question is not listed above, please contact us.

Customer Service hours are 5 a.m. – 5 p.m. (PST), 7 days a week.