Flowflex™ COVID-19 Antigen Home Test Package Insert

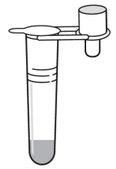
REF L031-118B5	REF L031-125M5	REF L031-125N5	REF L031-125P5	English

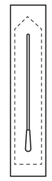
A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. For self-testing use. For use under an Emergency Use Authorization (EUA) only.

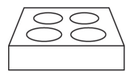
Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

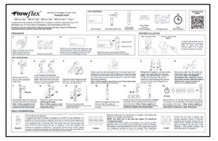
KIT CONTENTS


Test Cassette


Extraction Buffer Tube


Disposable Nasal Swab


Tube Holder (only for 25 test quantity)


Package Insert


Timer (Not included)

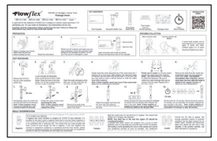
INSTRUCTION VIDEO:

PREPARATION

1.


Wash or sanitize your hands. Make sure they are dry before starting the test.

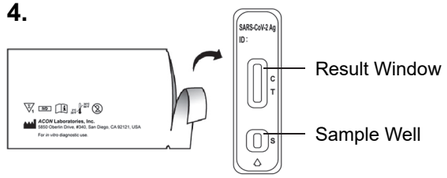
2.


Read the instructions.

3.


Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette foil pouch. Do not use if the pouch is damaged or open.

4.

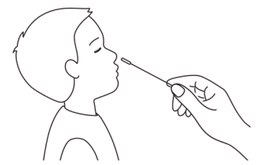


Open the pouch and locate the Result Window and Sample Well on the cassette.

SPECIMEN COLLECTION

SELF COLLECTION

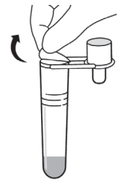
COLLECTION BY AN ADULT



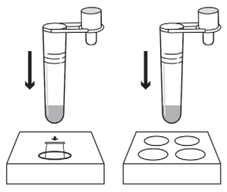
A nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

TEST PROCEDURE

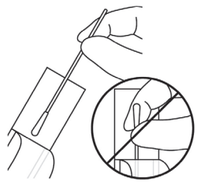
1.


Remove the foil from the top of the extraction buffer tube.

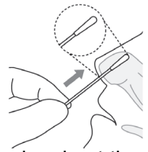
2.


Punch through the perforated circle on the kit box to form a tube holder. Place the tube in the tube holder. For 25 test quantity kit box the tube holder is provided.

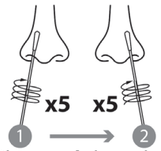
3.


Open the swab packaging at the stick end, not the swab end. Do not touch the swab head.

4.

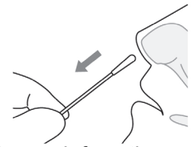

Gently insert the entire absorbent tip of the swab head into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.
Note: A false negative result may occur if the nasal swab specimen is not properly collected.

5.

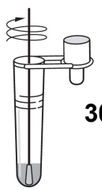


Firmly rub the **swab** in a circular motion around the inside wall of the nostril **5 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.

6.

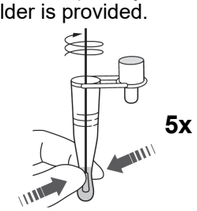

Remove the swab from the nostril and immediately place into the extraction buffer tube. ***Note: Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.***

7.



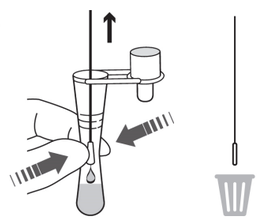
Immediately place the swab into the tube and swirl for 30 seconds. ***Note: A false negative result may occur if the swab is not swirled at least 30 seconds.***

8.

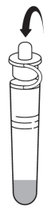


Rotate the swab 5 times while **squeezing the tube**. ***Note: A false negative result may occur if the swab is not rotated five times.***

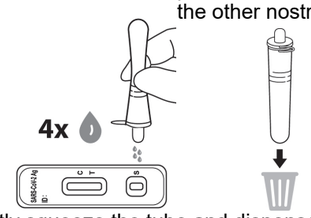
9.


Remove the swab while **squeezing the tube**. Dispose the swab in the trash.

10.

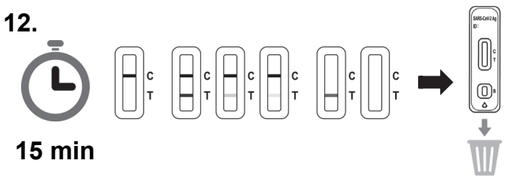

Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.

11.



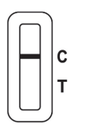
Gently squeeze the tube and dispense **4 drops** of solution into the Sample Well. Dispose the tube in the trash. ***Note: A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.***

12.

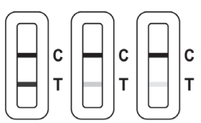


Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the trash. ***Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.***

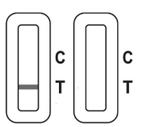
RESULT INTERPRETATION


Negative

Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected.
A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience symptoms or symptoms become more severe, please consult your healthcare provider. It is important that you work with your healthcare provider to help you understand the next steps you should take.


Positive

Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
NOTE: Any faint line in the test line region (T) should be considered positive.
A positive test result means that antigens from COVID-19 were detected, and it is very likely you currently have COVID-19 disease. Self-isolate to avoid spreading the virus to other people and consult your healthcare provider as soon as possible. Your healthcare provider will work with you to determine how best to care for you.


Invalid

Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid result. Review the instructions again and repeat the test with a new cassette. If the problem persists, call (800) 838-9502 for assistance.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY

- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, 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 IVDs 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.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparednessand-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- For detailed instructions, please visit: www.aconlabs.com

INTENDED USE

The Flow*flex* COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. The Flow*flex* COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally found in anterior nasal swabs during the acute phase of infection.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Individuals who test positive should self-isolate and consult their healthcare provider as additional testing may be necessary and for public health reporting.

Negative results are presumptive, and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. Healthcare providers will report all test results they received from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The Flow*flex* COVID-19 Antigen Home Test is intended for self-use or lay user testing another in a non-laboratory setting. The Flow*flex* COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY

The new coronaviruses belong to the beta genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the new coronavirus are the main source of infection; infected people without symptoms can also infect others. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read the Flow*flex* COVID-19 Antigen Home Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.
- The Test is intended to aid in the diagnosis of a current COVID-19 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Keep test kit and materials out of the reach of children and pets before and after use.
- Do not use on anyone under two years of age.
- Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use the test after the expiration date shown on the test cassette pouch.
- Do not use the test if the pouch is damaged or open.
- Do not reuse any kit components. Do not use with multiple specimens.
- Make sure there is sufficient light when testing.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Inadequate or improper nasal swab sample collection may yield false negative test results.
- Do not touch the swab head when handling the swab.
- The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- The chemicals in the reagent solution are hazardous to the skin and eye. Please see the below table for safety recommendations for skin and eye irritation. No personal protective equipment is recommended for use.

Hazard Category (mixture)	Hazard Statement for mixture	Labeling of Harm(s)
Not classified	Acute oral or dermal toxicity	None
Category 2	Eye irritation	May cause eye irritation
Category 3	Skin irritation	Causes mild skin irritation

- If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222

FREQUENTLY ASKED QUESTIONS

Q: WILL THIS TEST HURT?

A: 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.

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 Result Interpretation section).

Potential **benefits** include:

- The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the Flow*flex* COVID-19 Antigen Home Test detect proteins from the virus. Antigen tests are very specific for the COVID-19 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test is necessary and if you should continue isolating at home.

Q: HOW ACCURATE IS THIS TEST?

A: The performance of Flow*flex* COVID-19 Antigen Home Test was established in an all-comers clinical study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected or pair-collected by another study participant from 108 individual symptomatic patients (within 7 days of onset) suspected of COVID-19 and 64 asymptomatic patients. All subjects were screened for the presence or absence of COVID-19 symptoms within two weeks of study enrollment. The Flow*flex* COVID-19 Antigen Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. The Flow*flex* COVID-19 Antigen Home Test correctly identified 93% of positive specimens and 100% of negative specimens.

Q: WHAT IF YOU TEST POSITIVE?

A: A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19 disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

Q: WHAT IF YOU TEST NEGATIVE?

A: A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

IMPORTANT

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

HEALTHCARE PROVIDERS

Please visit www.aconlabs.com to obtain the complete instructions for use and fact sheet for healthcare providers.

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* Laboratories, Inc.**
San Diego, CA 92121, USA
aconlabs.com
Customer Support: 1-800-838-9502

Number: 1151297701
Effective Date: 2021-10-17