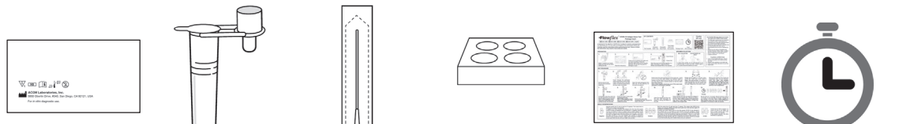
Flow*flex*® COVID-19 Antigen Home Test Package Insert

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)

Flow*flex* QR code

The Flow*flex* Web App allows you to track and report your COVID-19 test results

- The Web App is optional and not required to run a COVID-19 test. It will assist you in interpreting your visual test result and report your result to local health authorities.
- Ensure you have an internet connection and scan the Flow*flex* QR code or go to www.flowflexcovid.com prior to starting the test.
- Ensure you are using a compatible web browser (Chrome, Firefox, Edge, or Safari) and your electronic device has a camera.
- Click on “Report Your Test Result”.
- Create an account.

To perform a COVID-19 test

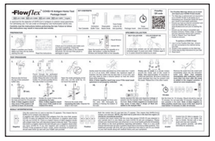
1. Log in to the Flow*flex* Web App - Ensure you are connected to the internet during your test.
2. Answer a few questions on the Web App.
3. Follow step-by-step instructions for your test.
4. Read result.

PREPARATION

1.

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

2.

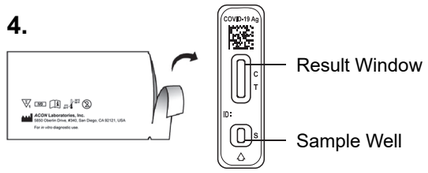


Read the instructions.

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.

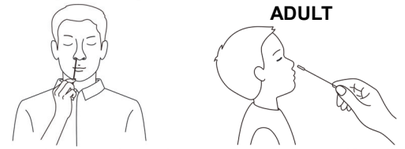
4.



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

SPECIMEN COLLECTION

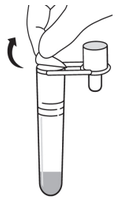
SELF COLLECTION **COLLECTION BY AN ADULT**



An anterior 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.

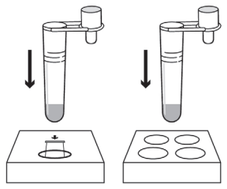
TEST PROCEDURE

1.



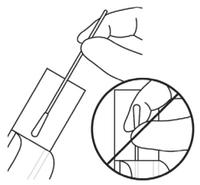
Remove the foil from the top of the extraction buffer tube.

2.



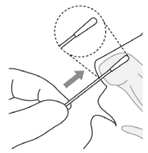
Punch through the perforated circle on the kit box to form a tube holder. Place the tube in the tube holder. For 25 test quantity kit box the tube holder is provided.

3.



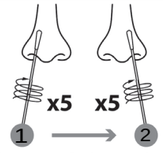
Open the swab packaging at the stick end, not the swab tip. Do not touch the swab tip.

4.



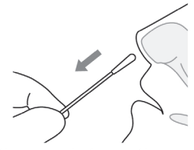
Gently insert the entire absorbent tip of the swab into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child’s head while swabbing.
Note: A false negative result may occur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

5.



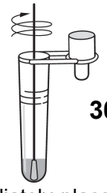
Firmly rub the **swab** in a circular motion around the inside wall of the nostril **5 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.

6.



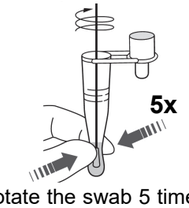
Remove the swab from the nostril and immediately place into the extraction buffer tube. ***Note: Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.***

7.



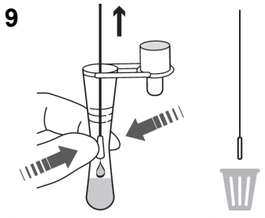
Immediately place the swab into the tube and swirl for 30 seconds. ***Note: A false negative result may occur if the swab is not swirled at least 30 seconds.***

8.



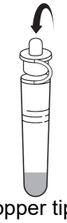
Rotate the swab 5 times while **squeezing the tube**. ***Note: A false negative result may occur if the swab is not rotated five times.***

9



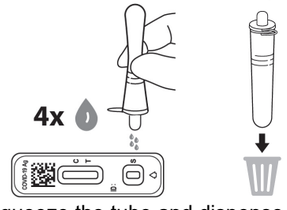
Remove the swab while **squeezing the tube**. Dispose of the swab in the trash.

10.



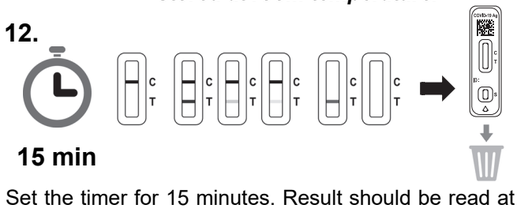
Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.

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.***

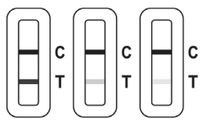
RESULT INTERPRETATION

Negative

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. **To increase the chance that the negative result for COVID-19 is accurate, you should:**

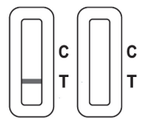
- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative test result indicates that antigens from the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your healthcare provider.



Positive

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red or pink test (T) line with the control line (C) should be read as positive. ***You do not need to perform repeat testing if you have a positive result at any time.***
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).



Invalid

If a control (C) line is not visible, the test is invalid. Re-test with a new swab and new test cassette.
If the problem persists, call (800) 838-9502 for assistance.

HOW TO USE THIS TEST

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

TEST INTERPRETATION

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY

- In the USA, 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-preparedness-and-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.flowflexcovid.com

INTENDED USE

The Flow*flex* COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The Flow*flex* COVID-19 Antigen Home Test can be performed with or without the supervision of a telehealth proctor. 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, which is generally detectable in nasal (nares) samples 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 and the agent detected may not be the definitive cause of disease.

Individuals who test positive with the Flow*flex* COVID-19 Antigen Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

All 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 measures such as isolating from others and wearing masks. 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 who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All 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 non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 or older. The Flow*flex* COVID-19 Antigen Home Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- The Test is intended to aid in the diagnosis of active COVID-19. 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.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Leave the test cassette sealed in its pouch until just before use. Once opened, the test cassette should be used within 60 minutes.
- Do not use the test after the expiration date shown on the test cassette pouch. For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not re-use. 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.
- False negative test results may occur if a specimen is incorrectly collected or handled.
- Do not touch the swab tip when handling the swab.
- 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.
- This test has not been validated for use with a video camera and faint bands may not be visible to a telehealth proctor due to differences between cameras.
- If applicable: Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components.
- The Reagent Solution contains a harmful chemical (see table below).

Hazardous Ingredients for the Reagent Solution		
Chemical Name	**Harms (GHS) code for each ingredient**	**Concentration**
TX-100	H302 Acute oral toxicity H315 Skin irritation H318 Serious eye damage H400 Short-term (acute) aquatic hazard H410 Long-term (chronic) aquatic hazard	1%
Sodium Azide	H300 Acute oral toxicity H310 Acute dermal toxicity H373 Oral, Brain toxicity H400 Short-term (acute) aquatic hazard H410 Long-term (chronic) aquatic hazard	0.02%

- 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**

Serial Testing Information and Limitations

- If you have symptoms of COVID-19 that started within the last 7 days, you may need to test at least twice over three days with at least 48 hours between tests.
- If you do not have symptoms of COVID-19, you may need to test at least three times over five days with at least 48 hours between tests.
- For serial testing, if your first test result is negative, you should test again in 48 hours if you have symptoms on the first day of testing, and test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing. You may need to purchase additional tests to perform this serial (repeat) testing.
- 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 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March, 2021 and May, 2021. 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 SARS-CoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

STORAGE AND STABILITY

- Store Flow*flex* COVID-19 Antigen Home Test between 2-30°C (36-86°F) until use.
- Ensure all kit components are at room temperature before use.
- Kit contents are stable until the expiration date printed on the outer packaging.
- Do not use beyond the expiration date.

FREQUENTLY ASKED QUESTIONS

Q: WHAT IS COVID-19?
A: COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

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 Warnings and 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 SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. Individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Flow*flex* COVID-19 Antigen 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 negative result when you have COVID-19 than a molecular test would.

Q: HOW ACCURATE IS THIS TEST?
A: 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 www.flowflexcovid.com.

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?
A: A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and the test should be run again, using a new test cassette and extraction buffer tube.

IMPORTANT

This test is intended to be used as an aid in the clinical diagnosis of active COVID-19. 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 report the test result through the Flow*flex* Web App or provide all results obtained with this product to their healthcare provider for public health reporting.

HEALTHCARE PROVIDERS

Please visit www.flowflexcovid.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
flowflexcovid.com
Customer Support: 1-800-838-9502

Number: 1151297706
Effective Date: 2023-03-15

120

65

27

Easy to Use

Quick Results

For in vitro diagnostic use.
For use under an Emergency Use Authorization (EUA) only.

COVID-19 Test for ages 2 and up

REF L031-118B5

COVID-19 Antigen Home Test

Flowflex®

1 TEST

1130525705

This test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those within 7 days of symptom onset or with or without symptoms or other epidemiological reasons to suspect COVID -19.

This test is used for testing nasal swab samples collected, processed, and dispensed onto the cassette. Results are read at 15 minutes.

If you have symptoms of COVID-19, you may need to test at least twice over three days with at least 48 hours between tests.

If you do not have symptoms of COVID-19, you may need to test at least three times over five days with at least 48 hours between tests.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing.

ACON®

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

This test does NOT determine if you had COVID-19 in the past or if you have immunity. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular 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, 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.

Contents:
- 1 Test Cassette
- 1 Extraction Buffer Tube
- 1 Disposable Nasal Swab (Sterile Nasal Swab)
- 1 Package Insert (En/Es)

Needed but not provided:
- Timer

IVD

2°C 36°F

30°C 86°F

Scan to learn more about the test

For symbol glossary, refer to the Package Insert

(01)00682607660261

LOT XXXXXXXXX

(17)YYMMDD

YYYY-MM-DD

(10)XXXXXXXXXX

Made in China

For more info on expiration dating, visit
www.fda.gov/covid-tests

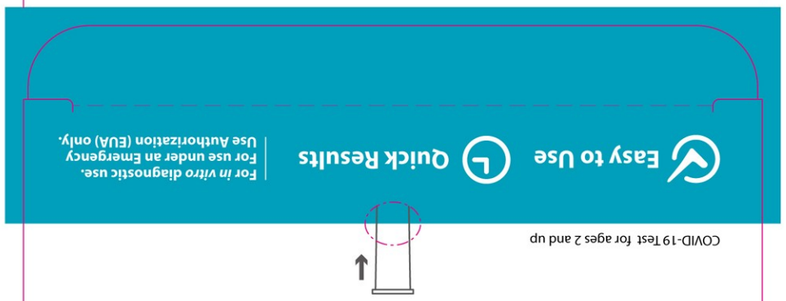
LXXXXXX-XX

6 82607 66026 1

120

65

38



REF L031-125M5

COVID-19 Antigen Home Test

Flowflex® 2 TESTS

1130525805

(01)00682607660278 LOT XXXXXXXXX
(17)YYMMDD YYYY-MM-DD
(10)XXXXXXXXXX Made in China

For more info on expiration dating, visit
www.fda.gov/covid-tests LXXXXXX-XX

Flowflex® COVID-19 Antigen Home Test

This test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those without symptoms or other epidemiological reasons to suspect COVID-19.

This test is used for testing nasal swab samples collected, processed, and dispensed onto the cassette. Results are read at 15 minutes.

If you have symptoms of COVID-19, you may need to test at least twice over three days with at least 48 hours between tests.

If you do not have symptoms of COVID-19, you may need to test at least three times over five days with at least 48 hours between tests.

Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing.

ACON®

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San Diego, CA 92121, USA
Customer Support 1-800-838-9502
flowflexcovid.com

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Contents:
- 2 Test Cassettes
- 2 Extraction Buffer Tubes
- 2 Disposable Nasal Swabs (Sterile Nasal Swabs)
- 1 Package Insert (En/Es)

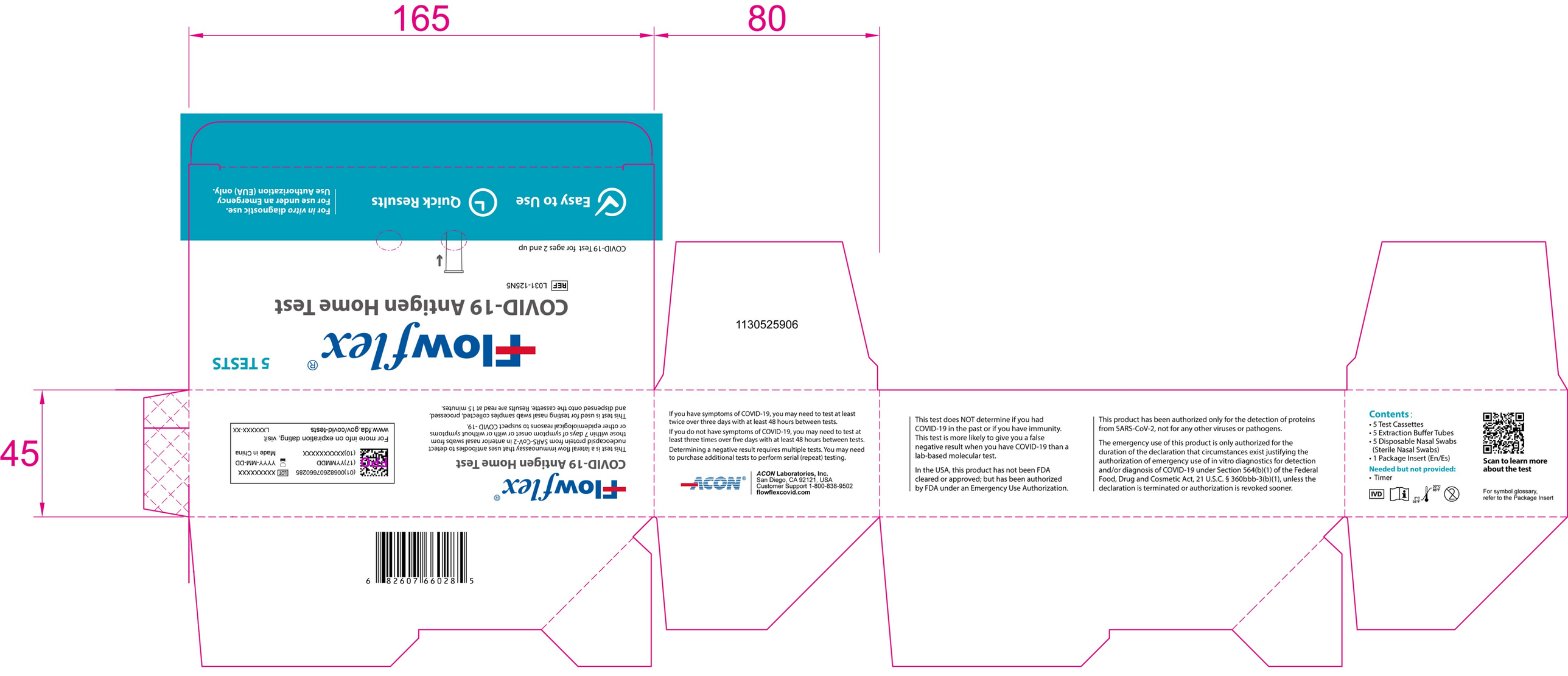
Needed but not provided:
- Timer

IVD 30°C 86°F 2°C 36°F

Scan to learn more about the test

For symbol glossary, refer to the Package Insert

6 82607 66027 8


165
80
45
Easy to Use
Quick Results
For *in vitro* diagnostic use.
For use under an Emergency Use Authorization (EUA) only.
COVID-19 Test for ages 2 and up
REF L031-125N5
COVID-19 Antigen Home Test
Flowflex
5 TESTS
1130525906
This test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those within 7 days of symptom onset or with without symptoms or other epidemiological reasons to suspect COVID-19.
This test is used for testing nasal swab samples collected, processed, and dispensed onto the cassette. Results are read at 15 minutes.
Flowflex
COVID-19 Antigen Home Test
If you have symptoms of COVID-19, you may need to test at least twice over three days with at least 48 hours between tests.
If you do not have symptoms of COVID-19, you may need to test at least three times over five days with at least 48 hours between tests.
Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing.
ACON
ACON Laboratories, Inc.
San Diego, CA 92121, USA
Customer Support 1-800-838-9502
flowflexcovid.com
This test does NOT determine if you had COVID-19 in the past or if you have immunity. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
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Contents :
• 5 Test Cassettes
• 5 Extraction Buffer Tubes
• 5 Disposable Nasal Swabs (Sterile Nasal Swabs)
• 1 Package Insert (En/Es)
Needed but not provided:
• Timer
IVD
2°C 30°C
86°F
Scan to learn more about the test
For symbol glossary, refer to the Package Insert
(01)00682607660285
(17)YYMMDD
(10)XXXXXXXXXX
LOT XXXXXXXXX
YYYY-MM-DD
Made in China
For more info on expiration dating, visit
www.fda.gov/covid-tests
LXXXXXX-XX
6 82607 66028 5

152 mm

48 mm

69 mm

47 mm

167 mm

Flowflex®

COVID-19 Antigen Home Test

Contents:
- 5 Test Cassettes
- 5 Extraction Buffer Tubes
- 5 Disposable Nasal Swabs (Sterile Nasal Swabs)
- 1 Package Insert (En/Es)

Needed but not provided:
- Timer

1130563804

Flowflex®

REF L031-125N5

Easy to Use Quick Results

COVID-19 Antigen Home Test

Results in 15 Minutes

15 min.

Scan to learn more about the test

COVID-19 Test for ages 2 and up

This test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those within 7 days of symptom onset or with or without symptoms or other epidemiological reasons to suspect COVID -19.

This test is used for testing nasal swab samples collected, processed, and dispensed onto the cassette. Results are read at 15 minutes.

5 TESTS

6 82607 66028 5

IVD

2°C 36°F 30°C 86°F

For symbol glossary refer to the Package Insert

ACON Laboratories, Inc.
San Diego, CA 92121, USA
Customer Support 1-800-838-9502
flowflexcovid.us

If you have symptoms of COVID-19, you may need to test at least twice over three days with at least 48 hours between tests.

If you do not have symptoms of COVID-19, you may need to test at least three times over five days with at least 48 hours between tests.

Determining a negative result requires multiple tests. You may need to perform serial (repeat) testing.

(01)00682607660285 (17)YYMMDD (10)XXXXXXXXXX

LOT XXXXXXXXX

YYYY-MM-DD

Made in China

For more info on expiration dating, visit www.fda.gov/covid-tests

LXXXXXX-XX

Flowflex®

REF L031-125N5

Easy to Use Quick Results

COVID-19 Antigen Home Test

Results in 15 Minutes

15 min.

Scan to learn more about the test

For *in vitro* diagnostic use.
For use under an Emergency Use Authorization (EUA) only.

5 TESTS

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HOLLOW OUT

R7

Acon T2T Sleeve

01/18/2023

4.7244 in

COVID-19

RAPID ANTIGEN TEST

eMed®

Download on the App Store

GET IT ON Google Play

Flowflex® Test-to-Treat

COVID-19 Rapid Antigen Test

Includes:

- 24/7 Telehealth Visit for COVID-19
- COVID-19 Rapid Antigen Test

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

IVD 2°C 36°F 30°C 86°F

EMCOV-001

COVID-19

RAPID ANTIGEN TEST

2.0894 in

0.8278 in

eMed®

Flowflex® Test-to-Treat

COVID-19 Rapid Antigen Test

START HERE

eMed.com

DO NOT OPEN

UNTIL INSTRUCTED

This outer label is a sleeve. Remove sleeve to view full label located on the inner box.

1.0633 in | 2.5604 in | 1.0633 in | 2.5604 in | 0.9843 in

125

210

93

COVID-19 Test for ages 2 and up

Easy to Use

Quick Results

For in vitro diagnostic use.
For use under an Emergency Use Authorization (EUA) only.

Flowflex®

25 TESTS

COVID-19 Antigen Home Test

REF L031-125P5

1130553305

Flowflex®

COVID-19 Antigen Home Test

(01)00682607660476
(17)YYMMDD
(10)XXXXXXXXXX
LOT XXXXXXXX
YYYY-MM-DD
Made in China

For more info on expiration dating, visit www.fda.gov/covid-tests

LXXXXXX-XX

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Contents:

- 25 Test Cassettes
- 25 Extraction Buffer Tubes
- 25 Disposable Nasal Swabs (Sterile Nasal Swabs)
- 1 Tube Holder
- 1 Package Insert (En/Es)

Needed but not provided:

- Timer

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San Diego, CA 92121, USA
Customer Support 1-800-838-9502
flowflexcovid.com

IVD

For symbol glossary, refer to the Package Insert

Flowflex®

COVID-19 Antigen Home Test

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