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

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

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. For in vitro diagnostics use.

Carefully read these summary instructions before performing the test. Failure to follow the instructions may result in inaccurate results. A full IFU with performance data can be found at: www.flowflexcovid.com

INTENDED USE

The Flow*flex* COVID-19 Antigen Home Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days of symptom onset.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

The Flow*flex* COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

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

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established during December 2022 to March 2023 when COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

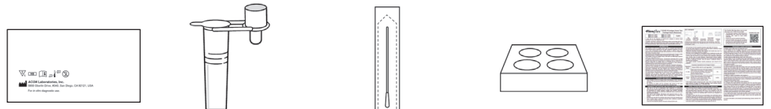
STORAGE AND HANDLING

- Store Flow*flex* COVID-19 Antigen Home Test between 2-30°C (36-86°F) until use. The test should be performed in an environment between 5-40°C (41-104°F).
- Kit contents are stable until the expiration date printed on the outer packaging and should not be used beyond the expiration date.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- **This test is for use in individuals with symptoms of respiratory infection that started within the last 6 days and serial testing should be performed for initial negative results (see SERIAL TESTING section). You may need to purchase additional tests to perform this serial (repeat) testing.**
- **This test is read visually. Individuals with impaired vision or color-impaired vision should ensure help in interpretation of their test results.**
- Do not use the test after the expiration date shown on the test cassette pouch.
- 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.

KIT CONTENTS



Test Cassette (in pouch) | Extraction Buffer Tube (in pouch) | Disposable Nasal Swab | Tube Holder (only for 25 test quantity) | Package Insert

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.

- Once opened, the test cassette should be used within 60 minutes.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample as this may lead to incorrect results.
- Follow the instruction carefully; false negative test results may occur if a specimen is incorrectly collected or handled.
- The test is not a substitute for consultation with a healthcare provider and should not be used to determine treatments without provider supervision. Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are necessary.
- The reagent solution contains harmful substances and should not be ingested.

Hazardous Ingredients for the Reagent Solution

Chemical Name	Harms (GHS) code for each ingredient	Concentration
TX-100	Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318 Short-term (acute) aquatic hazard (Category 1), H400	1%
ProClin 300	Acute toxicity, Oral (Category 4), H302 Acute toxicity, Inhalation (Category 4), H332 Skin corrosion (Category 1B), H314 Serious eye damage (Category 1), H318 Skin sensitization (Category 1), H317	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 your first test result is negative, you should test again in 48 hours.
- 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.
- All negative results with this test 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.

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

- The Web App is optional. It will assist you in understanding your visual test result and reporting your result to local health authorities.
- Ensure you have an internet connection.
- Scan the Flow*flex* QR code prior to starting the test or go to www.flowflexcovid.com for instructions on how to perform the test with the App and how to report your results.

Flow*flex* QR code

FREQUENTLY ASKED QUESTIONS

Q: WHAT DOES THIS TEST DO AND NOT DO?

A: 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 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 a healthcare professional to discuss your results and if any additional testing is required.

Q: WHO SHOULD AND SHOULD NOT USE THIS TEST?

A: The Flow*flex* COVID-19 Antigen Home Test is authorized for use with self-collected anterior nasal (nares) swab samples from individuals 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. Do not use this test on anyone under 2 years of age or who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.

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. However, 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: 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 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.

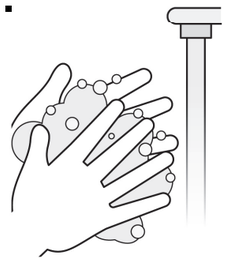
Q: WHAT DOES AN INVALID TEST RESULT MEAN?

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.

For further information on the disease and epidemiology, please visit the CDC website.

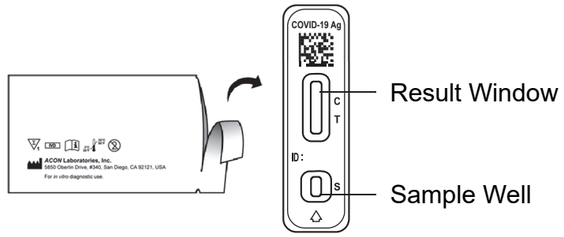
PREPARATION

1.



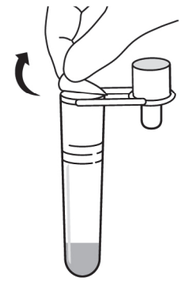
Wash hands.

2.



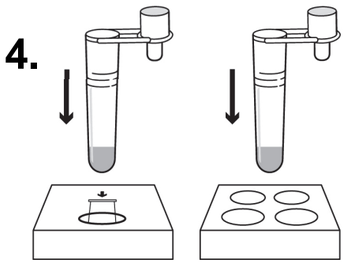
Remove the test cassette from pouch. Locate the Result Window and Sample Well on the cassette.

3.



Remove tube from pouch. Remove the foil from tube.

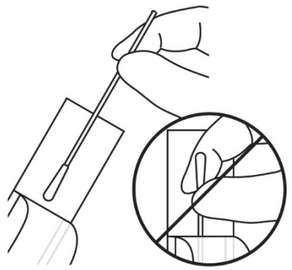
4.



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

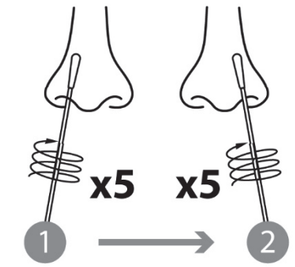
TEST PROCEDURE

1.



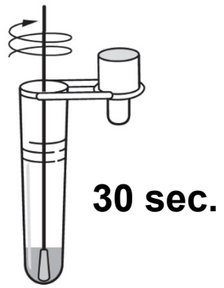
Open swab package at stick end. Take out swab.

2.



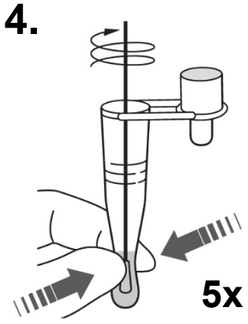
Gently insert tip of swab into 1 nostril (½ to ¾ of an inch). **With children, insert swab less than ¾ of an inch.**
Firmly rub swab in a circular motion against the inside wall of nostril **5 times** (15 sec.). Repeat this in the other nostril.

3.



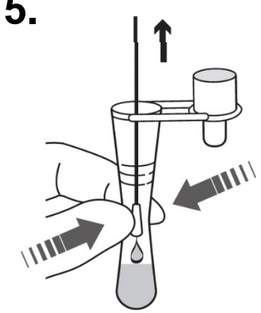
Remove the swab and place into tube. Swirl swab in tube for 30 seconds.

4.



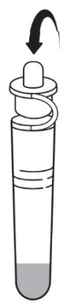
Rotate swab 5 times while **squeezing tube**.

5.



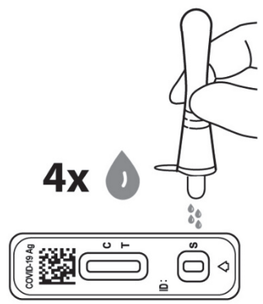
Remove swab while **squeezing tube**. Discard swab.

6.



Attach dropper tip and mix by swirling or flicking tube.

7.



Gently squeeze and put **4 drops** into Sample Well. Discard tube.

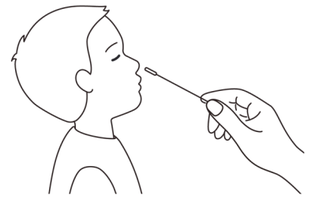
8.

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

RESULT GUIDE

Negative

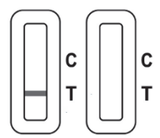
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. **Test again in 48 hours if you have an initial negative result**.

Positive

If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint 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.



Invalid

If a control (C) line is not visible, 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.

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