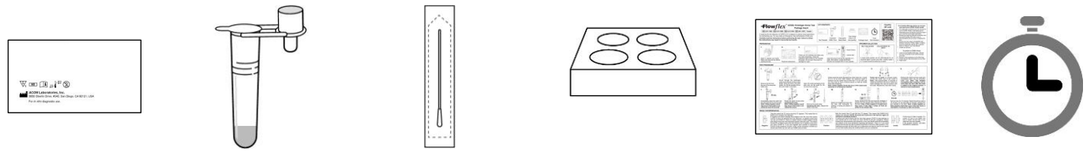
Flowflex™ COVID-19 Antigen Home Test Package Insert

REF L031-126H5	REF L031-126J5	REF L031-126K5	REF L031-126L5	English

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. For self-testing use. For the most up to date information on COVID-19, please visit: www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection.html.

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)

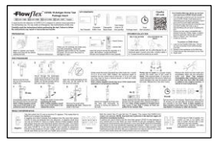
Flowflex Website

PREPARATION

1.

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

2.

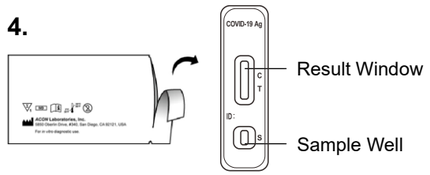


Read the instructions.

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.

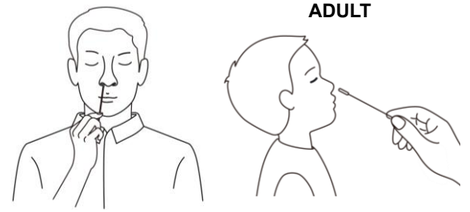
4.



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

SPECIMEN COLLECTION

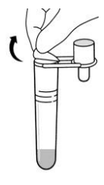
SELF COLLECTION | **COLLECTION BY AN ADULT**



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.

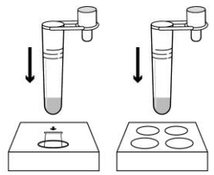
TEST PROCEDURE

1.



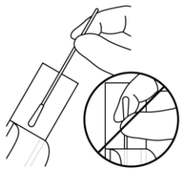
Remove the foil from the top of the extraction buffer tube.

2.



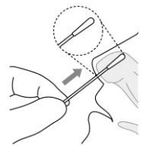
Punch through the perforated circle on the kit box to form a tube holder. Place the tube in the tube holder. For 25 test quantity kit box the tube holder is provided.

3.



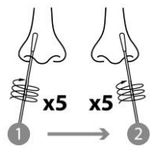
Open the swab packaging at the stick end, not the swab tip. Do not touch the swab tip.

4.



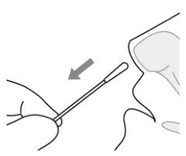
Gently insert the entire absorbent tip of the swab into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing. ***Note: A false negative result may occur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

5.



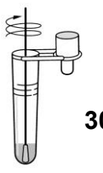
Firmly rub the **swab** in a circular motion around the inside wall of the nostril **5 times**. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.

6.



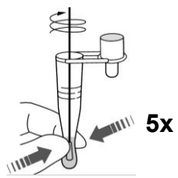
Remove the swab from the nostril and immediately place into the extraction buffer tube. ***Note: Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.***

7.



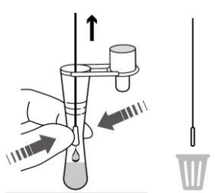
Immediately place the swab into the tube and swirl for 30 seconds.
Note: A false negative result may occur if the swab is not swirled at least 30 seconds.

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.

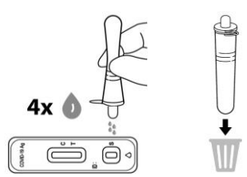


Remove the swab while **squeezing the tube**. Dispose the swab in the trash.

10.

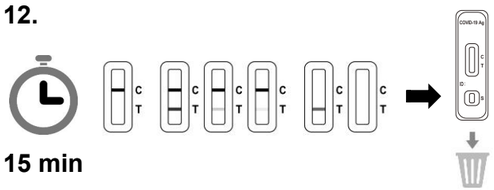
Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.

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.



15 min

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

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

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

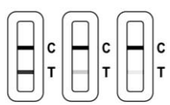
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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 that antigens from the virus that causes COVID-19 were not detected from the specimen.
To increase the chance that the negative result for COVID-19 is accurate, you should:

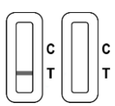
- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative result is presumptive, meaning it is not certain that you do not 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 all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.



Positive

Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected. ***NOTE: Any faint red or pink line in the test line region (T) should be considered positive.***
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). You do not need to perform repeat testing if you have a positive result at any time. Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.



Invalid

Control line (C) fails to appear. 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.

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. This test is authorized for 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 test is intended for serial testing of symptomatic individuals for use at least twice with 48 hours between tests, or for serial testing of asymptomatic individuals for use at least three times with 48 hours between tests. 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. 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 treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. 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 as public health reporting may be required.

The Flow*flex* COVID-19 Antigen Home Test is intended for self-use or lay user testing another in a non-laboratory setting.

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.
- 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.
- Do not use on anyone under two years of age.
- Children aged 2 to 13 years of age should be tested by an adult.
- 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.
- 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.
- 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. The buffer contains a potentially toxic substance, should not be ingested, and should be kept out of reach of children and pets.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- The Reagent Solution contains a harmful chemical (see table below).

Hazardous Ingredients for the Reagent Solution (Extraction Buffer)		
Chemical Name/ Concentration	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 Long-term (chronic) aquatic hazard (Category 1), H410	1%
Sodium Azide	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	0.02%

- If the reagent solution contacts the skin or eye, flush with plenty of water.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March and May 2021. Clinical performance has not been established with 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.
- Cross-reactivity with human coronavirus HKU1 cannot be completely ruled out.

SERIAL TESTING (REPEAT TESTING) INFORMATION AND LIMITATIONS

- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
- Symptomatic individuals that test negative should repeat testing at least twice over three days with at least 48 hours between tests and at least three times over five days with at least 48 hours between tests if they are asymptomatic.
- The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.
- 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.

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.).

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 THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

A: There are different kinds of tests for the 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. Antigen tests are very specific for the SARS-CoV-2 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 test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that 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: 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 in that clinical study. The study was based on testing only once. **However, 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.**

Cumulative Positive Percentage Agreement (PPA) results by days since symptom onset

Days Since Symptom Onset	Specimens Tested	Cumulative Positive Flow*flex* COVID-19 Antigen Home Test	Cumulative Positive RT-PCR	Cumulative PPA
0 to 1 day	29	6	7	86%
0 to 2 days	64	15	16	94%
0 to 3 days	90	20	21	95%
0 to 4 days	96	21	22	95%
0 to 5 days	100	23	24	96%
0 to 6 days	106	26	28	93%
0 to 7 days	108	28	30	93%
Asymptomatic	64	11	12	92%

Q: IS THERE OTHER INFORMATION AVAILABLE DESCRIBING THE PERFORMANCE OF THIS TEST?

A: The Limit of Detection (LoD) in nasal matrix was confirmed to be 2.5 x 10^3 $TCID_{50}$/mL. Microbial cross-reactivity and interference was evaluated by testing a panel of related pathogens and microorganisms, including 15 viruses and 13 bacteria, that are likely to be present in the nasal cavity. 24 common substances that are naturally present or that may be artificially introduced into the nasal cavity or nasopharynx were also evaluated for interference in the presence of SARS-CoV-2 virus (USA-WA1/2020).

Q: WHAT IF YOU TEST POSITIVE?

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. Your healthcare provider will work with you to determine how best to care for you based on your test result, medical history, and symptoms.

Q: WHAT IF YOU TEST NEGATIVE?

A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. However, negative results do not rule out SARS-CoV-2 infection.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. 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. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. 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 determination 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.

HEALTHCARE PROVIDERS

Please visit www.flowflextest.ca 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
	Caution		

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

Number: 1151426201
Effective Date: 2023-xx-xx