

Rapid SARS-CoV-2 Antigen Test Card

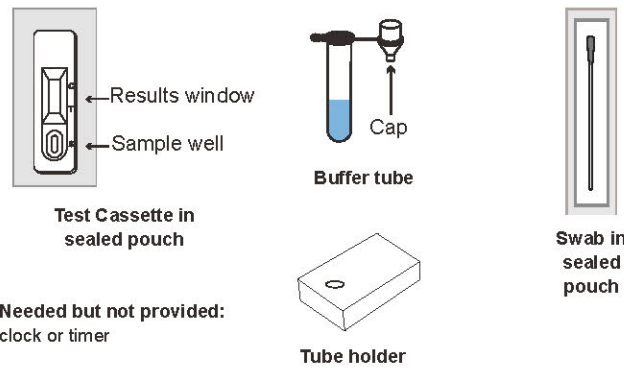
USER INSTRUCTIONS

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

In *vitro* diagnostic use only.

- For this test to work properly, read the instructions fully before starting the test.
- For the most up to date information on COVID-19, please visit: <https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing-screening-contact-tracing/information-patients-guide-self-testing.html>
- This home test kit has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Kit Contents



Storage and Stability

Store the kit at 2-30°C / 36-86°F and protect from direct sunlight. The expiration date of the materials is indicated on the external packaging. Do not freeze the kit.

Preparation

- Wash your hands with soap and water, or use hand sanitizer, before performing the test.
- Check test expiration date on the test cassette pouch.
- Bring the kit to room temperature when you are ready to begin the test.



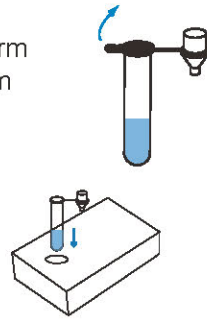
Note

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

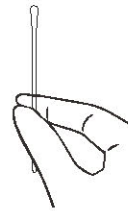
- When you are ready to perform the test, remove the seal from the buffer tube and place the tube in the tube holder.

Open it away from your face and be careful not to spill any of the liquid.



- Peel open the swab packaging and gently take out the swab.

Be careful not to touch the soft, fabric tip of the swab.



- Holding the stick end of the swab, gently insert the entire absorbent tip of the swab into the nostril no more than 1/2 to 3/4 inch. There is no need to go deeper.

Slowly rotate the swab in a circular motion 5 times by firmly pressing against the inside walls of the nostril for a total of 15 seconds. Do not just spin the swab.



Gently remove the swab and repeat in the other nostril using the same swab.

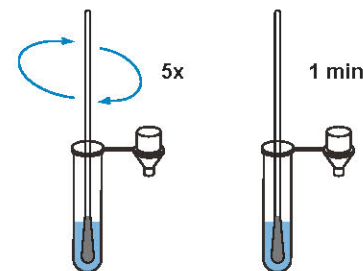


WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

When swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to hold the child's head while swabbing.

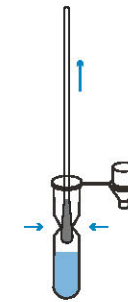
- Place swab into buffer tube. Rotate swab 5 times.

Set a timer and leave swab in buffer tube for 1 minute.

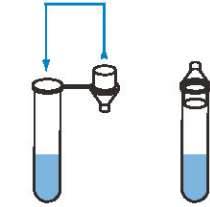


- Pinch buffer tube with fingers and remove the solution from swab as much as possible.

WARNING: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

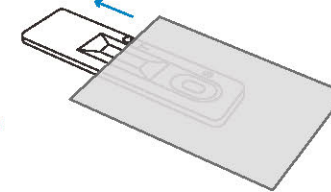


- Press the cap onto the buffer tube until it is secure.

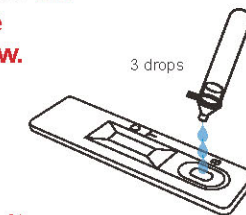


- Open the pouch and remove the test cassette. Place the cassette on a flat and level surface.

WARNING: Once opened, the test cassette must be used within 30 minutes, otherwise inaccurate results may occur.



- Invert the buffer tube and add 3 drops of test sample into the sample well (S) by gently squeezing the extraction tube. **Do not add test sample to the rectangular results window.**



WARNING: Adding other than the recommended number of drops may result in inaccurate results.

- Set a timer and read the results at 15 minutes.



WARNING: Do not read the result before 15 minutes or after 30 minutes.

After test is completed, dispose of used materials in trash.

Read and Interpret the Results

WARNING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.

Look at the result window and locate the letters C and T on the side of the window. A pink/purple line should always appear at the C position; this is a control line and signals that the test is working properly.

◀ Negative result



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 antigens from the virus that causes COVID-19 were not detected from the specimen. A negative result does not rule out COVID-19. 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. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow up care with your health care provider. You should test again in 24 hours (but no more than 48 hours), regardless of whether or not you have symptoms.

◀ Positive result



If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple test (T) line with the control line (C) should be read as 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). 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 result



If a control line (C) is not visible, even if the test line is visible, the result must be considered invalid.

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 and tube.

Intended Use

The Rapid SARS-CoV-2 Antigen Test Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The test is authorized for individuals with symptoms of COVID-19 within the first 6 days of symptom onset, or without symptoms or other epidemiological reasons to suspect COVID-19.

This test is also authorized for home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The test is authorized for individuals aged 2 years and older with symptoms of COVID-19 within the first 6 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19.

The Rapid SARS-CoV-2 Antigen Test Card does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) 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 with the Rapid COVID-19 Antigen Test Card should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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 who test negative and continue to experience COVID-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.

The Rapid SARS-CoV-2 Antigen Test Card is authorized for self-use and/or as applicable an adult lay user testing another person 2 years or older in a non-laboratory setting.

Warnings, Precautions, and Safety Information

Read the Rapid SARS-CoV-2 Antigen Test Card instructions 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 SARS-CoV-2 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 2 years of age.
- Do not open the kit contents until ready for use. If the test cassette is open for longer than 30 minutes, 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 6 months.
- Inadequate or improper nasal swab sample collection may yield false negative test results.
- Do not touch the swab head when handling the swab.
- Test immediately, but no more than 1 hour after collecting the sample on the swab and no more than 30 minutes after mixing into buffer.
- 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.
- In the event of spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.
- Use only the components of this test kit.
- All test materials must be at room temperature before use.
- You should wear a face mask if swabbing others.
- Exposure to humidity may decrease the stability of the test. The test should be performed immediately after removing it from the pouch.
- Collect specimen and immediately perform test according to instructions.
- This test is read visually. Individuals with impaired vision or color-impaired vision may not be able to adequately interpret test results.

Warnings, Precautions, and Safety Information (Cont'd)

- Wash hands thoroughly or use hand sanitizer after handling.
- Dispose of kit contents and patient samples in household trash.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
- The test does not differentiate between SARS-CoV and SARS-CoV-2.
- Children 2 to 13 years of age should not swab themselves and should instead be swabbed by an adult.
- The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for the test line to show up.
- Test devices are single use only and should be discarded after use. Do not re-use the test device.
- This test detects both symptomatic and non-symptomatic SARS-CoV-2 infection. You may need to purchase additional tests to perform this serial (repeat) testing for non-symptomatic SARS-CoV-2 infection.
- The solution in the tube contains a hazardous ingredient (see table below), which is harmful if inhaled, swallowed, or exposed to skin. Avoid contact with your skin, eyes, nose, or mouth. If the extraction solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice.

Hazard Category (mixture)	GHS Hazard Class for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)	Recommended PPE Statement
Category 2/2A	Eye Irritation	Causes serious eye irritation (H319)	Sodium chloride 7647-14-5/1% TERGITOL 15-S-9/1%	Wear eye protection
Category 3	Skin Irritation	Causes mild skin irritation (H316)	TERGITOL 15-S-9/1%	NA

Serial Testing and Limitations

- Testing for all should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.
- 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.
- If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.
- If both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider if you are at high risk for COVID-19.

Frequently Asked Questions

Q: WHAT IS COVID-19?

A: COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 and by infected people without symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?

A: If no control line shows up on the test, the result is invalid (even if any test line shows up). 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 all new test components.

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 TEST AND A 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 Rapid SARS-CoV-2 Antigen 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 the Rapid SARS-CoV-2 Antigen Test Card was established in a prospective clinical study of symptomatic individuals using an EUA molecular test as a comparator method. The data from this study were analyzed using the minimum recommended number of low positives demonstrating that the test correctly identified 82.7% of positive samples and correctly identified 99.1% of negative samples. For more detailed information on test performance please see Section 2.6 of the Health Care Provider Instructions for Use.

Frequently Asked Questions (Cont'd)

A negative result in individuals with or without symptoms does not rule out COVID-19. You can still infect others if you have a negative result. COVID-19 antigen tests are less sensitive than molecular (PCR) tests. The performance of antigen tests can vary with the amount of virus in your sample. Therefore, you should contact your healthcare provider to determine if additional testing with a highly sensitive COVID-19 molecular test is needed. Additional information is available in the Healthcare Provider Instructions for Use at www.bosonbio.com.

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

A: Yes. Please see the Healthcare Provider Instructions for Use available at www.bosonbio.com for additional information. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

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. Testing should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

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. You should test again in 24 to 48 hours. If you receive a second negative result 24 to 48 hours after your first negative result, then you are likely not infected with 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.

Index of Symbols

	Manufacturer		Date of manufacture
	Contains sufficient for <n> test		Catalogue number
	<i>In vitro</i> diagnostic medical device		Use-by date
	Consult instructions for use		Batch code
	Store between 2-30°C / 36-86°F		Do not reuse

Materials Provided

Components	1 Test per Box	2 Tests per Box	4 Tests per Box	5 Tests per Box	8 Tests per Box	10 Tests per Box	20 Tests per Box	40 Tests per Box
Rapid SARS-CoV-2 Antigen Test Card	1	2	4	5	8	10	20	40
Sterilized Swab	1	2	4	5	8	10	20	40
Extraction Buffer Tube	1	2	4	5	8	10	20	40
Tube Holder	1 (packaging)	1 (packaging)	1	1	2	2	5	5
Quick Reference Instructions	1	1	1	1	2	2	5	5



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