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- REF 1N40C5-20-US
- REF 1N40C5-40-US

Rapid SARS-CoV-2 Antigen Test Card

USER INSTRUCTIONS

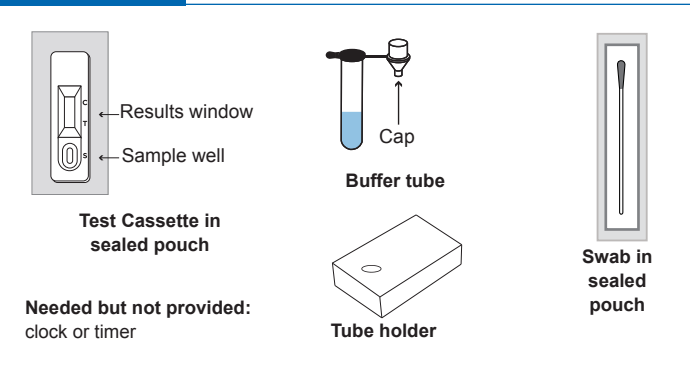
A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens.

For Emergency Use Authorization (EUA) use only.

In vitro diagnostic use only.

- For more information on EUAs 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

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. Do not use kit past its expiration date. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit <http://www.fda.gov/covid-tests>.

Preparation

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

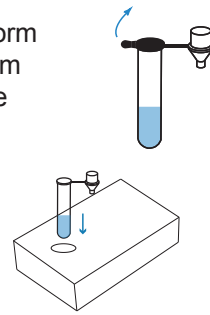
Note

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

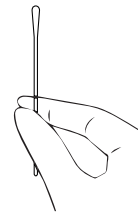
4. When you are ready to perform the test, remove the seal from the buffer tube and place the tube in the tube holder.

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



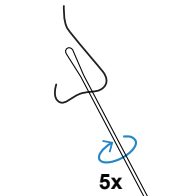
5. Peel open the swab packaging and gently take out the swab.

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

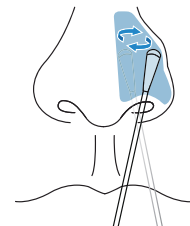


6. Holding the stick end of the swab, gently insert the entire absorbent tip of the swab into the nostril no more than 1/2 to 3/4 inch. There is no need to go deeper.

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.

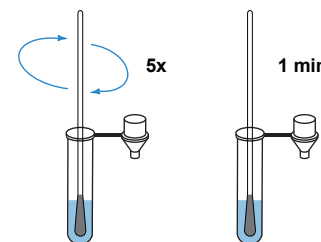


WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

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.

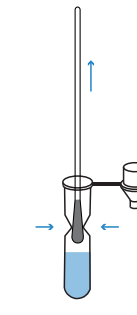
7. Place swab into buffer tube. Rotate swab 5 times.

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

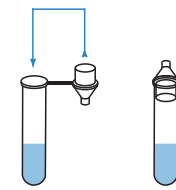


8. Pinch buffer tube with fingers and remove the solution from swab as much as possible.

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

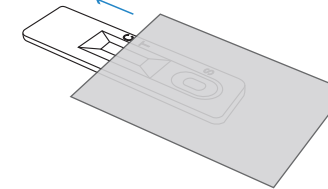


9. Press the cap onto the buffer tube until it is secure.



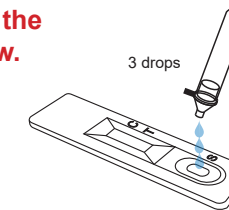
10. Open the pouch and remove the test cassette. Place the cassette on a flat and level surface.

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



11. 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.



12. 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

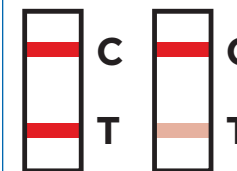


If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. **To increase the chance that the negative result for COVID-19 is accurate, you should:**

- 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.

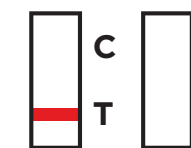
A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results 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 health care provider.

◀ Positive result



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



If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

Read and Interpret the Results (Cont'd)

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.

To report your test result, please go to www.bosoncov.com and follow the instructions

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.

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 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 individual aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 6 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 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 past medical 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 testing may be necessary.

All negative results should be treated as 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-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. All healthcare providers will report all test results they receive 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 Rapid SARS-CoV-2 Antigen Test Card is authorized for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years or older in a non-laboratory setting.

The Rapid SARS-CoV-2 Antigen Test Card is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Warnings, Precautions, and Safety Information

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- 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.
- 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 had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.
- 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.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 30 minutes.
- 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.
- 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 harmful chemicals (see table below). If the solution contacts your 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.

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

- 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

Limitations

- 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 January 2022 and February 2022. 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.

Frequently Asked Questions

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.

Frequently Asked Questions (Cont'd)

- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

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 Rapid SARS-CoV-2 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 false negative result when you have COVID-19 than a molecular test would.

HOW ACCURATE IS THIS TEST?

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.bosoncovt.com.

WHAT IF I HAVE A POSITIVE TEST RESULT?

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.

WHAT IF I HAVE A NEGATIVE TEST RESULT?

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.











WHAT DOES AN INVALID TEST RESULT MEAN?

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 you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

Index of Symbols

	Manufacturer		Date of manufacture
	Contains sufficient for <n> tests		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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