**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

**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**

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.

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**Test Procedure**

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

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

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

4. 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.

6. Holding the stick end of the swab, gently insert the entire absorbent tip of the swab into the nostril no more than ½ to ¾ inch. There is no need to go deeper.

7. 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.

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

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

10. Place the cassette on a flat and level surface.

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.

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

**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.

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**Kit Contents**

- Test Cassette in sealed pouch
- Buffer tube
- Swab in sealed pouch
- Tube holder
- Clock or timer
- Needed but not provided:
  - Sample well
  - Result window

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

When swabbing others, please wear a 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.

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**WARNING:** Do not read the result before 15 minutes or after 30 minutes.
**Wash hands thoroughly or use hand sanitizer after handling.**

- **Diagnose at least 2 of the 10 listed symptoms for at least 15 minutes.**
- **There is sufficient evidence that this test is highly sensitive and specific for COVID-19.**
- **The blood samples in the extraction tube may yield false negative test results.**
- **The test is intended to be used within 48 hours of collection.**
- **Be sure the test kit is within the expiration date.**
- **Do not mix the test strip with the test buffer in the extraction tube.**
- **Store between 2-30°C / 36-86°F (packaging).**
- **Materials Provided**
- **Manufacturer**
- **Date of manufacture**
- **Catalogue number**
- **In vitro diagnostic medical device**
- **Use-by date**
- **Batch code**
- **Store between 2-30°C / 36-86°F**
- **Do not re-use**

**Q: WHAT IS COVID-19?**

A: COVID-19 is an acute respiratory disease caused by the SARS-CoV-2 virus, a novel coronavirus. SARS-CoV-2 was first identified in a person from Wuhan, China, in December 2019. The virus is spread from person to person when an infected person coughs, sneezes, or talks, and another person breathes in the virus. The virus can also be spread through touching a surface or object that has the virus on it and then touching the mouth or nose with that contaminated hand. COVID-19 is highly contagious, and people can spread the virus even before they show symptoms. The incubation period, or the time between exposure to the virus and the appearance of symptoms, can range from 1 to 14 days, with most people experiencing symptoms within 5 days. Common symptoms include fever, cough, shortness of breath, fatigue, muscle or body aches, headache, new loss of taste or smell, nausea, vomiting, and diarrhea. The virus can be spread from people who are asymptomatic or pre-symptomatic, making it difficult to contain.

**Q: WHAT IS SERIAL TESTING?**

A: Serial testing refers to testing over time to determine if COVID-19 was present in your sample. If your first and second tests are negative, you may not have COVID-19, but you should continue to monitor your health and seek medical attention if symptoms develop.

**Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN TEST AND A MOLECULAR TEST?**

A: There are different types of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus, while antigen tests detect viral proteins. Antigen tests are typically used for rapid testing in low-resource settings or when there is limited access to molecular testing. Antigen tests are usually done in a clinic or laboratory and may take longer to get results than rapid tests. Molecular tests are usually done in a laboratory and may take several days to get results. Molecular tests are more accurate than antigen tests, but antigen tests can be used in situations where molecular testing is not available or when results are needed quickly.
Rapid SARS-CoV-2 Antigen Test Card

Home Test

For the rapid qualitative determination of SARS-CoV-2 antigen in anterior nasal swab specimens.

Results in 15 minutes

COVID-19 TEST

1 Test

Need help? Contact us at support@bosoncovt.com or call +1-800-689-7794.

Ages 2 and up

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www.bosoncovt.com

Contents:
1x SARS-CoV-2 Antigen Test Card
1x Sterilized Swab
1x Extraction Buffer Tube
1x Quick Reference Instructions

Tube Holder

• Items necessary to use the kit, but not provided:
  - Timer
  - For symbol glossary, refer to Instructions for Use.
  - Read all instructions carefully.
  - Keep testing kit and components away from children and pets before or after use.
  - For ages 2 to 13, an adult must collect and test the anterior nares specimen.
  - You will need at least two tests per person.
  - You may need to purchase additional tests to perform serial (repeat) testing.
  - This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
  - This test does NOT determine if you had COVID-19 in the past or if you have immunity.
  - 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 the 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.
  - 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 in anterior nasal (nares) swabs from individuals 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 individuals without symptoms or other epidemiological reasons to suspect COVID-19.
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Home Test

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Results in 15 minutes

COVID-19 TEST

2 Tests

Ages 2 and up

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Contents:
2x SARS-CoV-2 Antigen Test Card
2x Sterilized Swab
2x Extraction Buffer Tube
1x Quick Reference Instructions

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  • Tube Holder
  • Timer
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UDI

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Home Test
For the rapid qualitative determination of SARS-CoV-2 antigen in anterior nasal swab specimens.
For in vitro Diagnostic Use Only.
For Use Under an Emergency Use Authorization (EUA) Only.
Results in 15 minutes

COVID-19 TEST
4 Tests
Need help? Contact us at support@bosoncovt.com or call +1-800-630-7794.

Ages 2 and up

• Items necessary to use the kit, but not provided:
  - Timer
• For symbol glossary, refer to Instructions for Use.
• Read all instructions carefully.
• Keep testing kit and components away from children and pets before or after use.
• For ages 2 to 13, an adult must collect and test the anterior nares specimen.

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www.bosoncovt.com

Contents:
4x SARS-CoV-2 Antigen Test Card
4x Sterilized Swab
4x Extraction Buffer Tube
1x Tube Holder
1x Quick Reference Instructions

UDI

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Home Test
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Results in 15 minutes
COVID-19 TEST
5 Tests
Need help? Contact us at support@bosoncovt.com or call +1-800-689-7794.

Contents:
• 5x SARS-CoV-2 Antigen Test Card
• 5x Sterilized Swab
• 5x Extraction Buffer Tube
• 1x Tube Holder
• 1x Quick Reference Instructions

UDI

XXXXXX
YYYY-MM-DD

Ages 2 and up

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- Timer

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COVID-19 TEST
8 Tests
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8x SARS-CoV-2 Antigen Test Card
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8x Extraction Buffer Tube
2x Tube Holder
2x Quick Reference Instructions

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For the rapid qualitative determination of SARS-CoV-2 antigen in anterior nasal swab specimens.

For in vitro Diagnostic Use Only.

For Use Under an Emergency Use Authorization (EUA) Only.

Results in 15 minutes

COVID-19 TEST

10 Tests

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Ages 2 and up

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Contents:
10x SARS-CoV-2 Antigen Test Card
10x Sterilized Swab
10x Extraction Buffer Tube
2x Tube Holder
2x Quick Reference Instructions

UDI

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Results in 15 minutes

COVID-19 TEST
20 Tests

Need help? Contact us at support@bosoncovt.com or call +1-850-689-7756.

Ages 2 and up

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Contents:
20x SARS-CoV-2 Antigen Test Card
20x Sterilized Swab
20x Extraction Buffer Tube
5x Tube Holder
5x Quick Reference Instructions

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Results in 15 minutes

40 Tests

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40x Sterilized Swab
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5x Quick Reference Instructions

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