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 more information on EUAs visit: https://www.fda.gov/emergency-preparedness-and-response/cdrh-emergency-use-authorizations

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

**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.**

**Note**

**Kit Contents**

- Results window
- Sample well
- Buffer tube
- Test Cassette in sealed pouch
- Swab in sealed pouch

**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.

**Test Procedure**

1. 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.
2. Peel open the swab packaging and gently take out the swab.
   - Be careful not to touch the soft, fabric tip of the swab.
3. 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.
   - 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.
4. Place swab into buffer tube. Rotate swab 5 times.
   - Set a timer and leave swab in buffer tube for 1 minute.
5. 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.
6. Press the cap onto the buffer tube until it is secure.
7. 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.
8. 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.
   - If the Control (C) line is visible, but the Test (T) line is not visible, 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.
9. Set a timer and read the results at 15 minutes.
   - 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.
10. WARNING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.
   - WARNING: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.
   - WARNING: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test interpretations may occur.
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**Read and Interpret the Results**

- 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 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 if 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 healthcare provider. You should test again in 24 hours (but no more than 48 hours), regardless of whether or not you have symptoms.
- A positive test result means that the virus that causes COVID-19 was detected in your sample and 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.
- 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.

**WARNING**

- If a Control (C) line is not visible, even if the test line is visible, the result must be considered invalid.
The Rapid SARS-CoV-2 Antigen Test Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein (NCP) antigen in antigenically intact viral particles from 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 non-prescription home use with adult-collected anterior nasal (nasal) swabs samples from individuals aged 2 years or older tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The test is also authorized for use 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-2 and SARS-CoV-1.

The test is intended for the diagnosis of SARS-CoV-2 nucleocapsid protein antigen. Antigen immunologically detectable in anterior nasal (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 vaccination or infection with other viruses. The antigen detected may not be the 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 more sensitive test. Positive results may also be necessary, if there is a high likelihood of COVID-19, such as in an individual with close contact with COVID-19 or with suspected exposure to COVID-19 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.

Warnings, Precautions, and Safety Information

- Wash hands thoroughly or use hand sanitizer after handling.
- Dispose of kit and patient samples in appropriate waste bin.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- The immune response varies depending on the type of 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 use themselves and should instead be tested 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.
- Devices are only single use 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.
- The solution in the tube contains a hazardous ingredient (see table below), which is harmful if inhaled, swallowed, or entered into the eyes. 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 inhalation persists, seek medical advice: https://www.pson.com/Contact-us or 1-800-222-1222.

Serial Limitations and Limitations

Testing for COVID-19 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.

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

- Testing for serial testing should be presumptive and correlate 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 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.

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.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive result indicates that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. COVID-19 antigen tests are less sensitive than molecular (PCR) tests. 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 a rapid antigen test performed 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 need to purchase additional tests to perform this serial (repeat) testing.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative result indicates that you do not have COVID-19 because proteins from the virus that causes COVID-19 were not found in your sample. 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 use the test correctly or the level of antigen from the virus causing COVID-19 was too low to be detected. Your healthcare provider may suggest you need another test to determine if you have COVID-19.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN TEST AND A MOLECULAR TEST?
A: Molecular tests are used to detect the SARS-CoV-2 virus itself, while antigen tests detect proteins made by the SARS-CoV-2 virus. Molecular tests can detect SARS-CoV-2 in people who do not have symptoms, and are more sensitive than antigen tests. Antigen tests are less sensitive than molecular tests, but are faster to perform and require less laboratory equipment. Antigen tests are not recommended for serial (repeat) testing.

Q: WHAT IS THE INDEX TEST?
A: The performance of the Rapid SARS-CoV-2 Antigen Test Card was established in a prospective clinical study involving symptomatic individuals using an EUA molecular test as a comparator method. The data from this study was analyzed using the minimum information necessary to determine that the test is performed correctly. The test was identified with 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.
Rapid SARS-CoV-2 Antigen Test Card
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.

COVID-19 TEST

Need help? Contact us at support@bosoncovt.com or call +1-888-352-8394

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

- Items necessary to use the kit but not provided
- Timer
- For best results, refer to instructions for use
- Read all instructions carefully
- Keep testing kit and components away from children and pets
- For use by persons 12 years of age and older
- For ages 2 to 11, an adult must collect and test the
  patient’s sample appropriately.
- 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 a duration of the declaration that circumstances exist
  at the time of this authorization, to be removed or revised when the circumstances that provided the basis for the
  declaration cease to be the case, or when the FDA publishes a withdrawal or revision to the authorization.
- The Rapid SARS-CoV-2 Antigen Test Card is a lateral flow immunocassette intended for the qualitative detection of
  nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal (nasal) 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 5 days of symptom onset, or individuals without symptoms or
  other epidemiological reasons to suspect COVID-19.