**Rapid SARS-CoV-2 Antigen Test Card**

**USER INSTRUCTIONS**

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal swabs. For Emergency Use Authorization (EUA) use only.

- In vitro diagnostic use only.
- For the most up to date information on COVID-19, please visit: [https://www.fda.gov/covid-tests](https://www.fda.gov/covid-tests)

In vitro diagnostic use only.

**For Emergency Use Authorization (EUA) use only.**

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

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.
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. Hold 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.
7. Gently remove the swab and repeat in the other nostril using the same swab.
8. Place swab into buffer tube. Rotate swab 5 times.
9. Set a timer and leave swab in buffer tube for 1 minute.
10. 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.

11. Press the cap onto the buffer tube until it is secure.
12. Set a timer and read the results at 15 minutes. 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.

**Read and Interpret the Results**

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, 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).

**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.
Read and Interpret the Results (Cont’d)

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 the virus that causes COVID-19, not for any other use. The performance of the product is only useful for the duration of the declaration that conditions exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under 21CFR840.20 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 368(b)(3)(A)), unless the declaration is terminated or authorized is rescinded.

Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for asymptomatic individuals, or at least three 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 fever symptoms longer than 3 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 aged 14 years or older and child under the age of 14 years should be tested by an adult.

Do not use on anyone under 2 years of age.

Wear a mask or other face-covering when collecting a specimen from a child or another individual.

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 infection as compared to a molecular test, especially in samples with low viral load.

The performance of this test was evaluated based on the evaluation of a limited number of clinical specimens collected between January 2022 and January 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 clinical evaluation. The performance of the test at any time vary depending on the prevalent variants, 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. You should continue to follow COVID-19 infection control procedures until the results are confirmed.

This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

Inconclusive test results may occur if the 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 Interpretation sections for more information).
- Possible cross-reactions with unrelated antibodies.
- Possible misinterpretation of test results.

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)

WHAT IS THE DIFFERENCE BETWEEN AN INTERVAL COVID-19 AND MOLECULAR TESTS?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19 and 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 accuracy.

WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive result means that it is very likely you have COVID-19 because the virus that causes COVID-19 was 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 your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

INDEX OF SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tr>
<td>M0</td>
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<tr>
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<td>WE</td>
<td>Package number</td>
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<tr>
<td>USE</td>
<td>In vitro diagnostic device</td>
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<tr>
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<td>Use-by date</td>
</tr>
<tr>
<td>CT</td>
<td>Batch code</td>
</tr>
</tbody>
</table>

Materials Provided

- 1 Test per Box
- 2 Tests per Box
- 4 Tests per Box
- 5 Tests per Box
- 6 Tests per Box
- 10 Tests per Box
- 20 Tests per Box
- 40 Tests per Box

Components

- Rapid SARS-CoV-2 Antigen Test Card
- Rapid SARS-CoV-2 Antigen Test Card
- Tube Holder
- Extraction Buffer Tube
- Extraction Buffer Tube
- (packaging)
- (packaging)

Number: 082316 Effective Date: 2022-12
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.

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

XC410004

Xiamen Boson Biotech Co., Ltd.
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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

• 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.
  - 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 EUA.
  - 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. §380bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
  - Determining a negative result requires multiple tests. 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.
  - 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. The test is authorized for use at least twice over three days with at least 48 hours between tests. For asymptomatic individuals, the test is authorized for use at least three times over five days with at least 48 hours between tests.
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.

Results in 15 minutes

COVID-19 TEST

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Ages 2 and up

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2x Extraction Buffer Tube
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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.
Results in 15 minutes

COVID-19 TEST
4 Tests

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

Ages 2 and up

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

UDI
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 EUA.
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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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For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, please visit: http://www.fda.gov/covid-tests
Rapid SARS-CoV-2 Antigen Test Card
Home Test
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For in vitro Diagnostic Use Only.
For Use Under an Emergency Use Authorization (EUA) Only.
Results in 15 minutes
COVID-19 TEST
5 Tests
Need help? Contact us at support@bosoncovt.com or call +1-800-689-7794.
Ages 2 and up
Contents:
5x SARS-CoV-2 Antigen Test Card
5x Sterilized Swab
5x Extraction Buffer Tube
1x Tube Holder
1x Quick Reference Instructions
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Home Test
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For in vitro Diagnostic Use Only.
For Use Under an Emergency Use Authorization (EUA) Only.
Results in 15 minutes
COVID-19 TEST
8 Tests
Need help? Contact us at support@bosoncovt.com or call +1-800-689-7794.
Ages 2 and up
Contents:
8x SARS-CoV-2 Antigen Test Card
8x Sterilized Swab
8x Extraction Buffer Tube
2x Tube Holder
2x Quick Reference Instructions

Items necessary to use the kit, but not provided:
- Timer
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Rapid SARS-CoV-2 Antigen Test Card
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Results in 15 minutes

COVID-19 TEST
10 Tests

Need help? Contact us at support@bosoncovt.com or call +1-800-689-7794.
Ages 2 and up

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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COVID-19 TEST
20 Tests
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Ages 2 and up
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

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

Ages 2 and up

Contents:
- 40x SARS-CoV-2 Antigen Test Card
- 40x Sterilized Swab
- 40x Extraction Buffer Tube
- 5x Tube Holder
- 5x Quick Reference Instructions

UDI

Items necessary to use the kit, but not provided:
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