### 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/cdrh-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

- **Antigen Test Card:** Rapid SARS-CoV-2 Antigen Test Card
  - **1N40C5-1-US**
  - **1N40C5-2-US**
  - **1N40C5-4-US**
  - **1N40C5-5-US**
  - **1N40C5-8-US**
  - **1N40C5-10-US**
  - **1N40C5-20-US**
  - **1N40C5-40-US**

- **Test Cassette in sealed pouch**

- **Swab in pouch**

- **Buffer tube**

- **Tube holder**

- **Results window**

- **Sample well**

### 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.

### Test Procedure

1. **Open test cassette pouch.**

2. **Peel open the swab packaging and gently take out the swab.**

3. **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.**

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

5. **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.**

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

7. **Place swab into buffer tube. Rotate swab 5 times. Set a timer and leave swab in buffer tube for 1 minute.**

8. **Peel open the swab packaging and gently take out the swab.**

9. **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.**

10. **Press the cap onto the buffer tube until it is secure.**

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

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 healthcare 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

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.
The Rapid SARS-CoV-2 Antigen Test Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen in nasal secretion sample with self-collected anterior nasal (nares) swabs from individuals aged 2 years and older when tested twice over three days with at least 24 hours between tests and no more than 48 hours between tests. The test is intended to detect the acute phase of infection. The test does not differentiate between SARS-CoV-2 and SARS-CoV-2 variant. The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for the test to show up.

In the event of spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.

The chemicals in the reagent solution are hazardous to the skin and eye. Please see the below table for safety precautions.

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Labeling of Harm(s)</th>
<th>Recommended PPE Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>Eye/eye irritation EYE IRITATION</td>
<td>Wear eye protection</td>
</tr>
<tr>
<td>Category 2</td>
<td>Skin irritation SKIN IRRITATION</td>
<td>Wear gloves</td>
</tr>
<tr>
<td>Category 3</td>
<td>Inhalation INHALATION</td>
<td>Wear respiratory protection</td>
</tr>
</tbody>
</table>

Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.

Do not ingest any kit components.

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 kit.

Do not inject any kit components.

Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.

Do not use any spray-in rinses or rinsing solutions for use. If the test cassette is open for longer than 30 minutes, invalid test results may occur.

Do not use the test if the pouch is damaged or open.

Do not use any kit components.

Do not use with any other tests.

Do not mix test components.

Do not use the test if you are pregnant or breastfeeding.

Do not use nasopharyngeal, oral, or rectal swabs.

Do not use any kit components.

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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

COVID-19 TEST
2 Tests
Ages 2 and up

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

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

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Tube Holder

- Home necessary to use the kit, but not provided.
- Timer
- For symbol meaning, refer to Instructions for Use.
- For instructions: carefully.
- Keep testing kit and components away from children and pets.
- Before or after use.
- For ages 2 to 15, an adult must collect and test the infant nasal specimen.
- You will need at least two tests per person.
- You may need to purchase additional tests to perform serial (repeat) testing.
- The 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 detect if you have COVID-19 in the past or if you have immunity.
- The test result does not relieve you of the responsibility of taking other actions as necessary to protect public health as recommended by FDA, prior to granting Emergency Use Authorization.
- This product has been authorized only for the detection of pathogens 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 of emergency by FDA, under Section 564(c)(4) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §360bbb-3(s)(4), unless the declaration is terminated or authorization is revoked sooner.
- The Rapid SARS-CoV-2 Antigen Test Card is a lateral flow immunochromatographic test intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens from individuals with symptoms of COVID-19 within the first 10 days of symptom onset, or individuals without symptoms or other epidemiological reasons to suspect COVID-19.

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