**Home Use**

Advin COVID-19 Antigen Test @Home

Quick Reference Guide

For use under Emergency Use Authorization only

For in vitro diagnostic use

**KIT CONTENTS**

- Test Cassette
- Extraction Buffer Tube
- Disposable Nasal Swab
- Quick Reference Guide
- Timer (Not included)
- Disposal Bag

**SPECIMEN COLLECTION**

Self-collected the nasal swab samples by individuals aged 14 years or older. Or adult collect nasal swab samples from individuals aged 2 years or older. Children aged 13 years old and younger should be tested by a parent or legal guardian.

**TEST PROCEDURE**

1. Wash or sanitize your hands and keep them dry before testing.
2. Peel off the aluminum foil on the extraction buffer tube.

⚠️ Tube contains liquid

3. Place the extraction buffer tube in the tube holder on the kit box.

4. Remove nasal swab from its packaging. DO NOT touch the swab tip.

5. Prepare to collect sample. If collecting from a child, you may need another person to steady the child’s head while swabbing.

6. Gently insert swab ½ - ¾ inch into first nostril, or until you feel resistance. Slowly make at least 5 rotations with the swab firmly against the walls of the nostril for approximately 15 seconds.

7. Repeat step #6 in your second nostril using the same swab.

⚠️ Swab both nostrils. DO NOT insert the swab any deeper if you feel resistance or pain. Inaccurate test result may occur if the nasal swab specimen is not properly collected. Collect specimen and immediately perform the test according to the instructions.

8. Take the tube out of the tube holder. Place the swab into the tube, secure the swab tip is in the liquid inside the tube.

9. Squeeze the swab tip at least 5 times from outside of the tube, while the swab tip remains in the liquid.

10. While squeezing the sides of the vial firmly, pull the swab out to remove excess liquid.

11. Dispose of the swab in provided disposal bag.

12. Firmly press the dropper tip on the extraction buffer tube.

13. Remove the cassette from its packaging and place it on a clean flat surface. Find the Result Window and Specimen Well on the cassette.

14. Add 3 drops of solution into the circular sample well, labeled as “S” on the test cassette.

⚠️ Do not add test sample to the rectangular results window. Do not touch the sample well with dropper tip. Do not hold the dropper tube more than ½ above sample well. Adding other than the recommended number of drops may result in inaccurate results.

15. Set timer for 10 minutes. Do not move or lift the test cassette. Read the test result at 10 minutes.

⚠️ Do not read test results before 10 minutes or after 30 minutes

**RESULT INTERPRETATION**

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

<table>
<thead>
<tr>
<th>Status on Test</th>
<th>Test result</th>
<th>Second Result</th>
<th>Third Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Symptoms</td>
<td>Day 1</td>
<td>Day 3</td>
<td>Day 5</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive for COVID-19</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>N/A</td>
<td>Negative for COVID-19</td>
<td></td>
</tr>
</tbody>
</table>

| Without Symptoms | |
| Positive | N/A | N/A | Positive for COVID-19 |
| Negative | Negative | Positive | 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.

**COVID-19 Positive (+)**

- If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red/purple 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).

Individuals who test positive with the Advin COVID-19 Antigen Test @Home should self-isolate and seek follow-up care with their physician or healthcare provider.

**COVID-19 Negative (-)**

- 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.

All negative results should be treated as presumptive and confirmation 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 or 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.

**Invalid**

- If the control (C) line is not visible, the test is invalid. Re-test with a new swab and test device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor or manufacturer for technical support.

Report your test result(s) at HYPERLINK: https://makemytestcount.org/?utm_source=stubstack&utm_medium=email MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.
If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222

WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TESTS?

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 (PIUF), available at http://www.advinibo.com.

WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive test 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 antibodies 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 within 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 test result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new nasal swab should be collected for the test.