Quick Reference Guide

Advin COVID-19 Antigen Test @Home

For use under Emergency Use Authorization only

For in vitro diagnostic use

KIT CONTENTS

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

Bring test kit to room temperature (59-86 °F / 15-30 °C).


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, ensure the swab tip is in the liquid inside the tube.
   - Stir the swab tip against the bottom and side of the tube for at least 15 times.
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.
   - Dispose of the swab in provided disposal bag.
11. Firmly press the dropper tip on the extraction buffer tube.
12. Remove the cassette from its packaging and place it on a clean flat surface. Find the Result Window and Specimen Well on the cassette.
13. Add 3 drops of solution into the circular sample well, labeled as "S" on the test cassette.
14. 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.
15. Dispose of all used test kit components in the Disposal Bag provided. Dispose of the bag in household trash. Wash your hands or use hand sanitizer after completing all steps.

RESULT INTERPRETATION

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 education and self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false 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.

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 is 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 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.

If the Control (C) line is not visible, the test is invalid. The test with a new swab and new test device. Inaccurate specimen collection or incorrect procedural techniques are the most likely reasons for control line failure. Revise the procedure and repeat the test with a new test kit. 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=substack&utm_medium=email] Maskly/TestCount.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.
Test results from the COVID-19 Antigen Test @ Home is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older with adult collected anterior nasal (nasal) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over five days at least with 48 hours between tests, and for individuals without symptoms of COVID-19 with recent infections or recent exposures.

The Advin COVID-19 Antigen Test @ Home is only for use under the Food and Drug Administration’s Emergency Use Authorization. This product has not been FDA cleared or approved.

HOW TO USE THIS TEST

Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19 should seek follow-up care with their physician or healthcare provider.

HOW ACCURATE IS THIS TEST?

The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Advin COVID-19 Antigen Test @Home, 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.

WHAT DOES AN INVALID TEST RESULT MEAN?

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 you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider. Healthcare providers should report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory in Vitro Diagnostics (LIVD) Test Code Mapping for CoV-19 Tests provided by the CDC.

The Advin COVID-19 Antigen Test @ Home is intended for non-prescription use-self and/or, as applicable, for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.

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