ADVIN BIOTECH

Home Use

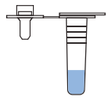
Advin COVID-19 Antigen Test @Home

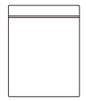
Quick Reference Guide

For use under Emergency Use Authorization only
For *in vitro* diagnostic use

KIT CONTENTS


Test Cassette


Extraction Buffer Tube


Disposal Bag


Disposable Nasal Swab


Quick Reference Guide


Timer (Not included)

Bring test kit to room temperature (59-86 °F / 15-30 °C). Read the instructions before starting the test procedure. Check expiration date printed on test. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit At-Home OTC COVID-19 Diagnostic Tests: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests

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

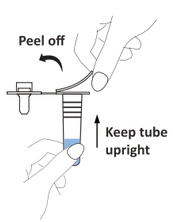
1

Wash or sanitize your hands and keep them dry before testing.

2

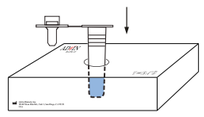
Peel off the aluminum foil on the extraction buffer tube.

⚠ Tube contains liquid.



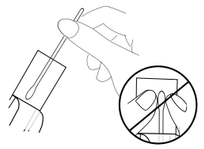
3

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



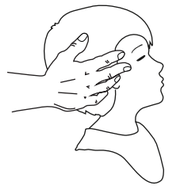
4

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



5

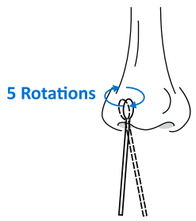
Prepare to collect sample. If collecting from a child, you may need another person to steady the child's head while swabbing.



6

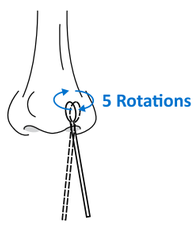
Gently insert swab ½ - ¾ inch into **first** nostril, or until you feel resistance.

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.



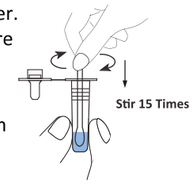
⚠ Swab both nostrils
DO NOT insert the swab any deeper if you feel resistance or pain.

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

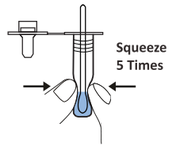
Take the tube out of the tube holder. Place the swab into the tube, ensure the swab tip is **in the liquid inside the tube**.

Stir the swab tip against the bottom and side of the tube for at least **15 times**.



9

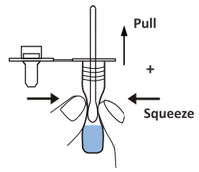
Squeeze the swab tip at least **5 times** from outside of the tube while the swab tip remains in the liquid.



10

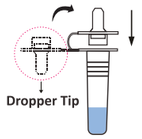
While **squeezing** the sides of the vial firmly, **pull** the swab out to remove excess liquid.

Dispose of the swab in provided disposal bag.



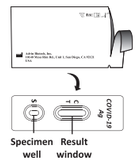
11

Firmly press the dropper tip on the extraction buffer tube.



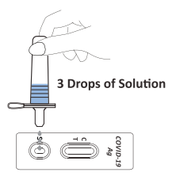
12

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

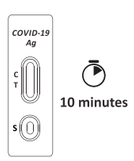
Add 3 drops of solution into the circular sample well, labeled as "S" on the test cassette.



⚠ 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 ¼" above sample well. Adding other than the recommended number of drops may result in inaccurate results.

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 the bag in household trash. Wash your hands or use hand sanitizer after completing all steps.

RESULT INTERPRETATION

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

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	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 new 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=substack&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.

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- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Intended Use

The Advin 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 (nares) swab samples from individuals aged 14 years or older or with adult-collected anterior nasal (nares) 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 three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.
The Advin COVID-19 Antigen Test @ Home does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. 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 as additional testing may be necessary.
All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. 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 measures such as isolating from others and wearing masks. Negative result 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.
Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.
Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will 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 SARS-CoV-2 Tests provided by the CDC.
The Advin COVID-19 Antigen Test @ Home is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.
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, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Warning, Precautions and Safety Information

- 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 SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five 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 symptoms for longer than 7 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 age 14 years and older. Children age 2 to 14 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit "At-Home OTC COVID-19 Diagnostic Tests": https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes. However, exposure to humidity may decrease the stability of the test. The test should be performed immediately after removing it from the pouch.
- Do not read test results before 10 minutes or after 30 minutes. Results read before 10 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- If you suspect the presence of blood on the swab, discard the swab, make sure you are not bleeding, and repeat the test with a fresh one.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- The test is intended to be performed immediately or shortly after obtaining the nasal swab specimen. Do not test the nasal swab specimens more than 1 hour after collecting the specimen on the swab.
- Wash hands thoroughly or use hand sanitizer after handling.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water.

If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222

Chemical Name	GHS Code for each Ingredient	Concentration
Triton X-100	• Harmful if swallowed. (H302) • Causes skin irritation. (H315) • Causes serious eye damage. (H318) • Very toxic to aquatic life with long lasting effects. (H410)	0.5%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19
- For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

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 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between April 2022 to May 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 the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, 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. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

Frequently Asked Questions (FAQ)

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 Result Interpretation sections for more information).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

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.

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 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 (IFU), available at http://www.advinbio.com.

WHAT IF I HAVE A POSITIVE TEST RESULT?
A positive 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 antigens 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 with 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 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.

Index of Symbols

	Consult Instructions for Use	Σ	Tests per kit	2	Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		

Version: 03
Part # IN36403
Effective date: 01/01/2025

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