ASSURE-100

Rapid COVID-19 Home Test

For use under Emergency Use Authorization (EUA) only. Carefully read instructions before performing test.

Failure to follow the instructions may result in inaccurate test results.

An anterior nasal swab can be self-collected by an individual age 14 years and older. Children ages 2 to 13 years should be tested by an adult.

In vitro diagnostic use only.

A. PREPARE FOR TEST

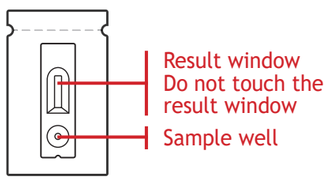
1. **Wash** or **sanitize** your hands. Make sure they are dry before starting the test.

2. Check your kit contents. Use only 1 of each of the following for each test.
   Check expiration date on the test cassette pouch.

1 Swab | 1 Cassette in Packaging | 1 Solution Vial

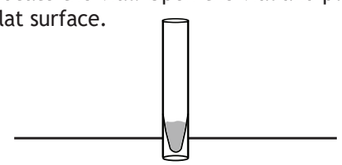
Timer (not included)

3. When you are ready to proceed with the test, open the foil pouch of the cassette. Locate the circular sample well.



Note: Testing should commence immediately after opening the sealed pouch.

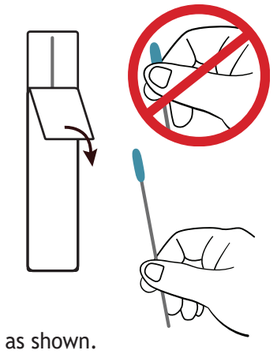
4. Locate the vial. Open the vial and place on flat surface.



B. COLLECT NASAL SAMPLE

5. Open the swab packaging at the stick end, not the swab end.

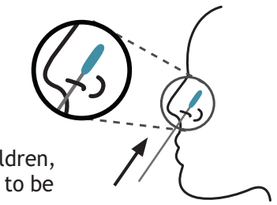
   Do not touch the swab tip.



6. **Swab** both nostrils as shown.

Gently **insert the entire soft tip** of the swab into a nostril (usually 1/2-3/4 of an inch).

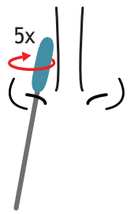
a. Insert up to 3/4 of an inch.



You do not need to go deeper. With young children, the swab may not need to be inserted so far.

Using medium pressure, rub the swab against all of the inside walls of your nostril.

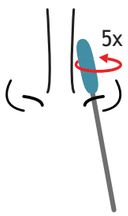
b. At least 5 big circles.



Make at least **5 big circles**, taking at least **15 seconds** per nostril. Do not just spin the swab.

Using the same swab, **repeat** step 6 in the second nostril.

c. At least 5 big circles.



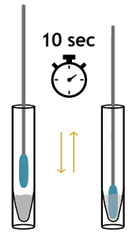
STOP

Check: Did you swab both nostrils?

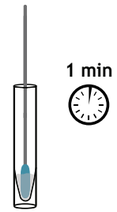
A false negative may occur if the nasal swab is not properly collected.

C. TEST PROCEDURE

7. After swabbing each nostril, immediately **place** swab into the vial and slowly move up and down for 10 seconds.

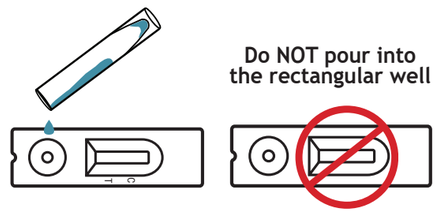


8. Push swab all the way to the bottom of the vial and leave for 1 minute. Following this, dispose of the swab.



9. Place test cassette with the sample well facing up on a flat level surface and **CAREFULLY** pour **ALL** of the liquid content **GENTLY** into sample well to avoid spilling.

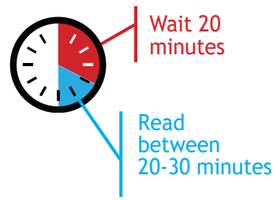
   It is normal for a minimal amount of the liquid to remain in the bottom of the vial.



10. Start your timer for **20 minutes**.

Read the result at **20 minutes**.

Do not read the result *before* 20 minutes or *after* 30 minutes.



Note: A false negative or false positive result may occur if the test result is read before 20 minutes or after 30 minutes.

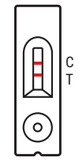
D. TEST INTERPRETATION

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 pink/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.

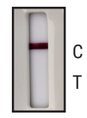
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely that you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

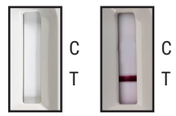
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **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.

Invalid



If the Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

Report your test result(s) at 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.

ASSURE-100 Rapid COVID-19 Home Test Instructions for Use

For Use Under an Emergency Use Authorization (EUA) Only.
For In Vitro Diagnostic Use (IVD) Only.

INTENDED USE

The ASSURE-100 Rapid COVID-19 Home Test is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

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 adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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 ASSURE-100 Rapid COVID-19 Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal swab specimens 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 agent detected may not be the definite cause of disease. Individuals who test positive with the ASSURE-100 Rapid COVID-19 Home Test 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 of patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative 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.

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. 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 CDC.

The ASSURE-100 Rapid COVID-19 Home Test 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 ASSURE-100 Rapid COVID-19 Home Test 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.

FREQUENTLY ASKED QUESTIONS (FAQ)

What are the known and potential risks and benefits of this test?

Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (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 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-us-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 ASSURE-100 Rapid COVID-19 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 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 www.assure-test.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.

WARNINGS, 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 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 13 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.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- Do not read test results before 20 minutes or after 30 minutes. Results read before 20 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- 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.

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

Chemical Name	Harms (GHS) code for each ingredient	Concentration
Triton X-100	Harmful if swallowed (H302) Cause skin irritation (H315) Causes serious eye damage (H318)	1%
Sodium Azide	Harmful if swallowed (H300) Cause skin irritation (H310), Causes serious eye irritation (H319) Aquatic hazard (H400, H410)	0.09%
EDTA-disodium salt	Causes mild skin irritation (H316), Causes serious eye irritation (H319)	1.5%
Sodium Chloride	Causes serious eye irritation (H319)	1.5%

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

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 March 2022 and May 2022. The clinical performance has not been established in 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.

STABILITY AND STORAGE

Store the kit at room temperature 65-86°F (18-30°C) and protect from direct sunlight. Do not use past the expiration date. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

Manufactured for Oceanit Foundry, LLC
828 Fort Street Mall, Suite 600
Honolulu, HI 96816, USA

Made in S. Korea

Date of last revision: 12/22/22

Simple. Fast. Accurate.

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ASSURE-100
Rapid COVID-19 Home Test

Developed in Hawaii

2°C-30°C 36°F-86°F 1 2 IVD REF 531-101

1 Test

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For Emergency Use
Authorization only.

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1 Test

1 Test

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BORE DA BIOTECH

ASSURE-100
Rapid COVID-19 Home Test

The ASSURE-100 Rapid COVID-19 Home Test is a lateral flow immunoassay intended for the detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swabs from those 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 those 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.

- For Emergency Use Authorization (EUA) only.
- For in vitro diagnostic use.
- For use in ages two (2) years and up.
- 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 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.
- 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.
- This test does NOT determine if you had COVID-19 in the past or if you have immunity.
- For up-to-date test kit expiration dating please visit: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list

BOX CONTENTS:

1 Test Cassette
1 Nasal Swab
1 Solution Vial
1 Instructions for Use

Simple. Fast. Accurate.

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ASSURE-100
Rapid COVID-19 Home Test

Developed in Hawaii

2°C–30°C 36°F–86°F 2 IVD 531-102

ASSURE-100
Rapid COVID-19 Home Test

2 Tests

For Emergency Use Authorization only.

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531-102
IVD
2
36°F–86°F
2°C–30°C

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2 Tests

2 Tests

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- This test does NOT determine if you had COVID-19 in the past or if you have immunity.
- For up-to-date test kit expiration dating please visit: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list

BOX CONTENTS:

2 Test Cassettes
2 Nasal Swabs
2 Solution Vials
1 Instructions for Use

Developed in Hawaii

25 Tests

2°C – 30°C 36°F – 86°F 25 IVD REF 531-125

ASSURE-100
Rapid COVID-19 Home Test

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ASSURE-100
Rapid COVID-19 Home Test

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ASSURE-100
Rapid COVID-19 Home Test

2°C – 30°C 36°F – 86°F 25 IVD REF 531-125

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BOX CONTENTS:

25 Test Cassettes
25 Nasal Swabs
25 Solution Vials
1 Instructions for Use

REF 531-125

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