Nano-Check™ COVID-19 Antigen At-Home Test Quick Reference Instruction

Catalog No. MD-8150
For Use Under an Emergency Use Authorization(EUA) Only
For *In Vitro* Diagnostic Use, For Use with Kit provided Swabs

IMPORTANT! How To Use This Test

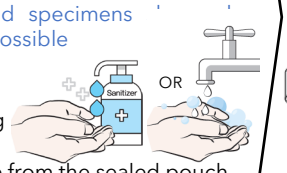
- *Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours 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.*

Scan the QR code to watch and follow "Nano-Check COVID-19 Antigen At-Home Test" instruction video on smart phone.

Each step has a corresponding instructional video on the website. Watch the video and perform the test according to the instructions

Note: Freshly collected specimens processed as soon as possible

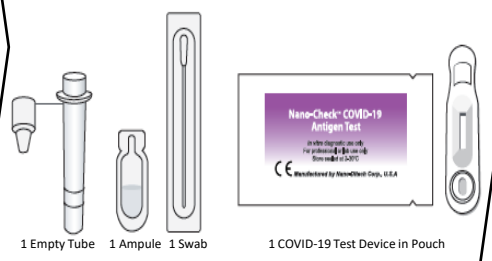
Wash hands with soap and water or use hand sanitizer before starting the test.



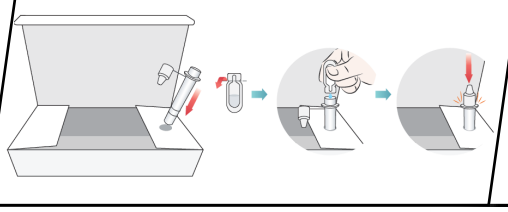
Remove the test device from the sealed pouch immediately before use. Conduct all testing on a level surface

1 Prepare Materials

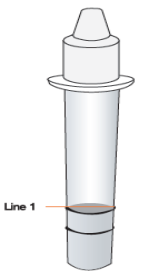
Open the package, take out the COVID-19 Test device in pouch, empty tube, ampule, and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Device.



Please look carefully, there are two lines on the empty tube. Insert the empty tube through the circle hole on the side flap of kit box to form a tube holder. Flip over the TOP part of the ampule cap, then squeeze the ampule completely into the empty tube. Close the tube tightly with the dropper tip.



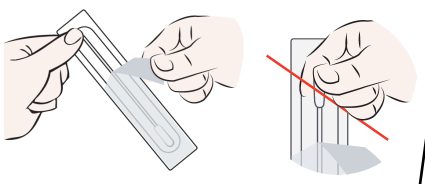
Please confirm that the liquid level is at or above line 1, then go to Step 2 Collect Sample.



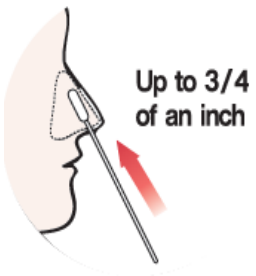
Note:
It is acceptable if the liquid level is above the line 1. However, please do not proceed with this test, if the liquid level is below the line1, as this may result in false or invalid results.

2 Collect Sample

A. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use.

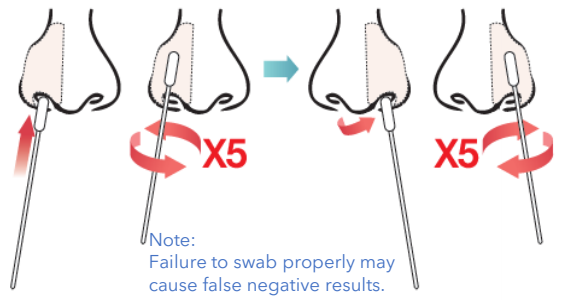


B. Gently insert the entire absorbent tip of the swab (about 1 /2 to 3/4 of an inch) into your nostril



Note:
With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person to hold the child's head while swabbing.

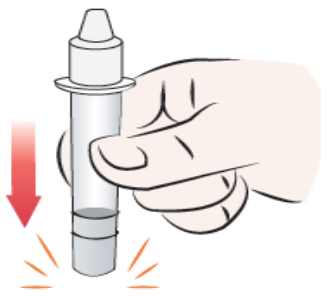
C. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 5 times (Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the swab). Using the same swab, repeat the same sample collection procedure for the other nostril. Be sure to brush **BOTH** nostrils with the **SAME SWAB**.



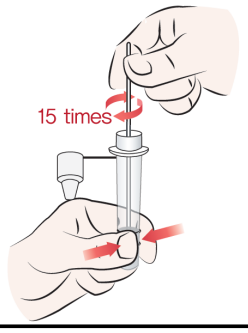
Note:
Failure to swab properly may cause false negative results.

3 Process Sample

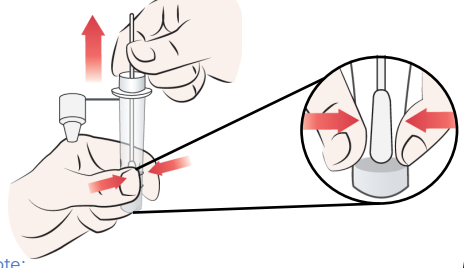
A. Tap the tube vertically on the table and remove the dropper tip to open the tube.



B. Insert the swab into the tube until the swab head touches the bottom of the tube. Hold the swab head at the bottom of the tube tightly by squeezing the tube. Then stir the swab at least 15 times.

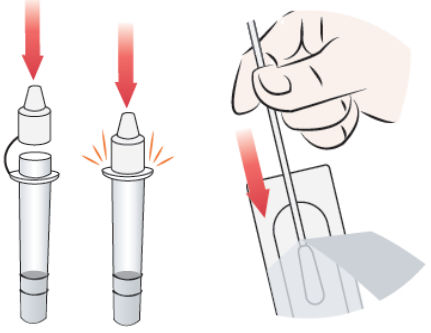


C. Squeeze the sides of the tube to express as much liquid as possible from the swab head, and then remove the swab.



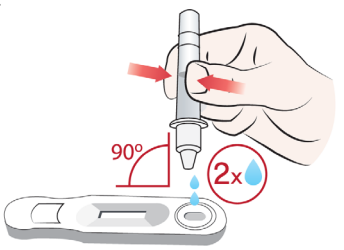
Note:
If you don't squeeze the swab head, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

D. Firmly close the dropper tip, put the swab back into the package. Safely dispose of the swab and the package.



4 Add Sample

Hold the tube vertically to dispense the sample. Add 2 drops of sample to the Sample loading hole of the COVID-19 Test device.



Note: A false negative or invalid result may occur if too little solution is added to the test device.

5 Wait 15 Minutes

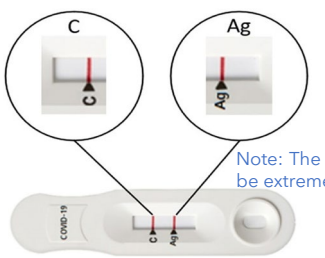
Wait 15 minutes after adding sample to the Sample loading hole and read the results at 15 minutes visually.

Note:
Do NOT interpret your test result until after your 15-min timer has completed, as the Ag line may take as long as 15 minutes to appear.

6 Read Result

Results should not be read after 30 minutes (Result shown at 2x magnification).

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.



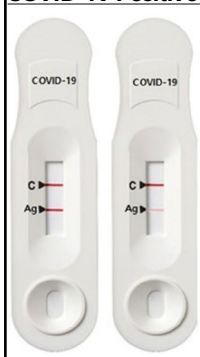
7 Test Result Interpretation

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

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 (+) Result

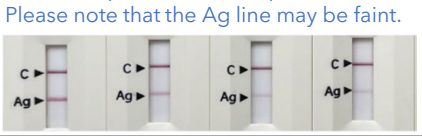


If the Control (C) line and the Test (Ag) line are visible, the test is positive. Any faint visible colored Test (Ag) line with the control line (C) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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).

Below are photos of actual positive tests.
Please note that the Ag line may be faint.



COVID-19 Negative (-) Result

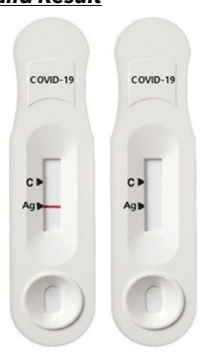
If the Control (C) line is visible, but the Test (Ag) line is not visible, the test is negative.

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

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does 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 the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

Invalid Result



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

Invalid result means that the test did not function correctly. **You will need to retest with a fresh sample, new ampule, and new test device.**

If upon retesting, the test result is still invalid, contact our technical support

8 Dispose the test kit

After test is completed, dispose the kit components in trash and wash your hands.

9 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

Manufactured for Nano-Ditech Corp.
259 Prospect Plains Road, Building K. Cranbury, NJ 08512, USA
1-855-297-7877 https://www.nanoditech.com/
P/N EP-3438-QR0 (May 2023)
Cat. No. ND-MD8150

NANO-DITECH CORPORATION

Nano-Check™ COVID-19 Antigen At-Home Test Quick Reference Instruction

Catalog No. MD-8150

The Nano-Check™ COVID-19 Antigen At-Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved. Please read this instruction for use before using the test. For use with direct anterior nasal swab specimens.

INTENDED USE

The Nano-Check™ COVID-19 Antigen At-Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen 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 adult collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 6 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 Nano-Check™ COVID-19 Antigen At-Home Test does not differentiate between SARS-CoV or SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) 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 definitive cause of disease. Individuals who test positive with Nano-Check™ COVID-19 Antigen At-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 or 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 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 CDC.

The Nano-Check™ COVID-19 Antigen At-Home Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The Nano-Check™ COVID-19 Antigen At-Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

FREQUENTLY ASKED QUESTIONS

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 Nano-Check™ COVID-19 Antigen At-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 https://www.nanoditech.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

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.**
- An anterior nasal (nares) swab sample can be self-collected by an individual age 14 years and older. Children aged 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 touch the swab tip.
- Once opened, the test card should be used within 90 minutes.
- **Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false negative, false positive, or invalid result**.
- Ensure that there is sufficient lighting for testing and interpretation.
- When collecting an anterior nasal (nares) swab sample, only use the swab provided in the kit.
- 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.
- If you have had symptoms longer than 6 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Freshly collected specimens should be processed as soon as possible.
- This product is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Testing should be performed in an area with good lighting and room temperature condition.
- Dispose of all materials in household waste.
- Wash hands thoroughly or use hand sanitizer before and after the test.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result. Make sure to swirl and plunge the swab up and down in extraction buffer while squeezing the sides of the tube for 15 times; squeezing the swab head at least once or more in the reagent tube during the swab removal procedure. Insufficient swirling or squeezing of the swab head may produce false negative results.
- **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	Harms (GHS Code) for each ingredient	Concentration
Gentamicin	Skin sensitization (H317)	4%
Sodium Azide	Acute Tox. 2 (Oral), H300, Acute Tox. 1 (Dermal), H310	0.09%

- 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

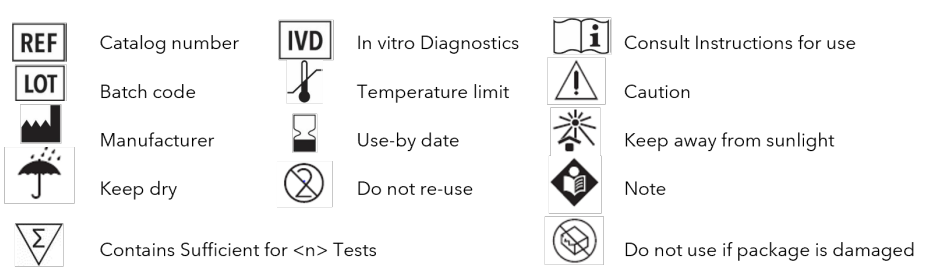
LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between June 2022 and July 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.
- 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.
- 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 the individual likely have COVID-19.
- These test results are shown as lines of color. Because these lines can be very faint, users with conditions affecting their vision - such as far-sightedness, glaucoma, or color blindness - are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- False negative results may occur in individuals who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin. There was no interference up to 3,500 ng/mL of biotin in the samples.

STORAGE CONDITIONS

Store the Nano-Check™ COVID-19 Antigen At-Home Test between 36-86°F (2-30°C) in a place out of direct sunlight and out of reach of children. Reagents and devices must be used at room temperature 65-86 °F (18-30 °C) before use. The unsealed cassette may be used for 1.5 hours. It is recommended to use the test kit immediately after opening. The expiration date assigned at manufacturing is on the outer package box. For information about current expiration dates for Nano-Check™ COVID-19 Antigen At-Home Test, visit At-Home OTC COVID-19 Diagnostic Tests.

Index of Symbols



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C:45 M:80 Y:0 K:0 Pantone: 513 C

C:20 M:40 Y:0 K:0 Pantone: 522 C

C:0 M:0 Y:100 K:0 Pantone: Proces Yellow C

C:0 M:0 Y:0 K:100

2 TESTS

Nano-Check™ COVID-19

Antigen At-Home Test

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At-Home Result in 15 Mins

2 x COVID-19 Test Device | 2 x Ampule | 2 x Empty Tube | 2 x Swab | 1 x Quick Reference Instructions

*Not Provided: Timer

EASY A Simple Nasal Swab

FAST 15 Results in 15 Minutes

FDA Emergency Use Authorization

2+ years Suitable for ages

Scan the QR code to watch and follow the "Nano-Check™ COVID-19 Antigen At-Home Test" instruction video on smart phone.
For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests
For Emergency Use Authorization (EUA) only
For in vitro diagnostic use
In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA

The Nano-Check™ COVID-19 Antigen At-Home Test is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen 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 adult collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 6 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.

✔ DO USE	⊘ DO NOT USE
✔ As an aid in the diagnosis of COVID-19	⊘ On anyone under 2 years of age
✔ If you are concerned that you have been exposed to COVID-19	⊘ If you are prone to nose bleeds
	⊘ If you have had a facial or head injury/surgery in the last 6 months

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.

(01)20895160002780

(2D-Data Matrix) GTIN(01): 00895160002780
Lot No.(10): HTxxxx
Mfg date(11): yymmdd
Use by(17): yymmdd

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