**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

**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 should be tested according to the instructions on the website. Watch the video and perform the test according to the instructions on the website.

**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.

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

D. Firmly close the dropper tip, put the swab and the package.

**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.

**Note:** With children, the maximum depth of insertion into the nostril may be less than 1/4 of an inch, and you may need to have a second person to hold the child's head while swabbing.

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 Collect Sample.

**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. 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 specimens 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.

D. Firmly close the dropper tip, put the swab and the package.

**Read Result**

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

**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).

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

**Test Result Interpretation**

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

<table>
<thead>
<tr>
<th>Status on First Day of Testing</th>
<th>First Result Day 1</th>
<th>Second Result Day 2</th>
<th>Third Result Day 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Symptoms</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Without Symptoms</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Positive for COVID-19

Negative for COVID-19

N/A

**Note:** If too little solution is added to the test device.

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) will 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 your 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 tests 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.

**Dispose the test kit**

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

**Report your test result(s) at Makemytestcount.org**—a 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
P/N EP-3438-QR0 (May 2023)
Cat. No. ND-MD8150

**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.
The Nano-Check™ COVID-19 Antigen At-Home Test is intended for non-prescription self-use and/or as an applicable at-home 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 (false negative or false positive test results).

Potential benefits include:
• 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/coronavirus-sars-cov-2-testing/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 materials 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, the presence of viral antigens does not always mean the virus is present in the sample.

HOW ACCURATE IS THIS TEST?

Clinical studies have shown that antigen tests are more accurate than molecular tests when 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 go here: https://www.cdc.gov/coronavirus/2019-ncov/lab-testing-laboratories/index.html

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. For repeat testing, if you test negative a second time, you should test at least twice more 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 must still self-isolate. 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 was the method not 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.

WARNING, PRECAUTIONS, AND SAFETY INFORMATION

• Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
• The Nano-Check COVID-19 Antigen At-Home Test was not cleared or approved by the Food and Drug Administration’s 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. § 360bb-b(1)(f), unless the declaration is terminated, or is revised sooner.
• Serial testing should be performed in individuals with negative results at least twice over three days (within 48 hours between tests) for asymptomatic individuals and three times over five days (with at least 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.
• An anterior nasal (nasal) swab sample can be self-collected by an individual aged 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 re-use test card after 90 minutes. Results read before 90 minutes may lead to a false negative or false positive result.
• Ensure that there is sufficient lighting for testing and interpretation of results.
• When collecting an anterior nasal (nasal) 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 antigen diagnostic test kits, visit The FDA's website.
• 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 conditions.
• 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 nullify the test result. Make sure to thrash 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. Inefficient 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 face, eyes, nose, or mouth. 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.poisontips.org or 1-800-222-1222

LIMTATIONS

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. Test 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 a 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 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, the presence of the virus that causes COVID-19 has 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 nearsightedness, glaucoma, or color blindness - are encouraged to seek assistance to interpret results accurately (e.g., using glasses, additional light source, or another person).
• Results that indicate the test is invalid may be incorrectly collected or handled.
• 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 conditions.
• 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 nullify the test result. Make sure to thrash 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. Inefficient swirling or squeezing of the swab head may produce false negative results.
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STORAGE CONDITIONS

Store the Nano-Check™ COVID-19 Antigen At-Home Test between 36-86 °F (18-30 °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 within one hour of opening the test kit.

To avoid potential exposure to the virus, the following handling instructions should apply to you. Refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://www.nanochecktech.com.

Chemical Name | Harms (GHS Code) for each ingredient | Concentration
--- | --- | ---
Gentamicin | Skin sensitization (H317) | 4%
Sodium Azide | Acute Tox. 2 (D0l), H300, Acute Tox. 1 (Dermal), H310 | 0.09%

For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-sars-cov-2-testing/emergency-use-authorization
For the most up-to-date information on COVID-19, please visit: www.cdc.gov_COVID19

Cleaning and disinfection of surfaces and equipment used as the sole basis for treatment or patient management decisions, including infection control measures is required. Individuals should provide all results obtained with this product to their healthcare provider for public health surveillance, as required by law, 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.
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 (2D-Data Matrix)

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.

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.

GTIN(01): 00895160002780
Lot No.(10): HTxxxx
Mfg date(11): yymmdd
Use by(17): yymmdd

*Nots Included: Timer

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