EN

GENABIO

Quick Reference Instructions

GenaCheck® COVID-19 Rapid Self-Test

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal swab specimens.
For *in vitro* diagnostic use only
Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results. A full IFU with performance data can be found at https://www.genabio.com/COVID-19

Warnings and Precautions

Read all instructions carefully before performing the test. Failure to follow directions may produce inaccurate test results.
· Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.
· This test is for use in individuals with symptoms of respiratory infection that started within the last 5 days and serial (repeat) testing should be performed for initial negative results (see Interpretation of Results section). You may need to purchase additional tests to perform this serial (repeat) testing.
- This test is read visually. Individuals with impaired vision should ensure help in interpretation of their test results.
- Ensure that there is sufficient lighting for testing and interpretation.
- Do not use this test kit beyond its expiration date.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single use. Do not re-use.
- Do not use the test on children under 2 years of age.
- Wear a face mask or other face covering when collecting specimen from a child or another individual.
- Use of personal protection materials such as gloves is recommended. Change gloves between tests.
- The test should be performed immediately after removing from the pouch. Do not use the test cassette after it has been opened for one hour.
- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a nasal sample.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- In the event of spillage, ensure the spill is cleaned thoroughly using a suitable disinfectant.
- Do not ingest any kit components.
- Wash hands thoroughly before and after handling.
- Ensure that hands are completely dry if you used hand sanitizer prior to testing.
- Dispose of kit components and patient samples in household trash.

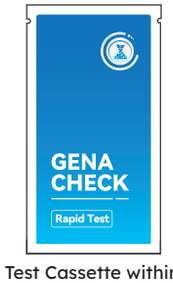
Keep the testing kit and kit components away from children and pets before and after use. The chemicals in the reagent solution may be hazardous to the skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org/ or call: 1-800-222-1222.

Chemical Name	GHS Code		Concentrations w/w%
Triton X-100	H302	Harmful if swallowed	0.10%
	H315	Causes skin irritation	
	H318	Causes serious eye damage	
NP40	H302	Harmful if swallowed	1%
	H315	Causes skin irritation	
	H318	Causes serious eye damage	
	H319	Causes serious eye irritation	

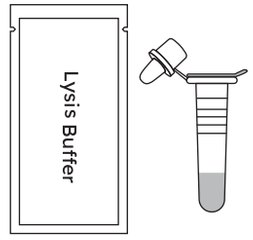
Test Procedure

1 Prepare Materials

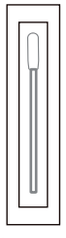
Open the package and take out the Test Cassette within a Foil Pouch, Lysis Buffer, Anterior Nasal Swab, and the Quick Reference Instructions.
If the product was refrigerated, allow the test components (Test Cassette within a Foil Pouch and Lysis Buffer) to equilibrate to room temperature [59-86°F(15-30°C)] before starting the Test Procedure.

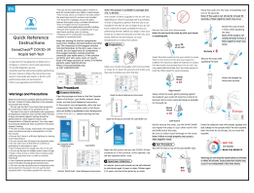


Test Cassette within a Foil Pouch



Lysis Buffer


Anterior Nasal Swab

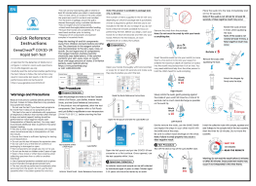

Quick Reference Instructions

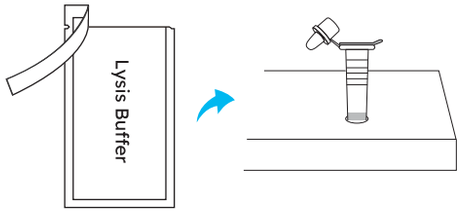
Note: This product is available in package sizes of 2, 4, 20 tests.

The number of items supplied in the kit will vary depending on which kit package size is purchased. A timer is required to perform the test and is not included in the test kit. Do not begin if you do not have at least 25 minutes available to focus on performing the test. Before you begin, wash your hands for at least 20 seconds and then dry your hands. Perform the test indoors, at room temperature on a clean, flat surface.

2 Preparation

Clean your hands thoroughly with hand sanitizer or soap for at least 20 seconds and make sure they are dry before you start the test.


Read the Quick Reference Instructions

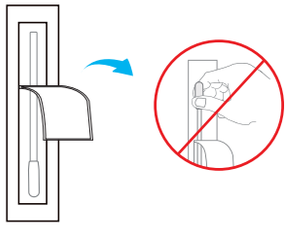


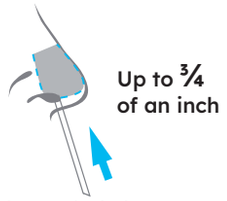
Open the foil pouch and take the Lysis Buffer out

Open the foil pouch and put the COVID-19 test cassette on a flat surface. Once opened, use the test cassette within 1 hour.

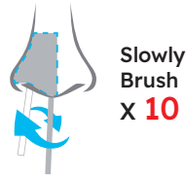
3 Specimen Collection

An anterior nasal swab sample can be self-collected by individuals aged 14 years or older. Children aged 2-13 years old should be tested by an adult.


Remove the swab from the package.
Note: Do not touch the swab tip with your hands or anything else.

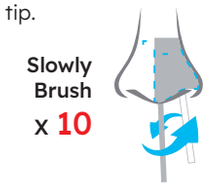


Insert the entire swab tip into your nostril (no more than ¾ of an inch (1.9 cm) into your nose). For children the maximum depth of insertion of swabs into the nostril may be less than ¾ of an inch. You may need additional help from the other person to hold the child's head for swab sampling.



Right Nostril

Slowly rotate the swab, gently pressing against the inside of your nostril 10 times for a total of 15 seconds. Get as much nasal discharge as possible on the swab tip.

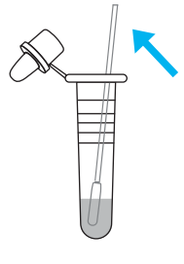


Left Nostril

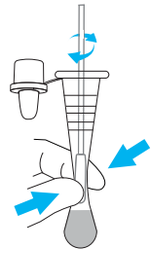
Gently remove the swab, use the SAME SWAB and repeat the steps in your other nostril with the SAME end of the swab.
Be sure to collect nasal drainage on the swab.
Note: Failure to swab properly may cause a false negative result.

4 Test Procedure

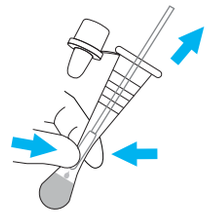
Tear off the seal on top of the Lysis Buffer tube.

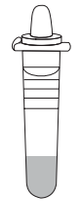


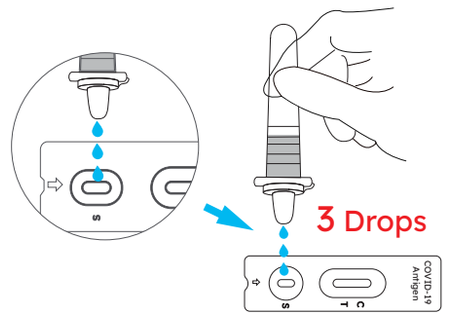
Place the swab into the tube immediately and stir for 30 seconds.
Note: If the swab is not stirred for at least 30 seconds, a false negative result may occur.



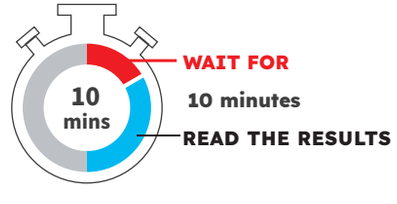
Rotate the swab at least 5 times while squeezing the tube.
Note: If the swab is not rotated at least 5 times, a false negative result may occur.


Remove the swab while squeezing the tube.


Attach the dropper tip firmly onto the tube.



Invert the collection tube with sample, squeeze and add **3 drops** to the sample well of the test cassette. Start the timer for 10 minutes. Do not move the cassette.



Warning: Do not read the result before 10 minutes or after 30 minutes. Inaccurate test results may occur if not interpreted in this time frame.

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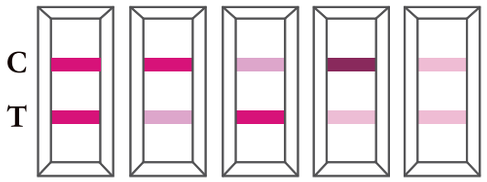
5 Result Interpretation

Positive



The test is Positive if:
There are two colored lines.
There are two colored lines, even if the color of the line next to the T is Faint. Look Closely!
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.

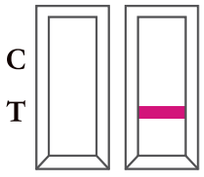
Note: Any faint visible pink color test (T) line should be interpreted as positive, when the Control (C) line is also present. The Test (T) line may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Control (C) line should not be compared to that of the Test (T) line for interpretation of the test result.

Negative

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

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. Repeat testing is needed to improve test accuracy. If your first test result is negative, you must repeat testing (serial testing) with another test between 24 and 48 hours later, however negative results do not rule out infection.

Invalid



If no line appears in the Control (C) area, the test results are invalid regardless of the presence or absence of a line in the Test (T) area. An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, re-test with a new swab and new test device.

For detailed instructions, please visit:
https://www.genabio.com/COVID-19

Intended Use

The GenaCheck COVID-19 Rapid Self-Test is a visually read lateral flow immunoassay test intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from March 2024 to October 2024 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspect.

Materials

Materials Provided

- Test Cassette within a Foil Pouch
- Lysis Buffer
- Anterior Nasal Swab
- Quick Reference Instructions

Materials Required but Not Provided

- Timer, Clock or Watch

Storage and Stability

Store the GenaCheck® COVID-19 Rapid Self-Test between [36-86°F(2-30°C)]. Ensure that all kit contents are at room temperature before use. Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date. The test cassette must remain in the sealed pouch until use.

Limitations

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2024 and October 2024 when the Omicron strain was most prevalent. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected..
- 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 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.
- A false-negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Excessive non-alcohol hand sanitizer lotion may interfere with test result if it contaminates the specimen.
- This test is read visually. Because test 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). This test has not been validated for use by those with color-impaired vision.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes or other conditions listed by CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are 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 additional follow-up may be needed.

Frequently Asked Questions

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?
A: 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.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: 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, like the GenaCheck COVID-19 Rapid Self-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.

Q: HOW ACCURATE IS THIS TEST?
A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causesCOVID-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.genabio.com/COVID-19

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?
A: 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.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?
A: 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 48hours since antigen tests are not as sensitive as molecular tests. If you have a negative result, it does not rule out SARS-CoV-2 infection. or infection with other pathogens; 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.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: 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.

Q: DO I HAVE TO REPORT MY RESULTS? (OPTIONAL)
A: Report your test result(s) at MakeMyTestCount.org - this voluntary and anonymous reporting helps public health teams understand COVD-19 spread in your area and across the country and informs public health decisions.
Securely report your GenaCheck® COVID-19 Rapid Self-Test result to public health teams by visiting:
https://makemytestcount.org/genabiodiagnostics

Healthcare Providers

Please visit **https://www.genabio.com/COVID-19** to obtain the complete instructions for use.

Index of Symbols

Do Not Re-use		Consult Quick Reference Instructions	
Test Per Kit		Store At 36-86°F(2-30°C)	
LOT	Batch Number	REF	Catalog #
UDI	Unique Device Identifier	IVD	In Vitro Diagnostic Medical Device
Expiration Date		Keep Away From Sunlight	
Keep Dry		Do Not Use If Package Is Damaged	

Assistance

For questions or comments please call Genabio Customer Service at 1-800-614-3365 (9:00 a.m. to 5:00 p.m. EST).

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Document No.: RA9-Q02800-00