EN

GENABIO®

Quick Reference Instructions

Genabio® COVID-19 Rapid Self-Test Kit

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal swab specimens. For self-testing use. For use under an Emergency Use Authorization (EUA) only. Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Genabio Diagnostics Inc. (via Email: info@genabio.com, or via Phone: 1-800-614-3365. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (Phone: 800.FDA.1088; Fax: 800.FDA.0178; http://www.fda.gov/medwatch).

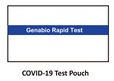
How to Use This Test

- 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, the 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If your 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.

Step by Step Instructions

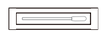
1 Prepare Materials

Open the package and take out the COVID-19 Test Pouch, Pre-filled Tube, Anterior Nasal Swab, and the Quick Reference Instructions.
If stored refrigerated, allow test components (COVID-19 Test Pouch and Pre-Filled Tube) to equilibrate to room temperature (15–30°C or 59-86°F) before starting the Test Procedure.



COVID-19 Test Pouch


Pre-Filled Tube

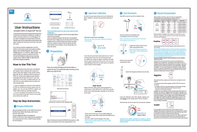

Anterior Nasal Swab


Quick Reference Instructions

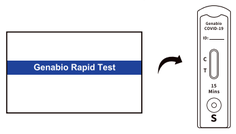
Note: This product comes in a 1-test, 2-test, 5-test, or 25-test configuration.
The number of items supplied in the kit will vary depending on which kit was purchased.
A timer is required to perform the test and is not included in the test kit. Do not begin if you do not have at least 25 minutes available 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 instructions.

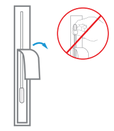
Check the kit's contents and the expiration date.

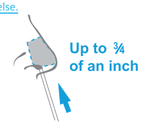


Open the foil pouch and put the COVID-19 test cassette on a flat surface. Once opened, use the test cassette within 1 hour.

3 Specimen Collection

An anterior nasal swab sample can be self-collected by adults. Children 2-13 years old should be tested by an adult.


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



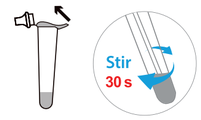
Insert the entire soft end of the swab into your nostril no more than ¾ of an inch (1.5 cm) into your nose.
For children the maximum depth of insertion of swabs into the nostril may be less than ¾ of an inch. You may need additional help from the other person to hold the child's head for swab sampling.

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 soft end of the swab.

Left Nostril
Gently remove the swab, use the SAME SWAB and repeat 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 collection tube.

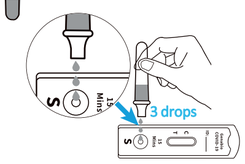


Place the swab into the collection tube immediately and stir for 30 seconds.
Note: If the swab is not stirred at least 30 seconds, a false negative result may occur.


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.

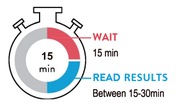

Remove the swab while squeezing the tube.


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 15 minutes. Do not move the cassette.



Warning: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test results may occur if not interpreted in this time frame.

5 Result Interpretation

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

Status on First Day of Testing	First Result Day 1	Second Result Day 3	ThirdResult 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.

Positive

Control (C) line and Test (T) line both appear as pink-colored lines in the show window.
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 an intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Contorl (C) line should not be compared to that of the Test (T) line for interpretation of the test result.
You do not need to perform repeat testing if you have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

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 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.
Report your test result(s) at Genabio.com/covid under "Report Test Results" – this voluntary reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

PANTONE 286C
C:100 M:88: Y:0 K:0

PANTONE 2995 C
C:100 M:0 Y:0 K:0

PANTONE 485 C
C:0 M:100 Y:100 K:0

PANTONE Black
C:0 M:0 Y:0 K:100

EN

GENABIO®

For Emergency Use Authorization (EUA) Only
For In Vitro Diagnostic Use

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

Intended Use

The Genabio®COVID-19 Rapid Self-Test Kit is a lateral flow immunoassay device 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. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The Genabio®COVID-19 Rapid Self-Test Kit 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 patient 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 the Genabio®COVID-19 Rapid Self-Test Kit 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 Genabio®COVID-19 Rapid Self-Test Kit 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 Genabio®COVID-19 Rapid Self-Test Kit 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.

Warning and Precaution

- 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.
- Read all instructions carefully before performing the test. Failure to follow directions may product inaccurate test results.
- **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.
- Do not touch swab tip.
- Testing should occur immediately after opening the pouch.
- To ensure correct results, you must follow the instructions for use
- Use only the contents provided in the test kit.
- Test components are single use. Do not re-use.
- 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.
- Do not use the test on children under 2 years of age.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and children aged 2 to 13 years of age should be tested by an adult.
- Wear a face mask or other face covering when collecting specimen from a child or another individual.
- False negative test results may occur if a specimen is incorrectly collected or handled.
- Do not read the test result before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Once opened, the test card should be used with 30 minutes.
- Keep 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 blow). 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.**
- 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 https://www.cdc.gov/COVID-19
- Ensure that there is sufficient lighting for testing and interpretation.

Chemical Name	GHS Code for applicable Ingredient	Concentrations W/W %
Triton X-100	Harmful if swallowed(H302) Cause skin irritation(H315) Cause serious eye damage(H318)	0.10%
ProClin*300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction(H317)	0.05%

Limitation

- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- There is a higher chance of false negative results with home use 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 you a negative result when you have 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 you likely have COVID-19.
- These test results are shown as lines of color. Because these lines can be very faint, users with vision impairment - such as far-sightedness or glaucoma - are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person with no vision impairment).
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2022 and June 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.

Frequently Asked Questions

Q: WHAT IS COVID-19?
A: COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 infection and by infected people without symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS OR BENEFITS THIS TEST?
A: Potential risks include:
•Possible discomfort during sample collection.
•Possible incorrect test results (see Result Interpretation Section)
Potential benefits include:
•The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
•The results of this test may help limit the spread of COVID-19 to your family and others in your community.

Q: WILL THIS TEST HURT?
A: No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

Q: WHAT IS SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19. If you do not have any symptoms, testing should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

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 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.genabio.com.

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. Your healthcare provider will work with you to determine how best to care for you based on your test result, medical history, and symptoms.

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 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.

Q:WHAT DOES AN INVALID TEST RESULT MEAN?
A: If no control line shows up on the test, the result is invalid (even if any test line shows up). 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 the test should be run again, using all new test components.

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 such as the Genabio®COVID-19 Rapid Self-Test Kit, 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: IS THERE OTHER INFORMATION AVAILABLE DESCRIBING THE PERFORMANCE OF THIS TEST?
A: Yes. Please see the Healthcare Provider Instructions for Use available at https://www.genabio.com for additional information. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

Important

Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

Healthcare Providers

Please visit https://www.genabio.com to obtain the complete instructions for use and fact sheet for healthcare providers.

Storage and Stability

Store the Genabio®COVID-19 Rapid Self-Test Kit 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.
For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests

Symbols

REF	Catalogue Number	IVD	In vitro diagnostic Use Only
LOT	Lot Number (Batch Code)		Tests Per Kit
	Use By (Expiration Date)		Manufacturer
	Temperature Limitations (Storage Temperature)	UDI	Unique Device Identifier
	One Time Use (Single Use Only)		Consult Quick Reference Instructions

The extraction buffer solution in the extraction buffer tube contains a hazardous ingredient as shown in above table. If the extraction buffer solution contacts the skin or eye, immediately wash with plenty of running water. In case the irritation persists, please seek medical advice at: https://www.poison.org/contact-us or 1-800-222-1222.

In the USA

1. This test is intended to be used as an aid to clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness.
2. In USA - This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other virus 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 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.

Manufactured for Genabio Diagnostics Inc.
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More Information:

Document No.: RA9–Q00300–00