EN

GENABIO

User Instructions

Genabio COVID-19 Rapid Self-Test Kit

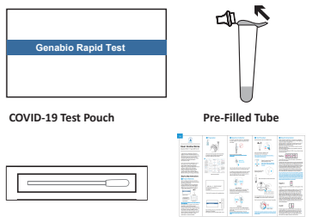
A rapid test for the detetion of SARS-CoV-2 atigens in anterior nasal swab specimens. For self-testing use. For use under an Emergency Use Authoriztion (EUA) only. Carefully read the instrutions before performing the test. Failure to follow the instrutions may result in inaccurate test results.

If you have any questions regarding the use of this product or if you want to report a test system problem, please contact Genabio Diagnotics 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).

Step by Step Instructions

1 Prepare Materials

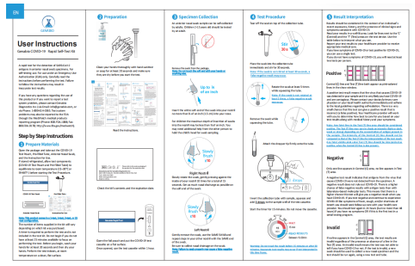
Open the package and take out the COVID-19 Test Pouch, Pre-filled Tube, Anterior Nasal Swab, and the Instruction for Use.
If stored refrigerated, allow test components (COVID-19 Test Pouch and Pre-Filled Tube) to equilibrate to room temperature (15–30°C or 59-86°F) before starting the Test Procedure.



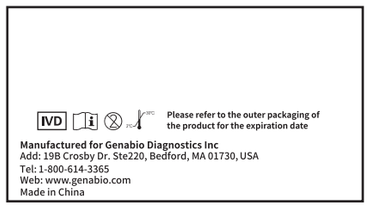
Note: This product comes in a 1-test, 2-test, 5-test, or 25 -test configuration.
The number of items supplied in the kit will vary depending on which kit was purchased.
A timer is required to perform the test and is not included in the test kit. Do not begin if you do not have at least 25 minutes available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

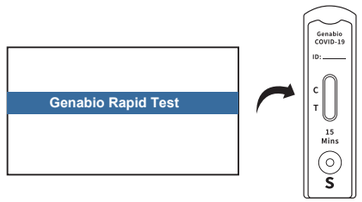
Clean your hands thoroughly with hand sanitizer or soap for at least 20 seconds and make sure they are dry before you start the test.



Read the instructions.



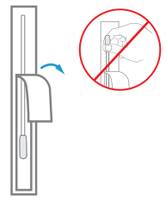
Check the kit's contents and the expirtion date.



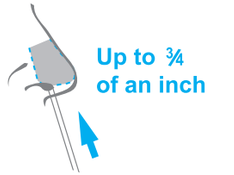
Open the foil pouch and put the COVID-19 test cassette on a flat surface.
Once opened, use the test cassette within 1 hour.

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.

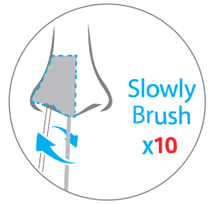


Remove the swab from the package.
Note: Do not touch the soft end with your hands or anything else.



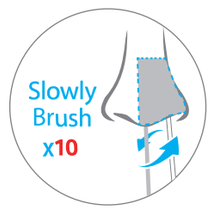
Insert the entire soft end of the swab into your nostril no more than ¾ of an inch (1.5 cm) into your nose.

For children the maximun 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.

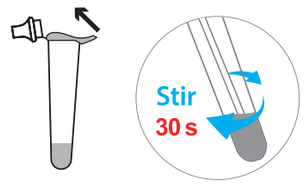


Left Nostril

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.

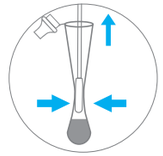
4 Test Procedure

Tear off the seal on top of the collection tube.



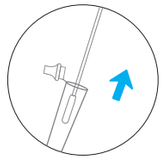
Place the swab into the collection tube immediately and stir for 30 seconds.

Note: If the swab is not stirred at least 30 seconds, a false negative result may occur.

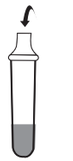


Rotate the swab at least 5 times while squeezing the tube.

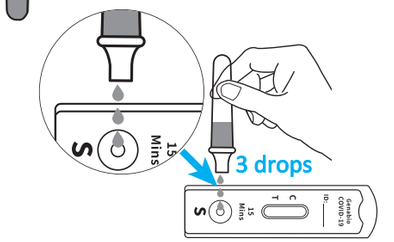
Note: If the swab is not rotated at least 5 times, a false negative result may occur.



Remove the swab while squeezing the tube.

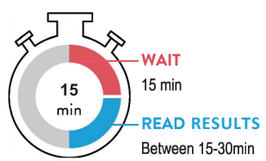


Attach the dropper tip firmly onto the tube.



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.

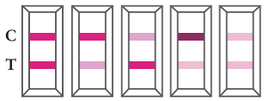


Warning: Do not read the result before 15 minutes or after 30 minutes. Inaccurate test results may occur if not interpreted in this time frame.

5 Result Interpretation

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.
Read your results in a well-lit area. Look for lines next to the 'C' (Control) and the 'T' (Test) areas on the test device. Use the table below to interpret what you see.
Report your test results to your healthcare provider to receive appropriate medical care.
If you have symptoms of COVID-19 or test positive for COVID-19, you can use a single test.
If you do not have symptoms of COVID-19, you will need at least two tests per person.

Positive



Control (C) line and Test (T) line both appear as pink-colored lines in the show window.

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.

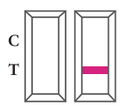
Note: Any faint line in the Test (T) line area should be considered positive. The Test (T) line may vary in shade an intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Control (C) line should not be compared to that of the Test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

Negative

Only one line appears in Control (C) area, no line appears in Test (T) area.

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected from the specimen. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough, and/or shortness of breath you should seek follow-up care with your health care provider. You should test again in 24 hours (but no more than 48 hours) if you have no symptoms OR if this is the first test in a serial testing program.

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, a new swab should be used to collect a new nasal specimen and the test should be run again, using a new test and tube.

EN

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

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

Intended Use

The Genabio COVID-19 Rapid Self-Test Kit is a rapid 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 2 years or older, with symptoms of COVID-19 within the first 7 days of symptom onset.

This test is also intended for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The Genabio COVID-19 Rapid Self-Test Kit does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen 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 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 definite 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.

Negative results should be treated as 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 decisions. 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as, an individual with close contact with COVID-19 or with suspected exposure to COVID- 19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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 from their healthcare provider. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for COVID-19 Tests provided by CDC.

The Genabio COVID-19 Rapid Self-Test Kit is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older.
The Genabio COVID-19 Rapid Self-Test Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

Warning and Precaution

- 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.
- 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 contact to the body occurs, flush with copious amount of water. If irritation persist, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.
- Do not use the test on children under 2 years of age.
- 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.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products (e.g., 1% bleach) may result in an incorrect test result.

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 POTENTIAL RISKS AND BENEFITS OF 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: Based on the interim results of a clinical study where the COVID-19 Antigen Self-Test was compared to an FDA authorized high sensitivity SARS-CoV-2 test, COVID-19 Antigen Self-Test correctly identified 91.89% of positive specimens and 100% of negative specimens.
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. Based on this information, negative results may require additional testing to confirm your result. Please talk to your healthcare provider to determine if you need additional testing.

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 found in your sample. If you do not have symptoms, you should test again in 24 to 48 hours. If you receive a second negative result 24 to 48 hours after your first negative result, then you are likely not infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the limit of detection. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. 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 COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular test. This means that there is a higher chance this test will give you 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 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

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. 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 **www.genabio.com** to obtain the complete instructions for use and fact sheet for healthcare.

Storage and Stability

Store the Genabio COVID-19 Rapid Self-Test Kit between 2-30 ℃ (36-86 °F). 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.

Symbols

REF	Catalogue number	IVD	In vitro diagnostic use only
LOT	Lot Number (Batch Code)	Σ	Tests Per Kit
	Use by (Expiration Date)		Manufacturer
	Temperature Limitations (Storage Temperature)		Date of Manufacture
	One Time Use (Single Use Only)		Consult Instructions for Use

Hazardous Ingredient for Reagent

Hazardous ingredients	CAS No.	GHS Code for applicable Ingredient	W/W %
Triton X-100	9036-19-5	Harmful if swallowed(H302) Cause skin irritation(H315) Cause serious eyedamage(H318)	0.1 %
ProClin®300	96118-96-6	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 %

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:

Manufactured in China