User 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: 1-800-614-1365). Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (Phone: 800-FDA-1188; 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.

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.

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 any other area.

Up to ¾ of an inch
Insert the entire soft end of the swab into your nostril no more than ¾ of an inch (1.7 cm) into your nose. For children the maximum depth of insertion of swab 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.

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.

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.

Insert 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.

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 likely that 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 invalid. The Test (T) line may vary in shade of intensity (light or dark, weak or strong) depending upon 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 invalid, 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 in 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 healthcare 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.
The Genabio COVID-19 Rapid Self-Test Kit does not differentiate individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 14 years or older.

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)(2)(C) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, unless the declaration is terminated, or authorization is revoked sooner.

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For more on EUA, please visit: https://www.fda.gov/medical-devices/emergency-authorization-
on-legal-regulatory-and-policy-framework/emergency-use-authorization

For the most up-to-date information on COVID-19, please visit: https://covid.cdc.gov

For Serial testing programs, addiitional confirmatory testing with a molecular test is recommended in individuals with negative rapid test results. Based on COVID-19 illness. Please talk to your healthcare provider to determine if you need additional testing.

A negative result does not rule out COVID-19 infection. It is possible for this test to be false negative if a specimen is incorrectly collected.

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 providers.

Storage and Stability

The Genabio COVID-19 Rapid Self-Test Kit between 2-30 °C (36-86 °F). If the contents are at a higher or lower 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 used.

Hazardous Ingredient for Regent

The extraction buffer solution in the extraction tube contains 1.0 N acetic acid, 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.poisong.org/contact-us or 1-800-222-1222.

In the USA

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More Information:

Manufacturer for Genabio Diagnostics Inc.

Add: 198 Crissy Dr. Sn222,Baoding,MA 01730,USA
Tel: 1-800-614-3365
Email: info@genabio.com

www.genabio.com

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More Information:
The Genabio COVID-19 Rapid Self-Test Kit is a lateral flow chromatographic immunoassay method intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or with other epidemiological reasons to suspect COVID-19.

For use under the Emergency Use Authorization (EUA) only.

For ages 2 through 13, an adult must collect and test the anterior nasal specimen.

This test does NOT determine if you had COVID-19 in the past or if you have immunity.

If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to purchase additional tests to perform serial (repeat) testing.

In vitro diagnostic medical device.
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Invitrodiagnostic medical device
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IVD (In vitro diagnostic medical device)