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.0883; Fax: 800.FDA.0783; 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, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
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• If your test is positive, then proteins from the virus should be identified in your sample. A positive test result indicates that the virus that causes COVID-19 was detected in your sample.

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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.
   Insert the entire soft end of the swab into your nostril no more than ¼ 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.

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 ¼ 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.

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 inserted at least 30 seconds, a false negative result may occur.

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

<table>
<thead>
<tr>
<th>Status on First Day</th>
<th>First Result</th>
<th>Second Result</th>
<th>Third Result</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web Symptoms</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td>No Line</td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td>Positive</td>
<td>Negative</td>
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<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
</tbody>
</table>

   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.

   Control (C) line 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 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 positive test 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 positive 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.

   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 test result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, test with a new swab and new test device.

   Reporter’s test results 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.
For Emergency Use Authorization (EUA) Only

This test has not been FDA cleared or approved but has been authorized for emergency use 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 aged 14 years and older. Children aged 2 to 13 years may 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 IVD 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:

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 and older or open.

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 date of this test, please refer to: https://www.fda.gov/covid-19-tests

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.

• If you have had symptoms longer than 7 days you should consider taking at least three times over five days with at least 48 hours between tests.

• Do not use the test kit beyond its expiration date.
• Do not use the test kit with expiration date.

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 coinfection with other viruses and should not be used as the sole basis for treatment or patient care decisions. False negative results may occur if a specimen is incorrectly collected or handled.

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 most broadly spread person-to-person, both by individuals with symptoms of COVID-19 (EUA) and by infected people who are asymptomatic. On the current knowledge, the incubation period is 1 to 14 days, ranging from 2 to 12 days. Clinical 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 EFFECTS OF THIS TEST?

A: Potential risks include:
• Possible discomfort during sample collection.
• Possible incorrect result due to reagent cross-contamination (see Reagent Interlaboratory Performance). Potential benefits include:
• The results, along with other information, can help you and your healthcare provider make 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: WHAT IF I HAVE A NEGATIVE TEST RESULT?

A: A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. However, you should continue to monitor your health and symptoms. If you have symptoms of COVID-19, you should consult your healthcare provider for medical advice about your positive result.

Q: WHAT IS SERIAL TESTING?

A: Serial testing is when one person tests themselves multiple times for 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 symptomatic at any time. This test does not provide all results with this product to their healthcare provider for public health reporting.

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 IS THE EUA?

A: An EUA is a declaration that the declaration that circumstances exist justifying the authorization of emergency use of IVD 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.

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 and older. This test is authorized for individuals with symptoms of COVID-19 from the first 7 days of symptoms to three times over five 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-2 variants of concern for the purposes of public health reporting.

These test results are shown as lines of color. Because these lines can be very faint, users with vision impairment - such as farsightedness 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 April 2022. The performance has not been established for all circulating variants but is anticipated to be reflective of the performance of the test for laboratory-based molecular tests.

The performance of the clinical evaluation 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.

• Use only the contents provided in the test kit.
• Test kit contents include:
  • Infant test swab
  • Test cassette
  • 1 test strip
  • User instruction manual

Warning and Precaution

• Do not use the test kit beyond its expiration date.
• Do not use the test kit with expiration date.

False negative test results may occur if a specimen is incorrectly collected or handled.

Serial testing should be performed in individuals with negative test results and should not be used as the sole basis for treatment or patient care decisions. False negative test results may occur if a specimen is incorrectly collected or handled.

How many times should individuals with asymptomatic COVID-19 symptoms test themselves in order to rule out SARS-CoV-2 infection; you may still be infected and may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

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 symptomatic at any time. This test does not provide all results with this product to their healthcare provider for public health reporting.

In the USA

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.

In 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 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.

Contact Information

Manufactured for Genabio Diagnostics Inc.
Add: 798 Cleveland Ave, Bedford, MA 01730 USA
Tel: 1-800-614-22-122
Email: info@genabio.com

More Information:

https://www.genabio.com/
The Genabio COVID-19 Rapid Self Test Kit is a lateral flow chromatographic immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. 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.

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

• For in vitro diagnostic use.
• For Emergency Use Authorization (EUA) only.
• For ages 2 through 13, an adult must collect and test the anterior nares specimen.
• This test does NOT determine if you had COVID-19 in the past or if you have immunity.
• For asymptomatic individuals, the test is for serial testing at least twice over three days with at least 48 hours between tests.
• For asymptomatic individuals, the test is for serial testing at least three times over five days with at least 48 hours between tests.
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DO USE
- As an aid in the diagnosis of COVID-19.
- If you are concerned that you have been exposed to COVID-19.

DO NOT USE
- On anyone under 2 years of age.
- If you are prone to nose bleeds.
- If you have had a facial or head injury/surgery in the last 6 months.
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