COVID-19 Antigen Home Test

Instructions For Use

For Emergency Use Authorization (EUA) Only.

In vitro diagnostic use only.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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(a)(3) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b(a)(3)(B)(i), unless the declaration is terminated or Authorization is revoked sooner.

For use with anterior nasal swab specimens.

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.

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.

Note: Check test components and confirm test is not expired prior to use. Use within 2 hours after opening the foil pouch (step 11).

For the most current expiration dates of this test, please refer to: http://www.fda.gov/covid-test

SPECIMEN COLLECTION

Children between 2-13 years of age should be tested by an adult.

COMPONENTS

SARS-CoV-2 Antigen Test Cassette
Sample Tube
Disposable Sterile Swab
Timer (not included)

TEST STEPS

1. Please wash and dry your hands thoroughly before the test.

2. Read the Instructions for use carefully.

3. Confirm the liquid level is at or above Line 1 in the sample tube. Then proceed to collecting the nasal swab sample.

   Note: If the liquid level is below Line 1 in the sample tube, DO NOT proceed with the test. The test result will not be accurate. If the sample tube liquid level is below Line 1, use a new kit.

4. Take the swab out of the package and do not touch the sampling end.

   Note: Do not touch the swab tip with your fingers.

5. Carefully insert the swab 1/2 to 3/4 of an inch into the nostril. Under moderate pressure, swab the nostril at least 5 times for at least 15 seconds total.

   Note: For young children, the swab may not need to be inserted so far. Stop pushing the swab in if you feel any kind of resistance.

6. Repeat sampling with the same swab in the other nostril.

   Note: Failure to swab property may cause false negative results.

7. Tap the sample tube vertically several times on the table. Open the larger cap on the sample tube.

8. Insert the swab and soak in the liquid for at least 15 seconds, stir the swab several times, and squeeze the tube walls onto the tip 3 times.

9. Pinch tube walls while removing swab to squeeze excess liquid from tip.

10. Open the foil pouch and place the test cassette on a flat surface.

11. Open the small cap at the front end of the sample tube, and place exactly 4 drops into the sample well (S) of the test cassette.

   Note: False negative or invalid results may occur if too little sample is added. Do not touch or move the test cassette during this time.

12. Start a timer and read the result at 15 minutes. Do not read test before 15 minutes, even if the Control (C) line appears sooner. Do not read after 30 minutes.

   Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

   Test again in 48 hours if the individual has symptoms on the first day of testing.

   Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

13. Throw away all used test kit components in the trash.

TEST INTERPRETATION

Note: Test results for COVID-19 are reported within 15 minutes. Do not read test before 15 minutes, even if the Control (C) line appears sooner. Do not read after 30 minutes.

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

COVID-19 Positive (+): As shown in Fig. 1, if both the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red/purple test (T) line with the control line (C) should be read as positive.

Note: 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 you are very likely to have COVID-19 and are contagious. Make contact your doctor/pediatrician 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 which is incorrect (a false positive).

COVID-19 Negative (-): As shown in Fig. 2, if the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

Note: To increase the chances that the negative result for COVID-19 is accurate, you should test again in 48 hours if the individual has symptoms on the first day of testing.

Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative test result indicates that you most likely have COVID-19. It was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of incorrect negative results with antigen tests compared to laboratory-based tests such as RT-PCR tests. If the test is negative but COVID-19-like symptoms or fever, cough, and/or shortness of breath persist, follow up testing for SARS-CoV-2 with a molecular test for other respiratory viruses is recommended. If applicable, seek follow-up care with the primary health care provider.

Note: If the Control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

For use with anterior nasal swab specimens.

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The Hotgen™ COVID-19 Antigen Home Test is a lateral flow immunosay 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 specimens from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged two years or older.

The Hotgen™ COVID-19 Antigen Home Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or coinfection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the Hotgen™ COVID-19 Antigen Home Test 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.

This test is intended for use by an individual aged two years or older. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab specimens from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged two years or older.

Store Hotgen™ COVID-19 Antigen Home Test in a dry place between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. It is stable before the expiration date marked on the packaging.

INDEX OF SYMBOLS

LIMITATIONS

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.

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 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.

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 your both 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.

Incorrect test results may occur if a specimen is incorrectly collected or handled.
COVID-19 Antigen Home Test

At-home Use  Results in 15 Mins

For Emergency Use Authorization (EUA) only. The rapid test device and all its components are approved by the FDA to be used in EUA. The product is being utilized to detect the presence of SARS-CoV-2, which is the causative agent of COVID-19. The manufacturer is responsible for monitoring the performance of the device. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit


HOW THIS TEST WORKS

The test uses a rapid antigen test that works with the COVID-19 test kit box and needs to be charged or a minute approach. If the sample does not contain SARS-CoV-2 RNA, it will be treated as a negative result.

WARNINGS

Do not use in anyone older than 3 years of age.

CONTENTS

OATC COVID-19 Test Cassette 1 test

 sample tube 2 ml or 3 ml

 Disposable Swab 1 pc

Made in China

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Tel +86 966-2919  Email cs@hotgen.info Website: www.hotgen.info

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COVID-19 Antigen Home Test

At-home Use  Results in 15 Mins

For Emergency Use Authorization (EUA) only. For in vitro diagnostic use. In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.

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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.

http://www.fda.gov/covid-tests

HOW THIS TEST WORKS

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WARNINGS

1. Discard the Swab and Test Cassette
2. Sample Tube
3. Sample Tube Cap

Do not connect Strips-Cov-2 virus no red test line (T) appears

Immediately if dehydration or exposure to air for at least 30 minutes

Do not use on anyone who is prone to anaphylaxis or has had severe reactions

Beijing Hotgen Biotech Co., Ltd.
COVID-19 Antigen Home Test

- At-home Use
- Results in 15 Mins

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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 566(B)(3) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbd-3(b)(3), unless the declaration is terminated or authorization is rescinded sooner.

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.

http://www.fda.gov/covid-tests

HOW THIS TEST WORKS
COVID-19 Antigen Home Test

At-home Use  Results in 15 Mins

This product has been authorized only for the detection of proteins from SARS-CoV-2 in respiratory specimens to aid in the diagnosis of COVID-19 under section 564.1 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. It will be a class I medical device for the determination of SARS-CoV-2 RNA in respiratory specimens.

Determined a negative result requires multiple tests. You may need to purchase additional tests to perform several tests. This test is not likely to give you a false-negative result when you have COVID-19 or a 99.9% chance of being positive for SARS-CoV-2 RNA.

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HOW THIS TEST WORKS

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WARNINGS