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(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.

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 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.

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

HOW TO USE THIS TEST

1. Read the Instructions for use carefully.
2. Check kit components and confirm test is not expired prior to use.
3. Use within 2 hours after opening the foil pouch (step 1).
4. 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.
6. Note: For young children, the swab may not need to be inserted so far. Stop pushing the swab if you feel any kind of resistance.
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 swab tip 3 times.
9. Pinch tube walls while removing swab to squeeze excess liquid from tip.
10. Squeeze
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.
12. 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.

COMPONENTS

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

SPECIMEN COLLECTION

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

TEST STEPS

1. Please wash and dry your hands thoroughly before the test.
2. Read the Instructions for use carefully.
3. Note: Confirm liquid level is at or above Line 1 in the sample tube. Then proceed to collecting the nasal swab sample.
4. Take the swab out of the package and do not touch the sampling end.
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.
6. Note: For young children, the swab may not need to be inserted so far. Stop pushing the swab if you feel any kind of resistance.
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 swab tip 3 times.
9. Pinch tube walls while removing swab to squeeze excess liquid from tip.
10. Close the sample tube with the larger tube cap.
11. Open the foil pouch and place the test cassette on a flat surface.
12. Note: Do not touch the swab tip with your fingers.
13. Close the sample tube during this time.
14. 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.

TEST INTERPRETATION

- 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 purple line (T) line with the control line (C) should be read as 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: False negative or false positive results may occur if too little sample is added. Do not touch or move the test cassette during this time.

For use with anterior nasal swab specimens.
The Hotgen™ COVID-19 Antigen Home Test 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 (nasal) swab samples from individuals aged 16 years or older and adult collected anterior nasal (nasal) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms consistent with COVID-19 for at least three 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 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 (nasal) 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 the 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. 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 if your symptoms persist or become more severe.

What are the known and potential risk and benefits for the test?

Potential risks:

- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.
- Individuals should provide all results obtained with this product to their healthcare provider.

What do I have to pay attention to in order to get the most exact test result possible?

- Wear a mask during the collection of the sample and refer to the Use (IFU), available at www.hotgen.info.
- Store at room temperature 46°F to 86°F (8°C to 30°C) before use. It is stable over the expiration date marked on the packaging.

How do the test work?

The N-protein of the SARS-CoV-2 virus reacts with the coating of the test line and leads to a color change, i.e. a red line appears. If the sample does not contain SARS-CoV-2 virus, no red test line (T) appears.

What is the difference between an antigen and molecular test?

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 Hotgen™ COVID-19 Antigen Home Test, detect proteins from the virus. Due to 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.

How accurate is this test?

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 www.hotgen.info.

What if I have a positive test result?

A positive test 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.

What if I have a negative test result?

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 do not have symptoms and received a negative result, you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help understand the next steps you should take.

INDEX OF SYMBOLS

- OTC
- Batch code
- Manufacturer
- Catalogue number
- Date of manufacture
- Do not re-use
- In vitro diagnostic medical device
- Keep dry
- Keep away from sunlight
- Do not use if the packaging is damaged
- Manufacturer
- Date of manufacture
- Temperature limit
- Reference
- Contaminants
- Solution for use
-avy-by-date

STORAGE AND OPERATION CONDITIONS

Store Hotgen™ COVID-19 Antigen Home Test in a dry place between 38-86°F (3-30°C). Ensure all test components are at room temperature 46°F-86°F (8°C-30°C) before use. It is stable before the expiration date marked on the packaging.

version number: V.2023-0

<table>
<thead>
<tr>
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What does an invalid test result mean?

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 you should test again with a new test.

The test strip is very detailed. Why is this or what am I doing wrong?

The reason for a clearly visible discoloration of the test strip is that too large a quantity of drops has been dispensed from the test tube into the test cassette well. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is severely discolored. Please test the new test kit according to the instructions for use.

What should I do if I did the test but don’t see a control line?

In this case the test result is to be considered invalid. This can possibly be caused by incorrect test operation. Please repeat the test with a new test kit according to the instructions for use. If you have any further invalid test results, contact your doctor or a COVID-19 Test center.

Can this test cassette be reused or used by more than one person?

This test cassette is for single use and cannot be reused or used by more than one person.

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COVID-19 Antigen Home Test

At-home Use  Results in 15 Mins

HOW THIS TEST WORKS

The test uses a monoclonal antibody test with the nasal cavity of the test kit and needs to be charged immediately after the sample is taken. It can provide test results within 15 minutes.

CONTENTS

- 1 COVID-19 Antigen Test Cassette 1 Test
- Sample Tube 1: 0.5 ml
- Disposable Gloves 1 pair

WARNINGS

- Do not use on anyone who is prone to childhood or has been infected with the virus within the past six months.
- Do not use on anyone under 2 years of age.
- Use within 2 hours after opening the kit pack.
- Use without abandoning instructions.
- Do not touch the testing area of the test kit.

Made in China
Tel: 800+1 966-2919
Email: cs@hotgen.info
Website: www.hotgen.info

Beijing Hotgen Biotech Co., Ltd.
No. 12, Xilin Road, Fangdian Industrial Park, Changping District, Beijing, 102208, P.R. China


For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit
COVID-19 Antigen Home Test

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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

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Howard Biotech Co., Ltd.

Beijing Hotgen Biotech Co., Ltd.

WARNINGS

CONTENTS

HOW THIS TEST WORKS