Hotgen™

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.

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.
· If you 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.

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.

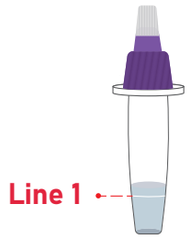
2

Read the Instructions for use carefully.

Note: Check kit 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

3

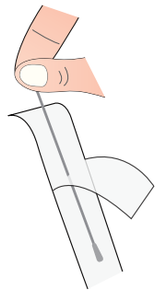
Confirm the liquid level is at or above Line 1 in the sample tube. Then proceed to collecting the nasal swab sample.



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

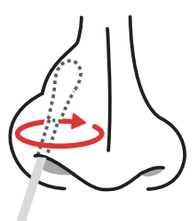
Take the swab out of the package and do not touch the sampling end.



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

5

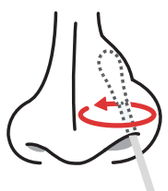
Carefully insert the swab 1/2 to 3/4 of an inch into the nostril. Under moderate pressure, swab the nostril at least 5 times for at least 15 seconds total.



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

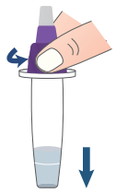
Repeat sampling with the same swab in the other nostril.



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

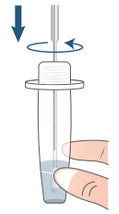
7

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



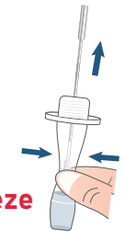
8

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 swab tip 3 times.



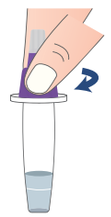
9

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



10

Close the sample tube with the larger tube cap.

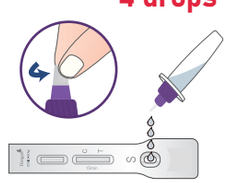


11

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

12

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.

13

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.

14

Throw away all used test kit components in the trash.

TEST INTERPRETATION

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

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

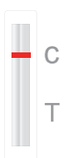
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Fig. 1

Positive

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 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).

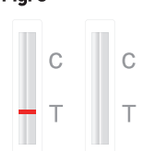
Fig. 2



Negative

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 chance 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 the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

Fig. 3



Invalid

Invalid: As shown in Fig. 3, 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.

INTENDED USE

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 (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individual aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 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 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 co-infection with other viruses. The agent detected may not be the definite 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 for public health reporting and to receive appropriate medical care. 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 SARS-CoV-2 Tests provided by CDC.

The Hotgen™ COVID-19 Antigen Home Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting.

The Hotgen™ COVID-19 Antigen Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. The product has not been FDA cleared or approved.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

· Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

· 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 individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**

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

· 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.

· Do not use on anyone under 2 years of age.

· Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.

· Do not use if any of the test kit contents or packaging is damaged.

· Test components are single-use. Do not re-use.

· Do not use kit past its expiration date.

· Do not touch the swab tip.

· Once opened, the test cassette should be used within 2 hours.

· Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.

· 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 the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name	Subcomponent	GHS Code for each Ingredient	Concentrations
KV-300	5-Chloro-2-Methyl-4-Isothiazolin-3-One	H316, Skin Sensitization	0.00255%
	2-Methyl-4-Isothiazolin-3-One	H316, Skin Sensitization	0.00081%

· 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: www.cdc.gov/COVID19

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 both your 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.

· This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

· Incorrect test results may occur if a specimen is incorrectly collected or handled.

FREQUENTLY ASKED QUESTIONS (FAQ)

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

Potential risks include:

· Possible discomfort during sample collection.

· Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

· 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.

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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

Always follow the instructions for use exactly. Perform the test immediately after collecting the sample. Put the drops from the sample tube only into the designated well of the test cassette. Dispense four drops from the sample tube. Too many or too few drops can lead to an incorrect or invalid test result.

How does 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 the 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 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 selfisolate 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 have a negative result, it does not rule out SARS CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

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 discolored. 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 repeat the test with a 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.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

INDEX OF SYMBOLS

	Use-by date	LOT	Batch code		Consult instructions for use
Σ	Contents sufficient for <n> tests		Temperature limit	REF	Catalogue number
	Date of manufacture		Manufacturer		Do not re-use
IVD	In vitro diagnostic medical device		Keep away from sunlight		Keep dry
	Warnings		Do not use if the packaging is damaged	OTC	Over the counter

STORAGE AND OPERATION CONDITIONS

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.

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APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION
Approved: November, 2022;
Version number: V.2022-11.03[Eng.]

Hotgen™

1 Test

FDA Emergency Use Authorization

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

6 936700 405200

REF HGCG134S0101

OTC IVD

HOW THIS TEST WORKS

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.

CONTENTS

- SARS-CoV-2 Antigen Test Cassette 1 test
- Sample Tube 0.5 mL× 1 pc
- Disposable Sterile Swab 1 pc

⚠ WARNINGS

- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- Use within 2 hours after opening the foil pouch.
- Do not use on anyone under 2 years of age.
- Required but not included in the test kit: a timer.

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Made in China

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests

LOT

2 Tests

Hotgen™

FDA Emergency Use Authorization

COVID-19 Antigen Home Test

At-home Use **Results in 15 Mins**

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· http://www.fda.gov/covid-tests

REF HGCG134S0102

OTC IVD

6 936700 403916

Beijing Hotgen Biotech Co., Ltd.

LOT

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

- SARS-CoV-2 Antigen Test Cassette 2 tests
- Sample Tube 0.5 mL×2 pcs
- Disposable Sterile Swab 2 pcs

WARNINGS

- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- Use within 2 hours after opening the foil pouch.
- Do not use on anyone under 2 years of age.
- Required but not included in the test kit: a timer.

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CONTENTS

- SARS-CoV-2 Antigen Test Cassette 5 tests
- Sample Tube 0.5 mL×5 pcs
- Disposable Sterile Swab 5 pcs

⚠ WARNINGS

- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
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LOT

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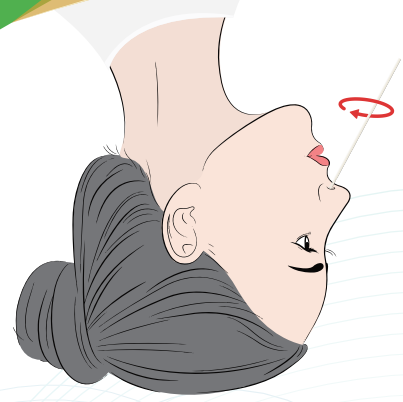
Beijing Hotgen Biotech Co., Ltd.

REF HGCG134S0105

OTC　IVD



5 Tests

Hotgen™

FDA Emergency Use Authorization

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.
· 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.
· 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

Beijing Hotgen Biotech Co., Ltd.

HOW THIS TEST WORKS

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.

CONTENTS

- SARS-CoV-2 Antigen Test Cassette 10 tests
- Sample Tube 0.5 mL×10 pcs
- Disposable Sterile Swab 10 pcs

⚠ WARNINGS

- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- Use within 2 hours after opening the foil pouch.
- Do not use on anyone under 2 years of age.
- Required but not included in the test kit: a timer.

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Made in China

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit
https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests

LOT

Beijing Hotgen Biotech Co., Ltd.

6 936700 405224

OTC IVD

REF HGCG134S0110

10 Tests

Hotgen™

FDA Emergency Use Authorization

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.

· 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.

· 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

Hotgen™

FDA Emergency Use Authorization

20 Tests

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.
- 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.
- 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

REF HGCG134S0120   OTC   IVD

HOW THIS TEST WORKS

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.

CONTENTS

- SARS-CoV-2 Antigen Test Cassette 20 tests
- Sample Tube 0.5 mL×20 pcs
- Disposable Sterile Swab 20 pcs

2°C 36°F 30°C 86°F   Σ 20

⚠ WARNINGS

- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- Use within 2 hours after opening the foil pouch.
- Do not use on anyone under 2 years of age.
- Required but not included in the test kit: a timer.

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Made in China

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests

Hotgen™

FDA Emergency Use Authorization

COVID-19 Antigen Home Test

At-home Use   Results in 15 Mins

20 Tests

LOT

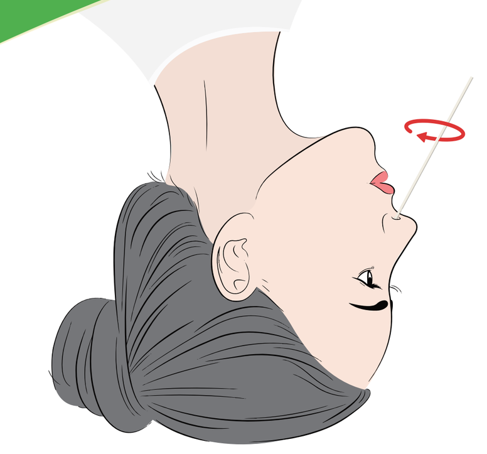
6 936700 405231

REF HGCG134S0140

OTC IVD

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.
- 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.
- 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

Hotgen™ FDA Emergency Use Authorization

40 Tests

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Hotgen™ FDA Emergency Use Authorization

COVID-19 Antigen Home Test

At-home Use Results in 15 Mins

40 Tests

6 936700 405248

HOW THIS TEST WORKS

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.

CONTENTS

- SARS-CoV-2 Antigen Test Cassette 40 tests
- Sample Tube 0.5 mL×40 pcs
- Disposable Sterile Swab 40 pcs

2°C 36°F 30°C 86°F 40

WARNINGS

- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- Use within 2 hours after opening the foil pouch.
- Do not use on anyone under 2 years of age.
- Required but not included in the test kit: a timer.