HEALGEN®

Rapid COVID-19 Antigen Self-Test

INTENDED USE

The Rapid COVID-19 Antigen Self-Test is a lateral flow test for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 (Coronavirus, or "COVID-19") from direct anterior nasal (nares) swab directly from individuals who are both symptomatic and asymptomatic. Nasal swab samples from individuals aged below 12 years or above 70 years should be collected by or under supervision of adults. This test is intended to aid in the rapid diagnosis of Coronavirus infections. If symptoms persist despite negative test results it is recommended to visit a healthcare professional to seek follow up care.

SUMMARY AND EXPLANATION

Coronavirus can cause an acute respiratory infectious disease known as COVID-19. Currently, people infected with coronavirus are the main source of infection; infected people can be a source of infection even if they do not show symptoms. Based on the current epidemiologic survey, the time between infection and disease onset is 1 to 14 days, most commonly 3 to 7 days. The main signs of infection include fever, fatigue and dry cough. In rare cases, nasal congestion, runny nose, sore throat, muscle pain and diarrhea are found in a few cases.

The Rapid COVID-19 Antigen Self-Test is for detection of nucleocapsid protein antigen of coronavirus.
The antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of coronavirus infection and subsequent care and treatment by healthcare professionals will help control the spread of coronavirus more efficiently and effectively.

PRINCIPLE OF THE TEST

The Rapid COVID-19 Antigen Self-Test is a lateral flow test that detects the nucleocapsid protein antigen of the coronavirus that causes COVID-19 from direct nasal swab. When added to the sample well, the prepared sample flows laterally on the test device. The test reaction wil take 15 minutes. If the test detects the relevant Coronavirus protein, a line will appear in the test line region (T) indicating a positive test result. Absence of the test line (T) suggests a negative test result. A line will always appear in the control line region (C) if the test has been performed correctly.

ITEMS SUPPLIED (GCCOV-502a-H1/H2/H3/H5)

1/2/3/5	Test Device(s)
1/2/3/5	Sterile Swab(s)
1/2/3/5	Extraction Tube(s) with Buffer and Tip(s)
1	Instructions For Use
1	Procedure Card

ITEMS REQUIRED BUT NOT PROVIDED

Clock, timer or stopwatch and plastic bag for waste.

WARNINGS

1. For *in vitro* diagnostic use only.
2. The test device should remain in the sealed pouch until use.
3. Do not use the test kit past its expiration date.
4. Swabs, tubes and test devices are for single use only.
5. Do not interchange or mix components from other kits.
6. Testing should only be performed using the swabs provided within the kit.
7. To obtain accurate results, do not use visually bloody or overly viscous (thick, sticky) samples.
8. Specimens must be processed as indicated in the Test Procedure section of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
9. Inadequate or inappropriate specimen collection and storage can affect results.
10. Use in very humid areas or when temperature is above or below 15-30°C can adversely affective results.
11. Collect kit components and swab samples in a plastic bag and dispose of as household waste.
12. Keep away from children to reduce the risk of accidental drinking of buffer liquid or swallowing of small parts.
13. Do not move the test device after applying the solution.

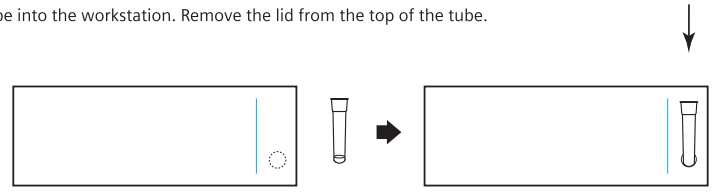
STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C).
2. Do not freeze any of the test kit components. Keep away from direct sunlight.
3. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.
4. Close the kit box and secure its contents when not in use.

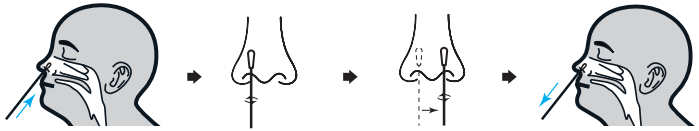
TEST PROCEDURE

Wash or sanitize your hands before performing the test. The test should be performed at room temperature (15-30°C). Allow the test to reach room temperature prior to use if any parts have been stored in a refrigerator.

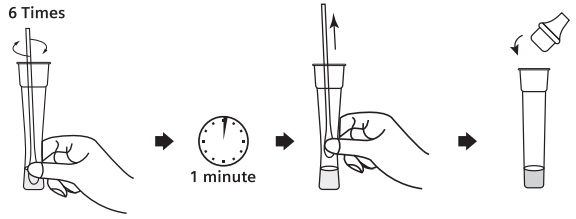
1. Insert the tube into the workstation. Remove the lid from the top of the tube.



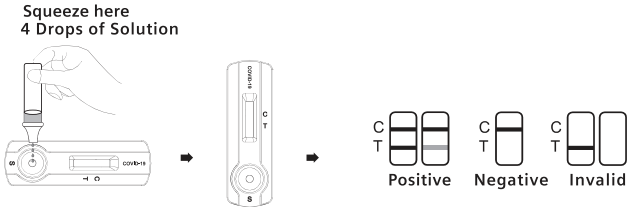
2. Open swab package where indicated. Pull the swab out by grasping the plastic end. Do not touch the absorbent swab tip.
3. Carefully insert absorbent tip of the swab into your left nostril. Ensure that the entire swab tip is inside your nostril (2–4cm deep). Do not insert the swab further after you feel resistance.
4. Roll the swab at least 5 times against the insides of your nostril. Ensure good contact between the swab and the insides of your nostril.
5. Remove the swab and insert into your right nostril. Repeat Step 4 and 5.



6. Remove the swab from your nostril and insert the swab into the tube in the workstation.
7. Mix well by rolling the swab at least 6 times while pressing the head of the swab against the bottom and sides of the tube.
8. Start timer. Leave the swab in the tube for 1 minute.
9. Squeeze the tube several times from the outside. Try to release as much solution from the swab as possible.
10. Remove swab and discard in a plastic bag.
11. Push the tip provided in the kit into the tube and ensure it fits tightly.



12. Remove the test device from the pouch and lay it on a flat clean surface.
13. Add 4 drops of the solution into the sample well of the test device by gently squeezing the tube.
14. Start timer and wait 15 minutes. It is important to read the results at 15 minutes.
15. Read your results (See interpretation of results section).



INTERPRETATION OF THE RESULTS

There are three possible types of results.

1. POSITIVE:

If the test device looks like either of the positive result windows as displayed above, you have a current Covid-19 infection. Please call you doctor or your local health department and make sure you adhere to local guidelines for self-isolation. Re-testing with other test methods such as a PCR test may be required.

2. NEGATIVE:

If the test device looks like the negative result window as displayed above, no Covid-19 infection could be detected. In a suspected case, repeat the test after 1-2 days since the virus cannot be accurately detected in all phases of an infection. Despite a negative test result, you still have to comply with all applicable rules regarding contact with others and protective measures

3. INVALID:

If your test result looks different, meaning there is no line visible or only one line at T, the result is invalid. This may be a result of the test execution, and the test should be repeated. If invalid test results continue, please contact your doctor or a COVID test center.

LIMITATIONS

1. Respiratory infection caused by microorganisms other than the Coronavirus will not be established with this test.
2. Failure to follow the Test Procedure may affect test performance and/or invalidate the test result.
3. False negative test results may occur if the level of antigen in the sample is below the minimum detection level of the test.
4. False negative results may occur if the sample is collected incorrectly.
5. False negative results may occur if the sample swab is not mixed well in the tube.
6. A negative result does not at any time rule out the presence of Coronavirus in the sample, as it may be present below the minimum detection level of the test.
7. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.
8. As with all *in vitro* diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
9. Positive test results do not rule out co-infections with other pathogens.
10. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
11. The amount of antigen in a specimen may decrease as the disease duration progresses. Therefore, specimens collected more than 10 days after COVID-19 infection may have low antigen levels that are below the minimum detection limit of the test. Testing such a specimen is more likely to result in a false negative rapid test result than testing based on a PCR assay (the evaluation of which is performed in the laboratory).
12. Negative results do not rule out Coronavirus infection and do not liberate you from applicable rules for spread control (such as contact to others and protective measures).

FREQUENTLY ASKED QUESTIONS

Will this test hurt?

The nasal swab may cause slight discomfort. To obtain an accurate test result it is important to swab the nostril as instructed in the test procedure. Discomfort may be increased if swab is inserted beyond recommended depth. If sharp pain is experienced, do not swab the nostril any further.

What are the potential benefits and risks of this test?

Potential benefits:

- The test can determine if you have COVID-19.
- The results, along with other information, can help your healthcare provider make informed decisions about your care.
- You can help limit the spread of COVID-19 by knowing your infection status with this test.

Potential risks:

- Possible discomfort during swabbing.
- Possible incorrect test results (see interpretation of results and limitations sections).

What are the differences between COVID-19 molecular, antigen, and antibody tests?

There are three main types of COVID-19 tests available, and there are significant differences between them. Molecular tests (also known as PCR tests) detect the genetic material of the Coronavirus. The Rapid COVID-19 Antigen Self-Test is an antigen test. Antigen tests detect for proteins, which are small pieces, belonging to the Coronavirus. Antibody tests detects antibodies that the immune system in your body produces in response to previous COVID-19 infection. Antibody tests cannot be used to diagnose active COVID-19 infection.

How accurate is the Rapid COVID-19 Antigen Self-Test?

The Rapid COVID-19 Antigen Self-Test identified 97.25% of COVID-19 positive samples and 100% of COVID-19 negative samples. The overall accuracy of the Rapid COVID-19 Antigen Self-Test is 98.73%. The samples used to determine the performance of this test were collected during a clinical study conducted in the USA. The samples were confirmed positive and negative by a USFDA emergency use authorized PCR test.

What does it mean if I have a positive result?

A positive test result means that proteins from the virus that causes COVID-19 was found in your swab sample. It is likely that you may be required to self-isolate at home to prevent the spread of COVID-19. Please also observe the relevant rules for spread control and contact your doctor or local health department. In this case, it is recommended to have the result confirmed with an alternative test method such as a PCR test.

What does it mean if I have a negative result?

A negative test results means that you are unlikely to have COVID-19. The test did not detect the virus proteins in the swab sample, but it is possible for this test to give a negative result that is incorrect. Incorrect negative results (false negative) can be caused by several factors:

- The amount of antigen in the swab sample may decrease over the length of infection.
- You may test negative before you develop symptoms.
- Further reasons as specified under the limitations section.

If you are unwell, your symptoms become worse or you develop new symptoms it is important that you seek a healthcare professional right away.

Does this test detect all the virus variants?

All viruses can change, and the virus which causes COVID-19 is known to have a number of these changed versions, called variants. The Rapid COVID-19 Antigen Self-Test detects a part of the virus which is known to be less likely to change over time; the nucleocapsid protein, which is a small piece of SARS-CoV-2. The variants seen primarily impact another part of the SARS-CoV-2 virus, the spike protein. However, if you test negative but are still unwell, your symptoms become worse, or you develop new symptoms, it is important that you seek a healthcare professional right away.

REFERENCES

1. Julien Favresse, Constant Gillot, Maxime Oliveira, Julie Cadrobbi, Marc Elsen, Christine Eucher, Kim Laffineur, Catherine Rosseels, Sandrine Van Eeckhoudt, Jean-Baptiste Nicolas, Laure Morimont Jean-Michel Dogné and Jonathan Douxfils. Head-to-Head Comparison of Rapid and Automated Antigen Detection Tests for the Diagnosis of SARS-CoV-2 Infection J. Clin. Med. 2021, 10, 265.
2. Ignacio Torres, Sandrine Poujois, Eliseo Albert, Gabriela Álvarez, Javier Colomina and David Navarro. Point-of-care evaluation of a rapid antigen test (CLINITEST® Rapid COVID-19 Antigen Test) for diagnosis of SARS-CoV-2 infection in symptomatic and asymptomatic individuals February 11, 2021.
3. Public Health England.SARS-CoV-2 lateral flow antigen tests: evaluation of VOC1 (Kent, UK) and VOC2 (South Africa) Published 12 February 2021.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C / 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
					Manufacturer

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
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Website: www.healgen.com

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Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GCCOV-502a-H1
GCCOV-502a-H2
GCCOV-502a-H3
GCCOV-502a-H5
CE 0123

Swab information

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Jiangsu 225109 China

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CE 0197

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