CLINITEST®

RAPID COVID-19 ANTIGEN SELF-TEST

QUICK REFERENCE INSTRUCTIONS

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.

INTRODUCTION

IMPORTANT

- Read instructions carefully before starting the test.
- For non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older, or adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset for serial testing for use at least twice over three days with at least 48 hours between tests.

Also for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older, or adult-collected anterior nasal swab samples from individuals aged 2 years or older, without symptoms or other epidemiological reasons to suspect COVID-19 for serial testing for use at least three times over five days with at least 48 hours between tests.

- Test setup is about 5 minutes. The result must be read at 15 minutes.
- All test materials must be at room temperature before use.
- You should wear a face mask if swabbing others.
- You must follow the test directions carefully to get an accurate result.
- Visit https://labtest.recurohealth.com/signup/CLINITEST to access the optional Recuro Health web app, using a compatible mobile phone (Requires modern mobile web browser, e.g. Chrome, Safari). The App includes access to video instructions, test timers, help with results interpretation and test reporting features. If you have any questions about using the test or reading the results please call our customer care hotline.

Telephone: 1-833-933-2340
E-Mail: covidhometest-USA.dl@siemens-healthineers.com
https://www.clinitest.siemens-healthineers.com/us

HOW TO USE THIS TEST

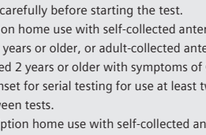
Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, 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.

WASH HANDS

Wash your hands with soap and water for 30 seconds or use hand sanitizer. Make sure hands are dry before starting.



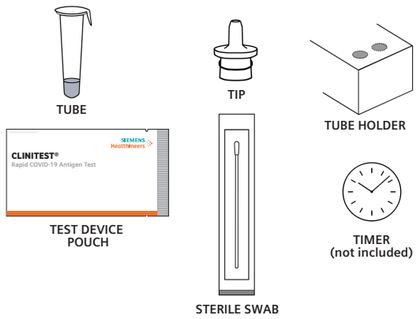
GATHER MATERIALS

Check expiration date of the test kit before use. Expiration date is printed on the box and each test pouch. **Do not use if test is expired.**

PREP

Remove all contents in the box. Read instructions.

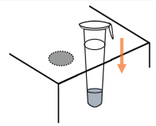
Do not start Step 1 until you are ready to begin the test.



STEP 1.

PLACE TUBE IN TUBE HOLDER

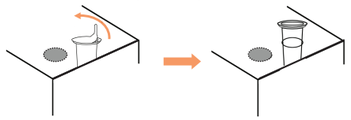
Find tube holder shown on the back of the box. Push tube through outlined hole.



STEP 2.

OPEN TUBE

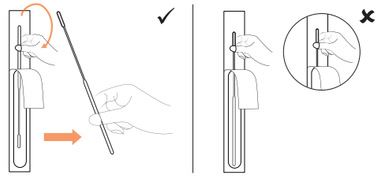
Remove the seal from the tube. Avoid spilling the liquid. Make sure the tube is standing up straight.



STEP 3.

OPEN SWAB

Open the swab pouch on the end opposite the swab tip by peeling back the pouch cover. Hold the **plastic stick end** of the swab and remove from pouch. Be careful not to touch the tip of the swab.

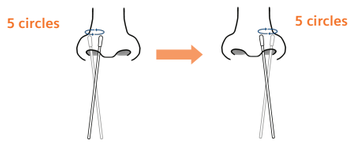


SWAB BOTH NOSTRILS

Carefully insert swab tip into one nostril about **1/2 to 3/4 of an inch deep.** Do not insert the swab any further if you feel any resistance. Rub the insides of the nostril in a complete circle at least **5 times.** Make sure that you are rubbing the insides of the nostril. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab Remove swab from the nostril and **repeat in your other nostril.**

NOTE: *If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.*

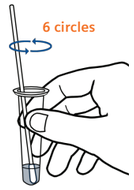
NOTE: *Failure to swab properly may cause false negative results.*



STEP 4.

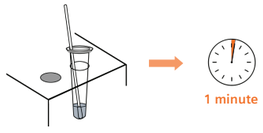
PLACE SWAB IN TUBE

Remove the swab from your nostril. Immediately take the tube out of the tube holder and insert swab tip **into the liquid inside the tube**. Mix vigorously by rolling the swab tip **at least 6 times** on the bottom and sides of the tube.



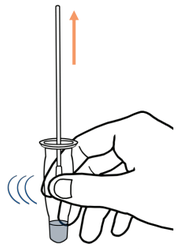
PLACE TUBE IN TUBE HOLDER

Place the tube back into the tube holder. Keep the swab inside of the tube.
Start timer for 1 minute.



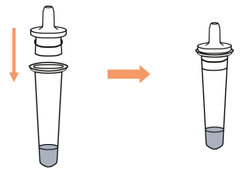
REMOVE SWAB FROM TUBE

After 1 minute take the tube out of the tube holder.
As you remove the swab from the tube, **squeeze swab tip several times** from outside of the tube. Try to release as much liquid from the swab as possible. Dispose the swab in the trash.



INSERT TIP

Take a tube tip from the kit and push it into the top of the tube. Make sure there is a tight fit.



STEP 5.

OPEN TEST DEVICE

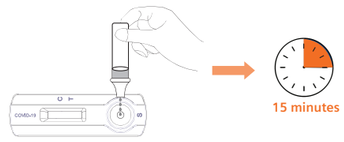
Open the test device pouch by tearing the area circled below. Place the test device on a **flat surface.**

ADD 4 DROPS

Hold the tube straight up and down above the test device and gently squeeze to add **4 drops** of solution into the sample well, labeled as "S" on the test device. **Adding more or less than 4 drops of solution into the sample well may result in incorrect results.**

START TIMER

Start timer for 15 minutes.
Do not move the test device. Keep on a flat surface.



STEP 6.

READ TEST RESULT

After 15 minutes find result window, labeled as "C" (for Control) and "T" (for Test) on the test device. It is important to read your **test result at 15-20 minutes.** False negative or false positive results can occur if test results are read before 15 minutes or after 30 minutes. Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

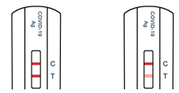
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19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

Below are examples for positive, negative and invalid test results. Used test materials should be thrown away as household waste.

COVID-19 POSITIVE

If the test device looks like the examples below, then protein from the virus that causes COVID-19 **was detected** in the sample. The test is positive if there are **two pink/red lines present, one at the Control "C" line and one at the Test "T" line.** Look very closely for line next to "T". This line can be very faint. Any visible pink/red "T" line is a positive result when the "C" line is also present.



IF THE TEST IS POSITIVE

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).

COVID-19 NEGATIVE

If the test device looks like the example below then protein from the virus that causes COVID-19 **was not detected**. You will only see **one line next to "C" and there will not be any line visible next to"T".**

IF THE TEST IS NEGATIVE

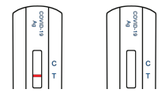
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 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 negative 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 negative 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.

INVALID

If the test device looks like the examples below then the test **was not able to give a result** and you must **repeat the test with a new swab, a new tube, and a new test device.** The test is INVALID if there is no line next to "C".



IF THE TEST IS INVALID

If at **15 minutes the line next to the "C" does not appear,** even if any shade of **pink/red "T" line appears,** the **test result is invalid**. If the test result is invalid, a new swab should be collected, and the test should be performed again with a new tube and test device.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY

- 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: https://www.cdc.gov/COVID19
- For detailed instructions, please visit: https://www.clinitest.siemens-healthineers.com/us
- For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

INTENDED USE

The CLINITEST® Rapid COVID-19 Antigen Self-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 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 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 CLINITEST® Rapid COVID-19 Antigen Self-Test does not differentiate between SARS-CoV or SARSCoV-2.

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 co-infection with other viruses and the agent detected may not be the definitive cause of disease. Individuals who test positive with the CLINITEST® Rapid COVID-19 Antigen Self-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 CLINITEST® Rapid COVID-19 Antigen Self-Test is intended for non-prescription self-use and/or, as applicable, for an adult lay user testing another aged 2 years or older. The CLINITEST® Rapid COVID-19 Antigen Self-Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read the CLINITEST® Rapid COVID-19 Antigen Self-Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- **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.**
- The Test is intended to aid in the diagnosis of a current COVID-19 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Keep test kit and materials out of the reach of children and pets before and after use.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- 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.
- The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for a test line to show up.
- Do not use on anyone under two years of age.
- Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use the test after the expiration date shown on the kit box.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single-use. Do not re-use.
- Make sure there is sufficient light when testing. For best results, read test in a well-lit area.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Inadequate or improper nasal swab sample collection may yield false negative test results.
- Do not touch the swab tip (specimen collection area) when handling the swab.
- Once opened, the test card should be used within 60 minutes.
- The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the tube.
- The solution in the tube and the test device contains an ingredient that is hazardous to skin and eyes (see table below). If contact with the body occurs, rinse with water. If irritation persists, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name/CAS	GHS Code for applicable Ingredient	Concentration (%)
Sodium Azide/26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.02% (device) and 0.05% (tube)
Triton/9002-93-1	Acute Tox. 4 (Oral), H302	1.5%

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 November 2021 – February 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

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation section).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed 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.

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

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the CLINITEST® Rapid COVID-19 Antigen Self-Test, detect proteins from the virus. Antigen tests are very specific for the SARS-CoV-2 virus but are not as sensitive as molecular tests. 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.

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.clinitest.siemens-healthineers.com/us.

Q: WHAT IF YOU TEST POSITIVE?
A: 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.

Q: WHAT IF YOU TEST NEGATIVE?
A: 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.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: If no control line shows up on the test, the result is invalid (even if any test line shows up). 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 the test should be run again, using a new test and tube.

IMPORTANT

This test is intended to be used as an aid in the clinical diagnosis of a current 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 concerned at any time.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting.

HEALTHCARE PROVIDERS

Please visit https://www.clinitest.siemens-healthineers.com/us to obtain the complete instructions for use and fact sheet for healthcare providers.

Index of Symbols

	Manufacturer		Date of manufacture
Σ	Contains sufficient for <n> tests	REF	Catalogue number
IVD	*In vitro* diagnostic medical device		Use-by date
	Consult instructions for use	LOT	Batch code
	Temperature limit		Do not reuse

SIEMENS Healthineers

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

Revision Date: 2023-02, B22347-04 Rev. D

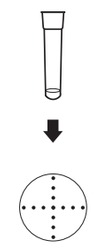
- For *in vitro* diagnostic use.
- For Emergency Use Authorization (EUA) only.
- This test can be used at home on people aged 2 years old and up.
- Items necessary to use the kit, but not provided:
  - Timer
- For Symbol Glossary, refer to Instructions for Use.

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.

The CLINITEST® Rapid COVID-19 Antigen Self-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 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 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.

Visit https://labtest.recurohealth.com/signup/CLINITEST to access the optional Recuro Health web app, using a compatible mobile phone (Requires modern mobile web browser, e.g. Chrome, Safari). The App includes access to video instructions, test timers, help with results interpretation and test reporting features.

*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.



Insert tube here
Inserte el tubo aquí

LOT

REF GCCOV-502a-H1US
(11561587)

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

00816490025733

www.clinitest.siemens-healthineers.com/us

B01598-01

SIEMENS Healthineers

CLINITEST®

Rapid COVID-19 Antigen Self-Test

Contents of the kit:
1 Test Device
1 Sterile Swab
1 Extraction Tube with Buffer and Tip
Instructions for Use

Σ 1

A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens in 15 minutes.

Distributed by Siemens Healthineers

IVD 2°C 30°C

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

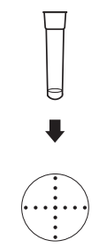
- For *in vitro* diagnostic use.
- For Emergency Use Authorization (EUA) only.
- This test can be used at home on people aged 2 years old and up.
- Items necessary to use the kit, but not provided:
  - Timer
- For Symbol Glossary, refer to Instructions for Use.

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.

The CLINITEST® Rapid COVID-19 Antigen Self-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 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 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.

Visit https://labtest.recurohealth.com/signup/CLINITEST to access the optional Recuro Health web app, using a compatible mobile phone (Requires modern mobile web browser, e.g. Chrome, Safari). The App includes access to video instructions, test timers, help with results interpretation and test reporting features.

*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.



Insert tube here
Inserte el tubo aquí

LOT

REF GCCOV-502a-H2US
(11561908)

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

00816490025979

www.clinitest.siemens-healthineers.com/us

B01638-01

SIEMENS Healthineers

CLINITEST®

Rapid COVID-19 Antigen Self-Test

Contents of the kit:
2 Test Devices
2 Sterile Swabs
2 Extraction Tubes with Buffer and Tips
Instructions for Use

Σ 2

A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens in 15 minutes.

Distributed by Siemens Healthineers

IVD 2°C 30°C

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200 mm x 70 mm x 32 mm

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LOT

REF **GCCOV-502a-H4US**
(11561910)

00816490025948

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

www.clinitest.siemens-healthineers.com/us

B01639-02

SIEMENS Healthineers

CLINITEST®

Rapid COVID-19 Antigen Self-Test

Contents of the kit:
4 Test Devices
4 Sterile Swabs
4 Extraction Tubes with Buffer and Tips
Instructions for Use

Σ 4

A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens in 15 minutes.

Distributed by Siemens Healthineers

IVD

2°C – 30°C

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- This test can be used at home on people aged 2 years old and up.
- Items necessary to use the kit, but not provided:
  - Timer
- For Symbol Glossary, refer to Instructions for Use.

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LOT

REF **GCCOV-502a-H5US**
(11556712)

00816490025740

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

www.clinitest.siemens-healthineers.com/us

B01601-02

SIEMENS Healthineers

CLINITEST®

Rapid COVID-19 Antigen Self-Test

Contents of the kit:
5 Test Devices
5 Sterile Swabs
5 Extraction Tubes with Buffer and Tips
Instructions for Use

Σ5

A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens in 15 minutes.

Distributed by Siemens Healthineers

IVD

2°C 30°C

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