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 splintering 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 plastic shield. Place the swab tip inside of the tube. Be sure to not touch the tip of the swab.

SWAB BOTH NOSTRILS
Carefully insert swabs into one nostril about 1/2 to 3/4 of an inch deep. Do not insert 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 very young children, you may not need to insert the swab as far into the nostril. To very young children, you may not need to insert the swab as far into the nostril.

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

STEP 4. PLACE SWAB IN TUBE
Remove the swabs 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 15 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.

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.

STEP 6. READ TEST RESULT
After 1 minute first 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. Below are examples for positive, negative and invalid test results.

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
A positive test result means that the virus that causes COVID-19 was detected in your sample and that you have COVID-19. This is important to be under the care of a healthcare provider. It is likely you will be asked to isolate yourself at home to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is incorrect (a false positive). If you test positive, follow the CLEANSURE Rapid COVID-19 Antigen Self-Test instructions. 

IF THE TEST IS NEGATIVE
If the test device looks like the examples 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 INVALID
If at 15 minutes the line next to the “C” does not appear, or if any swirl of debris is a “T” line appearance, 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 swab and test device.

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

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

PREP
Remove all contents in the box. Read instructions. Do not start Step 1 until you are ready to begin the test.

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

TEST DEVICE POUCH
STERILE SWAB
TUBE
TUBE HOLDER
TIME (IN MINUTES)
5 circles
5 circles

CLINITEST® RAPID COVID-19 ANTIGEN SELF-TEST QUICK REFERENCE INSTRUCTIONS

For Emergency Use Authorization (EUA) Only.

In vitro diagnostic use only.

In the US, 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 purposes. The emergency use of this product is authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use 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. § 360a-360b(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 4 years or older, or adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms or other epidemiological reasons to suspect COVID-19 when tested twice within a 24 hour period and no more than 48 hours apart.
- Test results are negative, you may not have COVID-19.
- If you test positive and continue to experience COVID-19 like symptoms, cough or shortness of breath, you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result with all other aspects of your health such as symptoms and epidemiological factors to decide how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have the virus causing COVID-19. It is important you work with your healthcare provider to help you understand the next steps you should take. If you DO NOT have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests. If your first test was a negative test result, you may not have COVID-19.

NOTE: For very young children, you may need another person to steady the child. Do not handle child’s face or mouth. With very young children, you may not need to insert the swab as far into the nostril.

NOTE: If at 15 minutes the line next to the “C” does not appear, or if any swirl of debris is a “T” line appearance, 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 swab and test device.

COVID-19 NEGATIVE
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
A negative test result means that protein from the virus that causes COVID-19 was not detected in your sample. If you took this test while you have symptoms, a negative test result usually means that your current illness was not caused by COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. Negative results do not rule out COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19-like symptoms of fever, cough or shortness of breath, you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result with all other aspects of your health such as symptoms and exposures to decide how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have the virus causing COVID-19. It is important you work with your healthcare provider to help you understand the next steps you should take. If you DO NOT have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests. If your first test was a negative test result, you may not have COVID-19.

IF THE TEST IS INVALID
If at 15 minutes the line next to the “C” does not appear, or if any swirl of debris is a “T” line appearance, 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 swab and test device.

IF THE TEST IS POSITIVE
A positive test result means that the virus that causes COVID-19 was detected in your sample and that you have COVID-19. This is important to be under the care of a healthcare provider. It is likely you will be asked to isolate yourself at home to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is incorrect (a false positive). If you test positive, follow the CLEANSURE Rapid COVID-19 Antigen Self-Test instructions.
Chemical Name/CAS  |  GIF Code for applicable analytes  |  Concentration  
--- | --- | ---  
Sodium Azide/26628-22-8  |  Acute Tel. 2 (Chol), HD50  |  0.02% (v/v) and 0.05% (v/v)  
Triphenylboron 9-1  |  Acute Tel. 4 (Chol), HD30  |  1.5%  

Serious Testing Information and Instructions:  
• If you have symptoms of COVID-19 that started with the last day that you can use a single test.  
• Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours (and no more than 48 hours) between tests. You may need to purchase additional tests to perform this serial (repeat) testing.  
For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.  
• If your second test result is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.  
• If both your first and second test results are negative, you may not have COVID-19, however you should follow-up with your healthcare provider if you are at high risk for COVID-19.  

Frequently Asked Questions  
Q: WHAT IS COVID-19?  
A: COVID-19 is an acute respiratory infection caused by SARS-CoV-2 virus, a new Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms and by people who are asymptomatic or only have mild symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-illness.html.  

Q: WILL THIS TEST HURT?  
A: No, the test will not hurt, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.  

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?  
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.  

Q: WHAT IS SERIAL TESTING?  
Serial testing when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing is more likely to detect COVID-19 within the first 7 days of symptom onset. There is a higher chance this test will give you a negative result when you have COVID-19.  

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTGEN 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. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.  

Q: HOW ACCURATE IS THIS TEST?  
A: In a clinical evaluation where results from the CLINITEST® Rapid COVID-19 Antigen Home Test were compared to an FDA authorized molecular SARS-CoV-2 test, the CLINITEST® Rapid COVID-19 Antigen Home Test correctly identified 95.4% of positive specimens and 99.3% of negative specimens. The performance of this test is still being evaluated in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.  

Q: WHAT IF YOU TEST POSITIVE?  
A: A positive test result means that antigens from the virus that causes COVID-19 were not detected in your sample. If you have symptoms consistent with COVID-19, you should continue to self-isolate at home for at least 10 days from the first day that symptoms started, or as directed by your healthcare provider. If you do not have symptoms, you should undergo a second rapid antigen test 24 to 48 hours after your first negative result, then you are likely not infected with COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a negative result that is incorrect (false-negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may have a negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was too low to be detected. The amount of antigen in a sample may decrease the longer you have symptoms and you may test negative and continue to experience symptoms of fever, cough and/or breathlessness that you should seek follow-up care with your healthcare provider. Your healthcare provider will consider the test result together with all of your clinical information, as well as your medical history (such as symptoms, possible exposures, and geographic location of places you have recently travelled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.  

The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.
**Contents of the kit:**

- 1 Test Device
- 1 Sterile Swab
- 1 Extraction Tube with Buffer and Tip
- Instructions for Use

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. 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.

**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.

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**CLINITEST® Rapid COVID-19 Antigen Self-Test**

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

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. 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 an immunochromatographic membrane assay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 7 days of symptom onset or those with or without symptoms or other epidemiological reasons for suspicion of COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

For Symbol Glossary, refer to Instructions for Use.

*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 authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of an in vitro diagnostic device to test for COVID-19 under Section 566(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**

Distributed by Siemens Healthineers
CLINITEST®
Rapid COVID-19 Antigen Self-Test

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

Distributed By Siemens Healthineers

Healthineers Limited Liability Company
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Website: www.healgen.com

2°C
30°C

For Symbol Glossary, refer to Instructions for Use.

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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.

If you have symptoms of COVID-19, you can use a single test.
If you do not have symptoms of COVID-19, you will need at least two tests per person.
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 an immunochromatographic membrane assay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 7 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.
CLINITEST®

Rapid COVID-19 Antigen Self-Test

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

If you have symptoms of COVID-19, you can use a single test.

If you do not have symptoms of COVID-19, you will need at least two tests per person. It is recommended to perform the second test in the same timeframe.

This test is not designed to replace a laboratory-based molecular test.

The CLINITEST® Rapid COVID-19 Antigen Self-Test is an immunochromatographic membrane assay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 7 days of symptom onset or those with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Distributed by Siemens Healthineers

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