RAPID COVID-19 ANTIGEN SELF-TEST

For Emergency Use Authorization (EUA) Only.

In vitro diagnostic use only.

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

Remove all contents in the box. Read instructions.

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 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.

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. 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 with symptoms of COVID-19 within the first 24 hours of symptom onset (to prevent transmission) and/or in any individual with symptoms of COVID-19 who is able to self-administer (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 this test device by the Director of the Center for Devices and Radiological Health under one or more of sections 564(a)(1) or 360bbb-3(b)(1) of the Act, unless the declaration is terminated or revoked sooner.

E-Mail: covidhometest-USA.dl@siemens-healthineers.com
Telephone: 1-833-933-2340

- Test setup is about 5 minutes. The result must be read at 15 minutes.
- You must follow the test directions carefully to get an accurate result.

NOTE:
If you have any questions about using the test or reading the results please call our customer help line.
Telephone: 1-833-633-2340
E-Mail: covidhometest-USA.dl@siemens-healthineers.com

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

SWAB BOTH NOSTRILS

Carefully insert swabs into one nostril about 1/2 to 1 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 using swabs for your child, please make sure to hold your child steady while swabbing.

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

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 1.

PLACE TUBE IN TUBE HOLDER

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

STEP 2.

OPEN TUBE

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

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.

STEP 3.

SWAB BOTH NOSTRILS

Carefully insert swabs into one nostril about 1/2 to 1 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 using swabs for your child, please make sure to hold your child steady while swabbing.

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 up and down 6 times.

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 15 minutes 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. Test results are read before 15 minutes or after 30 minutes. Below are examples for positive, negative and invalid test results. Use test materials should be thrown away after use.

COVID-19 POSITIVE
If the test device looks like the examples below, then protein from the virus that causes COVID-19 was detected - the sample was positive for 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 and/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 history such as symptoms and possible 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 both your first and second test results are negative, you may not have COVID-19.

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”.

INVALID
If the test device looks like the example 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 line next to “C”.

IF THE TEST IS POSITIVE
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. If you are experiencing COVID-19-like symptoms of fever, cough and/or shortness of breath you should 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 with the CLINITEST® Rapid COVID-19 Antigen Self-Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

IF THE TEST IS INVALID
At 15 minutes the line next to the “C” does not appear; even if any shade of color is present. “C” line is a negative test result if the test is invalid. In the test kit, the control line is present, a new swab, and a new test device is needed.

IF THE TEST IS NEGATIVE
A negative test result means that the virus that causes COVID-19 was not detected in your sample and it is very unlikely that you have COVID-19. If you do not have COVID-19 symptoms and your result is negative, you may not have COVID-19. If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/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 history such as symptoms and possible 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 both your first and second test results are negative, you may not have COVID-19.

IF THE TEST IS INVALID
If the test device looks like the example 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 line next to “C”.

IF THE TEST IS POSITIVE
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. If you are experiencing COVID-19-like symptoms of fever, cough and/or shortness of breath you should 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 with the CLINITEST® Rapid COVID-19 Antigen Self-Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.
• Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past.
• Test components are single-use. Do not re-use.
• Do not use on anyone under two years of age.
• This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
• Keep test kit and materials out of the reach of children and pets before and after use.
• If your first test is positive, this test will likely produce a false positive result. If your second test is positive, the test result may be inaccurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether another test is necessary and if you should continue isolating at home. There is a higher chance this test will give you a negative result when you have COVID-19.

Q: WHAT IS COVID-19?
A: COVID-19 is an acute respiratory infection caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by respiratory droplets from coughing, sneezing, or talking and by contact with infected surfaces or objects. The virus may also be spread by asymptomatic individuals, meaning those who are infected with the virus but have no symptoms.

Q: WHAT IS THE CLINITEST® Rapid COVID-19 Antigen Test?
A: The CLINITEST® Rapid COVID-19 Antigen Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with 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. This test is also authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

Q: HOW DOES THE CLINITEST® Rapid COVID-19 Antigen Test Work?
A: The CLINITEST® Rapid COVID-19 Antigen Test is a qualitative test. The test can detect the presence of the SARS-CoV-2 virus in nasal swabs from individuals who have symptoms of COVID-19. The test is not a quantitative test and cannot determine the amount of SARS-CoV-2 virus in a sample. The test results are based on the presence or absence of specific antigens associated with the SARS-CoV-2 virus. The presence of these antigens indicates the presence of the virus in the nasal swab.

Q: WHAT ARE THE LIMITATIONS OF THE CLINITEST® Rapid COVID-19 Antigen Test?
A: The test results are not always accurate, and the test should be repeated with a new test cassette if the first test is positive. If your first test is positive, you should be tested again with a new test cassette. If your second test is positive, you should seek medical attention immediately. If your first test is negative, you should be tested again with a new test cassette. If your second test is negative, you should continue to isolate at home and seek medical attention if your symptoms persist.

Q: WHAT ARE THE POTENTIAL RISKS OF THE CLINITEST® Rapid COVID-19 Antigen Test?
A: The CLINITEST® Rapid COVID-19 Antigen Test is intended for non-prescription self-use and/or, as applicable, for an adult lay user testing an aged 2 years or older. The CLINITEST® Rapid COVID-19 Antigen Test is not for use under the Food and Drug Administration’s Emergency Use Authorization.

Q: WHAT IS A CONTROL LINE?
A: A control line is a line that appears on the test strip if the test is performed correctly. The control line indicates that the test was performed correctly and that the test results are valid. If the control line does not appear, the test result is invalid.

Q: WHAT IS AN INVALID TEST RESULT?
A: An invalid test result means that the test was not able to tell you if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal sample and the test should be repeated using a new test cassette.

Q: WHAT IS SERIAL TESTING?
A: Serial testing is 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 earlier than a single test, especially when you do not have symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours (and no more than forty-eight hours) between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

Q: WHAT IS THE CLINITEST® Rapid COVID-19 Antigen Home Test?
A: The CLINITEST® Rapid COVID-19 Antigen Home Test is an FDA authorized molecular SARS-CoV-2 test, the CLINITEST Rapid COVID-19 Antigen Home Test correctly identified 86.5% of SARS-CoV-2 positive samples and 99.4% of SARS-CoV-2 negative samples. The performance of this COVID-19 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 circulating at the time and location of testing. The performance of this test may vary depending on the variants circulating including newly emerging strains of SARS-CoV-2 and their prevalence, which over time may change.

Q: WHERE CAN I FIND MORE INFORMATION ABOUT THE CLINITEST® Rapid COVID-19 Antigen Test?
A: For more information, please visit: www.healgen.com or www.clinitest.siemens-healthineers.com/us.

Q: WHAT ARE THE INGREDIENTS OF THE CLINITEST® Rapid COVID-19 Antigen Test?
A: The CLINITEST® Rapid COVID-19 Antigen Test contains the following ingredients: Sodium Azide (CAS: 26628-22-8) as an anti-microbial agent, and Phosphate Buffer Solution (CAS: 7052-14-6) for dilution of test components.
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 to suspect COVID-19
when tested twice over three days with at least 24 hours (and no more than 48 hours)
between tests.

*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 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.

**For Symbol Glossary, refer to Instructions for Use.**

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

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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 to suspect COVID-19 when tested twice over three days with at least 24 hours and no more than 48 hours between tests.

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.

*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.

www.clinitest.siemens-healthineers.com/us
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

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.

www.clinitest.siemens-healthineers.com/us
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.