For Emergency Use Authorization (EUA) Only.

An in vitro diagnostic only.

In vitro

For Emergency Use Authorization (EUA) only.

authorization is revoked sooner.

viruses or pathogens. The emergency use of this product is only authorized for

authorized only for the detection of proteins from SARS-CoV-2, not for any other

authorized by FDA under an Emergency Use Authorization. This product has been

within the first 7 days of symptom onset. Also for non-prescription home use

from individuals aged 14 years or older, or adult-collected anterior nasal swab

and each test pouch.

- You must follow the test directions carefully to get an accurate result.

- You should wear a face mask if swabbing others.

- Make sure hands are dry before starting.

- Wash your hands with soap and water for 30 seconds or use hand sanitizer.

- Do not use if test is expired

- Check expiration date of the test kit before use. Expiration date is printed on the

- Be sure to collect any nasal drainage that may be present on the swab.

- Make sure that you are rubbing

- Hold the tube straight up and down above the test device and gently squeeze to

- The result must be read at 15 minutes.

- All test materials must be at room temperature before use.

- Make sure there is a tight

- Take a tube tip from the kit and push it into the top of the tube.

- A new test device.

- If the test device looks like the examples below then the test

- If the test device is positive

- If the test is invalid

- If the test is negative

- If you test positive with the CLINITEST Rapid COVID-19 Antigen Self-Test you

- If you test negative with the CLINITEST Rapid COVID-19 Antigen Self-Test you

- A false negative or false positive results can occur if test results are read before

- COVID-19 negative

- COVID-19 positive

- Invalid

- If the test device looks like the examples below from the virus that

- This means you could possibly still have COVID-19 even

- It is important you work with

- Your healthcare provider will work with

- A very small chance that this test can give a positive result that is incorrect (a false positive).

- This means you could possibly still have COVID-19 even

- False negative or false positive results can occur if test results are read before

- Test setup is about 5 minutes. The result must be read at 15 minutes.

- If the test device looks like the examples below from the virus that causes COVID-19

- The tube will not be any color next to "T".

- You will only see

- You should self-isolate and seek follow-up care with your healthcare provider as

- It is very likely you have COVID-19

- The test device is invalid.

- False negative or false positive results can occur if test results are read before

- If the test device looks like the examples below from the virus that causes COVID-19

- For Emergency Use Authorization (EUA) only.

- A negative test result means that the protein from the virus that causes COVID-19

- The test device is invalid.

- Your healthcare provider will work with you to determine the best care for you based on your test results along with medical history and your symptoms.

- It is important to read your test result at 15 minutes or after 30 minutes.

- Adding too little or too much solution into the sample well may result in incorrect results.

- A new test device.

- If you DO NOT have COVID-19 symptoms and your result is negative, you should

- A new test device.

- If you test negative with the CLINITEST Rapid COVID-19 Antigen Self-Test you

- Test materials must be thrown away as household waste.

- Make sure that you are rubbing

- If you test positive with the CLINITEST Rapid COVID-19 Antigen Self-Test you

- Correct result

- Incorrect result

- The test device is invalid.

- False negative or false positive results can occur if test results are read before

- The test device is invalid.

- The test device is invalid.

- Your healthcare provider will help you understand the next steps you should take.

- If you DO NOT have COVID-19 symptoms and your result is negative, you should

- There is a very small chance that this test can give a positive result that is incorrect (a false positive).
If you have symptoms of COVID-19 that started within the last 7 days, 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.
- Testing for asymptomatic individuals may need to purchase additional tests to perform this serial (repeat) testing.

If your first and second test is positive, then proteomes from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

If your first or second test is 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.

Q: WHAT IS COVID-19?
A: COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, by both individuals with symptoms and asymptomatic individuals without symptoms and infected with SARS-CoV-2. The agents detected may not be the definite cause of disease. Individuals who test positive with CLINITEST® Rapid COVID-19 Antigen Test Self-Test should self-isolate and seek follow up care with your physician or healthcare provider as additional testing may be necessary.

Q: WHAT IF YOU TEST NEGATIVE?
A: If both your first and second tests 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.

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 may be used in a serial (repeat) testing.

Q: HOW IS SERIAL TESTING PERFORMED?
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 may be used in a serial (repeat) testing.

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- Possible test errors to collect and process the test results.
- 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 the test may help limit the spread of COVID-19 to your family and others in your community.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive test result means that antitgens from the virus that causes COVID-19 were detected and it is very likely you currently have COVID-19. If you should contact your local health department to stop the spread of the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. There is a chance that this test may give a false positive result that is wrong (false positive result). Follow-up care with your healthcare provider is necessary to determine how best to care for you and based on your test result(s) along with your medical history, and your symptoms.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive test result means that antitgens from the virus that causes COVID-19 were detected and it is very likely you currently have COVID-19. If you should contact your local health department to stop the spread of the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. There is a chance that this test may give a false positive result that is wrong (false positive result). Follow-up care with your healthcare provider is necessary to determine how best to care for you and based on your test result(s) along with your medical history, and your symptoms.

Q: WHAT MAY PRODUCE FALSE-NEGATIVE RESULTS?
A: False-negative results may occur when there is a low likelihood of COVID-19, such as in individuals without known exposure to COVID-19 or residing in communities with low prevalence of illness.

Q: WHAT IS THE RISK OF FALSE-NEGATIVE RESULTS?
A: The risk 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: WHAT IF YOU TEST NEGATIVE?
A: If the test cassette is open for an hour or longer, invalid test results may occur. 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 get a false negative result if you do not perform the test correctly or if the level of antigen from the virus causing COVID-19 is below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) 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.

Q: HOW COMPLETE IS THE CLINITEST® RAPID COVID-19 ANTIGEN SELF-TEST?
A: 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 detection performance of these variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variant circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which time frame.

Q: WHAT IS THE RISK OF FALSE-POSITIVE RESULTS?
A: False-positive results may occur when there is a low likelihood of COVID-19, such as in individuals without known exposure to COVID-19 or residing in communities with low prevalence of illness.

Q: WHAT IS THE RISK OF FALSE-POSITIVE RESULTS?
A: The risk of false-positive results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a positive result when you do not have COVID-19.

Q: WHAT IS A SYMPTOM OF COVID-19?
A: A clinical evaluation comparing the CLINITEST® Rapid COVID-19 Antigen Test Self-Test to an EUA authorized Molecular Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC. If the test cassette is open for an hour or longer, invalid test results may occur. 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 get a false negative result if you do not perform the test correctly or if the level of antigen from the virus causing COVID-19 is below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek care with your healthcare provider. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) 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 detection performance of these variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variant circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which time frame.
**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.

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.

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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.

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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 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.

**CLINITEST®**

Rapid COVID-19 Antigen Self-Test

Distributed by Siemens Healthineers

www.clinitest.siemens-healthineers.com/us
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

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.

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

Insert tube here
Inserte el tubo aquí

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

Distributed by Siemens Healthineers

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.

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