**QUICK REFERENCE INSTRUCTIONS**

**RAPID COVID-19 ANTIGEN SELF-TEST**

**CLINITEST®**

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 opened 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 swab tightly and wet the end of the swab and remove from pouch. Be careful not to touch the tip of the swab.

**STEP 4. PLACE SWAB IN TUBE**

Immediately take the test out of the tube holder and insert swab tip into the liquid inside the tube. Mix vigorously by rotating the swab at least 15 times on the bottom and sides of the tube.

**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 against 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 the first test result window, labeled as "C" (Control) and "T" (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.

<table>
<thead>
<tr>
<th>Pathology of Testing</th>
<th>Test Result</th>
<th>Test Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Symptoms</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
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<tr>
<td>Without Symptoms</td>
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<td>B</td>
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<tr>
<td>Negative</td>
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</tbody>
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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.

**STOPPING CRITERIA**

If at any time the test result is invalid, then the test result is invalid and the test should be repeated. You should seek follow-up care with your health care provider.

**COVID-19 POSITIVE**

If the test device looks like the example 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. Test results should be reported to 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. The test result is negative. Any mobile phone can be used to scan the "T" line. If the "C" line is also present then the test result is invalid.

**IF THE TEST IS POSITIVE**

Do not 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 healthcare provider, local health authority, or local physician or your local health authority immediately and adhere to the local guidelines regarding isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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

**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.

**NOTE**

Failure to swab properly may cause false negative results.

**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**

If at any time the test result is invalid, then the test result is invalid and the test should be repeated.

You may be instructed to self-isolate, call 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).

**IF THE TEST IS NEGATIVE**

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

- Test again in 48-72 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 test 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 in 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 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 no line next to "C" or "T".
INTENDED USE

The CLINITEST® Rapid COVID-19 Antigen 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 collection 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, as a potentially confirmatory test in individuals who have tested negative in a nucleic acid amplification test 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 the days with at least 48 hours between tests. The CLINITEST® Rapid COVID-19 Antigen Test does not differentiate between SARS-CoV-1 or SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleoprotein antigen, which is generally detectable in anterior nasal (nasal) 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 healthcare provider or physician.

Additional safety information for healthcare providers.

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

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. If you continue to have symptoms of COVID-19 after two tests with negative results, you may not have COVID-19, however you should follow up with a healthcare provider.

NOTE: 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 eyes, nose, or mouth to the solution in the tube.

The solution in the tube contains sodium azide 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.potentially.org or 1-800-222-1222)

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. 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 negative antigen test results are presumptive and confirmation with a molecular assay may be necessary. If your test result is negative and you have symptoms of COVID-19, you should seek additional testing 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 real usually 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 EUA go to: https://www.fda.gov/emergency-preparedness-and- response/medical-legislation/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 a false negative result 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 and may apply to you, please refer to the performance data in the Healthcare Provider Instructions for use (IFI), available at https://www.clintest.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 self-isolate 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 the sensitivity of COVID-19 antigen tests is 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 between tests for a total of three tests. If you have a negative result, it does not rule out your SARS-CoV-2 infection; however you should follow up with a healthcare provider.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: DOES THIS 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 test sample should be used to collect a new nasal specimen and the test should be run again, using a new test and tube.

Q: WHAT IS THE INTRICATE OF THE TEST?

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 test sample should be used to collect a new nasal specimen and the test should be run again, using a new test and tube.

LAKE HEALTHCARE PROVIDERS

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

Page 2
Rapid COVID-19 Antigen Self-Test

**CLINITEST®**

### Contents of the kit:

- 1 Test Device
- 1 Sterile Swab
- 1 Extraction Tube with Buffer and Tip
- 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.**

**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.**

Visit [https://labtest.recurohealth.com/signup/CLINITEST](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.

**For in vitro diagnostic use.**

**For Emergency Use Authorization (EUA) 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 diagnostic tests 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**

**www.clinitest.siemens-healthineers.com/us**
Rapid COVID-19 Antigen Self-Test

For in vitro diagnostic use.

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*For in vitro diagnostic use.

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

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

Distributed by Siemens Healthineers
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.

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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.

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

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