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PLEASE READ THE FOLLOWING COVID-19 TEST KIT NOTICE CAREFULLY BEFORE PURCHASING ANY TEST KITS (DEFINED BELOW). THE TEST KITS HAVE BEEN AUTHORIZED BY THE FDA UNDER AN EMERGENCY USE AUTHORIZATION (THE "EUA"). THE EUA AND THIS NOTICE CONTAINS VERY IMPORTANT INFORMATION ABOUT CUSTOMER'S OBLIGATIONS, INCLUDING WITH RESPECT TO THE CLINICAL ADMINISTRATION OF THE TEST KITS.

FACT SHEET FOR HEALTHCARE PROFESSIONALS

Siemens Healthineers **December 29, 2021**

CLINITEST Rapid COVID-19 Antigen Self-Test

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the CLINITEST Rapid-COVID-19 Antigen Self-Test.

The CLINITEST® Rapid COVID-19 Antigen Self-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 (nares) 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 (nares) 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 (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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.

All individuals who use this assay are required to receive and should carefully review the CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions before they use the test.

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

The CLINITEST® Rapid COVID-19 Antigen Self-Test is authorized for non-prescription home use with self-collected anterior nasal (nares) 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 (nares) 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 (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The CLINITEST Rapid COVID-19 Antigen Self-Test is authorized for non-prescription home use with

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.
- The CLINITEST Rapid COVID-19 Antigen Self-Test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.
- The CLINITEST Rapid COVID-19 Antigen Self-Test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with the virus that causes COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (*see links provided in "*Where can I go for updates and more information?*" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and therefore the patient is infected with the virus and presumed to be contagious. COVID-19 test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The CLINITEST Rapid COVID-19 Antigen Self-Test has been designed to minimize the likelihood of false positive test results. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potential COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All healthcare providers must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result with this test means that SARS-CoV-2 antigens were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent

exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings (Interim Guidance) (see links provided in "*Where can I go for updates and more information?*" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November and December 2021. The clinical performance has not been established in 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.

What do I need to know about Serial Testing in Asymptomatic Individuals?
In asymptomatic individuals, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risk of false negative results. Additional clinical studies are underway to assess the performance of rapid antigen tests when used with serial testing. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 antigen is present, but does not rule out coinfection with other pathogens.

Additional confirmatory testing with a molecular test for negative results may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in "*Where can I go for updates and more information?*" section).

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative antigen

tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to fact sheet for individuals and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

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Revision Date: 2021-12-29 B22352-01 Rev. A

SIEMENS Healthineers

CLINITEST®

RAPID COVID-19 ANTIGEN SELF-TEST

Health Care Provider Instructions for Use (IFU)

For Emergency Use Authorization (EUA) Only.

***In vitro* diagnostic use only.**

Revision Date: 2021-12-29, B22348-01 Rev. A

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1. INTENDED USE

The CLINITEST® Rapid COVID-19 Antigen Self-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 (nares) 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 (nares) 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 (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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.

The CLINITEST® Rapid COVID-19 Antigen Self-Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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. The agent detected may not be the definite cause of disease. Individuals who test positive with 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.

Negative results should be treated as 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 decisions. 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 use under the Food and Drug Administration's Emergency Use Authorization.

2. EXPLANATION OF THE TEST

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The CLINITEST Rapid COVID-19 Antigen Self-Test is a rapid, qualitative immunochromatographic assay for the determination of the presence of SARS-CoV-2 antigens in direct human anterior nasal swab specimens. The test strip is composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 nucleocapsid antigen is present in the sample, a complex forms between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T).

3. MATERIALS PROVIDED

Contents of the 1 Test Kit:

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

Contents of the 5 Test Kit:

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

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

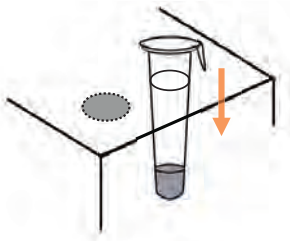
5. QUALITY CONTROL

Each CLINITEST Rapid COVID-19 Antigen Self-Test has a built-in internal procedural control. The reddish-purple line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. A distinct visible pink/red Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid and a new test should be performed. External run controls are not required to use the CLINITEST Rapid COVID-19 Self-Test in a home setting.

6. TEST PROCEDURES

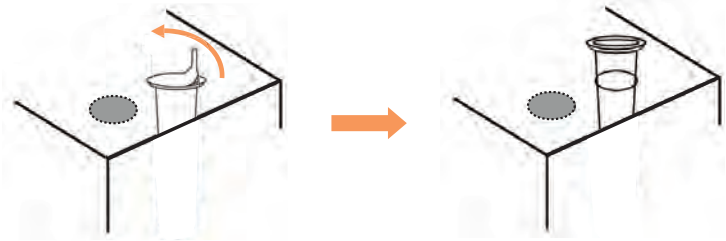
Step 1. PLACE TUBE IN TUBE HOLDER

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



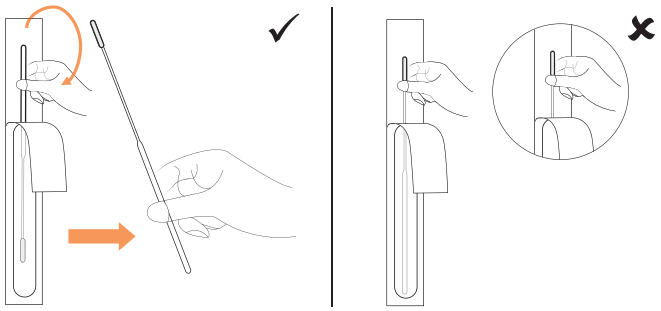
Step 2. OPEN TUBE

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

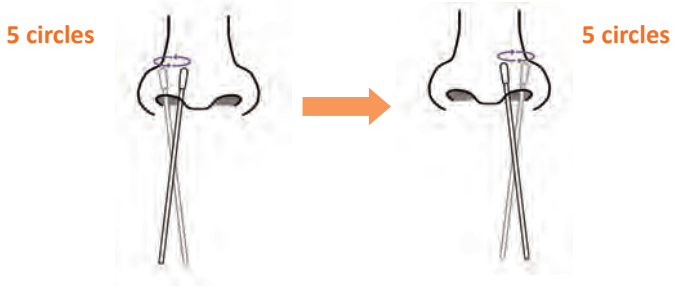


Step 3. OPEN SWAB

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. Do NOT touch the swab end and only handle by the stick end.



SWAB BOTH NOSTRILS



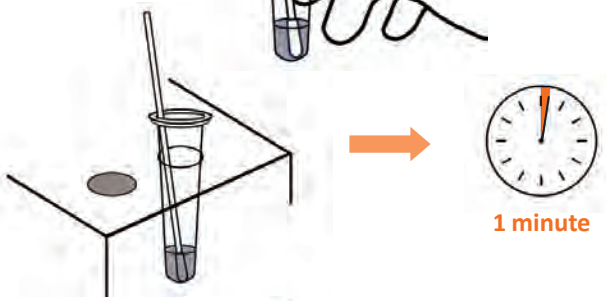
Carefully insert swab tip into one nostril about **1/2 to 3/4 of an inch deep.** Do not insert the swab any further if you feel any resistance. Rub the insides of the nostril in a complete circle at least **5 times.** Make sure that you are rubbing the insides of the nostril. Do not simply roll the swab. 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 with the SAME swab.**

NOTE: *If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold 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



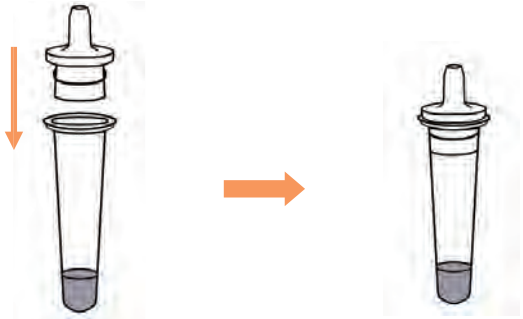
Place the tube back into the tube holder. Keep the swab inside of the tube. **Start timer for 1 minute.**

NOTE: *Do not remove swab before 1 minute has elapsed. Early removal of the swab may cause false negative results.*

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.

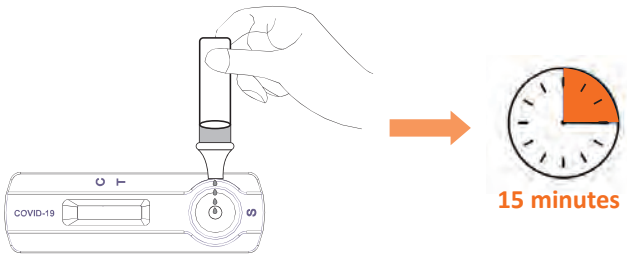
NOTE: *Please ensure the tip is securely fitted before proceeding.*

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.

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

7. INTERPRETATION OF THE RESULTS

COVID-19 POSITIVE

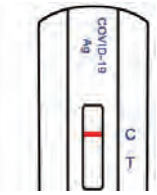
If the test device looks like the examples below, then protein from the virus that causes COVID-19 **was detected** in the sample. The test is positive if there are **two pink/red lines present, one at the Control "C" line and one at the Test "T" line.** Look very closely for line next to "T". This line 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 i**t is very likely you have COVID-19** and it 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 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.

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

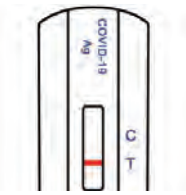
A **negative test result** means that protein from the virus that causes **COVID-19 was not detected** in your sample. If you took this test while you have symptoms, a negative test result usually means that your current illness was not caused by COVID-19. However, it is possible for this test to give 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 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 an second test results are negative, you may not have COVID-19.

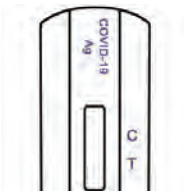
INVALID

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.





8. STORAGE AND STABILITY

- CLINITEST Rapid COVID-19 Antigen Self-Test should be stored between 2 to 30 °C (35.6 to 86 °F).
- Kit components in the CLINITEST Rapid COVID-19 Self-Test are stable until the expiration date printed on the label.
- The Test Device must remain in the sealed foil pouch until use.

9. WARNINGS & PRECAUTIONS

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.

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- 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.
- Follow directions for use. Operation of this test should not deviate from the provided instructions. If the the test instructions are not followed, the test results should NOT be interpreted. The test should then be repeated with a new cassette.
- 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.
- You should wear a face mask if swabbing others.
- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- Children aged 2 to 13 years of age 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 test cassette pouch.
- 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.
- 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. If more than 30 minutes has elapsed, do not interpret the test results 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.poison.org/contact-us 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	1.43×10^5 $TCID_{50}$/mL
Triton/9002-93-1	Acute Tox. 4 (Oral), H302	1.43×10^5 $TCID_{50}$/mL

10. LIMITATIONS

1) 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.
2) Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
3) Do not use this test for individuals under [2] of age. The swab included in the kit is designed for collection of samples from adults and additional safety measures are needed for safe collection in children under 14 years of age.
4) 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 a COVID-19.
5) This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.

6) The amount of antigen in a sample may decrease as the duration of illness increases.

7) A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.

8) The performance of the CLINITEST Rapid COVID-19 Antigen Self-Test was evaluated using the procedures provided in these Instructions for Use (IFU) only. Modifications to these procedures may alter the performance of the test.

9) Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over three days with at least 24 but not more than 48 hours between tests has not been determined.

10) This test detects both viable (live) and non-viable SARS-CoV-2. Test performance depends on the amount of viral antigen in the sample and may or may not correlate with viral culture results performed on the same sample.

11) Test results must be evaluated in conjunction with other clinical data available to the physician.

12) Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

13) Positive test results do not rule out co-infections with other pathogens.

14) Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

15) Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

16) Negative results should be treated as presumptive and confirmed with a molecular assay for clinical management, if necessary.

17) The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2021 to December 2021. The clinical performance has not been established in 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.

11. PERFORMANCE CHARACTERISTICS

a. Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the CLINITEST Rapid COVID-19 Antigen Self-Test was determined using serial dilutions of the gamma irradiated SARS-CoV-2 (USA-WA1/2020). A 50-µL sample of gamma irradiated SARS-CoV-2 diluted in PNW was pipetted onto the dry swab and allowed to absorb for at least 10 seconds. The swab was then transferred to a pre-filled vial of buffer and mixed for a minimum of swab six (6) times on the bottom and sides of the tube and remained in the tube for 1 minute as described in the IFU. Following addition and mixing of the PNW sample, four (4) drops were added to the sample well of each device as described in the IFU. Test results were read visually at 15 minutes. LoD confirmation testing was performed by testing twenty (20) replicates at the preliminary (1X) LoD concentration. The confirmed LoD for the CLINITEST Rapid COVID-19 Antigen Self-Test was 7.0×10^3 $TCID_{50}$/mL.

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of heat-inactivated clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Compared to an EUA authorized RT-PCR method, the CLINITEST Rapid COVID-19 Antigen Self-Test detected 100% of heat-inactivated Omicron samples at a Ct-value of 23.6 (n=2) and 100% of live virus Omicron samples at a Ct-value of 21.6 (n=5). Omicron dilutions at lower viral concentrations (Ct-values greater than 23.6 for heat-inactivated virus and greater than 21.6 for live virus) were not detected by the CLINITEST Rapid COVID-19 Antigen Self-Test in this study. Performance in the detection of SARS-CoV-2 Omicron variant was also demonstrated compared to the SARS-CoV-2 B.1.2 and Delta variants.

SARS-CoV-2 Variant Detection in Heat-Inactivated and Live Samples			
CLINITEST COVID-19 Ag Test	**B.1.2 (HI)**	**Delta (HI)**	**Omicron (HI)**
	25.3 (n=2)	22.1 (n=2)	23.6 (n=2)
	B.1.2 (Live)	**Delta (Live)**	**Omicron (Live)**
	26.8 (n=2) Lot 1	25.6 (n=2) Lot 1	21.6 (n=5)
	26.8 (n=2) Lot 2	24.1 (n=2) Lot 2	

(HI: Heat-Inactivated)

	Heat-Inactivated Samples		Live Samples	
Sample	**Average N2 Ct (n=3)**	**Percent Positive (n=2)**	**Average N2 Ct (n=3)**	**Percent Positive (n=5)**
Omicron- Dilution 1	21.2	100%	19.3	100%
Omicron-Dilution 2	22.4	100%	19.8	100%
Omicron-Dilution 3	23.6	100%	20.9	100%
Omicron- Dilution 4	24.6	0%	21.6	100%
Omicron-Dilution 5	25.8	0%	22.9	0%
Omicron-Dilution 6	27.0	0%	23.9	0%
Omicron-Dilution 7	28.1	0%	24.9	0%
Omicron-Dilution 8	29.5	0%	26.0	0%
Omicron-Dilution 9	30.5	0%	26.9	0%
Omicron-Dilution 10	31.7	0%	27.7	0%
Omicron-Dilution 11	N/A	N/A	28.8	0%

b. High-dose hook effect

The CLINITEST Rapid COVID-19 Antigen Self-Test was tested up to 2.86 x 10^6 $TCID_{50}$/mL of gamma irradiated SARS-CoV-2 (USA-WA1/2020) and no high-dose hook effect was observed.

c. Endogenous Interfering Substances

The CLINITEST Rapid COVID-19 Antigen Self-Test was evaluated for performance in the presence of potentially interfering substances that might be present in a respiratory specimen. Negative specimens were evaluated in triplicate to confirm that the potentially interfering substances were not cross-reactive with the test. Specimens containing 3x LoD SARS-CoV-2 (1x LoD is 7.0 x 10^3 $TCID_{50}$/mL) were also evaluated in the presence of interfering substances in triplicate to confirm that SARS-CoV-2 could still be detected. Interfering substances testing was performed using a panel of endogenous and exogenous substances tested at concentrations recommended by the FDA. At the concentrations tested none of the substances caused a false-positive test result in unspiked samples or interfered with the detection of a true positive test result in 3X LoD spiked samples.

Substance	Concentration
Whole blood	4%
Mucin (porcine stomach, type II)	0.50%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
Nasal Drops (Phenylephrine)	15% v/v

Substance	Concentration
Mupirocin	10 mg/mL
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Fluticasone Propionate	5% v/v
Body and Hand Lotion	0.5% w/v
Body Lotion with 1.2% dimethicone	0.5% w/v

Nasal Spray (Oxymetazoline)	15% v/v
Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	10% v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL

Hand Lotion	5% w/v
Hand Sanitizer with Aloe, 69% ethyl alcohol	5% w/v
Hand Sanitizer Cream Lotion	15% v/v
Hand Sanitizer, 85% ethanol, fast drying	15% v/v
Hand soap liquid gel	10% v/v

d. Analytical Specificity: Cross-reactivity and Microbial interference

Cross-reactivity and interference studies were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen of the nasal cavity. Each organism and virus were tested in both the absence and presence of inactivated SARS-CoV-2 (SARS-CoV-2 isolate USA-WA1/2020). All testing samples were prepared in the negative nasal wash. No cross-reactivity was observed for any of the organisms tested, except for SARS-coronavirus which exhibited cross-reactivity when tested at 1.58×10^4 $TCID_{50}$/mL (Table 8). A titration of SARS-CoV was performed to find the concentration at which cross reactivity was no longer observed. Cross reactivity was no longer observed for SARS-CoV at 1.58×10^2 $TCID_{50}$/mL. These results are not unexpected in that the CLINITEST Rapid COVID-19 Antigen Self-Test targets the nucleocapsid protein which is present on both the SARS-CoV and SARS-CoV-2 viruses.

ID	Organism	Concentration Tested for Cross Reactivity	Concentration Tested for Microbial Interference
229E	Human coronavirus 229E	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
OC43	Human coronavirus OC43	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
NL63	Human coronavirus NL63	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
SARS	SARS-coronavirus	1.58×10^4 $TCID_{50}$/mL	N/A
SARS1:1000	SARS-Coronavirus	1.58×10^2 $TCID_{50}$/mL	1.58×10^2 $TCID_{50}$/mL
MERS	MERS-coronavirus	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
AV1	Adenovirus	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
hMPV	Human metapneumovirus 4 Type B2	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
P1	Parainfluenza virus 1	3.60×10^5 $TCID_{50}$/mL	3.60×10^5 $TCID_{50}$/mL
P2	Parainfluenza virus 2	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
P3	Parainfluenza virus 3	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
P4	Parainfluenza virus 4b	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
FluA	Influenza A	1.43×10^5 $CEID_{50}$/mL	1.43×10^5 $CEID_{50}$/mL
FluB	Influenza B	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
EV68	Enterovirus 68	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
RSV	Respiratory syncytial virus	1.43×10^5 pfu/mL	1.43×10^5 pfu/mL
RV	Rhinovirus	1.43×10^5 $TCID_{50}$/mL	1.43×10^5 $TCID_{50}$/mL
HI	*Haemophilus influenzae*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
SPN	*Streptococcus pneumonia*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
SPY	*Streptococcus pyogenes*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
CA	*Candida albicans*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
CA	*Candida albicans (Kansas City Test)*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
BP	*Bordetella pertussis*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
MP	*Mycoplasma pneumonia*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
CP	*Chlamydia pneumoniae*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
LP	*Legionella pneumophila*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
MT	*Mycobacterium tuberculosis*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
PC	*Pneumocystis carinii*	1.25×10^6 nuclei/mL	1.25×10^6 nuclei/mL
PJ	*P. jiroveci-S. cerevisiae*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
SA	*Staphylococcus aureus* subsp. *aureus*	1.00×10^6 cfu/mL	1.00×10^6 cfu/mL
SE	*Staphylococcus epidermidis*	4.66×10^5 cfu/mL	2.33×10^5 cfu/mL
PNM	Pooled Negative Matrix	N/A	N/A

e. Flex Study

A robust use of CLINITEST Rapid COVID-19 Antigen Self-Test was demonstrated by six (6) flex studies as follows;

1) Non-level positioning of Test Device
2) Varying the Extraction Solution volume
3) Varying the swab rotation number
4) Sample volume variability
5) Result reading time variability
6) Temperature and humidity

12. CLINICAL EVALUATION

A prospective study was completed at five (5) sites in the United States for clinical validation of the CLINITEST Rapid COVID-19 Antigen Self-Test for the detection of the SARS-CoV-2 in subject-collected anterior nasal (AN) swab samples. The study evaluated the investigational test's performance in symptomatic individuals (those suspected of COVID-19). A total of 268 symptomatic subjects were enrolled and each were currently experiencing symptoms associated with COVID-19, **within 7 days of symptom onset**. Each enrolled subject either self-collected one sample from their anterior nasal passages (from both nostrils), or had one sample collected from him/her by another individual. Each subject then had a mid-turbinate sample (from both nostrils) collected from him/her by one of the study personnel. Test results from the CLINITEST Rapid COVID-19 Antigen Self-Test Test (candidate test) were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. As shown, the positive percent agreement (PPA) is 86.5% and the negative percent agreement (NPA) is 99.3% with the 95% confidence interval bounds of 79.6% to 91.3% for the PPA and 95.9% to 100% for the NPA, respectively.

CLINITEST Rapid COVID-19 Antigen Self-Test	RT-PCR Positives	RT-PCR Negatives	Total
Positives	115	1	116
Negatives	18	134	152
Total	**133**	**135**	**268**
Positive Percent Agreement (PPA) = (115/133) x 100% = 86.5% (95% CI = 79.6 to 91.3%)			
Negative Percent Agreement (NPA) = (134/135) x 100% = 99.3% (95% CI = 95.9 to 100.0%)			

Age and Gender Distribution and positive Rate of Symptomatic Subjects Within First 7 Days of Symptom Onset				
Subject Age	**Female**	**Male**	**Positives**	**% Positivity Rate**
<14 years of age	**10**	**15**	3	12.0%
14-24 years of age	**22**	**13**	20	57.1%
>24-64 years of age	**102**	**82**	94	51.1%
≥65 years of age	**13**	**11**	16	66.7%
Total	**147**	**121**	**133**	**49.6%**

Positive Results Broken Down by Days Since Symptom Onset				
Days Post Symptom Onset	**Number of Samples Tested**	**Confirmed Positives**	**RT-PCR Positives**	**PPA**
0	5	2	2	100.00%
1	45	20	24	83.33%
2	77	30	31	96.77%
3	54	26	27	96.30%
4	33	13	16	81.25%
5	28	10	14	71.43%
6	13	7	8	87.50%
7	13	7	11	63.64%
Total	**268**	**115**	**133**	**86.47%**

13. TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at (833) 933-2340
(Available Hours: Mon. to Fri.: 9 a.m. – 5 p.m. PST) or covidhometest-USA.dl@siemens-healthineers.com.

Test system problems may also be reported to the FDA using the MedWatch reporting system
(phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

14. ORDERING AND CONTACT INFORMATION

Siemens Healthineers

covidhometest-USA.dl@siemens-healthineers.com

www.clinitest.siemens-healthineers.com/us

15. INTERNATIONAL SYMBOL USAGE

You may see one or more of these symbols on the labelling/packaging of this product:

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

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

SIEMENS Healthineers

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. 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 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.
- 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.

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

www.clinitest.siemens-healthineers.com/us

WASH HANDS

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

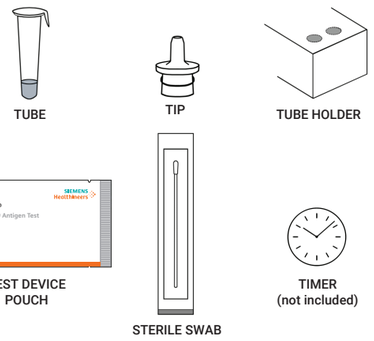
GATHER MATERIALS

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.

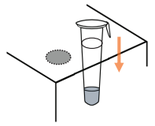
Do not start Step 1 until you are ready to begin the test.



STEP 1.

PLACE TUBE IN TUBE HOLDER

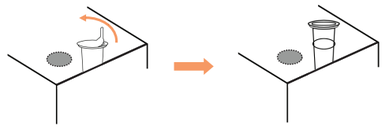
Find tube holder shown on the back of the box. Push tube through outlined hole.



STEP 2.

OPEN TUBE

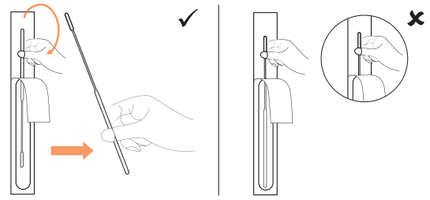
Remove the seal from the tube. Avoid spilling the liquid. Make sure the tube is standing up straight.



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.

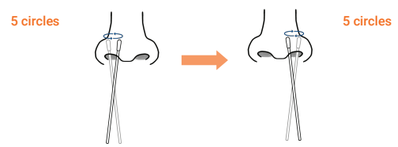


SWAB BOTH NOSTRILS

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.*

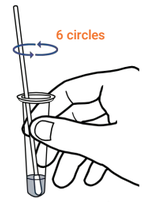
NOTE: *Failure to swab properly may cause false negative results.*



STEP 4.

PLACE SWAB IN TUBE

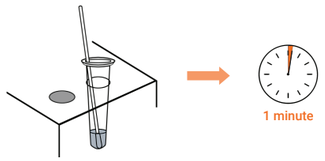
Remove the swab from your nostril. Immediately take the tube out of the tube holder and insert swab tip **into the liquid inside the tube**. Mix vigorously by rolling the swab tip **at least 6 times** on the bottom and sides of the tube.



PLACE TUBE IN TUBE HOLDER

Place the tube back into the tube holder. Keep the swab inside of the tube.

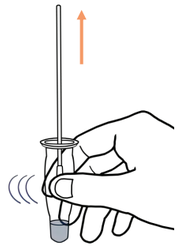
Start timer for 1 minute.



REMOVE SWAB FROM TUBE

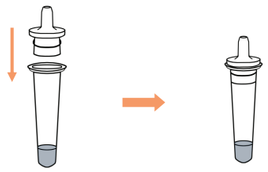
After 1 minute take the tube out of the tube holder.

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.**

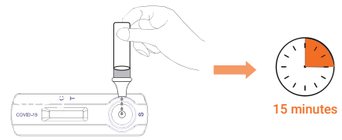
ADD 4 DROPS

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.

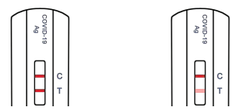
READ TEST RESULT

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.

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.

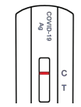


IF THE TEST IS POSITIVE

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 it 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 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.

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

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 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 an second test results are negative, you may not have COVID-19.

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: www.cdc.gov/COVID19
- For detailed instructions, please visit: www.clinitest.siemens-healthineers.com/us

Intended Use

The CLINITEST® Rapid COVID-19 Antigen Self-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 (nares) 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 (nares) 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 (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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.

The CLINITEST® Rapid COVID-19 Antigen Self-Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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. The agent detected may not be the definite cause of disease. Individuals who test positive with 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.

Negative results should be treated as 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 decisions. 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 use under the Food and Drug Administration's Emergency Use Authorization.

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.

- Follow directions for use.
- 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.
- You should wear a face mask if swabbing others.
- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- Children aged 2 to 13 years of age 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 test cassette pouch.
- 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.
- 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.poison.org/contact-us 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%

Serial Testing Information and Limitations

- 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. 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.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- If your first or second test 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 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.

Frequently Asked Questions

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, both by individuals with symptoms of COVID-19 infection and by infected people without 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-testing/symptoms.html.

Q: WILL THIS TEST HURT?
A: No, the nasal swab is not sharp, 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?
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.

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 (i.e. testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

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. 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: A clinical evaluation comparing the CLINITEST® Rapid COVID-19 Antigen Self-Test to an EUA authorized Molecular SARS-COV-2 test was conducted. For clinical evaluation results please use the following QR code or web address.

www.clinitest.siemens-healthineers.com/us

The performance of this test is still being studied 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 detected and it is very likely you currently have COVID-19. If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. There is a chance that this test can give a positive result that is wrong (a false positive result). Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. If you do not have symptoms and you receive a second negative result 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 get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was 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 follow up 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 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 SARSCoV-2 and their prevalence, which change over time.

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

SIEMENS Healthineers

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

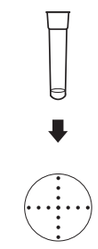
Revision Date: 2021-12-15, B22347-01 Rev. A

- 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.

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.



Insert tube here
Inserte el tubo aquí

LOT

REF GCCOV-502a-H1US
(11561587)

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

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 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.

Insert tube here
Inserte el tubo aquí

Insert tube here
Inserte el tubo aquí

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.

LOT

REF GCCOV-502a-H5US
(11556712)

00816490025740

www.clinitest.siemens-healthineers.com/us

B01601-01

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

Σ 5

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

December 29, 2021

Robert Zinck, M.S.
Regulatory Affairs Manager
Siemens Healthineers
511 Benedict Avenue
Tarrytown, NY 10591

Device:	CLINITEST Rapid COVID-19 Antigen Self-Test
EUA Number:	EUA210639
Company:	Siemens Healthineers
Indication:	Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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.

Dear Mr. Zinck:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Siemens Healthineers.
[2] For ease of reference, this letter will use the term "your product" to refer to the CLINITEST Rapid COVID-19 Antigen Self-Test used for the indication identified above.

emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details
Your product 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 (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

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[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) 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 (nares) swab samples from individuals aged 14 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, 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. The CLINITEST Rapid COVID-19 Antigen Self-Test does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares) swabs 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 coinfection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with your product should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as 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 decisions. 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 the Centers for Disease Control and Prevention.

Your product is performed using anterior nasal (nares) swab samples from individuals aged 2 years and older. When using your product, the individual places the tube in the tube holder and

removes the seal from the tube. The swab is then removed from its packaging and the individual collects an anterior nasal swab sample by inserting the swab into the nostril and rubbing the insides of the nostril in a complete circle at least 5 times, taking at least 15 seconds to collect the specimen (including any nasal drainage) before repeating the process in the second nostril. The swab is then immediately inserted into the liquid inside the tube. The tube is mixed vigorously by rolling the swab tip at least 6 times on the bottom and sides of the tube. The tube is placed back in the tube holder (with the swab in place) and allowed to sit for one minute. After one minute the swab is removed from the tube while squeezing the swab tip from outside the tube to release as much liquid from the swab as possible. The swab is discarded and the tube capped with the tube tip. The test device is removed from the pouch and placed on a flat surface. Four drops of the solution are applied into the sample well of the test device. The individual then starts the 15 minute timer. If the extracted specimen contains SARS-CoV-2 antigens, a pink/red-colored T (Test) Line, along with a pink/red-colored C (Control) Line will appear on the test device indicating a positive result. This control line indicates that the test was performed correctly. Test results are interpreted visually after 15-20 minutes based on the presence or absence of visually detectable colored lines at the control line (C) and/or test line (T). Test results should not be read after 30 minutes.

The CLINITEST Rapid COVID-19 Antigen Self-Test includes the following materials or other authorized materials (as may be requested under Condition L. below): test device, sterile swab, extraction tube with buffer and tip, tube holder, and "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI).

Your product includes an internal control line (C) that must generate the expected result for a test to be considered valid, as outlined in the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" and the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI).

The labeling entitled "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)", and the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI), (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the two CLINITEST Rapid COVID-19 Antigen Self-Test box labels (1-, or 5-pack) and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers:[5] Siemens Healthineers - CLINITEST Rapid COVID-19 Antigen Self-Test

The above described product when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

[5] Note that the information typically found in a Fact Sheet for Individuals is contained in the QRI that will be available to end users as set forth in the Conditions of Authorization (Section IV).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Siemens Healthineers (You), and Authorized Distributor(s)[6]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any

[6] "Authorized Distributor(s)" are identified by you, Siemens Healthineers in your EUA submission as an entity allowed to distribute your product.

available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" for your product in the shipped kit using the CLINITEST Rapid COVID-19 Antigen Self-Test box labels (1-, or 5-pack) and make the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)", and the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" available electronically on your website(s).

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributors using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Siemens Healthineers (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" and the Fact Sheet for Healthcare Providers electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "CLINITEST Rapid COVID-19 Antigen Self-Test Healthcare Provider Instructions for Use (IFU)" and Fact Sheet for Healthcare Providers in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[7] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study

[7] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. You must submit to FDA a summary report within 90 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the "CLINITEST Rapid COVID-19 Antigen Self-Test Quick Reference Instructions" (QRI) along with any proposed corrective action, as necessary.

T. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

V. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your test, if requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

W. You must further evaluate the clinical performance of your product in pediatric individuals <14 years of age, an FDA agreed upon post authorization clinical evaluation study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling

updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

X. You must develop a mobile phone application or website to further facilitate results reporting by the individual using your product and submit to FDA such application or website within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

Conditions Related to Printed Materials, Advertising and Promotion

Y. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Z. No descriptive printed matter, including advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

AA. All descriptive printed matter, including advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
- 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.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure