

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.

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1. **INTENDED USE**

The CLINITEST® Rapid COVID-19 Antigen Self-Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

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

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease.

Individuals who test positive with the CLINITEST® Rapid COVID-19 Antigen Self-Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks.

Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. 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 in a non-laboratory setting. The CLINITEST® Rapid COVID-19 Antigen Self-Test is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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 2 Test Kit:

- 2 Test Devices
- 2 Sterile Swabs
- 2 Extraction Tubes with Buffer and Tips
- 1 Tube Holder
- Instructions for Use

Contents of the 4 Test Kit:

- 4 Test Devices
- 4 Sterile Swabs
- 4 Extraction Tubes with Buffer and Tips
- 1 Tube Holder
- Instructions for Use

Contents of the 5 Test Kit:

- 5 Test Devices
- 5 Sterile Swabs
- 5 Extraction Tubes with Buffer and Tips
- 1 Tube Holder
- Instructions for Use

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Optional Recuro Health web app for reporting
- iPhone or Android phone for using the optional web app (Requires modern mobile web browser e.g. Chrome, Safari)

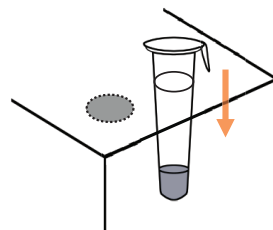
5. QUALITY CONTROL

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

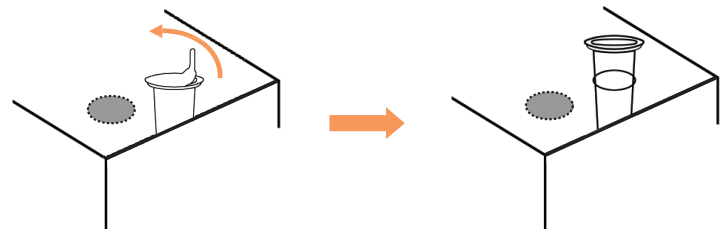
Step 1. PLACE TUBE IN TUBE HOLDER

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



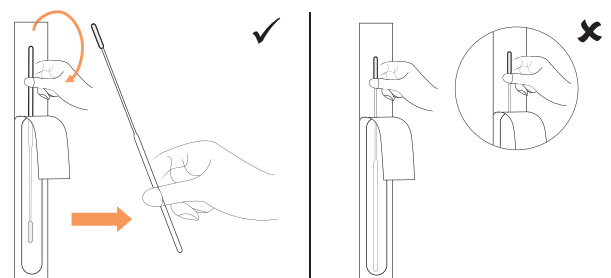
Step 2. OPEN TUBE

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



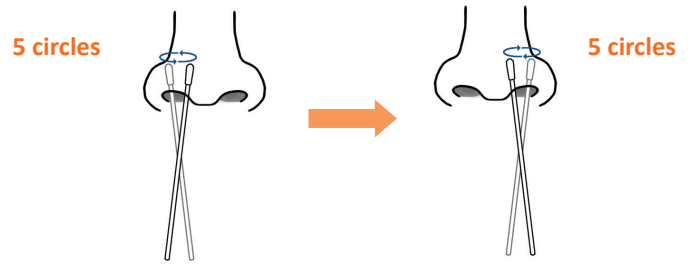
Step 3. OPEN SWAB

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

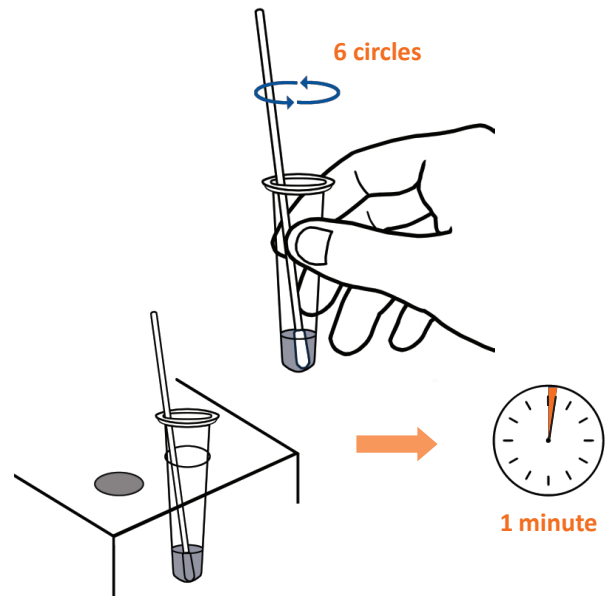
Carefully insert swab tip into one nostril about **1/2 to 3/4 of an inch deep**. Do not insert the swab any further if you feel any resistance. Rub the insides of the nostril in a complete circle at least **5 times**. Make sure that you are rubbing the insides of the nostril. Do not simply roll the swab.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



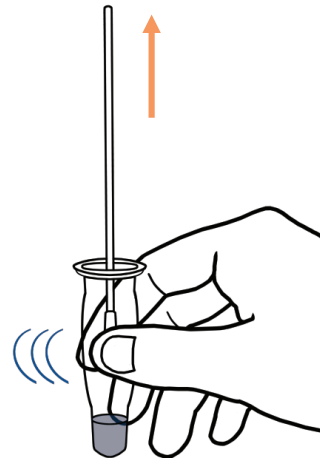
PLACE TUBE IN TUBE HOLDER

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

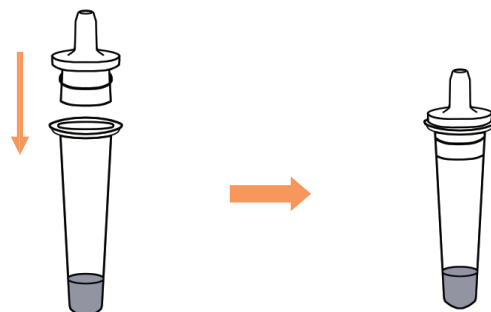
After 1 minute take the tube out of the tube holder. As you remove the swab from the tube, **squeeze swab tip several times** from outside of the tube. Try to release as much liquid from the swab as possible. Dispose the swab in the trash.



INSERT TIP

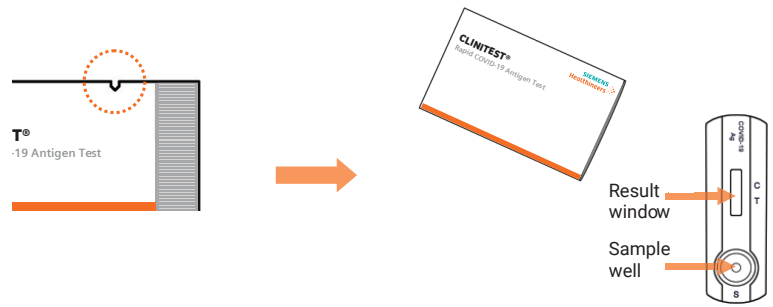
Take a tube tip from the kit and push it into the top of the tube. Make sure there is a tight fit.

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



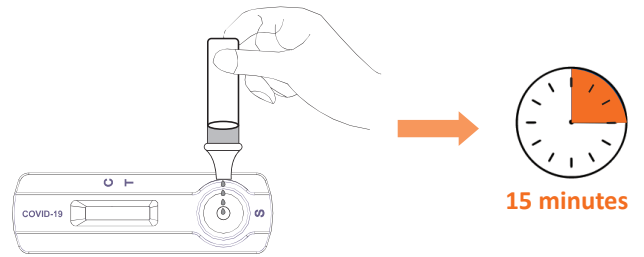
Step 5. OPEN TEST DEVICE

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

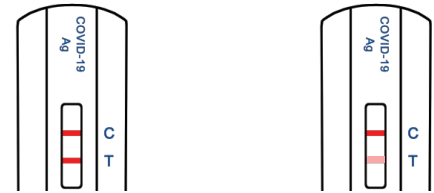
Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

| Status on first day of Testing | First Result Day 1 | Second Result Day 3 | Third Result Day 5 | Interpretation |
|--------------------------------|--------------------|---------------------|--------------------|-----------------------|
| With Symptoms | Positive | N/A | N/A | Positive for COVID-19 |
| | Negative | Positive | N/A | Positive for COVID-19 |
| | Negative | Negative | N/A | Negative for COVID-19 |
| Without Symptoms | Positive | N/A | N/A | Positive for COVID-19 |
| | Negative | Positive | N/A | Positive for COVID-19 |
| | Negative | Negative | Positive | Positive for COVID-19 |
| | Negative | Negative | Negative | Negative for COVID-19 |

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.

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.



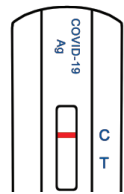
Repeat testing does not need to be performed if patients have a positive result at any time.

IF THE TEST IS POSITIVE

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient’s doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). 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 the CLINITEST Rapid COVID-19 Antigen Self-Test should self-isolate and seek follow up care with their physician or healthcare provider as 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.

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

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

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, 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. 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.

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

9. WARNINGS & PRECAUTIONS

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- 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.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- This test is read visually. Users with impaired vision or color-impaired vision may not be able to read the test.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older.
- 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 kit box.
- 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.
- Once opened, the test card should be used within 60 minutes.
- 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.poisonhelp.org> 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% |

- For more information on EUAs please visit: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization>
- For the most up to date information on COVID-19, please visit: <http://www.cdc.gov/COVID19>

10. LIMITATIONS

- 1) The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2021 – February 2022. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- 2) 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.
- 3) There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- 4) This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- 5) The amount of antigen in a sample may decrease as the duration of illness increases.
- 6) 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.
- 7) 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.
- 8) 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.
- 9) Test results must be evaluated in conjunction with other clinical data available to the physician.
- 10) Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result. Incorrect test results may occur if a specimen is incorrectly collected or handled.
- 11) If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.

- 12) Positive test results do not rule out co-infections with other pathogens.
- 13) 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.
- 14) Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- 15) Negative results should be treated as presumptive and confirmed with a molecular assay for clinical management, if necessary.
- 16) 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 TCID₅₀/mL. Based upon the testing procedure for this study the LoD of 7.0×10^3 TCID₅₀/mL equates to 350 TCID₅₀/Swab.

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)

| Sample | Heat-Inactivated Samples | | Live Samples | |
|---------------------|--------------------------|------------------------|---------------------|------------------------|
| | 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 2.86×10^6 TCID₅₀/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 7.0×10^3 TCID₅₀/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 |
| 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 |

| 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 |
| 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 TCID₅₀/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 TCID₅₀/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 | <i>Haemophilus influenzae</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| SPN | <i>Streptococcus pneumoniae</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| SPY | <i>Streptococcus pyogenes</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| CA | <i>Candida albicans</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| CA | <i>Candida albicans</i> (Kansas City Test) | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| BP | <i>Bordetella pertussis</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| MP | <i>Mycoplasma pneumoniae</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| CP | <i>Chlamydia pneumoniae</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| LP | <i>Legionella pneumophila</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| MT | <i>Mycobacterium tuberculosis</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| PC | <i>Pneumocystis carinii</i> | 1.25×10^6 nuclei/mL | 1.25×10^6 nuclei/mL |
| PJ | <i>P. jiroveci-S. cerevisiae</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| SA | <i>Staphylococcus aureus</i> subsp. <i>aureus</i> | 1.00×10^6 cfu/mL | 1.00×10^6 cfu/mL |
| SE | <i>Staphylococcus epidermidis</i> | 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. Serial Performance

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

| DAYS AFTER FIRST PCR POSITIVE TEST RESULT | ASYMPTOMATIC ON FIRST DAY OF TESTING | | | SYMPTOMATIC ON FIRST DAY OF TESTING | | |
|---|---|------------------|------------------|-------------------------------------|------------------|------------------|
| | Ag Positive / PCR Positive (Antigen Test Performance % PPA) | | | | | |
| | 1 Test | 2 Tests | 3 Tests | 1 Test | 2 Tests | 3 Tests |
| 0 | 9/97 (9.3%) | 35/89 (39.3%) | 44/78 (56.4%) | 34/57 (59.6%) | 47/51 (92.2%) | 44/47 (93.6%) |
| 2 | 17/34 (50.0%) | 23/34 (67.6%) | 25/32 (78.1%) | 58/62 (93.5%) | 59/60 (98.3%) | 43/43 (100%) |
| 4 | 16/21 (76.2%) | 15/20 (75.0%) | 13/15 (86.7%) | 55/58 (94.8%) | 53/54 (98.1%) | 39/40 (97.5%) |
| 6 | 20/28 (71.4%) | 21/27 (77.8%) | 16/18 (88.9%) | 27/34 (79.4%) | 26/33 (78.8%) | 22/27 (81.5%) |
| 8 | 13/23 (56.5%) | 13/22 (59.1%) | 4/11 (36.4%) | 12/17 (70.6%) | 12/17 (70.6%) | 7/11 (63.6%) |
| 10 | 5/9 (55.6%) | 5/8 (62.5%) | | 4/9 (44.4%) | 3/7 (42.9%) | |

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
 2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
 3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

b. Clinical Performance

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 277 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 85.4% and the negative percent agreement (NPA) is 99.3% with the 95% confidence interval bounds of 78.4% to 90.9% for the PPA and 95.9% to 100% for the NPA, respectively.

CLINITEST Rapid COVID-19 Antigen Self-Test (candidate) results vs. Comparator results

| | Comparator Positives | Comparator Negatives | Total |
|---|----------------------|----------------------|------------|
| Candidate Positives | 117 | 1 | 118 |
| Candidate Negatives | 20 | 139 | 159 |
| Total | 137 | 140 | 277 |
| Positive Percent Agreement (PPA) = $(117/137) \times 100\% = 85.4\%$ (95% CI = 78.4 to 90.9%) | | | |
| Negative Percent Agreement (NPA) = $(139/140) \times 100\% = 99.3\%$ (95% CI = 96.1 to 100%) | | | |

Age and Gender Analysis

| Subject Age | Female | Male | Comparator Positives | % Positivity Rate (by Comparator) |
|---------------------|------------|------------|----------------------|-----------------------------------|
| <14 years of age | 16 | 18 | 7 | 20.6 |
| 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 | 153 | 124 | 137 | 49.5 |

Clinical Performance in Subjects on Different Symptomatic Days

| Days of COVID-19 Symptoms | Number of Specimens Tested | Investigational Positives | Comparator Positives |
|---------------------------|----------------------------|---------------------------|----------------------|
| Day 0-1 | 53 | 22 | 27 |
| Day 2 | 79 | 31 | 32 |
| Day 3 | 55 | 27 | 27 |
| Day 4 | 35 | 14 | 17 |
| Day 5 | 28 | 10 | 14 |
| Day 6 | 14 | 7 | 9 |
| Day 7 | 13 | 7 | 11 |
| Total | 277 | 118 | 137 |

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

<http://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 |
|  | <i>In vitro</i> diagnostic medical device |  | Use-by date |
|  | Consult instructions for use |  | Batch code |
|  | Temperature limit |  | Do not reuse |