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.

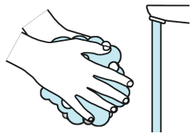
Telephone: 1-833-933-2340

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.



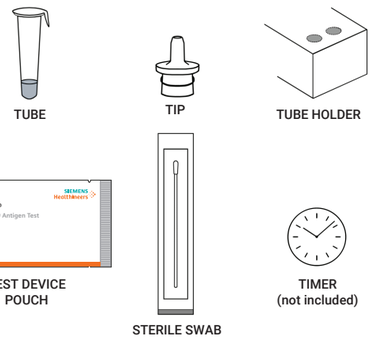
GATHER MATERIALS

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.

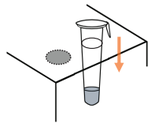
Do not start Step 1 until you are ready to begin the test.



STEP 1.

PLACE TUBE IN TUBE HOLDER

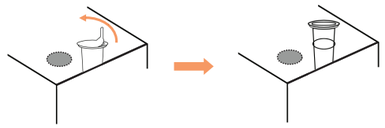
Find tube holder shown on the back of the box.
Push tube through outlined hole.



STEP 2.

OPEN TUBE

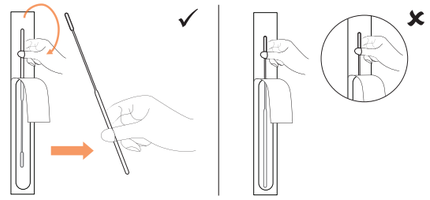
Remove the seal from the tube. Avoid spilling the liquid.
Make sure the tube is standing up straight.



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.

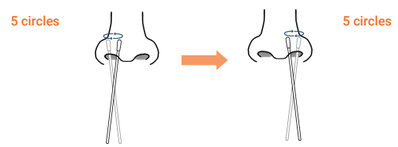


SWAB BOTH NOSTRILS

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.*

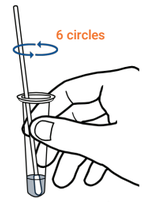
NOTE: *Failure to swab properly may cause false negative results.*



STEP 4.

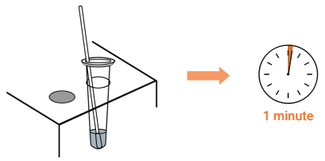
PLACE SWAB IN TUBE

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.



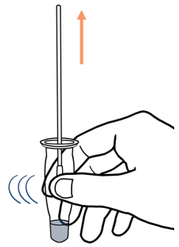
PLACE TUBE IN TUBE HOLDER

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



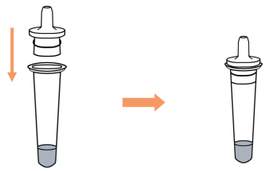
REMOVE SWAB FROM TUBE

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

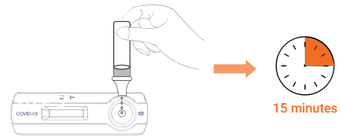
Open the test device pouch by tearing the area circled below.
Place the test device on a **flat surface.**

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.



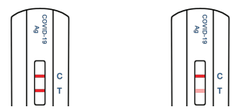
STEP 6.

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.

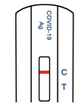


IF THE TEST IS POSITIVE

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.