

Frequently Asked Questions

CLINITEST Rapid COVID-19 Antigen Self-Test

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General Questions

When should the CLINITEST® Rapid COVID-19 Antigen Self-Test be used?

The CLINITEST Rapid COVID-19 Antigen Self-Test is intended to aid in the rapid diagnosis of SARS-CoV-2 (the virus that causes COVID-19) infections. The test quickly provides you with an important test result to help make daily decisions safely and confidently.

What symptoms might I experience if I have COVID-19?

Typical symptoms include coughing, fever, runny/stuffy nose or sneezing, and/or loss of smell and taste. First symptoms appear 1 to 14 days (in most cases 3 to 7 days) after being infected.

What are the advantages of the CLINITEST Rapid COVID-19 Antigen Self-Test?

No specialized laboratory equipment or professional training are required. A simple nasal swab produces accurate, high-quality results in just 15 minutes, so you can quickly find out whether you or a family member are infected by SARS-CoV-2.

Does the test work for younger children, e.g., for toddlers?

The test is approved for self-administration by people 12 years of age and older. Younger children can be tested by an adult following directions. The test is not approved for infants and toddlers.

Can this test be used for international travel requirements for COVID testing?

The COVID-19 testing guidance for airlines and cruise ships varies both by country of origin and country of destination. We suggest you check the CDC for the most up-to-date travel guidance and confirm directly with your ticketing airline/cruise ship. The CLINITEST Rapid COVID-19 Antigen Self-Test does not currently have an affiliation with a telehealth service provider (proctoring) or any associated apps to monitor users while they administer their tests and provide certification of a negative test to travel.

Components

What components are included in the CLINITEST Rapid COVID-19 Antigen Self-Test?

CLINITEST Rapid COVID-19 Antigen Self-Test kits include:

- Test devices (cassettes)
- Sterile swabs
- Instructions for use
- Quick-reference guide

Depending on the configuration, kits also include either:

- Vials with buffer solution, and
- Extraction tubes and tips

—or—

- Prefilled extraction tubes with buffer solution and tips

Storage and Stability

What is the shelf life of the test?

The shelf life is 24 months from the date of manufacture. Each test kit is stamped with an expiration date. Do not use the test after the expiration date.

Can I use the test after the expiration date?

No. We cannot ensure the accuracy of an expired test.

How long can I use the test device (cassette) once I have opened the sealed packaging?

Please use the test device within an hour after removing it from its sealed package. Discard test device if it has been unpackaged more than an hour.

How long is the buffer solution stable after opening the bottle?

- For kits containing prefilled buffer tubes:
If properly stored and sealed, the prefilled buffer tubes will last until the expiration date printed on the outside packaging of the test kit. The prefilled buffer tubes are designed for single use only and must be discarded after each use. Discard any expired buffer solution.

- For kits containing bottles of buffer solution:
The buffer bottle should be used within 6 months of first opening the bottle. Discard any expired buffer solution.

How must the test be stored?

Store the CLINITEST Rapid COVID-19 Antigen Self-Test away from sunlight at room temperature or refrigerated (2–30°C/36–86°F).

My CLINITEST self-tests arrived in the mailbox while I was on vacation. Can I still use them?

Test performance may be affected if exposed to prolonged extreme temperatures. If your test has been left in an extreme temperature environment (i.e., being left outside in temperatures exceeding 45°C/113°F or below-freezing temperatures above –20 ±10°C), it is recommended that you use a different test.

How can I find out when my test expires?

The expiration date is printed on the side panel of the kit box, next to the "hourglass" symbol. It is also printed on the back of each foil test pouch. The format of the expiration date is YYYY-MM-DD.

Handling

What temperature should the test be at the time of use?

Use the test at room temperature (15–30°C/59–86°F).

The test was accidentally exposed to the sun for several days. Can I still use the test?

No. The test must be stored away from sunlight at a temperature of 2–30°C (36–86°F). We cannot ensure the accuracy of improperly stored tests.

We can only test outdoors (below 15°C). Can the test be used?

No. The test must be used at room temperature (15–30°C/59–86°F) to ensure effective results.

Is there a time limit for which tests can withstand temperatures outside of 2–30°C/36–86°F?

There is no defined time limit for exposure to extreme temperatures, but prolonged exposure should be avoided. The test must be stored away from sunlight at a temperature of 2–30°C (36–86°F). We cannot ensure the accuracy of improperly stored tests. The test must be used at room temperature (15–30°C/59–86°F) to ensure effective results.

Robustness studies have been conducted to demonstrate the Rapid COVID-19 Antigen Test's tolerance to harsh storage and transport temperatures, where the product was placed at 45 ±3°C for 2 days followed by –20 ±10°C for 2 additional days. The test was allowed to equilibrate to room temperature for 1 day after each extreme storage cycle. The test performed as expected, exhibiting acceptable tolerance at extremes of 45 ±3°C for 2 days followed by –20 ±10°C for 2 days. Testing above 45 ±3°C was not performed and is therefore undetermined and not supported. As the IFU states, allow the test device and materials to equilibrate to room temperature (15–30°C) before use. The "C" or control line is one indicator of reliability and should also be used to assess test performance.

Is my test ok to use immediately upon bringing it in from the summer heat?

If the Rapid COVID-19 Antigen Test has been stored at temperatures above 45°C/113°F, DO NOT USE the test kit. If the test has been left outside in high temperatures (not exceeding 45°C/113°F), bring the test kit into your home and leave it unopened at room temperature for at least 1 day before opening. As the IFU states, allow the test device and materials to equilibrate to room temperature (15–30°C) before use. Robustness studies have been conducted to show the test performed as expected when exposed to extreme temperatures of 45 ±3°C for 2 days after storage at room temperature for 1 day to equilibrate. The "C" or control line is one indicator of reliability and should also be used to assess test performance.

If the test is frozen, can I still use it once it returns to room temperature?

If the Rapid COVID-19 Antigen Test has been stored at temperatures below –20°C/–4°F, DO NOT USE the test kit. The test can still be used as long as it was not exposed to temperatures lower than –20°C and is stored at room temperature for 1 day to equilibrate to room temperature before beginning the test procedure. Once the test kit has been brought to room temperature, open the test kit and perform the test according to the instructions for use. The "C" or control line is one indicator of reliability and should also be used to assess test performance.

How is a nasal swab collected?

Carefully insert the swab into the left nostril, and gently roll the swab 5 times along the walls of the nostril (nasal lining). Repeat this procedure with the same swab in the right nostril, and gently remove the swab. Illustrated instructions for use and a quick-reference guide are included in every test package.

Can I take the nasal swab sample and then do the test at a later time?

No. Test the sample immediately after swabbing your nose.

I took the nasal swab from only one nostril. Now the swab has already been placed into the extraction buffer. Can I read and interpret the test result?

No. Tests are accurate only if you swab both nostrils as instructed.

I took the test device (cassette) out of the sealed packaging 2 weeks ago. Can I still use it today?

No. Test devices that have been unsealed more than an hour are not effective and should be discarded.

I took the swab out of the sealed packaging 2 weeks ago. Can I still use it today?

No. Swabs should be used immediately after they are unsealed. Otherwise, they may no longer be sterile, and the test is effective only when using sterile swabs.

I accidentally dropped the swab on the floor. Can I still use it?

No. Swabs must be sterile. Test results are inaccurate if the swab is contaminated by dirt or material other than nasal lining.

I injured myself when I inserted the swab into my nose, or the swab is stained with blood for another reason. What should I do?

If you injured yourself, the test will not produce an accurate result. Please consult your healthcare provider or emergency medical service provider. Please follow the instructions you receive from your doctor or the healthcare provider.

I left the swab standing in the tube for more than 1 minute. Will this affect the test result?

Yes. Failure to follow the test procedure may affect test performance and/or invalidate the test result.

Should I shake the buffer solution before using it?

No. This may cause bubbles and result in incorrect droplet volumes.

I added too many drops of the buffer solution to the tube. Will this affect the test result?

According to the test procedure, you should add 10 drops of the buffer solution to the tube. However, a manufacturer's study showed that an additional 1 or 2 drops will not affect the test result.

I dispensed too many drops onto the test device. Will this affect the test result?

According to the test procedure, you should add exactly 4 drops of the sample solution into the sample well. Please use a new test.

I am worried that the swab was not sufficiently immersed in buffer solution. Is that a problem?

According to the test procedure, you should press the head of the swab against the bottom and sides of the tube, rolling it at least 6 times. After leaving the swab in the tube for 1 minute, you should press together the sides of the tube and completely squeeze out the swab. If you are unsure whether you used the test correctly, we encourage you to repeat the test.

I accidentally dispensed the solution onto the test device without using the tip provided in the kit. Will this affect the test result?

Yes. The test may not work properly if you did not push the tip provided in the kit firmly into the tube to dispense the solution.

I accidentally got some of the extraction buffer on my hands. What should I do?

Simply wash your hands with running water.

I accidentally tipped over the tube and spilled some of the buffer. Can I proceed with the test?

If you received the test kit with prefilled buffer tubes, please use a new tube.

Can I use water instead of buffer solution?

No. The test works only with the buffer solution.

Can the CLINITEST Rapid COVID-19 Antigen Test be used with samples obtained by alternative methods, for example, by gargling?

No. The test works only with samples collected using a nasal swab.

Can I swab in the mouth to collect the sample?

No. The test works only with samples collected using a nasal swab.

Can the extraction buffer solution be used as a gargle solution?

No. The buffer solution should be used only with the test, as directed. If you accidentally get the buffer solution in your skin/eyes/mucous membranes, rinse the affected area thoroughly with running water.

Is it absolutely necessary to place the test device (cassette) on an even surface during the test procedure?

Yes. The test device must be placed on a flat, clean surface. Failure to follow the test procedure may affect test performance and/or invalidate the test result.

I waited longer than 15 minutes to read the test result. Is the result still valid?

It is important to read the result at 15 minutes. If you've waited more than 15 minutes, we cannot ensure the accuracy of the test, and you should retest.

Disposal

How do I dispose of the test and its components?

Place used test components in the swab plastic bag and dispose of them with your household waste.

Interpretation of Results

My result is positive. What should I do?

A positive test result means that proteins from the virus that causes COVID-19 were found in your swab sample. Please observe the relevant rules for spread control and contact your doctor or local health department. If your test is positive, you should have the result confirmed using an alternative test method, such as a PCR test.

My result is negative. What should I do?

A negative test result means that you are unlikely to have COVID-19. The test did not detect the virus proteins in the swab sample, but it is possible for this test to give a negative result that is incorrect. Incorrect negative results (false negative) can be caused by several factors:

- The amount of antigen in the swab sample may decrease over the length of infection.
- You may test negative before you develop symptoms.
- Other reasons as specified in the Limitations section.

If you are unwell, your symptoms become worse, or you develop new symptoms, it is important that you seek a healthcare provider right away.

My test result is negative, but I have disease symptoms. How should I proceed?

If you feel uncertain despite a negative test result, call or visit your doctor or healthcare provider for guidance.

My test result is invalid (control line failed to appear). Do I have to use a new swab, or can I use the remaining extraction solution?

Each test should be used only once. If your test doesn't work, retest using a new test.

What are possible reasons for failure of a control line to appear?

The control line won't appear if you didn't use the test as directed. For example, you may have used an insufficient sample volume, taken your sample incorrectly, or used an expired test.

The control line is only faintly visible. How should I proceed?

As long as the control line is visible, test results are reliable.

I am not sure if there is a very faint line next to the "T."

Even a faint line at the "T" indicates a positive result. If in doubt, please repeat the test or contact your doctor or emergency medical service provider for additional guidance.

The lines on my test results look dark/black and not pink or red. Are these results still valid?

As stated in the test kit instructions for use (IFU), any presence of a line in the "T" region at 15 minutes should be considered a positive result. The "T" or test line may be darker or lighter than the "C" or control line. It should also be noted that the test line may appear very dark, but it is not an indication of the severity of infection or the progression of disease state.

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