

Number: 146976400 Date: 2023-09-21



Method A



Method B

Before testing, scan the QR code to watch the "how to use" video.
<https://www.citestdiagnostics.com/Home/ProductInfo/397>

Do not put anything (including food, drink, gum and tobacco products) in the mouth for at least 10 minutes prior to collection.
Wash your hands with soap or hand sanitizer with at least 60% alcohol for at least 20 seconds before testing, prepare a timer.

TESTING PROCEDURE

<p>01</p> <p>Deeply cough 3-5 times.</p> <p>Note: Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.</p>	<p>02</p> <p>Remove the funnel and plastic tube; fit the funnel onto the tube.</p>	<p>03</p> <p>Gently spit oral fluid into the funnel. The oral fluid (non-bubble) should just reach the height of scale line. Note: If there's not enough oral fluid collected, repeat this step.</p>	<p>Method A</p> <p>04</p> <p>Remove the funnel. Place the used funnel in a plastic bag and tightly sealed, the collection device must be removed from the tube before proceeding to Step 5. Place the tube onto the tube holder. Tear to open the buffer and add entire buffer into the tube with oral fluid.</p>	<p>05</p> <p>Fit the tube tip onto the tube. Gently squeeze the tube 10-15 times to mix well.</p>	<p>06</p> <p>Remove the test device from the sealed foil pouch and use it within one hour.</p> <p>Place the test device on a level surface. Invert the tube and add 2 drops of solution to the specimen well(S) of the test device and then start the timer. Do not move the test device during test.</p> <p>Read the result at 15 minutes. Do not interpret the result after 20 minutes.</p>	<p>07</p> <p>After the test is completed, place all the components of the test kit into a plastic bag and tightly sealed, and dispose of them according to local regulations. Do not reuse any used components of the kit. Wash your hands thoroughly after the testing.</p>
	<p>02</p> <p>Remove the collection device from the sealed foil pouch. Do not touch the sponge.</p>	<p>03</p> <p>Insert the sponge of the collection device into your mouth. Swab around gums and tongue. Place it under tongue for 2-3 minutes until the sponge becomes soft. Withdraw the collection device from your mouth.</p>	<p>Method B</p> <p>04</p> <p>Remove the cap from the tube. Put the collection device with the oral fluid into tube and press the sponge thoroughly to release the oral fluid. The oral fluid (non-bubble) should just reach the height of 0.5 mL line. Note: If there's not enough oral fluid collected, repeat step 3. Place the used collection device in a plastic bag and tightly sealed.</p>	<p>05</p> <p>Tear to open the buffer and add entire buffer into the tube with oral fluid. Tighten the tube cap. Gently shake the tube 10-15 times to mix well.</p>		

READ RESULTS

Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result and carefully follow your local COVID guidelines/requirements.

POSITIVE: * Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of the color in the test region (T) should be considered positive.

A positive result means it is very likely that you have COVID-19, but the positive samples should be confirmed. Follow the guidance from your local State or Territory Health Department, including for reporting of positive results and confirmation testing if required. If unwell, seek medical assistance.



NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test line region (T).

You are unlikely to have 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. This means you could possibly still have COVID-19 even though the test result is negative.

Follow the guidance from your local State or Territory Health Department if symptomatic. If unwell, contact a medical practitioner for follow up clinical care.



INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test kit or report repeated invalid results to the sponsor.



WARNINGS AND PRECAUTIONS

1. Read the entire package insert prior to performing test.
2. For self-testing *in vitro* diagnostic use only.
3. The test is for one time use only, do not reuse the test. Do not use after the expiration date.
4. Do not eat, drink or smoke in the area where the specimens or kits are handled.
5. **Do not drink the buffer in the kit.** Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
6. Do not use test if pouch is damaged.
7. Wash hands thoroughly before and after handling.
8. Store the test kit out of reach of children and pets.
9. Test for children should be used under the supervision of an adult.
10. The used test should be discarded according to local regulations.

STORAGE

Store the test at 35.6-86 °F (2-30 °C). Do not open the pouch until ready for use. **DO NOT FREEZE.** Keep dry. The test kit is stable until the expiration date printed on the outer packaging.

