SARS-CoV-2 (COVID-19) Antigen Rapid Test (Oral Fluid)

Package Insert

REF INCP-CT802H | English

For Self-testing

Number: 146976400 Date: 2023-05-09

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

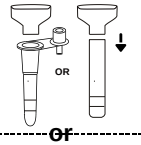
01

Deeply cough 3-5 times.

Note: Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.

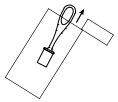
Method A

02 Remove the funnel and plastic tube; fit the funnel onto the tube.



or

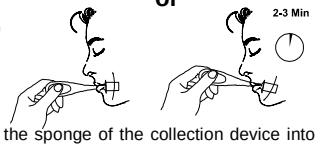
02 Remove the collection device from the sealed foil pouch. Do not touch the sponge.



03 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.

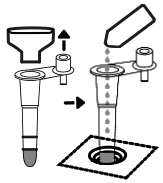
or

03



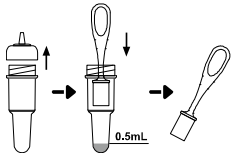
Insert the sponge of the collection device into your mouth. Swab around gums and tongue.
Place it under tongue for **2-3 minutes** until the sponge becomes soft.
Withdraw the collection device from your mouth.

04 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.



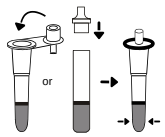
or

04



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.

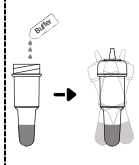
05



Fit the tube tip onto the tube. Gently squeeze the tube **10-15 times** to mix well.

or

05



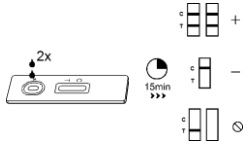
Tear to open the buffer and add entire buffer into the tube with oral fluid.
Tighten the tube cap. Gently shake the tube **10-15 times** to mix well.

Method B

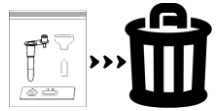
06 Remove the test device from the sealed foil pouch and use it within one hour.

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.

Read the result at **15 minutes.**
Do not interpret the result after 20 minutes.



07 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.



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.

For Customer Support Helpline: Call (+61)299592400 9am-7pm (AEST) 7 days per week for information on the correct use of this test and for interpretation of the test results.

INTENDED USE

The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is a single-use test kit intended to detect the SARS-CoV-2 nucleocapsid protein antigens in human oral fluid. This test is designed for home use with self-collected oral fluid samples. The test is intended for use in symptomatic individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset, and to test asymptomatic individuals limited to contacts of confirmed COVID-19 case or probable case and to at-risk heath workers.

The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is qualitative immunochromatography and is an aid diagnosis of COVID-19.

The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).

BACKGROUND

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

TEST PRINCIPLE

The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Nucleocapsid protein Antigens in human oral fluid specimen.

MATERIALS

Materials Provided

- Test device
- Buffer
- Package insert
- Collection device
- Biosafety bag
- Tube holder (Provide for Method A device)

Materials required but not provided

- Timer

LIMITATIONS

1. Failure to follow the testing steps may give inaccurate results.
2. The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is for self-testing *in vitro* diagnostic use only.
3. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
4. If the test result is negative or non-reactive and clinical symptoms persist or being in a high risk setting or where there is an occupational risk or other requirement. Repeat testing, e.g., within 1 – 3 days, is recommended if there is ongoing suspicion of infection, high risk setting, or occupational or other requirement.
5. The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is less reliable in the later phase of infection and in asymptomatic individuals.
6. Negative results may not mean that a person is not infectious and if symptoms are present you must seek immediate further testing via the PCR Method.
7. A negative result does not rule out infection with another type of respiratory virus.
8. If testing is not performed within the first 7 days of symptom onset，it is possible for this test to give a negative result that is incorrect (a false negative).
9. The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is a presumptive test only and the need for confirmatory testing of positive results by a laboratory PCR test and for follow-up clinical care.
10. A negative result means that you are negative or that the viral load is too low to be recognized by the test. Follow the guidance from your local State or Territory Health Department if symptomatic. If unwell, contact a medical practitioner for follow up clinical care.
11. If a Positive result is given, 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.
12. Positive result cannot determine if a person is infectious.

PERFORMANCE

Clinical performance

A clinical evaluation was conducted comparing the results obtained using the SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) with RT-PCR (Nasopharyngeal swab) test result.

The clinical trial included 649 oral fluid specimens. The results demonstrated 99.4% specificity and 94.3% sensitivity with an overall accuracy of 97.1%.

	PCR confirmed sample number	Correct identified	Rate
Positive sample	349	330	94.6% (Sensitivity) (95%CI*: 91.6%~96.7%)
Negative sample	352	350	99.4% (Specificity) (95%CI*: 98.0%~99.9%)
Total	701	680	97.0% (Total Accuracy) (95%CI*: 95.5%~98.1%)

94.6% Sensitivity: In total 349 PCR confirmed positive samples: 330 PCR confirmed positive samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid). There are 19 false negative cases.

99.4% Specificity: In total 352 PCR confirmed negative samples: 350 PCR confirmed negative samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid). There are only 2 false positive cases.

97.0% Accuracy: In total 701 PCR confirmed samples: 680 PCR confirmed samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid).

The observed accuracy may vary depending on the prevalence of the virus in the population.

*Confidence Intervals

Days since symptom onset	RT-PCR positive	COVID-19 Antigen Rapid Test (Oral Fluid) Positive	PPA
0~2	284	267	94.0%
3~5	34	34	100%
6~7	31	29	93.5%

Ct Value	RT-PCR positive	SARS-CoV-2 Antigen Rapid Test Positive	PPA
Ct≤25	69	69	100%
25<Ct≤30	163	161	98.8%
Ct>30	117	100	85.5%

Asymptomatic clinical performance

The asymptomatic clinical trial included 482 asymptomatic oral fluid specimen. The result demonstrated 99.6% specificity and 92.4%sensitivity with an overall accuracy of 96.3%

	PCR confirmed sample number	Correct identified	Rate
Positive sample	223	206	92.4% (Sensitivity) (95%CI*: 88.1%~95.5%)
Negative sample	259	258	99.6% (Specificity) (95%CI*: 97.9%~99.9%)
Total	482	464	96.3% (Total Accuracy) (95%CI*: 94.2%~97.8%)

92.4% Sensitivity: In total 223 PCR confirmed positive asymptomatic samples: 206 PCR confirmed positive asymptomatic samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid). There are 17 false negative cases.

99.6% Specificity: In total 259 PCR confirmed negative asymptomatic samples: 258 PCR confirmed negative asymptomatic samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid). There are only 1 false positive cases.

96.3% Accuracy: In total 482 PCR confirmed asymptomatic samples: 464 PCR confirmed samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid).

The observed accuracy may vary depending on the prevalence of the virus in the population.

*Confidence Intervals

Ct Value	RT-PCR positive	SARS-CoV-2 Antigen Rapid Test Positive	PPA
Ct≤25	28	28	100%
25<Ct≤30	108	107	99.1%
Ct>30	87	71	81.6%

Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below.

Adenovirus type 3	*Influenza B*	*Corynebakterium*	*Streptococcus pneumoniae*
Adenovirus type 7	*Measles*	*Escherichia coli*	*Streptococcus salivarius*
Human coronavirusOC43	*Mumps*	*Moraxella catarrhalis*	*Streptococcus sp Gruppe F*
Human coronavirus 229E	*Parainfluenza virus 2*	*Neisseria lactamica*	*Pseudomonas aeruginosa*
Human coronavirus NL63	*Parainf luenza virus 3*	*Neisseria subflava*	*Staphylococcus epidermidis*
Human coronavirus HKU1	*Arkanobakterien*	*Candida albicans*	*Staphylococcus aureus subspaureus*
Influenza A H1N1	*Influenza A H3N2*	*MERS-corona virus*	*Respiratory syncytial virus*
SARS-CoV-1	*Human Rhinovirus 2*	*Human Rhinovirus 14*	*Human Rhinovirus 16*
Legionella pneumophila Philadelphia	*Bordetella pertussis A639*	*Enterovirus Type 68 (2007 Isolate)*	*Chlamydia pneumoniae*
Haemophilus influenzae type b	*Mycoplasma pneumoniae M129*		

Interfering Substances

Test results will not be interfered by following substances:

Dexamethasone	Oxymetazoline	Coca Cola	Tobramycin
Mucin	Milk	Rebetol	Tea
Flunisolide	Orange juice	Relenza	Toothpaste
Mupirocin	Mouthwash	Tamiflu	Caffeine
Phenylephrine	Whole Blood	HAMA	Biotin
Throat lozenges	Chewing gum	Breath mints	

Variant

The SARS-CoV-2 variant Alpha (UK B.1.1.7), Delta (Indian B.1.617.2), Gamma (B.1.1.28), VUI-21ARP-03 (Indian B.1.617.3), Omicron (B.1.1.529 and BA.2) and Beta (South Africa B.1.351) could be detected out by the COVID-19 Antigen Rapid Test at specific concentrations.

Usability Study:

Of the 206 participants, test interpretation of a test panel by 109 laymen, testing of 30 oral fluid samples self-collected by 30 positive donors and evaluation of usability by 67 laymen.Test results by 109 laymen did show that laymen can read a range of results from negative over weak positive to positive and that they can identify invalid results as well. 92.11 % of the results were correct. The vast majority of lay users can interpret the test correctly. The majority of false results did occur with the weak positive samples. All positive results have been analysed correctly. 64 out of 65 negative samples confirmed by PCR were also tested negative with the antigen test, which correlates to the specificity of 98.46% in this particular sample pool.

Due to the positive evaluation by the study participants, the SARS-CoV-2 (COVID-19) Antigen Rapid Test (Oral Fluid) and the underlying IFU are rated as a test that is easy to understand and perform and suitable for self-administration by laymen.

EXTRA INFORMATION

1. **How do I know if the Test worked well?**
   The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human oral fluid. When the control line(C) appears, it means the test unit is performing well.
2. **How soon can I read my results?**
   You can read your results after 15 minutes as long as a colored line has appeared next to the Control region(C), do not read result after 20 minutes.
3. **When is the best time to run the test?**
   Test can be done at any time of the day.
4. **Can the result be wrong? Are there any factors that can affect the test result?**
   The results will only give accurate results as far as the fresh human oral fluid is used and followed the instructions carefully. Nevertheless, the result can be incorrect.
   Non-SARS-CoV-2 coronavirus strains or other interference factors may cause a preliminary positive result.
5. **How to read the test if the color and the intensity of the lines are different?**
   The color and intensity of the lines have no importance for result interpretation. The test should be considered as Positive whatever the color intensity of the test line (T) is.
6. **What do I have to do if the result is positive?**
   A positive result means the presence of SARS-CoV-2 antigens. A positive results means it is very likely you have COVID-19 and the result 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.
7. **What do I have to do if the result is negative?**
   A negative result means that you are negative or that the viral load is too low to be recognized by the test. 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 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.

For CUSTOMER SUPPORT HELPLINE: Call (+61)299592400 9am-7pm (AEST) 7 days per week

For information on the correct use of this test and for interpretation of the test results.

LOCAL CONTACT DETAILS

TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT

STATE AND TERRITORY CONTACT NUMBERS

To locate your nearest Covid testing center and Laboratory please contact

Australian Capital Territory Coronavirus Helpline (8am-8pm daily)	02 6207 7244 https://health.act.gov.au/
New South Wales Coronavirus Helpline (Service NSW 24/7)	137 788 https://www.health.nsw.gov.au/
Northern Territory Coronavirus National Hotline (National Helpline)	1800 020 080 https://health.nt.gov.au/
Queensland Coronavirus Helpline (134COVID)	134 268 https://www.health.qld.gov.au/
South Australia Coronavirus Helpline (9am -5 pm Daily)	1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Public Health Hotline (Coronavirus)	1800 671 738 https://www.health.tas.gov.au/
Victoria Coronavirus Hotline (24/7)	1800 675 398 https://www.dhhs.vic.gov.au/
Western Australia Coronavirus Hotline 13COVID (8am- 6pm Mon-Fri)	1800 595 206 https://www.healthywa.wa.gov.au/

Contact the TGA to report poor performance or usability issues in the self-test environment (report an issue via the Users Medical Device Incident Report, email: iris@tga.gov.au or call 1800 809 361)

LITERATURE REFERENCES

1. BACKINGER, C.L. and KINGSLEY, P.A., Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care, Rockville, MD, U.S. Food and Drug Administration, Center for Devices and Radiological Health, HHS Pub. FDA 93-4258.

INDEX OF SYMBOLS

IVD	*In vitro* diagnostic medical device		Tests per kit
2°C 30°C	Temperature limit 2-30 °C		Use by
	Do not use if package is damaged	LOT	Batch code
	Manufacturer		Consult Instructions For Use
	Do not reuse	REF	Catalog #
	Keep dry.		

CITEST DIAGNOSTICS INC.
170-422 Richards Street
Vancouver BC, V6B 2Z4, Canada

Sponsor by:
LC & Partners Pty Ltd.
Add:Level 32, 101 Miller Street, North Sydney NSW 2060, Australia
Tel: (61) 2-99592400