

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

Package Insert REF INCP-CT802H | English For Self-testing

Number: 146976400 Date: 2023-09-21



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



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.
- 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.
- 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.

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 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 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 ß 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 PRINCIPI F

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

MATERIAL S

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

- Failure to follow the testing steps may give inaccurate results.
- The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is for self-testing in vitro diagnostic use only.
- The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations
- 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.
- A negative result does not rule out infection with another type of respiratory virus.
- 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

For Funnel method

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 701 oral fluid specimens. The results demonstrated 99.4% specificity and 94.6% sensitivity with an overall accuracy of 97.0%.

	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%Cl*: 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

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%Cl*: 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

For Sponge Method

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 500 oral fluid specimens. The results demonstrated 100% specificity and 90.7% sensitivity with an overall accuracy of 97.2%

	PCR confirmed sample number	Correct identified	Rate
Positive sample	150	136	90.7% (Sensitivity) (95%Cl*: 84.8%~94.8%)
Negative sample	350	350	100% (Specificity) (95%CI*: 99.0%~100%)
Total	500	486	97.2% (Total Accuracy) (95%CI*: 95.4%~98.5%)

90.7% Sensitivity: In total 150 PCR confirmed positive samples: 136 PCR confirmed positive samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid). There are 14 false negative cases. 100% Specificity: In total 350 PCR confirmed negative samples: 350 PCR confirmed negative samples w

correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) 97.2% Accuracy: In total 500 PCR confirmed samples: 486 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 Asymptomatic clinical performance

The asymptomatic clinical trial included 332 asymptomatic oral fluid specimen. The result demonstrated 100%

	PCR confirmed sample number	Correct identified	Rate
Positive sample	38	34	89.5% (Sensitivity) (95%CI*: 75.2%~97.1%)
Negative sample	294	294	100% (Specificity) (95%CI*: 98.8%~100%)
Total	332	328	98.8% (Total Accuracy) (95%CI*: 96.9%~99.7%)

89.5% Sensitivity: In total 38 PCR confirmed positive asymptomatic samples: 34 PCR confirmed positive asymptomatic samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid). There are 4 false negative cases.

100% Specificity: In total 294 PCR confirmed negative asymptomatic samples: 294 PCR confirmed negative asymptomatic samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid). 98.8% Accuracy: In total 332 PCR confirmed asymptomatic samples: 328 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

Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low nathogenic 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	Bordetella pertussis A639	Human Metapneumovirus 16 Type A1
Parainfluenza virus 1	Parainfluenza virus 4	Mycobacterium tuberculosis	Streptococcus pyogenes
Pneumocystis carinii			

Interfering Substances

Test results will not be interfered by following substances:				
Arcanobacterium Pseudomonas aeruginosa		Adenovirus Type 7	Human Metapneumovirus 16 Type A1	
Candida albicans	Staphylococcus aureus subspaureus	Parainfluenza virus 1	Parainfluenza virus 2	
Corynebacterium	Staphylococcus epidermidis	Parainfluenza virus 3	Parainfluenza virus 4	
Escherichia coli	Streptococcus pneumoniae	Influenza A	Influenza B	
Moraxella catarrhalis	Streptococcus salivarius	Enterovirus Type 68 (2007 Isolate)	Rhinovirus Type 1A	
Neisseria lactamica	Streptococcus sp group F	Chlamydophila pneumoniae	Haemophilus influenzae type b	
Nesseria subllava	Respiratory syncytial virus	Legionella pneumophila Philadelphia	Mycobacterium tuberculosis	
SARS-coronavirus (SARS-CoV-1)	MERS-coronavirus	Streptococcus pyogenes	Bordetella pertussis A639	
Human coronavirus OC43	Human coronavirus NL63	Mycoplasma pneumoniae M129	Pneumocystis carinii Delanoe and Delanoe	
Human coronavirus 229E	Human coronavirus HKU1			
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.

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

What do I have to do if the result is negative? 7.

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

STATE AND TERRITORT CONTACT NUMBERS	
To locate your nearest Covid testing center and Laboratory please co Australian Capital Territory Coronavirus Helpline (8am-8pm daily)	ntact 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) Contact the TGA to report poor performance or usability issues in the	1800 595 206 https://www.healthywa.wa.gov.au/ 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	$\overline{\mathbb{V}}$	Tests per kit
2°C 1 30°C	Temperature limit 2-30 °C		Use by
8	Do not use if package is damaged	LOT	Batch code
***	Manufacturer	(m	Consult Instructions For Use
2	Do not reuse	REF	Catalog #
Ť	Keep dry.		

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