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

Package Insert

For Self-testing

REF INCP-CT802H | English

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

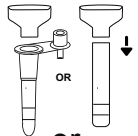
01

Deeply cough 3-5 time

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

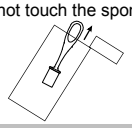
Method A

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



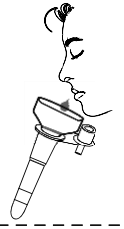
or

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



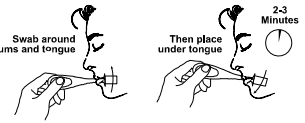
03

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

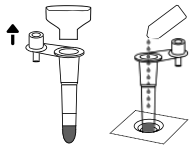
03



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 collector in a plastic bag and tightly sealed.
Place the tube onto the tube holder.
Tear to open the buffer and add entire buffer into the tube with oral fluid.



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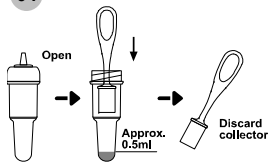
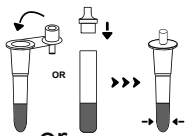
04



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 collector in a plastic bag and tightly sealed.

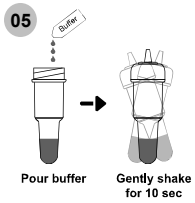
05

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



or

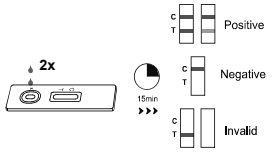
05



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.

06

Remove the test device from the sealed foil pouch and use it within one hour.
Place the test cassette 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 cassette during test.



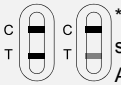
07

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.

Method B

READ RESULTS

Please share your test result with your healthcare provider 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.

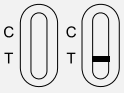
A positive result means it is very likely that you have COVID-19, but the positive samples should be confirmed. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.

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

If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest medical facility according to the rules of your local authority. In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of the infection.

Even with a negative test result, distance and hygiene rules must be observed, mitigation/traveling, attending events and etc should follow your local COVID guidelines/requirements.



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 contact with your doctor or a COVID-19 test center.

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 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. If the result is preliminary positive, share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.
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**.

INTENDED USE

The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 antigens in human oral fluids. The virus causes COVID-19. This test is designed for home use with self-collected oral fluid samples from symptomatic / asymptomatic individuals who are suspected of being infected with COVID-19. This test is designed for the use by layperson. The SARS-CoV-2 (COVID-19) Rapid Test (Oral Fluid) only indicates a preliminary result; the confirmation of the final result should be based on the clinical diagnosis.

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.

REAGENTS

The test device contains anti-SARS-CoV-2 Nucleocapsid protein antibodies.

MATERIALS

Materials Provided

- Test device
- Buffer
- Package insert
- Collection device
- Biosafety Bag (optional)

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, it is because the very early infection virus may not be detected. It is recommended to test again with a new test 1-2 days later or go to the hospital to rule out infection.
5. Positive results of the test may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

PERFORMANCE

Clinical performance

A clinical evaluation was conducted comparing the results obtained using the SARS-CoV-2 (COVID-19) Rapid Test with RT-PCR 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	297	280	94.3% (Sensitivity)
Negative sample	352	350	99.4% (Specificity)
total	649	630	97.1% (Total Accuracy)

94.3% Sensitivity: In total 297 PCR confirmed positive samples: 280 PCR confirmed positive samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test. There are 17 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. There are only 2 false positive cases.

97.1% Accuracy: In total 649 PCR confirmed samples: 630 PCR confirmed samples were correctly detected by SARS-CoV-2 (COVID-19) Rapid Test.

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

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 at certain concentrations.

Description	Test Level	*Description*	Test Level
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/ml	*Arkanobakterien*	1.0x10^8 org/ml
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/ml	*Candida albicans*	1.0x10^8 org/ml
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/ml	*Corynebakterium*	1.0x10^8 org/ml
Human coronavirus 229E	5 x 10^5 $TCID_{50}$/ml	*Escherichia coli*	1.0x10^8 org/ml
Human coronavirus NL63	1 x 10^5 $TCID_{50}$/ml	*Moraxella catarrhalis*	1.0x10^8 org/ml
Human coronavirus HKU1	1 x 10^6 $TCID_{50}$/ml	*Neisseria lactamica*	1.0x10^8 org/ml
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/ml	*Neisseria subflava*	1.0x10^8 org/ml
Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml	*Pseudomonas aeruginosa*	1.0x10^8 org/ml
Influenza B	3.16 x 10^6 $TCID_{50}$/ml	*Staphylococcus aureus subspaureus*	1.0x10^8 org/ml
Measles	1.58 x 10^4 $TCID_{50}$/ml	*Staphylococcus epidermidis*	1.0x10^8 org/ml
Mumps	1.58 x 10^4 $TCID_{50}$/ml	*Streptococcus pneumoniae*	1.0x10^8 org/ml
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml	*Streptococcus salivarius*	1.0x10^8 org/ml
Parainf luenza virus 3	1.58 x 10^8 $TCID_{50}$/ml	*Streptococcus sp Gruppe F*	1.0x10^8 org/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml	*MERS-corona virus*	1.17 x 10^4 $TCID_{50}$/ml

Interfering Substances

Test results will not be interfered by following substances at certain concentrations:

Substance	Concentration	Substance	Concentration
Dexamethason e	0.8 mg/mL	*Rebetol*	4.5 μg/mL
Mucin	50 μg/mL	*Relenza*	282 ng/mL
Flunisolide	6.8 ng/mL	*Tamiflu*	1 .1 μg/ml
Mupirocin	12 mg/mL	*Tobramycin*	2.43 mg/mL
Oxymetazoline	0.6 mg/mL	*Tea*	33.3 mg/ml
Milk	11.2%	*Toothpaste*	/
Orange juice	100%	*Caffeine*	1 mg/ml
Mouthwash	2%	*Phenylephrine*	12 mg/mL
Coca Cola	/	/	/

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. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner / doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.

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.

If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility using the rules of your local authority. In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection. Distance and hygiene rules must still be observed. Even with a negative test result, distance and hygiene rules must be observed, mitigation/traveling, attending events and etc should follow your local COVID guidelines/requirements.

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
EC REP	Authorized Representative in EU	REF	Catalog #
2	Do not reuse	CE 1434	CE mark

CITEST DIAGNOSTICS INC.
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Vancouver BC, V6B 2Z4, Canada

CE 1434

EC REP
CMC MEDICAL DEVICES & DRUGS, S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga-Spain

Number: 146663600
Effective date: 2022-03-22