SARS-CoV-2 (COVID-19) Antigen Rapid Test (Saliva)
Package Insert
For Self-testing

REF ICOV-803H	English

【INTENDED USE】

The SARS-CoV-2 (COVID-19) Antigen Rapid Test (Saliva) is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 in human saliva. This test is designed for home use[1] with self-collected saliva samples from symptomatic individuals who are suspected of being infected with SARS-CoV-2.

The SARS-CoV-2 (COVID-19) Antigen Rapid Test (Saliva) obtain a preliminary results only, the final confirmation should be based on clinical diagnosis results.

【SUMMARY】

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.

【PRINCIPLE】

The SARS-CoV-2 (COVID-19) Antigen Rapid Test (Saliva) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human saliva specimen.

【REAGENTS】

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

【WARNING】

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 touch the test window of the test device.
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 with 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.**

【ITEMS PROVIDED】

- •Test Device
- •Biosafety Bag (optional)
- •Package Insert
- •Specimen Container (optional)

【ITEMS NOT PROVIDED】

- •Timer

【TESTING】

Before Testing

Important: Do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

Wash your hands with soap and water for at least 20 seconds before testing. If soap and water are not available, use hand sanitizer with at least 60% alcohol. **Allow the test device to reach to room temperature (15-30 °C) prior to testing.**

Deeply cough 3-5 times.

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

Method 1:

Step 1:

Remove the test device from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

Take off the device cap.

Step 2:

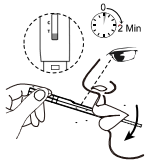
Place the tongue against the upper and lower jaws and roots to enrich the saliva. Insert the sponge end into the mouth, actively **swab around the gums** on both sides of the mouth **(10-15 times)** to assist saturation.

Step 3:

Put the absorbent wick **under the tongue** to collect saliva until the flow appear in the test window **(approximately 2 min)** and then take out the device and close the device cap .

Place the test device on a flat and level surface. Then start a timer.

Note: Keep the test device level during sampling, the hand-held part cannot be lower than the sponge. Do not move the test device during testing.

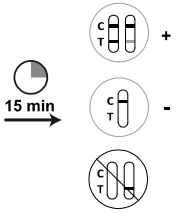


Step 4:

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

After test is completed, place the all the components of the test kit in a plastic bag and dispose according to local regulation. Do not reuse any used components of the kit.

Wash hands thoroughly after test disposal.



Method 2:

Step 1:

Collect enough fresh saliva specimen (at least 0.5 mL) in a single use disposable cup.

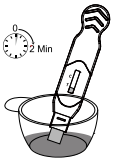
Step 2:

Remove the test device from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch. Take off the device cap.

Step 3:

Place the absorbent wick into the saliva specimens and let the absorbent wick to immerse in and absorb saliva fully.

Keep the device up right until the flow appear in the test window **(approximately 2 min)**.



Step 4:

Then take out the device and close the device cap. Place the test device on a flat and level surface. Then start a timer.

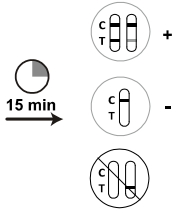
*NOTE: Do not move the test device during testing. Do not touch the test window of the test device.

Step 5:

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

After test is completed, place the all the components of the test kit in a plastic bag and dispose according to local regulation. Do not reuse any used components of the kit.

Wash hands thoroughly after test disposal.



【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 color in the test region (T) should be considered positive.

A positive results means it is very likely 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 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 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 an 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 or contact with your doctor or a COVID-19 test center.

【LIMITATIONS】

1. Failure to follow the testing steps may give inaccurate results.
2. The SARS-CoV-2 (COVID-19) Antigen Rapid Test (Saliva) 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 COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

【PERFORMANCE CHARACTERISTICS】

Clinical performance

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

The clinical trial included 1300 saliva specimens. The results demonstrated 99.7% specificity and 99.0% sensitivity with an overall accuracy of 99.6%.

	PCR confirmed sample number	Correct identified	Rate
Positive sample	100	99	99.0%(Sensitivity)
Negative sample	1200	1196	99.7%(Specificity)
total	1300	1295	99.6%(Total Accuracy)

99.0% Sensitivity: In total 100 PCR confirmed positive samples: 99 PCR confirmed positive samples were correctly detected by SARS-CoV-2 (COVID-19) Antigen Rapid Test. There are 1 false negative case.

99.7% Specificity: In total 1200 PCR confirmed negative samples: 1196 PCR confirmed negative samples were correctly detected by SARS-CoV-2 (COVID-19) Antigen Rapid Test. There are only 4 false positive cases.

99.6% Accuracy: In total 1300 PCR confirmed samples: 1295 PCR confirmed samples were correctly detected by SARS-CoV-2(COVID-19) Antigen 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	*Arcanobacterium*	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	*Corynebacterium*	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 10^6 $TCID_{50}$/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
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml	*Staphylococcus epidermidis*	1.0x10^8 org/ml
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/ml	*Streptococcus pneumoniae*	1.0x10^8 org/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml	*Streptococcus salivarius*	1.0x10^8 org/ml
MERS-coronavirus	1.17 x 10^4 $TCID_{50}$/ml	*Streptococcus sp group F*	1.0x10^8 org/ml

Interfering Substances

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

Substance	Concentration	Substance	Concentration	Substance	Concentration
Dexamethasone	0.8 mg/ml	Rebetol	4.5 μg/ml	Orange juice	100%
Mucin	50 μg/ml	Relenza	282 ng/ml	Mouthwash	2%
Flunisolide	6.8 ng/ml	Tamiflu	1.1 μg/ml	Caffeine	1 mg/ml
Mupirocin	12 mg/ml	Tobryamycin	2.43 mg/ml	Coca Cola	/
Oxymetazoline	0.6 mg/ml	Tea	33.3 mg/ml	Toothpaste	/
Phenylephrine	12 mg/ml	Milk	11.2%	/	/

【Q&A】

1. How do I know if the Test worked well?

SARS-CoV-2 (COVID-19) Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human saliva. 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. However It is recommended to collect the first saliva in the morning.

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 saliva 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.

【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	For *in vitro* diagnostic use only	Σ	Tests per kit	EC REP	Authorized Representative
2°C 30°C	Store between 2-30°C		Use by	2	Do not reuse
	Do not use if package is damaged	LOT	Lot Number	REF	Catalog #
	Manufacturer		Consult Instructions For Use		

Hangzhou AllTest Biotech Co.,Ltd.
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CE 1434

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Number: 146688400
Effective date: 2022-04-22