forsure

COVID-19 Antigen Rapid Test Kit (Saliva) Self-Testing

INTENDED USE

The COVID-19 Antigen Rapid Test Kit (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 design for home use with self-collected saliva samples from symptomatic individuals who are suspected of being infected with COVID-19. The COVID-19 Antigen Rapid Test Kit (Saliva) obtain a preliminary result only, the final confirmation should be based on clinical diagnostic 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 diarrhoea are found in a few cases.

PRINCIPLE

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

REAGENTS

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

PRECAUTIONS

1. This Instruction for Use (IFU) must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For self-testing *in vitro* diagnostic use only. Do not use after expiration date.
3. The test is for one time use only. Do not reuse the test.
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 water immediately if there is contact.
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 and requirements.
9. Testing on children should be done by adults.
10. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature (2-30℃). The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

TEST COMPONENTS

Items Provided

- Test Devices
- Instruction for Use (IFU)
- Buffer
- Collection Device (funnel & tube w/tube tip)
- Biosafety bag

Items Required but not provided

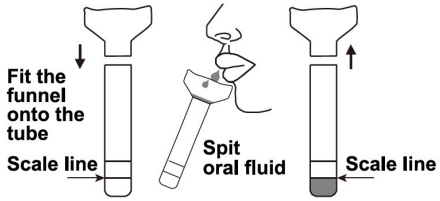
- Timer

DIRECTIONS FOR USE

Do not place anything in the mouth including food, drink, chewing gum or tobacco products for at least 10 minutes prior to saliva collection. Wash your hand with soap and water or hand sanitizer (with 60% alcohol content and above) for at least 20 seconds before testing.

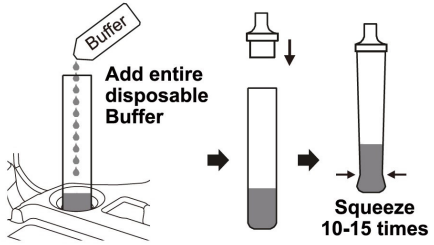
Specimen Collection

Remove the collection device, Fit the funnel onto the tube. Deeply cough 3 - 5 times. Keep your distance from other people during coughing. Gently spit saliva into the funnel. The saliva (non-bubble) should just reach the height of the scale line. If there is not enough saliva, repeat the steps. Then place the funnel into the Biosafety Bag.



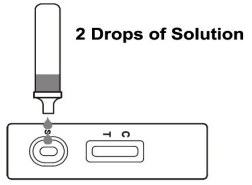
Specimen Preparation

Tear open the buffer and add entire buffer solution into the tube with the saliva. Fit the tube tip onto the tube. Gently squeeze the tube 10-15 times to mix well.



Testing

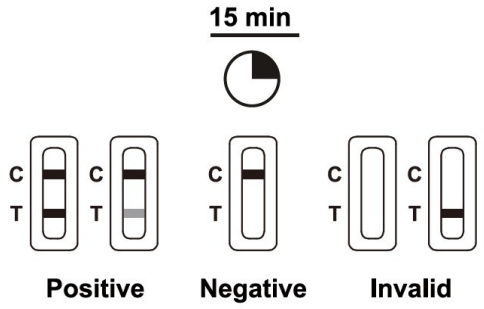
Remove the test device from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch. Place the device on a flat and level surface, invert the tube and add 2 drops of solution to the specimen well (S) and start the time.



To watch Instruction for Use in Audio Visual, scan this QR Code.

RESULTS

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



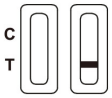
POSITIVE: *Two coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the Test region (T). Positive result in the Test region indicates detection of SARS-CoV-2 antigens in the sample.

*NOTE: The intensity of the colour 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 colour in the test region (T) should be considered positive.

A positive result means it is very likely you have COVID-19. You should immediately go into isolation in accordance to the local authority guidelines and immediately contact the local health department. You should test again with PCR for confirmation.

NEGATIVE: One coloured line appears in the control region (C). No apparent coloured line appears in the test line region (T) indicates a Negative COVID-19 Antigen test result.

You are unlikely to have COVID-19. However, it is possible for this test to give a false negative result. If you experience symptoms such as headache, fever, loss of sense of smell or taste, isolate yourself and report to your local health department of your symptoms. Repeat the test 1-2 days later as the coronavirus cannot be detected in all phases of infection.



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.

AFTER PERFORMING THE PROCEDURE

Make sure all COVID-19 Antigen Test Kit tools are placed in the BioSafety Bag and fastened properly. Dispose of the BioSafety Bag containing this kit in the trash. Perform disinfection of the procedure area with an appropriate disinfection solution after the testing procedure. Wash hands with soap and water after completing the procedure to avoid cross -contamination.

REPORTING OF RESULTS

All COVID-19 Self-Test Kit test results whether positive, negative or invalid must be self-reported into the MySejahtera application. Users are responsible for reporting actual results and not falsifying results to prevent the implications of infection to others.

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

LIMITATIONS

1. Failure to follow the steps may give inaccurate results.
2. The COVID-19 Antigen Rapid Test Kit (Saliva) is for *in vitro* diagnostic self-testing only. This test should be used for detection of SARS-CoV-2.
3. The results obtained with the test should only be considered with other clinical findings from other laboratories and evaluations.
4. If the test result is negative or non-reactive and clinical symptoms persist, it is due to the very early infection where the virus may not be detected.
5. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The COVID-19 Antigen Rapid Test (Saliva) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the COVID-19 Antigen Rapid Test (Saliva). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

	PCR confirmed sample numbers	Correctly Identified	Rate
Positive Samples	101	91	90.1% (Sensitivity)
Negative Samples	305	303	99.3% (Specificity)
Total	406	394	97.0% (Total Accuracy)

90.1% Sensitivity: In total 101 PCR confirmed positive samples, 91 PCR confirmed positive samples were correctly identified by COVID-19 Antigen Rapid Test. There are 10 false negative cases.

99.3% Specificity: In total 305 PCR confirmed negative samples, 303 PCR confirmed negative samples were correctly identified by COVID-19 Antigen Rapid Test. There are 2 false negative positive cases.

97% Accuracy: In total 406 PCR confirmed samples, 394 PCR confirmed samples were correctly identified by COVID-19 Antigen Rapid Test.

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

Specificity Testing with Various Viral Strains

The COVID-19 Antigen Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

Description	Test Level
Adenovirus type 3	3.16×10^4 $TCID_{50}$/ml
Adenovirus type 7	1.58×10^5 $TCID_{50}$/ml
Human coronavirus OC43	1×10^6 $TCID_{50}$/ml
Human coronavirus 229E	5×10^5 $TCID_{50}$/ml
Human coronavirus NL63	1×10^6 $TCID_{50}$/ml
Human coronavirus HKU1	1×10^6 $TCID_{50}$/ml
Influenza A H1N1	3.16×10^5 $TCID_{50}$/ml
Influenza A H3N2	1×10^5 $TCID_{50}$/ml
Influenza B	3.16×10^6 $TCID_{50}$/ml
Parainfluenza virus 2	1.58×10^7 $TCID_{50}$/ml
Parainfluenza virus 3	1.58×10^8 $TCID_{50}$/ml
Respiratory syncytial virus	8.89×10^4 $TCID_{50}$/ml
MERS-coronavirus	8.89×10^4 $TCID_{50}$/ml

$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

Cross-reactivity

The following organisms were tested, and all found to be negative when tested with the COVID-19 Antigen Rapid Test (Saliva):

Arcanobacterium	1.0×10^8 org/ml
Candida albicans	1.0×10^8 org/ml
Corynebacterium	1.0×10^8 org/ml
Escherichia coli	1.0×10^8 org/ml
Moraxella catarrhalis	1.0×10^8 org/ml
Neisseria lactamica	1.0×10^8 org/ml
Neisseria subflava	1.0×10^8 org/ml
Pseudomonas aeruginosa	1.0×10^8 org/ml
Staphylococcus aureus subspaureus	1.0×10^8 org/ml
Staphylococcus epidermidis	1.0×10^8 org/ml
Streptococcus pneumoniae	1.0×10^8 org/ml
Streptococcus pygenes	1.0×10^8 org/ml
Streptococcus salivarius	1.0×10^8 org/ml
Streptococcus sp group F	1.0×10^8 org/ml

Interfering Substances

The following substances were tested with COVID-19 Antigen Rapid Test (Saliva) and no interference was observed:

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

BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501
2. Backinger, C.L. and Kingsley P.A. Recommended for Developing User Instruction Manual for Medical Devices Used in Home Health Care, Rockville, MD US Food and Drug Administration. Centre for Devices and Radiological Health, HHS Pub., FDA 93-4258.

FREQUENTLY ASKED QUESTIONS

How do I know if the test worked well?

When the control line (C) appears, it means the test has been performed correctly.

How soon can I read my results?

You can read your results after 15 minutes as long as the coloured line has appeared at control region (C). Do not read after 20 minutes.

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.

Can the result be wrong? Are there any factors that can affect the test result?

The results will only be accurate as far as the saliva is used and instructions followed carefully. Nevertheless, the result can be incorrect.

How to read the test if the colour and the intensity of the lines are different?

The colour and intensity of the lines have no importance for the result interpretation. The test should be considered as positive whatever the colour intensity of the test line (T) is.

What do I have to do is the result is positive?

A positive result means SARS-CoV-2 antigens is detected in saliva, and it is very likely you have COVID-19.

Positive results must be reported to MySejahtera (subject to the Prevention and Control of Infectious Diseases Act 1988 [Act 342])

Individuals are requested to go in person to a private health facility, COVID-19 Assessment Center (CAC) or a nearby health clinic for health assessment and further action. These individuals are required to wear face masks when leaving the house and avoid riding public transport.

What do I have to do is the result is negative?

A negative result means SARS-CoV-2 antigens is not detected or that viral load is too low to be recognized by the test. However, it is possible for this test to give a false negative result. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, go to a private health facility or health clinic for a health assessment.

If you fall under contact to a COVID-19 case, you must continue to undergo compulsory quarantine until the end of the quarantine period.

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For in-vitro diagnostics use


Storage between 2-8°C


Single Use


Manufacturer


Read instructions before use


Keep away from rain


Keep away from sunlight


Expiry date. Do not use beyond this date