COVID-19 Antigen Rapid Test

(Oral Fluid)

EN: For Self-testing
COVID-19 Antigen Rapid Test (Oral Fluid)

DE: Test zur Eigenanwendung
COVID-19 Antigen Schnelltest (Speichel)

SV: För självtest
Covid-19-antigensnabbtest (saliv)

DA: Til selvtest
COVID-19 antigen-hurtigtest (spyttest)

FI: Kotitesti
COVID-19-pika-antigeenitesti (syljestä)

NO: For selvtesting
COVID-19 antigen hurtigtest (Oralvæske)

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COVID-19 Antigen Rapid Test (Oral Fluid)

Package Insert
For Self-testing
English

【INTENDED USE】

The COVID-19 Antigen Rapid Test (Oral Fluid) is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 in human oral fluid. This test is designed for home use[1] with self-collected oral fluid samples. The test is intended for use in symptomatic individuals meeting the case definition for COVID-19, and to test asymptomatic individuals limited to contacts of confirmed COVID-19 cases or probable cases and to at-risk health workers.
The COVID-19 Antigen Rapid Test (Oral Fluid) obtain a preliminary results 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 diarrhea are found in a few cases.

【PRINCIPLE】

The COVID-19 Antigen Rapid Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human oral fluid 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 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 and young people 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 •Collection device (Funnel, tube and tube tip)
•Buffer •Package insert •Biosafety Bag

【ITEMS NOT PROVIDED】

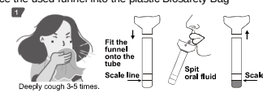
•Timer

【TESTING】

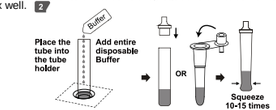
Before Testing
Do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.
Wash your hands with soap and water for at least 20 seconds before testing. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

Step 1: Specimen collection
Remove the funnel and plastic tube; fit the funnel onto the tube.
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.

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 the above specimen collection steps.
Place the used funnel into the plastic Biosafety Bag



Step 2: Specimen preparation
Tear to open the buffer and add entire buffer to the tube with oral fluid. Fit the tube tip onto the tube. Gently squeeze the tube **10-15 times** to mix well.



Step 3: 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 test cassette on a flat and 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 developing.

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 plastic Biosafety 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 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 is negative.
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, migration/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 COVID-19 Antigen 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 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 COVID-19 Antigen Rapid Test with RT-PCR test result.
The clinical trial included 406 oral fluid specimens. The results demonstrated 99.3% specificity and 90.1% sensitivity with an overall accuracy of 97.0%.

	PCR confirmed sample number	Correct identified	Rate
Positive sample	101	91	90.1% (Sensitivity)
Negative sample	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 detected 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 detected by COVID-19 Antigen Rapid Test. There are only 2 false positive cases.
97% Accuracy: In total 406 PCR confirmed samples: 394 PCR confirmed samples were correctly detected by COVID-19 Antigen Rapid Test.
The observed accuracy may vary depending on the prevalence of the virus in the population.

Complement clinical performance

The complement clinical trial included 171 asymptomatic oral fluid specimens. The results demonstrated >99.9% specificity and 90.1% sensitivity with an overall accuracy of 95.9%.

	PCR confirmed sample number	Correct identified	Rate
Positive sample	71	64	90.1% (sensitivity)
Negative sample	100	100	>99.9% (Specificity)
Total	171	164	95.9% (Total Accuracy)

90.1% Sensitivity: In total 71 PCR confirmed positive samples: 64 PCR confirmed positive samples were correctly detected by COVID-19 Antigen Rapid Test. There are 7 false negative cases.
>99.9% Specificity: In total 100 PCR confirmed negative samples: 100 PCR confirmed negative samples were correctly detected by COVID-19 Antigen Rapid Test.
95.9% Accuracy: In total 171 PCR confirmed samples: 164 PCR confirmed samples were correctly detected by 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
Adenovirus type 3	3.16×10^5 TCID$_{50}$/ml
Adenovirus type 7	1.58×10^5 TCID$_{50}$/ml
Human coronavirus OC43	1×10^5 TCID$_{50}$/ml
Human coronavirus 229E	5×10^5 TCID$_{50}$/ml
Human coronavirus NL63	1×10^5 TCID$_{50}$/ml
Human coronavirus HKU1	1×10^5 TCID$_{50}$/ml
Influenza A H1N1	3.16×10^5 TCID$_{50}$/ml
Influenza A H3N2	1×10^5 TCID$_{50}$/ml
Influenza B	3.16×10^5 TCID$_{50}$/ml
Parainfluenza virus 2	1.58×10^7 TCID$_{50}$/ml
Parainfluenza virus 3	1.58×10^6 TCID$_{50}$/ml
Respiratory syncytial virus	8.89×10^4 TCID$_{50}$/ml
MERS-coronavirus	1.17×10^4 TCID$_{50}$/ml
Arcanobacterium	1.0×10^5 org/ml
Candida albicans	1.0×10^5 org/ml
Corynebacterium	1.0×10^5 org/ml
Escherichia coli	1.0×10^5 org/ml
Moraxella catarrhalis	1.0×10^5 org/ml
Neisseria lactamica	1.0×10^5 org/ml
Neisseria subflava	1.0×10^5 org/ml
Pseudomonas aeruginosa	1.0×10^5 org/ml
Staphylococcus aureus subspaureus	1.0×10^5 org/ml
Staphylococcus epidermidis	1.0×10^5 org/ml
Streptococcus pneumoniae	1.0×10^5 org/ml
Streptococcus salivarius	1.0×10^5 org/ml
Streptococcus sp group F	1.0×10^5 org/ml

Interfering Substances

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

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

【Q&A】

1. How do I know if the Test worked well?
COVID-19 Antigen Rapid Test 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. However It is recommended to collect the first oral fluid 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 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.
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, migration/traveling, attending events and etc should follow your local COVID guidelines/requirements.