Test your health

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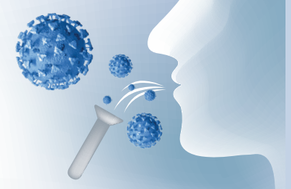
PRIMA®

PRIMACOVID®

PRIMA® HOME TEST

COVID-19 SALIVA SELF-TEST

Rapid self-test for the qualitative detection of SARS-CoV-2 antigens present in the human oral fluid specimen



15 min. | 1 test

SYMBOLS

Read the instructions before use	Biological Risk	Keep Dry
IVD In vitro diagnostic medical device	REF List number	Manufacturer
Expiry date (last day of the month)	+2°C 30°C Temperature limits	Do not reuse
Do not use if the package is damaged	Σn Sufficient for <n> test	CE EC Marking
LOT Lot number	EC REP Authorised Representative in the European Community	

SARS-CoV-2 AND COVID-19

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) has been recognized as the virus responsible for the COVID-19 pandemic.
As with other respiratory diseases, SARS-CoV-2 can cause an asymptomatic infection, causing mild symptoms such as cold, sore throat, cough and fever, loss of taste and/or sense of smell, or more severe symptoms such as pneumonia and respiratory distress with a fatal outcome. The incubation period of SARS-CoV-2 varies from 1 to 14 days, with an average of 3 to 7 days.

PRINCIPLE AND INTENDED USE OF THE TEST

COVID-19 Saliva Self-Test is single use qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid antigens in human oral fluid specimens. The test device contains anti SARS-CoV-2 antibodies. This test is designed for home use with self-collected oral fluid samples from symptomatic individuals suspected of being infected with COVID-19. The COVID-19 Saliva Self-Test provides only a preliminary result, but the final confirmation should be based on clinical diagnostic results.

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F.A.Q – QUESTIONS AND ANSWERS

HOW DO I KNOW IF THE COVID-19 SALIVA SELF-TEST WORKED WELL?

COVID-19 Saliva Self -Test is a rapid chromatographic immunoassay far the qualitative detection of SARS-CoV-2 antigens present in human oral fluid. To serve as a procedural control, the C line will always appear indicating that the test was performed correctly.

WHEN CAN THE TEST BE USED?

The COVID-19 Saliva Self-Test can be carried out at any time of the day. Nevertheless, it is recommended to collect the oral fluid in the morning.
In particular, its use is recommended in the following situations: (1) in the case of symptomatic individuals: within the first 5 days of the onset of symptoms, when the viral load is highest; (2) in case of close contact with positive individuals: in this case, the antigen test must be done as soon as possible, within the first 7 days of contact (both in the case of symptoms and in the absence of symptoms); (3) in all situations/areas where access to molecular tests is limited or not possible; (4) for screening in high-risk areas and closed environments, facilities such as nursing and care homes or residential environments for persons with disabilities, schools, prisons, detention centers or other reception facilities. In case of repeated screening, this should be performed every 2-4 days. The COVID-19 Saliva Self-Test is not to be used in emergency situations.

WHAT SHOULD BE DONE IF THE RESULT IS POSITIVE?

A positive result means the presence of SARS-CoV-2 antigens. A positive result 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.

WHAT SHOULD BE DONE 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. 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 alter 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.

WHAT IS THE DIFFERENCE BETWEEN ANTIGENIC AND MOLECULAR TESTS?

There are different types of tests for COVID-19. Molecular tests (also known as PCR tests) detect the genetic material of the virus. While, antigenic tests detect the proteins of the virus. Antigenic tests are very specific for the virus but are not as sensitive as molecular tests. This means that a positive result tends to be accurate, but a negative result does not rule out infection. If you get a negative result but your symptoms persist, contact your doctor anyway.

CAN THE RESULT BE INCORRECT?

The result is correct if the instructions are followed carefully, and fresh human oral fluid is collected. Coronavirus strains (not SARS-CoV-2) or other interference factors may give preliminary positive results. *The substances at the below concentration (table 1) will not interfere with test results:*

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

Table 1. Interfering substances list.

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table 2 below at certain concentrations:

SUBSTANCE	CONCENTRATION
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Coronavirus umano OC43	1 x 10^6 TCID50/ml
Coronavirus umano 229E	5 x 10^5 TCID50/ml
Coronavirus umano NL63	1 x 10^6 TCID50/ml
Coronavirus umano HKU1	1 x 10^8 TCID50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H1N1	1 x 10^5 TCID50/ml
Neisseria subflava	1 x 10^8 org/ml
Pseudomonas aeruginosa	1 x 10^8 org/ml
Stahylococcus aureus subspaureus	1 x 10^8 org/ml
Stahylococcus salivarius	1 x 10^8 org/ml
Stahylococcus pneumoniae	1 x 10^8 org/ml
Influenza B	3.16 x 10^6 TCID50/ml
Parainfluenza Virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza Virus 3	1.58 x 10^8 TCID50/ml
Respiratory Syncitial Virus	8.89 x 10^4 TCID50/ml
MERS-Coronavirus	1.17 x 10^4 TCID50/ml
Arcanobacterium	1 x 10^8 org/ml
Candida albicans	1 x 10^8 org/ml
Corynebacterium	1 x 10^8 org/ml
Escherichia coli	1 x 10^8 org/ml
Moraxella catarrhalis	1 x 10^8 org/ml
Neisseria Lactamica	1 x 10^8 org/ml
Stahylococcus sp group F	1 x 10^8 org/ml

Table 2. Cross-reactive substances list.

IS THE RESULT RELIABLE IF READ AFTER 20 MINUTES?

No. The test must be read 15 minutes after the procedure is completed. Do not read the results after 20 minutes.

HOW TO INTERPRET THE TEST IF THE COLOUR AND INTENSITY OF THE TEST AND CONTROL LINES ARE DIFFERENT?

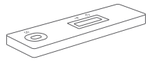
The color and intensity of the lines are not important for the interpretation of the result. Any shade of color in the T region should be considered positive. Please refer to the indications and pictures in the section “result interpretation” to correctly evaluate the results.

WHAT IS THE ACCURACY OF THE COVID-19 SALIVA SELF-TEST?

The test is very accurate. Evaluation reports show a relative Sensitivity of 90.1% (95% CI: 82.5-95.1%) and a relative Specificity of 99.3 % (95% CI: 97.7%-99.9%). The accuracy of the test is 97.0% (95% CI: 94.9-98.5%).

CONTENT

✻ The number of the testing devices of the kit may vary. For the exact number of tests contained, please refer to the "content" section on the external box.



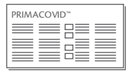
•✻ hermetically sealed aluminium pouch containing:
- 1 COVID-19 ORAL FLUID ANTIGEN RAPID TEST cassette
- 1 desiccant bag

The desiccant packet must not be used. Dispose of it with household waste without opening it.

•✻ collection kit with plastic tube, dropper tip and funnel.

•✻ COVID-19 ORAL FLUID ANTIGEN RAPID TEST extraction buffer

•✻ biohazard specimen bag.

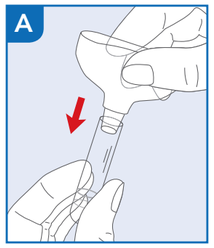


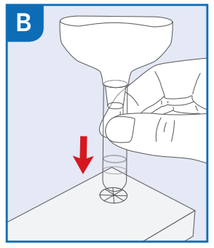
•1 instructions for use leaflet

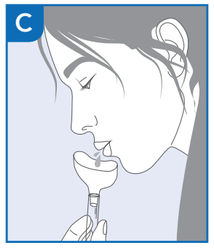
Material required but not supplied: a device to measure time (i.e. timer, watch).

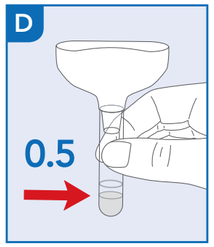
PRECAUTIONS

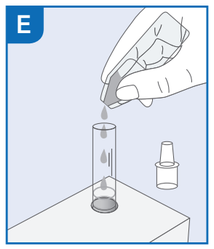
- Read these instructions for use carefully before performing the test.
- Open all sealed components (test, extraction buffer) only before performing the Test.
- Keep the Test out of the reach of children.
- Do not use the Test after the expiry date or if the package has been damaged.
- Do not use test if the pouch is damaged.
- Use the test once only. All kit components are single use.
- The test is for external use only.
- Wash hands thoroughly before and alter handling.
- In vitro diagnostic self-testing device for individual use.
- Do not eat, drink, or smoke in the area where specimens or kits are handled.
- After use, all components can be disposed according to local regulations; all specimens should be considered potentially hazardous and handled in the same manner as an infectious agent Store the kit components at a temperature between +2°C and +30°C. Do not freeze.
- If the preliminary result is positive, share the test result with your healthcare provider and carefully follow your local COVID-19 guidelines.
- Do not swallow the buffer. Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contact occurs.
- Children and young people should perform the test under adult supervision.

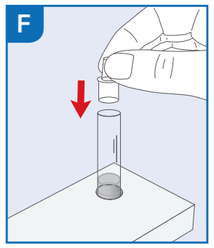


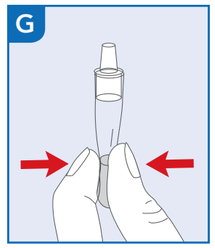


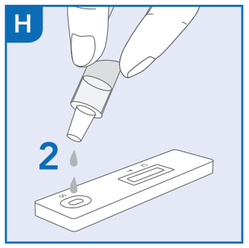












TEST PROCEDURE

BEFORE TESTING PROCEDURE: Do not place anything in the mouth including food, drink, chewing 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.

1) Lay out the material needed as follows: open the aluminium bag, take out only the cassette and dispose of the desiccant bag. Place the cassette on a clean, dry, flat surface. Shake the sample collection tube to release the liquid deposited on the cap. Then unscrew the blue cap. Place the sample collection tube containing the extraction buffer in the hole (stand tube) on the external box.

2) Fit the funnel onto the plastic tube (–FIG. **A**) and place the collection kit in the stand tube present on the external box. –FIG. **B**

3) 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 the distance from other people.

4) Split the oral fluid (without bubbles) into the funnel until reaching the first scale line –FIG. **C, D**. If you do not collect enough oral fluid repeat the sampling procedure described in point 3.

5) Dispose the funnel inside the biosafety bag provided.

6) Open the extraction buffer vial and add the entire buffer onto the plastic tube containing the oral fluid previously collected. –FIG. **E**

7) Insert the dropper tip –FIG. **F**. Gently squeeze the tube 10-15 times to mix well the solution. –FIG. **G**

8) Dispense 2 drops of extracted sample into the sample well (S) of the test cassette and start the timer –FIG. **H**. Do not move the cassette during testing.

9) Wait 15 minutes and read the results obtained as follows.

10) After the test is completed, place all the components in the plastic biosafety bag and dispose according to local regulations. Do not reuse any kit component.

11) Wash your hands thoroughly after test disposal.

RESULT INTERPRETATION

READ THE RESULT AT 15 MINUTES. DO NOT READ THE RESULT AFTER 20 MINUTES.

Please share your test result with your healthcare provider and carefully follow your local COVID-19 guidelines/requirements.

POSITIVE

Two coloured lines appear. A coloured line must always appear in the Control line region (C) and another line should appear in the Test line region (T).

WHAT SHOULD I DO?

SARS-CoV-2 antigens are present in the specimen and were detected by the test.

A positive result means it is very likely you have COVID-19, but it should be confirmed through PCR test.

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.

***NOTE: The colour intensity of the control and test lines may vary depending on the concentration of SARS-CoV-2 antigens present in the sample. Therefore, any shade of colour in the T region should be considered positive.**

NEGATIVE

A coloured line appears in the Control line region (C). No line appears in the Test line region (T).

WHAT SHOULD I DO?

The test did not detect the presence of SARS-CoV-2 antigens in the sample. You are unlikely to have COVID-19. However, it is possible far 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 alter 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-19 guidelines/requirements.

INVALID

The Control line (C) does not appear.

WHAT SHOULD I DO?

Review the procedure and repeat the test with a new device and a new sample or contact your doctor. Insufficient sample volume or incorrect execution of the procedure are the most likely reasons for the absence of the control line (invalid result).

LIMITATIONS

1. Failure to follow the testing steps may give inaccurate results.
2. The COVID-19 Saliva Self-Test 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 possible at an early stage where the virus may not be detected. It is recommended to perform 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.