Test your health

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PRIMA®

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 ANTIGEN SELF-TEST is single use qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Nucleocapsid antigens in human nasal swab specimens. The test is intended to be used with self-collected nasal swab specimens. It can be used 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. SARS-CoV-2 Antigens are generally detectable in the upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine the infectious status. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow-up care from their healthcare provider.

F.A.Q – QUESTIONS AND ANSWERS

HOW DOES COVID-19 ANTIGEN SELF-TEST WORK?

The test is for the qualitative detection of SARS-CoV-2 antigens in self-collected swab specimens. A positive result indicates SARS-CoV-2 antigens present in the specimen. 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 ANTIGEN SELF-TEST can be carried out at any time of the day. 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 ANTIGEN 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?

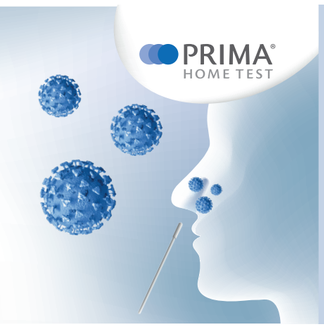
A negative result means that you are negative or that the viral load is too low to be recognized by the test. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. If you experience symptoms such as headaches, migraines, fever, 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.

PRIMACOVID®

COVID-19 ANTIGEN SELF-TEST

Rapid self- test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens in human nasal specimens

15 min.



MEDICAL DEVICE INSIDE THE KIT

STERILE EO STERILE SWAB

Address: Medico Technology Co., Ltd
Room 201 of building 14th and building 17th,
HengyiLane Yuanhu Road, Zhangbei Industrial Park,
Longcheng Street, Longgang district,
Shenzhen, Guangdong, China
www.medicoswab.com

CE 0413

EC REP Wellkang Ltd (www.CE-marking.eu)
Enterprise Hub,
NW Business Complex,1,
BeraghmoreRd.Derry,
BT488SE, N. Ireland, UK

SYMBOLS

Read the instructions before use	Biological Risk	Keep Dry
In vitro diagnostic medical device	List number	Manufacturer
Expiry date (last day of the month)	Temperature limits	Do not reuse
Do not use if the package is damaged	Sufficient for <n> test	EC Marking
Authorised Representative in the European Community	Sterilized using Ethylene Oxide	Lot number

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. Nevertheless, the result can be incorrect if inadequate sampling volume or if the test cassette gets wet before test performing, or if the number of extraction buffer drops are less than 3 or more than 4. Besides, due to the immunological principles involved, incorrect results may occur: It is always recommended to consult the doctor for such tests based on immunological principles.

The substances at the below concentration (table 1) will not interfere with test results:

SUBSTANCE	CONCENTRATION
Whole Blood	20µl/ml
Mucin	50µg/ml
Budesonide Nasal Spray	200µl/ml
Dexamethasone	0.8mg/ml
Flunisolide	6.8ng/ml
Mupirocin	12mg/ml

SUBSTANCE	CONCENTRATION
Oxymetazoline	0.6mg/ml
Phenylephrine	12mg/ml
Rebetol	4.5µg/ml
Relenza	282ng/ml
Tamiflu	1.1µg/ml
Tobramycin	2.43mg/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
Human coronavirus 229E	5x 10^5 TCID50/ml
Human coronavirus NL63	1x 10^5 TCID50/ml
Human coronavirus OC43	1 x 10^6 TCID50/ml
MERS coronavirus Florida	1.17x10^4 TCID50/ml
Human coronavirus HKU1	1x 10^5 TCID50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/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 syncytial virus	8.89 x 10^4 TCID50/ml
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human Rhinovirus 16	8.89 x 10^5 TCID50/ml

SUBSTANCE	CONCENTRATION
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Arcanobacterium	1.0x10^8 org/ml
Candida albicans	1.0x10^8 org/ml
Corynebacterium	1.0x10^8 org/ml
Escherichia coli	1.0x10^8org/ml
Moraxella catarrhalis	1.0x10^8 org/ml
Neisseria lactamica	1.0x10^8 org/ml
Neisseria subflava	1.0x10^8 org/ml
Pseudomonas aeruginosa	1.0x10^8 org/ml
Staphylococcus aureus subspaureus	1.0x10^8org/ml
Staphylococcus epidermidis	1.0x10^8 org/ml
Streptococcus pneumoniae	1.0x10^8 org/ml
Streptococcus pyogenes	1.0x10^8 org/ml
Streptococcus salivarius	1.0x10^8 org/ml
Streptococcus sp group F	1.0x10^8 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 ANTIGEN SELF-TEST?

The test is very accurate. The COVID-19 ANTIGEN SELF-TEST was evaluated with clinical nasal swab specimens whose status was confirmed using RT-PCR (nasopharyngeal swab). The sensitivity was calculated for the range from high to low viral load. The results are presented in the following tables.

		RT-PCR, Ct ≤25	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	261	3
	Negative	0	611
	Total	261	614

Diagnostic sensitivity (Ct≤25): 100% (CI: 98.9%-100%)
Overall agreement (Ct≤25): 99.7% (CI: 99.0% - 99.9%)
Diagnostic specificity: 99.5% (CI: 98.6% - 99.9%)

		RT-PCR, Ct ≤30	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	335	3
	Negative	1	611
	Total	336	614

Diagnostic sensitivity (Ct≤30): 99.7% (CI: 98.4% - 99.9%)
Overall agreement (Ct≤30): 99.6% (CI: 98.9% - 99.9%)
Diagnostic specificity: 99.5% (CI: 98.6% - 99.9%)

		RT-PCR, Ct ≤33	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	381	3
	Negative	4	611
	Total	385	614

Diagnostic sensitivity (Ct≤33): 99.0% (CI: 97.4% - 99.7%)
Overall agreement (Ct≤33): 99.3% (CI: 98.6% - 99.7%)
Diagnostic specificity: 99.5% (CI: 98.6% - 99.9%)

		RT-PCR, Ct <36	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	423	3
	Negative	12	611
	Total	435	614

Diagnostic sensitivity (Ct<36): 97.2% (CI: 95.2% - 98.6%)
Overall agreement (Ct<36): 98.6% (CI: 97.7% - 99.2%)
Diagnostic specificity: 99.5% (CI: 98.6% - 99.9%)

Note: There are 12 specimens with very low viral load(Ct≥36), 8 of them were correctly identified.

The COVID-19 ANTIGEN SELF-TEST was evaluated with clinical nasal swab specimens from asymptomatic individuals whose status was confirmed using RT-PCR (nasopharyngeal swab). The sensitivity was calculated for the range from high to low viral load. The results are presented in the following tables.

		RT-PCR, Ct ≤25	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	20	1
	Negative	0	99
	Total	20	100

Diagnostic sensitivity (Ct≤25): 100% (CI: 86.1% - 100%)
Overall agreement (Ct≤25): 99.2% (CI: 95.4% - 100%)
Diagnostic specificity: 99.0% (CI: 94.6% - 100%)

		RT-PCR, Ct ≤30	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	64	1
	Negative	0	99
	Total	64	100

Diagnostic sensitivity (Ct≤30): 100% (CI: 95.4% - 100%)
Overall agreement (Ct≤30): 99.4% (CI: 96.6% - 100%)
Diagnostic specificity: 99.0% (CI: 94.6% - 100%)

		RT-PCR, Ct ≤33	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	75	1
	Negative	0	99
	Total	75	100

Diagnostic sensitivity (Ct≤33): 100% (CI: 96.1% - 100%)
Overall agreement (Ct≤33): 99.4% (CI: 96.9% - 100%)
Diagnostic specificity: 99.0% (CI: 94.6% - 100%)

		RT-PCR, Ct ≤38	
		Positive	Negative
COVID-19 ANTIGEN SELF-TEST	Positive	87	1
	Negative	2	99
	Total	89	100

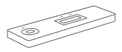
Diagnostic sensitivity (Ct≤38): 97.8% (CI: 92.1% - 99.7%)
Overall agreement (Ct≤38): 98.4% (CI: 95.4% - 99.7%)
Diagnostic specificity: 99.0% (CI: 94.6% - 100%)

BIBLIOGRAPHY

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine 2020.
2. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020 (https://www.who.int/dg/speeches/detail/who-director-general-s opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)
3. Centers for Disease Control and Prevention, Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines clinicalspecimens.html)
4. European Centre for Disease Prevention and Control. Options for the use of rapid antigen tests for COVID-19 in the EU/EEA - first update. 2021. https://www.ecdc.europa.eu/en/publications-data/optionsuse-rapid-antigen-tests-covid-19-eueea-first-update
5. WHO, Advice on the use of point-of-care immunodiagnostic tests for COVID-19 https://www.who.int/ news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19
6. Council of the European Union, Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the E, 20 January 2021.

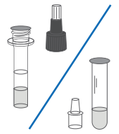
CONTENT

✻ 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 ANTIGEN SELF-TEST cassette
1 desiccant bag

Do not open the sealed aluminium bag until just before performing the test. Take care to open it as marked. The desiccant packet must not be used. Dispose of it with household waste without opening it.



•✻ sample collection tube with dropper containing the COVID-19 ANTIGEN SELF-TEST extraction buffer

•✻ sterile nasal swab

•✻ biohazard specimen bag

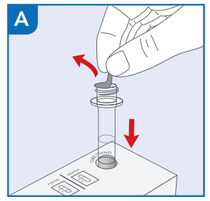
•1 instructions for use leaflet

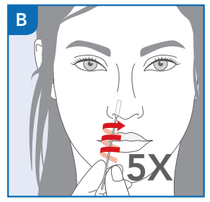
Material required but not supplied: a device to measure time (i.e. timer, watch).

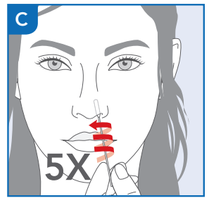
On the back of the test package there is a hole which can be used as a test tube holder.

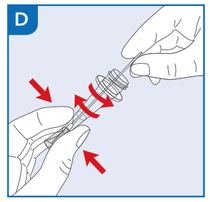
PRECAUTIONS

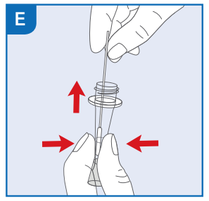
- Read these instructions for use carefully before performing the test. Follow the indicated time strictly.
- Open all sealed components (test, extraction buffer) only before performing the Test.
- Keep the Test out of the reach of children.
- Do not use the Test after the expiry date or if the package has been damaged.
- Do not use test if the pouch is damaged or opened.
- Use the test once only. All kit components are single use. Do not dismantle and touch the test window.
- 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 as packaged in the sealed pouch in a dry place at a temperature between +2°C and +30°C, avoiding areas of excess moisture. The test must remain in the sealed pouch until use. Do not freeze.
- This test is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.
- 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 should perform the test under adult supervision.
- Ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.

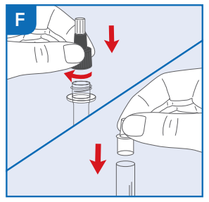


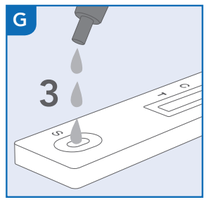












TEST PROCEDURE

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 aluminum bag, take out only the cassette and dispose of the desiccant bag. Place the cassette on a clean and level surface. Best results will be obtained if the test is performed immediately after opening the aluminum pouch.

2) Remove the cover of the tube with Extraction buffer and place the tube in the tube holder in the box. –FIG. **A**

3) Remove the sterile swab from the pouch.

4) Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the insides of your nostril for 5-10 times against the nasal wall.–FIG. **B**
Note: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain. When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended. If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

5) Gently remove the swab.

6) Using the same swab, repeat step 4 in your other nostril. –FIG. **C**. Withdraw the swab.

7) Place the swab into the Extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against to the tube and rotate the swab for 10-15 seconds. –FIG. **D**

8) Remove the swab while squeezing the swab head against the inside of the Extraction tube.–FIG. **E**

9) Place the swab in the biosafety bag.

10) Close the cap or fit the tube tip onto the tube. –FIG. **F**

11) Invert the specimen extraction tube and add 3 drops of extracted specimen to the sample well(S) of the test cassette and start the timer. –FIG. **G** Do not move the test cassette during test developing.

12) Read the result at 15 minutes. Do not read the result after 20 minutes. Note: after test is completed, place all the components into plastic Biosafety Bag and dispose according to local regulations.

RESULT INTERPRETATION

READ THE RESULTS AT 15 MINUTES. DO NOT READ THE RESULTS 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 to reflect this.

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.

***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.

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 test or contact with a COVID-19 test center.
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. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.

2. The COVID-19 ANTIGEN SELF-TEST will only indicate the presence of SARS-CoV-2 antigens in the specimen.

3. 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 kit or test with a molecular diagnostic device to rule out infection in these individuals.

4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

5. Positive results of COVID-19 may be due to infection with non- SARS-CoV-2 coronavirus strains or other interference factors.

6. Failure to follow these procedures may alter test performance.

7. False negative results may occur if a specimen is improperly collected or handled.

8. False negative results may occur if inadequate levels of viruses are present in the specimen.