

Test your health

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EC REP Qarad EC-REP BV
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PRIMACOVID®

COVID-19 NEUTRALISING IgG SEROLOGICAL TEST

Rapid self-test for the qualitative detection of COVID-19 antibodies produced after vaccination in human whole blood samples



MEDICAL DEVICE INSIDE THE KIT

STERILE R LANCET

Huain Tianda Medical Instruments Co., Ltd.
No. 106, East Songjiang Road, Huaiyin
Economic & Technological Development
Zone 223002 Huain City, Jiangsu - China

EC REP Shanghai International
Holding Corp GmbH
(Europe), Eiffelstrasse 80,
20537 Hamburg, Germany

STERILE R ANTISEPTIC CLEANSER GAUZE: 70% ALCOHOL

Phoenix Innovative Healthcare
Manufacturers Pvt. Ltd.
EL-209, Shil Mahape Road,
Electronic Zone, MIDC, TC Industrial Area,
Mahape, Navi Mumbai 400 710 MH | India

EC REP Advena Ltd.,
2nd Flr, Tower
Street, Swatar,
BKR 4013, Malta

SYMBOLS

Read the instructions before use	In vitro diagnostic medical device	Lot number
Expiry date (last day of the month)	List number	Manufacturer
Sterilised using irradiation	Temperature limits	Do not reuse
Authorised Representative in the European Community	Sufficient for <n> test	EC Marking

SARS-COV-2 AND COVID-19

Coronavirus SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) has been recognized as the causative agent of the "Coronavirus Disease 2019" (COVID-19) pandemic. SARS-CoV-2 can cause asymptomatic infection, mild symptoms such as cold, sore throat, loss of sense of smell and taste, cough and fever, or more severe symptoms such as pneumonia and breathing difficulties with even fatal results.

SPIKE PROTEIN AND NEUTRALISING ANTIBODIES

The SARS-CoV-2 virus is composed by a set of proteins containing its genome. One of the most important proteins in the virus infection process is the Spike protein. This protein covers the surface of the virus, forming characteristic bumps (making it look like a crown - hence the name 'Coronavirus'). The Spike protein binds to specific receptors on the surface of target cells and allows the virus to penetrate inside the cell. For this reason, antibodies against the Spike protein (in particular immunoglobulin G, IgG) can inhibit the interaction between virus and cells, preventing the infection process and the development of the associated disease. These antibodies are defined "neutralising", meaning that they are able to neutralise the virus infection process. Consequently, the Spike protein or portions thereof have been used as immunological targets in the approved vaccines against COVID-19. In this context, vaccinated people will produce IgG antibodies against SARS-CoV-2 Spike protein.

SEROLOGICAL TESTS DETECTING ANTIBODIES AGAINST THE SPIKE PROTEIN OF SARS-CoV-2

Serological tests can detect the immune response of the body to COVID-19 vaccination. Moreover, these tests detect the presence of antibodies in blood produced by the body in response to infections including SARS-CoV-2. These tests detect the body's immune response to the exposure to a virus but not the presence of the virus itself. Recent studies have shown that, in people infected by SARS-CoV-2, anti-Spike IgG antibodies are expressed within 14 days from symptoms onset.

In this context, a rapid test detecting antibodies against the Spike protein of SARS-CoV-2 can be of great interest for the general population, since it can reveal the presence of antibodies involved in virus neutralisation produced in response to infection or to vaccination.

Serological tests are not conclusive by themselves for the diagnosis of an ongoing SARS-CoV-2 infection and are not able to distinguish between an active and a past infection, as the antibodies persist long after the end of the infection. In addition to that, a positive result does not indicate that protective immunity has been acquired.

For more information see result interpretation section and FAQ section.

PRINCIPLE OF THE TEST

COVID-19 NEUTRALISING IgG SEROLOGICAL TEST is a rapid immunochromatographic assay for the qualitative detection of IgG antibodies against SARS-CoV-2 Spike protein in human blood samples. A diluent is used to dilute the sample and promote its flow along the test strip.

F.A.Q. QUESTIONS AND ANSWER

HOW DOES COVID-19 NEUTRALISING IgG SEROLOGICAL TEST WORK?

The test detects the presence of IgG class antibodies to the SARS-CoV-2 Spike protein by means of specific antibodies and colloidal gold nanoparticles embedded in the test strip.

WHEN CAN THE TEST BE USED?

COVID-19 NEUTRALISING IgG SEROLOGICAL TEST can be performed at any time of the day. The test can be taken by people who want to verify their immune response to vaccination, at the end of the vaccination cycle. If you are under pharmacological treatment, check with your doctor if the drugs you are taking (e.g. immunosuppressive drugs, corticosteroids, ...) can alter the levels of circulating antibodies. COVID-19 NEUTRALISING IgG SEROLOGICAL TEST is not for use in emergency situations.

DOES COVID-19 NEUTRALISING IgG SEROLOGICAL TEST DETECT OTHER PARAMETERS?

No. COVID-19 NEUTRALISING IgG SEROLOGICAL TEST only detects the presence of IgG antibodies anti-Spike protein in the blood sample. COVID-19 IgG SPIKE SELF-TEST is not intended for the assessment of protective immunity of vaccinated individuals: this evaluation is ongoing, and the scientific community is collecting data to identify the antibody concentration that will ensure effective protection by SARS-CoV-2 infections. The test does not necessarily detect SARS-CoV-2 ongoing infection.

CAN THE RESULT BE NOT CORRECT?

The test result is reliable as long as the instructions are carefully followed. However, the result may not be correct if: (I) the device comes into contact with other liquids before use; (II) the amount of blood and/or diluent is insufficient; (III) the number of drops dispensed into the well is incorrect; or (IV) the reading time of the result is not respected. The plastic pipette supplied, allows the correct volume of blood to be collected. False positive results may be due to past or current infections caused by other Coronaviruses or other interfering substances. Possible cross-reactions can be observed with Rheumatoid Factor (RF), Adenovirus IgM/IgG, Hepatitis C Virus (HCV) Igs, Antinuclear Antibodies (ANA). Due to the current lack of samples with very high concentrations of antibodies, the manufacturer cannot exclude the possibility that very high concentrations of IgG antibodies against SARS-CoV-2 Spike protein in the blood sample

could lead to false negative results (hook effect). It is not possible to ensure that the test will detect antibodies against all SARS-CoV-2 Spike variants.

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

The colour and intensity of the lines are not important for the interpretation of the results. Refer to the indications and to the images in the sections "Results Interpretation" to correctly evaluate the result.

IF READ AFTER 15 MINUTES, IS THE RESULT RELIABLE?

No. The test should be read 10 minutes after the end of the procedure and no later than 15 minutes. Results read after 15 minutes may not be correct (false positive results may appear).

DOES THE COVID-19 IgG SPIKE SELF-TEST DETECT ANTIBODIES PRODUCED POST VACCINATION?

Yes. The currently approved vaccines (Pfizer BioNTech, Moderna, Astrazeneca, Johnson & Johnson) induce the human body to produce antibodies against Spike protein, which is the target of COVID-19 NEUTRALISING IgG SEROLOGICAL TEST. PRIMA is conducting European specific studies on vaccinated people in order to evaluate the ability of the test to detect antibodies produced after vaccination. In the following table the positivity rates obtained with COVID-19 NEUTRALISING IgG SEROLOGICAL TEST after 14 days post-completion of the vaccination cycle are indicated. It is not clear yet for how long the antibodies will last from the vaccination.

VACCINE	Positivity rate % (95% Wilson Confidence Interval)
Pfizer BioNTech	98,3% (95% CI: 95,6-99,3%)
Moderna	95,2% (95% CI: 77,3-99,2%)
Oxford-AstraZeneca	98,5% (95% CI: 92,1-99,7%)

REFERENCES

- European Centre for Disease Prevention and Control, Disease background of COVID-19 (<https://www.ecdc.europa.eu/en/2019-ncov-background-disease>)
- <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>
- HUANG, Yuan, et al. Structural and functional properties of SARS-CoV-2 spike protein: potential antiviral drug development for COVID-19. Acta Pharmacologica Sinica, 2020, 41.9: 1141-1149.
- SHANG, Jian, et al. Structural basis of receptor recognition by SARS-CoV-2. Nature, 2020, 581.7807: 221-224
- Jeyanathan, M., Afkhami, S., Smail, F., Miller, M. S., Lichty, B. D., & Xing, Z. (2020). Immunological considerations for COVID-19 vaccine strategies. Nature Reviews Immunology, 20(10), 615-632.

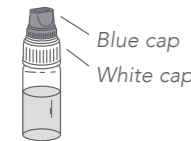
CONTENT OF THE KIT

* 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.

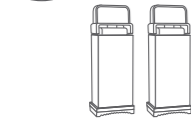


- * hermetically sealed aluminium pouch containing:
1 COVID-19 IgG SPIKE RAPID TEST cassette
1 desiccant bag

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.



- 1 vial with dropper tip containing the COVID-19 IgG SPIKE RAPID TEST DILUENT required for * test



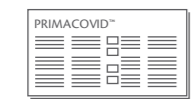
- * sterile lancets for self-drawing blood



- * transparent plastic bag containing a pipette for collecting blood



- * antiseptic skin cleanser gauze



- 1 instructions for use leaflet

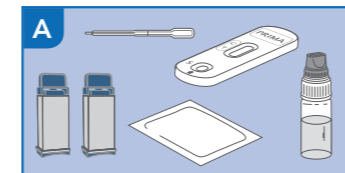


Material required but not supplied: cotton wool, which can be used to remove residual blood drops after the puncture, a device to measure time (i.e. timer, watch).

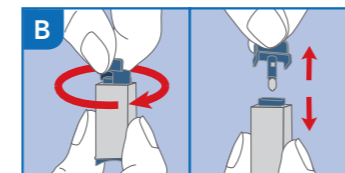
PRECAUTIONS

- COVID-19 NEUTRALISING IgG SEROLOGICAL TEST does not indicate the presence of the virus (and therefore whether or not a person is contagious, as is the case for nasal-opharyngeal swabs) but only the existence of antibodies against it.
- Read these instructions for use carefully before testing. The Test is reliable if the instructions are carefully followed.
- Keep kit components out of the reach of children.
- Do not use the Test after the expiration date or if the packaging is damaged.
- Use the Test and the sterile lancet only once.
- The Test is for external use only.
- In vitro diagnostic device for individual use.
- Follow the procedure exactly, using only specified quantities of blood and diluent.
- After use, dispose of all components according to local regulations, ask your pharmacist for advice.
- Not recommended for use by people taking medicines that make blood thinner (anticoagulants) or with haemophilia problems.
- Store the Test components at a temperature of +4°C to +30°C. DO NOT FREEZE.
- DO NOT SWALLOW.

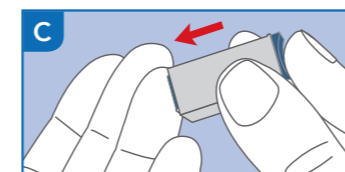
TEST PROCEDURE



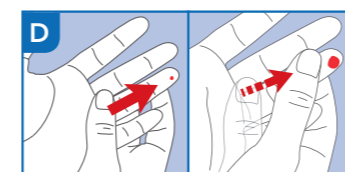
Bring the kit components at room temperature (15-30°C) before testing if the kit was stored refrigerated.



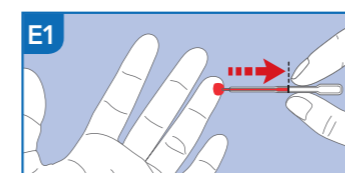
2) Wash hands with soap and warm water, rinse with clean water and allow to dry. Note: The use of warm water facilitates capillary blood collection as it induces vasodilation.



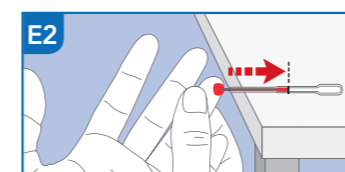
3) Use the provided gauze to clean the puncture site.



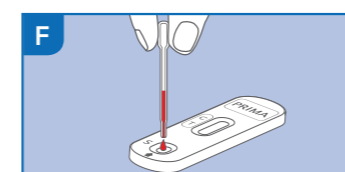
4) Carefully rotate the protective cap of the sterile lancet 360° without pulling it, then extract and discard the cap. –FIG. B



5) Carefully massage the finger chosen for the puncture (the side of the ring finger is recommended). It is important that the massage is done from the palm of the hand to the fingertip, to improve blood flow. Press the open end of the lancet (the side the cap has been extracted from), against the fingertip –FIG. C. The tip of the lancet automatically retracts after use. If the lancet does not work properly, discard it and use the second one supplied. If the second one is not required, it can be disposed of without special precautions.



6) Holding the hand downwards, massage the finger until a large drop of blood forms. It is important to massage from the palm of the hand to the fingertip to improve blood flow. –FIG. D

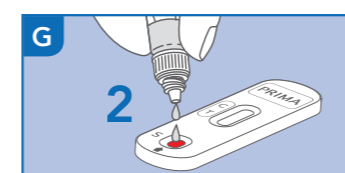


7) Take the pipette without pressing the bulb. Two sampling methods are suggested:

–FIG. E1: hold the pipette horizontally **without pressing the bulb** place it in contact with the drop of blood, it will enter the pipette by capillarity. Move the pipette away when the black line is reached. If there is not enough blood, continue to massage the finger until the black line is reached.

–FIG. E2: place the pipette on a clean, flat surface with the tip protruding from the surface, then place the drop of blood in contact with the pipette, it will enter by capillarity. If blood is not sufficient, continue massaging the finger until the blood has reached the black line.

Avoid, as far as possible, to continuously move the tip of the pipette away from the finger in order to prevent the formation of air bubbles.



8) Place the blood collected with the pipette into the well indicated on the cassette (S) by pressing the pipette bulb. –FIG. F



9) Unscrew the blue cap from the dropper vial (leave the white cap tightly screwed on). Deposit 2 drops into the well indicated on the cassette (S), wait for 5 seconds between the first and second drop. –FIG. G

10) Wait 10 minutes and then read the results as indicated.

RESULT INTERPRETATION

READ THE RESULTS AT 10 MINUTES. DO NOT READ THE RESULTS AFTER 15 MINUTES

POSITIVE



Two coloured lines* appear next to the C (Control) and T (Test) signs. This means that the test has detected the presence of class G immunoglobulins (IgG) against COVID-19 in the sample.

WHAT SHOULD I DO?

VACCINATED

The antibodies against COVID-19 have been produced and they have been detected. However, this result does not indicate that protective immunity has been acquired. It is important to continuously follow the public recommendation on COVID-19. If you have COVID-19 symptoms or you have been recently in contact with a positive subject, please contact your doctor anyway.

NOT VACCINATED

The antibodies against COVID-19 have been produced and they have been detected. The test is not able to distinguish between an active and a past infection, as the antibodies persist long after the end of the infection. It is necessary to contact immediately your doctor for additional information regarding local dispositions. Report to your doctor the result of the test, symptoms (if present) and potential contact with positive/infected persons. A positive result is not sufficient to indicate the development of COVID-19 disease, however, it is recommended that you discuss this with your doctor who will decide how to continue the diagnostic investigation. In addition to that, a positive result does not indicate that protective immunity has been acquired.

*NOTE: The colour intensity in the test line may vary depending on the concentration of antibodies against SARS-CoV-2 Spike protein present in the sample. Therefore, any shade of colour in the T line region should be considered positive. False positive results may be due to past or current infections caused by other coronavirus or other interferent substances.

NEGATIVE



A single-coloured line (of any intensity) appears next to the C (Control) sign. No line appears next to the T (Test) sign.

WHAT SHOULD I DO?

VACCINATED

The test did not detect the presence of IgG immunoglobulins against COVID-19 in the sample. They are either not present or are present in very low concentrations, not detectable by this diagnostic device. Probably you tested yourself too soon: (I) the production of antibodies may have not yet occurred or (II) the concentration of antibodies in the sample may be below the minimum detection limit of the test. Please try testing again later, at least a couple of weeks after the end of the vaccination cycle. Post-vaccination studies conducted by the manufacturer on vaccinated subjects with Pfizer BioNTech, Moderna and Oxford-AstraZeneca revealed positivity rates of at least 95.2% after 14 days post-completion of the vaccination cycle. It is not clear yet how long the antibodies will last from the vaccination. **If you have symptoms that can be traced back to COVID-19 contact your doctor anyway, he or she will decide how to continue the diagnostic investigation.**

NOT VACCINATED

The test did not detect the presence of IgG immunoglobulins against COVID-19 in the sample. They are either not present or are present in very low concentrations, not detectable by this diagnostic device. The test will show negative results under the following conditions: (I) the concentration of antibodies against SARS-CoV-2 Spike protein in the sample is below the minimum detection limit of the test; (II) the production of antibodies has not yet occurred at the time of sample collection; (III) the subject has contracted a variant of SARS-CoV-2 that has undergone major mutations in the Spike protein. The consequent produced antibodies may not be recognized by the Test. Furthermore, cases of absence of antibody response were reported in SARS-CoV-2 PCR positive patients, suggesting that not all infected patients develop antibodies. **Therefore, if you experience symptoms such as fever, dry cough, fatigue, soreness and muscle pain, sore throat, diarrhea, conjunctivitis, headache, loss of taste or smell, rash, contact your doctor even if the test results are negative.**

INVALID



The line next to the C (Control) sign does not appear.

WHAT SHOULD I DO?

VACCINATED

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

NOT VACCINATED

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