Test your health

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800061_IFU_02_5.0 03/2022

REF 800061

INSTRUCTIONS FOR USE

PRIMACOVID®

PRIMA® HOME TEST

CE 0483

COVID–19 SEROLOGICAL TEST

Rapid self test for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in human whole blood specimens

SARS-COV-2 AND COVID-19

On December 2019 a cluster of pneumonia cases of unknown aetiology was reported in Wuhan, Hubei Province, China. Subsequently, in January 2020, the Chinese Centre for Disease Control and Prevention (CDC) identified the Coronavirus SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) as the causative agent of this first outbreak and the related disease was defined as "Coronavirus Disease 2019" (COVID-19). The initial outbreak of COVID-19 in Wuhan spread rapidly, to the extent that, on 11 March 2020, the Director General of the World Health Organization declared COVID-19 a global pandemic.
As with other respiratory diseases, SARS-CoV-2 can cause asymptomatic infection, mild symptoms such as cold, sore throat, cough and fever, loss of sense of smell, or more severe symptoms such as pneumonia and breathing difficulties with even fatal results. The incubation period of COVID-19 varies from 1 to 14 days.

SEROLOGICAL TESTS THAT DETECT ANTIBODIES AGAINST SARS-CoV-2

Serological 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.
In the first few days following infection, when the immune response of the body is still developing, low levels of antibodies may go undetected. Recent studies have shown that, in people infected by SARS-CoV-2, IgM and/or IgG antibodies appear within 19 days after onset of symptoms (60% of cases within the first week and 90% within the second week).
Serological tests for SARS-CoV-2 antibodies can be used to know whether a person has been exposed to SARS-CoV-2. As such, they can be useful in: (1) aid diagnosis in symptomatic cases presenting late, in addition to but not as a replacement of molecular tests (nose-oropharyngeal swabs followed by PCR testing); (2) screen contacts for previous exposure; (3) seroprevalence surveys to define levels of population exposure (in particular asymptomatic persons).
These tests are not conclusive for the diagnosis of infection in progress, since the absence of antibodies does not exclude the possibility of early infection, despite the negative result on the serological test. Furthermore, these tests are not able to distinguish between an active and a past infection, as the antibodies persist long after the end of the infection. This limits the effectiveness and usefulness of the test for the early diagnosis of COVID-19, and is the main reason why serological tests should not be used as the sole basis for the diagnosis of COVID-19 which must be made by a physician in the light of other factors.

PRINCIPLE OF THE TEST

COVID-19 SEROLOGICAL TEST is a rapid immunocromatographic assay for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in human blood samples. A diluent is used to dilute the sample and promote its flow along the test strip.
This test indicates that the body has been exposed to SARS-CoV-2, since specific antibodies directed against it are detected. The protective effect of such antibodies to SARS-CoV-2 over time is still being investigated by the international scientific community, so the detection of such antibodies does not indicate that protective immunity has been achieved.

CONTENTS 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/IgM RAPID TEST cassette
  1 desiccant bag

- ✻ sterile lancets for self-drawing blood

- 1 vial with dropper tip containing the COVID-19 IgG/IgM RAPID TEST diluent required for ✻ test

- ✻ 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, a device to measure time (i.e. timer, watch).
· 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.

MEDICAL DEVICES INSIDE THE KIT

STERILE R Lancet
SteriLance Medical (Suzhou) Inc.
No. 68 Litanghe Road
Xiangcheng
CE 0197 *Suzhou 215133 - China*

Antiseptic cleanser gauze: 70% Alcohol
Vitrex Medical A/S
Vasekaer 6-8
CE *DK-2730 Herlev*
Denmark

EC REP *Emergo Europe*
Prinsessegracht 20
2514 AP The Hague
The Netherlands

SYMBOLS

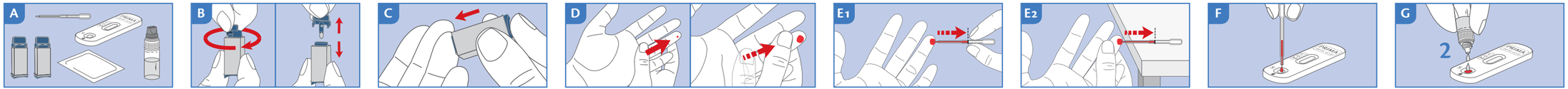
Read the instructions before use	IVD *In vitro diagnostic device*	LOT *Lot number*
Expiry date (last day of the month)	REF *List number*	*Legal manufacturer*
STERILE R *Sterilised using irradiation*	+4°C 30°C *Temperature limits*	*Do not reuse*
EC REP *Authorised Representative in the European Community*	n *Sufficient for <n> tests*	CE *CE marking*

REFERENCES

1. *European Centre for Disease Prevention and Control, Disease background of COVID-19 (https://www.ecdc.europa.eu/en/2019-ncov-background-disease)*
2. *https://www.who.int/emergencies/diseases/novel-coronavirus-2019*
3. *https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en*
4. *Long, Q., Liu, B., Deng, H. et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nat Med (2020)*
5. *European Centre for Disease Prevention and Control. An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA. 1 April 2020.*
6. *FIND. Rapid Diagnostic Tests For Covid-19. https://www.finddx.org/wp-content/uploads/2020/05/FIND_COVID-19_RDTs_18.05.2020.pdf*

PRECAUTIONS

1. **The COVID-19 SEROLOGICAL TEST does not indicate the presence of the virus (and therefore whether or not a person is contagious as is the case for nose-oropharyngeal swabs) but only the existence of antibodies against it.**
2. **Read these instructions for use carefully before testing. The Test is reliable if the instructions are carefully followed.**
3. **Keep the Test out of the reach of children.**
4. **Do not use the Test after the expiration date or if the packaging is damaged.**
5. **Follow the procedure exactly, using only specified quantities of blood and diluent.**
6. **Store the Test components at a temperature of +4°C to +30°C. Do not freeze**
7. **Use the Test and the sterile lancet only once.**
8. **The Test is for external use only. DO NOT SWALLOW.**
9. **Not recommended for use by people taking medicines that make the blood thinner (anticoagulants) or people with hemophilia problems.**
10. **After use, dispose of all components according to local regulations, ask your pharmacist for advice.**
11. **In vitro diagnostic device for individual use.**
12. **Warning: the device does not detect antibodies produced after vaccination against SARS-CoV-2.**



TEST PROCEDURE

1) Wash hands with soap and warm water, rinse with clean water and allow to dry. If this is not possible, use the provided gauze as an alternative.
   Note: The use of warm water facilitates capillary blood collection as it induces vasodilation.

2) Prepare the necessary material as follows: open the aluminium pouch, take out only the test cassette and throw away the desiccant bag. Open the plastic packet containing the pipette. –**FIG. A**

3) Carefully rotate the protective cap of the sterile lancet 360° without pulling it. Extract and discard the released cap. –**FIG. B**

4) 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 phalanx, 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.

5) Holding the hand down, massage the finger until a large drop of blood forms. It is important to massage from the palm of the hand to the phalanx to improve blood flow. –**FIG. D**

6) 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 shelf, 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.

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

8) 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**

9) **Wait 10 minutes**.

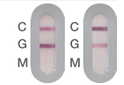
RESULTS INTERPRETATION

READ THE RESULT AT 10 MINUTES.
DO NOT READ THE RESULTS AFTER 20 MINUTES

10 min.

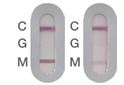
IgG POSITIVE*

Two coloured lines appear in the reading window next to the C (Control) and G (IgG) signs. This means that the test has detected the presence of class G immunoglobulins (IgG) in the sample.
This result does not indicate that protective immunity has been acquired.
Immediately contact your physician and report this result.



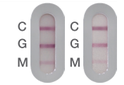
IgM POSITIVE*

Two coloured lines appear in the reading window next to the C (Control) and M (IgM) signs. This means that the test has detected the presence of class M immunoglobulins (IgM) in the sample.
This result does not indicate that protective immunity has been acquired.
Immediately contact your physician and report this result.



IgG AND IgM POSITIVE*

Three coloured lines appear in the reading window next to the signs C (Control), G (IgG) and
M (IgM). This means that the test has detected the presence of class G and M immunoglobulins (IgG + IgM) in the sample.
This result does not indicate that protective immunity has been acquired.
Immediately contact your physician and report this result.



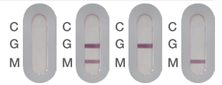
***NOTE:** The colour intensity in the test line regions may vary depending on the concentration of SARS-CoV-2 antibodies present in the sample (as seen in the images). Therefore, any shade of colour in the G and M line regions should be considered positive. False positive results may be due to past 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 by the G (IgG test line) and M (IgM test line) signs. The test did not detect the presence of G or M class immunoglobulins in your sample. They are either not present or are present in very low concentrations, not detectable by this diagnostic system.
If you have symptoms that can be traced back to COVID-19 contact your doctor anyway.

INVALID

The line next to the C (Control) sign does not appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the absence of the control line (invalid result). Review the procedure and repeat the test with a new device and a new sample.



F.A.Q. – QUESTIONS AND ANSWERS

HOW DOES THE COVID-19 SEROLOGICAL TEST WORK? The test detects the presence of IgG and IgM antibodies to SARS-CoV-2 by means of specific antibodies and colloidal gold nanoparticles embedded in the test strip.

WHEN CAN THE TEST BE USED? COVID-19 SEROLOGICAL TEST can be performed at any time of the day. The test can be carried out by anyone who has been or suspects to have been in contact with infected people, people with COVID-19 symptoms, people living in proximal areas to possible outbreaks or anyone who wants to be aware of a possible infection. In case of exposure to the virus, IgG and/or IgM antibodies to SARS-CoV-2 are observed within 19 days from the onset of symptoms (60% of cases within the first week and 90% within the second week). If the test is performed too early the result obtained may not be indicative and it is therefore recommended to perform the test 10-20 days after the onset of symptoms. 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 SEROLOGICAL TEST is not for use in emergency situations.

DOES COVID-19 SEROLOGICAL TEST DETECTS OTHER PARAMETERS? No. The COVID-19 SEROLOGICAL TEST only detects the presence of IgG and/or IgM antibodies in the blood sample, which is indicative of virus infection and subsequent immune response. The test does not necessarily detect SARS-CoV-2 ongoing infection.

CAN THE RESULT BE NOT CORRECT? The result is correct as long as the instructions are carefully followed. However, the result may not be correct if: the device comes into contact with other liquids before use, if the amount of blood and/or diluent is insufficient, if the number of drops dispensed into the well is incorrect or if the reading time of the result is not respected. The plastic pipette supplied allows to be sure that the volume of collected blood is correct. False positive results may be due to past or current infections caused by other Coronavirus or other interferent substances. Possible cross-reactions can be observed with RSV IgG, Common Coronavirus NL63 IgG, Rheumatoid Factor (RF), Mycoplasma pneumoniae IgG/IgA and IgM. Due to the current lack of samples with very high concentrations of antibodies, the manufacturer cannot exclude the possibility that very high concentrations of antibodies against SARS-CoV-2 in the blood sample could lead to false negative results (hook effect).

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 result. Refer to the indications and to the images in the section "Results Interpretation" to correctly evaluate the result.

IF READ AFTER 20 MINUTES, IS THE RESULT RELIABLE? No. The test should be read 10 minutes after the end of the procedure and no later than 20 minutes. Results read after 20 minutes may not be correct (false positive results may appear).

WHAT SHOULD BE DONE IF THE RESULT IS POSITIVE? If the result is positive (for IgG and/or IgM) it means that IgG and/or IgM antibodies to SARS-CoV-2 are present in the blood sample. You should consult your physician and report the result obtained with this test. A positive result is not sufficient to indicate the development of COVID-19 disease or current SARS-CoV-2 infection, however, it is recommended that you discuss this with your physician who will decide how to continue the diagnostic investigation. False positive results may be obtained due to cross-interferences with pre-existing antibodies to other pathogens (such as other coronaviruses) or other possible causes. Possible cross-reactions can be observed with RSV IgG, Common Coronavirus NL63 IgG, Rheumatoid Factor (RF), Mycoplasma pneumoniae IgG/IgA and IgM.

WHAT TO DO IF THE RESULT IS NEGATIVE? If the result is negative, the test did not identify the presence of IgG and/or IgM antibodies to SARS-CoV-2. This result may mean that SARS-CoV-2 infection has not occurred or is at an early stage where specific antibodies have not yet been developed. Furthermore, cases of absence of antibody response were reported in SARS-CoV-2 PCR positive patients, suggesting that not all infected persons 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.

DOES A POSITIVE RESULT ONLY FOR IgG INDICATE IMMUNITY TO SARS-COV-2? NO, scientists agree that in case of exposure to the virus, IgG and/or IgM antibodies are produced by day 19 from the onset of symptoms, but it is not yet known how long these protective antibodies remain in the body and whether they can protect against future infections.

WHAT IS THE ACCURACY OF THE COVID-19 SEROLOGICAL TEST? The test is very accurate. Evaluation reports show a sensitivity of 98.92% (95% CI: 94.2-99.8%) for IgG and 92.98% (95% CI: 83.3-97.2%) for IgM compared to the reference method (ELISA). The combined IgG and IgM Specificity is 98.3% (95% CI: 95.2 - 99.4%).