COVID-19 IgG/IgM RAPID TEST

A rapid test for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in human whole blood, serum or plasma specimens. For professional in vitro diagnostic use only.

COVID-19

On December 2019 a cluster of pneumonia cases of unknown aetiology was reported in Wuhan, Hubei Province, China. In January 2020, the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), belonging to the β genus, was identified 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. Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Six coronavirus species are known to cause human disease. 229E, OC43, NL63, and HKU1 are prevalent and typically cause common cold symptoms in immunocompetent individuals. The two other strains (SARS-COV and MERS-COV) are zoonotic in origin and have been linked to sometimes fatal illness. Currently, individuals infected by SARS-CoV-2 (both symptomatic and asymptomatic) are the main source of infection. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath, loss of taste and smell, breathing difficulties and fatigue. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are also reported in a few cases. In more severe cases, infection can cause pneumonia, Loss of sense of smell and taste severe acute respiratory syndrome, kidney failure and even death. Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing and avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

PRINCIPLE OF THE TEST

The COVID-19 IgG/IgM Rapid Test is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in whole blood, serum or plasma specimens. This test consists of two components, an IgG component and an IgM component. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the chromatography membrane by capillary action and reacts with the anti-human IgG in IgG test line region and/or with the anti-human IgM in the IgM test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line appears in the IgG test line region; similarly, if the specimen contains IgM antibodies to SARS-CoV-2, a colored line appears in the IgM test line region. If the specimen does not contain SARS-CoV-2 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REFERENCES

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164. PMID:22094080 DOI: 10.1016/B978-0-12-385885-6.00009-2
2. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24:490-502. PMID:27012512 DOI: 10.1016/j.tim.2016.03.003
3. Valenti L et al. SARS-CoV-2 seroprevalence trends in healthy blood donors during the COVID-19 Milan outbreak". Submitted to Eurosurveillance, 2020, medRxiv preprint doi: https://doi.org/10.1101/2020.05.11.20098442

CONTENT

THE BOX CONTAINS 1 KIT TO PERFORM THE TEST:

- 1* hermetically sealed aluminum pouch containing:
  - 1 COVID-19 IgG/IgM Rapid Test cassette
  - 1 desiccant bag
- 1* vial with dropper tip containing COVID-19 IgG/IgM Rapid Test buffer sufficient for 1* test
- 1 instruction for use leaflet
- OPTIONAL*: Transparent plastic bag containing 1* 10-20 µL pipette or 20µL capillary pipette for blood collection; 1* Sterile Lancet; 1* Antiseptic cleanser gauze.

* **The number of the testing devices of the kit may vary. For the exact number of tests contained and the presence of the sterile lancet, antiseptic cleanser gauze, 10-20 µL pipette or 20 µL capillary pipette for blood collection, please refer to the "content" section of the external box.**

- Material required but not supplied: a device for measuring time (i.e. timer, watch), lancet, centrifuge (plasma only), sample collection containers.
- Do not open the sealed aluminum pouch until just before performing the test. Take care to open it as marked.
- The desiccant bag must not be used. Dispose of it with household waste without opening it.

PRECAUTIONS

1. Operators are required to comply with local regulations in force and to operate according to good laboratory practice (GLP).
2. Read these Instructions for Use carefully before performing the Test. The Test is reliable only if the instruction are strictly followed.
3. For professional in vitro diagnostic use only.
4. Do not eat, drink or smoke in the area where samples or kits are handled.
5. Do not use the Test after the expiry date or if the package has been damaged.
6. Handle all samples as if containing infectious agents. Observe established precautions against microbiological hazards during all procedures and follow standard procedures for proper disposal of samples.
7. Wear protective clothing such as lab coats, disposable gloves and eye protection when specimens are tested.
8. Ensure that an adequate amount of sample is used for testing. Too much high or too much low sample amount may lead to deviations in the results.
9. After using, please dispose of all components according to the local waste disposal laws.
10. Humidity and temperature may adversely affect the results.
11. Store as packaged in the sealed bag at room temperature or in the refrigerator (2-30°C). The test is stable until the expiry date printed on the sealed bag. The test should remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiry date.

SAMPLE COLLECTION AND PREPARATION

COVID-19 IgG/IgM Rapid Test can be performed using whole blood (from vein or fingertip puncture), serum or plasma.

FINGERSTICK: WHOLE BLOOD COLLECTION

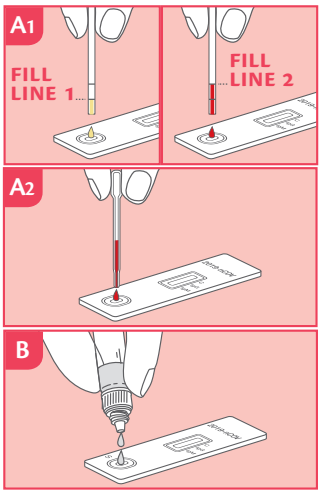
1. Wash the patient's hand with soap and warm water or clean with the alcohol swab (supplied with the kit). Allow to dry.
2. Massage the hand without touching the sampling site towards the tip of the middle or ring finger.
3. Prick the skin of the fingertip with a sterile lancet, remove the first drop of blood.
4. Gently massage the hand from the palm to the fingers to form a drop of blood on the sampling site.
5. Add the whole blood sample to the test using the pipette:
   a. In case of 10-20 µL pipette: squeeze the pipette and release it once in contact with the drop of blood. The blood will enter into the pipette.
   b. In case of capillary pipette (20 µL): take the pipette without pressing the bulb and place it in contact with the drop of blood. The blood will enter into the pipette by capillary action.
   c. Continue massaging your finger until the blood has reached the Fill Line 2 (20 µL) on the 10-20 µL pipette or the black line of the capillary pipette (20 µL). Avoid moving it away from the finger as much as you can, in order to prevent the formation of air bubbles.
6. Deposit blood collected with the pipette into the sample well (S) of the cassette by pressing the pipette body (10-20 µL pipette) or bulb (20 µL capillary pipette).
7. Whole blood collected from fingerstick should be tested immediately.

SERUM, PLASMA, BLOOD: VENOUS SAMPLING

1. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only non-hemolyzed samples.
2. Test must be performed immediately after sampling. Do not leave samples at room temperature for extended periods.
   - Serum and plasma samples may be stored at 2-8°C for up to 7 days; for long-term storage, serum and plasma samples should be stored below -20°C.
   - Whole blood collected by venous sampling may be stored at 2-8°C if the test is performed within 2 days of collection. Do not freeze whole blood samples.
3. Bring samples to room temperature before testing. Frozen samples should be completely thawed and mixed well before testing. Samples must not be frozen and thawed repeatedly.
4. If samples are shipped, they must be packaged in accordance with local regulations on the transport of infectious agents.
5. EDTA K2, sodium heparin, sodium citrate and potassium oxalate may be used as anticoagulants for sample.

INSTRUCTIONS FOR USE

Allow the test, sample, buffer and/or controls to reach room temperature (15-30°C) prior to testing.



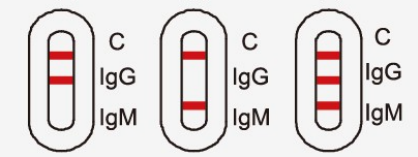
1. Open the aluminum bag, take out the test cassette and use it within 1 hour. **Best results are obtained if the test is performed immediately after opening the foil pouch.**
2. Place the cassette on a clean, level surface**.**
3. **For whole blood (fingerstick and venous sampling):** fill the 10-20 µL pipette up to **Fill Line 2** (in case of capillary pipette, fill it up to the black line) and transfer **20 µL** of whole blood sample into the sample well (S) of the test cassette, then add 1-2 drops of buffer and start the timer (Illustrations A_1,A_2 ,B). **Wait for 5 seconds between the first and second drop of buffer**. As an alternative, **20 µL** of sample from venous blood can be dispensed with a laboratory micropipette.
4. **For serum and plasma:** fill the 10-20 µL pipette up to **Fill Line 1** (Illustration A1) and transfer **10 µL** of sample to the sample well (S), then add 1-2 drops of buffer (Illustration B) and start the timer. **Wait for 5 seconds between the first and second drop of buffer**. As an alternative, **10 µL** of sample from serum and plasma can be dispensed with a laboratory micropipette.
5. Wait for the colored lines to appear. Read the results at 10 minutes.

NOTE: It is recommended not to use the buffer later than 6 months after opening the vial.

RESULTS INTERPRETATION

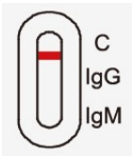
READ THE RESULTS AT 10 MINUTES.

IgG POSITIVE*: Two colored lines appear. A colored line should always appear in the control line region (C) and another line should be in the IgG line region.
IgM POSITIVE*: Two colored lines appear. A colored line should always appear in the control line region (C) and another line should be in the IgM line region.
IgG and IgM POSITIVE*: Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines are visible in the IgG and IgM line regions.

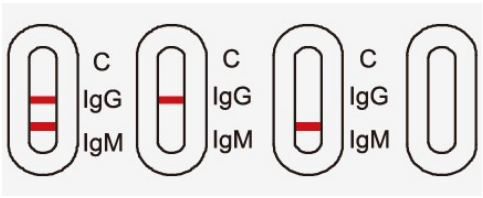


***NOTE:** The color intensity in the control and test line regions may vary depending on the concentration of SARS-CoV-2 antibodies present in the sample. Therefore, any shade of color in the test line region should be considered positive. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strain or other interference factors.

NEGATIVE: A colored line appears in the control line region (C). No line appears in the IgG region and the IgM regions.



INVALID: The control line does not appear. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the absence of the control line. Review the procedure and repeat the test with a new device. If the problem persists, discontinue use of the test kit immediately and contact your local distributor.



LIMITATIONS

1. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The COVID-19 IgG/IgM Rapid Test is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to SARS-CoV-2 in whole blood, serum or plasma specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with the clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to SARS-CoV-2 can be determined by this qualitative test.
3. The COVID-19 IgG/IgM Rapid Test will only indicate the presence of IgG and IgM antibodies to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections. 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 and clinical symptoms persist, it is recommended to re-sample the patient a few days later or test with a molecular diagnostic device to rule out infection in these individuals. Negative results do not exclude SARS-CoV-2 infection especially in patients who have been in contact with the virus.

5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
6. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test, or the novel coronavirus antibody did not appear at the time of sample collection
7. In the early infection, anti-SARS-COV-2 antibodies concentrations may be below detectable levels. Therefore, it is not recommended to use the test in early diagnosis of COVID-19.
8. The continued presence or absence of antibodies cannot be used to evaluate the success or failure of the therapy. At this time, it is unknown how long IgM or IgG antibodies may persist following infection.
9. Conditions of immunosuppression (e.g. cortisone therapy) or immunodeficiency may affect the reliability of the result. The test is therefore not recommended in such cases.

PERFORMANCE

SENSITIVITY, SPECIFICITY

COVID-19 IgG/IgM Rapid Test was evaluated in multiple hospitals/research centers, in comparison with commercial reference PCR test; the results ,when tested with specimens collected from individuals positive to PCR test at ≥ 11 days post-symptom onset, show high Sensitivity and Specificity reaching up to: **Sensitivity: 100% and Specificity: 99.2 %** for IgG[3]. Combined results for IgM and IgG are shown in Table 1.

Table 1. Clinical studies results, combined for IgM and IgG

Method		PCR	
COVID-19 IgG/IgM Rapid Test (≥ 11 days post-symptom onset)	Result	Positive	Negative
	Positive (IgG e/o IgM)	133	9
	Negative	6	403
	Total Results	139	412

COMBINED DATA (IgG/IgM)

Sensitivity: 95.7% (95% CI: 92.3%-99.1%)

Specificity: 97.8% (95%CI:96.4%-99.2%)

Accuracy: 97.3% (95% CI: 95.9%-98.6%)

CROSS-REACTIVITY

COVID-19 IgG/IgM Rapid Test was tested with immunoglobulin positive samples for anti-influenza A virus, anti-influenza B virus, antiRSV (Respiratory Synzytial Virus), anti-Adenovirus, anti-Measles, HAMA, Rheumatoid Factor, non-specific IgG, non-specific IgM, anti-EV71, anti-Parainfluenza virus, anti-Syphilis, anti-H. Pylori, anti-HIV, anti-HCV, and to HBsAg. Results showed no cross-reactivity. However, false positive results may occur due to cross-reactivity from other Coronavirus pre-existing antibodies or other possible causes.

INTERFERING SUBSTANCES

The following compounds have been tested with COVID-19 IgG/IgM Rapid Test and no interference was observed: Triglycerides: 100 mg/dL, Haemoglobin: 1000mg/dL,Total Cholesterol: 15mmol/L, Bilirubin: 60mg/dL, Ascorbic Acid: 20mg/dL

REF 100061-P

PRIMA Lab SA
Via Antonio Monti 7
CH-6828 Balerna - Switzerland
T. +41 91 605 1030
sales@primalabsa.ch
www.primalabsa.ch

Lancet

STERILE R

SteriLance Medical (Suzhou) Inc. No.68 Litanghe Road Xiangcheng Suzhou 215133, China

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

Antiseptic Cleanser Gauze: 70% Alcohol

Vitrex Medical A/S
Vasekaer 6-8 DK-2730 Herlev, Denmark

Baoying County Fukang Medical Appliance Co., Ltd. Guangyang Road Huangcheng Town Industrial Area Baoying County 225800 Jiangsu, China

EC REP Sungo Certification Company Limited RM101, Maple House, 118 High Street Purley - London - England

SYMBOLS

CE	EC Mark	LOT	Lot number	STERILE R	Sterilizzato mediante radiazioni		Expiry date (last day of the month)
	Do not reuse		Legal Manufacturer	IVD	In-vitro diagnostic device	Σ	Sufficient for <n> tests
	Read the instructions before use	REF	List number	2°C 30°C	Temperature limits	EC REP	Authorized Representative in the European community

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