COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma - Cassette) Product code: CCOV-200

INTENDED USE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary SARS-CoV-2 infections.

INTRODUCTION

COVID-19(Corona Virus Disease) is the infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness. About 2% of people with the disease have died. People with fever, cough and difficulty breathing should seek medical attention. People can catch COVID-19 from others who have the virus. The disease can spread from person to person through small droplets from the nose or mouth which are spread when a person with COVID-19 coughs or exhales. These droplets land on objects and surfaces around the person. Other people then catch COVID-19 by touching these objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. Most estimates of the incubation period for COVID-19 range from 1-14 days.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of SARS-CoV-2 antigen coated colored particles for the detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum, or plasma.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to SARS-CoV-2, if present in the specimen, reacts with the anti-human IgM and the SARS-CoV-2 antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region.

Therefore, if the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to SARS-CoV-2, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to SARS-CoV-2, 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.

PRODUCT CONTENTS

The test cassette contains to specific antigen conjugated gold colloid particles and anti-human IgM, anti-human IgG coated on the membrane.

MATERIALS SUPPLIED

1. Test cassette 2. Dropper
3. Buffer 4. Instructions for use

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2.Timer
3. Centrifuge (for plasma only) 4. Micropipette
5. Lancets (for fingerstick whole blood only) 6. Sterile Alcohol Prep Pad

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- For single use only.
- Apply the specimen dropping right exactly into specimen well (S) carefully to be sure that all specimen is transferred into strip inside the cassette.
- Use micropipette for adding of specimen to dispense exact amount of specimen.
- Do not eat, drink, smoke, or apply cosmetics where immunodiagnostic materials are being handled and tests are being performed.
- Do not pipette by mouth.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- The used tests, specimens and potentially contaminated material should be discarded according to the local regulations.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- After bringing the pouch (containing the test kit) to room temperature, use the test cassette within one hour of removal from the pouch at a relative humidity of ≤ 60% .

Issued Date &Revision 2020.09.09/8 COM.RIFU.387 CKS-114

- Avoid spilling samples. Wipe spills immediately and decontaminate affected surfaces.
- Provide adequate ventilation.
- Warning-potential biohazards material: all blood derivatives should be considered potentially infectious; it is recommended that these specimens be handled and safe disposed as medical waste using established good laboratory working practices.
- Materials used to clean spills, including gloves, should be disposed of as potentially biohazardous waste.
- Do not use test kit beyond expiry date.
- The test device should never be reused.
- Use a fresh transfer pipette for each whole blood, serum, or plasma specimen.
- The COVID-19 IgG/IgM Rapid Test should remain in its original sealed pouch until ready for use. Do not use the test if the seal is broken or the pouch is damaged.
- Frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.
- As with all diagnostic tests, it should be kept in mind that an identification diagnosis cannot be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
- The reliability of the results depends on correct implementation of the following Good Laboratory Practices.
- Avoid exposure of the tests to excessive heat or sunlight during storage.
- Do not change the assay procedure. Prefer to use micropipette; however, if you have to use dropper, follow the instructions.

SPECIMEN COLLECTION AND PREPARATION:

- The test can be performed with whole blood (fingerstick or venous), serum, and plasma samples prepared by clinical, commonly used anticoagulants (EDTA, heparin, sodium citrate).
- Fingerstick whole blood samples shall be tested immediately after collection and should never be frozen.
- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection and should never be frozen.
- Serum and plasma samples can be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- Bring shipped specimens to room temperature prior to testing.
- Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.
- Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C).
- Use the specimen immediately after it is completely thawed.
- For serum or plasma specimens, separate the serum or plasma as soon as possible using standard centrifuge techniques to avoid hemolysis.
- Use only clear, non-hemolyzed specimens.

TEST PROCEDURE

The following steps are taken when conducting fingerstick whole blood specimen testing:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab.
- Allow the patient's hand to air-dry.
- Massage the patient's hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the patient's skin on the fingertip of the middle or ring finger with a sterile lancet.
- Rub the patient's hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Holding the dropper vertically, collect and place one (1) drop in the specimen well (S).
- If you use micropipette take 20 µl sample and drop in the specimen well (S).
- Add two (2) drops of buffer (approximately 80-100µl) to the specimen well (S). Avoid trapping air bubbles in the specimen well (S).
- Specimen and buffer mixture migrate upward on the membrane chromatographically by capillary action. When the fluid reaches the control and test strips, lines can become visible. Start a timer. After 10 minutes, conduct a reading to determine whether the IgG or IgM strip shows positive results via a line that appears on the test strip. For optimum readings, 10-15 min recommended by taking account of safety margin. Readings should not be taken after 20 minutes. Although, test and control lines shall be visible before 10 min when the mixture reaches the control and test lines and after 15 min, the most clear and optimum vision must be obtained between 10-15 min interval. After 20 min there is no validation for the results because there is a risk of false positive.

The following steps are taken when conducting venous whole blood specimen testing:

- Draw blood following laboratory procedure for obtaining venous whole blood samples.
- Collect samples in tubes (plain tube (red top, no additive) could be used)
- Using the provided dropper or a micropipette, collect blood sample.
- If using the provided dropper, hold the dropper vertically and collect and place one (1) drop in the specimen well (S). Prefer to use micropipette instead of dropper to dispense exact

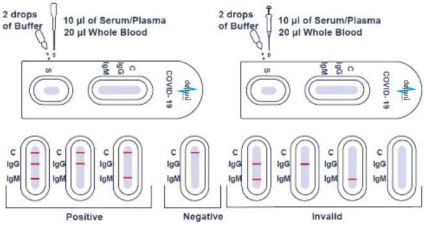
amount of specimen. Do not use dropper, if it is not mandatory.

- If using a micropipette, take a 20 µl sample and drop in the specimen well.
- Add two (2) drops of buffer (approximately 80-100µl) to the specimen well (S). Avoid trapping air bubbles in the specimen well (S).
- Specimen and buffer mixture migrate upward on the membrane chromatographically by capillary action. When the fluid reaches control and test strips, lines can become visible. Start a timer. After 10 minutes, conduct a reading to determine whether the IgG or IgM strip shows positive results via a line that appears on the test strip. For optimum readings, a 10-15-minute time interval is recommended. Readings should not be taken before10 minutes or after 20 minutes, even when test and control lines are visible.

The following steps are taken when conducting plasma or serum testing:

- Draw blood following laboratory procedure for obtaining serum or plasma specimens.
- Collect plasma or serum specimens in tubes. Venous whole blood and serum are to be collected using plain red tubes (glass tubes with no additives). For plasma samples, commercially available anticoagulant-treated tubes should be used.
- Using the provided dropper or a micropipette, collect a plasma or serum sample from a clear, well-mixed, non-hemolyzed specimen.
- If using the provided dropper, hold the dropper vertically and place one (1) drop in the specimen well (S). Prefer to use micropipette instead of dropper to dispense exact amount of specimen. Do not use dropper, if it is not mandatory.
- If using a micropipette, take a 10 µl sample and drop in the specimen well (S).
- Add two (2) drops of buffer (approximately 80-100µl) to the specimen well (S). Avoid trapping air bubbles in the specimen well (S).
- Specimen and buffer mixture migrate upward on the membrane chromatographically by capillary action. When the fluid reaches control and test strips, lines can become visible. Start a timer. After 10 minutes, conduct a reading to determine whether the IgG or IgM strip shows positive results via a line that appears on the test strip. For optimum readings, a 10-15-minute time interval is recommended. Readings should not be taken before10 minutes or after 20 minutes, even when test and control lines are visible.

Figure 1: Potential results and readings.



Note: It is definitely recommended to prefer micropipette than dropper. Transferring of more specimen than 20µl can cause accumulation of specimen at the bottom of reading window. And it can cause confusion in interpretation.

INTERPRETATION OF RESULTS

IgG and IgM POSITIVE:* Three lines appear. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region (IgG) and IgM test line region (IgM). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary SARS-CoV-2 infection.

IgG POSITIVE:* Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region (IgG). The result is positive for SARS-CoV-2 virus specific-IgG and is probably indicative of secondary SARS-COV-2 infection.

IgM POSITIVE:* Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region (IgM). The result is positive for SARS-CoV-2 virus specific-IgM antibodies and is indicative of primary SARS-COV-2 infection.

***NOTE:** The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-CoV-2 antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-CoV-2 antibody concentration can be determined by this qualitative test.
2. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of SARS-CoV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2.
3. In the early onset of fever, anti-SARS-CoV-2 IgM concentrations may be below detectable levels.
4. The continued presence or absence of antibodies cannot be

Issued Date &Revision 2020.09.09/8 COM.RIFU.387 CKS-114

used to determine the success or failure of therapy.

5. Results from immunosuppressed patients should be interpreted with caution.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
7. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of SARS-CoV-2 infection.
8. All performance data shows the results for the below mentioned run tests, results may show difference in every test studies due to test population or other dynamics.
9. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
10. Not for the screening of donated blood.
11. Some cross reactivity can observe with samples positive for SARS-CoV antibody and Rheumatoid Factor. It is possible to cross-react with samples positive for MERS-CoV antibody.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The COVID-19 IgG/IgM Rapid Test Cassette was compared with a leading commercial PCR. The study included 482 specimens for IgG and 493 specimens for IgM.

		Confirmed Clinical Diagnosis		Total Results
IgG Results for COVID-19 IgG/IgM Rapid Test	Results	Positive	Negative	
	Positive	89	2	91
	Negative	0	391	391
Total Results		89	393	482

Sensitivity: 100% (95%CI: 96.1%~100.0%)*
Specificity: 99.5% (95%CI: 98.1%~99.9%)*
Accuracy: 99.6 % (95%CI: 98.4%~99.9%)* *CI

		Confirmed Clinical Diagnosis		Total Results
IgM Results for COVID-19 IgG/IgM Rapid Test	Results	Positive	Negative	
	Positive	92	3	95
	Negative	8	390	398
Total Results		100	393	493

Sensitivity: 92.0% (95%CI: 83.8%~96.6%)*
Specificity: 99.2% (95%CI: 97.7%~99.8%)*
Accuracy: 97.8 % (95%CI: 96.0%~98.9%)* *CI

Cross-reactivity

The COVID-19 IgG/IgM Rapid Test Cassette (whole blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-Corona virus NL63, anti-Corona virus OC-43, anti-Corona virus 229E, anti-Corona virus HKU1, anti-RSV, anti-Adenovirus, HBsAg, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to SARS-CoV-2 negative specimens.

Acetaminophen: 20 mg/dL	Acetylsalicylic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Bilirubin: 1g/dL
Ethanol: 1%	Creatine: 200 mg/dL
Caffeine: 20 mg/dL	Albumin: 2 g/dL
Gentisic Acid: 20 mg/dL	Hemoglobin: 1000mg/dL
Oxalic Acid: 60mg/dL	Uric acid: 20 mg/ml

None of the substances at the concentration tested interfered in the assay.

REFERENCE

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020.
2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
4. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502

CE	CE marking	2°C 30°C	Storage temperature limitation
IVD	For in vitro diagnostic use		Expiry date
	Manufacturer		Consult Instruction for use
Σ	Test per kit		Do not re-use
LOT	Lot code		

MANUFACTURER
DEJAVU MEDIKAL SAN. TİC. LTD. ŞTİ.
İncilipınar Mh. Ali Fuat Cebesoy Blv. Doktorlar Sitesi No:9 Şehitkamil / Gaziantep / Turkey
Phone: +90 342 215 1144,
Fax: +90 342 215 1146
E-mail : info@dejavumedikal.com
Website : www.dejavumedikal.com

Issued Date &Revision 2020.09.09/8 COM.RIFU.387 CKS-114