COVID-19 IgG/IgM Rapid Test

For detection of COVID-19 antibodies in Human Serum, Plasma or Whole Blood.

Package: 40T/kit

Catalogue No: UNCOV-40

INTENDED USE

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

SUMMARY

COVID-19(Corona Virus Disease) is an 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 ill seriously and has difficult breathing among senior 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 carry the virus. The disease can spread from person to person through small droplets from the nose or mouth when a person with COVID-19 coughs or exhales. These droplets land on objects or surfaces around the patients, like soap or towel that patients have used. Other people then may catch COVID-19 by touching those objects or surfaces, then touching their eyes, nose or mouth. People can also catch COVID-19 if they massage the hand without touching the puncture site by rubbing breathe in droplets from a person with COVID-19 who coughs out or exhales droplets. The incubation period for COVID-19 generally ranges from 1-14 days.

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

DETECTION PRINCIPLE

COVID-19 IgG/IgM Rapid Test (Whole Blood/ Serum/ Plasma) is a qualitative membrane-based immunoassay for the detection of COVID-19 antibodies in whole blood, serum, or plasma. This test consists of two test lines, an IgG line and an IgM line. In the IgG line, anti-human IgG is coated in IgG test line region.

During testing, the sample reacts with COVID-19 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 sample contains IgG antibodies to COVID-19, a colored line will appear in IgG test line region. In the IgM line, anti-human IgM is coated in IgM test line region. During testing, the sample reacts with anti-human IgM. IgM antibodies to COVID-19, if present in the sample, reacts with the anti-human IgM and the COVID-19 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 sample contains IgG antibodies to COVID-19, a colored line will appear in IgG test line region. If the sample contains IgM antibodies to COVID-19, a colored line will appear in IgM test line region. If the sample does not contain antibodies to COVID-19, 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 sample has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where samples or kits are handled.
3. Handle all samples cautiously as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of samples.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
5. The used tests, samples and potentially contaminated should be discarded according to the local regulation.
6. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30℃). The test cassette is stable before 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 after the expiration date.

SAMPLE COLLECTION AND PREPARATION

* COVID-19 IgG/IgM Rapid Test (Whole Blood/ Serum/ Plasma) can be performed using whole blood, serum, or plasma.
* To collect fingertip whole blood samples.
* Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
* Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
* Rub the hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site.
* Add the fingertip Whole Blood sample to the test cassette by using micro-pipette measuring 50 µL. The dropper provided with the test dispenses approximately 30 µL in one drop.
* Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
* Test should be performed immediately after sample collection. Do not leave the samples at room temperature for prolonged periods.
* Serum and plasma samples may be stored at 2-8℃ for up to 3 days. For long-term storage, samples should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 2 days of collection. Do not freeze whole blood samples. Whole blood collected by fingertip should be tested immediately.
* Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
* If samples are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

MATERIALS

Materials supplied

* Test cassettes
* Package inserts
* Buffer bottle

Materials required but not provided

* Sample collection containers
* Centrifuge (for plasma only)
* Micropipette
* Timer
* Lancets (for fingertip whole blood only)

TEST PROCEDURE

* Keep the test cassette, sample, buffer, and/or controls to room temperature(15-30℃) prior to testing.
* Bring the pouch to room temperature before opening. Take the test cassette from the sealed pouch and use it within one hour.
* Place the test cassette on a clean and level surface, for Serum or Plasma Samples.
* To use a dropper: Hold the dropper vertically, draw the sample and transfer the sample to the sample well of the test cassette (one drop/approximately 20 μL), then add 1drop of buffer (approximately 50 μL) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
* To use a micropipette: Pipette and dispense 20 μL of sample to the sample well of the test cassette, then add 1 drops of buffer (approximately 50 μL) to the sample well and start the timer. For Whole Blood Samples.
* To use a dropper: Hold the dropper vertically, draw the sample and transfer the sample to the sample well of the test cassette (two drops/approximately 40 μL), then add 1 drops of buffer (approximately 50 μL) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
* To use a micropipette: Pipette and dispense 40 μL of sample to the sample well of the test cassette, then add 1 drop of buffer (approximately 50 μL) to the sample well and start the timer.
* Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS

1. **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 and IgM test line region. The color intensities of the lines do not have to match. the result is positive for IgG & IgM antibodies and is indicative of secondary COVID-19 infection.

2. **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. The result is positive for CovID-19 virus specific-IgG and is probably indicative of secondary COVID-19 infection.

3. **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. The result is positive for COVID-19 virus specific-IgM antibodies and is indicative of primary COVID-19 infection. NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of COVID-19 antibodies in the sample. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive.

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

5. **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.

PERFORMANCE

1. Positive reference of product compliance rate: The positive reference of product compliance rate should be 5/5.
2. Negative reference of product compliance rate: The negative reference of product compliance rate should be 10/10.
3. Minimum detection limit: The minimum detection limit of reference product S1 should be negative, S2 and S3 should be positive.
4. Repeatability: Two reference products are tested for repeatability. Each test is repeated 10 times and should be positive.
5. Specificity analysis:

   5.1 Cross-reaction:

   This product does not have cross reaction with positive samples of parainfluenza virus antibody, influenza A virus antibody, influenza B virus antibody, Chlamydia pneumoniae antibody, Mycoplasma pneumoniae antibody, adenovirus antibody, respiratory syncytial virus antibody, hepatitis B surface antibody, type C Hepatitis virus antibody, Treponema pallidum antibody, human immunodeficiency virus antibody, EB virus antibody, measles virus antibody, cytomegalovirus antibody, enterovirus 71 antibody, mumps virus antibody, chicken pox-zoster virus.

   5.2 Interfering substances:

   1) When the bilirubin concentration is ≤250 μmol/L, the hemoglobin content is ≤9 g/L, the triglyceride content is ≤15 mmol/L, the rheumatoid factor content is ≤80IU/mL, and the antinuclear antibody (ANA) titer is ≤ 1: 240, anti-mitochondrial antibody (AMA) ≤80U/mL, mouse IgG content ≤1000μg/mL, will not interfere with the detection results of this product.

   2) Histamine hydrochloride, alpha-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, abidol, levofloxacin, azithromycin, Ceftriaxone, meropenem, and tobramycin, they will have no effect on the test results of product.
6. Hook effect: Within the titer range of clinically positive samples of the new coronavirus antibody, the test result of this product does not show a hook effect.
7. The test results of this product are not affected by the disrupted new coronavirus-specific IgM antibodies.
8. The minimum detection limit and repeatability of 12 copies of 2019-nCoV novel coronavirus clinical positive serum samples were studied, and the results met the requirements.
9. Clinical performance: The in vitro diagnostic reagents used in the test are compared with the clinical diagnostic criteria of new coronavirus pneumonia to verify the clinical performance of this product. The enrolled cases were suspected cases of new coronavirus infection, a total of 615 cases, including 403 confirmed cases and 212 excluded cases. A comparative study was performed using in vitro diagnostic reagents for testing and the clinical diagnostic criteria of new coronavirus pneumonia. The test results show that the product has a clinical sensitivity of 98.511% (95% CI: 96.788%, 99.452%) and specificity of 88.208% (95% CI: 83.086%, 92.221%). In addition, 203 subjects received homologous serum/plasma and whole blood samples (125 of which were positive and 78 were negative) for comparative tests. The results show that the product is based on the serum/plasma test results, and the consistency rate of the whole blood test results is 96.85% (95% CI: 95.87% to 97.60%). After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of the epidemic.

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

EXPECTED VALUES

Primary COVID-19 infection is characterized by the presence of detectable IgM antibodies 3-7 days after the onset of infection.

Secondary COVID-19 infection is characterized by the elevation of COVID-19-specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.