PRODUCT INFORMATION & MANUAL

COVID-19 IgG/IgM Rapid Test
Immunodetection Kit

NBP2-89106

For detection of COVID-19 antibodies in Human Serum, Plasma or Whole Blood.
For research use only.
Not for diagnostic or therapeutic procedures.

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COVID-19 IgG/IgM Rapid Test

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.

BACKGROUND

COVID-19(Corona Virus Disease) is an infectious disease caused by the most recently discovered coronavirus, SARS-COV-2. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

Coronaviruses are enveloped positive-sense RNA viruses. Prior to the appearance of SARS-CoV-2, six coronaviruses were known to cause human infection. Sars-CoV-2 is highly infectious and causes a potentially fatal atypical pneurmoia, named Coronavirus disease 2019 (COVID-19) by the World Health Organization (WHO). The most common symptoms of COVID-19 reported are fever, tiredness, and dry cough. Other symptoms have included aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These are usually mild and begin gradually. The approximate recovery rate without treatment is 80%, though around 1/6 of COVID-19 infections lead to serious illness.

Serological assays are commonly used in research for detection of antibody responses caused by viral infection. In an immune response, IgM antibodies appear in the early stage, followed by the appearance of IgG during the mid to late disease stages. However, antibodies may be undetectable during the initial stages of viral infection.

COVID-19 IgG/IgM Rapid Test (Whole Blood/ Serum/ Plasma) is a rapid serology 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. 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.

KIT 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 STORAGE

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.

MATERIALS

Materials supplied

* Test cassettes
* Package inserts
* Buffer bottle

Materials required but not provided

* Samples: Serm, Plasma, or Whole Blood
* Centrifuge (for plasma only)
* Micropipette or Dropper
* Timer

TEST PROCEDURE

* Bring donor 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.
* Keep the test cassette, sample, buffer, and/or controls to room temperature(15-30℃) prior to testing. The results will be affected by high or low temperature
* 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.

SPECIFICITY

1. **Cross-reactivity:**
   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.

2. **Interfering substances:**
   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.
   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.

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. The sensitivity of the assay is 1 U/mL for IgM and 0.5 U/mL for IgG.
5. Repeatability: Two reference products are tested for repeatability. Each test is repeated 10 times and should be positive.
6. Hook effect: Within the titer range of positive donor 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 positive serum samples were studied, and the results met the requirements.

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) should be used for the detection of COVID-19 antibodies in serum, plasma or whole blood samples for 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 for the diagnosis of a 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 donor should be interpreted with caution.

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.