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Product Data Sheet

Product Name: COVID-19 IgG/IgM Rapid Test Kit (10 tests)

Catalogue No: 211006

Description: COVID-19 IgG/IgM Rapid Test Kit is a rapid chromatographic Immunoassay for the qualitative detection of IgG and IgM antibodies to COV1D-I9 in human serum, plasma or whole blood as an aid in the diagnosis of primary and secondary COVID-19 infections.

COV1D-19 (SARS-COV-2 Corona Virus Disease) is an infectious disease caused by the most recently discovered coronavirus. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some people become infected but don't develop any symptoms and don't feel unwell. People can become infected with 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-l9 coughs or exhales. The incubation period for COVID-19 generally ranges from 1-14 days.

Type: Lateral flow rapid test

Size: 10 Tests per kit

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

Shipping: This product may be shipped at ambient temperature.

Warranty Limitations: This kit is manufactured using raw materials procured from established suppliers with professional care. This kit is provided by a third party for Antibody Research Corporation. Our products are intended for use in research only and not for diagnostic, therapeutic, or other use. ARC makes no warranty of any kind with regard to its products, including but not limited to, the implied warranties of merchantabilities and fitness for a particular purpose. Our responsibilities shall be limited to replacement of any defective products. Any customer using ARC products contrary to these or other terms shall hold ARC harmless and indemnify it for any cost incurred from claims arising from such misuse. E&OE.

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Kit Instructions & Protocols for Use

Preface:

Please carefully read this instruction before using the kit.

Test Principle:

COVID-19 IgG/IgM Rapid Test is a qualitative membrane-based immunoassay for the detection of COVID-19 antibodies in serum, plasma, or whole blood. This test consists of two test lines, an lgG line and an lgM line, which is pre-coated with two mouse anti-human monoclonal antibodies separately.

During testing, the sample reacts with COVID-19 antigen-coated on conjugated pad. As the complex continues to travel up the strip, the anti-COVID-I9 IgM antibodies are bound on the IgM line, and the anti-COV1D-19 IgG antibodies are bound on the IgG line. The control (C) line appears when sample has flowed through the strip. The presence of anti-COVID-19 1gM and/or IgG will be indicated by a visible test line in the IgM and IgG region. To serve as a procedural control, the control line should always appear if the test procedure is performed properly and the reagents are working as intended.

Materials Supplied in the Test Kit:

1. Test Cassette: 10 Tests
2. Buffer: 1.5 mL
3. Dropper: 10 Pieces

Materials required but not supplied:

1. Sample collection container
2. Centrifuge (for plasma only)
3. Micropipette
4. Timer
5. Lancets (for finger prick whole blood only)

Important Notes:

1. For use by medical professional use only.
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.

Sample Collection and Preparation:

COVID-l9 IgG/lgM Rapid Test Kit can be performed using Serum, Plasma and or Whole Blood.

1. To collect finger, prick 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. Rub the hand gently from wrist to palm to finger to form a rounded drop of blood over the puncture site. Transfer the finger blood sample to the cassette by using by micropipette/dropper immediately.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
3. Test should be perforated immediately after sample collection.
4. Serum and plasma samples may be stored at 2-8°C for up to 3 days. For long-term storage, samples should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C 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.
5. 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.

Test Procedure: Keep the test cassette, sample, buffer to room temperature (15-30°C) prior to testing.

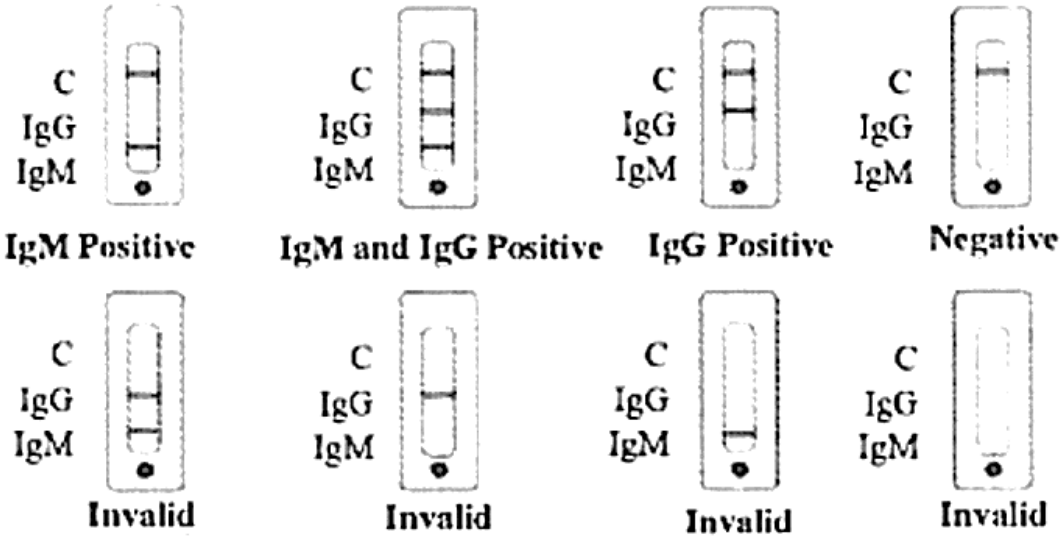
1. Bring the pouch to room temperature before opening. Take the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and flat surface.
3. For Serum or Plasma samples: add 20uL of sample into sample well, then add I drop of buffer (50uL) and start the timer. Avoid trapping air bubbles into the sample well.
4. For Whole Blood samples: add 20uL of sample into sample well, then add 3 drops of buffer (150uL) as soon as possible and start the timer. Avoid trapping air bubbles into the sample well. Note: It is recommended to add I more drop of buffer if the liquid flows too slowly.
5. Wait for the colored line(s) to appear. The result shall be read at 10 minutes. The result is valid within 20 minutes.
   Note: It is recommended to use serum or plasma as the priority sample types for testing, and whole blood samples can be used in urgent or special cases.

Interpretation of Results:

1. IgM Positive: Two lines appear. Colored lines should be in the control lane region (C) and IgM test line region. No line appears in IgG test line region.
2. IgG and IgM Positive: Three lines appear. Colored lines should be in the control lane region (C), IgG line test region and IgM line test region. The color intensities of the lines do not have to match.
3. IgG Positive: Two lines appear. Colored lines should be in the control line region (C) and IgG line test region. No line appears to IgM test line region.

Note: The intensity of the color in the IgG and or IgM test line region 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 cassette. If the problem persists, discontinue using the test kit and contact your local distributor.



Note: This figure is only used as a reference for judging results

Performance:

1. Positive reference of product compliance rate: should be 5/5.
2. Negative reference of product compliance rate: should be 10/10.
3. Minimum detection limit: The reference product SI should be negative, S2A, S2B and S3 should be positive.
4. Repeatability: Three reference products (S2A, S2B and S3) are tested. 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 antibody positive samples against parainfluenza virus, influenza A virus, influenza B virus, Chlamydia pneumoniae, Mycoplasma pneumoniae, adenovirus, respiratory syncytial virus, hepatitis B surface, Type C Hepatitis virus, Treponema pallidum, human immunodeficiency virus, EB virus, measles virus, cytomegalovirus, enterovirus 71, mumps virus, HKU1 virus, OC43 virus, NL63 virus, 229E virus and chicken pox-zoster virus

5.2 interfering substances:

1) When the bilirubin concentration is ≤250umoL/L, the hemoglobin content is ≤9g/L, the triglyceride content is ≤15mmoL/L, the rheumatoid factor content is ≤8OIU/mL, and the antinuclear antibody (ANA) titer is ≤1: 240, anti-mitochondrial antibody (AMA) ≤80U/mL, mouse IgG content ≤1000ug/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 coronas virus 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 clinical positive serum samples were studied, and the results met the requirements.
9. Clinical performance: The in vitro diagnostic reagents are compared with the clinical diagnostic criteria of 2019-nCoV to verify the clinical performance of this product. The enrolled cases were suspected eases of 2019-nCoV infection, a total of 1585 cases, including 421 confirmed cases and 1164 excluded cases The test results show that the product has a clinical sensitivity of 98.81% (95% CI: 97.25%, 99.61%) and specificity of 98.02% (95% CI: 97.05%, 98.74%). 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 consistency rate of the whole blood is 96.85% (95% CI: 95.87% to 97.60%), based on the serum/plasma test results.

Limitations:

1. COVID-19 Rapid Test is for in vitro diagnostic use only. The test should be performed using 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. In the early onset of fever, anti-COVID-19 lgM concentrations may be below detectable levels. 3. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy
3. Results from immunosuppressed patients should be interpreted with caution
4. As with all diagnostic tests. all results must be interpreted together with other clinical information available to the physician.
5. 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 tune preclude the possibility of COVID-19 infection.
6. This test has not been reviewed by the FDA.
7. Negative results do not rule out SARS-CeV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
8. 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.
9. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E, as limited number and variety of viruses that have been validated by cross-reaction tests.
10. Not for the screening of donated blood.