COVID-19 IgG/IgM Rapid Test (S/P/WB)

1. INTENDED USE

The COVID-19 IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG and IgM antibodies of COVID-19 in human serum, plasma or whole blood.

2. SUMMARY AND PRINCIPLE OF THE ASSAY

Coronavirus (CoV) belongs to order Nidovirales, family Coronavirus, and is divided into α、β、ɣ three genera. The α、β genera is only pathogenic to mammals, while the ɣ genus mainly causes infection in birds. CoV is mainly transmitted by direct contact with secretions, by aerosol or droplet, and there is also evidence that it can be transmitted by fecal-oral route.

So far, there have been seven types of human coronavirus (HCoV) that cause respiratory diseases in humans: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-CoV-2 is an important pathogen of human respiratory tract infection. Among them, the SARS-CoV-2 by wuhan viral pneumonia cases were found, the clinical manifestation of systemic symptoms such as fever, fatigue, dry cough, dyspnea, etc., can rapidly develop severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock and multiple organ failure, severe alkali metabolic disorders, etc., and even life threatening.

3. TEST PRINCIPLE

The COVID-19 IgG/IgM Rapid Test-Cassette is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 antigens conjugated with colloid gold (COVID-19 conjugates), 2) a nitrocellulose membrane strip containing two test bands (1 and 2 bands) and a control band (C band). The 1 band is pre-coated with monoclonal anti-human IgM for the detection of SARS-CoV-2 IgM antibodies, 2 band is pre-coated with reagents for the detection of SARS-CoV-2 IgG antibodies, and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. SARS-CoV-2 IgM antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored 1 band, indicating a SARS-CoV-2 IgM positive test result.

SARS-CoV-2 IgG antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored 2 band, indicating a SARS-CoV-2 IgG positive test result.

Absence of any test bands (1 and 2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

4. PACKAGE CONTENTS

1) Pouch contents: Test cassette, desiccant.

2) Sample buffer (5ml) per bottle for 25 tests

3) Test instruction.

5. MATERIAL PROVIDED

1) Lancet.

2) Alcohol wipe.

6. WARNINGS AND PRECAUTIONS

1) For professional in vitro diagnostic use only.

2) Do not reuse.

3) Do not use if the pouch seal or its packaging is compromised.

4) Do not use after the expiration date shown on the pouch.

5) Do not mix and interchange different specimens.

6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.

7) Wash hands thoroughly after finishing the tests.

8) Do not eat, drink or smoke in the area where the specimens or kits are handled.

9) Clean up spills thoroughly with appropriate disinfectants.

10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.

11) Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.

12) Keep out of children's reach.

7. SPECIMEN PREPARATION

1) Suitable for human serum, plasma or whole blood samples, including those prepared by clinical anticoagulants (EDTA, heparin, sodium citrate).

2) Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately. Store serum and plasma specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

3) Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

4) Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

8. ASSAY PROCEDURE

1) Bring the specimen and test components to room temperature（15～30 ℃） if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

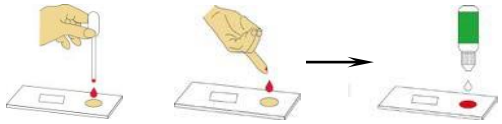
2) When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

3) Be sure to label the device with specimen's ID number.

4) Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 10 μL of specimen into the sample well making sure that there are no air bubbles.

5) Then add 2 drops (about 70-100 μL) of Sample Diluent immediately.

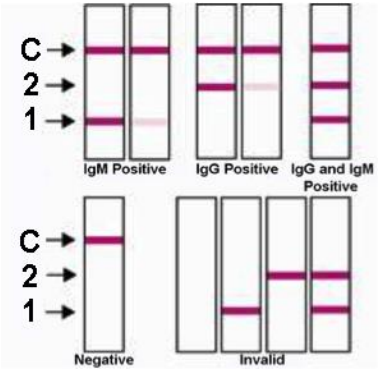
10 μL of specimen　　2 drops of sample diluent



6) Set up timer. Results can be read in 15 minutes.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

9. RESULT INTERPRETATIONS



Negative

If only the C band is present, the absence of any burgundy color in the both test bands (1 and 2) indicates that no SARS-CoV-2 antibody is detected in the specimen. The result is negative.

Positive

In addition to the presence of C band, if only 1 band is developed, the test indicates for the presence of SARS-CoV-2 IgM antibody. The result is positive.

In addition to the presence of C band, if only 2 band is developed, the test indicates for the presence of SARS-CoV-2 IgG antibody. The result is positive.

In addition to the presence of C band, both 1 and 2 bands are developed, the test indicates for the presence of both IgG and IgM SARS-CoV-2. The result is also positive.

Invalid

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

10. STORAGE AND STABILITY

1) Store in a dry place at 2 ~ 30°C away from light.

2) After opening the inner package, the test cassette will fail due to moisture absorption. Please use it within 1 hour.

11. LIMITATIONS

1) The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to SARS-CoV-2 in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

2) The sample should be tested in the laboratory with certain conditions.All samples and materials in the testing process shall be handled in accordance with the laboratory practice for infectious diseases.

3) The COVID-19 IgG/IgM Combo Rapid Test is limited to the qualitative detection of antibodies to SARS-CoV-2 in human serum, plasma or whole blood.

4) A negative result can occur if the quantity of SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

5) Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

6) The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.