COVID-19 IgG/IgM Rapid Test Device
Package Insert

INTENDED USE

The COVID-19 IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti–COVID-19 virus and IgM anti-COVID-19 virus in human whole blood, serum or plasma. It is intended to be used by the professionals as a screening test and as an aid in the diagnosis of infection with COVID-19 viruses. Any reactive specimen with the COVID-19 IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.[1,2] Six coronavirus species are known to cause human disease.[3] Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals.[3] The two other strains — severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) — are zoonotic in origin and have been linked to sometimes fatal illness.[4] Given the high prevalence and wide distribution of coronaviruses, the large genetic diversity and frequent recombination of their genomes, and increasing human–animal interface activities, novel coronaviruses are likely to emerge periodically in humans owing to frequent cross-species infections and occasional spillover events.[4,5]

In late December 2019, several local health facilities reported clusters of patients with pneumonia of unknown cause that were epidemiologically linked to a seafood and wet animal wholesale market in Wuhan, Hubei Province, China.[6] On December 31, 2019, the Chinese Center for Disease Control and Prevention (China CDC) dispatched a rapid response team to accompany Hubei provincial and Wuhan city health authorities and to conduct an epidemiologic and etiologic investigation. We report the results of this investigation, identifying the source of the pneumonia clusters, and describe a novel coronavirus detected in patients with pneumonia whose specimens were tested by the China CDC at an early stage of the outbreak. We also describe clinical features of the pneumonia in two of these patients.

The COVID-19 IgG/IgM Rapid Test detects IgG and IgM anti-COVID-19 virus in one test within 15 minutes. The test is user friendly, without cumbersome laboratory equipment, and requires minimal staff trainings.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Device (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 components, an IgG component and an IgM component. In the Test region, anti-human IgM and IgG is coated. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgM or IgG in test line region. If the specimen contains IgM or IgG antibodies to COVID-19, a colored line will appear in test line region.

Therefore, if the specimen contains COVID-19 IgM antibodies, a colored line will appear in test line region M. If the specimen contains COVID-19 IgG antibodies, a colored line will appear in test line region G. If the specimen does not contain COVID-19 antibodies, 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 appeared in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions
Disposable pipettes	For adding specimens use
Buffer	Phosphate buffered saline and preservative
Package insert	For operation instruction

MATERIALS

Materials Provided

- Test devices
- Buffer
- Alcohol pad
- Droppers
- Package insert
- Sterile lancet

Materials Required But Not Provided

- Timer

Centrifuge

WARNINGS AND PRECAUTIONS

- Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 4°C-30°C. The positive and negative controls should be kept at 4°C-8°C. If stored at 4°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

ASSAY PROCEDURE

Bring the specimen and test components to room temperature. Place the test device on a clean, flat surface.

1. Remove the buffer vial, sterile lancet and other materials. Open the cap of the buffer vial. Then place it on a clean and level surface.
2. Push the sterile lancet cap firmly into the body of the finger-puncturing device, then rotate the cap 90 degrees.
3. Carefully pull off the cap.
4. Use the provided alcohol swab to clean the puncture site.
5. Push the sterile lancet firmly into the chosen site. Let a large drop of free-flowing blood collect at the puncture site. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.

Whole blood

Fill the dropper with the specimen then add 2 drops of specimen into the sample well. Making sure that there are no air bubbles. Then add 1 drop of sample buffer immediately into the sample well.

Plasma or Serum

Fill the dropper with the specimen then add 1 drop of specimen into the sample well. Making sure that there are no air bubbles. Then add 1 drop of sample buffer immediately into the sample well.

6. Set up a timer. Read the result at 15 minutes. ***Don't read result after 30 minutes. To avoid confusion, discard the test device after interpreting the result***

INTERPRETATION OF ASSAY RESULT

POSITIVE RESULT:

IgG Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region G (G). The result is positive for COVID-19 specific-IgG and is probably indicative of secondary COVID-19 infection.

IgM Positive:* The colored line in the control line region (C) appears and a colored line appears in test line region M (M). The result is positive for COVID-19 virus specific-IgM antibodies and is indicative of primary COVID-19 infection.

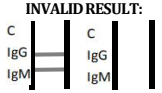
IgG and IgM Positive:* The colored line in the control line region (C) appears and two colored lines should appear in test line regions G and M (G and M). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary COVID-19 infection.

***NOTE:** The intensity of the color in the test line region(s) (G and M) will vary depending on the concentration of COVID-19 antibodies in the specimen. Therefore, any shade of color in the test line region(s) (G and M) should be considered positive.

NEGATIVE RESULT:

The colored line in the control line region (C) appears. No line appears in test line regions G and M (G and M).

INVALID RESULT:



Control line (C) 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
2. **External Control:** Good Laboratory Practice recommends using the external controls, positive and negative (provided upon request), to assure the proper performing of the assay.

PERFORMANCE CHARACTERISTICS

The COVID-19 IgG/IgM Rapid Test has been evaluated with a leading commercial test using clinical specimens. The results show that the accuracy is 90.19%.

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to COVID-19 virus from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The COVID-19 IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to COVID-19 virus in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. The COVID-19 IgG/IgM Rapid Test can not be used to differentiate if the infection is primary or secondary. No information of COVID-19 serotypes can be provided with this test.
4. A negative or non-reactive result for an individual subject indicates absence of detectable COVID-19 virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with COVID-19 virus.
5. A negative or non-reactive result can occur if the quantity of the COVID-19 virus 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.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. If the symptom persists, while the result from COVID-19 IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

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4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.
5. Wong G, Liu W, Liu Y, Zhou B, Bi Y, Gao GF. MERS, SARS, and Ebola: the role of super-spreaders in infectious disease. Cell Host Microbe 2015;18:398-401.
6. Report of clustering pneumonia of unknown etiology in Wuhan City. Wuhan Municipal Health Commission, 2019. (http://wjw.wuhan.gov.cn/front/web/showDetail/2019123108989. opens in new tab).

INDEX OF SYMBOLS

	Do not reuse		Do not use if package is damaged
4°C 30°C	Stored between 4-30℃		Consult instruction for use
	Caution	LOT	Lot number
	Use by	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		

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