2019-nCoV IgG/IgM Rapid Test Device
Package Insert

Cat.:COV-102 **Specimens:** Whole Blood/Serum/Plasma

Version: 01 **Effective Date:** 2020-02

For professional *in vitro* diagnostic use only.

INTENDED USE

The 2019-nCoV IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti–2019-nCoV virus and IgM anti-2019-nCoV 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 2019-nCoV viruses. Any reactive specimen with the 2019-nCoV 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 2019-nCoV IgG/IgM Rapid Test detects IgG and IgM anti-2019-nCoV virus in one test within 15 minutes. The test is user friendly, without cumbersome laboratory equipment, and requires minimal staff trainings.

PRINCIPLE

The 2019-nCoV IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of 2019-nCoV 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 2019-nCoV 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 2019-nCoV, a colored line will appear in test line region.

Therefore, if the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in test line region M. If the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in test line region G. If the specimen does not contain 2019-nCoV 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
- Droppers
- Package insert

Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Timer

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. 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 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°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.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Whole blood:

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.

Plasma

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture. Separate the plasma by centrifugation. Carefully withdraw the plasma into new pre-labeled tube.

Serum

Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture. Allow the blood to clot. Separate the serum by centrifugation. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 5 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. 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. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

ASSAY PROCEDURE

Bring the specimen and test components to room temperature Mix the specimen well prior to assay once thawed. Place the test device on a clean, flat surface.

For whole blood sample:

Fill the dropper with the specimen then add 1 drop (about 10 μL) of specimen into the sample well. Making sure that there are no air bubbles. Then add 2 drops (about 80 μL) of Sample Diluent immediately into the sample well.

For Plasma/ Serum sample:

Fill the dropper with the specimen then add 1 drop (about 10 μL) of specimen into the sample well. Making sure that there are no air bubbles. Then add 2 drops (about 80 μL) of Sample Diluent immediately into the sample well. 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 2019-nCoV specific-IgG and is probably indicative of secondary 2019-nCoV 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 2019-nCoV virus specific-IgM antibodies and is indicative of primary 2019-nCoV 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 2019-nCoV infection.

***NOTE:** The intensity of the color in the test line region(s) (G and M) will vary depending on the concentration of 2019-nCoV 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) falls 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

1. Clinical Performance For IgM Test

A total of 146 patient samples from susceptible subjects were tested by the 2019-nCoV IgG/IgM Rapid Test and by a reference PCR. Comparison for all subjects is showed in the following table:

	2019-nCoV IgM Rapid Test		
PCR Results	**Positive**	**Negative**	**Total**
Positive	42	2	44
Negative	0	102	102
Total	42	104	146

Relative Sensitivity: 95.5% (89.3%~100%)
Relative Specificity: 100% (99.8%~100%)
Overall Agreement: 98.6% (96.7%~100%) 95%CI

2. Clinical Performance For IgG Test

A total of 156 patient samples from susceptible subjects were tested by the 2019-nCoV IgG/IgM Rapid Test and by a reference PCR. Comparison for all subjects is showed in the following table:

	2019-nCoV IgG/IgM Rapid Test		
PCR Results	**Positive**	**Negative**	**Total**
Positive	54	0	54
Negative	2	100	102
Total	56	100	156

Relative Sensitivity: 100% (99.7%~100%) ; Relative Specificity: 98.0% (95.4%~100%)
Overall Agreement: 98.7% (97.0%~100%) 95%CI

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to 2019-nCoV virus in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The 2019-nCoV IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to 2019-nCoV 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 2019-nCoV IgG/IgM Rapid Test can not be used to differentiate if the infection is primary or secondary. No information of 2019-nCoV serotypes can be provided with this test.
4. A negative or non-reactive result for an individual subject indicates absence of detectable 2019-nCoV virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with 2019-nCoV virus.
5. A negative or non-reactive result can occur if the quantity of the 2019-nCoV 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 2019-nCoV 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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