2019-nCOV IgG/IgM Rapid Test Device

(Whole Blood/Serum/Plasma)

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Contents

1. Background

Early January 2020, a novel coronavirus (2019-nCoV) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019.

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Six coronavirus species are known to cause human disease. Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals. 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.

Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

2. Test Principle

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to 2019-nCoV in whole blood, serum or plasma specimen. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with 2019-nCoV 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 specimen contains IgG antibodies to 2019-nCoV. A colored line will appear in IgG test line region as a result of this. Similarly, anti-human IgM is coated in IgM test line region and if specimen contains IgM antibodies to 2019-nCoV, the conjugate-specimen complex reacts with anti-human IgM. A colored line appears in IgM test line region as a result.

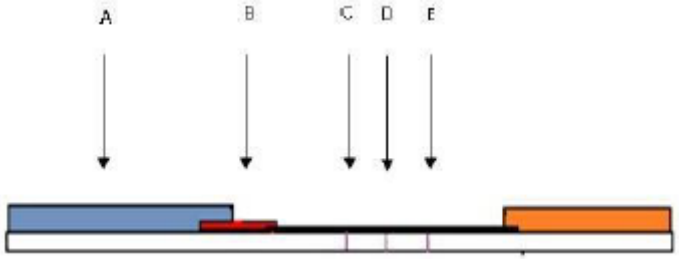
Therefore, if the specimen contains 2019-nCoV IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains 2019-nCoV IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain 2019-nCoV antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

3. Summary

Coronavirus (CoV) belongs to the genus Nestovirus, Coronaviridae, and is divided into three genera α, β, and γ. The genus α and β are only pathogenic to mammals. The genus γ mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.

So far, there are 7 types of human coronavirus (HCoV) that cause human respiratory diseases HCoV-229E,HCoV-OC4, SARS-CoV,HCoV-NL63, HCoV-HKU1, MERS-CoV and new coronaviruses (2019) , ls an important pathogen of human respiratory infections. Among them, the new coronavirus (2019) was discovered due to Wuhan virus pneumonia cases in 2019. The clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, and acute breathing. Distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. are even life-threatening.

4. Illustrations



As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the gold conjugate (B). 2019-nCoV IgG or/and IgM present in the specimen binds to the conjugate, forming a colored Novel coronavirus antibody-antigen complex. The mouse anti-human IgG and mouse anti-human IgM immobilized in the test zone of the membrane captures the test region (C) and test

region (D). The formation of a visible colored line in the test region indicates a positive result (C) or (D). The absence of a colored line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture colored conjugate regardless of test specimen composition. The resulting visible colored band (E) confirms control line.

5. Intended Use

The 2019-nCOV lgG/lgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of lgG & lgM antibody of WUHAN New Coronavirus in human whole blood, serum, or plasma as an aid in the diagnosis of 2019-nCOV infections.

6. Principle

This kit uses immunochromatography. The test card contains:

- colloidal gold-labeled recombinant new coronavirus antigen and quality control antibody gold markers

- two detection lines (G and M lines) and one quality Control line (C line) of nitrocellulose membrane.

The M line is immobilized with a monoclonal anti-human lgM antibody for detecting a new coronavirus lgM antibody the G line is immobilized with a reagent for detecting a new coronavirus lgG antibody and the C line is immobilized with a quality control antibody.

When an appropriate amount of the test sample is added to the sample hole of the test card, the sample will move forward along the test card under the action of the capillary. If the sample contains an lgM antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen. The immune complex will be captured by the anti-human lgM antibody immobilized on the membrane to form a purple-red M line, showing that the new coronavirus lgM antibody is positive.

If the sample contains an lgG antibody, the antibody will bind to the colloidal gold-labeled new coronavirus antigen, and the immune complex will be captured by the reagent immobilized on the membrane to form a purple-red G line, indicating that the new coronavirus lgG antibody is positive.

If the test lines G and M are not colored, a negative result is displayed. The test card also contains a quality control line C. The fuchsia quality control line C should appear

regardless of whether a test line appears. The quality control line is a color band of the quality control antibody immune complex. If the quality control line C does not appear, the test result is invalid, and the sample needs to be tested again with another test card.

7. Reagents

The test contains 2019-nCOV virus envelope protein particles and anti-human lgG, anti-human lgM antibody conjugated gold particles coated on the membrane.

8. Precautions

I. For professional in vitro diagnostic use only. Do not use the kit beyond the expiration date.

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

III. Do not use the test if the pouch is damaged.

IV. 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.

V. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

VI. The used test should be discarded according to local regulations.

9. Storage and Stability

- The original packaging should be stored at 4 ~ 30℃, to avoid light, keep dry.
- The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.**
- Do not use beyond the expiration date, especially at temperatures above 30℃ or under high humidity conditions, should be used immediately once it is opened.

10.SPECIMEN COLLECTION AND PREPARATION

I. The 2019-nCOV lgG/lgM Rapid Test Device is intended for use with human whole blood, serum or plasma specimens only.

II. Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.

III. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2 ~ 8℃ for up to 3 days. For long term storage, serum or plasma specimens 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 after collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

IV. Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.

V. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

VI. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

VII. Icteric, lipemic, hemolyzed, heat treated and contaminated sera may cause erroneous results.

11.Materials

- **Materials provided**
  - Test Devices
  - Buffer
  - Disposable plastic pipette
  - Package insert

- **Materials required but not provided**
  - Specimen collection containers
  - Centrifuge (for plasma only)
  - Micropipette
  - Timer
  - Lancets (for finger stick whole blood only)

12.Directions for Use

Allow the test device, specimen, buffer, and/or controls to reach room temperature (15 ~ 30℃) prior to testing.

I. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.

II. Place the test device on a clean and level surface.

❖ **For Serum or Plasma Specimens:**

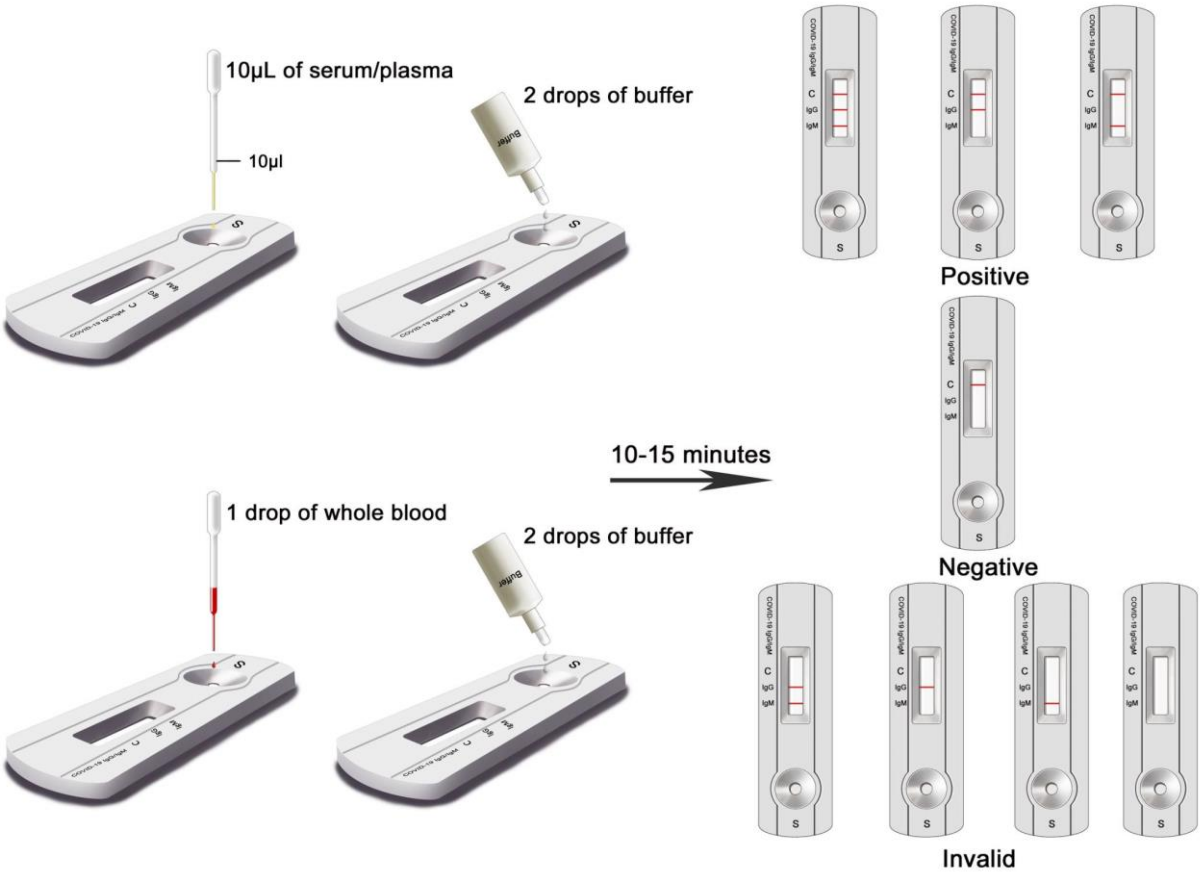
Using the **provided 10uL disposable pipette**, draw the specimen up to **the Fill Line**, and **transfer 10ul serum/plasma** to the specimen well of the test device, then **add 2 drops of buffer** and start the timer.

❖ **For whole blood (Venipuncture/Fingerstick) Specimens:**

Using the **provided 10uL disposable pipette**, and transfer 1 drop of Whole blood (approximately 20uL) to the specimen well of the test device, then add 2 drops of buffer and start the timer.

Note: *Specimens can also be applied using a micropipette.*

III. Wait for the colored line(s) to appear**. Read results at 10 minutes**. **Do not interpret the result after 15 minutes.**



13.Interpretation of Results

**IgG POSITIVE: ***The colored line in the control line region (C) appears and a colored line appears in test line region lgG. The result is positive for 2019-nCOV-lgG antibodies.

**IgM POSITIVE: ***The colored line in the control line region (C) appears and a colored line appears in test line region lgM. The result is positive for 2019-nCOV-lgM 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 lgG and lgM. The color intensities of the lines do not have to match. The result is positive for lgG & lgM antibodies.

***NOTE:** The intensity of the color in the test line region(s) lgG and/or lgM will vary depending on the concentration of 2019-nCOV antibodies in the specimen. Therefore, any shade of color in the test line region(s) lgG and/or lgM should be considered positive.*

NEGATIVE: The colored line in the control line region (C) appears. No line appears in test line regions lgG or lgM.

INVALID: There is no line appear in the c region.

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.

14.Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

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.

15.Performance Characteristics

Clinical Sensitivity, Specificity and Accuracy
The 2019-nCOV lgG/lgM Rapid Test Device has been evaluated with specimens obtained from a population of healthy, identified and suspectable persons.

- **For healthy persons:**
  The 2019-nCOV lgG/lgM Rapid Test Device was compared with RT-PCR Reagent using clinical specimens from 50 healthy persons.

Result	2019-nCOV IgG Rapid	2019-nCOV IgM Rapid	RT-PCR
Positive	0	0	0
Negative	50	50	50
Accuracy	100%	100%	100%

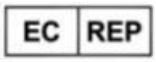
- **For identified persons:**
  The 2019-nCOV lgG/lgM Rapid Test Device was compared with RT-PCR Reagent using clinical specimens from 50 2019-nCOV identified patients.

Result	2019-nCOV IgG Rapid	2019-nCOV IgM Rapid	RT-PCR
Positive	48	46	50
Negative	2	4	0
Accuracy	96%	92%	100%

- **For suspectable persons:**
  The 2019-nCOV lgG/lgM Rapid Test Device was compared with RT-PCR Reagent using clinical specimens from 50 suspectable 2019-nCOV patients, the results of RT PCR are all negative.

Result	2019-nCOV IgG Rapid	2019-nCOV IgM Rapid	RT-PCR
Positive	37	36	0
Negative	13	14	50
Accuracy	74%	72%	0%

16.Symbols

Symbol	Meaning
	In vitro diagnostic medical device
	Manufacturer
	Date of Manufacture
	Do not reuse
	Batch code
	Catalogue number
	Storage temperature limit
	Authorized representative in the European Community
	Use by date
	Consult instruction foe use
	Meet the requirements of EC Directive 9 /79/EC
	The number of tests