2019-nCOV/COVID-19 IgG/IgM Rapid Test Device Package Insert

For the qualitative assessment of Coronavirus Disease 2019 (2019-nCOV or COVID-19) IgG/IgM in human serum/plasma/whole blood.
For professional In Vitro Diagnostic Use Only

INTENDED USE

The 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG&IgM antibody of Coronavirus Disease 2019 in human whole blood,serum,or plasma as an aid in the diagnosis of COVID-19 infections.

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-OC43,SARS-CoV,HCoV-NL63,HCoV-HKU1,MERS-CoV and novel coronaviruses (2019),is an important pathogen of human respiratory infections.Among them, the novel coronavirus (2019) was discovered 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.

PRINCIPLE

This kit uses immunochromatography.The test card contains:1) colloidal gold-labeled recombinant novel coronavirus antigen and quality control antibody gold markers;2) two detection lines (IgG and IgM lines) and one quality Control line (C line) of nitrocellulose membrane.The IgM line is immobilized with a monoclonal anti-human IgM antibody for detecting a novel coronavirus IgM antibody;the IgG line is immobilized with a reagent for detecting a novel coronavirus IgG 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 IgM antibody, the antibody will bind to the colloidal gold-labeled novel coronavirus antigen. The immune complex will be captured by the anti-human IgM antibody immobilized on the membrane to form a purple-red IgM line,showing that the novel coronavirus IgM antibody is positive.

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

If the test IgG and IgM lines 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.

REAGENTS

The test contains COVID-19 virus envelope protein particles and anti-human IgG,anti-human IgM antibody conjugated gold particles coated on the membrane.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use the kit beyond the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use the test if the pouch is damaged.
4. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. Negative results do not rule out 2019-nCOV/COVID-19 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. Result from antibody testing should not be used as the sole basis to diagnose or exclude 2019-nCOV/COVID-19 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.

STORAGE AND STABILITY

1. The original packaging should be stored at 2~ 30℃,to avoid light, keep dry.
2. 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.**
3. 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.

SPECIMEN COLLECTION AND PREPARATION

1. The 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device is intended for use with human whole blood, serum or plasma specimens only.
2. 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.
3. 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°C for up to 3 days. For long term storage, serum or plasma specimens 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 after collection.Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
4. Containers containing anticoagulants such as EDTA,citrate,or heparin should be used for whole blood storage.
5. 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.
6. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
7. Icteric,lipemic,hemolyzed,heat treated and contaminated sera may cause erroneous results.

MATERIALS

Materials provided

- Test Devices
- 5μL Disposable plastic pipette
- Buffer
- Package insert

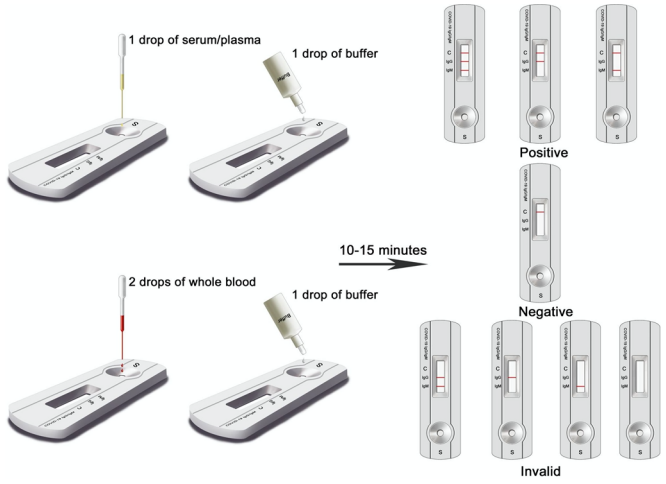
Materials required but not provided

- Specimen collection containers
- Micropipette
- Lancets (for finger stick whole blood only)
- Centrifuge (for plasma only)
- Timer
- Alcohol pad

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening.Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
- For **Serum or Plasma Specimens:**
  Using the **provided 5μL disposable pipette,and transfer 1 drop of serum/plasma** to the specimen well of the test device,then **add 1 drop of buffer,**and start the timer.
- For **Whole Blood (Venipuncture/Fingerstick) Specimens:**
  Using the **provided 5μL disposable pipette**,and **transfer 2 drops of whole blood (approximately 20μL)** to the specimen well of the test device,then **add 1 drop of buffer,** and start the timer.
  Note: Specimens can also be applied using a micropipette.
3. Wait for the colored line(s) to appear.**Read results at 10 minutes.Do not interpret the result after 15 minutes.**



INTERPRETATION OF RESULTS

IgG POSITIVE:*The colored line in the control line region (C) appears and a colored line appears in test line region IgG. The result is positive for COVID-19-IgG antibodies.

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

IgG AND IgM POSITIVE:*The colored line appears in the control line region (C) and two test line regions (IgG and IgM). The result is positive for COVID-19-IgG and COVID-19-IgM antibodies.

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

NEGATIVE: The colored line in the control line region (C) appears. No line appears in test line region IgG or IgM.

INVALID: There is no line appeared 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.

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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device has been compared to a leading commercial RT-PCR testing using clinical specimens.The results show that the 2019-nCoV/COVID-19 IgG/IgM Rapid Test Device has a high sensitivity and specificity.

For IgG testing

Method		RT-PCR		Total Results
2019-nCOV IgG/IgM Rapid Test Device	Results	Positive	Negative	
	Positive	233	2	235
	Negative	35	287	322
Total Results		268	289	557

Relative Sensitivity:233/268=86.94%(95%CI*:82.35%-90.49%)
Relative Specificity:287/289=99.31% (95%CI*:97.52%-99.92%)
Accuracy:520/557=93.36% (95%CI*: 90.96%-95.16%)
*Confidence Interval

For IgM testing

Method		RT-PCR		Total Results
2019-nCOV IgG/IgM Rapid Test Device	Results	Positive	Negative	
	Positive	223	7	230
	Negative	45	282	327
Total Results		268	289	557

Relative Sensitivity: 223/268=83.21%(95%CI*:78.19%-87.48%)
Relative Specificity:282/289=97.58% (95%CI*: 95.07%-99.02%)
Accuracy: 505/557=90.66% (95%CI*: 87.94%-92.95%)
*Confidence Interval

Sensitivity by Days Post Onset of Symptoms					
	Incubation	2-7days	7-13days	14-20days	20+days
Clinical Positive	1	8	8	21	47
RT-PCR Positive	1	8	7	19	45
Realy IgG Positve	1	3	7	20	46
Realy IgM Positve	1	6	7	14	20
Sensitivity by Days Post Onset of Symptoms					
	Incubation	2-7days	7-13days	14-20days	20+days
Realy IgG Positve	100%	37.50%	87.50%	95.24%	97.87%
Realy IgM Positve	100%	75.00%	87.50%	66.67%	42.55%

Cross-reactivity

The 2019-nCoV/COVID-19 IgG/IgM Rapid Test Device has been tested for anti-influenza A virus,anti-influenzaB virus,anti-RSV,anti-Adenovirus,HBsAg,anti-Syphilis,anti-HIV anti-rheumatoid factor,anti-M.Pneumonia,anti-Chlamydiapneumoniae and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the 2019-nCoV/COVID-19 IgG/IgM Rapid Test Device and no interference was observed.

Triglyceride:5000mg/dL	Ascorbic Acid: 20mg/dL	Hemoglobin 1000mg/dL
Bilirubin: 60mg/dL	Oxalic acid: 100mg/dL	Human serum albumin 2000mg/dL

LIMITATION OF USE

1. The accuracy of the test depends on the sample collection process. Improper sample collection, improper storage of samples, stale samples, or repeated freeze-thaw cycles of samples will affect the test results.
2. The test cassette only provides qualitative detection of the COVID-19 antibody in the sample. If you need to detect the specific content of an indicator, please use the relevant professional instruments.
3. The test result of this kit is for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests, and treatment
4. responses.
5. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.
6. Analysis of the possibility of false negative results：

① Unreasonable sample collection, transportation and processing may lead to false negative results.
② Genetic variations of virus can cause changes in antibody determinants, which can lead to false negative results.
③ The optimal sample type and sampling time after infection have not been verified, so collecting samples at different times on the same patient may avoid false negative results.

BIBLIOGRAPHY

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SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC
REF	Catalogue number	Σ	The number of test

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CE

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