2019-nCOV IgG/IgM Rapid Test Cassette
《Colloidal Gold Immunochromatography》

Package Insert

[PRODUCT NAME]

2019-nCOV IgG/IgM Rapid Test Cassette（Colloidal gold immunochromatographic assay）

[PACKING]

20 Test / Unite

[INTENDED USE]

2019-nCoVs IgG/IgM Rapid Test Cassette (GICA) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection N Protein of IgG and IgM antibodies to 2019-nCoVs in human whole blood, serum or plasma ， Applicable to the auxiliary diagnosis and screening of patients with new 2019-nCoVs disease.

The test detects protein 2019-nCoV of IgG and IgM antibodies by using 2019-nCov protein as antigen. IgM is the first antibody that appears in the body's immune system and is usually produced 3 to 7 days after exposure. IgM can be used to reflect whether the body is in an acute infection state and is an important indicator for early diagnosis. IgG is the main antibody produced by the re-immune response. It has high affinity, is widely distributed in the body and has a higher content and has important immune effects. The detection of total antibodies in patients with 2019-nCoVs infection can reflect the production of antibodies at different infection periods, reducing the impact of the single detection window period. At the same time, the detection target is increased compared to the single target, which can significantly improve the detection rate and reduce missed diagnosis.

[PRINCIPLE]

The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses mouse anti-human IgM antibody (test line IgM) , mouse anti-human IgG (test line IgG) immobilized on a nitrocellulose strip membrane. The

burgundy colored conjugate pad contains colloidal gold conjugated to recombinant 2019-nCoV antigens conjugated with colloid gold (2019-nCoV conjugates) and IgG-gold conjugates. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to 2019-nCoV conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anit-human IgG) the complex is trapped forming a burgundy colored band which confirm are active test result. Absence of a colored band in the test region indicates a non-reactive test result.

The test contains an internal control (C band) which should exhibit a burgundy colored band on any of the test bands. Otherwise, the test result is invalid.

[MATERIALS SUPPLIED]

COMPONENTS		20 test/unit	Composition
1. Test Cassette		20x	Nitrocellulose membrane, N protein, S protein, mouse anti-human IgM antibody, mouse anti-human IgG antibody, anti-N protein antibody, anti-S protein antibody, tetra chloroauric acid, etc.
2. Diluent Buffer		100uL×20 vial	Phosphate buffer, Tween-20, etc.
3. Blood Collection Set	Lancets（for fingerstick whole blood only）	20 x	Sterile lancet.
	Alcohol Pad	20 x	75% Alcohol cotton tablets, sterile dry cotton balls
	Disposable Pipette	20uL×20	Aseptic tubing

[STORAGE AND STABILITY]

The kit can be stored in dark place at room temperature or refrigerated (2-30°C) for 18 months.

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Manufacturing date and expiration date are printed on the label.

[SPECIMEN COLLECTION AND PREPAREATION]

1. 2019-nCoV IgG/IgM Rapid Test Cassette can be performed using either whole blood, serum or plasma.

2. Serum and plasma specimens may be stored at 2-8℃for up to 3 days after sealing. For 6 month storage s, specimens should be kept at -20℃. For 48 month storage s, specimens should be kept below -70℃. Specimens (-20℃) The test results are stable within 3 times of freezing and thawing, but it is still recommended to avoid repeated freezing and thawing. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed, mixed well and equilibrate to room temperature prior to testing. Specimens should not be frozen and thawed repeatedly. Whole blood or Whole blood collected by fingerstick must be tested within 8 hours.

3 To collect Fingerstick Whole Blood Specimens:

3.1 Wash the patient’ s hand with soap and warm water or clean with an alcohol pad. Allow to dry.

3.2 Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

3.3 Puncture the skin with a sterile lancet. Wipe away the first sign of blood.

3.4 Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

3.5 Add the Fingerstick Whole Blood specimen to the test by using a disposable micropipette:

3.6 Touch the end of the disposable micropipette to the blood until filled to approximately 20μ L. Press the wound with sterile dry cotton ball (cotton swab).

[TEST PROCEDURE]

1. Test Preparation: allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing, it may take 30 minutes.
2. Assay steps; use a 20μl pipette to draw 10μl of plasma (serum) or 20μl of whole blood

(Fingerstick Whole Blood) dropwise into the sample application area, then add 2 ~ 3 drops of diluent and start timing. Wait for the purple-red band to appear The results should be interpreted within 10-20 minutes, and the interpretation results will be invalid after 20 minutes.

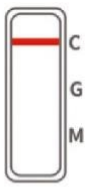
[QUALITY CONTROL]

A procedural control is included in the test. A red line appearing in the control region (C) is the internal 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.

NEGATIVE:

If only the C band is present, the absence of any burgundy color in the both T bands (IgG and IgM) indicates that no anti-2019-nCoV antibodies are detected in the specimen. The result is negative.



Negative

IgM POSITIVE:

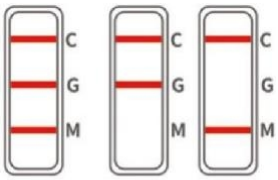
In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of IgM anti-2019-nCoV in the specimen. The result is IgM anti-2019-nCoV positive.

IgG POSITIVE:

In addition to the presence of C band, if only IgG band is developed, the test indicates for the presence of IgG anti-2019-nCoV in the specimen. The result is IgG anti-2019-nCoV positive.

IgG and IgM POSITIVE:

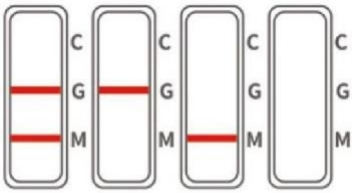
In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-2019-nCoV in the specimen. The result is IgG and IgM anti-2019-nCoV positive.



Positive

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.



Invalid

[LIMITATIONS]

1. The 2019-nCOV IgG/IgM Rapid Test Cassette is for in vitro diagnostic use only.

2. This test should be only used for detection of IgG and IgM antibody to 2019-nCOV in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to 2019-nCOV can be determined by this qualitative test.

3. The 2019-nCOV IgG/IgM Rapid Test Cassettewill only indicate the presence of IgG and IgM antibodies to 2019-nCOV in the specimen and should not be used as the sole criteria for the diagnosis of 2019-nCOV infections. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of 2019-nCOV infection

[PERFORMANCE CHARACTERISTICS]

1.Appearance and character

The outer packaging box should be flat, without damage, and the text and external identification should be clear; the packaging of the test card should be sealed without damage; the packaging of the diluent should be sealed without leakage.

2. Consistent rate

2.1 Negative consistent rate: The kit detects 10 new reference antibodies of the company's new coronavirus (2019-nCoV) antibody, and the consistent rate should be 100%.

2.2 Positive coincidence rate: The kit detects the enterprise's new coronavirus (2019-nCoV) IgM antibody positive reference product and the enterprise's new coronavirus (2019-nCoV) IgG antibody positive reference product, and the consistent rate should be 100%.

3. Reproducibility

3.1 Negative Repeat Rate: Use the kit to test the same enterprise negative reference 10 times. The negative repeat rate should be 100%.

3.2 Positive repetition rate: Use the kit to detect the same company's new coronavirus (2019-nCoV) IgM antibody positive reference and IgG antibody positive reference 10 times each.The positive repetition rate should be 100%.

4. Batch difference

Use 3 lot kits to detect the same company's new coronavirus (2019-nCoV) IgM antibody positive reference and IgG antibody positive reference 10 times each, and the positive repeat rate should be 100%.

5. Thermal stability

Take the validity period of the kit at 37 ℃ for 3 days, and check itsconsistent rate and repeatability. It should meet the requirements of 2 and 3.

[WARNINGS AND PRECAUTIONS]

1. For professional In Vitro diagnostic use only. Do not use after expiration date.

2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

3. Do not use it if the tube/pouch is damaged or broken.

4. Test is for single use only. Do not re-use under any circumstances.

5. 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.

6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

7. Humidity and temperature can adversely affect results.

8. Specimens storage: serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.

[REFERENCES]

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[4] Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019[J]. New England Journal of Medicine, 2020.

[5] Zhou L, Liu H G. Early detection and disease assessment of patients with novel coronavirus pneumonia[J]. Chinese journal of tuberculosis and respiratory diseases, 2020, 43: E003.