Samples for evaluation use only

JusChek

2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The 2019-nCoV IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human whole blood, serum or plasma specimen.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The 2019-nCoV 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 colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-human IgM and anti-human IgG as the capture reagent, 2019-nCoV antigen as the detection reagent. A goat anti-mouse IgG is employed in the control line system.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures 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. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
8. The used test should be discarded according to local regulations.
9. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood Specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol pad. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**.
    - Touch the end of the capillary tube to the blood until filled to approximately 20μL. Avoid air bubbles.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 7 days, for long term storage, serum/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 of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

MATERIALS

Materials provided

- Test cassettes
- Droppers
- Package insert
- Buffer

Materials required but not provided

- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Capillary tubes
- Centrifuge (for plasma only)
- Timer
- Pipette

DIRECTIONS FOR USE

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

1. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.
   For **Serum or Plasma** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen to the **fill line** (approximately 10μL), and transfer the specimen to the specimen well (S), then add **2 drops of buffer** (approximately 80 μL), and start the timer.
   - To use a pipette: To transfer **10 μL** of specimen to the specimen well(S), then **add 2 drops of buffer** (approximately 80 μL), and start the timer.

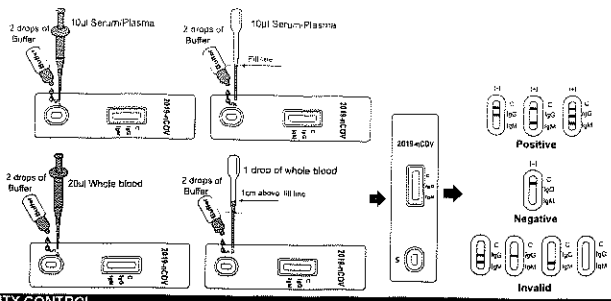
   For **Venipuncture Whole Blood** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20μL) of specimen to the sample well(S). Then add **2 drops of buffer** (approximately 80 μL) and start the timer.
   - To use a pipette: To transfer **20 μL** of whole blood to the specimen well(S), then **add 2 drops of buffer** (approximately 80 μL), and start the timer.

   For **Fingerstick Whole Blood** specimen:
   - To use a dropper: Hold the dropper vertically, draw the specimen about **1 cm above the fill line** and transfer **1 full drop** (approx. 20μL) of specimen to the sample well(S). Then add **2 drops of buffer** (approximately 80 μL) and start the timer.
   - To use a capillary tube: Fill the capillary tube and transfer **approximately 20μL of fingerstick whole blood specimen** to the specimen well (S) of test cassette, then **add 2 drops of buffer** (approximately 80 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.

INTERPRETATION OF RESULTS

IgG POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgG line region.
IgM POSITIVE:* Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the IgM line region.
IgG and IgM POSITIVE:* Three colored lines appear. One colored line should always appear in the control line region (C) and two test lines should be in the IgG line region and IgM line region.
***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of 2019-nCoV antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the IgG region and IgM region.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. 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 colored line appearing in the control region (C) is an 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.[1]

LIMITATIONS

1. The test Procedure and the interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to SARS-CoV-2 in whole blood, serum or plasma specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. 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 Cassette (Whole blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
4. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
5. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended to re-sample the patient a few days later or test with a molecular diagnostic device to rule out infection in these individuals.
6. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.
7. The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test, or the novel coronavirus antibody has not appeared at the time of sample collection (Asymptomatic stage).
8. In the early infection, anti-SARS-COV-2 antibodies concentrations may be below detectable level. Therefore it is not recommended to use the test in early diagnosis of COVID-19.
9. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
10. Results from immunosuppressed patients should be interpreted with caution.
11. At this time, it is unknown how long IgM or IgG antibodies may persist following infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial PCR; the results were tabulated as below.

IgG Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	Positive**	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Results		20	50	70

Relative Sensitivity: 100% (95%CI*: 86.0%-100%) *Confidence Interval
Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)
Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

IgM Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	Positive**	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Results		20	50	70

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%) *Confidence Interval
Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)
Accuracy: 92.9% (95%CI*: 84.1%-97.6%)
**All the 20 positive specimens were collected from hospitalized individuals who were clinically confirmed positive for SARS-CoV-2 infection. At the time of sample collection these individuals exhibited severe symptoms or they were in recovery stage.

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of three specimens: a negative, a IgG positive, and a IgM positive. The negative, IgG positive, and IgM positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same three specimens: a negative, a IgG positive, and a IgM positive. Three different lots of the 2019-nCoV IgG/IgM Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, IgG positive, and IgM positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, Anti-Measles, HAMA, RF, non-specific IgG, non-specific IgM, anti-EV71, anti-Parainfluenza virus, HBsAg, anti-Syphilis, anti-H.Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Triglyceride: 100 mg/dL Ascorbic Acid: 20mg/dL Hemoglobin: 1000mg/dL
Bilirubin: 60mg/dL Total cholesterol: 15mmol/L

BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry. Clinical Chemistry 1981;27:493-501

Index of Symbols

IVD	For in vitro diagnostic use only		Tests per kit	EC REP	Authorized Representative
2°C 30°C	Store between 2-30°C		Use by		Do not reuse
	Do not use if package is damaged	LOT	Lot Number	REF	Catalog #
	Manufacturer		Consult Instructions For Use		

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

WARNING STATEMENT

- Negative results do not rule out SARS-CoV-2 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.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
- Not for the screening of donated blood.