SCREEN

Screen Test COVID-19
2019-nCoV IgG/IgM Rapid Test Cassette
Single use kit
Package Insert

REF INCP-402S	English

A rapid test for the qualitative detection of IgG and IgM antibodies to 2019-nCoV in human Fingerstick whole blood 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 Fingerstick whole blood 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 (Fingerstick Whole Blood) is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to 2019-nCoV in Fingerstick whole blood 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.

【MATERIALS 】

Materials provided

- Test cassettes
- Droppers
- Package insert
- Lancets
- Alcohol pads
- Buffers

Materials required but not provided

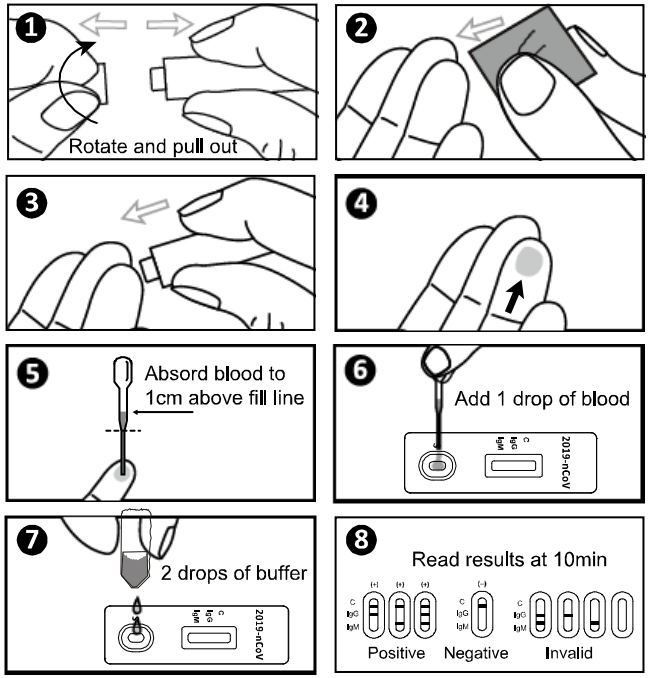
- Timer

【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.
3. Use the provided alcohol pad to clean the fingertip of the middle finger or ring finger as the puncture site.
4. Carefully rotate and pull off the lancet cap. Push the sterile lancet firmly into the fingertip of the middle finger. Do not use the first drop of blood. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
5. Hold the dropper vertically, draw the blood to 1cm above the fill line and transfer **1 full drop of whole blood** (approximately 20μL) to the specimen well (**S**), then **add 2 drops of buffer** (approximately 80 μL), and start the timer. See illustration below.
6. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.

Note: This test can also be run with serum/plasma specimen according to the following instructions: Aspirate the serum/Plasma to the Fill line (Approx. 10μL), and transfer it to the specimen well (S) of the test cassette, then add 2 drops of buffer and start the timer. Read results at 10 minutes. Do not read results after 20 minutes.



【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 Fingerstick 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 (Fingerstick whole blood) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to SARS-CoV-2 in Fingerstick whole blood specimen 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 SARS-CoV-2 can be determined by this qualitative test.
3. The 2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick whole blood) 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

1) The kit 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.

2) An evaluation was conducted by comparison with Clinical diagnosis results; the results were tabulated as below.

Method			Clinical diagnosis	
2019-nCoV IgG/IgM Rapid Test	Results		Positive***	Negative
	Positive	IgM	1	11
		IgG+IgM	33	
		IgG	28	
	IgG+IgM Negative		2	283
	Total Results		64	294

Relative Sensitivity: 96.9% (95%CI*: 89.2%-99.6%) *Confidence Interval
Relative Specificity: 96.3% (95%CI*: 93.4%-98.1%)
Accuracy: 96.4% (95%CI*: 93.9%-98.1%)

***All the 64 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 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 (Fingerstick Whole Blood) 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 (Fingerstick Whole Blood) 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 (Fingerstick Whole Blood) 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	Σ	Tests per kit	EC REP	Authorized Representative
	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		

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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.

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