ACRO BIOTECH, INC

2019-nCoV IgG/IgM Rapid Test Cassette Single use kit (Fingerstick Whole Blood) 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

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.[1]

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases.[2] Six coronavirus species are known to cause human disease.[3] Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals.[3] 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.[4]

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.[5]

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.[5]

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. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. 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.
7. The used test should be discarded according to local regulations.
8. 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
- Plastic bags
- Buffers

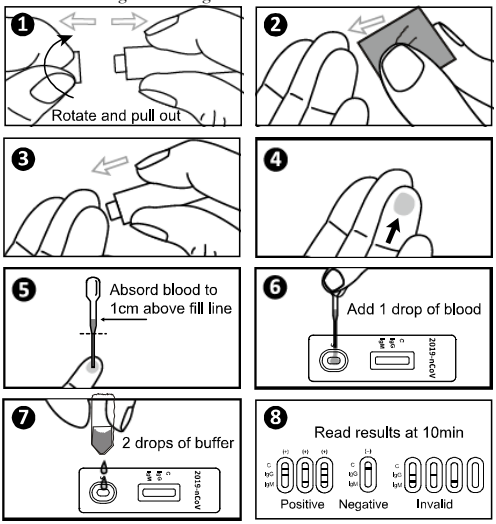
Materials required but not provided

- 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 swab to clean the fingertip of the middle finger or ring finger as the puncture site.
4. Carefully rotate and pull off the sterile 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.
7. Place the used tests into the plastic ziplock bags provided and seal, discard according to local regulations.



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.

LIMITATIONS

1. 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 2019-nCoV in Fingerstick Whole Blood 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.
2. The 2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood) will 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.
3. 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.
5. 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 novel coronavirus antibody has not appeared at the time of sample collection (Asymptomatic stage).

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The 2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood) was compared with a leading commercial PCR; the results show that 2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood) has a high sensitivity and specificity.

IgG Result

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

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

IgM Result

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

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)
Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)
Accuracy: 92.9% (95%CI*: 84.1%-97.6%)
*Confidence Interval

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, 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: 50 mg/dL
Ascorbic Acid: 20mg/dL
Hemoglobin: 1000mg/dL
Bilirubin: 60mg/dL
Total cholesterol: 6mmol/L

BIBLIOGRAPHY

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2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.PMID:22094080 DOI:10.1016/B978-0-12-385885-6.00009-2
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502.PMID:27012512 DOI:10.1016/j.tim.2016.03.003
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192. PMID:30531947 DOI:10.1038/s41579-018-0118-9
5. World Health Organization (WHO). Coronovirus. https://www.who.int/health-topics/coronavirus

Index of Symbols

IVD	For in vitro diagnostic use only	Σ	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		

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