MedicalSystem

Coronavirus Disease 2019 Antibody (IgM/IgG) Combined Test Kit

A rapid test for the qualitative detection of IgM&IgG antibody to SARS-CoV-2 in human serum, plasma or whole blood. For professional in vitro diagnostic use only.

INTENDED USE

The COVID-19 IgM/IgG Antibody (IgM/IgG) Combined Test Kit is a rapid chromatographic immunoassay for the qualitative detection of IgM&IgG antibody to SARS-CoV-2 in human serum, plasma or whole blood as an aid in the diagnostic of COVID-19 infections. Negative results do not preclude COVID-19 infection and should not be used as the sole basis for treatment or other patient management decisions.

BACKGROUND

Coronaviruses are a large family of viruses that are systematically classified as Coronaviridae (Coronaviridae). Coronavirus is a single-stranded RNA virus with a positive envelope and a diameter of about 80-120nm, 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, HCoV-NL63, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2, is an important pathogen of human respiratory infections. Among them, SARS-CoV-2 is a new coronavirus strain that has never been found in humans before, it caused COVID-19. The clinical manifestations of COVID-19 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.

Generally, the body can produce IgM and IgG antibodies after being infected with the virus. IgM antibodies generally begin to increase within 1 week of the initial infection and peak in 2 to 3 weeks. IgG appears later than IgM, and generally appears about 14 days after infection, peaks at 5 weeks, and can last for 6 months or even years. The patient's recovery period is 4 times or more than the acute phase IgG antibody titer or when decreased, it has clinical diagnostic significance for viral infection.

PRINCIPLE

The COVID-19 IgM/IgG Antibody (IgM/IgG) Combined Test is a qualitative, lateral flow immunoassay for the detection of IgM&IgG antibody to SARS-CoV-2 in human serum, plasma or whole blood. In this test, a monoclonal anti-human IgM antibody and a monoclonal anti-human IgG antibody is separately coated on the test line regions of the test device. During testing, the specimen reacts with the SARS-CoV-2 recombinant antigens that are labeled onto latex particles. The mixture migrates up the membrane to react with the antibodies to human IgM and/or human IgG on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

REAGENTS

The kit contains SARS-CoV-2 Spike Protein and Nucleocapsid protein labeled particles and anti-human IgG, anti-human IgM antibody coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- Proper specimen collection storage and transport are critical to the performance of this test.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens

are being tested.

- The used test should be discarded according to local regulations.

MAIN COMPONENTS

Material Provided

- 25 Individual sealed pouches, each pouch contains:
  - ■ 1 x Test cassette
  - ■ 1 x Desiccant pouch
- · 25 disposable droppers
- Buffer (2*3 mL)
- Package insert

Material Required but Not Provided

- Specimen Collection Containers
- Centrifuge (for plasma only)
- Timer
- Lancets (for finger stick whole blood only)

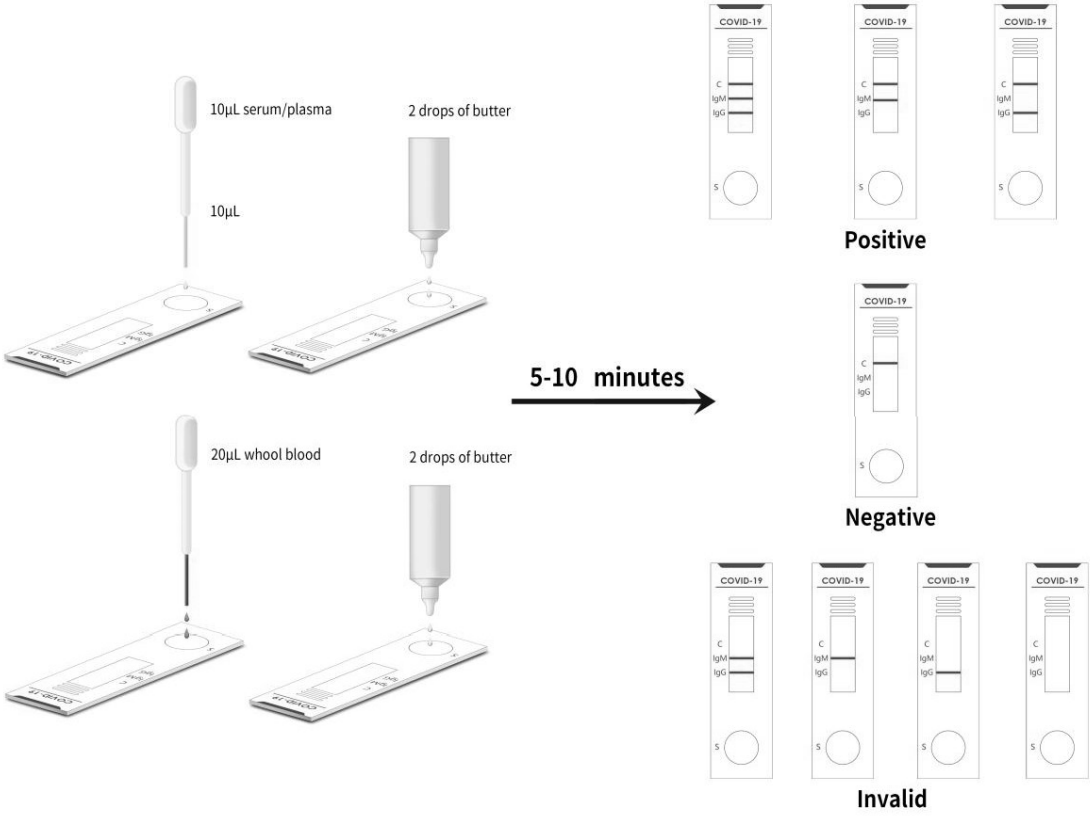
STORAGE AND STABILITY

Store as packaged 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. Buffer solution should be re-capped in time after use. Keep away from sunlight,

DIRECTIONS FOR USE

Allow the test cassette, specimen, buffer to equilibrate to room temperature (15-30°C) prior to testing.

- Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
- Transfer 10 µL of serum / plasma specimen or 20 µL (1 drop) of whole blood specimen to the sample well, then add about 80uL (about 2-3 drops) of buffer and start the timer.
- Wait for the colored line(s) to appear. Read the result at 5-10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

- IgG POSITIVE: *The colored line in the control line region (C) appears and a colored line appears in test line region IgG indicates that COVID-19-IgG antibody was detected in the sample.
- IgM POSITIVE: *The colored line in the control line region (C) appears and a colored line appears in test line region IgM indicates that COVID-19-IgM antibody was detected in the sample, and is indicative of primary COVID-19 infection.
- IgG AND IgM POSITIVE: *The colored line in the control line region (C) appears and two-colored lines should appear in test line regions IgG and IgM. The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies.
- NEGATIVE: The colored line in the control line region (C) appears. No line appears in test line regions IgG or IgM.
- INVALID: There is no line appear in the control line region (C).

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External Quality Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.

LIMITATIONS

- The COVID-19 IgM/IgG Antibody (IgM/IgG) Combined Test is for professional in vitro diagnostic use only. This test is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies.
- The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Limited by the method of antibody detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
- Positive test results do not rule out co-infections with other pathogens.

PERFORMANCE

A. Sensitivity and Specificity

The COVID-19 IgM/IgG Antibody (IgM/IgG) Combined Test has been evaluated with 760 clinical samples, which include 286 confirmed case and 474 confirmed excluded case samples. Test Result are listed in the below.

		Clinical Case		
		Confirmed	Excluded	Total
COVID-19 Antibody (IgM/IgG) Combined Test Kit	Positive	280	39	319
	Negtive	6	435	441
	Total	286	474	760

Result analysis:

The sensitivity is 97.90 %, the specificity is 91.77% and the total consistent is 94.08%.

The K value of Kappa analysis is 0.877, which means the test results of the kit are in reasonable comparability with the confirmed / excluded results.

B. Cross-reactivity

The following specimens were tested and all found to be negative when tested with the The COVID-19 IgM/IgG Antibody (IgM/IgG) Combined Test:

Chlamydia pneumoniae antibody
Mycoplasma pneumoniae antibody
Respiratory syncytial virus antibody
Adenovirus antibody
EB virus antibody
HIV antibody
HCV antibody
Treponema pallidum antibody
H.pylori antibody

C. Precision

Within run precision was determined by using 10 replicates of three different specimens containing different concentrations of antibody. The negative and positive values were correctly identified 100% of the time.

Between run precision was determined by using the three different specimens containing different concentrations of antibody in 3 different lots of test devices. Again negative and positive results were correctly identified 100% of the time.

REFERENCES

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2. Che Xiaoyan, Hao Wei, Qiu Liwen, Pan Yuxian, Liao Zhiyong, Xu Hua, Chen Jinjun, Hou Jinlin, Patrick CY Woo, Susann KP Lau, Kwok Yung Yuen, Huang Zhen. Antibody response of patients with severe acute respiratory syndrome (SARS) to nucleocapsid antigen of SARS-associated coronavirus. [J]. Journal of First Military Medical University, 2003(07): 637-639.

SYMBOL

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Caution		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

CE

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