RAPID 2019-NCOV IGG/IGM COMBO TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF IGG AND IGM ANTIBODIES TO
2019 NOVEL CORONAVIRUS IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD

Catalog Number: 1N38C2

For In Vitro Diagnostic Use Only

INTENDED USE

Rapid 2019-nCoV IgG/IgM Combo Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of IgG and IgM antibodies to 2019 novel coronavirus (2019-nCoV, SARS-CoV-2) in human serum, plasma, or whole blood. Rapid 2019-nCoV IgG/IgM Combo Test Card is a supplement detection for COVID-19 suspected infected patients besides nucleic acid test, which could greatly raise the accuracy of the detection for COVID-19.

SUMMARY

Corona Virus Disease 2019 (COVID-19) is an acute infectious disease caused by 2019 novel coronavirus (SARS-CoV-2). The incubation period of the disease is infectious and ranges from 1-14 days (mostly 3-7 days). Asymptomatic infections may also be the source of infection. Respiratory droplets and contact are the main routes of transmission. The initial symptoms of the patients include fever, fatigue and coughing, which gradually develops into dyspnea and other serious manifestations. Most of the patients have a good prognosis. Some of the severe cases may have acute respiratory distress syndrome or septic shock, or even death. At present, there is no specific treatment for the disease.

There are several days of incubation period after infection with 2019-nCoV. IgM antibodies can be detected soon after the incubation period and remain for a short time. IgM positive in blood samples can be an indicator of acute infection. IgG antibodies appear after a few days of incubation period and remain for a long time. IgG positive in blood samples can be an indicator of present or previous infection.

PRINCIPLE

Rapid 2019-nCoV IgG/IgM Combo Test Card utilizes the principle of immuno-chromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgM line in the test window is closer to the sample well followed by IgG line. As the test sample flows through the membrane within the test device, the colored 2019-nCoV recombinant antigen-colloidal gold conjugate forms complexes with specific antibodies (IgM and/or IgG) to 2019 novel coronavirus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test is performed properly, regardless of the presence or absence of anti-2019 novel coronavirus antibodies in the specimen.

MATERIALS PROVIDED

1. Rapid 2019-nCoV IgG/IgM Combo Test Card
2. Sample buffer
3. 2 µL capillary pipet
4. Instructions for Use

MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or timer, safety lancets, alcohol prep-pad, specimen collection container, centrifuge, biohazard waste container. disposable gloves, disinfectant.

STORAGE

1. Store the test device at 4 to 30°C in the original sealed pouch. Do Not Freeze.
2. The expiration date indicated on the pouch was established under these storage conditions.
3. The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately. Do not reuse the device.

PRECAUTIONS

1. For **professional *in vitro*** diagnostic use only.
2. Do not use the product beyond the expiration date.
3. Do not use the product if the pouch is damaged or the seal is broken.
4. Handle all specimens as potentially infectious.
5. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material. When the assay procedure is completed, dispose specimens after autoclaving at 121° C for at least 20 min or treating with 0.5% Sodium Hypochlorite for 1-2 hours.

SPECIMEN COLLECTION AND PREPARATION

1. The serum, plasma or whole blood specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
3. The test works best on fresh whole blood / serum / plasma samples. If testing cannot be performed immediately, serum / plasma may be stored at 2-8ºC up to 3 days in case of delay in testing. For long-term storage, serum / plasma specimens can be frozen at -20ºC for 3 months or -70ºC for longer period. Avoid repeated freezing/thawing cycles.
4. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

PROCEDURE

1	Bring the kit components to room temperature before testing.
2	Open the pouch and remove the Card. Once opened, the test card must be used immediately.
3	Label the test card with patient identity.

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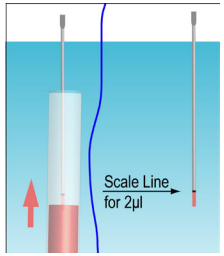

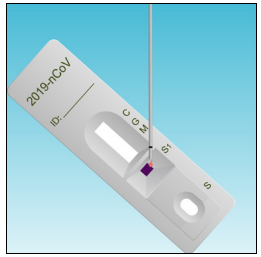

Withdraw the blood specimen with the capillary pipet provided, gently squeeze out the extra specimen to leave 2 µL in the pipet as marked with the scale line. Apply 2 µL of blood specimen to the “S1” area as marked.

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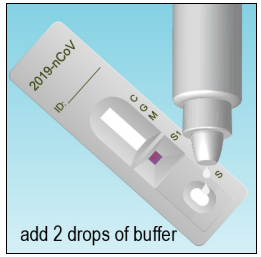

Add 2 drops of sample buffer (approximately 80-100 µL) to well marked as “**S**”.

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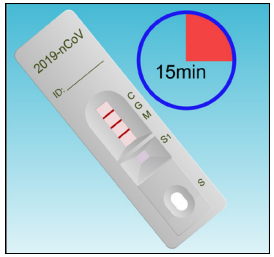

Read the result at 15 minutes. A strong positive sample may show result earlier.

Note: Results after 20 minutes may not be accurate.

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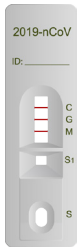
INTERPRETATION OF RESULTS

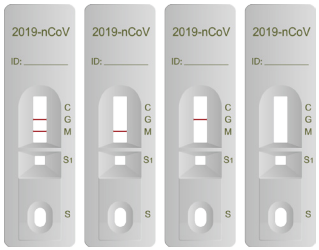
POSITIVE

		
Both IgG/IgM Positive	**IgM Positive** **IgG Negative**	**IgM Negative** **IgG Positive**
Control line and both test lines appear. It indicates the possibility of acute secondary infection.	Both control line and the second test line (the lower test line which is closer to the sample well) appear. It indicates the possibility of primary infection.	Both control line and the second test line (the higher test line) appear. It indicates the possibility of secondary infection or past infection.

NEGATIVE

	Only control line appears.

INVALID

	The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

PERFORMANCE CHARACTERISTICS:

Accuracy
A total of 74 specimens from confirmed patients were tested, the results showed that 65 specimens were IgM positive and/or IgG positive, and the clinical sensitivity was 87.8%. A total of 305 specimens from healthy persons were tested, the results showed that 302 specimens were both IgM and IgG negative, 1 specimen was IgM positive, 2 specimens were IgG positive, and the clinical specificity was 99.0%. The accuracy was 96.8%.

Assay Specificity

1. Other infectious diseases
Rapid 2019-nCoV IgG/IgM Combo Test has tested samples that were infected by the following diseases: Influenza A Virus, Influenza B Virus, Adenovirus, Rotavirus and Mycoplasma Pneumoniae. All the samples showed no effect on the specificity of the assay.

2. Blood compounds
Rapid 2019-nCoV IgG/IgM Combo Test has tested samples with high Rheumatoid Factor (RF), Bilirubin, Triglyceride and Hemoglobin. The results showed that these compounds had no effect on the specificity of the assay up to the listed concentration.

Rheumatoid Factor	80 IU/mL
Bilirubin	342 μmol/L
Triglyceride	37 mmol/L
Hemoglobin	10 mg/mL

3. Common drugs
Rapid 2019-nCoV IgG/IgM Combo Test has tested samples with common drugs. The results showed that these drugs had no affect on the specificity of the assay.
Histamine Hydrochloride, Interferon-α, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin.

LIMITATIONS

1. The test is limited to the qualitative detection of anti-2019-nCoV antibody levels in serum, plasma, or whole blood specimen. The exact concentration of anti-2019-nCoV antibody cannot be determined by this assay.
2. Although the test is very accurate in detecting anti-2019-nCoV antibody, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. In the early stage of infection, if IgM and IgG antibodies are not produced or the titer is very low, false negative results will occur. It is suggested that patients should collect samples again after 7-14 days, and test at the same time with the last collected samples to confirm whether there is serologically positive transfer or significant increase in titer. In the later stage of infection, IgM titer will decrease or even be negative, while IgG will continue to increase.

IVD 4°C 30°C CE

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