QUICK PROFILE™ 2019-nCoV IgG/IgM Test Card

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

REF QP-COVID19

For In Vitro Diagnostic Use Only

INTENDED USE

QuickProfile™ 2019-nCoV IgG/IgM 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 the 2019 novel coronavirus (2019-nCoV, SARS-CoV-2) in human serum, plasma, or whole blood. QuickProfile™ 2019-nCoV IgG/IgM Test Card is a supplemental rapid screening tool for symptomatic or asymptomatic carriers of the virus.

SUMMARY

Coronavirus Disease 2019 (COVID-19) is an acute infectious disease caused by the 2019 novel coronavirus (SARS-CoV-2). The incubation period of the disease is 1-14 days, usually 3-7 days. The incubation period is infectious. Asymptomatic carriers may also be sources of infection. Respiratory droplets and contact are the main routes of transmission. The initial symptoms of the patients are fever, fatigue and cough, and gradually developed dyspnea and other serious manifestations. Most of the patients have a good prognosis, but some of the severe cases may have acute respiratory distress syndrome, septic shock, or even death. At present, there is no specific treatment for the disease.

There are several days of incubation period after being infected by 2019-nCoV. IgM antibodies can be detected soon after incubation period and remain for a short time. IgM positive blood samples can indicate acute infection. IgG antibodies appear after few days of incubation period and remain for a long time. IgG positive blood samples can indicate current or previous infection.

PRINCIPLE

QuickProfile™ 2019-nCoV IgG/IgM Combo Test Card utilizes the principle of Immunochromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane 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 than the IgG line. As the test sample flows through the membrane within the test device, the colored–2019-nCoV antigen-colloidal gold conjugate forms complex with specific antibodies (IgM and/or IgG) of the 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 a positive test result. 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 has performed properly, regardless of the presence or absence of anti-2019 novel coronavirus antibodies in the specimen.

MATERIALS PROVIDED

1. QuickProfile™ 2019-nCoV IgG/IgM 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 30ºC in the original sealed pouch. Do Not Freeze.
2. The expiration date indicated on the pouch was based on 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 laboratory procedure and biosafety guidelines for the handling and disposal of potentially infectious material. When the assay procedure is completed, dispose specimens after autoclaving at 121º 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. Repeated freezing and thawing of the specimen should be avoided.
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 sample identification (ID).

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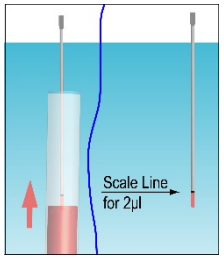

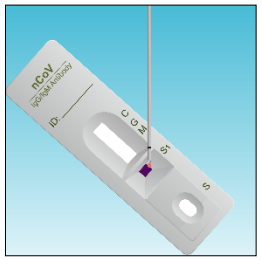

Withdraw the blood specimen with the capillary pipet provided, and gently squeeze out the extra specimen to leave 2µL in the pipet as marked with the scale line. Apply 2µL of blood specimen to the "S1" area as marked.

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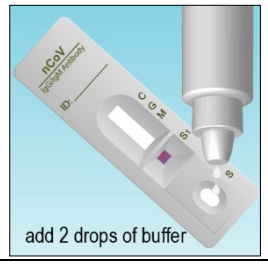
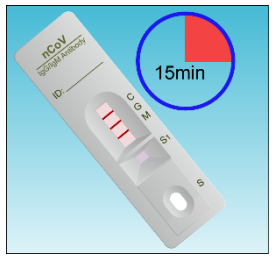
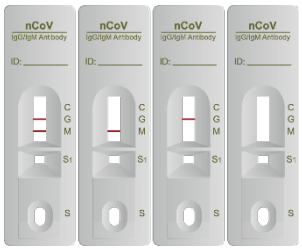
	
Add 2 drops of sample buffer (approximately 80-100µL) to well marked as "**S**".	Read the result at 15 minutes. A strong positive sample may show result earlier. ***Note: Results after 20 minutes may not be accurate.***

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 the 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, indicating a clinical sensitivity of 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, and 2 specimens were IgG positive, indicating a clinical specificity of 99.0%. The accuracy was 96.8%.

ASSAY SPECIFICITY

1. Other infectious diseases

QuickProfile™ 2019-nCoV IgG/IgM Test Card 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 assay.

2. Blood compounds

QuickProfile™ 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

QuickProfile™ 2019-nCoV IgG/IgM Combo Test has tested samples with common drugs. The results showed that these drugs had no effect 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 recommended that patients should collect samples again after 7-14 days, and test both the previously collected sample and the latest sample at the same time and compare the results to confirm whether there is serological positive conversion 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.

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