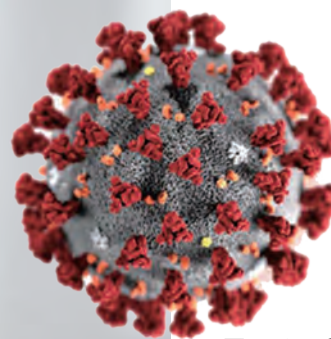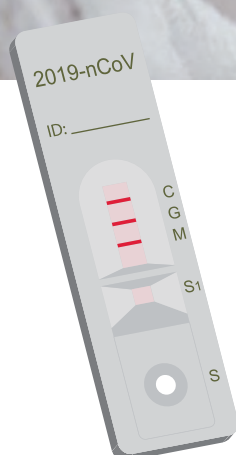# COVID-19
QuickProfile™ 2019-nCoV
IgG/IgM Test Card

POCT
CE Marked
Made in the USA

THE DISEASE
Coronavirus Disease 2019 (COVID-19) is an acute infectious disease caused by the 2019 novel coronavirus (SARS-CoV-2).
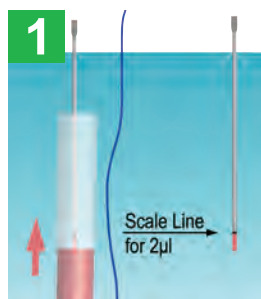
THE INCUBATION PHASE & SYMPTOMS
COVID-19 signs and symptoms may appear any time from 2 - 14 days after exposure to the virus. The incubation period is infectious. Asymptomatic carriers may also be sources of infection. Respiratory droplets and contact are the main routes of transmission. The initial symptoms of the patients are fever, fatigue, cough, and gradually developed dyspnea and other serious manifestations. Most of the patients have 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.

THE ANTIBODY TEST
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.
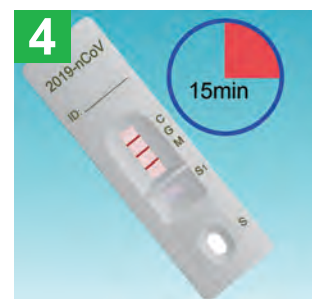
1 Collect and prepare the sample: Whole blood, serum or plasma.

2 Using the capilary pipet, transfer 2µLof sample to the area marked as "S1".

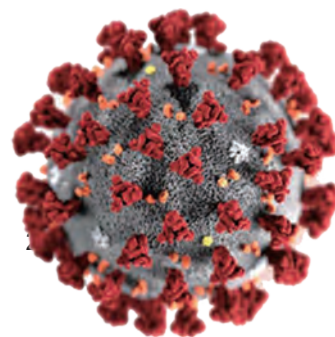**3** Add 2 drops of sample buffer (80-100µL) to well marked as "S".

4 Read the result at 15 minutes. A strong positive sample may show result earlier.
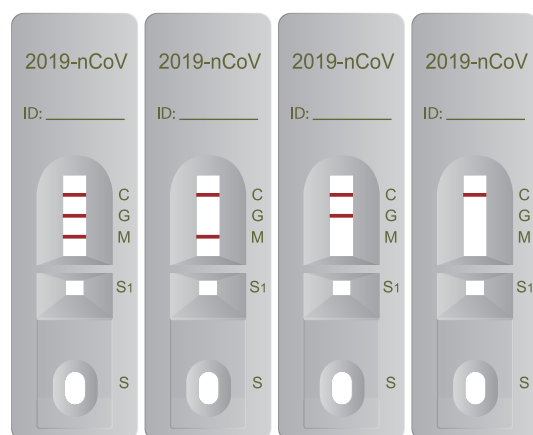
LumiQuick
DIAGNOSTICS, INC.

2946 Scott Blvd. Santa Clara, CA - USA - 95054
Tel.: +1(408)855-0061 - Fax: +1(408)855-0063
www.lumiquick.com   -   info@lumiquick.com

QuickProfile™ 2019-nCoV
IgG/IgM Test Card   **COVID-19**
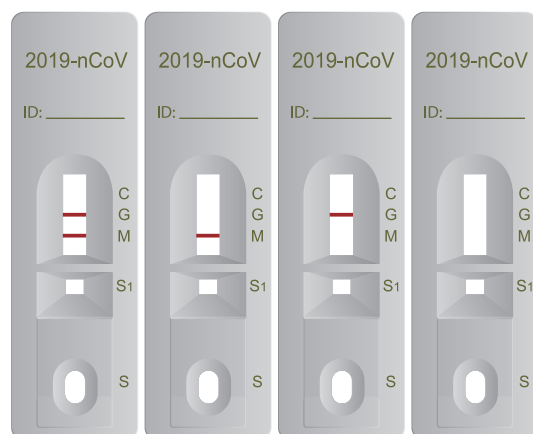
RESULTS INTERPRETATION

IgG/IgM Positive   **IgM Positive IgG Negative**   **IgM Negative IgG Positive**   **Negative**

Invalid

IgG/IgM RESPONSE TIME-LINE

Although several studies are still ongoing, SARS-CoV-2 antibodies may not be detectable before 3 days after onset of symptoms (or at least 7-10 days after infection with the virus). When IgM antibodies are present, they can indicate that a patient has an active or recent infection with SARS-CoV-2.

Patients tested early after infection may not have detectable IgM antibody despite active infection. IgG antibodies develop later following infection, and generally do not begin to appear until 7-10 days after infection. When IgG antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious, especially if detected with IgM antibodies. It is unknown how long IgM or IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

CLINICAL STUDIES

REFERENCE	QuickProfile™ 2019-nCoV IgG/IgM Test Card	
TEST RESULTS	**POSITIVE**	**NEGATIVE**
POSITIVE SAMPLE	65	3
NEGATIVE SAMPLE	9	302
TOTAL SAMPLES	74	305
ACCURACY	87.8%	99.0%

Ordering Information

Catalog No	Description	Qty of test per Kit
71108B	QuickProfile™ 2019-nCoV IgG/IgM Test Card	25 tests

Our antibody serology test is being offered to the USA market under the policy outlined in Section IV.D of the Policy for Diagnostic Tests for COVID-19. For details about the limitations, please consult the IFU.

LumiQuick DIAGNOSTICS, INC.

2946 Scott Blvd. Santa Clara, CA - USA - 95054
Tel.: +1(408)855-0061 - Fax: +1(408)855-0063
www.lumiquick.com   -   info@lumiquick.com