

COVID-19 SARS-CoV-2 Testing SOLUTIONS

QuickProfile™
2019-nCoV IgG/IgM Test
COVID-19 Antigen Test
2019-nCoV IgG EIA Kit
2019-nCoV IgM EIA Kit

Quicknostics®
COVID-19 RT PCR

CE Marked
Manufactured in the USA

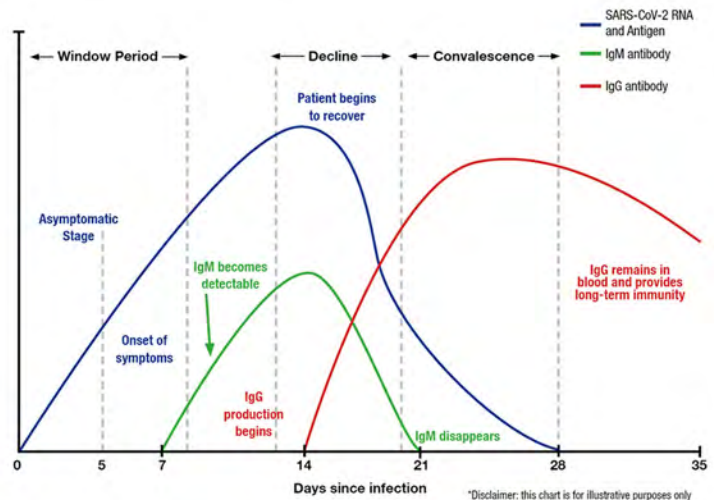
THE DISEASE

Coronavirus Disease 2019 (COVID-19) is an acute infectious disease caused by the 2019 novel coronavirus (SARS-CoV-2).

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.

Levels of SARS-CoV-2 RNA , Antigen and IgM & IgG after infection



IgG or IgM antibodies to SARS-CoV-2 will remain present in the body after infection. Studies have yet to confirm if they provide immunity to the infection.

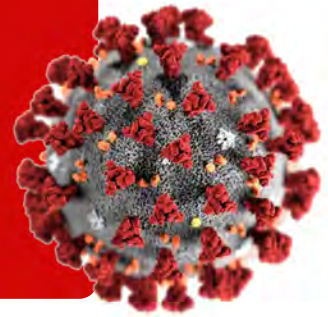


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COVID-19
SARS-CoV-2

Testing
SOLUTIONS

SEROLOGY TESTING



QuickProfile™ 2019-nCoV IgG/IgM Test Card

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Made in the USA

QuickProfile™ 2019-nCoV IgG/IgM Test Card is a lateral flow immunoassay designed for the rapid qualitative detection and differentiation of IgG and IgM antibodies to the 2019 novel coronavirus (SARS-CoV-2)



Material Provided

QuickProfile™ 2019-nCoV IgG/IgM Test Card
Sample buffer
2 µL capillary pipet
Instructions for Use

Characteristics and Performance

Attribute	Description
Sample	Serum, plasma, whole blood (Venous or finger prick)
Target	IgG and IgM antibodies to SARS-CoV-2
Sensitivity*	99.16% (95% CI: 98%-100%)
Specificity	97.05% (95% CI: 95.2%-99%)
Test time	15 min
Shelf Life	18 months
Storage	Between 4°C and 30°C

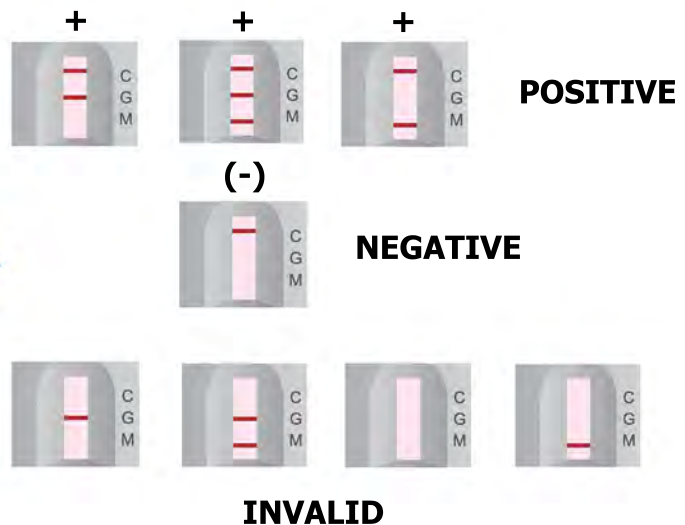
* From 238 samples, one week after symptoms onset

PROCEDURE

(Follow instruction on the IFU)



RESULT INTERPRETATION

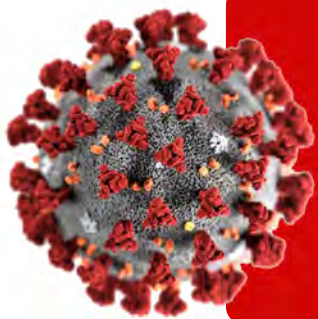


Ordering Information:

71108B -QuickProfile™ 2019-nCoV IgG/IgM Test Card 25 test/kit



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SARS-CoV-2**

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DIAGNOSTIC TESTING

QuickProfile™ COVID-19 Antigen Test

QuickProfile™ COVID-19 Antigen Test is a rapid in vitro immunochromatographic assay for the qualitative detection of SARS-CoV-2 virus antigen present in human nasopharynx.



COLLECTION:

Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection.

DO NOT USE TRANSPORT MEDIA

PROCEDURE

(Follow instruction in the IFU)



Materials Provided

- QuickProfile™ COVID-19 Antigen Test Strip
- Extraction buffer
- Sample extraction tube
- NP Swab
- Instructions for Use

RESULT INTERPRETATION



Characteristics and Performance

Analytical Sensitivity

Item	Limit of Detection
SARS-CoV-2, USA-WA 1/2020	3.80 x 10 ² TCID ₅₀ /mL
Recombinant N Protein 1	< 1 ng/mL
Recombinant N Protein 2	< 1 ng/mL
Recombinant N Protein 3	< 1 ng/mL

Ordering Information: 71110B QuickProfile™ COVID-19 Antigen Test 20 tests/kit



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