

BIOOLIDICS 2019-nCoV IgG/IgM ANTIBODY DETECTION KIT

PRODUCT CODE: CBB-F015016-B1



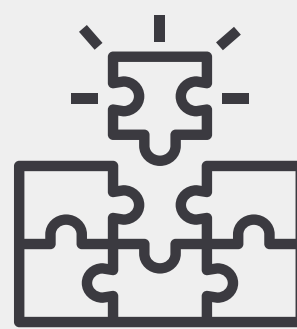
FAST

Rapid-results in 10 minutes, including symptomatic and asymptomatic recent or prior infections



INFORMATIVE

Validated with venous whole blood / serum / plasma²
Simultaneous evaluation of IgM and IgG antibodies to SARS-CoV-2



COMPLEMENTARY

Complements tests such as PCR¹, used in detecting recent or prior infections



APPROVALS



Product has received Provisional Authorisation from

- [Health Sciences Authority Singapore](#)
- [Ministry of Health Indonesia](#)
- [Food and Drug Administration Philippines](#)

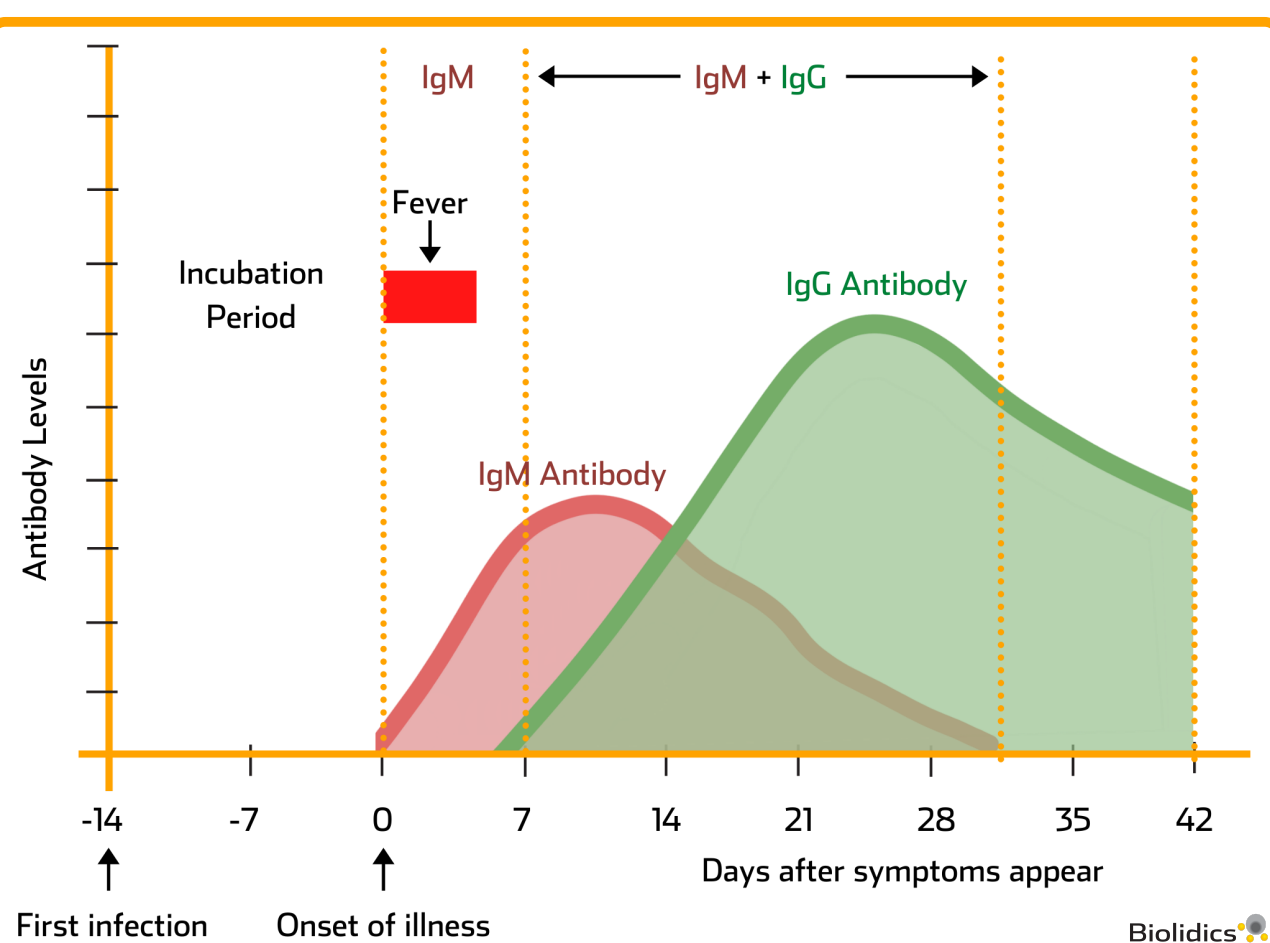


Fig. 1: Representative IgG and IgM antibody response to a viral infection overtime³

- Following a viral infection, IgM antibodies rise first, followed by IgG antibodies, that can last for weeks and more after an infection. The Biolidics' test detects presence of IgM and IgG antibodies to SARS-CoV-2.
- Positive result: IgG+ and/or IgM+ test lines indicate a recent or prior SARS-CoV-2 infection.
- Negative result: IgG- and IgM- test lines indicate antibodies to SARS-CoV-2 were not detected*.

*IgG/IgM antibodies for SARS-CoV-2 was undetected or antibody levels below limit of detection. The results from this test should not be used as the sole basis to diagnose, exclude SARS-CoV-2 infection and/or to inform infection status. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplemental testing (e.g. RT-PCR).

PERFORMANCE

SENSITIVITY

91.54%
(95% CI: 86.87% - 94.65%)

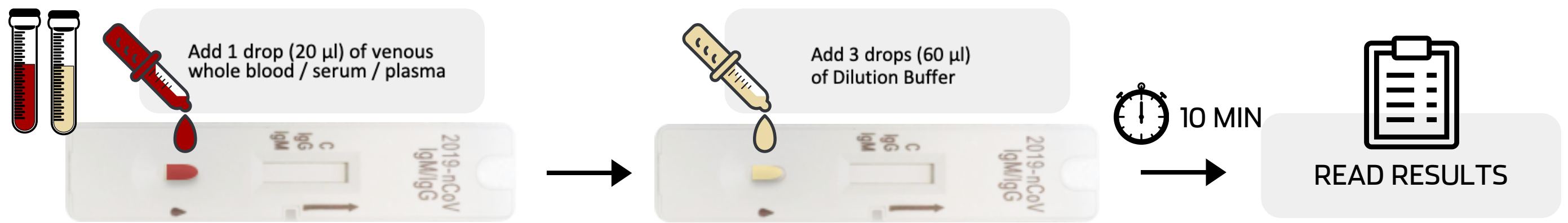
SPECIFICITY

97.02%
(95% CI: 94.74 % - 98.33%)

CONFORMITY⁴

95.09%
(95% CI: 92.99% - 96.58%)

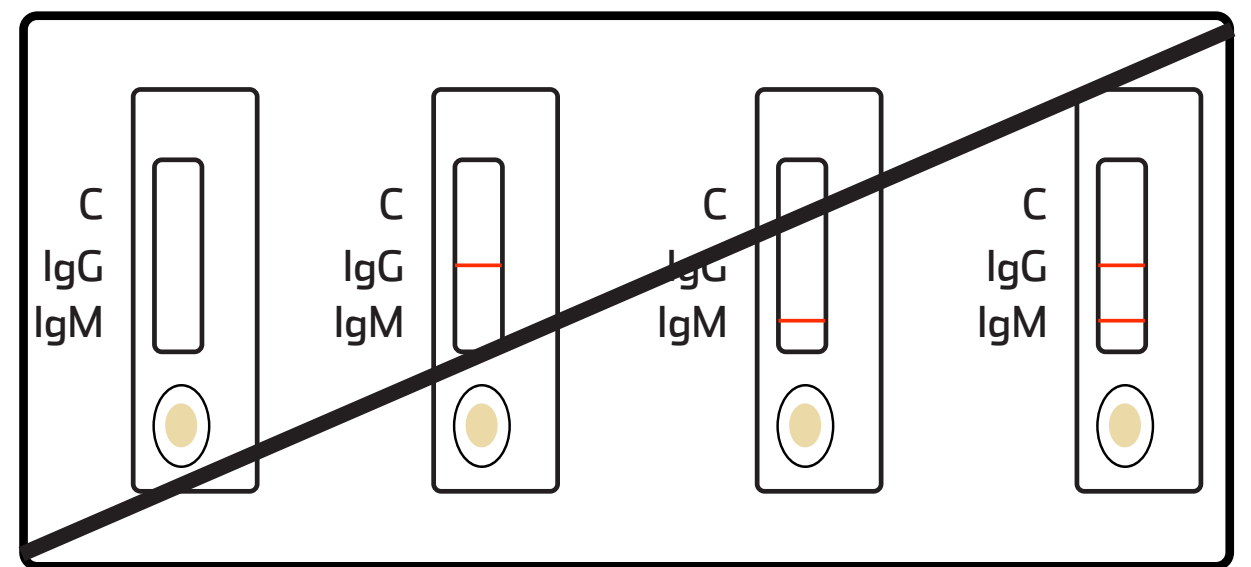
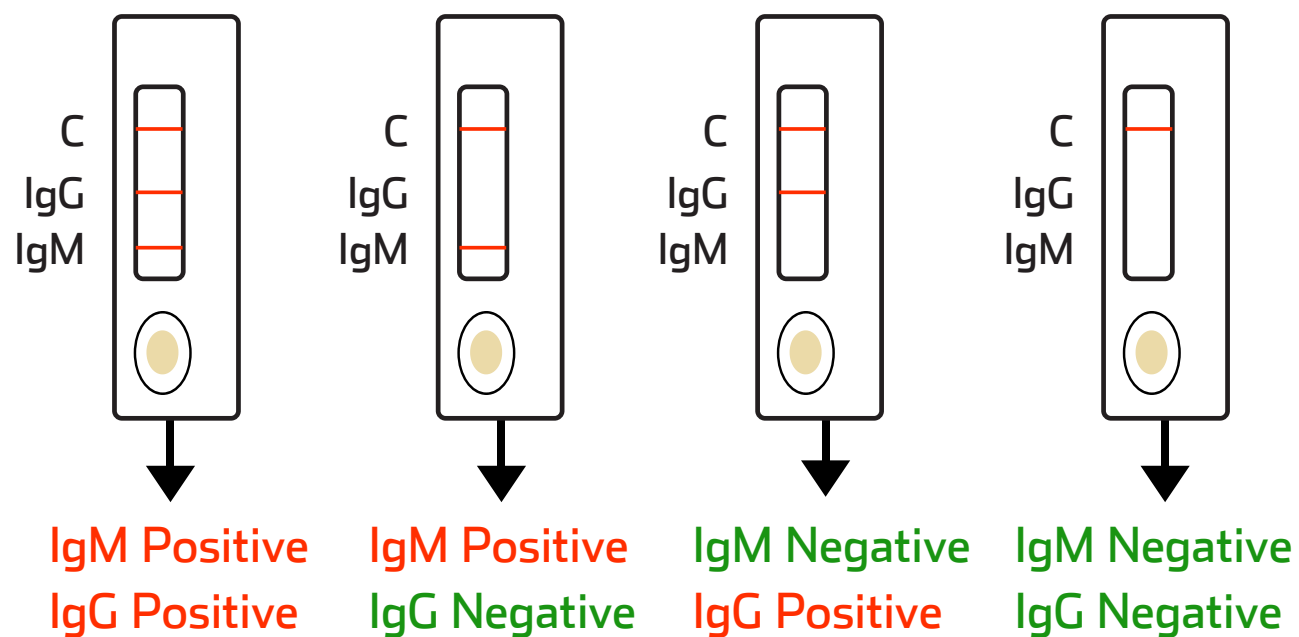
WORK FLOW



Limitations

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out other infections in these individuals.
- Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection.
- This test is intended for the detection of IgM and IgG antibodies to SARS-CoV-2 only and not for other viruses or pathogens.

TEST INTERPRETATION



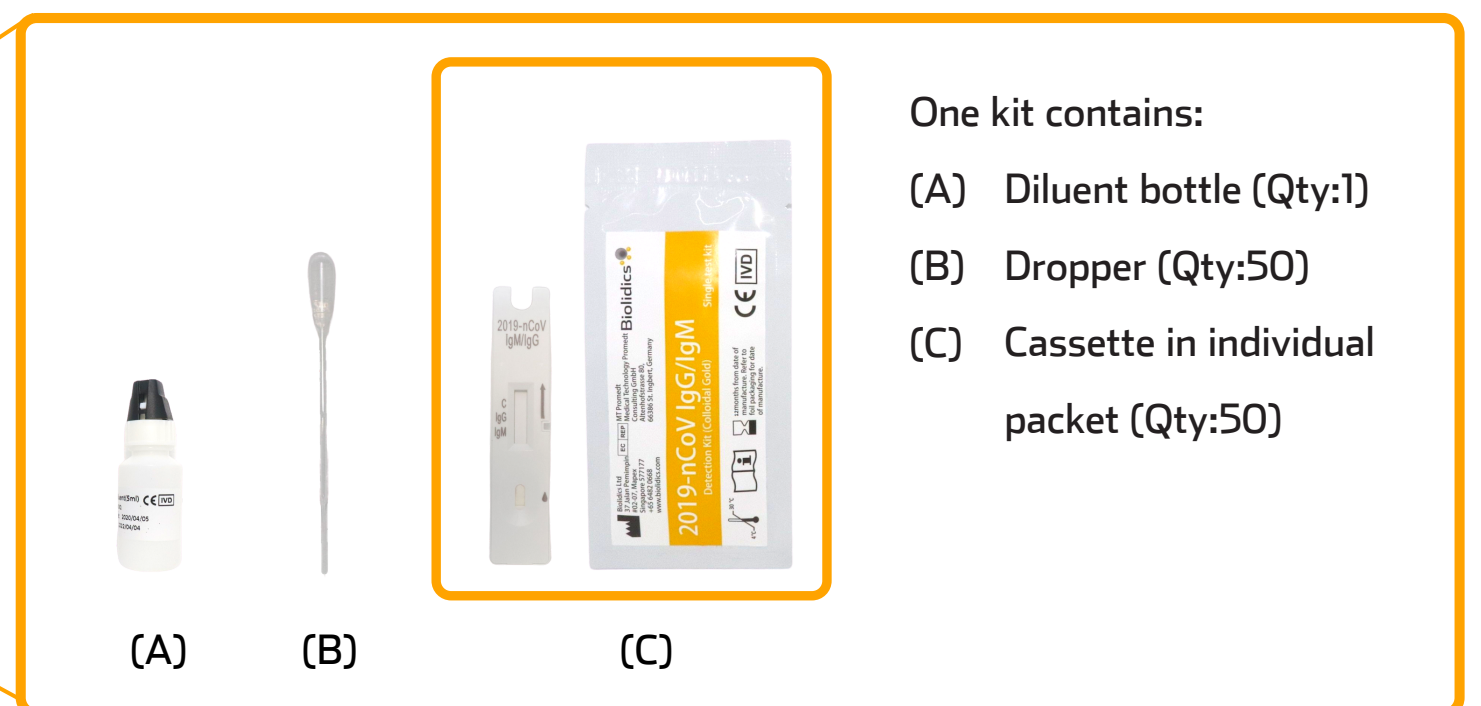
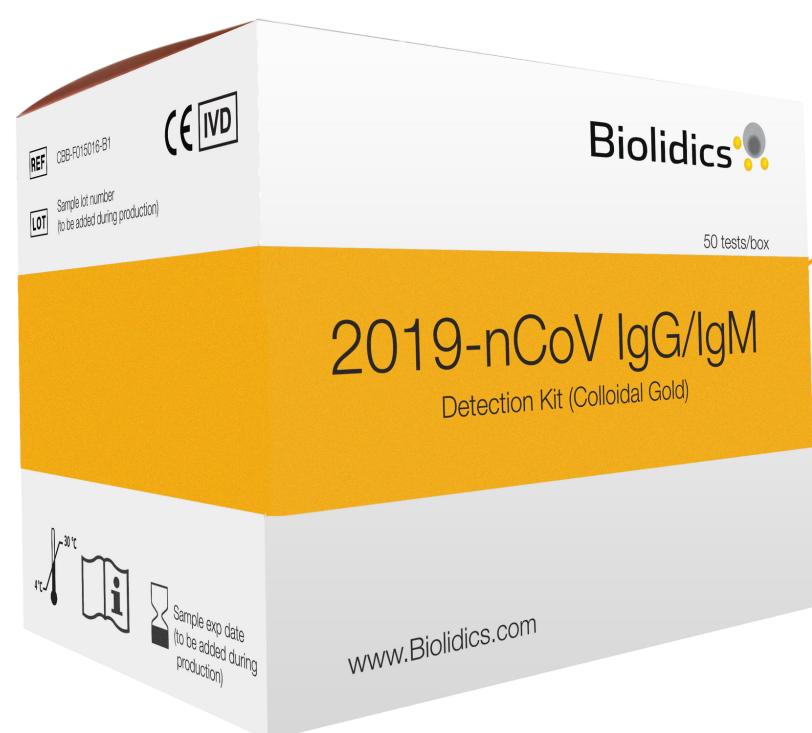
INVALID RESULTS

May need to undergo re-testing(C-band is absent)

SPECIFICATIONS

- Test time: 10 MIN
- Storage: 4°C - 30°
- Sample Type: Venous whole blood / Serum / Plasma
- Format: Cassette
- Shelf Life: 18 Months

Results*	Interpretation**
IgM Positive , IgG Positive	Suspected recent infection of SARS-Cov-2
IgM Positive , IgG Negative	Suspected recent infection of SARS-CoV-2
IgM Negative , IgG Positive	Patient suspected to have past infection (non-conclusive)
IgM Negative , IgG Negative	Antibody for SARS-CoV-2 Virus undetected OR low IgG/IgM level below limit of detection



ORDER INFORMATION

REQUEST FOR QUOTATION OR ENQUIRE ABOUT THIS PRODUCT

VISIT US AT: [HTTPS://WWW.BIOLIDICS.COM/REQUEST-FOR-A-QUOTATION](https://www.biolidics.com/request-for-a-quotation)

NAME: 2019-NCOV IGG / IGM ANTIBODY DETECTION KIT (50 TESTS/KIT)

CATALOGUE NUMBER: CBB-F015016-B1

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Footnote

¹ According to the Novel Coronavirus Pneumonia Diagnosis and Treatment Plan (7th Edition) published by general office of national health committee on 4th March 2020.

² Not recommended for finger prick test. Validations were performed on venous whole blood, serum and plasma.

³ Gwinnettclinic.com. 2020. COVID-19 Testing. [online] Available at: <<https://www.gwinnettclinic.com/covidtest>> [Accessed 10 May 2020].

⁴ Venous whole blood and serum specimens were tested using the 2019-nCoV IgG/IgM Detection Kit and results were compared to clinical diagnosis.