2019-nCoV IgG/IgM Antibody Detection Kit (Colloidal Gold)

Biolidics

Fast

Rapid-results in 10 minutes and includes antibody detection of silent and asymptomatic recent or prior infections

Complementary

Complements tests such as PCR[1], used in detecting recent or prior infections

Informative

Compatible with venous whole blood / serum / plasma[2]

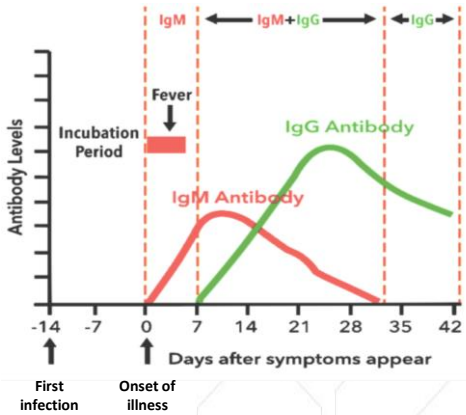
Simultaneous evaluation of IgM and IgG antibodies to SARS-CoV-2

[3]Submission No: PEUA200200

HSA 600:36/01

European CE Marking (DE/CA70/40838-154686)

FDA Food and Drug Administration PHILIPPINES



- IgM Antibodies are usually produced in the early/mid stage of an initial infection, whereas, the IgG Antibodies are present in the mid/late stage of infection onwards
- **Positive result** (IgG and/or IgM+) indicates recent or prior SARS-CoV-2 infection.
- **Negative result** indicates no anti-SARS-CoV-2 antibodies detected or suspected in the early stage (within first few days) of a SARS-CoV-2 infection.

Clinical Performance

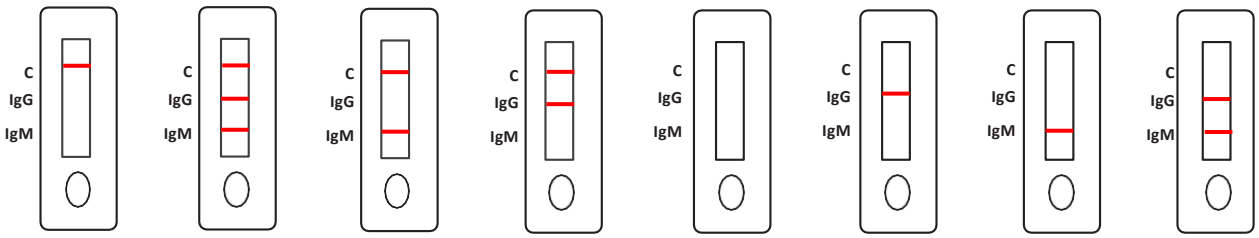
2019-nCoV IgG / IgM Antibody Detection Kit	Sensitivity	Specificity	Conformity[4]
	91.54% (95% CI: 86.87% - 94.65%)	**97.02%** (95% CI: 94.74 % - 98.33%)	**95.09%** (95% CI: 92.99% - 96.58%)

Workflow

Limitations

- This test has not been reviewed by the FDA.
- 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 has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens

Test Results Interpretation

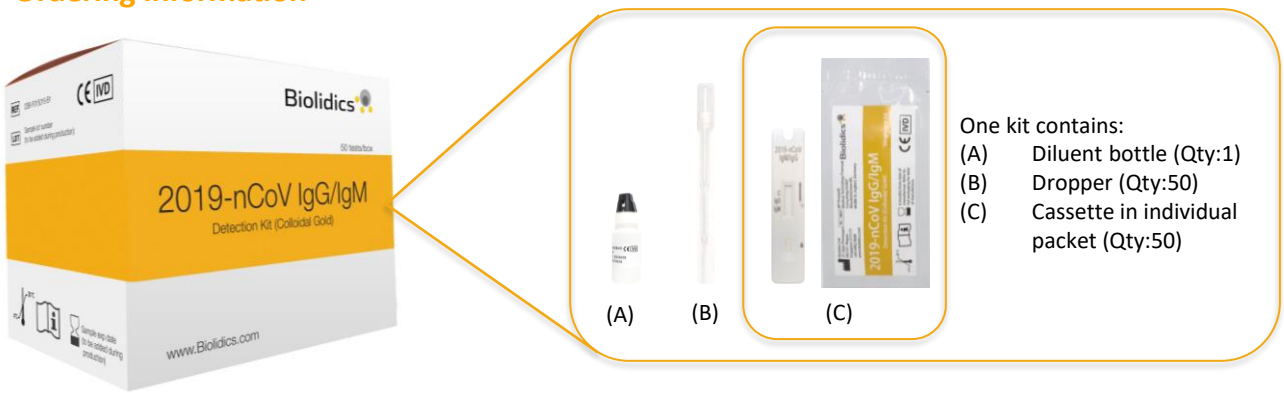


Results*	Interpretation**
IgM positive, IgG positive	Suspected recent infection of SARS-CoV-2
IgM positive, IgG negative	Suspected recent infection of SARS-CoV-2
IgM negative, IgG positive	Patient suspected to have past infection (non-conclusive)
IgM negative, IgG negative	Antibody for SARS-CoV-2 Virus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

* Results should only be evaluated if the C band is present. If it is absent, the test must not be evaluated and has to be discarded. A retest of the sample will be required.

** This test is intended to be an aid in identifying patients with an adaptive immune response to SARS-CoV-2 and positive IgG and/or IgM results indicates a recent or prior infection. This test is not intended for to diagnose acute SARS-CoV-2 infection and direct testing should be performed for diagnosis.

Ordering Information



Product code	Product name	Sample type	Storage condition	Format
CBB-F015016-B1	2019-nCoV IgG / IgM Antibody Detection Kit	Venous whole blood / Serum / Plasma	4°C to 30°C	Cassette

Biolidics Limited (formerly known as Clearbridge Biomedics Pte Ltd)
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+65 6482 0668 sales@biolidics.com
https://www.biolidics.com/2019-ncov-igg-igm-antibody-detection-kit

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] Biolidics Ltd has notified the US FDA that the 2019-nCoV antibody detection kit test has been validated, and will be distributed under the US FDA Guidance document titled "FDA Policy for Diagnostic Tests for Coronovirus Disease-2019 during the Public Health Emergency (issue March 16, 2020)", as outlined in Section IV.D. An EUA request has been submitted (submission number; PEUA200200).

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