

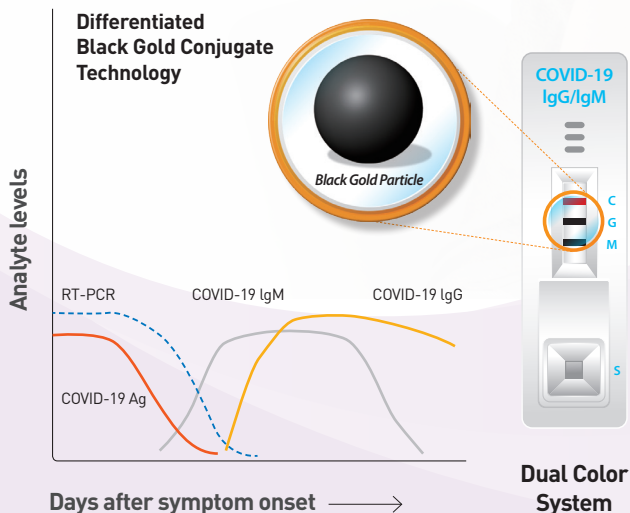
BIOCREDIT COVID-19 IgG / IgM Combo

SARS-CoV2 specific IgG and IgM antibody test

- » One-drop generates Two-results
- » Sensitivity (100%) and Specificity (97.3%) verified by clinical trial Institution
- » Rapid Test Time (10 ~ 15 min)
- » User friendly Dual Color System (Control line: Red, Test line for IgG/IgM : Black)
- » Simple detection of SARS-CoV2 specific IgG and IgM antibody

Core Technology Black Gold Particle

Performance Characteristics



Sensitivity and Specificity: BIOCREDIT COVID-19 IgG/IgM Combo has been evaluated with clinical specimens from 7 days after symptoms confirmed by RT-PCR. The results are summarized as below table

BIOCREDIT COVID-19 IgG/IgM Combo	RT-PCR		Sensitivity	Specificity
	Positive	Negative		
IgG	Positive	57	95.0% (57/60)	98.7% (148/150)
	Negative	3		
Total	60	150		
IgM	Positive	60	100.0% (60/60)	98.7% (148/150)
	Negative	0		
Total	60	150		

BIOCREDIT COVID-19 IgG/IgM Combo Total	RT-PCR		Sensitivity	Specificity
	Positive	Negative		
Positive	60	4	100.0% (60/60)	97.3% (146/150)
Negative	0	146		
Total	60	150		



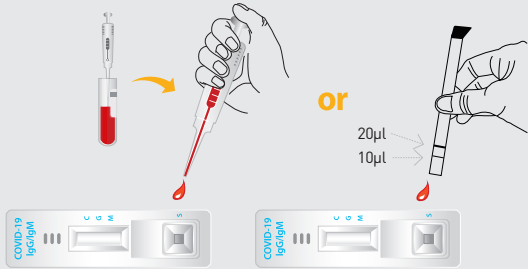
BIOCREDIT COVID-19 IgG/IgM Combo rapid test kit

Intended Use	For the qualitative detection of IgG and IgM antibody specific to SARS-CoV2
Package	25 Tests / kit
Storage	1~40°C (33.8~ 104°F)
Specimen Type	Serum, Plasma or Whole blood
Shelf life	24 months from manufacture date
Time to result	10~ 15 minutes

COVID-19 Rapid Diagnostic Test

PROCEDURE

Add 10 μ l (serum or plasma) or 20 μ l (whole blood) of specimen into the sample well (S) using provided capillary pipette or micropipette.



Add 3 drops of assay buffer into the sample well (S) of the device



Read the result within 10-15 minutes.



INTERPRETATION

NEGATIVE



One red line "C" within the result window.

POSITIVE



COVID-19 IgG Positive: Two bands ; black "G" test line and red "C" control line (C) within the test result window.



COVID-19 IgM Positive: Two bands ; black "M" test line and red "C" control line (C) within the test result window.



COVID-19 IgG & IgM Positive: Three bands ; black "G" and "M" test line, and red "C" control line (C) within the test result window

INVALID



No "C" line within the result window. It is recommended that the specimen be retested.