

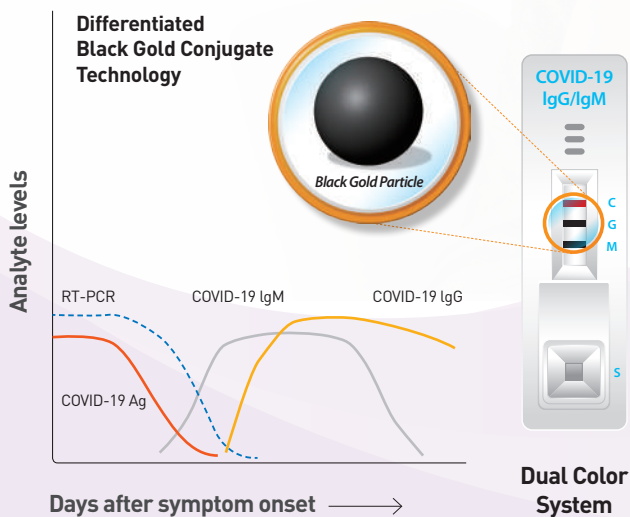
# BIOCREDIT COVID-19 IgG / IgM Combo

## SARS-CoV-2 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-CoV-2 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 confirmed by RT-PCR. The results are summarized as below table

BIOCREDIT COVID-19 IgG/IgM Combo	RT-PCR		Sensitivity	Specificity
	Positive	Negative		
IgM	Positive	52	100.0% (52/52)	98.7% (148/150)
	Negative	0		
<b>Total</b>	<b>52</b>	<b>150</b>		
IgG	Positive	49	94.2% (49/52)	98.7% (148/150)
	Negative	3		
<b>Total</b>	<b>52</b>	<b>150</b>		

BIOCREDIT COVID-19 IgG/IgM Combo Total	RT-PCR		Sensitivity	Specificity
	Positive	Negative		
Positive	52	4	100.0% (52/52)	97.3% (146/150)
Negative	0	146		
<b>Total</b>	<b>52</b>	<b>150</b>		



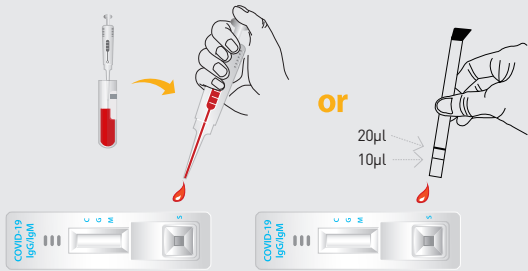
## BIOCREDIT COVID-19 IgG/IgM Combo rapid test kit

- Intended Use** For the qualitative detection of IgG and IgM antibody specific to SARS-CoV-2
- 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 $\mu$ l (serum or plasma) or 20 $\mu$ 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.