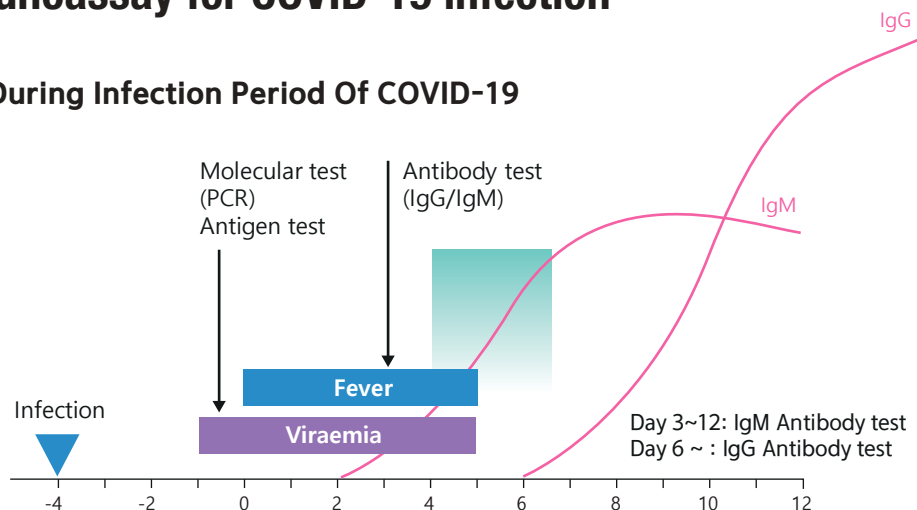


COVID-19 Quick Immunoassay



GenBody COVID-19 IgM/IgG test Rapid immunoassay for COVID-19 infection

Test Methods During Infection Period Of COVID-19



The outbreak of the novel coronavirus (COVID-19) rapidly transmit all over China and lots of countries. Although molecular test (RT-PCR) has become the standard method for diagnosis of this disease, the method has many limitations. In addition, the high false negative rates were reported. There is an urgent need for an accurate and rapid testing method that quickly identify large number of infected patients and asymptomatic carriers to prevent virus transmission and assure timely treatment of patients.

GenBody COVID-19 IgM/IgG device is a chromatographic immunoassay kit for the rapid and differential detection of immunoglobulin M (IgM) and immunoglobulin G (IgG) against COVID-19 using serum, plasma and whole blood.

Comparison With Molecular Testing

	Molecular Testing (RT-PCR)	GenBody COVID-19 IgM/IgG Rapid Test
Principle	Nucleic acid test of COVID-19	Antibody (IgM & IgG) detection in the bloods
Accuracy in the fields	-China: 30 ~ 50% (Jungangilbo.2020.02.13) -Depending on the swab positioning of specimen and yield of gene extraction	-Before Day 5: very low -After Day 5: 50 ~ 81% for IgM, 81 ~ 100% for IgG
Test time	>6 hours	10 minutes
Test cost	Very expensive	Economic
Users	Skilled & trained	Normal
Specimen	Throat, anal, nasopharyngeal, sputum	Whole blood, serum, plasma
Test capacity	Limited	Possible to bulk testing
Adv/disadvantages	<ul style="list-style-type: none"> • Good accurate at early stage. • Difficult to detect at latent or asymptomatic period. • Appropriate for early stage with limited cases of patients 	<ul style="list-style-type: none"> • Possible to detect at latent or asymptomatic period. • Inaccurate at from Day 0 to Day 5 after infection • Appropriate for 5 day-after with bulk cases of patients

Diagnostic Accuracy of GenBody COVID-19 IgM/IgG

Parameters	Performance (Ongoing)	Comments
Analytical sensitivity	1.84 S/CO for IgM 1.57 S/CO for IgG	w. ELISA
Sensitivity	Day 3 after symptom: IgM- 30%, IgG- 0% After Day 7 from symptom: IgM- 80%, IgG- >95%	w. limited cases
Specificity	IgM 98% (118/120), IgG: 99% (119/120)	

Interpretation Method

Molecular test	Antibody test		Interpretation
	IgM	IgG	
Positive	Negative	Negative	Acute infection (D1 ~ D3)
Positive	Positive	Negative	Acute infection (D3 ~ D8)
Positive	Positive	Positive	Infected (D8 ~ D15)
Positive	Negative	Positive	Infected (>D15) or secondary infected
Negative	Positive	Negative	Early stage of infection. Need the additional molecular test
Negative	Positive	Positive	Infection (D8 ~ D15), Need the additional molecular test
Negative	Negative	Positive	Past infection or (If IgG negative change to IgG positive) infected
Negative	Negative	Negative	Not infected

Ordering Information

Cat no.	Product Name	Package	Box Size (mm)	Carton Size(mm)
COVI040	GenBody COVID-19 IgM/IgG	20 Tests/Kit	215x125x75	470x410x470

