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COVID-19 Quick Immunoassay

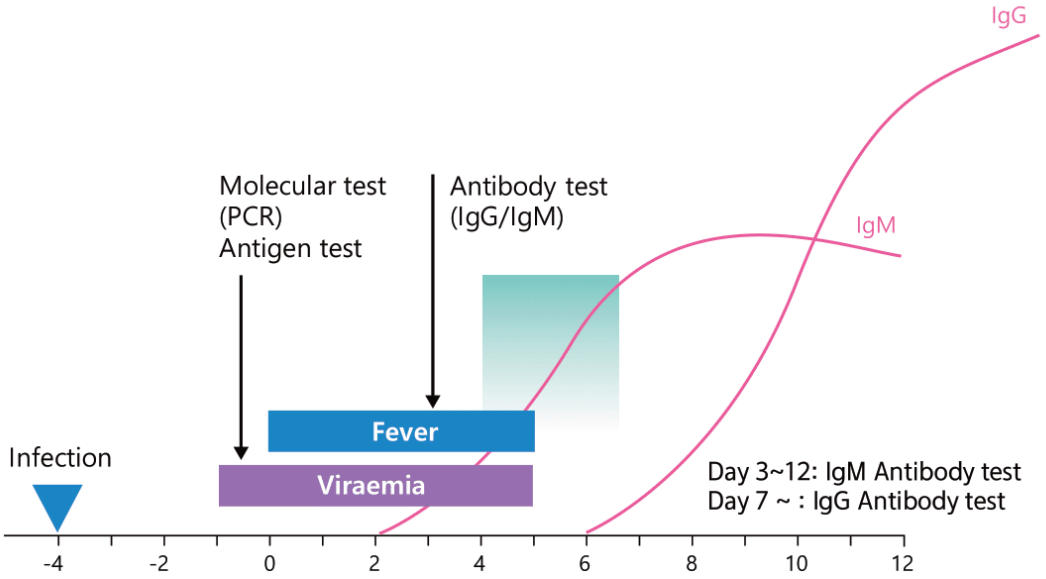
GenBody COVID-19 IgM/IgG

Rapid immunoassay for COVID-19 infection

GenBody Inc.
CHANGE AND INNOVATION

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 have many limitations. In addition, 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.

Test methods during infection period of COVID-19

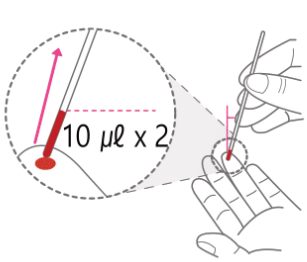


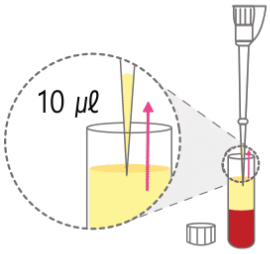
Comparison with molecular test

	Molecular test	GenBody COVID-19 IgM/IgG
Principle	Nucleic acid test of COVID-19	Antibody (IgM & IgG) detection in the bloods
Accuracy in the fields	- China: ~ 50% (Jungangilbo.2020.02.13) - Depending on the positive of specimen and yield of gene extraction	- Before Day 6: less than 50% - After Day 7: 50~81% for IgM, 81~95% for IgG (91% for IgM+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	• Good accurate at early stage. • Impossible to detect at latent or asymptomatic period. • Appropriate for early stage with limited cases of patients	• 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

(Ref. 2 / Ref. 5)

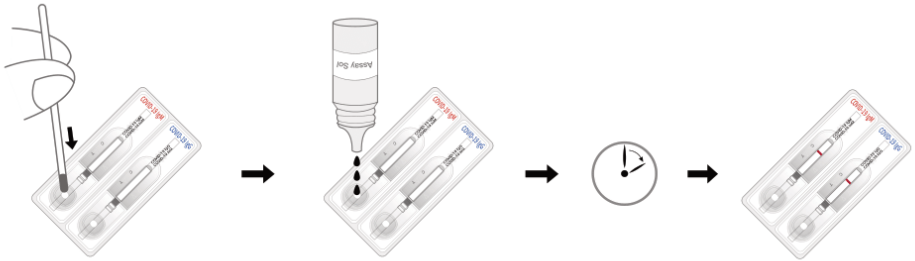
Test procedure of GenBody COVID-19 IgM/IgG





1 **Using capillary blood of finger**
With a capillary tube, collect the 10 (x 2) ㎕ of capillary blood up to the black line of the capillary tube.

2 **Using serum, plasma, or whole blood**
With a micropipette, collect the 10 ㎕ of serum, plasma or 20 ㎕ of whole blood.

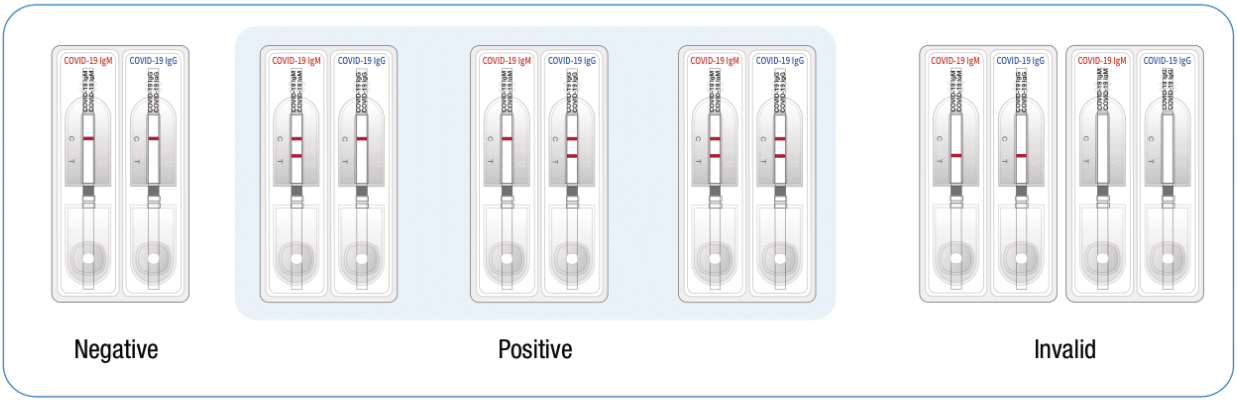


3 Add 10 ㎕ of serum/plasma or load 20 ㎕ of whole blood

4 Add 3 drops (~100 ㎕) of assay buffer

5 10 min

6 Reading



Negative

Positive

Invalid

Guideline of interpretation

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	Infected (D8 ~ D15), Need the additional molecular test
Negative	Negative	Positive	Passed infection or infected (IgG negative change to positive, or, 4 times increased intensity of IgG)
Negative	Negative	Negative	Not infected

Analytical sensitivity/cross-reactivity

- Detection limit (LoD): 1.84 s/CO for IgM and 1.57 s/CO for IgG.
- Not cross-reactive for RSV IgG positive, Influenza Ab positive, *Mycoplasma pneumoniae* Ab positive (IgG and IgM), Anti-HBs positive, HAV IgG positive, HCV Ab positive, HIV Ab positives (type 1 and type 2), *Treponema pallidum* positive, Dengue Ab positive (IgG and IgM), Zika Ab positive, Chikungunya IgG positive, Yellow fever IgG positive, West Nile Virus positive, Chagas positive, *Leishmania* positive, *Brucella* positive, *Toxoplasma gondii* positive, Rubella positive, Cytomegalovirus positive, Herpes simplex virus positive, Adenovirus IgM positive, *Leptospira* IgG positive, Japanese encephalitis virus Ab positive, *Salmonella typhi* Ab positive (IgG and IgM).
- May cross-react but not tested for SARS-CoV Ab, MERS-CoV Ab, and other conventional coronavirus such as HKU1, OC43, 229E, and NL63.

Interference

- Not interfered for human blood, hemoglobin, cholesterol, bilirubin, albumin, antiviral drugs, antibiotics, anti-inflammatory drugs, human chorionic gonadotropin (hCG), and mouse immunoglobulin.

Matrix equivalency

- Serum (25 samples), plasma (each of 25 samples by heparin, EDTA, and citrate), and whole blood (each of 25 samples by heparin, EDTA, and citrate) were not affected the reaction.

Prozone effect (Hook effect)

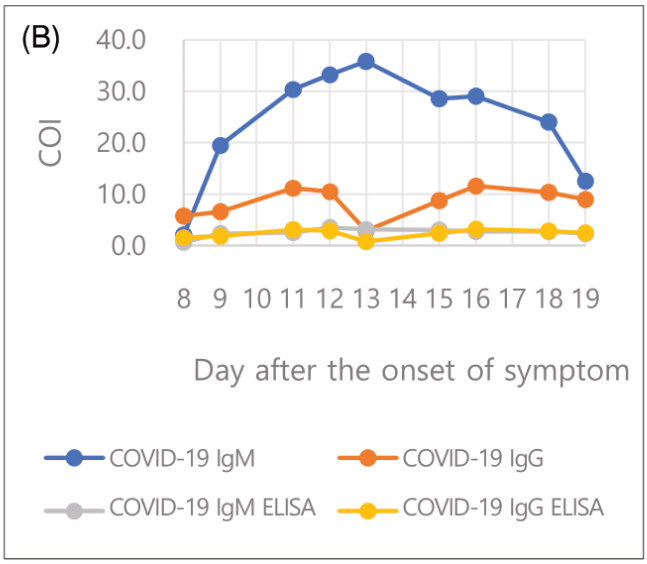
- No prozone effect at the titer of 9.0 s/CO for IgM and 9.5 s/CO for IgG

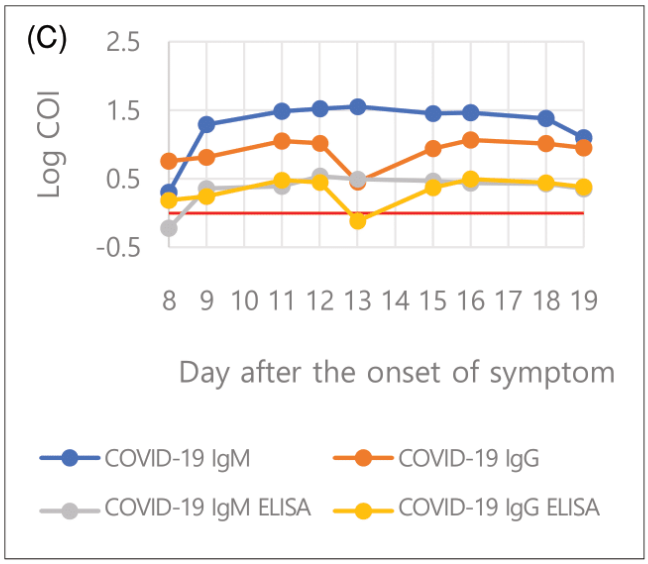
Seroconversion study with 2 patients

Patient	Onset of symptom	Symptom	Date of Sampling
ID-XXX11	Feb. 24, 2020	Nasal congestion	Mar. 03, 04, 06, 07, 08, 10, 11, 13, 14 – 9 samples
ID-XXX15	Mar. 01, 2020	Fever, cough	Mar. 11 (sampling 1, sampling 2, sampling 3), 12, 13, 14, 15, 16 (sampling 1, sampling 2), 17 (sampling 1, sampling 2, sampling 3), 19 – 12 samples

*Sampling at same day, the blooding was performed at different time.

Sample	2020-03-03		2020-03-04		2020-03-06		2020-03-07		2020-03-08		2020-03-10		2020-03-11		2020-03-13		2020-03-14	
result	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
confiscope Raw data	692,568	227,498	1,753,798	588,523	2,733,377	1,005,350	2,991,387	941,854	3,219,816	254,585	2,568,183	781,915	2,608,995	1,043,229	2,156,418	928,574	1,121,481	801,497
ELISA (s/CO)	2.31	0.68	2.29	1.76	2.47	3.02	3.44	2.82	3.13	0.76	2.86	2.34	2.73	2.73	3.12	2.67	2.28	2.27



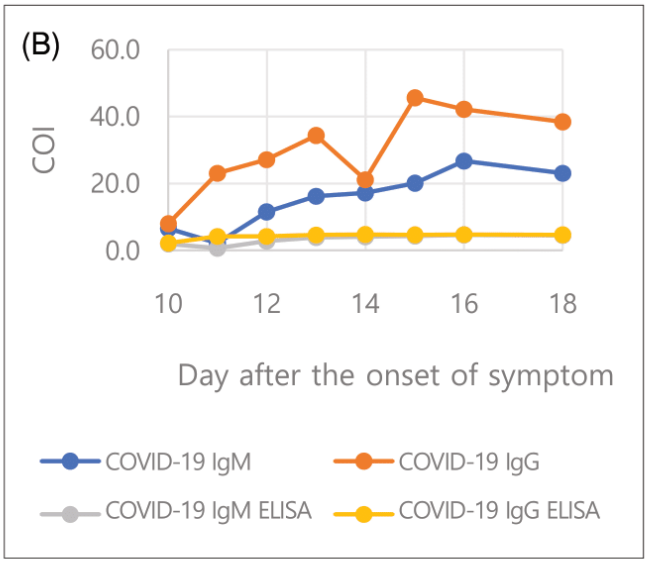


IRB No.: 202003026. **Period**: Mar. 1, 2020 ~ Mar. 31, 2020. **ELISA (in house)**: s/CO

Band intensity: measured by Confiscope G20 *COI, cutoff index

Fig. 1 The results of RDT using the sera from patient ID-XXX11 (A). Serological spectrum of COVID-19 infected patient (B) and its logarithmic analysis (C).

Sample	2020-03-11(1)		2020-03-11(2)		2020-03-11(3)		2020-03-12		2020-03-13		2020-03-14		2020-03-15		2020-03-16(1)		2020-03-16(2)		2020-03-17(1)		2020-03-17(2)		2020-03-19	
result	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
confiscope Raw data	655,366	936,251	759,728	950,036	368,965	246,545	1,995,441	2,081,137	1,035,130	2,445,731	1,460,743	3,089,387	1,546,842	1,907,032	2,418,757	4,106,909	1,190,445	4,093,522	2,649,952	4,655,336	2,166,324	2,928,624	2,080,084	3,458,473
ELISA (s/CO)	2.18	2.80	2.53	2.86	1.22	0.74	0.64	4.22	2.76	4.24	3.89	4.66	4.13	4.72	5.42	4.62	3.18	4.60	4.69	4.80	4.58	4.70	4.47	4.58



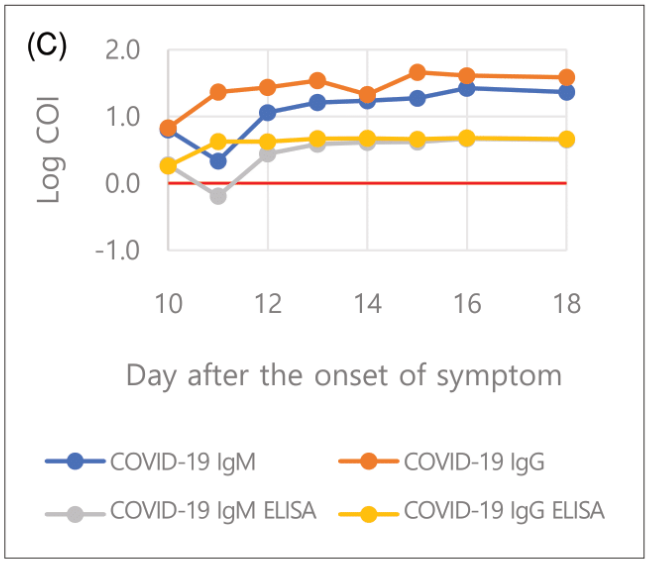


Fig. 2 The results of RDT using the sera from patient ID-XXX15 (A). Serological spectrum of COVID-19 infected patient (B) and its logarithmic analysis (C).

Multiple seroconversion study with 30 patients

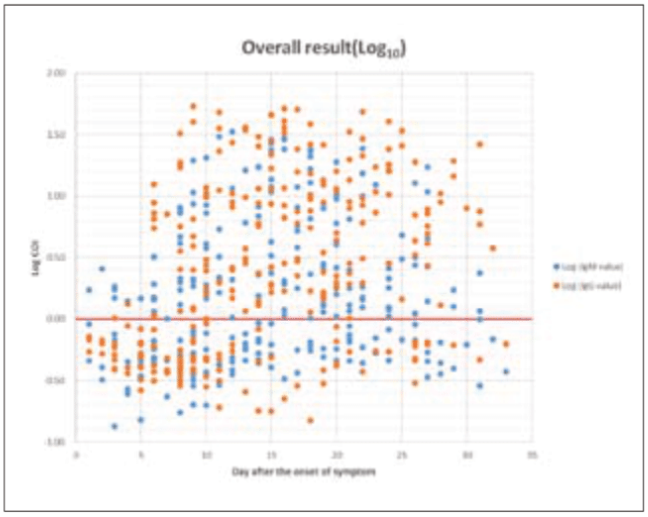


Fig. 3 Sero-conversion of anti-COVID19 IgM (blue circle) and anti-COVID-19 IgG (yellow circle) from the results of GenBody COVID-19 IgM/IgG rapid diagnostic test using 266 samples from 30 patients.

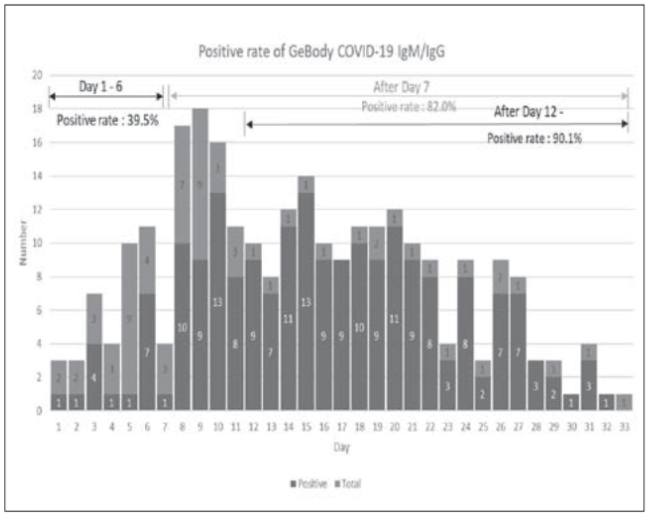


Fig. 4 Positive rate (%) of GenBody COVID-19 IgM/IgG using 266 samples from 30 patients.

Clinical study

Under the strict IRB regulation, we collected total 150 samples who were confirmed to be COVID-19 positive (30 samples listed in the below table) and its negative (120 samples not listed). The method of confirmation was RT-PCR (K** Inc., Korea). All the tests were performed in the D** University Hospital (Korea).

N=150		RT-PCR			Total
		Positive		Negative	
		Day 1~6	Day 7~		
GenBody COVID-19 IgM+IgG	Positive	3	22	3	28
	Negative	3	2	117	122
Total		6	24	120	150

The overall diagnostic performance of the kit;

- Positive percent agreement = 50% at Day 1~6, 91.7% at after Day 7
- Negative percent agreement = 97.5%
- Overall percent agreement = 95.2% at Day 1~6, 96.5% at after Day 7

Information of COVID-19 positive samples

Patient ID	Onset day	Symptom	Sampling date	Day after symptom	Result of GenBody COVID-19 IgM/IgG	
					IgM	IgG
ID-XXX243	21-Mar-20	sore throat	24-Mar-20	3	Negative	Negative
ID-XXX122	24-Feb-20	fever	1-Mar-20	6	Positive	Positive
ID-XXX132	27-Feb-20	headache	4-Mar-20	6	Positive	Negative
ID-XXX142	25-Feb-20	sore throat	2-Mar-20	6	Negative	Negative
ID-XXX248	20-Mar-20	myalgia	26-Mar-20	6	Negative	Positive
ID-XXX165	1-Mar-20	fever	8-Mar-20	7	Negative	Negative

Patient ID	Onset day	Symptom	Sampling date	Day after symptom	Result of GenBody COVID-19 IgM/IgG	
					IgM	IgG
ID-XXX14	22-Feb-20	fever, chest X-ray	1-Mar-20	8	Positive	Positive
ID-XXX143	24-Feb-20	nasal congestion	3-Mar-20	8	Positive	Positive
ID-XXX195	29-Feb-20	rhinorrhea	8-Mar-20	8	Positive	Positive
ID-XXX09	20-Feb-20	Cough	29-Feb-20	9	Positive	Positive
ID-XXX111	24-Feb-20	fever	4-Mar-20	9	Negative	Positive
ID-XXX39	23-Feb-20	cough, fever	4-Mar-20	10	Negative	Positive
ID-XXX84	20-Feb-20	fever	1-Mar-20	10	Negative	Positive
ID-XXX139	22-Feb-20	sore throat	3-Mar-20	10	Positive	Negative
ID-XXX175	1-Mar-20	fever, cough	11-Mar-20	10	Positive	Positive
ID-XXX225	9-Mar-20	cough	19-Mar-20	10	Positive	Positive
ID-XXX162	23-Feb-20	sore throat	5-Mar-20	11	Negative	Negative
ID-XXX202	6-Mar-20	anosmia	17-Mar-20	11	Negative	Negative
ID-XXX67	21-Feb-20	cough	4-Mar-20	12	Negative	Positive
ID-XXX241	12-Mar-20	myalgia,fever	24-Mar-20	12	Positive	Positive
ID-XXX166	22-Feb-20	fever	7-Mar-20	14	Positive	Positive
ID-XXX196	28-Feb-20	cough	13-Mar-20	14	Positive	Negative
ID-XXX208	2-Mar-20	myalgia	16-Mar-20	14	Positive	Positive
ID-XXX204	28-Feb-20	cough	17-Mar-20	18	Positive	Positive
ID-XXX263	2-Mar-20	fever	21-Mar-20	19	Positive	Positive
ID-XXX233	28-Feb-20	cough	19-Mar-20	20	Positive	Positive
ID-XXX258	24-Feb-20	sore throat	19-Mar-20	24	Positive	Positive
ID-XXX217	21-Feb-20	myalgia	18-Mar-20	26	Positive	Negative
ID-XXX253	23-Feb-20	myalgia	20-Mar-20	26	Positive	Positive
ID-XXX249	19-Feb-20	fever	19-Mar-20	29	Positive	Positive

References

1. Li Guo, *et al*. (2020) Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease. *Clinical Infectious Diseases*, ciaa310, DOI: 10.1093/cid/ciaa310.
2. Wei Zhang, *et al*. (2020) Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes. *Emerging Microbes & Infections*, 9:1, 386-389, DOI: 10.1080/22221751.2020.1729071.
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4. Zhengtu Li, *et al*. (2020) Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis. *Journal of Medical Virology*, DOI: 10.1002/jmv.25727.
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GenBody COVID-19 IgM/IgG

Rapid immunoassay for COVID-19 infection

Confiscope G20

Ordering Information

Cat no.	Product Name	Specification	Box Size (mm)	Carton Size (mm)
COVI040	GenBody COVID-19 IgM/IgG	-2 Lines/double device -20 Tests/Kit	215x125x75	470x420x470
COVI325	GenBody COVID-19 IgM/IgG 3.0	-3 Lines/single device -25 Tests/Kit	190x125x75	470x420x470
PQGB021	Confiscope G20	-Colorimetric analyzer	293x145x145	450x300x300

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