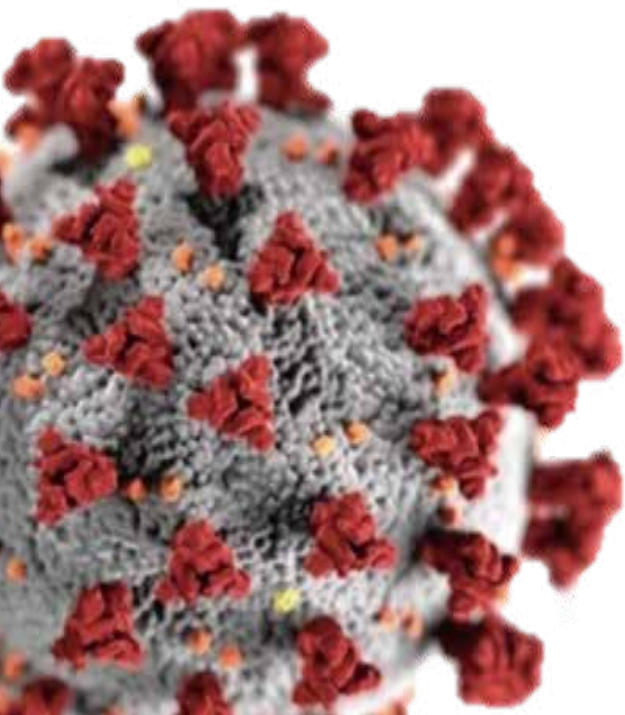


CHEXEL™

Check-up Excellence

COVID-19 IgM/IgG Test Kit

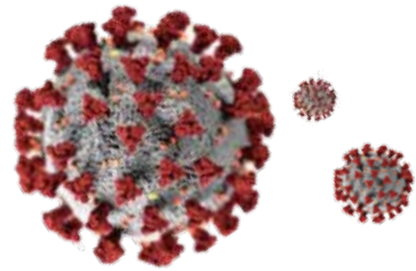


The Health Innovator 

COVID-19 IgM/IgG Test Kit

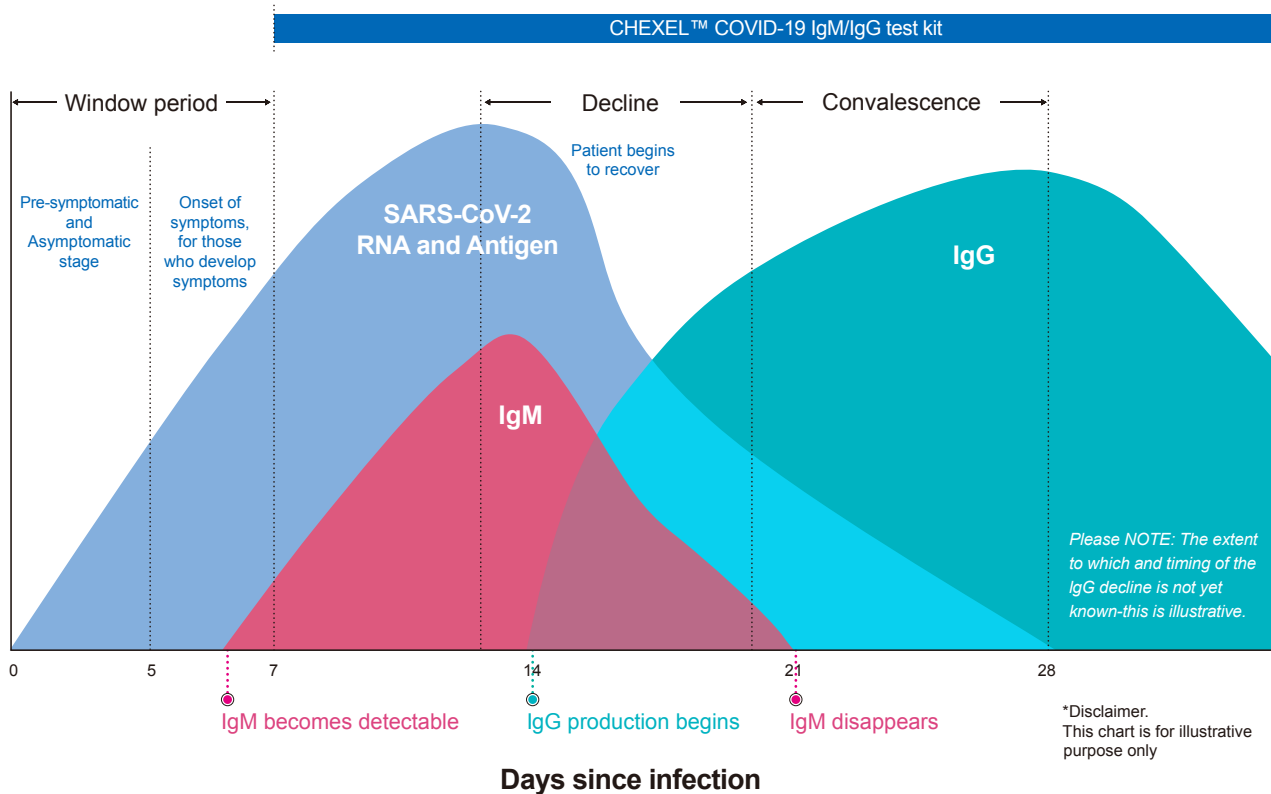
What is COVID-19?

COVID-19 is a contagious respiratory and vascular disease caused by SARS-CoV-2, a specific type of coronavirus. The World Health Organization (WHO) declared COVID-19 a 'pandemic' in March 2020. Rapid diagnosis of COVID-19 is critical for prevention and control of this pandemic.



Why Do We Need Antibody Tests?

■ SARS-CoV-2 RNA and Antigen ■ IgM ■ IgG



Reference.

1. Purpose and Options for Testing for SARS-CoV2 (the COVID-19 Virus): Considerations for World Bank Task Teams Managing COVID-19 Fast Track Facility Operations, The World Bank.
2. Cellular immune responses to severe acute respiratory syndrome coronavirus infection in senescent BALB/c Mice: CD4+ T cells are important in control of SARS-CoV infection. Jun Chen.
3. Chronological evolution of IgM, IgA, IgG and neutralisation antibodies after infection with SARS-associated coronavirus, P.-R. Hsueh.
4. SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients, Lirong Zou.
5. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, Fei Zhou.
6. CDC Tests for COVID-19, centers for Disease Control and Prevention.

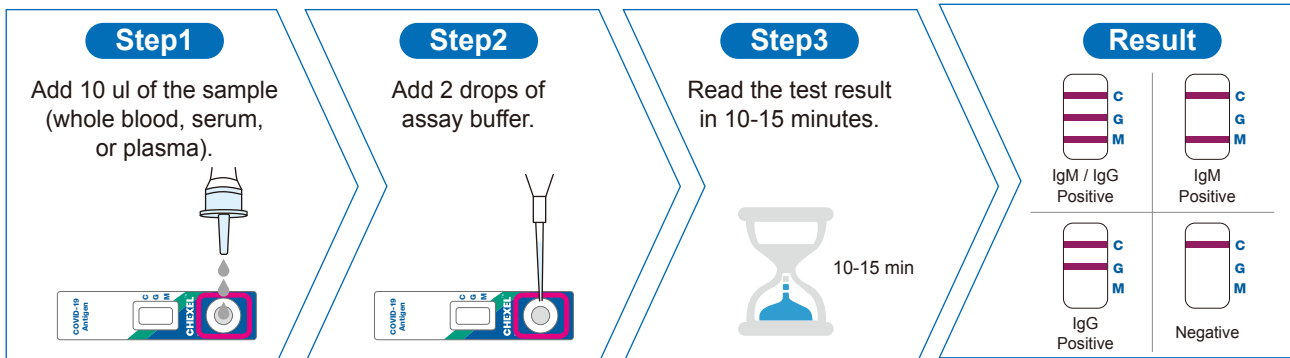
COVID-19 IgM/IgG Test Kit

Specifications

- Specimen: Whole blood, Serum, Plasma
- Test Time: Within 10-15 minutes
- Packing Unit: 25 Tests/Box
- Storage Condition: 2-30 °C / 36-86 °F
- Shelf Life: 12 months



Test Procedure

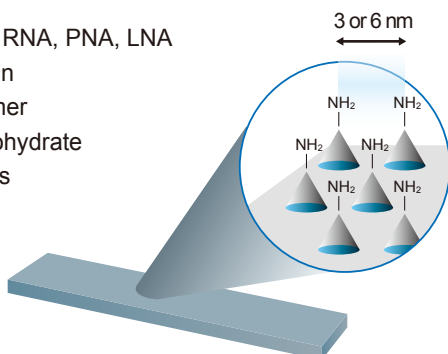


Key Technology: NanoCone[®]-Coated Surface

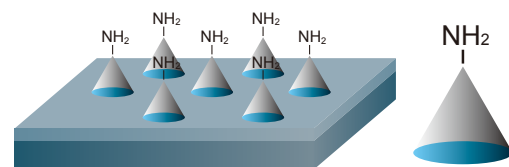
Proper lateral spacing for the biomolecules of YOUR interest

The spacing can be adjusted based on your needs.

- DNA, RNA, PNA, LNA
- Protein
- Aptamer
- Carbohydrate
- Others



NanoCone[®] Technology



Elongated Shelf Life

Low Coefficient of Variation

Covalent Conjugation of Antibodies

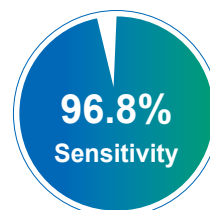
Ideal for Diagnostic Test Strips

COVID-19 IgM/IgG Test Kit

Performance

Clinical Evaluation

A total of 144 serum samples from patients confirmed by real-time PCR were analyzed, the results are as shown below. *



1) Performance with the result from a comparator equipment. **

CHEXEL COVID-19 IgM/IgG kit		Comparator (RT-PCR)		
		Positive	Negative	Total
Positive	IgG+ / IgM+	48	0	48
	IgG+ / IgM-	0	0	0
	IgG- / IgM+	14	0	14
Negative	IgG- / IgM-	2	80	82
Sub Total		64	80	144
Positive Percent Agreement (PPA)		96.8% (95% CI: 94.4 – 99.3%)		
Negative Percent Agreement (NPA)		100% (95% CI: 95.2 – 100%)		

2) Detection performance versus days from symptom onset. (Positive sample, N=64)

Days from symptom onset to blood collection	Number of RT-PCR positive samples	CHEXEL COVID-19 IgM/IgG kit performance against days from symptom onset to blood collection							
		IgM - / IgG -		IgM + / IgG -		IgM + / IgG +		IgM - / IgG +	
		%	Count	%	Count	%	Count	%	Count
≤7 days	31	3.26%	1	38.70%	12	58.06%	18	-	-
8-14 days	13	7.69%	1	15.39%	2	76.92%	10	-	-
15-21 days	12	-	-	-	-	100%	12	-	-
22-28 days	4	-	-	-	-	100%	4	-	-
29-32 days	4	-	-	-	-	100%	4	-	-
Total	64	3.16%	2	21.88%	14	75%	48	-	-

3) Result

		Reference device		Total
		Positive	Negative	
Test device (NB POSTECH)	Positive	62	0	62
	Negative	2	80	82
Total		64	80	144

- Clinical Sensitivity: 96.8% (62/64)
- Clinical Specificity: 100% (80/80)

* Conducted in July 2020 at Department of Laboratory Medicine, Korea University Guro Hospital

** Comparator equipment: Allplex 2019-nCoV assay (FDA marked, CE-IVD marked)

COVID-19 IgM/IgG Test Kit

Performance

• No cross-reactions

The following materials do not show the cross-reaction even when repeated 3 times.

NO.	Substances	Conc.	
		IgM	IgG
1	Anti-Influenza A antibody	100 µg/mL	100 µg/mL
2	Anti-Influenza B antibody	100 µg/mL	100 µg/mL
3	Anti-HBsAg antibody	100 µg/mL	100 µg/mL
4	Anti-p24 antibody(HIV)	100 µg/mL	100 µg/mL
5	Anti-MERS-CoV(beta coronavirus) panel	NCR	NCR
6	Anti-SARS-CoV(beta coronavirus) panel	NCR	NCR
7	Cross-reactivity panel COVID 229E	NCR	NCR
8	Cross-reactivity panel COVID HKU1	NCR	NCR
9	Cross-reactivity panel COVID NL63	NCR	NCR
10	Cross-reactivity panel COVID OC43	NCR	NCR

■ NCR : No cross reactions

• Not affected by Interfering Substances

NO.	Substances	Con. Level 1	Con. Level 2
1	Hemoglobin human	2.5mg/ml	5mg/ml
2	Bilirubin	0.25mg/ml	0.5mg/ml
3	Triglyceride Reagent	5mg/ml	10mg/ml
4	Ascorbic acid	0.05mg/ml	0.1mg/ml
5	Acetaminophen	0.05mg/ml	0.1mg/ml

COVID-19 IgM/IgG Test Kit

Key Features

High Sensitivity



High Specificity



High Reproducibility



Ordering information

Product No.	Description	Packing
GQLAGH	CHEXEL TM COVID-19 IgM/IgG Test Kit (25T)	25 tests

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