



NowCheck

Diagnostic Solutions for COVID-19

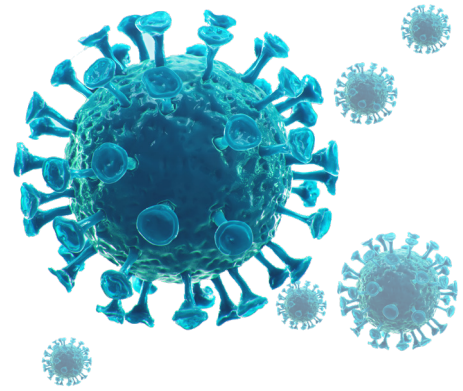


- NowCheck COVID-19 Ag Test
- NowCheck COVID-19 IgM/IgG Test
- Nowcheck COVID-19 Total Ab ELISA

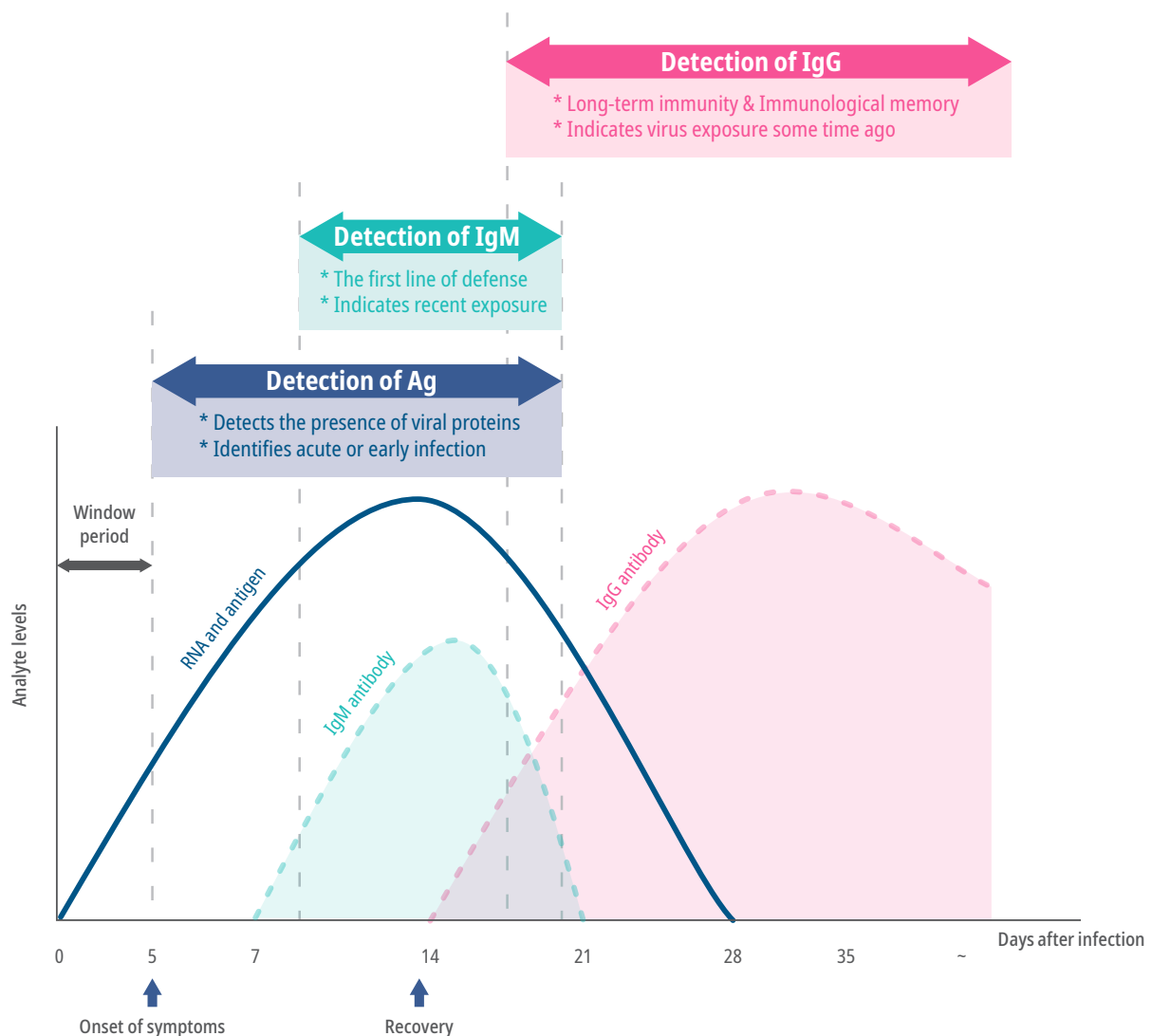


What is COVID-19?

Coronavirus disease 2019 (COVID-19) is a new disease, caused by a novel coronavirus (SARS-CoV-2) that has not previously been seen in humans. It is a respiratory illness that can spread from person to person. Current symptoms have included fever, cough, and shortness of breath or difficulty breathing. The rapid diagnosis of COVID-19 is critical for prevention and control of this pandemic.



Why We Need Antigen and Antibody Tests?



NowCheck COVID-19 Ag Test

The NowCheck COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx.

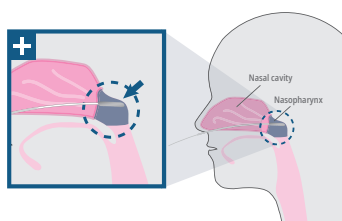
Specifications

- Sample : Nasopharyngeal swab
- Testing time : Within 30 min.
- Packing Unit : 25 Tests/Kit
- Storage Condition : 2-30°C (36-86°F)

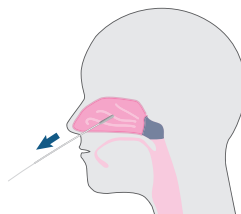


Test Procedure

- 1 Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



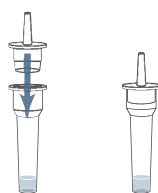
- 2 Withdraw the sterile swab from the nasal cavity.



- 3 Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.



- 4 Press the nozzle cap tightly onto the tube.



- 5 Apply 3 drops of extracted specimen to the sample hole of the test device.

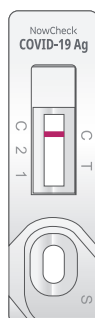


- 6 Read the test result in 15-30 min. Do not read after 30 min.

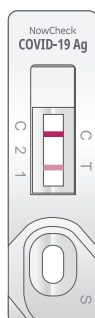
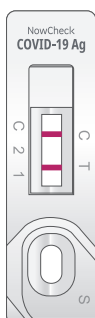


Test Result

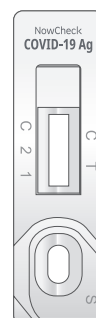
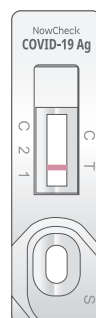
Negative



Positive



Invalid



NowCheck COVID-19 Ag Test

Performance

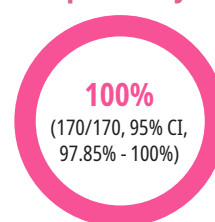
A total of 202 prospective specimens consisted of nasopharyngeal swabs from symptomatic patients.

:: Excellent Specificity compared to PCR

The NowCheck COVID-19 Ag Test showed 100% of specificity, compared to PCR assays.

		PCR		
		Positive	Negative	Total
NowCheck COVID-19 Ag Test	Positive	0	0	0
	Negative	0	170	170
	Total	0	170	170

Specificity

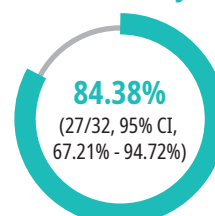


:: High Sensitivity compared to PCR

The NowCheck COVID-19 Ag Test showed 84.38% of sensitivity, compared to PCR assays.

		PCR		
		Positive	Negative	Total
NowCheck COVID-19 Ag Test	Positive	27	0	27
	Negative	5	0	5
	Total	32	0	32

Sensitivity



:: Low Limit of Detection (LoD)

The study used "SARS-CoV-2 (2019-nCoV) NCCP 43326/2020 / Korea" strain. The titer of cultured virus was confirmed by PCR. **The LoD is $1.25 \times 10^{3.2}$ TCID₅₀/ml.**

Concentration in Dilution tested (TCID ₅₀ /ml)	Result
$1 \times 10^{5.2}$	POS (10/10)
$1 \times 10^{4.2}$	POS (10/10)
$5 \times 10^{3.2}$	POS (10/10)
$2.5 \times 10^{3.2}$	POS (10/10)
$1.25 \times 10^{3.2}$	POS (25/25)
$6.12 \times 10^{2.2}$	NEG (18/25)

NowCheck COVID-19 Ag Test

Performance

:: No Cross-reactions

There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus.

Virus / Bacteria / Parasite	Result
SARS-coronavirus	POS
MERS-coronavirus	NEG
Adenovirus	NEG
Influenza A	NEG
Influenza B	NEG
Respiratory syncytial virus	NEG
Legionella pneumophila	NEG
Mycobacterium tuberculosis	NEG
Streptococcus pneumonia	NEG
Streptococcus pyrogens	NEG
Mycoplasma pneumoniae	NEG

Virus / Bacteria / Parasite	Result
Pooled human nasal wash	NEG
Coronavirus	NEG
MERS-Coronavirus	NEG
Human Metapneumovirus (hMPV) 3 Type B1	NEG
Human Metapneumovirus (hMPV) 16 Type A1	NEG
Parainfluenza virus	NEG
Rhinovirus A16	NEG

:: Not Affected by Interfering Substances

There was no interference with Endogenous/Exogenous interfering substances.

✓ Respiratory Specimens

Mucin, Blood or Biotin

✓ Anti-viral drugs

Zanamivir, Oseltamivir, Artemether-lumefantrine, Doxycycline hyclate , etc.

✓ Nasal sprays or drops

Phenylephrine, Oxymetazoline or Saline

✓ Anti-inflammatory medication

Acetaminophen, Acetylsalicylic acid or Ibuprofen

✓ Allergy relief medicine

Sodium Cromoglycate, Olopatadine Hydrochloride

✓ Antibiotics

Mupirocin, Tobramycin, Erythromycin or Ciprofloxacin

NowCheck COVID-19 IgM/IgG Test

NowCheck COVID-19 IgM/IgG Test is a rapid chromatographic immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum, plasma or whole blood.

Specifications

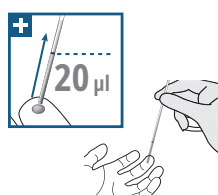
- Sample : Whole blood, Serum, Plasma
- Testing time : Within 15 min.
- Packing Unit : 25 Tests/Kit
- Storage Condition : 2-30°C (36-86°F)



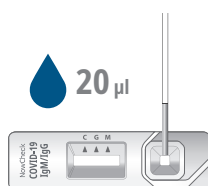
Test Procedure

[Using Capillary whole blood]

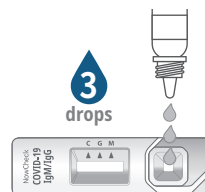
- 1 Collecting of Specimen**
Collect the 20µl of capillary whole blood to the black line



- 2 Adding of Specimen**
Add the collected blood to the sample hole



- 3 Dropping of buffer**
Add 3 drops (90µl) of buffer vertically

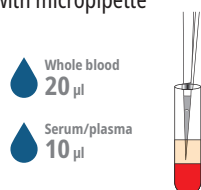


- 4 Reading Time**
Read the test result at 10-15 min.

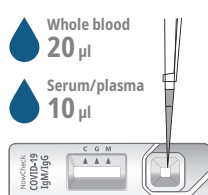


[Using serum/plasma/whole blood]

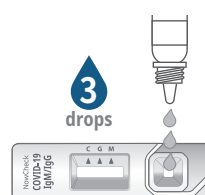
- 1 Collecting of Specimen**
Collect the serum, plasma (10µl) or whole blood (20µl) with micropipette



- 2 Adding of Specimen**
Add the collected blood to the sample hole



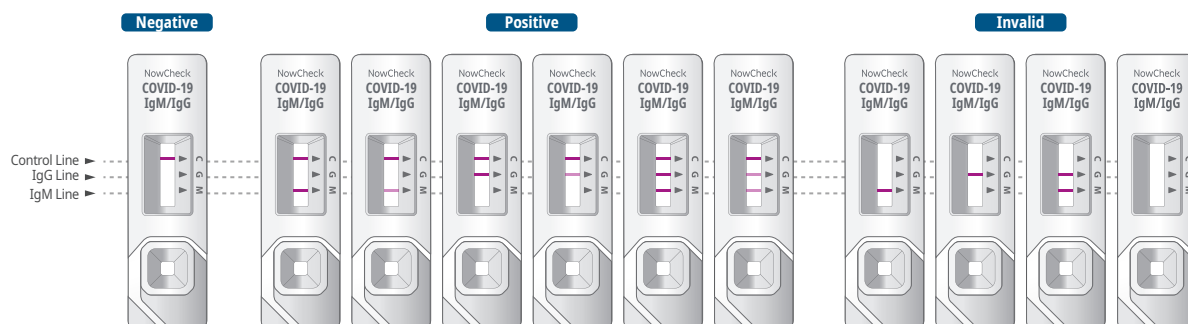
- 3 Dropping of buffer**
Add 3 drops (90µl) of buffer vertically



- 4 Reading Time**
Read the test result at 10-15 min.



Test Result

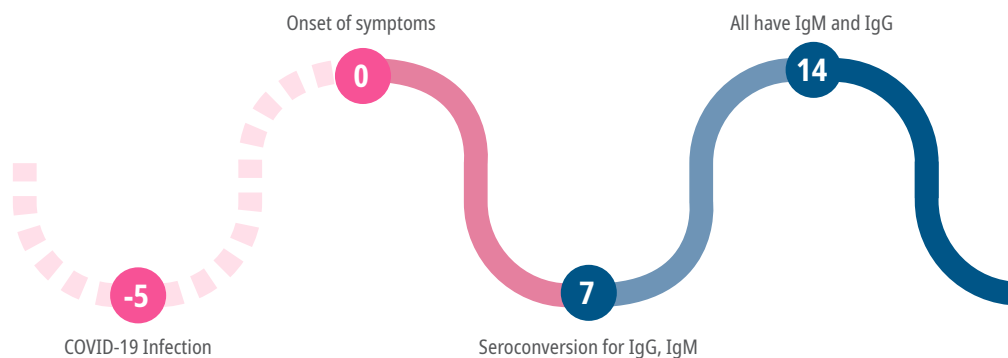


NowCheck COVID-19 IgM/IgG Test

Performance

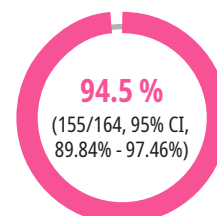
:: Good Sensitivity compared to PCR

The seroconversion time of IgM and IgG antibodies was estimated to be around 7 days after onset of symptom. The NowCheck COVID-19 IgM/IgG Test showed 94.5% of sensitivity, compared to PCR assays.



≥ 7 days after symptom onset		PCR		
		Positive	Negative	Total
NowCheck COVID-19 IgM/IgG Test	Positive	155	0	155
	Negative	9	0	9
	Total	164	0	164

Sensitivity

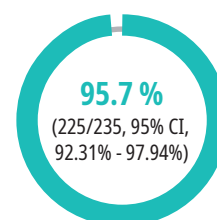


:: High Specificity compared to PCR

The NowCheck COVID-19 IgM/IgG Test showed 95.7% of specificity, compared to PCR assays.

		PCR		
		Positive	Negative	Total
NowCheck COVID-19 IgM/IgG Test	Positive	0	10	10
	Negative	0	225	225
	Total	0	235	235

Specificity



Diagnostic Solutions for COVID-19

Key Features

ACCURATE

Good correlation with PCR assays

ANYWHERE

No Specific equipment needed

EASE OF USE

Minimal operator -dependent steps

FAST RESULTS

Reliable Result within 30 min.

MARKET PRESENCE AND ACCEPTANCE

Minimal education required for users

STABLE

Long shelf-lives without refrigeration

Interpretation of results

Test Results			Clinical significance
Antigen	Antibody		
	IgM	IgG	
+	-	-	Window period of infection
+	+	-	Early phase of infection
+	+	+	Active phase of infection
+	-	+	Late or recurrent stage of infection
-	+	-	Early phase of infection (Ag results may be false-negative.)
-	-	+	Past infection, Recovered
-	+	+	Recovery stage of infection or false-negative on Ag Test

Ordering Information

Product No.	Product Name	Product Type	Packing Unit
RG1901DG	NowCheck COVID-19 Ag Test	Device	25 Tests/Kit
RB2901DG	NowCheck COVID-19 IgM/IgG Test	Device	25 Tests/Kit
EB4901PN	NowCheck COVID-19 Total Ab ELISA	Microplate	96 wells/Kit
EB4901PO			480 wells/Kit
RG1901CD	NowCheck COVID-19 Ag Control	Control	10 Tests/Kit
RB2901CD	NowCheck COVID-19 IgM/IgG Control	Control	10 Tests/Kit



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