NowCheck

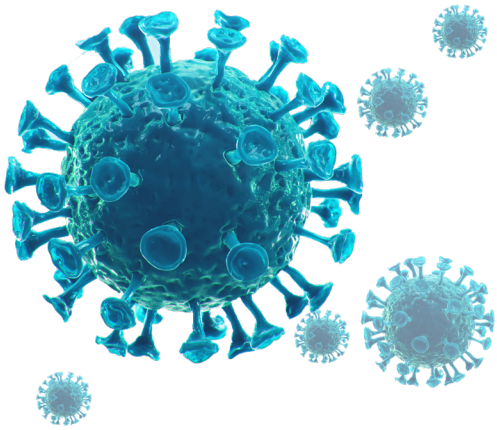
Diagnostic Solutions for COVID-19

- NowCheck COVID-19 Ag Test
- NowCheck COVID-19 IgM/IgG Test

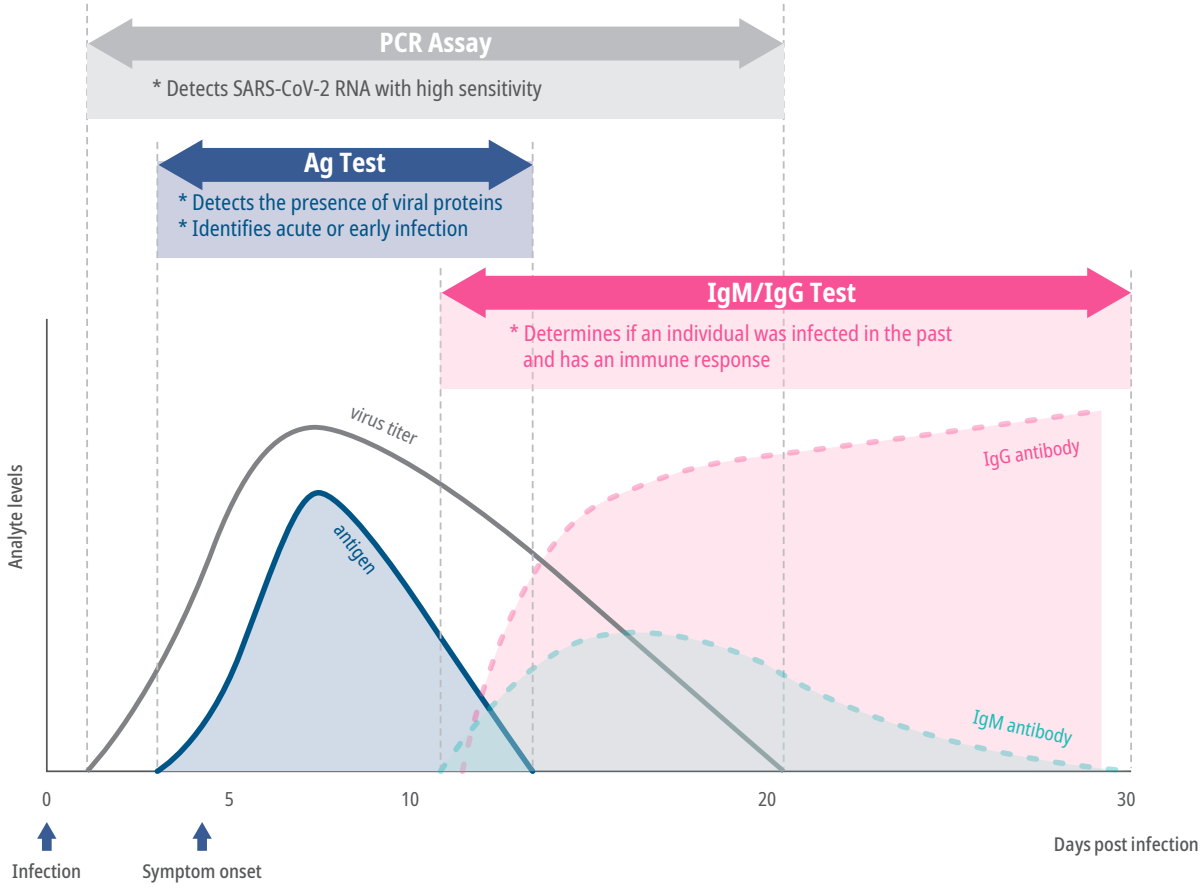
BIONOTE

What is COVID-19?

Coronavirus disease 2019 (COVID-19) is a new disease caused by a novel coronavirus (SARS-CoV-2). It is a respiratory illness that can spread from person to person. It is now rapidly spreading worldwide and has been announced as a pandemic by WHO. Presentations of COVID-19 have ranged from asymptomatic/mild symptoms to severe illness and mortality. The rapid diagnosis of COVID-19 is critical for the prevention and control of this pandemic.



Why Do 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 or nasal cavity.

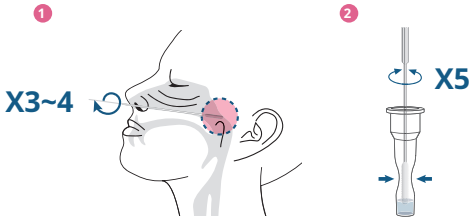
Specifications

- Sample : Nasopharyngeal swab, Nasal swab
- Testing time : 15~30 min.
- Packing Unit : 25 Tests/Kit
- Storage Condition : 2-30℃ (36-86℉)

Test Procedure

Nasopharyngeal swab

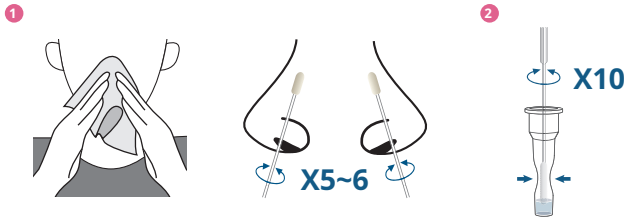
1. Insert a nasopharyngeal swab into the nostril of the patient, and rotate the swab over the posterior nasopharynx surface 3~4 times.
2. Insert the swab into an extraction buffer tube, and stir it more than 5 times while squeezing the tube.



or

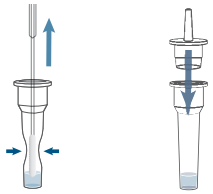
Nasal swab

1. After getting a patient to blow one's nose, insert a nasal swab into one of the nostrils, and rotate the swab against the nasal wall 5-6 times. Repeat in the other nostril, using the same swab.
2. Insert the swab into an extraction buffer tube, and stir it more than 10 times while squeezing the tube.



Analysis

3. Remove the swab while squeezing the sides of the tube, and press the nozzle cap tightly onto the tube.

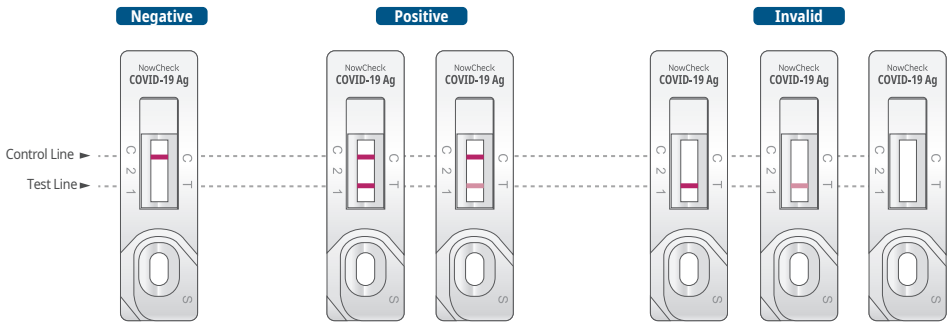


4. Apply 3 drops of the extracted specimen to the sample hole of the test device.

5. Read the test result after 15~30 min. The test can be read up to 30 min.

** Do not read test results after 30 min. It may give false results.

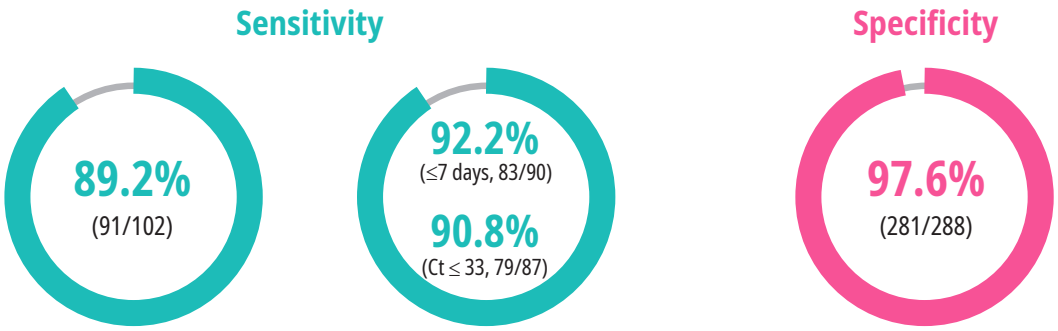
Test Result



NowCheck COVID-19 Ag Test

Performance

:: Clinical evaluation



*** Prospective diagnostic evaluation study in Brazil**

A total of 390 nasopharyngeal swab specimens were collected from symptomatic patients. Results of the test were compared to the routine, diagnostic RT-PCR (Lab-developed assay based on the US CDC protocol) result.

Specimens from symptomatic patients (N=390)		Real-time PCR		
		Positive	Negative	Total
NowCheck COVID-19 Ag Test	Positive	91	7	98
	Negative	11	281	292
	Total	102	288	390

Clinical Sensitivity = 89.2% (95%CI, 81.7% - 93.9%)
92.2% (95%CI, 84.8% - 96.2%) (Days ≤ 7 from symptom onset)
90.8% (95%CI, 82.9% - 95.3%) (Ct ≤ 33)
Clinical Specificity = 97.6% (95%CI, 95.1% - 98.8%)

Reference : https://www.finddx.org/covid-19/sarscov2-eval-antigen/

*** Prospective diagnostic evaluation study in Russia**

A total of 50 nasopharyngeal swab specimens were collected and the results were compared to the diagnostic RT-PCR result, which is used for clinical management.

Nasopharyngeal swab specimens (N=50)		Real-time PCR		
		Positive	Negative	Total
NowCheck COVID-19 Ag Test	Positive	24	0	24
	Negative	1	25	26
	Total	25	25	50

Clinical Sensitivity = 96% (95%CI, 79.65% - 99.9%)
Clinical Specificity = 100% (95%CI, 86.28% - 100%)

:: Limit of Detection (LoD)

SARS-CoV-2 strain tested	Virus stock titer	Sample type	LoD (final working titer)
NCCP 43326/ 2020 /Korea	$1 \times 10^{6.2}$ $TCID_{50}$/ml	Direct nasopharyngeal swab	$6.24 \times 10^{1.2}$ $TCID_{50}$/ml
		Direct nasal swab	$5.37 \times 10^{1.2}$ $TCID_{50}$/ml

NowCheck COVID-19 Ag Test

Performance

∷ No Cross-reactivity

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

Category	Sort	Result
Virus	SARS-coronavirus	POS
	MERS-coronavirus	NEG
	Human Coronavirus	NEG
	Influenza A	NEG
	Influenza B	NEG
	Respiratory syncytial virus	NEG
	Human Metapneumovirus (hMPV)	NEG
	Parainfluenza virus	NEG
	Rhinovirus	NEG
	Enterovirus	NEG
	Adenovirus	NEG
	Human immunodeficiency virus lysate	NEG

Category	Sort	Result
Bacteria	Haemophilus influenzae	NEG
	Mycoplasma pneumoniae	NEG
	Streptococcus pneumonia	NEG
	Streptococcus pyrogens	NEG
	Streptococcus salivarius	NEG
	Candida albicans	NEG
	Bordetella pertussis	NEG
	Moraxella catarrhalis	NEG
	Pseudomonas aeruginosa	NEG
	Staphylococcus epidermidis	NEG
	Mycobacterium tuberculosis	NEG
Others	Pooled human nasal wash – representative of normal respiratory microbial flora	NEG

∷ Not Affected by Interfering Substances

There was no interference with endogenous/exogenous interfering substances.

Antibiotics
Mupirocin, Tobramycin, Erythromycin, Ciprofloxacin

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

Anti-inflammatory drugs
Acetaminophen, Acetylsalicylic acid, Ibuprofen

Nasal sprays or drops
Neo-Synephrine, Afrin Nasal Spray, Rhinocort, etc.

Autoimmune disease
Human anti-mouse antibody, Rheumatoid factor

Serum protein
Whole Blood, EDTA anticoagulated

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.

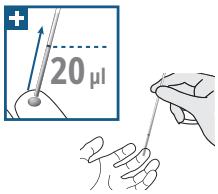
Specifications

- Sample : Whole blood, Serum, Plasma
- Testing time : 10~15 min.
- Packing Unit : 25 Tests/Kit
- Storage Condition : 2-30℃ (36-86℉)

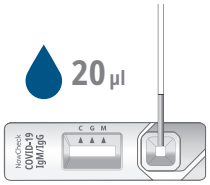
Test Procedure

[Using Capillary whole blood]

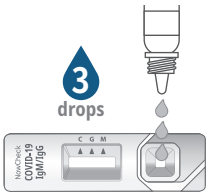
1. Collect the 20 µl of capillary whole blood to the black line



2. Add the collected blood to the sample hole



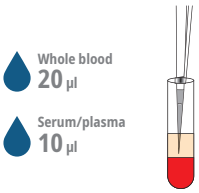
3. Add 3 drops (90 µl) of buffer vertically



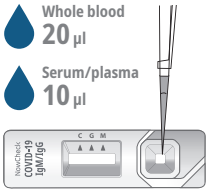
4. Read the test result in 10~15 min.

[Using serum/plasma/whole blood]

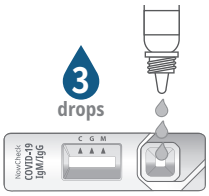
1. Collect the serum, plasma (10 µl) or whole blood (20 µl) with a micropipette



2. Add the collected blood to the sample hole

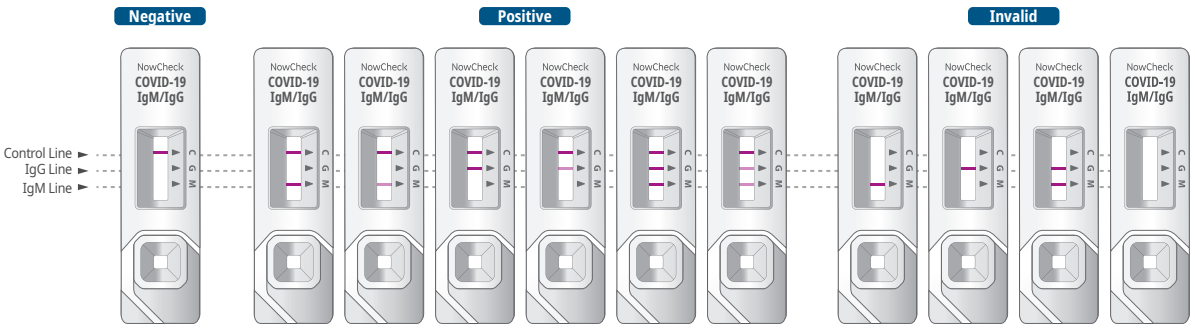


3. Add 3 drops (90 µl) of buffer vertically



4. Read the test result in 10~15 min.

Test Result



NowCheck COVID-19 IgM/IgG Test

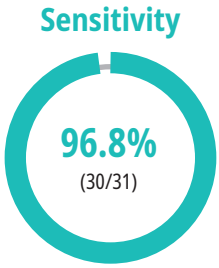
Performance

:: Clinical evaluation

A total of 105 serum samples from patients confirmed by Real-time PCR were analyzed.
The results are as shown below:

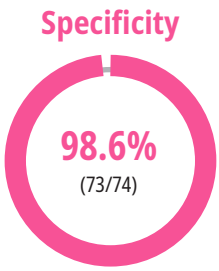
- Diagnostic Sensitivity

Positive samples (N=31)		NowCheck COVID-19 IgM/IgG Test			
		IgM(+)	IgG(+)	IgM(+) and/or IgG(+)	
Days (post-symptom onset)	0 - 7	100% (1/1)	100% (1/1)	100% (1/1)	96.8% (30/31)
	8 - 14	66.7% (2/3)	100% (3/3)	100% (3/3)	
	≥ 15	88.9% (24/27)	96.3% (26/27)	96.3% (26/27)	



- Diagnostic Specificity

Negative samples (N=74)	NowCheck COVID-19 IgM/IgG Test		
	IgM(-)	IgG(-)	IgM(-) and IgG(-)
Confirmed by Real time-PCR	98.6% (73/74)	100% (74/74)	98.6% (73/74)



The NowCheck COVID-19 IgM/IgG Test showed 96.8% of sensitivity and 98.6% of specificity, compared to the Real-time PCR method.

* Conducted in July 2020 at Department of Laboratory medicine, Seoul National University Bundang Hospital
** Reference: PowerChek™ 2019-nCoV Real-time PCR kit (KCDC approved, FDA EUA)

:: Limit of Detection (LoD)

The LoD of NowCheck COVID-19 IgM/IgG Test for SN titer was 1:40.

Diagnostic Solutions for COVID-19

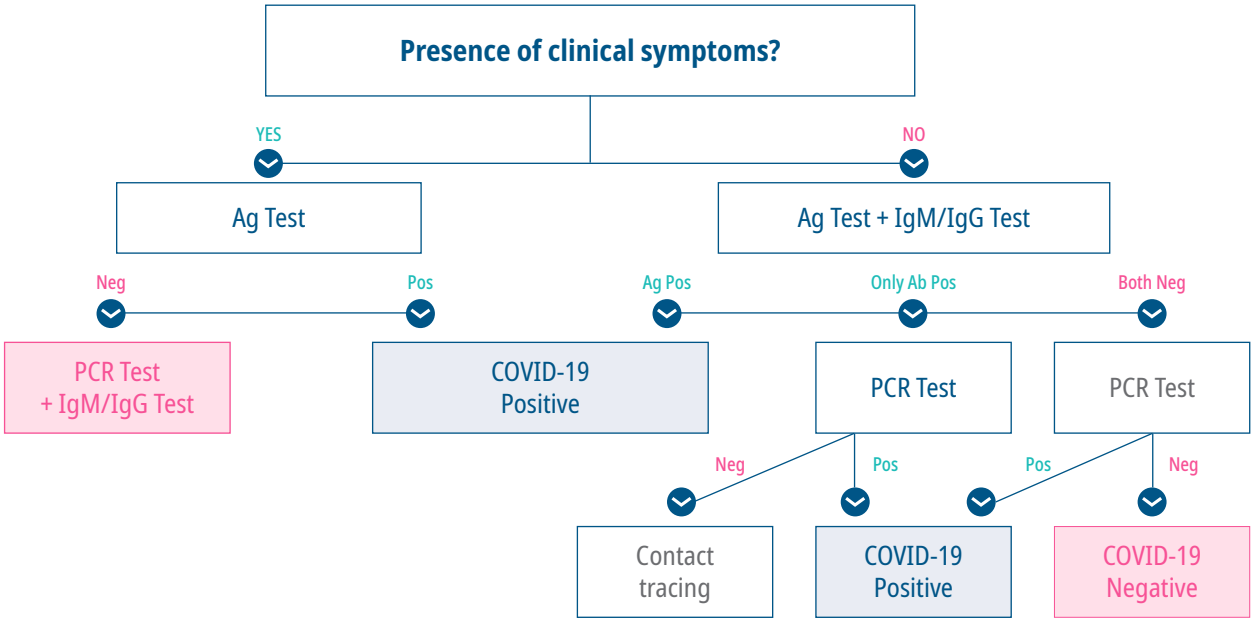
Key Features

ACCURATE	ANYWHERE	EASE OF USE
Good correlation with PCR assays	No specific equipment needed	Minimal operator -dependent steps

FAST RESULTS	MARKET PRESENCE AND ACCEPTANCE	STABLE
Reliable result within 30 min.	Minimal education required for users	Long shelf-life without refrigeration

Diagnostic Algorithm

For individuals suspected to have COVID-19



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
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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