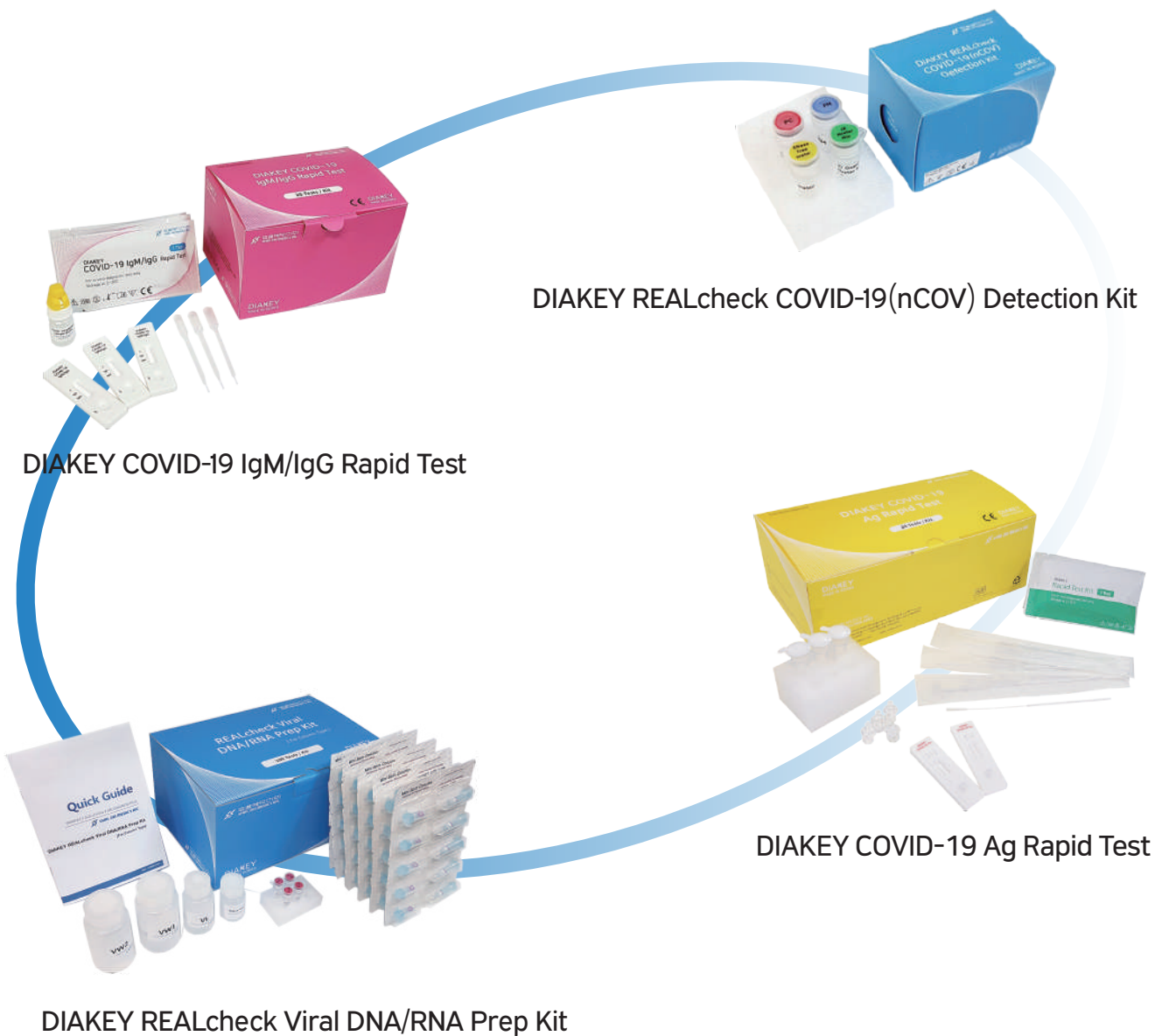




DIAKEY | MADE IN KOREA

DIAKEY Kits for testing COVID-19

Ab / Ag / Prep / qRT-PCR



CONTENTS

DIAKEY COVID-19 IgM/IgG Rapid Test

- ▷ Test within 15 minutes
- ▷ Available for human Whole Blood / Serum / Plasma
- ▷ Just 1 drop of Specimen(about 10μl) needed
- ▷ Simple & Convenient test procedure
- ▷ No big devices needed



DIAKEY COVID-19 Ag Rapid Test

- ▷ Test within 15 minutes
- ▷ Available for human Nasopharyngeal specimen
- ▷ Qualitative detection of SARS-COV-2 antigen
- ▷ Simple & Convenient test procedure
- ▷ No big devices needed

DIAKEY REALcheck Viral DNA/RNA Prep Kit

- ▷ High purity viral DNA/RNA extraction
- ▷ No enzyme required other than Proteinase K
- ▷ No use of organic solvent
- ▷ Designed for extracting Coronavirus RNA
- ▷ Used with DIAKEY REALcheck COVID-19(nCOV) Detection Kit



DIAKEY REALcheck COVID-19(nCOV) Detection Kit

- ▷ Detection by Multiplex onestep qRT-PCR
- ▷ High accuracy and precision
- ▷ Qualitative detection of RdRp, N gene of COVID-19
- ▷ Can be tested with small amount of specimen
- ▷ Used with DIAKEY REALcheck Viral DNA/RNA Prep Kit

DIAKEY | MADE IN KOREA

DIAKEY COVID-19 IgM/IgG Rapid Test



DIAKEY COVID-19 IgM/IgG Rapid Test device is a qualitative membranestrip based immunoassay for the detection of IgM and IgG to Novel coronavirus in human Whole Blood/Serum/Plasma.

PRODUCT CHARACTERISTICS

- ▷ Test within 15 minutes
- ▷ Available for human Whole Blood / Serum / Plasma
- ▷ Just 1 drop of Specimen(about 10µl) needed
- ▷ Simple & Convenient test procedure
- ▷ No big devices needed

Available specimen

20 Tests



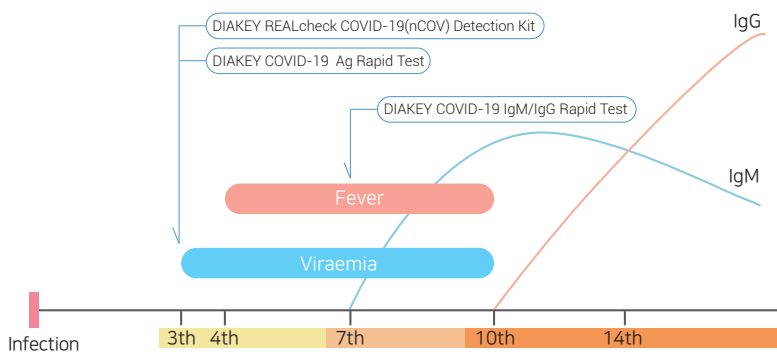
Whole Blood / Serum / Plasma

1 Test



Whole Blood only

APPLICATION OF TEST METHODS



The detection of only IgM means infected with a virus and it is early.

The detection of both IgM and IgG means that about 10 days have passed since the infection.

After COVID-19 Infection,

* 3 days later DIAKEY COVID-19 Ag Rapid Test

& DIAKEY REALcheck COVID-19(nCOV) Detection Kit

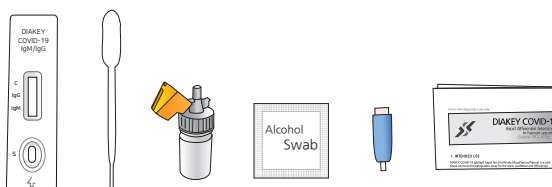
* 7 days later DIAKEY COVID-19 IgM/IgG Rapid Test

We have also COVID-19 antigen detection kit(DIAKEY COVID-19 Ag Rapid Test), qRT-PCR Test kit(DIAKEY REALcheck COVID-19(nCOV) Detection Kit) and qRT-PCR Prep kit(REALcheck Viral DNA/RNA Prep Kit).

If you want to get more information, please contact us.



Special package - 1Test package



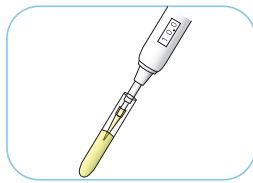
1 Test package is a kit for individual testing. All materials needed to test are in one pouch.

Materials provided in 1 Test package

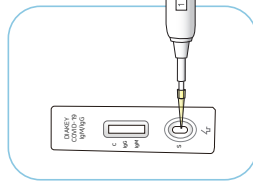
- 1 Test device
- 1 Dropper
- 1 Sample buffer
- 1 Alcohol swab
- 1 Lancet
- 1 Insert

TEST PROCEDURE

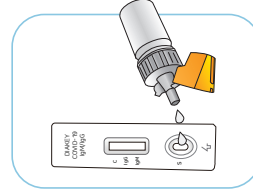
*Serum / Plasma



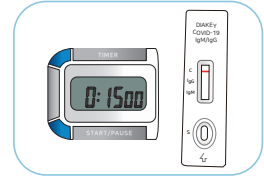
Take 10µl of specimen with a micro pipette.



Transfer 10µl of specimen to the specimen well (S) of the test device.

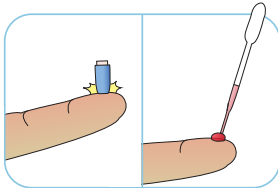


Add 2 drops buffer (70µl) to the specimen well (S) of the test device and start the timer(15 min).

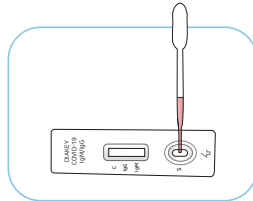


After 15 minutes, interpret the result. (negative / positive / invalid)

*Whole Blood



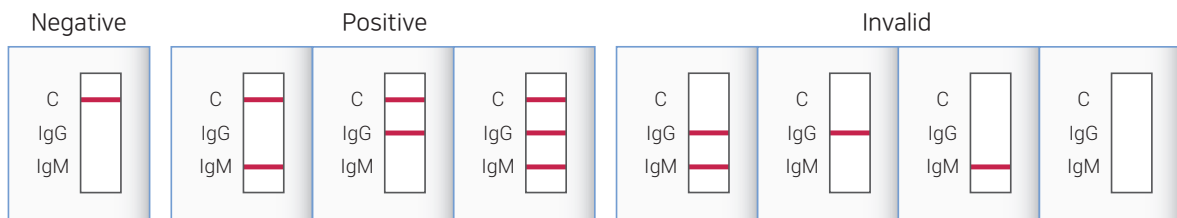
Take blood from the patient's finger with the lancet & dropper.



Transfer 10µl of specimen to the specimen well (S) of the test device.

- Please do not read the result after 20 min.
- The lancet and swab are only available in the 1T package.
- 1T package is Whole blood only.

RESULT INTERPRETATION



CLINICAL PERFORMANCE

- Tested in Korea
- Comparator : qRT-PCR
- Total samples : 90
- Positive samples : 60
- Negative samples : 30
- PPA : 91.67%
- NPA : 100%

DIAKEY COVID-19 IgM/IgG Rapid Test		Comparator / qRT-PCR		Total
		Positive	Negative	
Positive	IgM+/IgG+	47	0	47
	IgM+/IgG-	0	0	0
	IgM-/IgG+	8	0	8
Negative	IgM+/IgG+	5	30	35
Total		60	30	90

Positive Percent Agreement(PPA) = 55/60 (91.67%), 95% CI: 81.9% to 96.4%
 Negative Percent Agreement(NPA) = 30/30 (100%), 95% CI: 88.6% to 100.0%

ORDER INFORMATION

Product	Cat. No.	Test	Box Size(mm)	Storage	Shelf Life
DIAKEY COVID-19 IgM/IgG Rapid test	PF09	1	122g, 138×104×90	2°C to 30°C	24 months
	PF09	20	188g, 138×104×90	2°C to 30°C	

DIAKEY | MADE IN KOREA

DIAKEY COVID-19 Ag Rapid Test



· SARS-CoV-2 antigen detection

· Nasopharyngeal swab test

· Test time / 15 min

· Package / 20 tests/kit

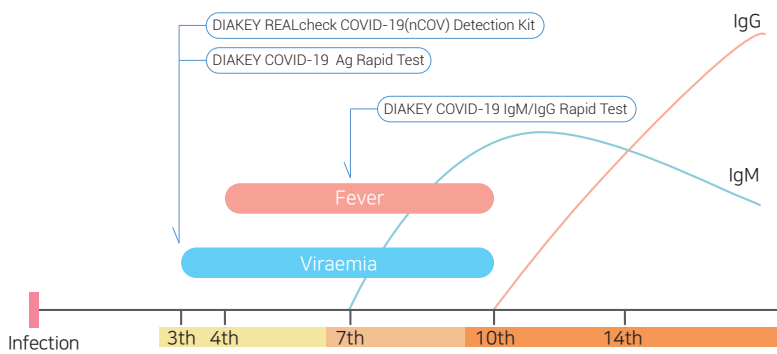
PRODUCT CHARACTERISTICS

- ▷ Rapid test time [15 minutes]
- ▷ Qualitative detection of SARS-COV-2 antigen in nasopharyngeal swab
- ▷ Able to check the presence of Ag before antibodies generation
- ▷ Simple & Convenient test procedure
- ▷ No big devices needed
- ▷ Shelf life: 1 year

Kit Components

- Device 20
 - Sterilized Swab 20
 - Extraction Buffer Tube 20
 - Nozzle Cap 20
 - Insert 1
- 20 Tests**

APPLICATION OF TEST METHODS



Viraemia means that the virus penetrates and spreads into your body's bloodstream.

Before antibodies are formed in the body, the infection can be diagnosed through antigen testing. Therefore, DIAKEY COVID-19 Ag Rapid Test is helpful to check whether COVID-19 is infected in the early stages.

After COVID-19 Infection,

- * 3 days later DIAKEY COVID-19 Ag Rapid Test & DIAKEY REALcheck COVID-19(nCOV) Detection Kit
- * 7 days later DIAKEY COVID-19 IgM/IgG Rapid Test

We have also COVID-19 antibodies detection kit(DIAKEY COVID-19 IgM/IgG Rapid Test), qRT-PCR Test kit(DIAKEY REALcheck COVID-19(nCOV) Detection Kit) and qRT-PCR Prep kit(DIAKEY REALcheck Viral DNA/RNA Prep Kit). If you want to get more information about them, please contact us.



COVID-19 Antibodies Detection - DIAKEY COVID-19 IgM/IgG Rapid Test



DIAKEY COVID-19 IgM/IgG Rapid Test is used to detect of COVID-19 Ab(IgM/IgG).

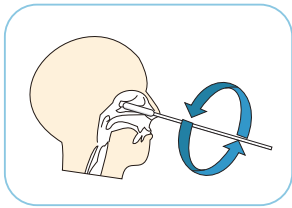
Types of kits provided - 20 Tests/Kit - 1 Test package (Individual Test Kit)

How to use this kit - Please visit our Youtube channel and watch the video.

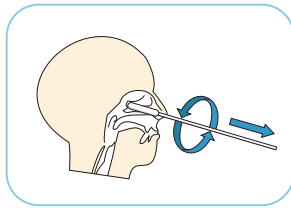
SHIN JIN MEDICS Youtube channel

<https://www.youtube.com/channel/UCUQiNTPOdYxyGPP3fV96nVQ>

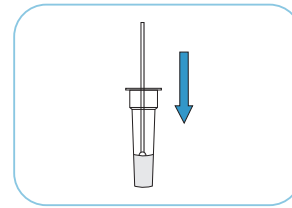
TEST PROCEDURE



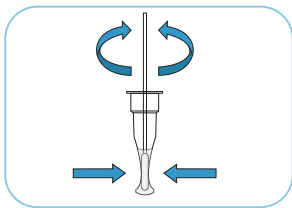
Insert a swab through the nostril, rub the surface of the nasopharynx.



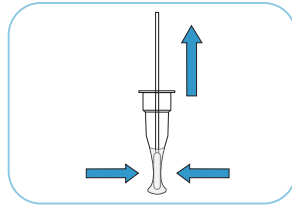
Slowly remove the swab while rotating it.



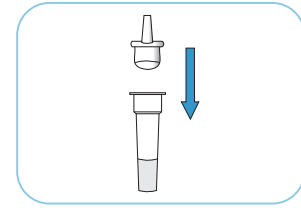
Insert the swab sample into the extraction buffer tube which contains extraction buffer.



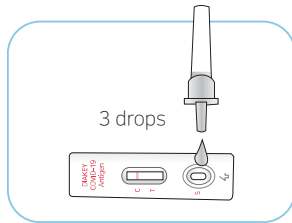
Roll the swab into the tube while squeezing it.



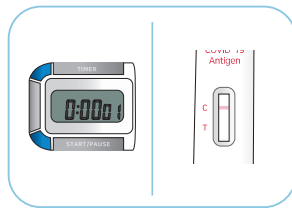
Keep squeezing the tube and remove the swab gently.



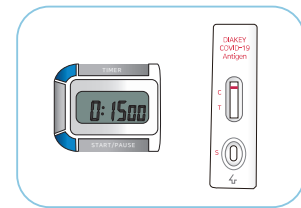
Place the nozzle cap into the tube tightly. The solution shouldn't leak.



Transfer 3 drops (approximately 100µL) to the specimen well(S) of the device.



Start the timer and wait for the lines to appear.

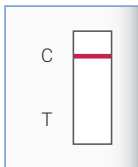


Interpretate the results after 15 min.

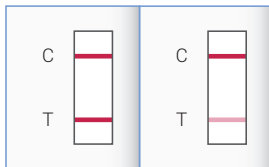
※ Results more than 20 minutes after the timer starts are invalid.

RESULT INTERPRETATION

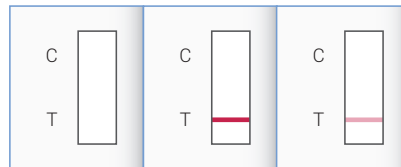
Negative



Positive



Invalid



C : Control line / T : Test line

If you get the invalid result, please test again with a new device.

ORDER INFORMATION

Product	Cat. No.	Test	Box Size(mm)	Storage	Shelf Life
DIAKEY COVID-19 Ag Rapid test	PF10	1	80g, 245×120×90	4°C to 30°C	12 months
	PF10	20	292g, 245×120×90	4°C to 30°C	

DIAKEY | MADE IN KOREA

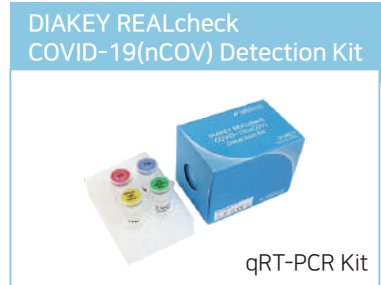
DIAKEY REALcheck Viral DNA/RNA Prep Kit



DIAKEY REALcheck Viral DNA/RNA Prep Kit is to extract various viral DNA/RNA such as Adenovirus, Norovirus, Zika virus, HCV, HIV, Yellow fever virus, Coronavirus, etc. The viral DNA/RNA can be extracted with high purity result.

PRODUCT CHARACTERISTICS

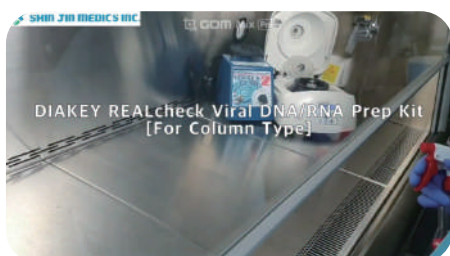
- ▷ High purity Viral DNA/RNA extraction
- ▷ No enzyme required other than Proteinase K
- ▷ No use of Organic solvent
- ▷ Designed for extracting COVID-19 RNA
- ▷ Can be used with DIAKEY REALcheck COVID-19(nCOV) Detection Kit



COMPONENTS

 Column	 VL	 VW1	+	 Quick Guide
 VW2	 RNase free water	 Proteinase K		

How to deal with DIAKEY REALcheck Viral DNA/RNA Prep Kit?



If you want to get more information on this DIAKEY REALcheck Viral DNA/RNA Prep Kit, Please visit our Youtube channel and watch the video.

SHIN JIN MEDICS Youtube channel
<https://www.youtube.com/channel/UCUQINTPOdYxyGPP3fV96nVQ>

GENERAL DESCRIPTION

DIAKEY REALcheck Viral DNA/RNA Prep Kit is to extract viral DNA/RNA from various samples such as serum, plasma, cell-free body fluids, cell-culture media, tissue, swab, etc., and the kit can be safely used without using an organic solvent. Various viral DNA/RNA such as Adenovirus, Norovirus, Zika virus, HCV, HIV, Yellow fever virus, Coronavirus, etc. can be extracted with high purity result.

FEATURE

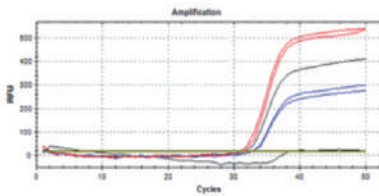
- High purity viral DNA/RNA can be extracted from various clinical samples
- High purity viral RNA can be extracted without adding carrier RNA
- Using glass fiber membrane column
- By using a non-alcoholic primary washing buffer, impurities can be removed effectively
- Easy extraction without enzyme treatment other than Proteinase K
- Can be safely extracted without using organic solvents

APPLICATION

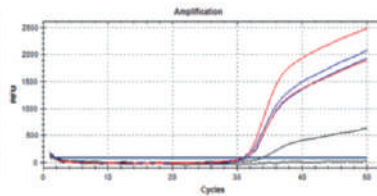
- Quantitative PCR(qPCR, qRT-PCR)
- Pathogen detection
- Poly-A selection
- cDNA synthesis
- Microarray
- Northern blot

PERFORMANCE

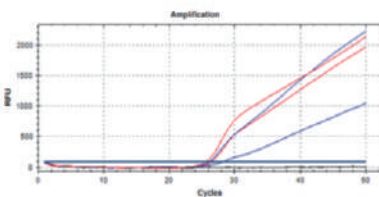
Hepatitis C virus (HCV)



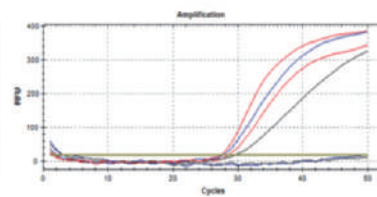
Dengue Virus (DV)



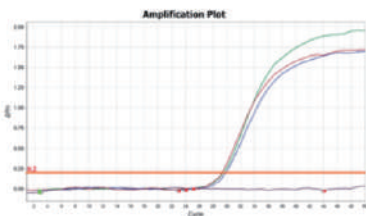
Measles Virus (MV)



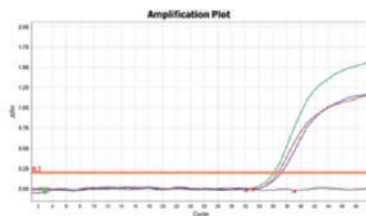
Zika Virus (ZV)



Adenovirus (DNA)



Norovirus (RNA)



ΔC_t value	SHINJIN	Q	K
HCV	31.1	35.2	32.9
DV	30.9	33.8	31.2
MV	26.0	ND	27.2
ZV	28.0	29.7	27.8

— SHINJIN MEDICS
— Q
— K

ΔC_t value	SHINJIN	Q	K
Adenovirus	29.2	29.5	29.8
Norovirus	34.7	34.8	35.0

— SHINJIN MEDICS
— Q
— K

ORDER INFORMATION

Product	Cat. No.	Prep	Box Size(mm)	Storage	Shelf Life
DIAKEY REALcheck Viral DNA/RNA Prep Kit	DP0110	100	833g, 299.5×199×150	15°C to 35°C	18 months

DIAKEY | MADE IN KOREA

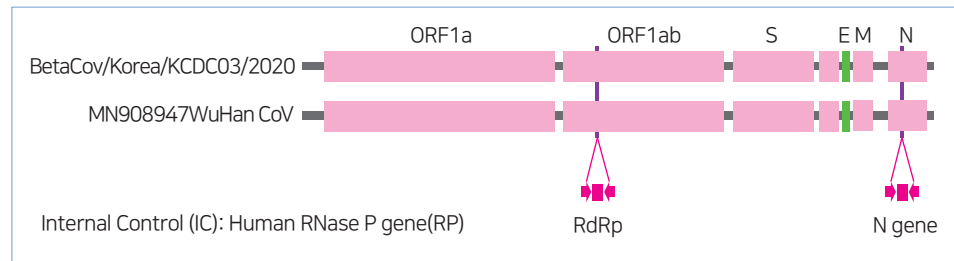
DIAKEY REALcheck COVID-19(nCOV) Detection Kit

DIAKEY REALcheck COVID-19(nCOV) Detection Kit is in vitro diagnostic reagent to qualitative detection of RdRp, N gene of COVID-19 by Multiplex OneStep qRT-PCR and for determining the presence of 2019_nCoV (COVID-19) infection in human clinical specimens such as nasal or tracheal swab samples.



DETECTION TARGET GENE

- ✓ RdRp gene
- ✓ N gene
- ✓ RP gene



COMPONENTS

2X OneStep qRT-PCR Master Mix[For Probe]	1 ml X 1 ea	<p>4 vials & 1 Insert in 1 Box</p>
PM(RdRp/N/RP Primer & Probe)	0.2 ml X 1 ea	
PC(Positive Control)	0.8 ml X 1 ea	
RNase free water	1 ml X 1 ea	

The Kit includes 2X OneStep qRT-PCR Master Mix(Including RTase, DNA Polymerase and RNase inhibitor) and PM(Primer Mixture). We also provide a PC(Positive Control(2019_nCoV)), which allows us to compare the results with clinical sample results to ensure correct interpretation of the results.

For Viral DNA/RNA Prep : **DIAKEY REALcheck Viral DNA/RNA Prep Kit**



When the procedure of viral DNA/RNA Prep, DIAKEY REALcheck Viral DNA/RNA Prep Kit can be used. To get information on how to use this Kit, Please visit our Youtube channel and watch the video.

SHIN JIN MEDICS Youtube channel

<https://www.youtube.com/channel/UCUQiNTPoDyxyGPP3fV96nVQ>

PROCEDURE

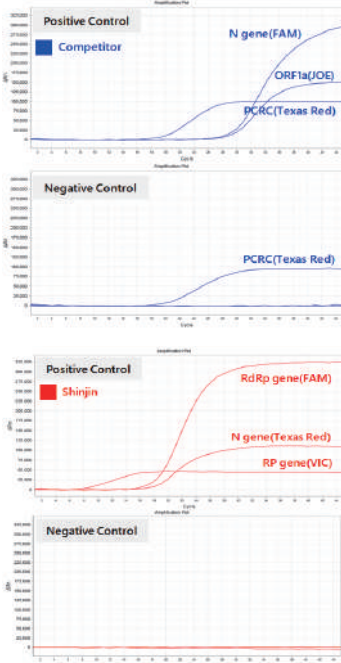
Sample Processing	RNA Preparation	Reaction Set-up	Data Analysis
Sampling swabs/sputum are pooled in a sufficient volume of sterile buffer.	DIAKEY REALcheck Viral DNA/RNA Prep Kit can be used in this step.	Reverse Transcription and Amplification (qRT-PCR)	Validity and qualitative result (Please refer to the table below).

Type	FAM	Texas Red	HEX(VIC)	Result Analysis
	RdRp gene	N gene	RP gene	
PC(Positive Control)	+	+	+	Valid
NC(Negative Control)	-	-	-	Valid
Sample 1	+	+	+/-	Positive
Sample 2	+	-	+/-	Positive
Sample 3	-	+	+/-	Positive
Sample 4	-	-	+/-	Negative

CAUTION!

It is recommended to proceed without interruption to avoid any degradation of isolated samples and reagents. If necessary, store isolated RNA at -70°C to -80°C before use and avoid repeated freezing and thawing.

SENSITIVITY



Target Gene (Competitor)	Copies No.					
	1 X 10 ⁷	1 X 10 ⁶	1 X 10 ⁵	1 X 10 ⁴	1 X 10 ³	1 X 10 ²
N	13.48	18.46	22.17	25.48	29.31	32.34
ORF1a	14.85	19.98	23.57	26.88	30.53	33.27
Ct AVE	14.17	19.22	22.87	26.18	29.92	32.81

Target Gene (SHIN JIN)	Copies No.					
	1 X 10 ⁷	1 X 10 ⁶	1 X 10 ⁵	1 X 10 ⁴	1 X 10 ³	1 X 10 ²
RdRp	13.65	19.37	22.76	26.14	29.73	32.67
N	15.45	20.99	23.90	26.99	30.38	33.15
Ct AVE	14.55	20.18	23.33	26.57	30.06	32.91
Agreement(%)	97.35	95.24	98.03	98.55	99.55	99.68

ORDER INFORMATION

Product	Cat. No.	Test	Box Size(mm)	Storage	Shelf Life
DIAKEY REALcheck COVID-19(nCOV) Detection Kit	MF01	100	27g, 50×70×55	-20°C to -15°C	6 months