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Product details

Product details	
Name of product	*AccuPower®* SARS-CoV-2 Real-Time RT-PCR Kit (Product Code : SCV-2122)
Manufacturer	8-11, Munpyeongseo-ro, Daedeok-gu, Daejeon 34302 Republic of Korea
Test description	• *Intended use of the product:* *AccuPower®* SARS-CoV-2 Real-Time RT-PCR Kit is an in vitro diagnostic kit that helps diagnose COVID-19(Coronavirus disease 2019). This kit is designed for the detection of SARS-CoV-2 (E gene and RdRp gene) RNA from a COVID-19(Coronavirus disease-19) suspected patient's sample such as sputum, nasopharyngeal swab, oropharyngeal swab through Real-Time Polymerase chain reaction (PCR). • *Sample type :* RNA from a suspected infection patient's sample (such as sputum, nasopharyngeal swab, oropharyngeal swab) • *Gene target(s)* E gene and RdRp gene • *Reagents included in the kit* The kit includes :

	Reagent	Quantity	Unit
①	Master Mix	1,000 ㎕/tube X 1 ea	1.5ml tube (green cap)
②	Enzyme Mix	500 ㎕/tube X 1ea	1.5ml tube (red cap)
③	Oligo Mix 1*	250 ㎕/tube X 1 ea	1.5ml tube (amber)
④	Oligo Mix 2	250 ㎕/tube X 1 ea	1.5ml tube (amber)
⑤	Positive Control (PC)	150 ㎕/tube X 1 ea	1.5ml tube (blue cap)

***Oligo Mix 1 :There is a green band on label's right side.**

• *Control material*
The Kit includes a positive control as indicated above

• *Number of reactions per kit*
50 tests / kit

• *Storage condition*
Below -20 ℃ for 6 months

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- *PCR platform compatibility*

  [Applicable Real-Time PCR instrument]

  ✓ ABI 7500 Fast Real-Time PCR System, Thermo Fisher Scientific, Cat.No. 4351106

  ✓ CFX96 Real-Time PCR Detection System, BIO-RAD, Cat.No. 1845096

  ✓ ExiCycler™96 Real Time PCR System, Bioneer Inc. Co., Cat. No. A-2060, A-2060-1

- *Extraction system compatibility*

  * For Nucleic acid extraction equipment, it is allowable that the extraction instrument that already installed can be used and proceed according to proper procedure under laboratory environment condition.

Analytical performance

The brief summary of the analytical performance of the applied product is following :

1 Limit of detection

Instrument	Target	LoD	95 % CI
ABI7500	E gene	9.77 copies/reaction	6.11~14.13 copies/reaction
	RdRp gene	6.92 copies/reaction	4.79~10.00 copies/reaction
CFX96™	E gene	6.76 copies/reaction	5.37~8.51 copies/reaction
	RdRp gene	6.76 copies/reaction	5.37~8.51 copies/reaction
Exicycler™ 96 Ver.3	E gene	6.03 copies/reaction	4.57~8.13 copies/reaction
	RdRp gene	6.92 copies/reaction	5.01~9.33 copies/reaction
Exicycler™ 96 Ver.4	E gene	6.76 copies/reaction	4.27~10.96 copies/reaction
	RdRp gene	6.03 copies/reaction	4.47~8.13 copies/reaction

2 Measurement range

The measuring range of the kit is 1.0 X 10^9copies / reaction to 1.0X10^1copies /reaction.

Target	Measurement Range
E gene	1.0X10^1~1.0X10^9 copies/reaction
RdRP gene	1.0X10^1~1.0X10^9 copies/reaction

3 ***Cross reactivity***

– the following 20 viruses were verified that there is no cross-reactivity.

Human Influenza virus A H3N2	Human Rhinovirus 14 (type B)	*Mycobacterium fortuitum*
Human Influenza virus B (Texas/6/11) (Victoria)	Human Metapneumovirus type 3	*Mycobacterium intracell*
Human Coronavirus 229E	Human Adenovirus type 3 (type B)	*Mycobacterium gordonae*
Human Coronavirus NL63	Enterovirus 70	*Mycobacterium chelonae*
Human Coronavirus OC43	Coxsackievirus B5	*Mycobacterium tuberculosis H37Rv*
Human Respiratory syncytial virus A	Echovirus 25	MERS-CoV
Human Respiratory syncytial virus B	Human Parechovirus 3	

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4 Interfering substance

The test substance containing the interfering substance was found to have a result within SD <2 , CV<5% compared to control.

Substances	*Concentration*	*Result findings*
Control	-	-
Napazoline hydrochloride	*5 μg/mℓ*	*No interference*
Xylomethazolin hydrochloride	*1 mg/mℓ*	*No interference*
Oxytetracycline Hydrochloride	*5 mg/g*	*No interference*
Hemoglobin	*40 mg/mℓ*	*No interference*
Human Whole blood	*10 ng/ul*	*No interference*
EDTA	*540 mg/dℓ*	*No interference*

5 Precision

To evaluate the repeatability of AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit, within-run, between-run, between-day, and total precision were determined. 2 replicates of three different concentrations of Positive Controls (1x PC, 1/10x PC, 1/1000x PC) per run were tested twice per day for 10 days. The standard deviation (SD) of the assay results are shown in Table.

Target	concentration (copy/rxn)	Within-run(SD)	Between-run(SD)	Between-day(SD)	Total precision(SD)
E gene	1×10^5	0.09	0.06	0.02	0.11
	1×10^4	0.06	0.03	0.04	0.08
	1×10^2	0.13	0.12	0.04	0.18
RdRp gene	1×10^5	0.07	0.06	0.04	0.10
	1×10^4	0.12	0.11	0.07	0.18
	1×10^2	0.12	0.08	0.03	0.15

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