RADI COVID-19 Detection Kit

REF: RV008



Get the result within 80 min for all suspected cases for 2019 novel coronavirus!

Introduction

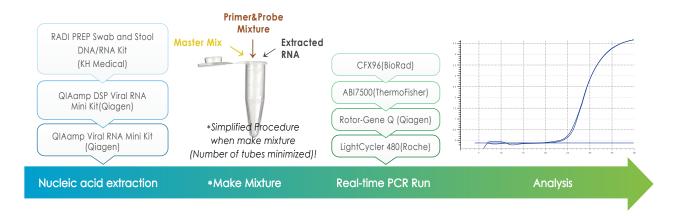
RADI COVID-19 Detection Kit is used for qualitative detection of 2019 novel coronavirus in human Nasal Swab or Sputum by using ABI 7500, Bio-Rad CFX 96 Platform, etc.

Product Specification



RADI COVID-19 Detection Kit			
Intended use	Qualitative detection of COVID-19		
Specimen type	RNA extracted in nasal swab or Sputum		
Target RdRP, S			
Product contents	 3X RT MasterMix (Yellow) COVID-19 Primer & Probe Mixture (Brown) COVID-19 positive control (Red) RNase free water (Blue) 		
LoD	0.66 copies/µl		
Storage condition	-25°C ~ -15°C		

Test Procedure



Ordering Information

KHMedical Ref	Product Name	Shelf Life	A.Menarini Ref
RV008	RADI COVID-19 Detection Kit	6 months	51586
MP002	RADI PREP Swab and Stool DNA/RNA Kit	18 months	51608
MPA004	Carrier Molecule	18 months	51607



Performance of RADI COVID-19 Detection Kit

Analytical Sensitivity (Limit of Detection)

To test the Sensitivity and Limit of Detection(LoD) of RADI COVID-19 Detection Kit, synthesized RNA by in vitro transcription was diluted to 4 concentrations and ran 24 times for each.

LoD is 0.66 copies/μθ

Target	Copies/µℓ	Mean Ct	Result in agreement	Percent agreement
	1.66	37.62	24/24	100%
S gene	0.66	39.88	23/24	95.83%
3 gene	0.5	40.18	24/24	100%
	0.33	39.57	20/24	83.32%

Target	Copies/µl	Mean Ct	Result in agreement	Percent agreement
RdRP gene	1.66	36.55	24/24	100%
	0.66	38.06	23/24	95.83%
	0.5	39.08	22/24	91.66%
	0.33	38.47	21/24	87.49%

*IPC mean Ct: 22.93

Cross Reactivity

RADI COVID-19 Detection KIT did not cross-react with any of 53 pathogens.

Comparative Evaluation by using WHO published Primer & Probe

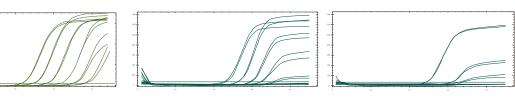
RADI COVID-19 Detection Kit's Primer & Probe design could detect up to 10 copies/rxn compared to WHO Primer & Probe which detect up to 10² copies/rxn for E gene and 10³ copies/rxn for RdRP gene.

	RADI COVID-19 Detection KIT			
Copies/rxn	S gene		RdRP	gene
106	21.06	21.2	21.46	21.63
10 ⁵	25.05	24.97	25.01	24.65
10 ⁴	28.99	29.22	28.22	28.29
10 ³	32.47	32.62	31.96	31.81
10 ²	36.51	36.41	35.4	35.18
10	39.95	39.66	39.18	38.05

WHO primer & probe					
E gene		RdRP gene			
23.24	22.72	24.75	24.78		
26.48	26.34	28.17	28.12		
29.90	29.88	31.44	31.31		
32.48	32.26	34.61	33.72		
35.69	36.76	N/A	N/A		
N/A	N/A	N/A	N/A		

WHO primer & probe

RADI COVID-19 Detection KIT



S gene

RdRP gene

E gene

RdRP gene





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