



OBTEQ JT REM COVID-19 qRT-PCR Kit



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OBTEQ JT REM COVID -19 qRT-PCR KT

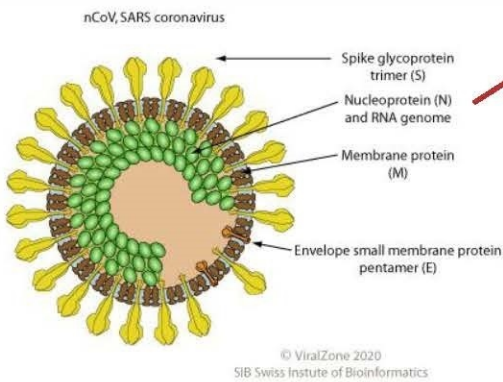
JT REM COVID-19 qRT-PCR Kit is used for *in vitro* diagnostics of novel coronavirus (SARS-CoV-2) in human oropharyngeal and nasopharyngeal swab and sputum samples. JT REM COVID-19 qRT-PCR uses Real-time RT-PCR. SARS-CoV-2 is first transcribed into cDNA by reverse transcriptase, and then cDNA is used as a template for PCR amplification. Primer and fluorescent probe were set to the N gene site in reference to US FDA's "FAQs on Diagnostic Testing for SARS-CoV-2. JT REM COVID-19 qRT-PCR can determine positive results through reaction of increased amount of fluorescent Tagman probe contained in the reagent, in real time.

Product Name	JT REM COVID-19 qRT-PCR Kit
Packaging Unit	96 tests/kit, box
Target Gene	N gene (SARS-CoV-2)
Running Time	1 hour 40 minutes
Storage	-20°C or below
Shelf-life	1 year from manufacturing date
Clinical Trial Results *	Positive Predictive Value (PPV) = 100% (95% CI 88.78-100) Negative Predictive Value (NPV) = 100% (95% CI 90.00-100)
Manufacturing	GMP for Pharmaceuticals, GMP for Medical Devices, ISO 13485:2016
Highly Recommended Machine	Bio-Rad CFX96, Thermo Fisher Scientific AB7500, Roche LC96

* We performed clinical trial based on 31 positive and 35 negative clinical samples in accordance with FDA's Emergency Use Authorization clinical study guidelines

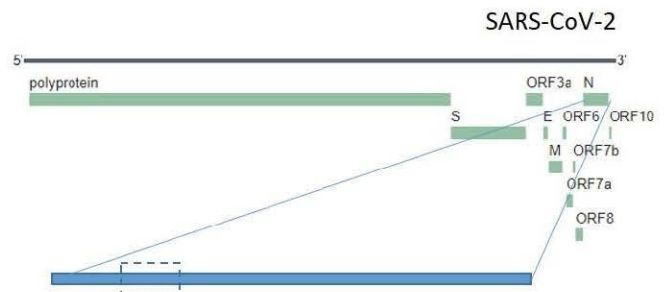
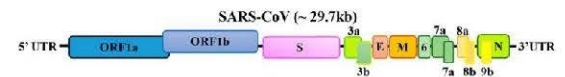
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Target Gene



Target : N gene

US CDC recommends N gene of SARS-CoV-2 for Real-Time PCR



Amplifying the target gene regardless of mutation

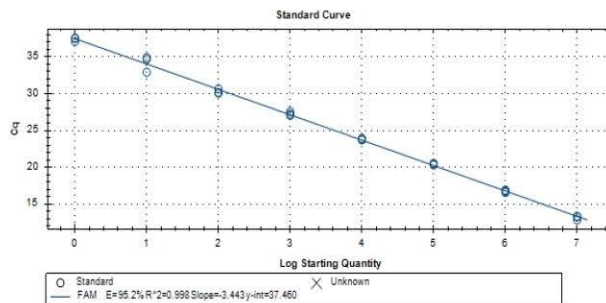
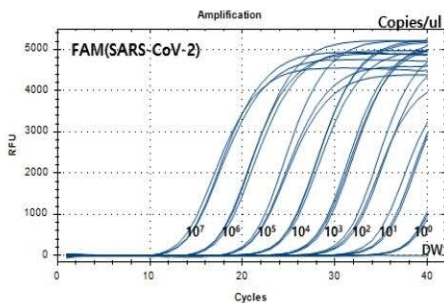
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Sensitivity

Diluted SARS-CoV-2 was detected with high sensitivity, with linearity.

LOD: 5 copies/μl



• Rxn cycle

50°C	30min
95°C	15min
95°C	5s
↻ 40cycle	
55°C	30s
4°C	10s

Lane	1	2	3	4	5	6	7	8	9	
Name	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Standard RNA	Negative Control	
Conc. (Copies/μl)	10 ⁷	10 ⁶	10 ⁵	10 ⁴	10 ³	10 ²	10 ¹	10 ⁰	-	
Result*	P	P	P	P	P	P	P	P	N	
Ct values	1	13.32	16.76	20.35	23.81	27.56	30.07	34.63	37.52	-
	2	12.88	16.59	20.50	23.74	27.06	30.15	32.9	37.08	-
	3	13.34	16.91	20.51	23.91	27.23	30.65	34.89	37.50	-
Mean	13.18	16.75	20.45	23.82	27.28	30.29	34.14	37.37	-	
STD	0.26	0.16	0.09	0.09	0.25	0.31	1.08	0.25	-	
CV%	1.97	0.96	0.44	0.36	0.93	1.04	3.17	0.66	-	

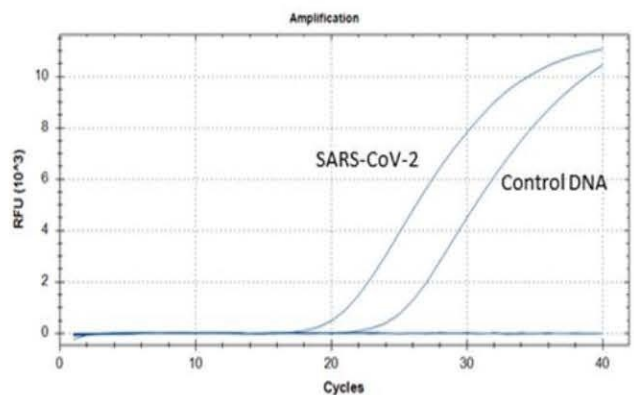
* P: Positive, N: Negative

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Specificity

No.	Virus	Result *
1	SARS-CoV-2 (β coronavirus)	P
2	MERS-CoV (β coronavirus)	N
3	HCoV-NL63 (α coronavirus)	N
4	Human Influenza A (CA/04, H1N1)	N
5	Human Influenza H3N2	N
6	Human Influenza B (Vic)	N
7	PED(SM98) (α coronavirus)	N

* P: Positive, N: Negative



JT REM COVID-19 qRT-PCR Kit
specifically detects SARS-CoV-2.

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Instruction for Use

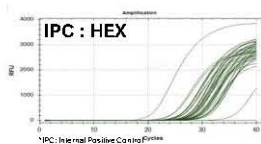
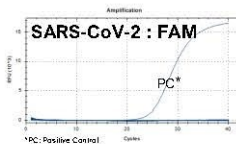
1. Preparation of reagent and extracted RNA
2. qRT-PCR



* Real-time PCR Machine: CFX96 (Bio-Rad)

Step	PCR Program (20µl reaction)		
	Temp	Time	Cycle
cDNA synthesis	50°C	30 min	1 cycle
Initial inactivation	95°C	15 min	1 cycle
Denaturation	95°C	5 sec	40 cycles
Elongation	55°C	30 sec	
Hold	4°C	10 sec	1 cycle

3. Reading



4. Data Analysis and Interpretation

Item	Fluorescent		Result
	FAM(SARS-CoV-2)	HEX(Human B2M)	
SAMPLE 1	+	+/- *	Positive
SAMPLE 2	-	+	Negative
SAMPLE 3	-	-	False Negative/Retest

* According to EUA summary (FDA), a high SARS-CoV-2 (target N gene) RNA load in the sample can lead to reduced or absent Internal Positive Control(IPC), thus making the test result positive.