

H.K.C.C.- INTERNATIONAL

Dear Sir, Madame,

Let me first introduce myself, my name is [REDACTED] 5.1.2e and [REDACTED] 5.1.2e for Mico Biomed in the Netherlands.

By means of this email I would like to offer you the Molecular Diagnostics Products for the Covid-19. The relevant information regarding the Molecular Diagnostics products is annexed hereto. The Cov-19 products meet the provisions of the WHO and EU Council as well.

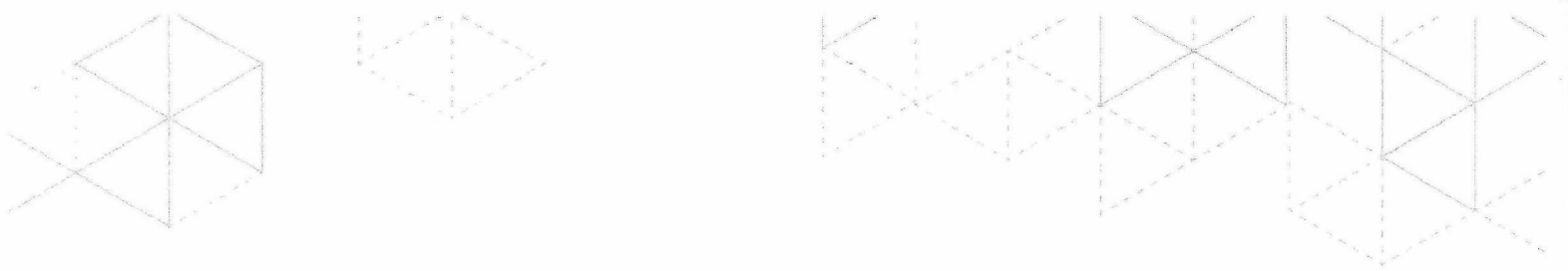
I would be most grateful if you would look into this matter at your earliest convenience and looking forward to hearing from you soon.

Sincerely,

[REDACTED] 5.1.2e

H.K.C.C. - INTERNATIONAL | ABN AMRO: NL06 ABNA 0610 3649 01 | KVK: 76245306

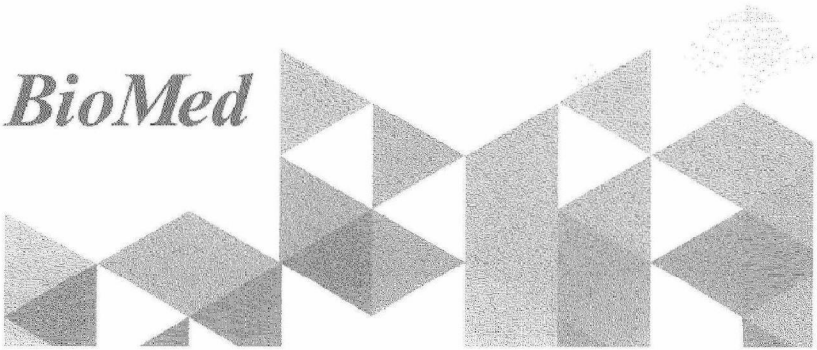
E-mail: [REDACTED] 5.1.2e @gmail.com | [REDACTED] 5.1.2e



Molecular Diagnostics for COVID-19

March 24, 2020

MiCo BioMed

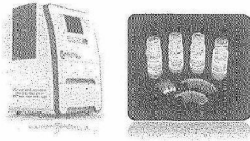


MiCo BioMed Products

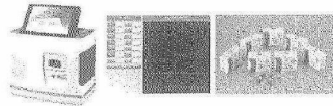
MiCo BioMed
Easy Answer to Life

LabChip-based Rapid POCT

1. Veri-Q PREP M16 & Kits

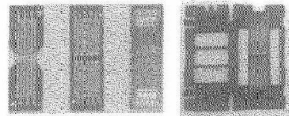


2. Veri-Q PCR 316 & Kits



RT-qPCR S/W & Diagnostic Kits

3. Veri-Q PCR LabChips & Case



**Molecular
Diagnostics**

LabChip-based
qPCR, Sample Prep
& Diagnostic Kits

**Biochemical
Diagnostics**

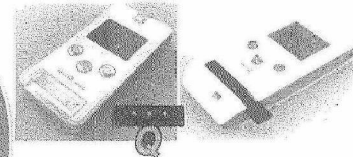
Biochemical Diagnostic
System and Strips
(Cholesterol, Hb,
Glucose)

MiCo BioMed

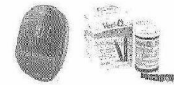
**Immunological
Diagnostics**

Rapid Microfluidic
Immunoassay System
(Optimizer, Assay Kits)

1. Blood Cholesterols



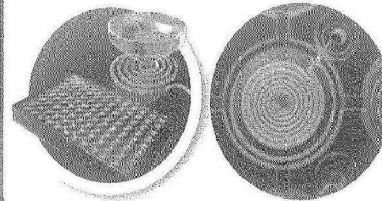
2. Blood Glucose



3. Hemoglobin



ELISA & Immunoassay
1~300X More Sensitive



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MiCo BioMed System

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VERI-Q PCR 316



LabChip

Disposable plastic
real-time PCR LabChip

Touch Screen

No need computer for operation

Easy-to-Use

User-friendly software

Mobile &
Battery

Mobile size (4.5 kg) &
Battery operation (12/24V)

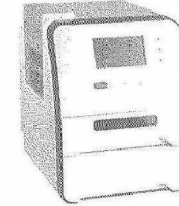
Ultrafast

Ultrafast real-time PCR with
dual-heat block

Data
Communication

Data transfer via internet

VERI-Q Prep M16



Compact

Disposable plastic
membrane column

Affordable

Inexpensive test cost

Easy-to-Use

Simple operation

Multiplexing

1 - 16 sample prep

Ultrafast

5-30 mins for 1-16 extraction




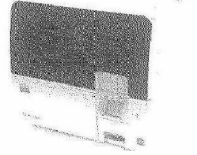
High
performance

Excellent extraction yield

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Sample Prep Comparison

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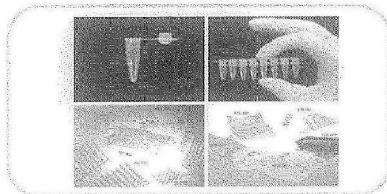
Company	MiCo BioMed	A	B	C
Name	Veri-Q PREP M16	MOOO	TOOO	QOOO
Figure				
Specimen type	Blood, serum, plasma, swab, tissue, sputum, food, etc.	Blood, serum, plasma, respiratory swab, etc.	Blood, serum, plasma, respiratory swab, etc.	Blood, serum, swab, tissue, sputum, etc.
Test number	1 - 16	1 - 16	1 - 8	1 - 12
Principle	<ul style="list-style-type: none"> ✓ Glass fiber filter ✓ Tube type 	<ul style="list-style-type: none"> ✓ Magnetic bead ✓ Cartridge type 	<ul style="list-style-type: none"> ✓ Magnetic bead 	<ul style="list-style-type: none"> ✓ Glass fiber filter ✓ Tube type
Running time	5 ~ 30 min	30 ~ 60 min	30 ~ 40 min	50 ~ 80 min
Weight	12 kg	11 kg	5 kg	70 kg
Etc.	✓ Semi-automation	✓ Semi-automation	✓ Semi-automation	✓ Semi-automation

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LabChip-based qPCR

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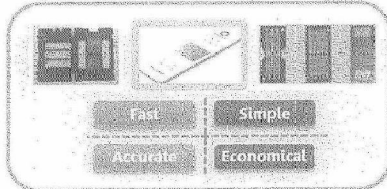
Tube-type Real-time PCR



60-120 min for 45 cycles of qPCR



LabChip-type Real-time PCR



25-40 min for RT & 45 cycles of qPCR

"Patents registered over 17 countries"

	<u>Tube-type Real-time PCR</u>		<u>LabChip-type Real-time PCR</u>
	A사 (A****)	B사 (C****)	MiCo BioMed (veri-Q PCR316)
Figure			
Test number	96	96	16
Tube type	Plate/ Strip	Plate/ Strip	LabChip
Fluorescent channel	5	5	4
Run time(45 cycles)	60-120 min	60-120 min	25-40 min
Weight	34kg	30kg	4.7kg
Property	<ul style="list-style-type: none"> • Large & heavy • Long running time • Expensive 		<ul style="list-style-type: none"> • Stand-alone • Fast running time • Battery operation • Bluetooth/Data Transfer via Smart Phone • Printing out • Affordable

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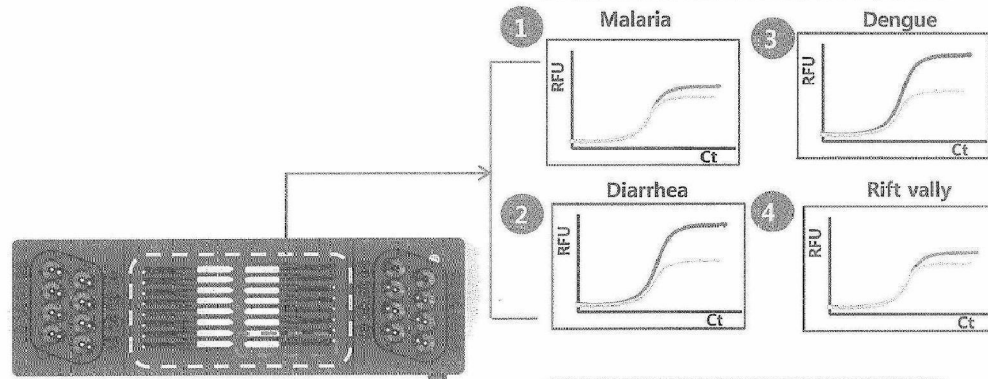
Multi Detection

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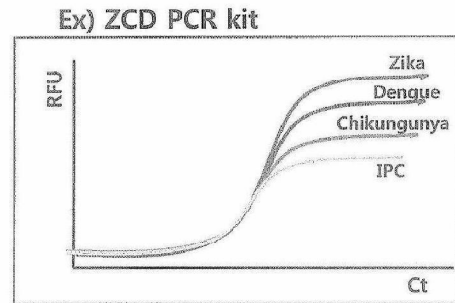
Multi Detection Panels

Fever Panel	Diarrhea Panel
Malaria (Pan/Pf/Pv) Zika Dengue Chikungunya Yellow fever Rift vally fever Malaria(Pm/Po/Pk)	V. Cholera Salmoella spp. Shigella Campylobacter Entrotoxigenic E. Coli Entameoba histolytica
Respiratory Panel	
MTB/MDR Influenza A B RSV SARS MERS 2019-nCoV	

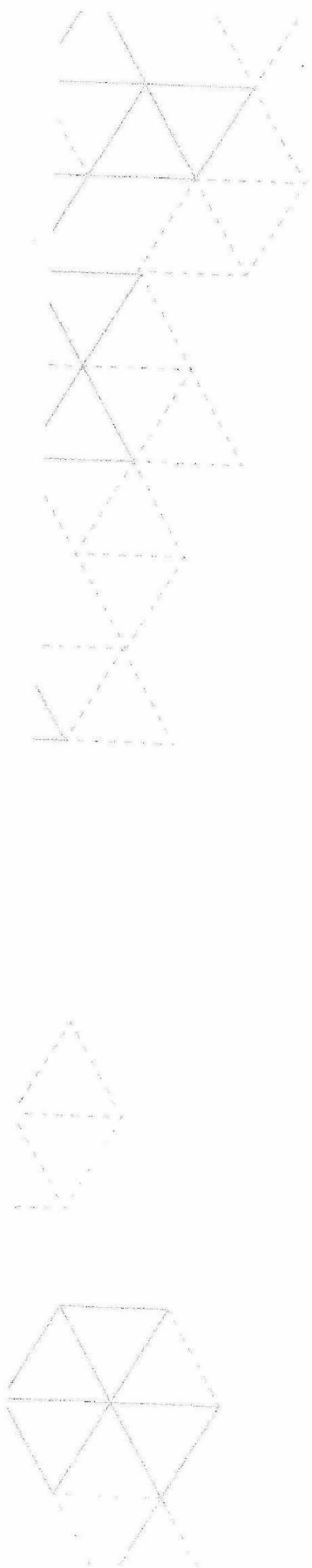
14 diseases /1 Chip



Multi Targets /1 Channel

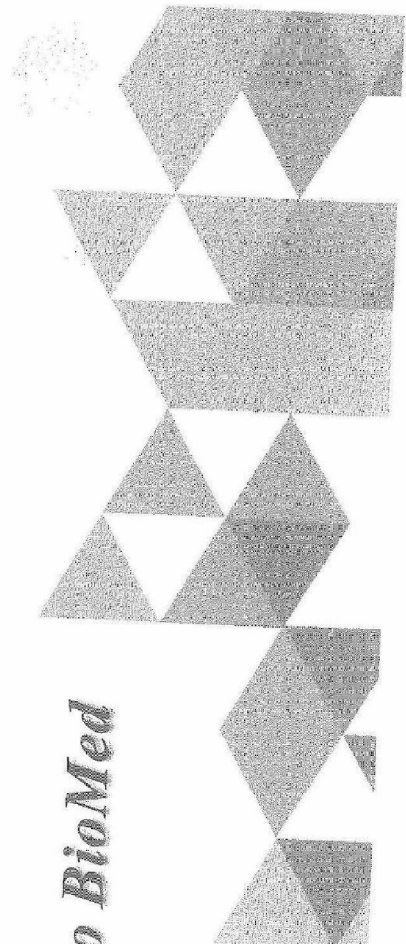


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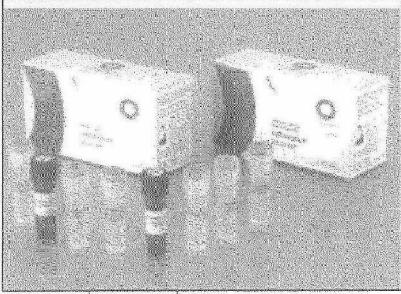
COVID-19 Detection Kit

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MBM COVID-19 Detection Kit

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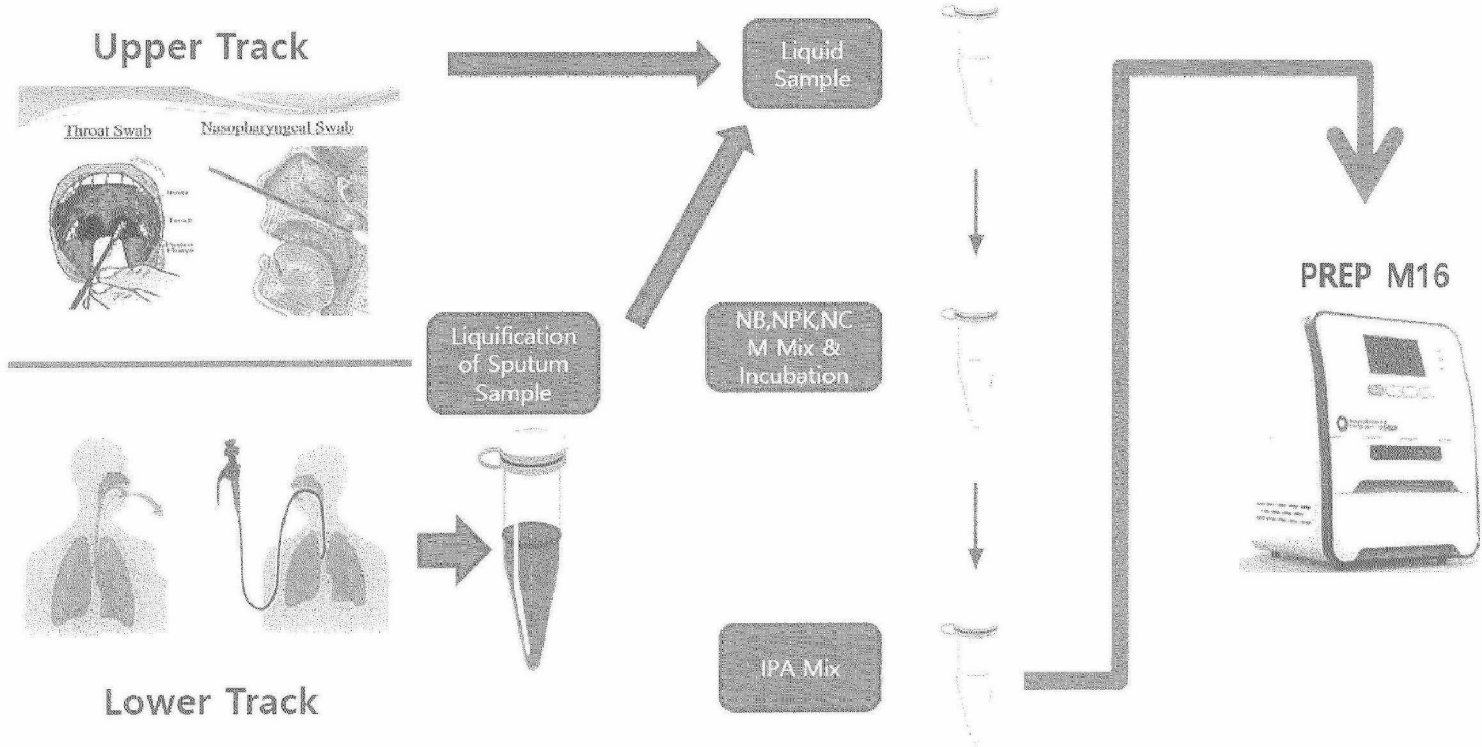


No.	Part Name	Part Label	Contents	Cap Color
1	2X One-Step RT-PCR Master mix	nCoV-QS-MMGR06	Real time PCR Master mix	Violet
2	Primer/Probe mix1	nCoV-QS-PPM1	Primer/Probe Mix1	Brown
3	Primer/Probe mix2	nCoV-QS-PPM2	Primer/Probe Mix2	Brown
4	Positive control	nCoV-QS-PC	Positive control DNA	Red
5	Internal positive control	nCoV-QS-IPC	Internal positive control	Yellow
6	Ultra pure water	nCoV-QS-DW	Ultra pure water	Green

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RNA Extraction

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Real-time PCR Result

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[Determination of Fluorescent dye and Threshold Line]

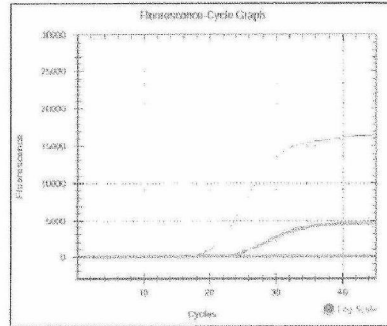
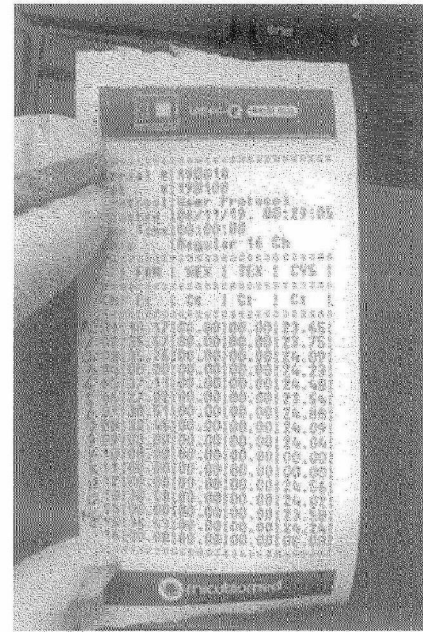
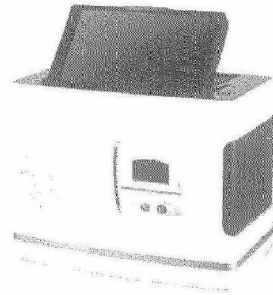
Target	Target	Fluorescent dye	Threshold	Cut-off Ct value
nCoV-QS-PPM1	nCoV	FAM	1000	< 40
	IPC	Cy5	1500	< 40
nCoV-QS-PPM2	nCoV	Cy5	1500	< 40
	IPC	HEX	500	< 40

※ Threshold line for Veri-Q PCR 316 machine.

[Results]

Sample	nCoV-QS-PPM1		nCoV-QS-PPM2		Result
	nCoV	IPC	nCoV	IPC	
	FAM	Cy5	Cy5	HEX	
Negative Control	-	-	-	-	Valid
Control	+/-	-	+/-	-	Invalid, re-test
Positive Control	+	+	+	+	Valid
Control	+/-	-	+/-	-	Invalid, re-test
Case 1	-	+	-	+	Negative
Case 2	+	+/-	-	+/-	nCoV
Case 3	+	+/-	-	+/-	Invalid, re-test
Case 4	-	+/-	+	+/-	Invalid, re-test
Case 5	-	-	-	-	Invalid, re-test

※ IPC may not be reduced or appeared due to higher amplification of other target genes.



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Sensitivity & Specificity

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Veri-Q
PCR316

No.	Organism	FP1		FP2	
		Target	IPC	Target	IPC
1	Human gDNA	N/D	26.88	N/D	25.06
2	Influenza virus A_H1	N/D	26.68	N/D	25.12
3	Influenza virus A_H3N2	N/D	26.83	N/D	25.09
4	Influenza virus B	N/D	27.05	N/D	25.44
5	Respiratory syncytial virus A	N/D	26.86	N/D	25.9
6	Respiratory syncytial virus B	N/D	26.98	N/D	25.33
7	Parainfluenza virus Type1	N/D	27.15	N/D	25.69
8	Parainfluenza virus Type2	N/D	26.85	N/D	25.29
9	Parainfluenza virus Type3	N/D	26.32	N/D	25.35
10	Adenovirus B-3	N/D	26.44	N/D	24.67
11	Adenovirus C-1	N/D	26.54	N/D	25.35
12	Adenovirus C-2	N/D	26.48	N/D	25.11
13	Enterovirus	N/D	26.37	N/D	25.12
14	Rhinovirus	N/D	26.15	N/D	24.99
15	Metapneumovirus	N/D	26.6	N/D	25.36
16	Coronavirus NL63	N/D	26.16	N/D	25
17	Coronavirus 229E	N/D	26.03	N/D	25.05
18	Coronavirus OC43	N/D	25.91	N/D	25.03
19	Coronavirus HKU-1	N/D	25.72	N/D	25.18
20	Coronavirus SARS	N/D	26.08	N/D	25.1
21	MERS	N/D	26.05	N/D	25.08
22	Chlamydia pneumoniae	N/D	26.12	N/D	25.32
23	Bordetella pertussis	N/D	26.18	N/D	25.22
24	Malaria(Plasmodium falciparum)	N/D	26.17	N/D	24.83
25	Dengue virus type1	N/D	26.2	N/D	25.32
26	Dengue virus type2	N/D	26.06	N/D	25.19
27	Dengue virus type3	N/D	26.26	N/D	24.98
28	Dengue virus type4	N/D	26.05	N/D	24.94
29	Haemophilus influenzae	N/D	25.99	N/D	25.56
30	Streptococcus pneumoniae	N/D	26.12	N/D	25.46
31	Streptococcus pyogenes	N/D	26.13	N/D	25.48
32	Seoul virus	N/D	25.99	N/D	25.36
33	West Nile virus	N/D	25.94	N/D	25.18
34	Yellow fever virus	N/D	26.18	N/D	25.27
35	Lassa virus (LASV)	N/D	26.04	N/D	25.3
36	Rift valley fever virus(RVVF)	N/D	25.93	N/D	25.57
37	Hantaan virus	N/D	25.93	N/D	25.67
38	Rickettsia powazekii	N/D	25.77	N/D	25.66
39	Rickettsia typhi	N/D	26.11	N/D	25.4
40	Salmonella typhi	N/D	25.92	N/D	25.5
41	Staphylococcus aureus	N/D	26.05	N/D	25.19
42	Yersinia enterocolitica	N/D	26.05	N/D	25.11
	Positive control	26.08	27.02	24.84	25.28
		25.73	25.97	24.57	25.22
		25.81	26.31	25.04	25.77
		N/D	26.48	N/D	24.57
	Negative Control	N/D	27.02	N/D	25.07
		N/D	25.83	N/D	25.26

BioRad
CFX96

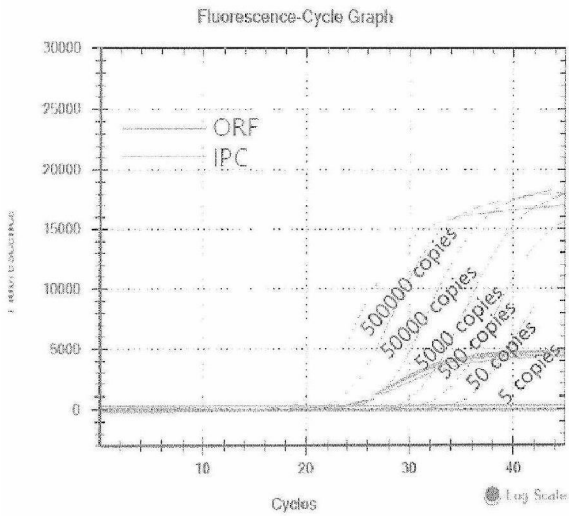
No.	Organism	FP1		FP2	
		Target	IPC	Target	IPC
1	Human gDNA	N/A	26.12	N/A	26.38
2	Influenza virus A_H1	N/A	27.81	N/A	26.36
3	Influenza virus A_H3N2	N/A	27.87	N/A	26.21
4	Influenza virus B	N/A	27.97	N/A	26.47
5	Respiratory syncytial virus A	N/A	27.96	N/A	26.41
6	Respiratory syncytial virus B	N/A	27.94	N/A	26.35
7	Parainfluenza virus Type1	N/A	27.96	N/A	26.16
8	Parainfluenza virus Type2	N/A	27.93	N/A	26.19
9	Parainfluenza virus Type3	N/A	27.79	N/A	26.07
10	Adenovirus B-3	N/A	28.51	N/A	25.6
11	Adenovirus C-1	N/A	27.92	N/A	27.19
12	Adenovirus C-2	N/A	26.42	N/A	26.79
13	Enterovirus	N/A	26.49	N/A	26.21
14	Rhinovirus	N/A	27.7	N/A	26.21
15	Metapneumovirus	N/A	26.32	N/A	26.65
16	Coronavirus NL63	N/A	28.08	N/A	26.4
17	Coronavirus 229E	N/A	27.94	N/A	26.38
18	Coronavirus OC43	N/A	28.02	N/A	26.28
19	Coronavirus HKU-1	N/A	27.95	N/A	26.32
20	Coronavirus SARS	N/A	27.91	N/A	26.26
21	MERS	N/A	27.82	N/A	26.17
22	Chlamydia pneumoniae	N/A	28.87	N/A	26.47
23	Bordetella pertussis	N/A	27.79	N/A	26.37
24	Malaria(Plasmodium falciparum)	N/A	28.04	N/A	26.07
25	Dengue virus type1	N/A	27.43	N/A	26.21
26	Dengue virus type2	N/A	28.04	N/A	26.38
27	Dengue virus type3	N/A	27.98	N/A	26.24
28	Dengue virus type4	N/A	27.81	N/A	26.41
29	Haemophilus influenzae	N/A	27.94	N/A	26.26
30	Streptococcus pneumoniae	N/A	27.86	N/A	25.18
31	Streptococcus pyogenes	N/A	27.91	N/A	26.25
32	Seoul virus	N/A	27.8	N/A	26.62
33	West Nile virus	N/A	27.59	N/A	27.98
34	Yellow fever virus	N/A	27.8	N/A	26.21
35	Lassa virus (LASV)	N/A	27.99	N/A	25.69
36	Rift valley fever virus(RVVF)	N/A	27.97	N/A	26.38
37	Hantaan virus	N/A	28	N/A	26.57
38	Rickettsia powazekii	N/A	28.24	N/A	26.51
39	Rickettsia typhi	N/A	27.82	N/A	26.47
40	Salmonella typhi	N/A	27.75	N/A	26.34
41	Staphylococcus aureus	N/A	27.88	N/A	26.38
42	Yersinia enterocolitica	N/A	27.79	N/A	26.22
	Positive control	28.23	27.99	26.84	26.27
	Negative Control	N/A	27.56	N/A	28.81

MiCoBioMed
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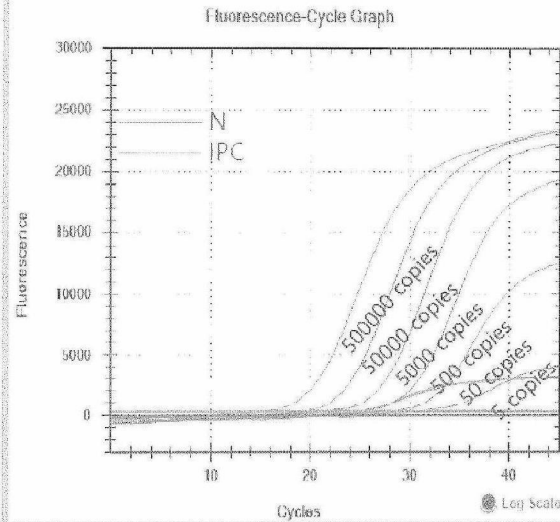
Real-time PCR Result

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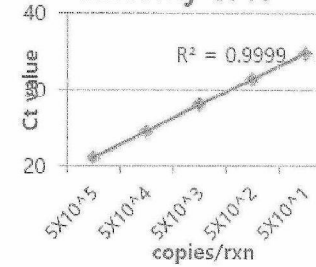
Reagent 1 for ORF Gene Detection



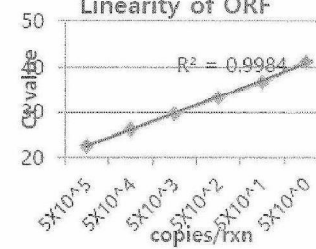
Reagent 2 for N Gene Detection



Linearity of N



Linearity of ORF

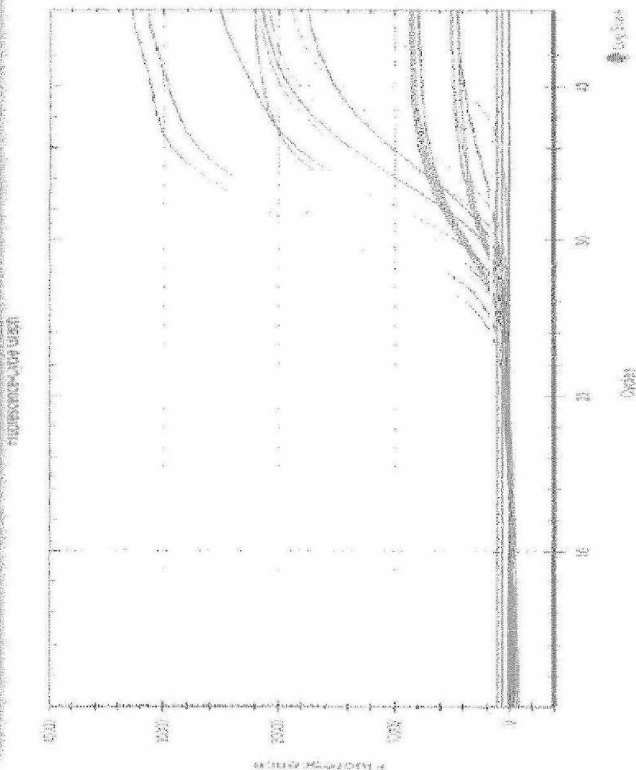


	ORF gene	N gene
Veri-Q PCR316 (LOD)	11 copies/rxn	10-15 copies/ rxn

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COVID-19 Detection from Real Patients

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Fluor	FAM	Cy5	Cy5	HEX	MBM qPCR	GZ qPCR
Target gene	ORF	IPC	N	IPC		
#1 (Upper)	28.63	26.46	27.56	25.63	POS	POS
#2 (Lower)	29.99	26.89	28.9	25.53	POS	POS
#3 (Lower)	31.16	26.74	29.83	25.52	POS	POS
#4 (Lower)	25.52	26.54	25.84	25.38	POS	POS
#5 (Upper)	36.46	26.39	32.13	25.33	POS	POS
PC	25.71	26.61	24.78	25.39	-	-
NC	N/D	26.29	N/D	25.32	-	-

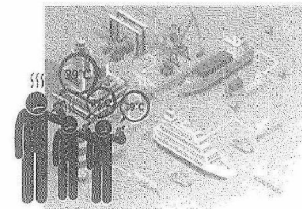
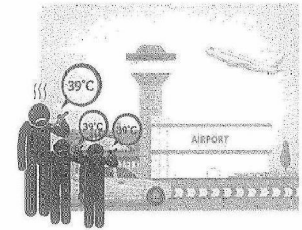
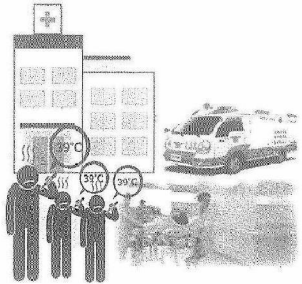


- Five patients samples were tested using LabChip-based real-time PCR.
- All results were the same as clinical results and other real-time PCR results.

Rapid RT- qPCR Test for COVID-19

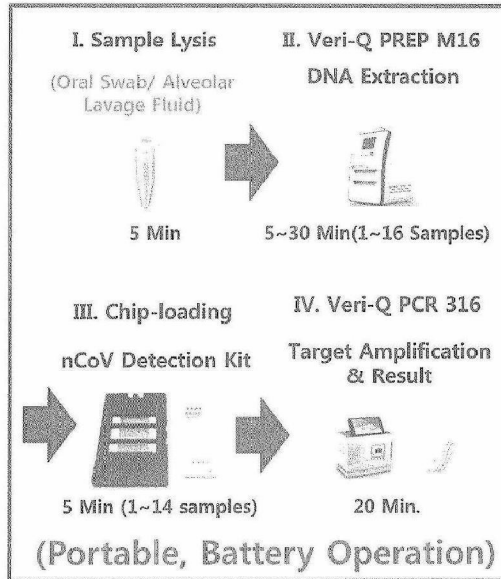
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On-site



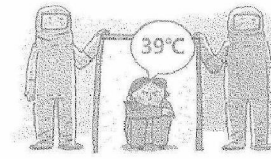
Molecular Diagnostics

within 1hr

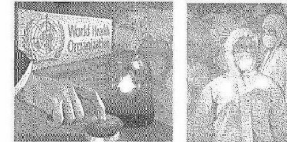


6 Patients/ One Test
Early Confirmatory Detection

Isolation & Care



Patient Isolation

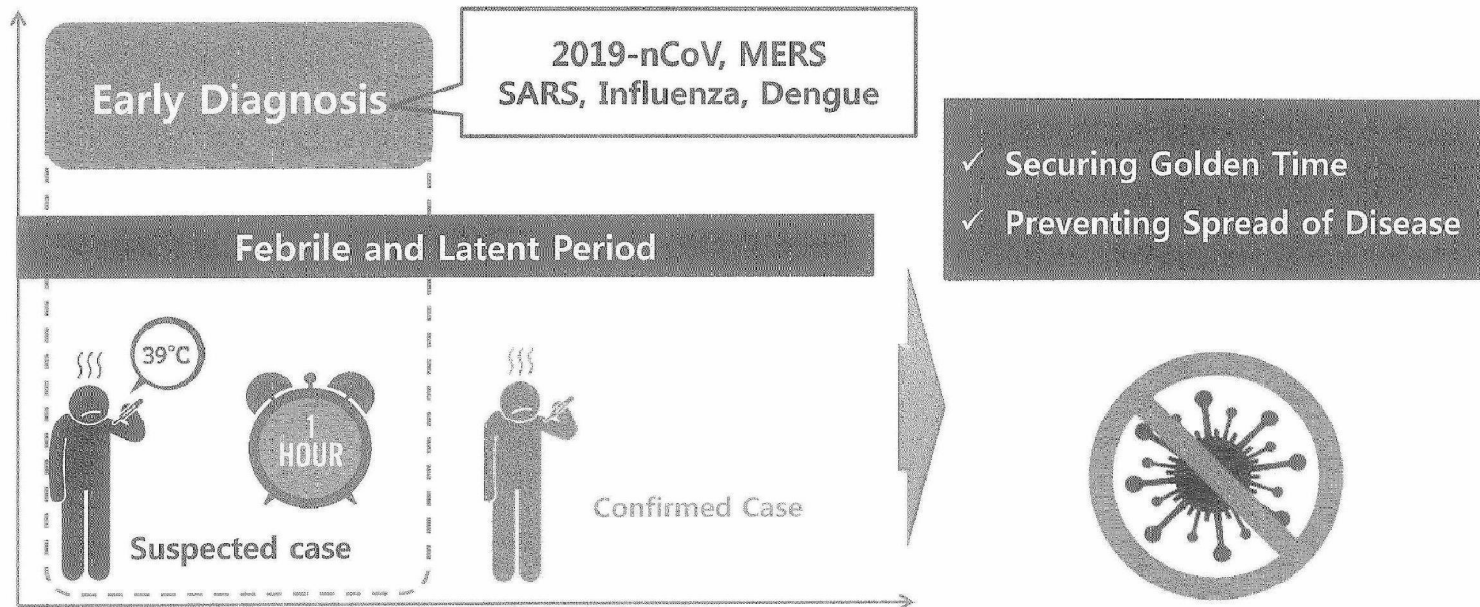


Control Tower

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Early Detection & Confirmation

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WHO recommendation:
Identify, isolate and care for patients in early stage.

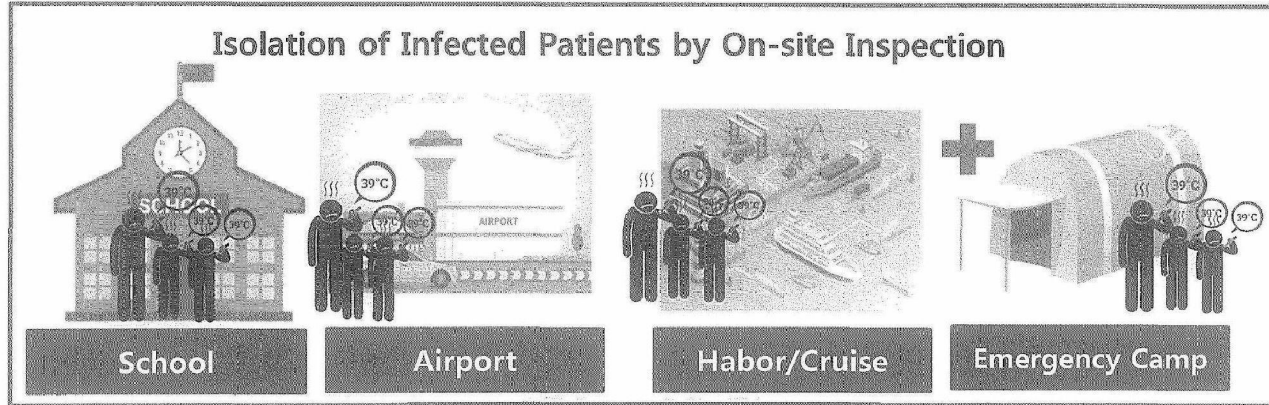
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On-Site Confirmation

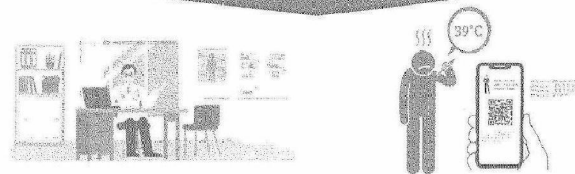
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Isolation of Infected Patients by On-site Inspection

Potential Sites



- Quarantine Spot
- Mobile Lab.



Faster Disease Control at On-site

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Comparison with Other System

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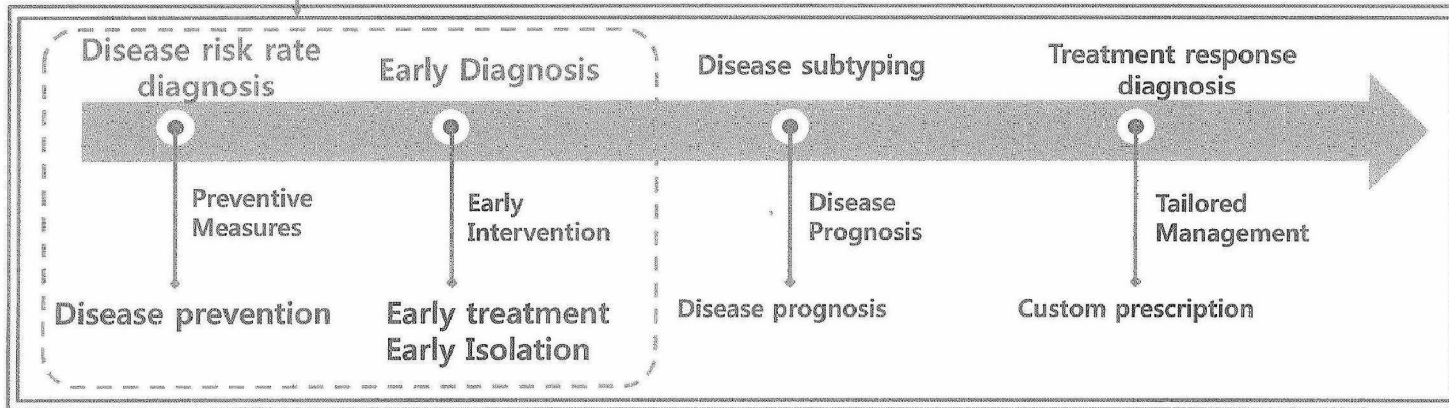
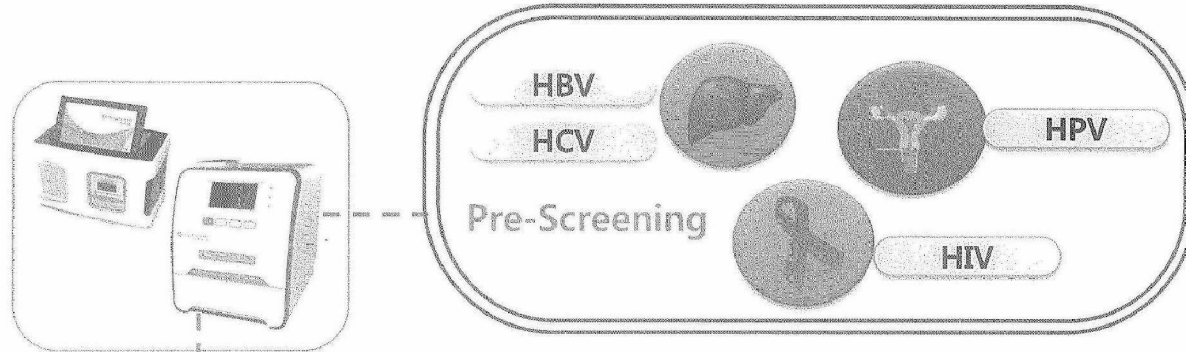
	MiCo BioMed(MBM) (Labchip based PCR+MBM Developed Kit)	Others (Imported Instrument + EUA Kit)	Remarks
PCR	About 30 min	2 Hours	2 blocks in PCR can shorten runtime to about 30 mins.
Sample Prep.	5 ~ 30 min (1~16 samples, 5 mins for 1 sample)	1.5 Hours	
Place of Installation	Suitable for small-medium hospitals with small sized instruments	Suitable for big hospitals or inspection centers	
Run time	Within 1 hour -Can test immediately after collecting samples(1 sample is available) → On-Site Emergency Use is possible	2-3 Hours -Can test after collecting some samples(Many hours are taken for collecting samples)	MBM 16 Channels vs Others 96 Channels
Instrument Price	Affordable	Expensive	

- EUA : Emergency Use Approval by KCDC
- MBM is waiting for EAU

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Pre-Screening

MiCoBioMed
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Clinical Performance Evaluation Report

MiCo BioMed

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Attestation

A panel of 16 samples initially screened for COVID-19 using the TIBMOL BIOL kit targeting the E and RdRP genes on a ABI 7500 device were selected for confirmation with Veri-Q PCR 136 COVID-19 detection kit (Micobiomed). Among the 16 selected samples, 8 were negatives and 8 were positives with different Ct values (Table). The confirmation results obtained with the Veri-Q PCR 136 targeting the ORF and N genes is resumed in the table below.



Table: Comparison of TIBMOL BIOL and Veri-Q PCR 136 (Micobiomed) COVID-19 detection Kits

Identifiant	TIBMOL BIOL Kit		Veri-Q PCR 136 Kit (Micobiomed)	
	E gene, Ct	RdRP gene, Ct	ORF gene, Ct	N gene, Ct
Cov/20/084	Neg	Neg	Neg	Neg
Cov/20/104	Neg	Neg	Neg	Neg
Cov/20/136	14,6	16,7	13,6	12,3
Cov/20/139	18,3	20,4	17,38	16,14
Cov/20/114	19,1	20,7	18,23	16,66
Cov/20/270	16,6	17,5	14,77	13,4
Cov/20/119	27,4	29,5	26,78	25,29
Cov/20/272	Neg	Neg	Neg	Neg
Cov/20/141	31,2	32,8	30,17	28,56
Cov/20/157	32,56	34,12	31,12	28,07
Cov/20/142	35,4	36,2	35,4	32,82
Cov/20/111	Neg	Neg	Neg	Neg
Cov/20/124	Neg	Neg	Neg	Neg
Cov/20/100	Neg	Neg	Neg	Neg
Cov/20/116	Neg	Neg	Neg	Neg
Cov/20/135	Neg	Neg	Neg	Neg

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Comparison with "A" (KCDC EUA Product)

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Company	MBM			A Company		
	ORF	N	Detection	E	RdRp	Detection
	COVID-19	COVID-19		Betacoronavirus	COVID-19	
10 ⁻⁶	3/3	3/3	100%	3/3	3/3	100%
0.9 X 10 ⁻⁶	3/3	3/3	100%	3/3	3/3	100%
0.8 X 10 ⁻⁶	3/3	3/3	100%	3/3	3/3	100%
0.7 X 10 ⁻⁶	3/3	3/3	100%	3/3	3/3	100%
0.6 X 10 ⁻⁶	3/3	3/3	100%	3/3	2/3	100%(?)
0.5 X 10 ⁻⁶	3/3	3/3	100%	3/3	3/3	100%
0.4 X 10 ⁻⁶	3/3	3/3	100%	3/3	3/3	100%
0.3 X 10 ⁻⁶	3/3	2/3	67%	3/3	1/3	33%
0.2 X 10 ⁻⁶	3/3	2/3	67%	2/3	0/3	0%
Detection	27/27(100%)	25/27(92.6%)	25/27(92.6%)	26/27(96.3%)	22/27(81.5%)	22/27(81.5%)

✓ MBM Product quality is superior or equal at least. (Test has done at MBM Lab.)

- Used Viral RNA distributed by KCDC..
- At 10⁻⁶ to 0.2 X 10⁻⁶ difference of sensitivity was shown.
MBM : 25/27(92.6%) VS A company : 22/27(81.5%)

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Comparison with KCDC EUA Products (COVID-19 Detection Kit)

*EAU:Emergenc Use Approval

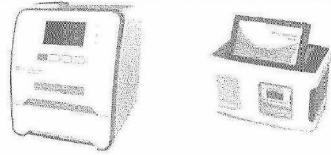

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	MiCo BioMed nCoV-QS Real-time PCR kit	Kogenebiotec PowerCheck 2019-nCoV Real-Time PCR Kit	Seegene Allplex 2019-nCoV Assay	SD BIOSENSOR M nCoV Real-Time Detection Kit	SolGent DiaPlexQ™ 2019 Novel Coronavirus nCoV Detection kit
System	Veri-Q PCR316 (MiCo BioMed)	BioRad CFX96, ABI7500	BioRad CFX96, ABI7500	BioRad CFX96, ABI7500	BioRad CFX96, ABI7500
Target gene	ORF – FAM N – Cy5 (WHO Recommended)	RdRp –FAM E – FAM	RdRp – Cal Red 610 N – Quasar 670 E – FAM	RdRp –FAM E – JOE (VIC 또는 HEX)	ORF1a – JOE/VIC N – FAM (WHO Recommended)
Nucleic acid	3 ul / 3ul	5ul / 5ul	8 ul	10 ul	5 ul
Run tim (PCR)	About 35min (45 cycles)	About 90 min (40 cycles)	About 69 min (45 cycles)	About 52 min (40 cycles)	About 120 min (45 cycles)
PCR Weight	4.7 Kg	30-35 Kg	30-35 Kg	30-35 Kg	30-35 Kg
Shelf Life	12 months after manufacturing	6 weeks after manufacturing	8 months after manufacturing	12 months after manufacturing	6 months after manufacturing
Samples	Sputum, Nasopharynx/Oropharynx swab	Sputum, Nasopharynx/Oropharynx swab	Sputum, Nasopharynx/Orophary nx swab,BAL	Sputum, Nasopharynx/Orophary nx swab	Sputum, Nasopharynx/Orophary nx swab
RNA Extraction Sys	Veri-Q PREP M16 (MiCo BioMed)	Qiacube (Qiagen) (?)	Qiacube (Qiagen) (?)	Qiacube (Qiagen) (?)	Qiacube (Qiagen) (?)
RNA Extract Run time	5-35 min (1-16 samples) (5 min for 1 st 1 sample)	30-90 min(1-12 samples)	30-90 min(1-12 samples)	30-90 min(1-12 samples)	30-90 min(1-12 samples)
PREP Weight	12 Kg	70 kg	70 kg	70 kg	70 kg

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Comparison of throughput

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For the COVID-19		MiCo bioMed System			Q* & A*/B*		
Picture							
Running time (1 run)	Sample Extraction	30 mins for 12 samples			40 mins for 12 sample extractions		
	PCR	35 mins for 45 cycles			120 mins for 45 cycles		
Reagent / PCR Throughput (10 hrs/day)		1 set PCR	2 sets PCR	3 sets PCR	2 plex reagent K**	3 plex reagent (S**, S**)	4 plex reagent (S**)
	Test per 1 run	6 (35 mins)	12 (35 mins)	18 (35 mins)	46 (120 mins)	94 (120 mins)	94 (120 mins)
	Runs per day	15	16	18	3.5	3.5	3.5
	Tests per day	90	192	324	161	329	329

- With MBM (2Prep + 3 PCR) throughput is almost the same with compared open system, but *cost effective*.
- For using 96 well open system, sample should be collected and transmitted to the labs (in case of Korea), more than 24 hours are taken to get the final PCR results. MBM system make it possible to *confirm the test result within 1 hour*.
- Cheap & small, movable, flexible to adapt to any circumstances; both increasing or decreasing suspected cases.

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Comparison : MiCo BioMed vs. GenXpert

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	MiCo BioMed	Cepheid
Instruments	PREP M16 + PCR316 (Sample Prep and qPCR Separated)	GenXpert (Sample Prep and qPCR Combined)
Target genes	ORF, N (WHO Recommended)	E, N
Limit of Detection (LOD) / Reaction	10 copies/reaction	250 copies/reaction
Lysed sample volume for one sample prep	500 ul	1000 ul
Sample volume for 1 real-time PCR	30 ul (High efficiency)	1000 ul (Low efficiency)
Repeated use of extracted RNA from loaded lysed sample	16 times (repeatable use)	Once (not repeatable use)
Shelf Life of Kit	12 months	(12 months ?)
Total reaction time for 1 sample	45 min	45 min
Machine Operation	By Touch screen	By Notebook
Battery operation	Car battery,	Not available
Data transfer through Smartphone	Android phone based data transfer	Not available
Print-out function	Receipt-type print-out of results	Not available
Tests/day(10hrs)/ 1 Instrument	90 samples	13 samples

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MiCo BioMed
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EC DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

16TU-CV19 has been classified as General IVDs and is in conformity with the essential requirements and provisions of Council Directive 98/79/EC on In Vitro Diagnostic Medical Device.

Name : MiCo BioMed Co.,Ltd.

Brand names	Veri-Q PAEP M16	
Common names	Viral DNA/RNA Prep Kit - Airway Clinical Sample	
Model names	16TU-CV19	
Catalogue number	7A133	
Component	Carrier molecule : NCN	Sample tube : NET
	Proteinase K : NPK	Elution tube : NET
	Binding buffer : NB	Tray lid : Lid
	Washing buffer 1 : NW1	Elution tray : NETR
	Elution buffer : NE	Waste tray : NWTR

Classification Others, general IVD

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC and EU Harmonized standards(EN ISO 13485:2016/AC:2016, EN ISO 14971:2012, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011) for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

EDMA code 15.90.40.01 Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus

Date of issue 25 February 2020

Signature Quality Representative : Sang-Hyun Lee

Signature



EC DECLARATION OF CONFORMITY

(Manufacturer's Declaration)

nCoV-Q5 has been classified as General IVDs and is in conformity with the essential requirements and provisions of Council Directive 98/79/EC on In Vitro Diagnostic Medical Device.

Manufacturer Name : MiCo BioMed Co.,Ltd.

Brand names	Veri-Q PCR 316	
Common names	Novel Coronavirus Detection Kit	
Model names	nCoV-Q5	
Catalogue number	7K105	
Component	2x One-Step RT-PCR Master mix :	nCoV-Q5-MMGR06
	Primer/Probe mixture1 :	nCoV-Q5-PPM1
	Primer/Probe mixture2 :	nCoV-Q5-PPM2
	Positive control :	nCoV-Q5-PC
	Internal positive control :	nCoV-Q5-IPC
	Nuclease free water :	nCoV-Q5-DW

Classification Others, general IVD

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC and EU Harmonized standards(EN ISO 13485:2016/AC:2016, EN ISO 14971:2012, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011) for In Vitro Diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

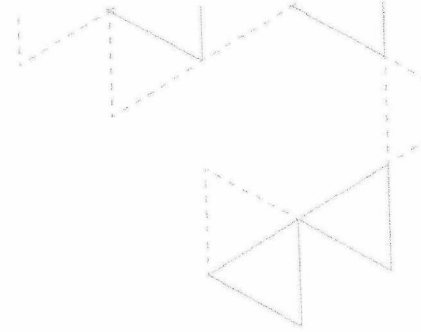
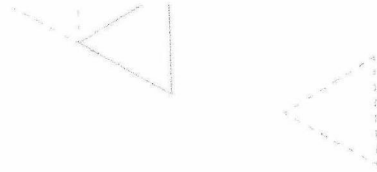
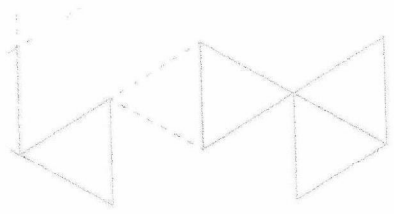
EDMA code 15.04.40.19 Coronavirus - NA reagents

Date of issue 25 February 2020

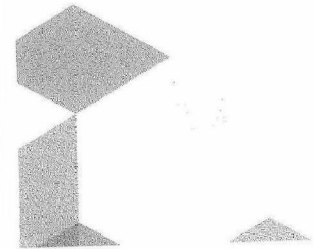
Signature Quality Representative : Sang-Hyun Lee



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THANK YOU !



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