COVID-19 Rapid Test Kit from South Korea

Clinical Data Information

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SHINJIN MEDICS INC. Product Clinical Data Result

COVID-19 IgM/IgG Rapid Kit

1) Product

COVID-19 IgM/IgG Rapid Kit Ver.1 (sample 2ul)

Lot.	Production Date	Expiration Date
DR2001-01	2020.2.23	2021.2.23

COVID-19 IgM/IgG Rapid Kit Ver.2 (sample 10ul)

Lot.	Production Date	Expiration Date
DR2001-02	2020.2.23	2021.2.23

2) Comparison

Real-Time PCR Kit

Lot.	Production Date	Expiration Date

3) Clinical Test Method

Patients samples confirmed with Real-Time PCR Kit are used to perform clinical test for COVID-19 IgM/IgG Rapid Kit ver.1 and ver.2. 60 positive samples

and 32 negative samples are used for clinical test. The result is considered as positive if the result of either IgG or IgM is positive.

Sensitivity = Positive result / (60) X100%

Specificity = Negative result / (32) X100%

4) Result

4-1) 60 samples

Reference			Ver.1 COVID-19 Positive raw result (Sample 2ul)		Ver.2 COVID-19 Negative raw result (Sample 10ul)	
No.	Specimen Collection Phase (After symptom)	Reference RT-PCR	COVID19 IgM	COVID19 IgG	COVID19 IgM	COVID19 IgG
1	Unknown	+	+	+	N	+
2	Unknown	+	+	+	N	+
3	Unknown	+	+	+	+	+
4	Unknown	+	N	N	+	+
5	Unknown	+	N	+	N	+
6	Unknown	+	+	+	N	+
7	Unknown	+	+	+	+	+
8	Unknown	+	+	+	+	+
9	Unknown	+	N	+	N	+

10	Unknown	+	N	+	N	+
11	Unknown	+	+	+	+	+
12	Unknown	+	N	+	N	+
13	Unknown	+	+	+	+	+
14	Unknown	+	+	+	+	+
15	Unknown	+	N	+	N	+
16	Unknown	+	N	+	N	+
17	Unknown	+	+	+	N	+
18	Unknown	+	+	+	N	+
19	Unknown	+	N	N	N	+
20	Unknown	+	+	+	N	+
21	Unknown	+	+	+	+	+
22	Unknown	+	+	+	+	+
23	Unknown	+	+	+	N	+
24	Unknown	+	N	+	N	+
25	Unknown	+	+	+	N	+
26	Unknown	+	+	+	N	+
27	Unknown	+	+	+	N	+
28	Unknown	+	+	+	+	+

29	Unknown	+	+	+	+	+
30	Unknown	+	+	+	N	+
31	Unknown	+	+	+	+	+
32	Unknown	+	+	+	+	+
33	Unknown	+	+	+	+	+
34	Unknown	+	+	+	+	+
35	Unknown	+	+	+	N	+
36	Unknown	+	+	+	N	+
37	Unknown	+	+	+	N	+
38	Unknown	+	N	N	N	N
39	Unknown	+	+	+	+	+
40	Unknown	+	N	+	N	+
41	Unknown	+	+	+	+	+
42	Unknown	+	N	+	N	+
43	Unknown	+	N	N	N	N
44	Unknown	+	N	N	N	+
45	Unknown	+	+	+	N	+
46	Unknown	+	N	+	N	N
47	Unknown	+	+	+	N	+

48	Unknown	+	+	+	N	N
49	Unknown	+	N	N	N	N
50	Unknown	+	+	+	+	+
51	Unknown	+	N	+	N	+
52	Unknown	+	+	+	N	+
53	Unknown	+	N	+	N	+
54	Unknown	+	+	+	+	+
55	Unknown	+	N	+	+	+
56	Unknown	+	+	+	N	+
57	Unknown	+	+	+	N	+
58	Unknown	+	+	+	+	+
59	Unknown	+	N	+	N	+
60	Unknown	+	N	N	N	+

4-2) 32 negative samples

Reference			Ver.1 COVID-19 Negative raw result (Sample 2ul)		Ver.2 COVID-19 Negative raw result (Sample 10ul)	
No.	Specimen Collection Phase (After symptom)	Reference RT-PCR	COVID19 IgM	COVID19 IgM	COVID19 IgM	COVID19 IgM
1	Unknown	N	N	N	N	N
2	Unknown	N	N	N	N	N
3	Unknown	N	N	N	N	N
4	Unknown	N	N	N	N	N
5	Unknown	N	N	N	N	N
6	Unknown	N	N	N	N	N
7	Unknown	N	N	N	N	N
8	Unknown	N	N	N	N	N
9	Unknown	N	N	N	N	N
10	Unknown	N	N	N	N	N
11	Unknown	N	N	N	N	N
12	Unknown	N	N	N	N	N
13	Unknown	N	N	N	N	N
14	Unknown	N	N	N	N	N
15	Unknown	N	N	N	N	N
16	Unknown	N	N	N	N	N
17	Unknown	N	N	N	N	N
18	Unknown	N	N	N	N	N
19	Unknown	N	N	N	N	N
20	Unknown	N	N	N	+	N

21	**Unknown**	**N**	**N**	**N**	**N**	**N**
22	**Unknown**	**N**	**N**	**N**	**N**	**N**
23	**Unknown**	**N**	**N**	**N**	**N**	**N**
24	**Unknown**	**N**	**N**	**N**	**N**	**N**
25	**Unknown**	**N**	**N**	**N**	**N**	**N**
26	**Unknown**	**N**	**N**	**N**	**N**	**N**
27	**Unknown**	**N**	**N**	**N**	**N**	**N**
28	**Unknown**	**N**	**N**	**N**	**N**	**N**
29	**Unknown**	**N**	**N**	**N**	**N**	**N**
30	**Unknown**	**N**	**N**	**N**	**N**	**N**
31	**Unknown**	**N**	**N**	**N**	**N**	**N**
32	**Unknown**	**N**	**N**	**N**	**N**	**N**

COVID-19 specimen		**Reference RT-PCR**	
		Positive	Negative
COVID-19 IgM/ IgG Rapid Test (ver.1)	Positive	53	0
	Negative	7	32
Total		60	32

Sensitivity =53/60X100%=88%

Specificity =32/32X100%=100%

COVID-19 specimen		Reference RT-PCR	
		Positive	Negative
COVID-19 IgM/ IgG Rapid Test (ver.2)	Positive	56	1
	Negative	4	31
Total		60	32

Sensitivity =56/60X100%=93%

Specificity =31/32X100%=97%

5) Conclusion

In total, compare with the result of RT-PCR inspection, COVID-19 IgM/IgG Rapid Kit Ver. 2 product is determined to be suitable for determining antibody test with sensitivity 93% and specificity 97%.