

## Conclusion

Comparison studies between the test device (SGTi-flex COVID-19 IgM/IgG) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 250 specimens.

SGTi-flex COVID-19 IgM/IgG		RT-PCR		
		Positive	Negative	Total
Test device	Positive	91	5	96
	Negative	9	145	154
	Total	100	150	250

(1) Accuracy (Overall agreement) =  $100 \times (91+145) / 250 = 94.40\%$

(2) Sensitivity (Positive agreement) =  $100 \times 91 / 100 = 91.00\%$

(3) Specificity (Negative agreement) =  $100 \times 145 / 150 = 96.67\%$

The result showed the accuracy (overall percent agreement) was 94.40 %. The sensitivity and specificity (positive and negative agreements were 91.00 % and 96.67 %, respectively.

SGTi-flex COVID-19 IgM/IgG is faster and easier to diagnose COVID-19 and it has good agreement with real-time RT-PCR test. Therefore, SGTi-flex COVID-19 IgM/IgG is a useful kit that can help in emergency situations where viral infections are expanding especially for community spread.

## Clinical Evaluation 1

SGTi-flex COVID-19 IgM/IgG was evaluated with the 100 serum samples collected from 50 positive and 50 negative patients who were confirmed by the real time RT-PCR with nasopharyngeal swab, oropharyngeal swab or sputum specimens.

The experiment was performed according to the instructions and each antibody was qualitatively judged by visual inspection.

### [Test Results for Positive Specimens]

No.	Date of symptoms onset	Specimen collection date	Days after onset	SGTi-flex COVID-19 IgM/IgG		
				IgM	IgG	Result

1	Feb. 28, 2020	Mar. 07, 2020	8	Positive	Positive	<b>Positive</b>
2	Mar. 04, 2020	Mar. 08, 2020	4	Positive	Positive	<b>Positive</b>
3	Mar. 03, 2020	Mar. 08, 2020	5	Negative	Negative	Negative
4	Feb. 28, 2020	Mar. 08, 2020	9	Positive	Positive	<b>Positive</b>
5	Mar. 01, 2020	Mar. 09, 2020	8	Positive	Positive	<b>Positive</b>
6	Mar. 02, 2020	Mar. 08, 2020	6	Positive	Positive	<b>Positive</b>
7	Mar. 02, 2020	Mar. 08, 2020	6	Positive	Positive	<b>Positive</b>
8	Feb. 28, 2020	Mar. 08, 2020	9	Positive	Positive	<b>Positive</b>
9	Feb. 29, 2020	Mar. 08, 2020	8	Negative	Negative	Negative
10	Mar. 04, 2020	Mar. 09, 2020	5	Positive	Positive	<b>Positive</b>
11	Mar. 01, 2020	Mar. 09, 2020	8	Negative	Positive	<b>Positive</b>
12	Mar. 03, 2020	Mar. 09, 2020	6	Positive	Positive	<b>Positive</b>
13	Mar. 01, 2020	Mar. 09, 2020	8	Positive	Positive	<b>Positive</b>
14	Mar. 04, 2020	Mar. 09, 2020	5	Negative	Negative	Negative
15	Feb. 20, 2020	Mar. 10, 2020	19	Positive	Positive	<b>Positive</b>
16	Mar. 04, 2020	Mar. 09, 2020	5	Negative	Positive	<b>Positive</b>
17	Feb. 28, 2020	Mar. 10, 2020	11	Positive	Positive	<b>Positive</b>
18	Mar. 02, 2020	Mar. 09, 2020	7	Positive	Negative	<b>Positive</b>
19	Feb. 28, 2020	Mar. 10, 2020	11	Positive	Positive	<b>Positive</b>
20	Feb. 25, 2020	Mar. 10, 2020	14	Positive	Positive	<b>Positive</b>
21	Feb. 23, 2020	Mar. 10, 2020	16	Positive	Positive	<b>Positive</b>
22	Mar. 01, 2020	Mar. 09, 2020	8	Positive	Positive	<b>Positive</b>
23	Feb. 20, 2020	Mar. 10, 2020	19	Positive	Positive	<b>Positive</b>
24	Feb. 25, 2020	Mar. 10, 2020	14	Positive	Positive	<b>Positive</b>
25	Feb. 24, 2020	Mar. 10, 2020	15	Positive	Positive	<b>Positive</b>
26	Feb. 27, 2020	Mar. 10, 2020	12	Positive	Positive	<b>Positive</b>
27	Feb. 28, 2020	Mar. 10, 2020	11	Negative	Negative	Negative
28	Feb. 28, 2020	Mar. 10, 2020	11	Positive	Positive	<b>Positive</b>
29	Feb. 25, 2020	Mar. 10, 2020	14	Negative	Negative	Negative
30	Mar. 06, 2020	Mar. 11, 2020	5	Positive	Positive	<b>Positive</b>
31	Mar. 05, 2020	Mar. 09, 2020	4	Positive	Positive	<b>Positive</b>
32	Mar. 05, 2020	Mar. 09, 2020	4	Positive	Positive	<b>Positive</b>
33	Feb. 22, 2020	Mar. 09, 2020	16	Positive	Positive	<b>Positive</b>
34	Feb. 26, 2020	Mar. 09, 2020	12	Positive	Positive	<b>Positive</b>
35	Feb. 16, 2020	Mar. 09, 2020	22	Positive	Positive	<b>Positive</b>
36	Feb. 14, 2020	Mar. 09, 2020	24	Positive	Positive	<b>Positive</b>
37	Feb. 15, 2020	Mar. 09, 2020	23	Positive	Positive	<b>Positive</b>
38	Feb. 20, 2020	Mar. 09, 2020	18	Positive	Positive	<b>Positive</b>
39	Feb. 18, 2020	Mar. 09, 2020	20	Positive	Positive	<b>Positive</b>
40	Feb. 18, 2020	Mar. 09, 2020	20	Positive	Negative	<b>Positive</b>
41	Feb. 20, 2020	Mar. 09, 2020	18	Positive	Positive	<b>Positive</b>

42	Feb. 18, 2020	Mar. 09, 2020	20	Positive	Positive	<b>Positive</b>
43	Feb. 18, 2020	Mar. 09, 2020	20	Positive	Positive	<b>Positive</b>
44	Feb. 14, 2020	Mar. 09, 2020	24	Negative	Positive	<b>Positive</b>
45	Feb. 24, 2020	Mar. 09, 2020	14	Positive	Positive	<b>Positive</b>
46	Feb. 24, 2020	Mar. 09, 2020	14	Positive	Negative	<b>Positive</b>
47	Feb. 20, 2020	Mar. 09, 2020	18	Positive	Positive	<b>Positive</b>
48	Feb. 19, 2020	Mar. 09, 2020	19	Positive	Positive	<b>Positive</b>
49	Feb. 17, 2020	Mar. 09, 2020	21	Positive	Positive	<b>Positive</b>
50	Feb. 19, 2020	Mar. 09, 2020	19	Positive	Negative	<b>Positive</b>

SGTi-flex COVID-19 IgM/IgG		RT-PCR		
		Positive	Negative	Total
Test device	Positive	45	1	46
	Negative	5	49	54
	Total	50	50	100

(1) Accuracy (Overall agreement) =  $100 \times (45+49) / 100 = 94.00\%$

(2) Sensitivity (Positive agreement) =  $100 \times 45 / 50 = 90.00\%$

(3) Specificity (Negative agreement) =  $100 \times 49 / 50 = 98.00\%$

## Clinical Evaluation 2

SGTi-flex COVID-19 IgM/IgG were evaluated with the 150 blood (serum or plasma) samples collected from 50 positive patients who were confirmed by the real time RT-PCR with nasopharyngeal swab, oropharyngeal swab or sputum specimens and 100 healthy donors.

The experiment was performed according to the instructions and each antibody was qualitatively judged by visual inspection.

SGTi-flex COVID-19 IgM/IgG		RT-PCR		
		Positive	Negative	Total
Test device	Positive	46	4	50
	Negative	4	96	100
	Total	50	100	150

(1) Accuracy (Overall agreement) =  $100 \times (46+96) / 150 = 94.67\%$

(2) Sensitivity (Positive agreement) =  $100 \times 46 / 50 = 92.00\%$

(3) Specificity (Negative agreement) =  $100 \times 96 / 100 = 96.00\%$