Test Report

Doc. ID:	R-LA-772-00
Revision:	00
Date:	May 13, 2020

Title :	**Comparison Study**
Product :	SGTi-flex COVID-19 IgM/IgG
Date :	May 13, 2020

Protocol No. P-LA-772-00

Revision History		
Rev.0	May 13, 2020	First study after design

Prepared by/ date	Reviewed by/ date	Approved by/ date
Kiyoung Park		Eunkyung Kim
May 13, 2020		May 13, 2020

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Attachment :

- Instructions for use

1. Objective of the test

This study was performed so as to do performance evaluation of SGTi-flex COVID-19 IgM/IgG with the predicate device in terms of accuracy according to the instructions for use, according to the pre-designed protocol, Comparison Study Protocol, P-LA-772-00 / Rev.00 / Mar. 20. 2020

2. Test location and duration

2.1 Clinical Evaluation 1

2.1.1 Test location: : Keimyung University Dongsan Hospital, Daegu, Korea
2.1.2 Test duration : Mar. 27~30, 2020
2.1.3 IRB approval No. : DSMC 2020-03-052

2.2 Clinical Evaluation 2

2.2.1 Test location: : Chungnam National University Hospital, Daejeon, Korea
2.2.2 Test duration: Mar. 27~May 11, 2020
2.2.3 IRB approval No. : CNUH 2020-03-057

2.3 Clinical Evaluation 3

2.3.1 Test location: : Eulji University Hospital, Daejeon, Korea
2.3.2 Test duration: Mar. 27~Apr. 20, 2020
2.3.3 IRB approval No. : EMC 2018-09-004

3.Responsibilities

3.1 Clinical Evaluation 1

3.1.1 Principle Investigator : Sunggyun Park / Assisatant Professor / Department of laboratory medicine at Keimyung Univ. Dongsan Hospital
3.1.2 Key contact : Eunkyung Kim / R&D dept. / Sugentech

3.2 Clinical Evaluation 2

3.2.1 Principle Investigator : Yeon-Sook Kim / Professor / Division of Infectious Disease, Department of Internal Medicine at Chungnam National University Hospital
3.2.2 Key contact : Eunkyung Kim / R&D dept. / Sugentech

3.3 Clinical Evaluation 3

3.3.1 Principle Investigator : Chunhwa Ihm / Associate Professor / Division of laboratory medicine at Eulji Univ. Hospital
3.3.2 Key contact : Eunkyung Kim / R&D dept. / Sugentech

4. Test Result

4.1 Test device(Candidate device)

Product Name	Manufacture	Lot No.
SGTi-flex COVID-19 IgM/IgG	Sugentech, Inc.	COVT20904

- The operators were trained by explaining the instructions for use (IFU) before using the test device and showing a trial test directly or how-to-use video.

4.2 Predicate device (Reference method) : Real time RT-PCR for COVID-19

4.3 Test Sample (Specimen)

4.3.1 Collection of specimens

(1) Positive samples

- 50 serum were retrospectively collected from patients who were confirmed positive by the real time RT-PCR (Allplex™ 2019-nCoV Assay (Manufacturer: Seegene, Inc.)) at Keimyung University Dongsan Hospital.
- 50 serum were retrospectively collected from patients who were confirmed positive by the real time RT-PCR (Powerchek™ 2019-nCoV Real-time PCR kit (Manufacturer: KogeneBiotech Co., Ltd.)) at Chungnam National University Hospital.
- To detect seroconversion, a total of 45 serum were sequentially obtained from the residual samples of 27 patients among 50 patients confirmed positive by real-time RT-PCR at Chungnam National University Hospital.
- Additionally, 18 serum were retrospectively collected from patients who were confirmed positive by the real time RT-PCR (Powerchek™ 2019-nCoV Real-time PCR kit (Manufacturer: KogeneBiotech Co., Ltd.)) at Chungnam National University Hospital.
- A total of 163 serum were paired samples obtained from the same subjects who provided nasopharyngeal swab, oropharyngeal swab or sputum samples which were used in the real time RT-PCR as confirmative diagnosis for COVID-19.

(2) Negative samples

- 50 serum were collected from patients who were confirmed negative by the real time RT-PCR (Allplex™ 2019-nCoV Assay (Manufacturer: Seegene, Inc.)) at Keimyung University Dongsan Hospital. The specimens were paired samples obtained from the same subjects who provided nasopharyngeal swab, oropharyngeal swab or sputum samples which were used in the real time RT-PCR as confirmative diagnosis for COVID-19.
- 280 serum were randomly chosen from clinically non-infected healthy individuals who visited for regular medical checkups before 2020 at Eulji University Hospital.
- 30 serum were prospectively collected with the consent of the healthy individuals who has no history of contact with a COVID-19 patient and no foreign visit history. They

were confirmed negative by the real time RT-PCR (Powerchek™ 2019-nCoV Real-time PCR kit (Manufacturer: KogeneBiotech Co., Ltd.)) at Chungnam National University Hospital.

The specimen were blind coded and randomized prior to testing.

4.3.2 Number of specimens
(1) Positive samples: 163 serum
(2) Negative samples: 360 serum

4.4. Test Result Data
4.4.1 Clinical Evaluation 1
(1) Positive samples : Test results are summarized at Table 1.

Table 1. Result of Clinical Evaluation 1 positive samples

No.	Age	Gender	Days after onset	Result			
				Clinical diagnosis (Real time PCR)	Test Device (SGTi- flex COVID-19 IgM/IgG)		
					IgM	IgG	Result
P01	79	M	8	+	+	+	+
P02	78	M	4	+	+	+	+
P03	59	F	5	+	-	-	-
P04	75	F	9	+	-	+	+
P05	64	M	8	+	+	+	+
P06	62	F	6	+	-	+	+
P07	74	F	6	+	+	+	+
P08	69	M	9	+	+	+	+
P09	68	F	8	+	-	-	-
P10	66	M	5	+	+	+	+
P11	57	F	8	+	-	+	+
P12	65	F	6	+	+	+	+
P13	71	F	8	+	+	+	+
P14	66	F	5	+	-	-	-
P15	79	M	19	+	+	+	+
P16	59	M	5	+	-	+	+
P17	79	M	11	+	+	+	+
P18	69	M	7	+	+	-	+
P19	80	M	11	+	+	+	+
P20	58	F	14	+	+	+	+
P21	61	F	16	+	+	+	+

P22	62	M	8	+	+	+	+
P23	68	M	19	+	+	+	+
P24	71	M	14	+	+	+	+
P25	64	M	15	+	+	+	+
P26	56	M	12	+	+	+	+
P27	78	M	11	+	-	-	-
P28	63	F	11	+	+	+	+
P29	87	F	14	+	-	-	-
P30	54	F	5	+	+	+	+
P31	80	F	4	+	+	+	+
P32	81	F	4	+	+	+	+
P33	57	F	16	+	+	+	+
P34	85	M	12	+	+	+	+
P35	54	F	22	+	+	+	+
P36	56	F	24	+	+	+	+
P37	53	F	23	+	+	+	+
P38	27	F	18	+	+	+	+
P39	41	F	20	+	+	+	+
P40	34	F	20	+	+	-	+
P41	51	M	18	+	+	+	+
P42	57	M	20	+	+	+	+
P43	49	F	20	+	+	+	+
P44	47	F	24	+	-	+	+
P45	33	M	14	+	+	+	+
P46	50	F	14	+	+	-	+
P47	80	F	18	+	+	+	+
P48	41	F	19	+	+	+	+
P49	50	F	21	+	+	+	+
P50	27	F	19	+	+	-	+

(2) Negative samples : Test results are summarized at Table 2.

Table 2. Result of Clinical Evaluation 1 negative samples

No.	Age	Gender	Result			
			Clinical diagnosis (Real time PCR)	Test Device (SGTi- flex COVID-19 IgM/IgG)		
				IgM	IgG	Result
N01	67	F	-	-	-	-
N02	84	F	-	-	-	-

N03	88	M	-	-	-	-
N04	83	F	-	-	-	-
N05	54	M	-	-	-	-
N06	80	M	-	-	-	-
N07	77	F	-	-	-	-
N08	87	M	-	-	-	-
N09	79	F	-	-	-	-
N10	80	M	-	-	-	-
N11	89	F	-	-	-	-
N12	78	M	-	-	-	-
N13	61	F	-	-	-	-
N14	89	M	-	-	-	-
N15	58	F	-	-	-	-
N16	68	M	-	-	-	-
N17	71	F	-	-	-	-
N18	55	F	-	-	-	-
N19	33	M	-	-	-	-
N20	42	M	-	-	-	-
N21	59	F	-	-	-	-
N22	77	M	-	+	-	+
N23	62	M	-	-	-	-
N24	16	M	-	-	-	-
N25	47	F	-	-	-	-
N26	56	F	-	-	-	-
N27	46	M	-	-	-	-
N28	76	F	-	-	-	-
N29	26	F	-	-	-	-
N30	66	F	-	-	-	-
N31	80	F	-	-	-	-
N32	85	M	-	-	-	-
N33	77	M	-	-	-	-
N34	86	M	-	-	-	-
N35	65	M	-	-	-	-
N36	55	M	-	-	-	-
N37	90	M	-	-	-	-
N38	88	F	-	-	-	-
N39	59	M	-	-	-	-

N40	65	M	-	-	-	-
N41	83	F	-	-	-	-
N42	73	F	-	-	-	-
N43	61	F	-	-	-	-
N44	82	F	-	-	-	-
N45	88	F	-	-	-	-
N46	67	F	-	-	-	-
N47	67	M	-	-	-	-
N48	62	M	-	-	-	-
N49	38	M	-	-	-	-
N50	67	M	-	-	-	-

4.4.2 Clinical Evaluation 2

(1) Positive samples : Test results are summarized at Table 3 and 4.

Table 3. Result of Clinical Evaluation 2 positive samples

No.	Age	Gender	Days after onset	Result			
				Clinical diagnosis (Real time PCR)	Test Device (SGTi- flex COVID-19 IgM/IgG)		
					IgM	IgG	Result
P01	22	F	3	+	+	-	+
P02	65	F	5	+	+	+	+
P03	65	M	5	+	-	-	-
P04	39	F	8	+	+	+	+
P05	31	M	5	+	+	+	+
P06	36	M	4	+	+	+	+
P07	35	M	5	+	+	+	+
P08	27	M	2	+	+	+	+
P09	26	M	7	+	+	+	+
P10	47	F	5	+	+	+	+
P11	23	M	27	+	+	+	+
P12	49	M	4	+	+	+	+
P13	80	M	9	+	+	+	+
P14	55	F	10	+	+	+	+
P15	59	F	6	+	+	+	+
P16	23	M	4	+	+	+	+
P17	51	M	14	+	-	+	+
P18	64	F	6	+	+	+	+

P19	25	M	0	+	-	-	-
P20	49	F	22	+	+	+	+
P21	22	F	5	+	+	+	+
P22	65	M	10	+	+	+	+
P23	62	M	7	+	+	+	+
P24	63	M	7	+	-	-	-
P25	32	M	12	+	+	+	+
P26	45	F	9	+	+	+	+
P27	61	F	16	+	+	+	+
P28	70	F	18	+	+	+	+
P29	53	F	6	+	+	+	+
P30	63	F	22	+	+	+	+
P31	78	F	17	+	+	+	+
P32	97	F	1	+	-	-	-
P33	86	F	7	+	+	-	+
P34	84	M	9	+	+	+	+
P35	58	M	8	+	+	+	+
P36	41	M	9	+	+	+	+
P37	47	F	15	+	+	+	+
P38	62	M	11	+	+	+	+
P39	65	M	14	+	+	+	+
P40	22	F	7	+	+	+	+
P41	65	M	10	+	+	+	+
P42	36	M	8	+	+	+	+
P43	65	F	9	+	+	+	+
P44	63	M	12	+	-	+	+
P45	35	M	9	+	+	+	+
P46	26	M	11	+	+	+	+
P47	27	M	6	+	+	+	+
P48	47	F	9	+	+	+	+
P49	23	M	6	+	+	+	+
P50	59	F	8	+	+	+	+
P51	48	F	40	+	+	+	+
P52	22	F	26	+	+	+	+
P53	44	M	31	+	+	+	+
P54	43	M	39	+	+	+	+
P55	47	M	37	+	+	+	+
P56	29	M	26	+	+	+	+
P57	21	F	22	+	+	+	+

P58	24	M	18	+	+	+	+
P59	61	M	11	+	+	+	+
P60	49	M	28	+	+	+	+
P61	24	F	14	+	+	+	+
P62	22	F	5	+	+	+	+
P63	22	M	42	+	+	+	+
P64	18	F	19	+	+	+	+
P65	24	F	50	+	+	+	+
P66	26	F	20	+	+	+	+
P67	48	M	36	+	+	+	+
P68	65	M	33	+	+	+	+

Table 4. Result of Clinical Evaluation 2 positive samples (Seroconversion)

No.	Table 3 result for reference					Result of Seroconversion samples				
	Clinical diagnosis (Real time PCR)	Days after onset	Test Device (SGTi- flex COVID-19 IgM/IgG)			Clinical diagnosis (Real time PCR)	Days after onset	Test Device (SGTi- flex COVID-19 IgM/IgG)		
			IgM	IgG	Result			IgM	IgG	Result
P01	+	3	+	-	+	+	15	+	+	+
P02	+	5	+	+	+	+	18	+	+	+
						+	22	+	+	+
P03	+	5	-	-	-	+	7	+	-	+
						+	14	+	+	+
						+	19	+	+	+
P04	+	8	+	+	+	+	10	+	+	+
						+	17	+	+	+
P06	+	4	+	+	+	+	16	+	+	+
						+	20	+	+	+
P07	+	5	+	+	+	+	18	+	+	+
P08	+	2	+	+	+	+	8	+	+	+
P09	+	7	+	+	+	+	13	+	+	+
P10	+	5	+	+	+	+	19	+	+	+
						+	25	+	+	+
P11	+	27	+	+	+	+	31	+	+	+
P12	+	4	+	+	+	+	13	+	+	+
						+	17	+	+	+
						+	20	+	+	+
	+	10	+	+	+	+	16	+	+	+

P14						+	23	+	+	+
						+	30	-	+	+
P15	+	6	+	+	+	+	12	+	+	+
						+	19	+	+	+
P16	+	4	+	+	+	+	17	+	+	+
						+	24	+	+	+
P17	+	14	-	+	+	+	20	+	+	+
						+	27	+	+	+
P22	+	10	+	+	+	+	22	+	+	+
P23	+	7	+	+	+	+	19	+	+	+
P24	+	7	-	-	-	+	19	+	+	+
P26	+	9	+	+	+	+	20	+	+	+
P27	+	16	+	+	+	+	29	+	+	+
P29	+	6	+	+	+	+	18	+	+	+
P30	+	22	+	+	+	+	38	+	+	+
P31	+	17	+	+	+	+	25	+	+	+
P32	+	1	-	-	-	+	15	+	+	+
						+	21	+	+	+
P33	+	7	+	-	+	+	14	+	+	+
						+	21	+	+	+
P34	+	9	+	+	+	+	16	+	+	+
						+	21	+	+	+
						+	25	+	+	+
P35	+	8	+	+	+	+	24	+	+	+
						+	31	+	+	+

(2) Negative samples : Test results are summarized at Table 5.

Table 5. Result of Clinical Evaluation 2 negative samples

No.	Age	Gender	Result			
			Clinical diagnosis (Real time PCR)	Test Device (SGTi- flex COVID-19 IgM/IgG)		
				IgM	IgG	Result
N01	50	F	-	-	-	-
N02	31	F	-	-	-	-
N03	33	M	-	-	-	-
N04	24	F	-	-	-	-
N05	24	F	-	-	-	-

N06	53	F	-	-	-	-
N07	24	F	-	-	-	-
N08	25	F	-	-	-	-
N09	29	F	-	-	-	-
N10	35	F	-	-	-	-
N11	31	F	-	-	-	-
N12	28	F	-	-	-	-
N13	25	F	-	-	-	-
N14	24	F	-	-	-	-
N15	27	F	-	-	-	-
N16	28	F	-	-	-	-
N17	26	F	-	-	-	-
N18	24	F	-	-	-	-
N19	25	F	-	-	-	-
N20	33	F	-	-	-	-
N21	24	F	-	-	-	-
N22	24	F	-	-	-	-
N23	23	F	-	-	-	-
N24	27	F	-	-	-	-
N25	23	F	-	-	-	-
N26	24	F	-	-	-	-
N27	26	F	-	-	-	-
N28	31	F	-	-	-	-
N29	29	M	-	-	-	-
N30	35	M	-	-	-	-

4.4.3 Clinical Evaluation 3

(1) Negative samples : Test results are summarized at Table 6.

Table 6. Result of Clinical Evaluation 3 negative samples

No.	Age	Gender	Result			
			Clinical diagnosis (Real time PCR)	Test Device (SGTi- flex COVID-19 IgM/IgG)		
				IgM	IgG	Result
N01	47	F	-	-	-	-
N02	55	M	-	-	-	-
N03	52	M	-	-	-	-

N04	63	F	-	-	-	-
N05	67	M	-	-	-	-
N06	55	F	-	-	-	-
N07	54	F	-	-	-	-
N08	71	M	-	-	-	-
N09	65	F	-	-	-	-
N10	66	F	-	-	-	-
N11	43	F	-	-	-	-
N12	48	M	-	-	-	-
N13	51	M	-	-	-	-
N14	55	M	-	-	-	-
N15	56	M	-	-	-	-
N16	61	M	-	-	-	-
N17	66	M	-	-	-	-
N18	69	F	-	-	-	-
N19	73	F	-	-	-	-
N20	72	M	-	+	-	+
N21	79	F	-	-	-	-
N22	67	F	-	-	-	-
N23	49	F	-	-	-	-
N24	50	F	-	-	-	-
N25	46	M	-	-	-	-
N26	44	F	-	-	-	-
N27	85	M	-	-	-	-
N28	79	F	-	-	-	-
N29	54	F	-	-	-	-
N30	52	F	-	-	-	-
N31	56	M	-	-	-	-
N32	53	M	-	-	-	-
N33	67	F	-	-	-	-
N34	61	M	-	-	-	-
N35	62	F	-	-	-	-
N36	77	F	-	+	-	+
N37	73	M	-	-	-	-
N38	49	M	-	-	-	-
N39	52	M	-	-	-	-
N40	47	F	-	-	-	-

N41	70	F	-	-	-	-
N42	72	M	-	-	-	-
N43	78	F	-	-	-	-
N44	35	F	-	-	-	-
N45	38	F	-	-	-	-
N46	57	F	-	-	-	-
N47	40	F	-	-	-	-
N48	43	F	-	-	-	-
N49	53	F	-	-	-	-
N50	49	F	-	-	-	-
N51	64	M	-	-	-	-
N52	61	M	-	-	-	-
N53	39	F	-	-	-	-
N54	48	M	-	-	-	-
N55	56	M	-	-	-	-
N56	57	M	-	-	-	-
N57	51	M	-	-	-	-
N58	40	F	-	-	-	-
N59	44	F	-	-	-	-
N60	72	F	-	-	-	-
N61	74	M	-	-	-	-
N62	80	F	-	-	-	-
N63	82	M	-	-	-	-
N64	43	M	-	-	-	-
N65	42	M	-	-	-	-
N66	43	F	-	-	-	-
N67	65	F	-	-	-	-
N68	72	F	-	-	-	-
N69	69	F	-	-	-	-
N70	67	F	-	-	-	-
N71	58	M	-	+	-	+
N72	61	M	-	-	-	-
N73	53	F	-	-	-	-
N74	58	F	-	-	-	-
N75	59	M	-	-	-	-
N76	54	F	-	-	-	-
N77	63	F	-	-	-	-

N78	62	M	-	-	-	-
N79	81	M	-	-	-	-
N80	57	M	-	-	-	-
N81	26	M	-	-	-	-
N82	20	M	-	-	-	-
N83	20	M	-	-	-	-
N84	29	M	-	-	-	-
N85	21	M	-	-	-	-
N86	21	M	-	-	-	-
N87	34	M	-	-	-	-
N88	35	M	-	-	-	-
N89	38	M	-	-	-	-
N90	32	M	-	-	-	-
N91	38	M	-	-	-	-
N92	37	M	-	-	-	-
N93	43	M	-	-	-	-
N94	45	M	-	-	-	-
N95	43	M	-	-	-	-
N96	42	M	-	-	-	-
N97	45	M	-	-	-	-
N98	44	M	-	-	-	-
N99	43	M	-	-	-	-
N100	46	M	-	-	-	-
N101	57	M	-	-	-	-
N102	54	M	-	-	-	-
N103	54	M	-	-	-	-
N104	50	M	-	-	-	-
N105	50	M	-	-	-	-
N106	56	M	-	-	-	-
N107	54	M	-	-	-	-
N108	52	M	-	-	-	-
N109	54	M	-	-	-	-
N110	57	M	-	-	-	-
N111	54	M	-	-	-	-
N112	58	M	-	-	-	-
N113	56	M	-	-	-	-
N114	63	M	-	-	-	-

N115	68	M	-	-	-	-
N116	64	M	-	-	-	-
N117	64	M	-	-	-	-
N118	67	M	-	-	-	-
N119	60	M	-	-	-	-
N120	69	M	-	-	-	-
N121	60	M	-	-	-	-
N122	63	M	-	-	-	-
N123	77	M	-	-	-	-
N124	75	M	-	-	-	-
N125	72	M	-	-	-	-
N126	70	M	-	-	-	-
N127	79	M	-	-	-	-
N128	76	M	-	-	-	-
N129	89	M	-	-	-	-
N130	87	M	-	-	-	-
N131	83	M	-	-	-	-
N132	81	M	-	-	-	-
N133	84	M	-	-	-	-
N134	25	F	-	-	-	-
N135	26	F	-	-	-	-
N136	28	F	-	-	-	-
N137	26	F	-	-	-	-
N138	28	F	-	-	-	-
N139	26	F	-	-	-	-
N140	26	F	-	-	-	-
N141	28	F	-	-	-	-
N142	30	F	-	-	-	-
N143	39	F	-	-	-	-
N144	37	F	-	-	-	-
N145	36	F	-	-	-	-
N146	39	F	-	-	-	-
N147	37	F	-	-	-	-
N148	30	F	-	-	-	-
N149	33	F	-	-	-	-
N150	37	F	-	-	-	-
N151	31	F	-	-	-	-

N152	44	F	-	-	-	-
N153	41	F	-	-	-	-
N154	47	F	-	-	-	-
N155	46	F	-	-	-	-
N156	43	F	-	-	-	-
N157	49	F	-	-	-	-
N158	42	F	-	-	-	-
N159	46	F	-	-	-	-
N160	41	F	-	-	-	-
N161	59	F	-	-	-	-
N162	56	F	-	-	-	-
N163	52	F	-	-	-	-
N164	51	F	-	-	-	-
N165	50	F	-	-	-	-
N166	59	F	-	-	-	-
N167	59	F	-	-	-	-
N168	62	F	-	-	-	-
N169	69	F	-	-	-	-
N170	63	F	-	-	-	-
N171	78	F	-	-	-	-
N172	74	F	-	-	-	-
N173	76	F	-	-	-	-
N174	75	F	-	-	-	-
N175	73	F	-	-	-	-
N176	75	F	-	-	-	-
N177	79	F	-	-	-	-
N178	72	F	-	-	-	-
N179	71	F	-	+	-	+
N180	76	F	-	-	-	-
N181	72	F	-	-	-	-
N182	75	F	-	-	-	-
N183	77	F	-	-	-	-
N184	75	F	-	-	-	-
N185	74	F	-	-	-	-
N186	81	F	-	-	-	-
N187	80	F	-	-	-	-
N188	80	F	-	-	-	-

N189	85	F	-	-	-	-
N190	95	F	-	-	-	-
N191	87	F	-	-	-	-
N192	85	F	-	-	-	-
N193	86	F	-	-	-	-
N194	82	F	-	-	-	-
N195	83	F	-	-	-	-
N196	80	F	-	-	-	-
N197	45	M	-	-	-	-
N198	57	M	-	-	-	-
N199	54	M	-	-	-	-
N200	63	F	-	-	-	-
N201	65	F	-	-	-	-
N202	64	F	-	-	-	-
N203	55	M	-	-	-	-
N204	68	M	-	-	-	-
N205	57	M	-	-	-	-
N206	44	M	-	-	-	-
N207	60	F	-	-	-	-
N208	61	F	-	-	-	-
N209	59	F	-	-	-	-
N210	59	F	-	-	-	-
N211	47	M	-	-	-	-
N212	61	M	-	-	-	-
N213	46	M	-	-	-	-
N214	51	M	-	+	-	+
N215	49	M	-	-	-	-
N216	46	F	-	-	-	-
N217	56	M	-	-	-	-
N218	44	F	-	-	-	-
N219	68	M	-	-	-	-
N220	46	M	-	-	-	-
N221	54	F	-	-	-	-
N222	48	M	-	-	-	-
N223	46	M	-	-	-	-
N224	55	M	-	-	-	-
N225	52	F	-	-	-	-

N226	55	M	-	-	-	-
N227	52	M	-	-	-	-
N228	51	M	-	-	-	-
N229	60	F	-	-	-	-
N230	51	M	-	-	-	-
N231	64	M	-	-	-	-
N232	49	F	-	-	-	-
N233	55	M	-	-	-	-
N234	49	F	-	-	-	-
N235	51	M	-	-	-	-
N236	53	M	-	-	-	-
N237	45	F	-	-	-	-
N238	61	M	-	-	-	-
N239	53	M	-	-	-	-
N240	53	M	-	-	-	-
N241	45	M	-	-	-	-
N242	51	M	-	-	-	-
N243	64	M	-	-	-	-
N244	57	M	-	-	-	-
N245	56	F	-	-	-	-
N246	57	M	-	-	-	-
N247	64	F	-	-	-	-
N248	53	M	-	-	-	-
N249	45	M	-	-	-	-
N250	51	M	-	-	-	-
N251	47	M	-	-	-	-
N252	58	M	-	-	-	-
N253	48	F	-	-	-	-
N254	51	M	-	-	-	-
N255	47	M	-	-	-	-
N256	45	F	-	-	-	-
N257	51	M	-	-	-	-
N258	46	F	-	-	-	-
N259	62	M	-	-	-	-
N260	64	M	-	-	-	-
N261	49	M	-	-	-	-
N262	51	M	-	-	-	-

N263	55	M	-	-	-	-
N264	66	F	-	-	-	-
N265	47	F	-	-	-	-
N266	47	F	-	-	-	-
N267	58	M	-	-	-	-
N268	55	M	-	-	-	-
N269	56	M	-	-	-	-
N270	53	M	-	-	-	-
N271	50	M	-	-	-	-
N272	46	M	-	-	-	-
N273	54	M	-	-	-	-
N274	72	F	-	-	-	-
N275	47	M	-	-	-	-
N276	55	M	-	-	-	-
N277	46	M	-	-	-	-
N278	55	M	-	-	-	-
N279	63	F	-	-	-	-
N280	44	M	-	-	-	-

6. Result Interpretation

Table 7. Performance analysis of Clinical Evaluation 1

		Reference method		
		Positive	Negative	Total
Test device	Positive	45	1	46
	Negative	5	49	54
	Total	50	50	100

(1) Accuracy (Overall percent agreement) = 100 x (45+49) / 100 = 94.00%
(95% CI : 87.52%~97.22%)
(2) Sensitivity(Positive percent agreement) = 100 X 45 / 50= 90.00%
(95% CI : 78.64%~95.65%)
(3) Specificity (Negative percent agreement) = 100 X 49 / 50 = 98.00%
(95% CI : 89.50%~99.65%)

Table 8. Performance analysis of Clinical Evaluation 2

		Reference method		
		Positive	Negative	Total
Test device	Positive	64	0	64
	Negative	4	30	34
	Total	68	30	98

(1) Accuracy (Overall percent agreement) = 100 x (64+30) / 130 = 95.92%
(95% CI : 89.97%~98.40%)
(2) Sensitivity(Positive percent agreement) = 100 X 64 / 68 = 94.12%
(95% CI : 85.83%~97.69%)
(3) Specificity (Negative percent agreement) = 100 X 30 / 30 = 100.00%
(95% CI : 88.65%~100.00%)

Table 9. Performance analysis of Clinical Evaluation 2 (Seroconversion)

		Reference method		
		Positive	Negative	Total
Test device	Positive	45	0	45
	Negative	0	0	0
	Total	45	0	45

(1) Sensitivity (Positive percent agreement) = 100 X 45 / 45 = 100.00%
(95% CI : 92.13%~100.00%)

Table 10. Performance analysis of Clinical Evaluation 3

		Reference method		
		Positive	Negative	Total
Test device	Positive	0	5	5
	Negative	0	275	275
	Total	0	280	280

(1) Specificity (Negative percent agreement) = 100 X 275 / 280 = 98.21%
(95% CI : 95.89%~99.23%)

Table 11. Total Clinical Performance analysis (Combined)

		Reference method		
		Positive	Negative	Total
Test device	Positive	154	6	160
	Negative	9	354	363
	Total	163	360	523

(1) Accuracy (Overall percent agreement) = 100 x (154+354) / 523 = 97.13%
(95% CI : 95.32%~98.25%)
(2) Sensitivity (Positive percent agreement) = 100 X 154 / 163 = 94.48%
(95% CI : 89.84%~97.07%)
(3) Specificity (Negative percent agreement) = 100 X 354 / 360 = 98.33%
(95% CI : 96.41%~99.23%)
(4) PPV (Positive predictive value) = 100 X 154 / 160 = 96.25%
(95% CI : 92.06%~98.27%)
(5) NPV (Negative predictive value) = 100 X 354 / 363 = 97.52%
(95% CI : 95.36%~98.69%)

Table 12. Total Clinical Performance analysis for IgM

		Reference method		
		Positive	Negative	Total
Test device IgM result	Positive	148	6	154
	Negative	15	354	369
	Total	163	360	523

(1) Accuracy (Overall percent agreement) = 100 x (148+354) / 523 = 95.98%
(95% CI : 93.94%~97.36%)
(2) Sensitivity (Positive percent agreement) = 100 X 148 / 163 = 90.80%
(95% CI : 85.37%~94.34%)
(3) Specificity (Negative percent agreement) = 100 X 354 / 360 = 98.33%
(95% CI : 96.41%~99.23%)
(4) PPV (Positive predictive value) = 100 X 148 / 154 = 96.10%
(95% CI : 91.76%~98.20%)
(5) NPV (Negative predictive value) = 100 X 354 / 369 = 95.93%
(95% CI : 93.40%~97.52%)

Table 13. Total Clinical Performance analysis for IgG

		Reference method		
		Positive	Negative	Total
Test device IgG result	Positive	147	0	147
	Negative	16	360	376
	Total	163	360	523

(1) Accuracy (Overall percent agreement) = 100 x (147+360) / 523 = 96.94%
(95% CI : 95.09%~98.11%)
(2) Sensitivity (Positive percent agreement) = 100 X 147 / 163 = 90.18%
(95% CI : 84.65%~93.87%)
(3) Specificity (Negative percent agreement) = 100 X 360 / 360 = 100.00%
(95% CI : 98.94%~100.00%)
(4) PPV (Positive predictive value) = 100 X 147 / 147 = 100.00%
(95% CI : 97.45%~100.00%)
(5) NPV (Negative predictive value) = 100 X 360 / 376 = 95.74%
(95% CI : 93.20%~97.36%)

Table 14. The sensitivity estimates for IgM over time

Days after symptom onset (days)	Number of IgM positive	Number of PCR positive	PPA	95% CI
≤7	30	37	81.1 %	65.79~90.52 %
8~14	42	48	87.5 %	75.30~94.14 %

15~21	45	45	100.0 %	92.13~100.00 %
≥22	31	33	93.9 %	80.39~98.32 %

Table 15. The sensitivity estimates for IgG over time

Days after symptom onset (days)	Number of IgM positive	Number of PCR positive	PPA	95% CI
≤7	27	37	73.0 %	57.02~84.60 %
8~14	44	48	91.7 %	80.45~96.71 %
15~21	43	45	95.6 %	85.17~98.77 %
≥22	33	33	100.0 %	89.57~100.00 %

Table 16. The sensitivity estimates for IgM/IgG combined over time

Days after symptom onset (days)	Number of IgM positive	Number of PCR positive	PPA	95% CI
≤7	31	37	83.8 %	68.86~92.35 %
8~14	45	48	93.8 %	83.16~97.85 %
15~21	45	45	100.0 %	92.13~100.00 %
≥22	33	33	100.0 %	89.57~100.00 %

7. Conclusion

Comparison studies between the test device (SGTi-flex COVID19 IgM/IgG) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 523 specimens.

The results showed the accuracy (Overalll percent agreement) was 97.13%. The sensitivity and specificity (positive and negative percent agreements) were 94.48% and 98.33%, respectively.

The Seroconversion study confirmed that IgM was first generated in patients with negative results for IgM or IgG antibodies in the early stages of infection, and that IgG was also produced over time.

When estimating the sensitivity of IgM and IgG over time from symptom onset for all positive samples, the proportion of IgM positive patients reached a peak of 100.0% approximately 15-21 days after symptom onset, whereas the proportion of IgG positive patients reached 100% approximately 22 days after symptom onset.