

Test Protocol

Doc. ID: P-LA-795-00

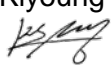

Revision: 00

Date: Jul. 07, 2020

Title :	Comparison Study
Product :	SGTi-flex COVID-19 IgG
Date :	Jul. 07, 2020

Revision History

Rev.0	Jul. 07, 2020	First study after design
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Prepared by/ date	Reviewed by/ date	Approved by/ date
Kiyoung Park 		EunKyung Kim 
Jul. 07, 2020		Jul. 07, 2020

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1. Introduction

In this study, we would like to evaluate the device performance in terms of accuracy compared to the predicate device. The predicate device is the previously approved product which is currently being marketed. The clinical performance study will be carried out in accordance with the local regulation, MFDS (Korean Health Authority) guideline.

2. Normative Standards

- EN 13612:2002, Performance evaluation of *in vitro* diagnostic medical devices
- CLSI Guideline, EP12-A2, Vol. 28, No. 3, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition
- CLSI Guideline, I/LA21-A2, Vol. 28, No. 22, Clinical Evaluation of Immunoassays, Approved Guideline – Second Edition

3. References

- MFDS Guideline, Medical Device Clinical Study, B1-2011-5-031, Korea

4. Product description

SGTi-flex COVID-19 IgG is an immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human whole blood, serum or plasma. The cassette contains a test strip which is located inside a plastic housing. When the sample and sample buffer are loaded to the sample well, the specific IgG antibodies to SARS-CoV-2 flow through the membrane, and move to the test line area and are accumulated by capture antibody immobilized on the membrane. The antigen-gold conjugate move to the test line area and attach to the specific IgG antibodies to SARS-CoV-2. This leads to the generation of a reddish colored band. The intensity of the band depends on quantity of specific IgG antibodies to SARS-CoV-2 and the test results are interpreted by user's eye according to the instructions for use.

5. Intended Use

The SGTi-flex COVID-19 IgG is a lateral flow immunoassay intended for qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, venous whole blood, or plasma (sodium heparin, lithium heparin, sodium citrate and tripotassium EDTA). The SGTi-flex COVID-19 IgG is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this

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time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of SGTi-flex COVID-19 IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for SGTi-flex COVID-19 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG assay.

The SGTi-flex COVID-19 IgG is only for use under the Food and Drug Administration's Emergency Use Authorization.

6. Description of Assay Method

Assay performs according to the instructions for use of each device. The instructions for use of each device is as follows:

6.1 Test Device : SGTi-flex COVID-19 IgG

[Sample preparation]

- (1) The test can be performed with whole blood, serum or plasma.
- (2) Test should be done immediately after sampling collecting. If samples are not used immediately after sampling collecting, samples can be stored in a container with a lid and refrigerated (2-8°C) for 5 days or frozen (-70°C).

[Preparation before test]

- (1) All specimens and reagents must be brought to room temperature for 15~30 minutes before use so that homogeneous state should be maintained.

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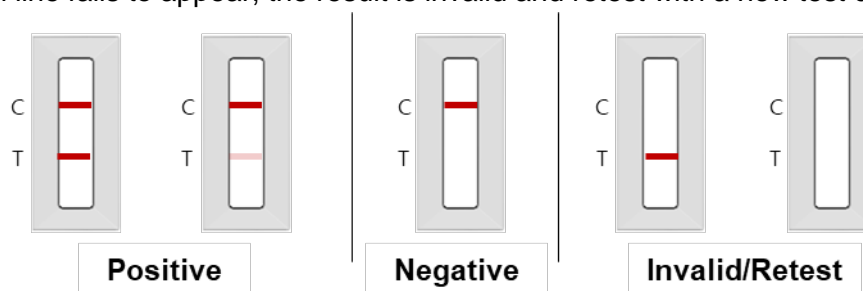
- (2) Test Cassette is sensitive to humidity. Perform the test immediately after opening the pouch.

[TEST PROCEDURE]

- (1) Open the pouch and take out the test cassette. Place it on a flat, dry and clean surface.
- (2) Using a micro pipette, add 10 μ L of specimen into the sample well.
- (3) After loading the sample, dispense 3 drops of sample buffer into the sample well of the cassette.
- (4) Read the results in 10~15 minutes after dispensing the sample. The result after 30 minutes is invalid.

[INTERPRETATION OF TEST RESULTS]

- (1) Positive
 - Test line (T) and Control line (C) are appeared in the result window: Positive for IgG antibody to SARS-CoV-2
- (2) Negative
 - If only Control line (C) appears in the result window: Negative for IgG antibody to SARS-CoV-2
- (3) Invalid / Retest
 - If control line fails to appear, the result is invalid and retest with a new test cassette



7. Devices to be used in the study

7.1 Test device

SGTi-flex COVID-19 IgG kits were selected from general batches manufactured under normal production process, and they are final release meeting the product's quality specification.

7.2 Predicate device : The reference method

Real time RT-PCR method used to diagnose COVID-19 in Chungnam National University Hospital.

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8. Specimen

8.1 Selection criteria

(1) Positive samples

- The specimens are residual serum samples to be discarded after research and use at Chungnam National University Hospital.
- It is classified as positive specimen based on the real time RT-PCR with nasopharyngeal swab, oropharyngeal swab or sputum specimens.
- The specimens are 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

- The specimens are residual serum samples to be discarded after research and use at Chungnam National University Hospital and Eulji University Hospital.
- 34 serum are classified as negative specimen based on the real time RT-PCR with nasopharyngeal swab, oropharyngeal swab or sputum specimens. The specimens are 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.
- 200 serum are randomly chosen from clinically non-infected healthy individuals before 2019.

8.2 Number of specimens

(1) Positive samples: 185 serum

(2) Negative samples: 234 serum

9. Test Procedure

- (1) One batch of each product is used for the test.
- (2) Tests are performed according to the instructions for use of each product.
- (3) The test results are interpreted by user's eyes according to the instructions for use.

10. Data Management

The data will be collected according to internal testing procedure.

11. Data Analysis

The result of comparison study is estimated by the agreement between the predicate device (reference method) and the new test devices. If errors are detected during the test,

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the error results are excluded from the final statistical analysis and the causes are identified and analyzed.

Table 1. Agreement table for comparison between predicate and test device

		Predicate device (Reference method)		
		Positive	Negative	Total
Test device	Positive	a	b	a+b
	Negative	c	d	c+d
	Total	a+c	b+d	n

(1) Accuracy (Overall percent agreement) = $100 \times (a+d) / n$

(2) Sensitivity (Positive percent agreement) = $100 \times a / (a+c)$

(3) Specificity (Negative percent agreement) = $100 \times d / (b+d)$

The comparison study is done according to CLSI EP12-A2 guideline.

12. Appendices

N/A

13. Termination of evaluation

The evaluations are terminated and the test results are processed statistically when the planned minimum number of samples are all tested and satisfied with the expected test results.

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Date: Jul. 20, 2020

Title :	Comparison Study
Product :	SGTi-flex COVID-19 IgG
Date :	Jul. 20, 2020

Protocol No. P-LA-795-00

Revision History

Rev.0	Jul. 20 2020	First study after design
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Prepared by/ date	Reviewed by/ date	Approved by/ date
Kiyoung Park 		Eunkyung Kim 
Jul. 20, 2020		Jul. 20, 2020

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Attachment :

- Instructions for use

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1. Objective of the test

This study was performed so as to do performance evaluation of SGTi-flex COVID-19 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-795-00 / Rev.00 / Jul. 07, 2020

2. Test location and duration

2.1 Test location: : Chungnam National University Hospital and Eulji University Hospital, Daejeon, Korea

2.2 Test duration: Jul. 15~17, 2020

2.3 IRB approval No. : CNUH 2020-03-057 and EMC 2018-09-004

3. Responsibilities

3.1 Principle Investigator 1 : Yeon-Sook Kim / Professor / Division of Infectious Disease, Department of Internal Medicine at Chungnam National University Hospital

3.2 Principle Investigator 2 : Chunhwa Ihm / Associate Professor / Division of laboratory medicine at Eulji Univ. Hospital

3.3 Key contact : Eunkyung Kim / R&D dept. / Sugentech

4. Enrollment Criteria

4.1 Inclusion criteria

- Case patients :

- i. The specimens are those of patients who were confirmed positive by the real time RT-PCR.
- ii. The specimens are 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.
- iii. The specimens are selected retrospectively and blind coded and randomized prior to testing.

- Control subjects :

- i. The specimens are from persons who were confirmed negative by the real time RT-PCR or from healthy individuals who visited for regular medical checkups before 2019.
- ii. For specimens negatively confirmed by RT-PCR, the specimens are paired samples obtained from the same subjects who provided nasopharyngeal swab,

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oropharyngeal swab or sputum samples which were used in the real time RT-PCR as confirmative diagnosis for COVID-19.

iii. The specimens are selected retrospectively and blind coded and randomized prior to testing.

4.2 Exclusion criteria

- Specimens with volume less than 50 µl are excluded.
- Specimens that are not stored below -70°C after 5 days of collection whose stability is uncertain are excluded.
- Specimens suspected of microbial contamination or damage due to improper storage of samples are excluded.

5. Test Result

5.1 Test device(Candidate device)

Product Name	Manufacture	Lot No.
SGTi-flex COVID-19 IgG	Sugentech, Inc.	COGT20101

- The operators were trained by explaining the instructions for use (IFU) before using the test device.

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

5.3 Test Sample (Specimen)

5.3.1 Collection of specimens

(1) Positive samples

- A total of 185 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.
- They 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.
- The patients with symptoms in Daejeon or Chungnam were asked to perform a PCR test through a screening clinic, and those confirmed positive by performing the PCR test were hospitalized. The residual serum samples that were kept after regular blood tests from patients who were admitted to the Chungnam National University Hospital were enrolled.

(2) Negative samples

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- 200 serum were randomly chosen from clinically non-infected healthy individuals who visited for regular medical checkups before 2019 at Eulji University Hospital.
- 34 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.
- As a control subjects, the specimens at Chungnam National University Hospital were voluntarily enrolled from the Chungnam National University Hospital through public notice of medical staff.

The specimen were blind coded and randomized prior to testing.

5.3.2 Number of specimens

- (1) Positive samples: 185 serum
- (2) Negative samples: 234 serum

5.3.3. Sample information

(1) Positive samples

No.	Age	Gender	Date of symptoms onset	Specimen collection date	Days after onset
P01	63	F	Feb. 14, 2020	Mar. 13, 2020	28
P02	49	M	Mar. 06, 2020	Mar. 26, 2020	20
P03	80	M	Mar. 15, 2020	Apr. 03, 2020	19
P04	70	F	Feb. 21, 2020	Mar. 19, 2020	27
P05	64	F	Mar. 18, 2020	Mar. 24, 2020	6
P06	55	F	Mar. 11, 2020	Apr. 17, 2020	50
P07	58	M	Jun. 15, 2020	Jun. 29, 2020	14
P08	31	M	Feb. 25, 2020	Mar. 10, 2020	14
P09	41	F	Mar. 17, 2020	Apr. 01, 2020	15
P10	41	M	Feb. 22, 2020	Mar. 13, 2020	20
P11	58	F	Mar. 13, 2020	Apr. 20, 2020	38
P12	36	F	Feb. 22, 2020	Mar. 10, 2020	17
P13	43	M	Mar. 09, 2020	Apr. 17, 2020	39
P14	35	M	Feb. 22, 2020	Feb. 27, 2020	5
P15	72	F	Jun. 11, 2020	Jun. 29, 2020	18
P16	57	F	Jun. 14, 2020	Jun. 30, 2020	16
P17	92	F	Jun. 13, 2020	Jun. 29, 2020	16

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P18	65	F	Feb. 22, 2020	Mar. 12, 2020	19
P19	62	M	Feb. 21, 2020	Mar. 17, 2020	25
P20	47	M	Mar. 11, 2020	Apr. 17, 2020	37
P21	40	M	Mar. 10, 2020	Apr. 06, 2020	27
P22	63	F	Feb. 22, 2020	Mar. 23, 2020	30
P23	40	M	Mar. 06, 2020	Mar. 23, 2020	17
P24	18	M	Mar. 12, 2020	Apr. 23, 2020	42
P25	63	M	Feb. 22, 2020	Mar. 05, 2020	12
P26	78	F	Mar. 03, 2020	Apr. 04, 2020	30
P27	65	M	Feb. 21, 2020	Apr. 02, 2020	41
P28	55	F	Feb. 14, 2020	Mar. 11, 2020	26
P29	97	F	Mar. 19, 2020	Apr. 04, 2020	16
P30	39	M	Feb. 21, 2020	Apr. 11, 2020	50
P31	66	F	Jun. 22, 2020	Jul. 06, 2020	14
P32	53	F	Mar. 07, 2020	Mar. 25, 2020	18
P33	60	F	Feb. 19, 2020	Mar. 26, 2020	36
P34	25	M	Mar. 25, 2020	Mar. 25, 2020	0
P35	29	M	Mar. 21, 2020	Apr. 30, 2020	40
P36	87	F	Mar. 20, 2020	Mar. 21, 2020	1
P37	33	F	Feb. 21, 2020	Apr. 18, 2020	57
P38	80	M	Mar. 12, 2020	Mar. 21, 2020	9
P39	35	M	Feb. 22, 2020	Apr. 16, 2020	54
P40	45	M	Feb. 22, 2020	Apr. 17, 2020	55
P41	53	M	Mar. 04, 2020	Mar. 23, 2020	19
P42	61	M	Feb. 19, 2020	Apr. 09, 2020	50
P43	48	F	Mar. 07, 2020	Apr. 17, 2020	41
P44	62	F	Feb. 21, 2020	Mar. 26, 2020	34
P45	43	F	Mar. 04, 2020	Mar. 21, 2020	17
P46	41	M	Mar. 17, 2020	Mar. 26, 2020	9
P47	59	F	Mar. 16, 2020	Mar. 24, 2020	8
P48	47	F	Mar. 09, 2020	Apr. 14, 2020	36
P49	86	M	Mar. 20, 2020	Mar. 27, 2020	7
P50	38	M	Mar. 17, 2020	Apr. 04, 2020	18
P51	24	M	Mar. 10, 2020	Apr. 10, 2020	31
P52	42	F	Feb. 22, 2020	Apr. 11, 2020	49

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P53	60	M	Jun. 13, 2020	Jun. 29, 2020	16
P54	46	M	Feb. 22, 2020	Apr. 09, 2020	47
P55	59	M	Mar. 16, 2020	May 04, 2020	49
P56	33	M	Feb. 22, 2020	Mar. 23, 2020	30
P57	68	F	Mar. 03, 2020	Apr. 09, 2020	34
P58	33	M	Feb. 25, 2020	Apr. 24, 2020	59
P59	67	F	Feb. 22, 2020	May 21, 2020	89
P60	45	F	Feb. 21, 2020	Mar. 01, 2020	9
P61	53	F	Mar. 05, 2020	Mar. 11, 2020	6
P62	23	M	Mar. 20, 2020	Mar. 26, 2020	6
P63	63	F	Jun. 10, 2020	Jun. 26, 2020	16
P64	49	F	Mar. 04, 2020	Apr. 08, 2020	35
P65	39	F	Feb. 22, 2020	Mar. 01, 2020	8
P66	61	M	Mar. 04, 2020	Apr. 09, 2020	36
P67	55	M	Mar. 13, 2020	Apr. 13, 2020	31
P68	55	F	Mar. 17, 2020	Apr. 14, 2020	28
P69	49	F	Mar. 13, 2020	Apr. 18, 2020	36
P70	65	M	Mar. 13, 2020	Apr. 17, 2020	35
P71	18	F	Mar. 25, 2020	Apr. 13, 2020	19
P72	47	M	Feb. 29, 2020	Apr. 09, 2020	40
P73	81	M	Jun. 14, 2020	Jun. 30, 2020	16
P74	48	M	Feb. 22, 2020	Mar. 09, 2020	16
P75	65	M	Feb. 18, 2020	Feb. 28, 2020	10
P76	65	F	Feb. 18, 2020	Mar. 23, 2020	34
P77	66	M	Feb. 22, 2020	Mar. 26, 2020	33
P78	49	M	Mar. 13, 2020	Apr. 22, 2020	40
P79	66	F	Mar. 26, 2020	May 07, 2020	42
P80	84	M	Mar. 16, 2020	Mar. 25, 2020	9
P81	86	F	Mar. 19, 2020	Apr. 10, 2020	22
P82	49	F	Feb. 21, 2020	Apr. 15, 2020	54
P83	78	M	Mar. 03, 2020	Apr. 13, 2020	39
P84	48	F	Feb. 21, 2020	Mar. 12, 2020	20
P85	57	F	Jul. 02, 2020	Jul. 09, 2020	7
P86	65	M	Feb. 22, 2020	Mar. 03, 2020	10
P87	65	F	Feb. 22, 2020	Apr. 04, 2020	42

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P88	33	F	Feb. 22, 2020	Mar. 11, 2020	18
P89	57	F	Mar. 11, 2020	Apr. 03, 2020	23
P90	70	F	Jun. 15, 2020	Jul. 01, 2020	16
P91	70	F	Feb. 22, 2020	Mar. 30, 2020	37
P92	55	F	Mar. 11, 2020	Mar. 21, 2020	10
P93	84	M	Mar. 15, 2020	Apr. 09, 2020	25
P94	41	M	Mar. 17, 2020	Apr. 27, 2020	41
P95	55	F	Mar. 16, 2020	Apr. 04, 2020	19
P96	53	F	Mar. 04, 2020	May 05, 2020	62
P97	58	M	Mar. 13, 2020	Mar. 21, 2020	8
P98	35	M	Mar. 25, 2020	Apr. 14, 2020	20
P99	20	F	May 08, 2020	Jun. 10, 2020	33
P100	48	M	Mar. 17, 2020	Apr. 18, 2020	32
P101	47	M	Mar. 09, 2020	Mar. 31, 2020	22
P102	62	F	Mar. 03, 2020	Mar. 30, 2020	27
P103	61	F	Feb. 19, 2020	Mar. 23, 2020	33
P104	24	F	Feb. 26, 2020	Apr. 16, 2020	50
P105	45	F	Mar. 17, 2020	Apr. 09, 2020	23
P106	22	F	Feb. 18, 2020	Mar. 04, 2020	15
P107	70	F	Jun. 15, 2020	Jun. 29, 2020	14
P108	24	M	Jul. 05, 2020	Jul. 08, 2020	3
P109	55	M	Mar. 11, 2020	Apr. 10, 2020	30
P110	47	F	Feb. 29, 2020	Mar. 09, 2020	9
P111	68	F	Jun. 15, 2020	Jun. 30, 2020	15
P112	65	F	Feb. 17, 2020	Mar. 06, 2020	18
P113	26	M	Feb. 25, 2020	Mar. 07, 2020	11
P114	47	M	Feb. 21, 2020	Mar. 11, 2020	19
P115	62	F	Mar. 11, 2020	May 19, 2020	69
P116	63	F	Feb. 17, 2020	Feb. 26, 2020	9
P117	50	F	Jun. 19, 2020	Jul. 03, 2020	14
P118	68	M	Feb. 21, 2020	Apr. 23, 2020	62
P119	84	F	Mar. 15, 2020	Apr. 06, 2020	22
P120	44	F	Feb. 29, 2020	Mar. 25, 2020	25
P121	51	M	Mar. 10, 2020	Mar. 24, 2020	14
P122	36	M	Feb. 25, 2020	May 06, 2020	71

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P123	27	M	Feb. 28, 2020	Mar. 05, 2020	6
P124	32	M	Feb. 23, 2020	Mar. 06, 2020	12
P125	58	M	Jun. 17, 2020	Jul. 01, 2020	14
P126	24	F	Mar. 29, 2020	Apr. 14, 2020	16
P127	61	M	Mar. 30, 2020	Apr. 17, 2020	18
P128	37	M	Mar. 17, 2020	Apr. 06, 2020	20
P129	66	M	Feb. 18, 2020	Apr. 02, 2020	44
P130	74	M	Mar. 15, 2020	Apr. 04, 2020	20
P131	62	M	Feb. 21, 2020	Feb. 24, 2020	3
P132	54	F	Mar. 18, 2020	Apr. 06, 2020	19
P133	72	F	Feb. 21, 2020	Apr. 09, 2020	48
P134	58	M	Jul. 04, 2020	Jul. 08, 2020	4
P135	76	F	Mar. 03, 2020	Apr. 30, 2020	55
P136	35	M	Feb. 21, 2020	Mar. 10, 2020	18
P137	40	F	Feb. 19, 2020	Mar. 13, 2020	23
P138	45	F	Feb. 21, 2020	Apr. 22, 2020	61
P139	21	F	May 08, 2020	May 29, 2020	21
P140	65	F	Feb. 21, 2020	Apr. 06, 2020	45
P141	61	F	Feb. 21, 2020	Apr. 10, 2020	49
P142	31	F	Mar. 21, 2020	Apr. 08, 2020	18
P143	36	M	Feb. 22, 2020	Mar. 09, 2020	16
P144	63	M	Feb. 14, 2020	Apr. 13, 2020	59
P145	61	F	Feb. 18, 2020	Mar. 11, 2020	22
P146	53	F	Feb. 14, 2020	Mar. 23, 2020	38
P147	65	M	Feb. 18, 2020	Mar. 28, 2020	39
P148	58	M	Feb. 22, 2020	Mar. 19, 2020	26
P149	36	M	Feb. 22, 2020	Mar. 01, 2020	8
P150	43	M	Mar. 20, 2020	Apr. 06, 2020	17
P151	22	M	Feb. 29, 2020	Apr. 05, 2020	36
P152	61	M	Mar. 15, 2020	Apr. 01, 2020	17
P153	71	M	Feb. 22, 2020	Mar. 12, 2020	19
P154	36	M	Feb. 22, 2020	Apr. 16, 2020	54
P155	49	F	Mar. 06, 2020	Mar. 10, 2020	4
P156	47	F	Mar. 09, 2020	Apr. 21, 2020	43
P157	54	F	Jul. 08, 2020	Jul. 09, 2020	1

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P158	85	F	Mar. 19, 2020	Apr. 03, 2020	15
P159	32	F	Mar. 17, 2020	Apr. 11, 2020	25
P160	64	F	Mar. 13, 2020	Apr. 06, 2020	24
P161	41	F	Feb. 18, 2020	Feb. 23, 2020	5
P162	71	M	Mar. 13, 2020	Apr. 03, 2020	21
P163	78	F	Mar. 03, 2020	Mar. 24, 2020	21
P164	47	M	Mar. 06, 2020	Apr. 09, 2020	34
P165	52	M	Mar. 16, 2020	Apr. 11, 2020	26
P166	22	F	Mar. 21, 2020	Mar. 26, 2020	5
P167	61	F	Feb. 19, 2020	Mar. 19, 2020	29
P168	63	M	Feb. 22, 2020	Mar. 19, 2020	26
P169	59	F	Mar. 13, 2020	May 12, 2020	60
P170	65	M	Feb. 17, 2020	Apr. 13, 2020	56
P171	25	M	Feb. 28, 2020	Apr. 21, 2020	53
P172	56	F	Feb. 29, 2020	Mar. 19, 2020	19
P173	60	F	Feb. 17, 2020	Mar. 10, 2020	22
P174	63	M	Feb. 18, 2020	Apr. 06, 2020	48
P175	54	M	Mar. 17, 2020	Apr. 16, 2020	30
P176	54	M	Feb. 21, 2020	Apr. 13, 2020	52
P177	47	F	Mar. 09, 2020	Apr. 07, 2020	29
P178	63	F	Feb. 14, 2020	Mar. 19, 2020	34
P179	71	F	Feb. 21, 2020	Mar. 23, 2020	31
P180	58	M	Jul. 08, 2020	Jul. 10, 2020	2
P181	65	M	Feb. 24, 2020	Apr. 23, 2020	59
P182	75	M	Feb. 18, 2020	Mar. 17, 2020	28
P183	52	M	Mar. 05, 2020	Apr. 27, 2020	53
P184	23	M	Feb. 07, 2020	Apr. 29, 2020	82
P185	64	F	Jun. 10, 2020	Jun. 24, 2020	14

(2) Negative samples
(Eulji University Hospital)

No.	Age	Gender	Specimen collection date	No.	Age	Gender	Specimen collection date
N01	53	F	Jul. 03, 2017	N101	46	F	Aug. 09, 2018
N02	76	M	Jul. 12, 2017	N102	48	M	Aug. 09, 2018
N03	56	M	Jul. 27, 2017	N103	57	F	Aug. 09, 2018

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N04	62	M	Jul. 31, 2017	N104	53	F	Aug. 10, 2018
N05	73	M	Jul. 31, 2017	N105	45	F	Aug. 10, 2018
N06	64	F	Jul. 31, 2017	N106	46	M	Aug. 10, 2018
N07	62	M	Aug. 02, 2017	N107	57	M	Aug. 10, 2018
N08	68	F	Aug. 04, 2017	N108	58	M	Aug. 10, 2018
N09	51	F	Aug. 08, 2017	N109	61	M	Aug. 10, 2018
N10	55	M	Aug. 09, 2017	N110	49	M	Aug. 13, 2018
N11	68	M	Aug. 10, 2017	N111	46	F	Aug. 13, 2018
N12	53	F	Aug. 10, 2017	N112	48	F	Aug. 13, 2018
N13	54	M	Aug. 10, 2017	N113	47	M	Aug. 13, 2018
N14	64	M	Aug. 17, 2017	N114	50	M	Aug. 16, 2018
N15	61	F	Aug. 17, 2017	N115	57	M	Aug. 16, 2018
N16	50	F	Aug. 17, 2017	N116	51	M	Aug. 17, 2018
N17	58	M	Aug. 23, 2017	N117	49	M	Aug. 17, 2018
N18	55	M	Aug. 23, 2017	N118	51	F	Aug. 20, 2018
N19	54	F	Aug. 24, 2017	N119	52	M	Aug. 21, 2018
N20	57	F	Aug. 28, 2017	N120	63	M	Aug. 22, 2018
N21	50	M	Aug. 29, 2017	N121	49	F	Aug. 22, 2018
N22	61	M	Aug. 29, 2017	N122	53	M	Aug. 22, 2018
N23	62	F	Aug. 30, 2017	N123	56	F	Aug. 22, 2018
N24	61	F	Sep. 06, 2017	N124	63	M	Aug. 23, 2018
N25	65	M	Sep. 06, 2017	N125	62	M	Aug. 23, 2018
N26	69	M	Sep. 06, 2017	N126	46	M	Aug. 24, 2018
N27	60	F	Sep. 12, 2017	N127	52	F	Aug. 24, 2018
N28	58	F	Sep. 14, 2017	N128	58	M	Aug. 27, 2018
N29	62	F	Dec. 12, 2017	N129	51	M	Aug. 27, 2018
N30	62	F	Dec. 18, 2017	N130	62	F	Aug. 27, 2018
N31	65	M	Jan. 16, 2018	N131	46	M	Aug. 27, 2018
N32	61	F	Jan. 23, 2018	N132	58	M	Aug. 27, 2018
N33	61	F	Jan. 25, 2018	N133	53	M	Aug. 28, 2018
N34	46	F	Jan. 29, 2018	N134	50	M	Aug. 28, 2018
N35	67	M	Jan. 31, 2018	N135	49	F	Aug. 28, 2018
N36	67	F	Jan. 31, 2018	N136	52	M	Aug. 28, 2018
N37	47	F	Feb. 06, 2018	N137	45	M	Aug. 29, 2018
N38	47	M	Feb. 06, 2018	N138	59	F	Aug. 29, 2018

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N39	58	M	Feb. 07, 2018	N139	55	F	Aug. 29, 2018
N40	46	M	Feb. 20, 2018	N140	47	F	Aug. 29, 2018
N41	52	F	Feb. 20, 2018	N141	48	F	Aug. 29, 2018
N42	74	F	Feb. 22, 2018	N142	53	F	Aug. 29, 2018
N43	49	F	Feb. 19, 2018	N143	59	F	Aug. 29, 2018
N44	65	F	Mar. 14, 2018	N144	66	F	Aug. 29, 2018
N45	61	F	Mar. 20, 2018	N145	50	F	Aug. 29, 2018
N46	73	F	Mar. 23, 2018	N146	66	F	Aug. 29, 2018
N47	48	M	Mar. 26, 2018	N147	66	F	Aug. 29, 2018
N48	49	F	Mar. 27, 2018	N148	60	F	Aug. 29, 2018
N49	49	F	Apr. 02, 2018	N149	63	F	Aug. 29, 2018
N50	67	F	Apr. 04, 2018	N150	55	F	Aug. 29, 2018
N51	61	F	Apr. 05, 2018	N151	49	F	Aug. 29, 2018
N52	49	M	Apr. 11, 2018	N152	53	F	Aug. 29, 2018
N53	48	F	Apr. 13, 2018	N153	56	F	Aug. 29, 2018
N54	48	F	Apr. 17, 2018	N154	58	F	Aug. 29, 2018
N55	53	F	Apr. 17, 2018	N155	56	F	Aug. 29, 2018
N56	49	F	Apr. 23, 2018	N156	51	F	Aug. 29, 2018
N57	61	F	Apr. 24, 2018	N157	65	F	Aug. 29, 2018
N58	71	M	Apr. 24, 2018	N158	60	F	Aug. 29, 2018
N59	62	F	Apr. 25, 2018	N159	56	F	Aug. 29, 2018
N60	56	F	Apr. 25, 2018	N160	53	M	Aug. 30, 2018
N61	61	F	Apr. 26, 2018	N161	62	M	Aug. 30, 2018
N62	51	F	May 03, 2018	N162	67	F	Aug. 30, 2018
N63	71	M	May 03, 2018	N163	52	F	Aug. 30, 2018
N64	46	M	May 04, 2018	N164	45	F	Aug. 30, 2018
N65	48	M	May 08, 2018	N165	60	F	Aug. 31, 2018
N66	56	F	May 09, 2018	N166	61	F	Aug. 31, 2018
N67	72	F	May 09, 2018	N167	55	F	Aug. 31, 2018
N68	55	F	May 10, 2018	N168	57	M	Sep. 03, 2018
N69	48	F	May 10, 2018	N169	51	F	Sep. 03, 2018
N70	50	M	May 14, 2018	N170	83	F	Sep. 03, 2018
N71	50	M	May 14, 2018	N171	53	F	Sep. 03, 2018
N72	46	M	May 14, 2018	N172	51	F	Sep. 03, 2018
N73	50	M	May 14, 2018	N173	49	F	Sep. 04, 2018

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N74	55	F	May 15, 2018	N174	62	M	Sep. 04, 2018
N75	59	M	May 15, 2018	N175	58	F	Sep. 05, 2018
N76	54	F	May 15, 2018	N176	65	M	Sep. 05, 2018
N77	52	F	May 16, 2018	N177	45	M	Sep. 05, 2018
N78	54	M	May 17, 2018	N178	65	F	Sep. 05, 2018
N79	53	F	May 17, 2018	N179	60	F	Sep. 05, 2018
N80	64	F	May 17, 2018	N180	47	F	Sep. 05, 2018
N81	46	M	May 18, 2018	N181	48	M	Sep. 05, 2018
N82	52	M	May 21, 2018	N182	50	M	Sep. 06, 2018
N83	53	F	May 24, 2018	N183	50	M	Sep. 06, 2018
N84	59	M	May 24, 2018	N184	45	F	Sep. 06, 2018
N85	68	F	May 24, 2018	N185	71	F	Sep. 06, 2018
N86	57	F	May 25, 2018	N186	58	M	Sep. 07, 2018
N87	51	M	May 28, 2018	N187	58	M	Sep. 07, 2018
N88	46	F	May 28, 2018	N188	63	F	Sep. 07, 2018
N89	56	F	May 29, 2018	N189	56	F	Sep. 07, 2018
N90	49	F	May 30, 2018	N190	68	F	Sep. 07, 2018
N91	53	M	Jun. 04, 2018	N191	56	F	Sep. 07, 2018
N92	48	F	Jun. 04, 2018	N192	64	F	Sep. 07, 2018
N93	51	M	Jun. 04, 2018	N193	59	F	Sep. 07, 2018
N94	46	M	Jun. 04, 2018	N194	61	F	Sep. 07, 2018
N95	47	F	Jun. 07, 2018	N195	61	F	Sep. 07, 2018
N96	45	F	Jun. 08, 2018	N196	55	F	Sep. 07, 2018
N97	47	M	Jun. 11, 2018	N197	62	F	Sep. 07, 2018
N98	53	M	Jun. 12, 2018	N198	64	F	Sep. 07, 2018
N99	57	M	Jun. 12, 2018	N199	49	F	Sep. 10, 2018
N100	51	M	Jun. 15, 2018	N200	50	F	Sep. 10, 2018

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No.	Age	Gender	Specimen collection date	No.	Age	Gender	Specimen collection date
N201	30	F	Jul. 13, 2020	N218	25	F	Jul. 14, 2020
N202	28	F	Jul. 13, 2020	N219	57	F	Jul. 14, 2020
N203	25	F	Jul. 13, 2020	N220	25	F	Jul. 14, 2020
N204	34	F	Jul. 13, 2020	N221	28	F	Jul. 14, 2020
N205	25	F	Jul. 13, 2020	N222	22	F	Jul. 14, 2020

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N206	31	F	Jul. 13, 2020	N223	47	F	Jul. 14, 2020
N207	57	F	Jul. 13, 2020	N224	38	F	Jul. 14, 2020
N208	22	F	Jul. 13, 2020	N225	33	F	Jul. 14, 2020
N209	23	F	Jul. 13, 2020	N226	35	F	Jul. 14, 2020
N210	39	F	Jul. 13, 2020	N227	25	F	Jul. 17, 2020
N211	25	F	Jul. 13, 2020	N228	25	F	Jul. 14, 2020
N212	25	F	Jul. 13, 2020	N229	25	F	Jul. 14, 2020
N213	37	M	Jul. 13, 2020	N230	32	F	Jul. 15, 2020
N214	48	F	Jul. 13, 2020	N231	24	F	Jul. 15, 2020
N215	25	F	Jul. 13, 2020	N232	23	F	Jul. 15, 2020
N216	24	F	Jul. 13, 2020	N233	24	F	Jul. 15, 2020
N217	24	F	Jul. 13, 2020	N234	24	F	Jul. 15, 2020

5.4. Test Result Data

5.4.1 Positive samples : Test results are summarized at Table 1.

Table 1. Result of positive samples

Specimen No.	Specimen Type	Result	
		Clinical diagnosis (Real time PCR)	Test Device (SGTi-flex COVID-19 IgG)
P01	serum	+	+
P02	serum	+	+
P03	serum	+	+
P04	serum	+	+
P05	serum	+	+
P06	serum	+	+
P07	serum	+	+
P08	serum	+	-
P09	serum	+	+
P10	serum	+	+
P11	serum	+	+
P12	serum	+	+
P13	serum	+	+
P14	serum	+	+
P15	serum	+	+
P16	serum	+	+
P17	serum	+	-

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P18	serum	+	+
P19	serum	+	+
P20	serum	+	+
P21	serum	+	+
P22	serum	+	+
P23	serum	+	+
P24	serum	+	+
P25	serum	+	+
P26	serum	+	+
P27	serum	+	+
P28	serum	+	+
P29	serum	+	+
P30	serum	+	+
P31	serum	+	+
P32	serum	+	+
P33	serum	+	+
P34	serum	+	-
P35	serum	+	+
P36	serum	+	-
P37	serum	+	+
P38	serum	+	+
P39	serum	+	+
P40	serum	+	+
P41	serum	+	+
P42	serum	+	+
P43	serum	+	+
P44	serum	+	+
P45	serum	+	+
P46	serum	+	+
P47	serum	+	+
P48	serum	+	+
P49	serum	+	-
P50	serum	+	+
P51	serum	+	+
P52	serum	+	+
P53	serum	+	+
P54	serum	+	+

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P55	serum	+	+
P56	serum	+	+
P57	serum	+	+
P58	serum	+	+
P59	serum	+	+
P60	serum	+	+
P61	serum	+	+
P62	serum	+	+
P63	serum	+	+
P64	serum	+	+
P65	serum	+	+
P66	serum	+	+
P67	serum	+	+
P68	serum	+	+
P69	serum	+	+
P70	serum	+	+
P71	serum	+	+
P72	serum	+	+
P73	serum	+	+
P74	serum	+	+
P75	serum	+	+
P76	serum	+	+
P77	serum	+	+
P78	serum	+	+
P79	serum	+	+
P80	serum	+	+
P81	serum	+	+
P82	serum	+	+
P83	serum	+	+
P84	serum	+	+
P85	serum	+	-
P86	serum	+	+
P87	serum	+	+
P88	serum	+	+
P89	serum	+	+
P90	serum	+	+
P91	serum	+	+

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P92	serum	+	+
P93	serum	+	+
P94	serum	+	+
P95	serum	+	+
P96	serum	+	+
P97	serum	+	+
P98	serum	+	+
P99	serum	+	+
P100	serum	+	+
P101	serum	+	+
P102	serum	+	+
P103	serum	+	+
P104	serum	+	+
P105	serum	+	+
P106	serum	+	+
P107	serum	+	+
P108	serum	+	-
P109	serum	+	+
P110	serum	+	+
P111	serum	+	+
P112	serum	+	+
P113	serum	+	+
P114	serum	+	+
P115	serum	+	+
P116	serum	+	-
P117	serum	+	+
P118	serum	+	+
P119	serum	+	+
P120	serum	+	+
P121	serum	+	+
P122	serum	+	+
P123	serum	+	+
P124	serum	+	+
P125	serum	+	+
P126	serum	+	+
P127	serum	+	+
P128	serum	+	+

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P129	serum	+	+
P130	serum	+	+
P131	serum	+	-
P132	serum	+	+
P133	serum	+	+
P134	serum	+	-
P135	serum	+	+
P136	serum	+	+
P137	serum	+	+
P138	serum	+	+
P139	serum	+	+
P140	serum	+	+
P141	serum	+	+
P142	serum	+	+
P143	serum	+	-
P144	serum	+	+
P145	serum	+	+
P146	serum	+	+
P147	serum	+	+
P148	serum	+	+
P149	serum	+	+
P150	serum	+	+
P151	serum	+	+
P152	serum	+	+
P153	serum	+	+
P154	serum	+	+
P155	serum	+	+
P156	serum	+	+
P157	serum	+	-
P158	serum	+	+
P159	serum	+	+
P160	serum	+	+
P161	serum	+	-
P162	serum	+	+
P163	serum	+	+
P164	serum	+	+
P165	serum	+	+

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P166	serum	+	+
P167	serum	+	+
P168	serum	+	+
P169	serum	+	+
P170	serum	+	+
P171	serum	+	+
P172	serum	+	+
P173	serum	+	+
P174	serum	+	+
P175	serum	+	+
P176	serum	+	+
P177	serum	+	+
P178	serum	+	+
P179	serum	+	+
P180	serum	+	-
P181	serum	+	+
P182	serum	+	+
P183	serum	+	+
P184	serum	+	+
P185	serum	+	+

5.4.2 Negative samples :Test results are summarized at Table 2

Table 2. Result of negative samples

Specimen No.	Specimen Type	Result	
		Clinical diagnosis (or Real time PCR)	Test Device (SGTi-flex COVID-19 IgG)
N01	serum	-	-
N02	serum	-	-
N03	serum	-	-
N04	serum	-	-
N05	serum	-	-
N06	serum	-	-
N07	serum	-	-
N08	serum	-	-
N09	serum	-	-
N10	serum	-	-

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N11	serum	-	-
N12	serum	-	-
N13	serum	-	-
N14	serum	-	-
N15	serum	-	-
N16	serum	-	-
N17	serum	-	-
N18	serum	-	-
N19	serum	-	-
N20	serum	-	-
N21	serum	-	-
N22	serum	-	-
N23	serum	-	-
N24	serum	-	-
N25	serum	-	-
N26	serum	-	-
N27	serum	-	-
N28	serum	-	-
N29	serum	-	-
N30	serum	-	-
N31	serum	-	-
N32	serum	-	-
N33	serum	-	-
N34	serum	-	-
N35	serum	-	-
N36	serum	-	-
N37	serum	-	-
N38	serum	-	-
N39	serum	-	-
N40	serum	-	-
N41	serum	-	-
N42	serum	-	-
N43	serum	-	-
N44	serum	-	-
N45	serum	-	-
N46	serum	-	-
N47	serum	-	-

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N48	serum	-	-
N49	serum	-	-
N50	serum	-	-
N51	serum	-	-
N52	serum	-	-
N53	serum	-	-
N54	serum	-	-
N55	serum	-	-
N56	serum	-	-
N57	serum	-	-
N58	serum	-	-
N59	serum	-	-
N60	serum	-	-
N61	serum	-	-
N62	serum	-	-
N63	serum	-	-
N64	serum	-	-
N65	serum	-	-
N66	serum	-	-
N67	serum	-	-
N68	serum	-	-
N69	serum	-	-
N70	serum	-	-
N71	serum	-	-
N72	serum	-	-
N73	serum	-	-
N74	serum	-	-
N75	serum	-	-
N76	serum	-	-
N77	serum	-	-
N78	serum	-	-
N79	serum	-	-
N80	serum	-	-
N81	serum	-	-
N82	serum	-	-
N83	serum	-	-
N84	serum	-	-

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N85	serum	-	-
N86	serum	-	-
N87	serum	-	-
N88	serum	-	-
N89	serum	-	-
N90	serum	-	-
N91	serum	-	-
N92	serum	-	-
N93	serum	-	-
N94	serum	-	-
N95	serum	-	-
N96	serum	-	-
N97	serum	-	-
N98	serum	-	-
N99	serum	-	-
N100	serum	-	-
N101	serum	-	-
N102	serum	-	+
N103	serum	-	-
N104	serum	-	-
N105	serum	-	-
N106	serum	-	-
N107	serum	-	-
N108	serum	-	-
N109	serum	-	-
N110	serum	-	-
N111	serum	-	-
N112	serum	-	-
N113	serum	-	-
N114	serum	-	-
N115	serum	-	-
N116	serum	-	-
N117	serum	-	-
N118	serum	-	-
N119	serum	-	+
N120	serum	-	-
N121	serum	-	-

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N122	serum	-	-
N123	serum	-	-
N124	serum	-	-
N125	serum	-	-
N126	serum	-	-
N127	serum	-	-
N128	serum	-	-
N129	serum	-	-
N130	serum	-	-
N131	serum	-	-
N132	serum	-	-
N133	serum	-	-
N134	serum	-	-
N135	serum	-	-
N136	serum	-	-
N137	serum	-	-
N138	serum	-	-
N139	serum	-	-
N140	serum	-	-
N141	serum	-	-
N142	serum	-	-
N143	serum	-	-
N144	serum	-	-
N145	serum	-	-
N146	serum	-	-
N147	serum	-	-
N148	serum	-	-
N149	serum	-	-
N150	serum	-	-
N151	serum	-	-
N152	serum	-	-
N153	serum	-	-
N154	serum	-	-
N155	serum	-	-
N156	serum	-	-
N157	serum	-	-
N158	serum	-	-

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N159	serum	-	-
N160	serum	-	-
N161	serum	-	-
N162	serum	-	-
N163	serum	-	-
N164	serum	-	-
N165	serum	-	-
N166	serum	-	-
N167	serum	-	-
N168	serum	-	-
N169	serum	-	-
N170	serum	-	-
N171	serum	-	-
N172	serum	-	-
N173	serum	-	-
N174	serum	-	-
N175	serum	-	-
N176	serum	-	-
N177	serum	-	-
N178	serum	-	-
N179	serum	-	-
N180	serum	-	-
N181	serum	-	-
N182	serum	-	-
N183	serum	-	-
N184	serum	-	-
N185	serum	-	-
N186	serum	-	-
N187	serum	-	-
N188	serum	-	-
N189	serum	-	-
N190	serum	-	-
N191	serum	-	-
N192	serum	-	-
N193	serum	-	-
N194	serum	-	-
N195	serum	-	-

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N196	serum	-	-
N197	serum	-	-
N198	serum	-	-
N199	serum	-	-
N200	serum	-	-
N201	serum	-	-
N202	serum	-	-
N203	serum	-	-
N204	serum	-	-
N205	serum	-	-
N206	serum	-	-
N207	serum	-	-
N208	serum	-	-
N209	serum	-	-
N210	serum	-	-
N211	serum	-	-
N212	serum	-	-
N213	serum	-	-
N214	serum	-	-
N215	serum	-	-
N216	serum	-	-
N217	serum	-	-
N218	serum	-	-
N219	serum	-	-
N220	serum	-	-
N221	serum	-	-
N222	serum	-	-
N223	serum	-	-
N224	serum	-	-
N225	serum	-	-
N226	serum	-	-
N227	serum	-	-
N228	serum	-	-
N229	serum	-	-
N230	serum	-	-
N231	serum	-	-
N232	serum	-	-

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N233	serum	-	-
N234	serum	-	-

6. Result Interpretation

Table 3. Clinical Performance analysis

		Reference method		
		Positive	Negative	Total
Test device	Positive	171	2	173
	Negative	14	232	246
	Total	185	234	419

(1) Accuracy (Overall percent agreement) = $100 \times (171+232) / 419 = 96.18\%$

(95% CI : 93.89%~97.64%)

(2) Sensitivity (Positive percent agreement) = $100 \times 171 / 185 = 92.43\%$

(95% CI : 87.70%~95.44%)

(3) Specificity (Negative percent agreement) = $100 \times 232 / 234 = 99.15\%$

(95% CI : 96.94%~99.77%)

Table 4. The IgG positive percent agreement (PPA) by time of sampling from symptoms onset

Days from symptom onset	Number of Samples Tested	SGTi-flex COVID-19 IgG Results		
		IgG Positive Results	IgG PPA	95% CI
0-7 days	17	7	41.2 %	21.61~63.99 %
8-14 days	24	22	91.7 %	74.15~97.68 %
≥15 days	144	142	98.6 %	95.08~99.62 %

Table 5. The IgG negative percent agreement (NPA)

Number of Samples Tested	SGTi-flex COVID-19 IgG Results		
	IgG Negative Results	IgG NPA	95% CI
234	232	99.15 %	96.94~99.77 %

7. Conclusion

Comparison studies between the test device (SGTi-flex COVID-19 IgG) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 419 specimens.

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The results showed the accuracy (Overall percent agreement) was 96.18%. The sensitivity and specificity (positive and negative percent agreements) were 92.43% and 99.15%, respectively.

When estimating the sensitivity of IgG over time from symptom onset for all positive samples, the proportion of IgG positive patients reached 98.6% approximately 15 days after symptom onset.