Test Report

Doc. ID:	R-LA-812-02
Revision:	02
Date:	Nov. 23, 2020

Title :	**Comparison Study**
Product :	SGTi-flex COVID-19 Ag
Date :	Nov. 23, 2020

Protocol No. P-LA-812-02

Revision History		
Rev.0	Aug. 07, 2020	First study after design
Rev.1	Sep. 08, 2020	Addition of the result for additional positive samples
Rev.2	Nov. 23, 2020	Addition of the result for additional positive samples

Prepared by/ date	Reviewed by/ date	Approved by/ date
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Nov. 23, 2020		Nov. 23, 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 Ag 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-812-02 / Rev.02 /Nov. 02. 2020

2. Test location and duration

2.1 Clinical Evaluation 1

2.1.1 Test location: : Laboratory room #216, Sugentech, Inc. Migun Techno World 2-cha, Daejeon, Korea
2.1.2 Test duration: Jul. 20~21. 2020

2.2 Clinical Evaluation 2

2.2.1 Test location: : Chungnam National University Hospital, Daejeon, Korea
2.2.2 Test duration: Sep. 02, 2020
2.2.3 IRB approval No. : CNUH 2020-03-057

2.3 Clinical Evaluation 3

2.2.1 Test location: : Chungnam National University Hospital, Daejeon, Korea
2.2.2 Test duration: Nov. 16, 2020
2.2.3 IRB approval No. : CNUH 2020-03-057

3.Responsibilities

3.1 Clinical Evaluation 1

3.1.1 Principle Investigator : Eunkyung Kim / R&D dept. / Sugentech
3.1.2 Key contact : Sunhee Lee / 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

3.2.1 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

4. Test Result

4.1 Test device(Candidate device)

Product Name	Manufacture	Lot No.
SGTi-flex COVID-19 Ag	Sugentech, Inc.	CAGT20901

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

4.3 Test Sample (Specimens)

4.3.1 Selection criteria

(1) Positive samples

- 25 Positive samples were provided by The National Biobank of Korea (NBK). Nasopharyngeal swabs and oropharyngeal swab which were positive based on the real time RT-PCR (Powerchek™ 2019-nCoV Real-time PCR kit (Manufacturer: KogeneBiotech Co., Ltd.)) were used.
- 58 Positive samples were retrospectively collected from patients who were confirmed positive by the real time RT-PCR at Chungnam National University Hospital. Nasopharyngeal swabs which were positive based on the real time RT-PCR (Powerchek™ 2019-nCoV Real-time PCR kit (Manufacturer: KogeneBiotech Co., Ltd.)) were used.
- 60 Positive samples were retrospectively collected from patients who were confirmed positive by the real time RT-PCR at Chungnam National University Hospital. Nasopharyngeal swabs which were positive based on the real time RT-PCR (Powerchek™ 2019-nCoV Real-time PCR kit (Manufacturer: KogeneBiotech Co., Ltd.)) were used.

(2) Negative samples

- Negative samples were provided by Samkwang Medical Lab.
- Nasopharyngeal swabs and oropharyngeal swab which are negative based on the real time RT-PCR (Biosewoom, RealQ 2019 nCoV Detection kit) were used.

4.3.2 Number of specimens

(1) Positive samples: 25 Nasopharyngeal swabs and oropharyngeal swab and 118 Nasopharyngeal swabs in VTM

(2) Negative samples: 100 Nasopharyngeal swabs and oropharyngeal swab in VTM

4.4. Test Result

Table 1. Performance analysis of Clinical Evaluation 1

		Reference method		
		Positive	Negative	Total
Test device	Positive	20	1	21
	Negative	5	99	104
	Total	25	100	125

(1) Accuracy (Overal agreement) = 100 x (20+99) / 125 = 95.20%
(95% CI : 89.92%~97.78%)
(2) Sensitivity (Positive percent agreement) = 100 X 20/25 = 80.00%
(95% CI : 60.87%~91.14%)
(3) Specificity (Negative percent agreement) = 100 X 99/100 = 99.00%
(95% CI : 94.55%~99.82%)

Table 2. Performance analysis of Clinical Evaluation 2

		Reference method		
		Positive	Negative	Total
Test device	Positive	56	0	56
	Negative	2	0	2
	Total	58	0	58

(1) Sensitivity (Positive percent agreement) = 100 X 56/58 = 96.55%
(95% CI : 88.27%~99.05%)

Table 3. Performance analysis of Clinical Evaluation 3

		Reference method		
		Positive	Negative	Total
Test device	Positive	60	0	60
	Negative	0	0	0
	Total	60	0	60

(1) Sensitivity (Positive percent agreement) = 100 X 60/60 = 100.00%
(95% CI : 93.98%~100.00%)

Table 4. Total Clinical Performance analysis

		Reference method		
		Positive	Negative	Total
Test device	Positive	136	1	137
	Negative	7	99	106
	Total	143	100	243

(1) Accuracy (Overal agreement) = 100 x (136+99) / 243 = 96.71%
(95% CI : 93.64%~98.32%)
(2) Sensitivity (Positive percent agreement) = 100 X 136/143 = 95.10%
(95% CI : 90.24%~97.61%)
(3) Specificity (Negative percent agreement) = 100 X 99/100 = 99.00%
(95% CI : 94.55%~99.82%)

Table 5. Total Clinical Performance analysis for Ct value and days after symptom onset

	Total
Clinical Sensitivity (95% CI); N	95.10% (90.24, 97.61); 143
Sensitivity Days ≤7, N	98.45% (94.52, 99.57); 129
Sensitivity Ct ≤33, N	97.14% (92.88, 98.88); 140
Sensitivity Ct ≤25, N	100.00% (96.30, 100.00); 100
Clinical Specificity (95% CI); N	99.00% (94.55, 99.82); 100

5. Conclusion

Comparison studies between the test device (SGTi-flex COVID-19 Ag) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 243 specimens.
The results showed the overall percent agreement was 96.71%. The positive and negative agreements were 95.10% and 99.00%, respectively.
The test deveice has a good concordance rate as 95% or higher but it seems to be slightly less sensitive than the real time RT-PCR method. However, SGTi-flex COVID-19 Ag is faster and easier to diagnose than RT-PCR and it has good agreement with RT-PCR. Therefore, SGTi-flex COVID-19 Ag is a useful kit that can help in emergency situations where viral infections are expanding.