Test Report

Doc. ID:	R-LA-812-01
Revision:	01
Date:	Sep.08, 2020

Title :	**Comparison Study**
Product :	SGTi-flex COVID-19 Ag
Date :	Sep. 08, 2020

Protocol No. P-LA-812-01

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

Prepared by/ date	Reviewed by/ date	Approved by/ date
Sunhee Lee		Eunkyung Kim
Sep. 08, 2020		Sep. 08, 2020

Table of Contents

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-812-01 / Rev.01 /Aug. 17. 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

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

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.

(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 58 Nasopharyngeal swabs in VTM

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

4.4. Test Result Data

4.4.1 Clinical Evaluation 1 Positive samples : Test results are summarized at Table 1.

Table 1. Result of Clinical Evaluation 1 positive samples

Sepcimen No.	Result	
	Clinical diagnosis (Real time PCR)	Test Device (SGTi- flex COVID-19 Ag)
P01	+	+
P02	+	+
P03	+	+
P04	+	+
P05	+	+
P06	+	-
P07	+	+
P08	+	-
P09	+	+

P10	+	+
P11	+	+
P12	+	+
P13	+	-
P14	+	+
P15	+	+
P16	+	+
P17	+	+
P18	+	+
P19	+	-
P20	+	+
P21	+	+
P22	+	-
P23	+	+
P24	+	+
P25	+	+

4.4.2 Clinical Evaluation 1 Negative samples :Test results are summarized at Table 2

Table 2. Result of Clinical Evaluation 1 Negative samples

Sepcimen No.	Result	
	Clinical diagnosis (Real time PCR)	Test Device (SGTi- flex COVID-19 Ag)
N01	-	-
N02	-	-
N03	-	-
N04	-	-
N05	-	-
N06	-	-
N07	-	-
N08	-	-
N09	-	-
N10	-	-
N11	-	-
N12	-	-

N13	-	-
N14	-	-
N15	-	-
N16	-	-
N17	-	-
N18	-	-
N19	-	+
N20		-
N21	-	-
N22	-	-
N23	-	-
N24	-	-
N25	-	-
N26	-	-
N27	-	-
N28	-	-
N29	-	-
N30	-	-
N31	-	-
N32	-	-
N33	-	-
N34	-	-
N35	-	-
N36	-	-
N37	-	-
N38	-	-
N39	-	-
N40	-	-
N41	-	-
N42	-	-
N43	-	-
N44	-	-
N45	-	-
N46	-	-
N47	-	-
N48	-	-
N49	-	-

N50	-	-
N51	-	-
N52	-	-
N53	-	-
N54	-	-
N55	-	-
N56	-	-
N57	-	-
N58	-	-
N59	-	-
N60	-	-
N61	-	-
N62	-	-
N63	-	-
N64	-	-
N65	-	-
N66	-	-
N67	-	-
N68	-	-
N69	-	-
N70		-
N71	-	-
N72	-	-
N73	-	-
N74	-	-
N75	-	-
N76	-	-
N77	-	-
N78	-	-
N79	-	-
N80	-	-
N81	-	-
N82	-	-
N83	-	-
N84	-	-
N85	-	-
N86	-	-

N87	-	-
N88	-	-
N89	-	-
N90	-	-
N91	-	-
N92	-	-
N93	-	-
N94	-	-
N95	-	-
N96	-	-
N97	-	-
N98	-	-
N99	-	-
N100	-	-

4.4.3 Clinical Evaluation 2 positive samples : Test results are summarized at Table 3.

Table 3. Result of Clinical Evaluation 2 positive samples

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

P17	+	+
P18	+	+
P19	+	+
P20	+	+
P21	+	+
P22	+	+
P23	+	+
P24	+	+
P25	+	+
P26	+	+
P27	+	+
P28	+	+
P29	+	+
P30	+	+
P31	+	+
P32	+	+
P33	+	+
P34	+	+
P35	+	+
P36	+	+
P37	+	+
P38	+	+
P39	+	+
P40	+	+
P41	+	+
P42	+	+
P43	+	+
P44	+	+
P45	+	+
P46	+	+
P47	+	+
P48	+	-
P49	+	+
P50	+	+
P51	+	+
P52	+	+
P53	+	+

P54	+	+
P55	+	+
P56	+	+
P57	+	+
P58	+	+

5. Result Interpretation

Table 4. 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 5. 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 6. Total Clinical Performance analysis

		Reference method		
		Positive	Negative	Total
Test device	Positive	76	1	77
	Negative	7	99	106
	Total	83	100	183

(1) Accuracy (Overal agreement) = 100 x (76+99) / 183 = 95.63%
(95% CI : 91.61%~97.77%)

(2) Sensitivity (Positive percent agreement) = 100 X 76/83 = 91.57%
(95% CI : 83.60%~95.85%)
(3) Specificity (Negative percent agreement) = 100 X 99/100 =
99.00%(95% CI : 94.55%~99.82%)

6. 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 183 specimens.
The results showed the overall percent agreement was 95.63%. The positive and negative agreements were 91.57% 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.