Test Report

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

Protocol No. P-LA-811-02

Revision History		
Rev.0	Apr. 10, 2020	First study after design
Rev.1	Aug. 05, 2020	Addition of High dose hook effect
Rev.2	Nov. 23, 2020	Addition of cross reactive substances

Prepared by/ date	Reviewed by/ date	Approved by/ date
Sunhee Lee	-	Eunkyung Kim
Nov. 23, 2020		Nov. 23, 2020

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1. Purpose

The analytical performance studies were carried out for SGTi-flex COVID-19 Ag Test as design verification according to the Analytical Performance Study Protocol, P-LA-811-02 / Rev.02 / Nov. 02, 2020

2. Test location and duration

2.1 Test location: Laboratory room #216, Sugentech, Inc. Migun Techno World 2-cha
2.2 Test duration: Mar. 17, 2020 – Apr. 03, 2020, Nov. 19, 2020

3. Responsibilities

3.1 Study Coordinator: Sunhee Lee / Preparation of test protocol & test report
3.2 Overall Supervisor: Eunkyung Kim / Final review and approval
3.3 Researcher: Soyoung Park, Jinsub Kim / Performance of testing

4. Test Results – Sensitivity

4.1 Test device

Table 1. Test device

Product Name	SGTi-flex COVID-19 Ag
Lot No.	CAGT20901
Manufacturing date	Mar. 16, 2020

4.2 Test Materials

(1) Normal human nasopharyngeal swab and oropharyngeal swab in extraction buffer is used as a basic matrix.
(2) The dilutions of certified reference material, Heat inactivated SARS-CoV-2 virus culture fluid (ATCC, VR-1986HK, 2019-nCoV/USAWA1/2020) and commercial antigen, recombinant SARS-CoV-2 nucleoprotein (2019-nCoV Nucelocapsid protein, Novoprotein, DRA31) were prepared by serial dilution in each matrix.
(3) One batch is used for the testing and each testing is to be performed 20 times repeatedly.

4.3 Test date : Mar. 17, 2020 and Jul. 24, 2020

4.4 Tested by : Soyoung Park / Dept. of R&D
Confirmed by : Eunkyung Kim / Dept. of R&D

4.5 Results

Table 2. Test result of sensitivity for SGTi-flex COVID-19 Ag
(Recombinant nucleocapsid protein)

	Result			
Matrix	Nasopharyngeal swab in buffer		Oropharyngeal swab in buffer	
Concentration (ng/mL)	Number of Positive/all	% Positive rate	Number of Positive/all	% Positive rate
1000	20/20	100	20/20	100
100	20/20	100	20/20	100
10	20/20	100	20/20	100
1	20/20	100	20/20	100
0.5	20/20	100	20/20	100
0.25	20/20	100	20/20	100
0.125	19/20	95	19/20	95
0.0625	10/20	50	10/20	50
0	0/20	0	0/20	0

Table 3. Test result of sensitivity for SGTi-flex COVID-19 Ag
(Heat-inactivated SARS-CoV-2)

	Result			
Matrix	Nasopharyngeal swab in buffer		Oropharyngeal swab in buffer	
Concentration ($TCID_{50}$/mL)	Number of Positive/all	% Positive rate	Number of Positive/all	% Positive rate
$1.6X10^4$	20/20	100	20/20	100
$1.6X10^3$	20/20	100	20/20	100
$8.0X10^2$	20/20	100	20/20	100
$5.3X10^2$	19/20	95	19/20	95
$4.0X10^2$	15/20	75	15/20	75
0	0/20	0	0/20	0

4.6 Conclusion

The sensitivity of SGTi-flex COVID-19 Ag is 0.125 ng/mL based on SARS-CoV-2 recombinant nucleoprotein and $5.3X10^2$ $TCID_{50}$/mL based on heat-inactivated SARS-CoV-2 (ATCC, VR-1986HK, 2019nCoV/USAWA1/2020).

5. Test Results - Specificity study

5.1 Test device

Table 4. Test device

Product Name	SGTi-flex COVID-19 Ag
Lot No.	CAGT20901
Manufacturing date	Mar. 16, 2020

5.2 Test Materials

(1) Various concentrations of potential cross-reactive substances, viruses and bacteria were diluted 10-fold in negative reference material (CAGN-01).
(2) The tests were performed according to the instructions for use.
(3) Each testing was performed 3 times repeatedly.
(4) The concentrations of cross-reactive substances are as follows:

Table 5. Concentrations of potential cross-reactive substances (Virus)

No.	Supplier	Potential cross-reactive substance	Concentration
1	ATCC	Alpha Coronavirus (229E), VR-740	> $5x10^3$ $TCID_{50}$ /ml
2	Sino biologicals	Beta Coronavirus (MERS) NP protein, 40068-V08B	0.25mg/mL
3	Sino biologicals	Beta Coronavirus (SARS-CoV) NP protein, 40143-V08B	0.25mg/mL
4	Zeptometrix	Beta Coronavirus OC43, NATCOV(OC43)-ST	RT-PCR Ct Value 22~25
5	NIBSC	Influenza A/H1N1 A/Brisbane/02/2018 (H1N1)pdm09-like virus, 13/234	48 µg HA/ml
6	NIBSC	Influenza A/H3N2 Influenza Antigen A/New Caledonia/71/2014, 15/238	60ugHA/ml
7	NIBSC	Influenza A/H5N1 Influenza Antigen A/Anhui/1/05, 07/290	99ugHA/mL
8	NIBSC	Influenza B Influenza Antigen B/Guangdong/120/2000, 01/546	40ugHA/ml
9	NIBSC	Epstein-Barr Virus, 08/316	RT-PCR Ct Value 30
10	NCCP	Rhinovirus group A, 40601	$1x10^6$ $TCID_{50}$/mL
11	NCCP	Respiratory Syncytial virus type A, 43179	$1x10^6$ $TCID_{50}$/mL

12	NCCP	Respiratory Syncytial virus type B, 43181	$1x10^6$ $TCID_{50}$/mL
13	Mybiosource	Mumps Virus, MBS318648	0.85 mg/mL
14	ATCC	Adenovirus type 5, ATCC® VR-1516™	5.8×10^{11} particles/ml
15	NIBSC	Human Coxsackie B4, 08/174	RT-PCR Ct Value 30
16	NIBSC	Human Meta pneumovirus, 08/320	RT-PCR Ct Value 30
17	NIBSC	Human Measles Mvi/Moscow Rus/1988 Genotype A, 03/168	RT-PCR Ct Value 30
18	NIBSC	Parainfluenza Virus serotype 1, 08/176	RT-PCR Ct Value 30
19	NIBSC	Parainfluenza Virus serotype 2, 08/178	RT-PCR Ct Value 30
20	NIBSC	Parainfluenza Virus serotype 3, 08/118	RT-PCR Ct Value 30
21	NIBSC	Parainfluenza Virus serotype 4, 08/180	RT-PCR Ct Value 30
22	Zeptometrix	Human Coronavirus NL63	10^8 copies/μL
23	-	Human Corona virus HKU1	*In silico*

Table 6. Concentrations of potential cross-reactive substances (Bacteria)

No.	Supplier	Potential cross-reactive substance	Concentration
1	MFDS	Group A streptococcus antigen, IVD-12/010	High titer product
2	MFDS	Group B streptococcus antigen, IVD-12/012	High titer product
3	MFDS	Streptococcus Pneumoniae antigen	High titer product
4	KCCM	Escherichia coli culture	10^8cells/ml
5	KCCM	Corynebacterium glutamicum culture	10^8cells/ml
6	KCCM	Lactobacillus plantarum culture	10^8cells/ml
7	KCCM	Legionella spp culture	10^8cells/ml
8	KCCM	Pseudomonas aeruginosa culture	10^8cells/ml
9	KCCM	Staphylococcus epidermidis culture	10^8cells/ml
10	NIBSC	Mycobacterium tuberculosis	5,000IU/mL

11	NCCP	Hemophilus influenzae	10^8cells/ml
12	KCTC	Streptococcus spp	10^7 cells/mL
13	KCTC	Candida albicans	10^5 copies/mL
14	Lee biosolutions	Pooled human nasal fluid	N/A
15	ATCC	Bordetella pertussis	$1.1X10^9$ copies/mL
16	ATCC	Mycoplasma pneumoniae	$7.21X10^7$ copies/mL
17	ATCC	Chlamydophila pneumoniae	$4.99X10^6$ copies/mL
18	CCARM	Legionella pneumophila	$9.5X10^9$ copies/mL
19	-	Pneumocystis jirovecii(PJP)	*In silico*

5.3 Test date : Mar. 31, 2020, Nov. 19, 2020

5.4 Tested by : Soyoung Park / Dept. of R&D
Confirmed by : Eunkyung Kim / Dept. of R&D

5.5 Results
The result of reactivity data is summarized at Table 7 and Table 8.

Table 7. Test result of reactivity (Virus)

No.	Cross-reactive substances (Virus)	Result		
		1st	2nd	3rd
1	Alpha Coronavirus (229E)	-	-	-
2	Beta Coronavirus (MERS) NP protein	-	-	-
3	Beta Coronavirus (SARS-CoV) NP protein	+	+	+
4	Beta Coronavirus OC43	-	-	-
5	Influenza A/H1N1 A/Brisbane/02/2018 (H1N1)pdm09-like virus (13/234)	-	-	-
6	Influenza A/H3N2 Influenza Antigen A/New Caledonia/71/2014 (H3N2, 15/238)	-	-	-
7	Influenza A/H5N1 Influenza Antigen A/Anhui/1/05 (H5N1, 07/290)	-	-	-
8	Influenza B	-	-	-

	Influenza Antigen B/Guangdong/120/2000 (01/546)			
9	Epstein-Barr Virus	-	-	-
10	Rhinovirus group A	-	-	-
11	Respiratory Syncytial virus type A	-	-	-
12	Respiratory Syncytial virus type B	-	-	-
13	Mumps Virus	-	-	-
14	Adenovirus type 5	-	-	-
15	Human Coxsackie B4	-	-	-
16	Human Meta pneumovirus,	-	-	-
17	Human Measles Mvi/Moscow Rus/1988 Genotype A	-	-	-
18	Parainfluenza Virus serotype 1	-	-	-
19	Parainfluenza Virus serotype 2	-	-	-
20	Parainfluenza Virus serotype 3	-	-	-
21	Parainfluenza Virus serotype 4	-	-	-
22	Human Coronavirus NL63	-	-	-

Table 8. Test result of reactivity (Bacteria)

No.	Cross-reactive substances (Bacteria)	Result		
		1st	2nd	3rd
1	Group A streptococcus antigen	-	-	-
2	Group B streptococcus antigen	-	-	-
3	Streptococcus Pneumoniae antigen	-	-	-
4	Escherichia coli culture	-	-	-
5	Corynebacterium glutamicum culture	-	-	-
6	Lactobacillus plantarum culture	-	-	-
7	Legionella spp culture	-	-	-
8	Pseudomonas aeruginosa culture	-	-	-
9	Staphylococcus epidermidis culture	-	-	-
10	Mycobacterium tuberculosis	-	-	-
11	Hemophilus influenzae	-	-	-
12	Streptococcus spp	-	-	-
13	Candida albicans	-	-	-
14	Pooled human nasal fluid	-	-	-
15	Bordetella pertussis	-	-	-
16	Mycoplasma pneumoniae	-	-	-

17	Chlamydophila pneumoniae	-	-	-
18	Legionella pneumophila	-	-	-

5.6 Conclusion

There was no cross-reactivity when testing SGTi-flex COVID-19 Ag in cross-reactive substances such as viruses, bacteria and pooled human nasal fluids except SARS-CoV. There was a cross-reactivity in Sars-CoV. The results showed no microbial interference with the organisms at the concentrations tested.

Pneumocystis jirovecii and Human coronavirus HKU1 were analyzed in silico via Basic Local Alignment Search Tool managed by National Center for Biotechnology Information to defined cross-reactivity or interference. For Pneumocystis jirovecii, 45.4% homology was found only a particular part of sequence across 9 % of the sequence. It is very unlikely that cross-reaction will occur.

The protein sequences between nucleocapsid protein sequence of human coronavirus HKU1 and nucleocapsid protein of SARS CoV-2 has only 36.7 % homology across 82% of sequences. The result of homology between two viruses is relatively very low but cross-reaction can occur.

6. Test Results - Interference

6.1 Test device

Table 9. Test device

Product Name	SGTi-flex COVID-19 Ag
Lot No.	CAGT20901
Manufacturing date	Mar. 16, 2020

6.2 Test Materials

(1) The negative reference material (CAGN-01) and a positive reference materials (CAGP-02, CAGP-03) manufactured according to SGTi-flex COVID-19 Ag Standard Material Manufacture and Maintenance (SOP-QC-223) were used.

(2) Various concentrations of potential interfering substances were prepared in negative and positive reference material. All those concentrations of the interfering substances are assured as higher than the recommended levels by the CLSI guideline, EP07-A2.

The concentrations of the interfering substances are as follows:

Table 10. Concentrations of the interfering substances

No	Interfering substance	Supplier	Concentration	Comment
1	Albumin	Sigma, A9647	50 mg/ml	Intrinsic interfering substance, CLSI EP7-A02
2	Glucose	Sigma, G8270	1.2 mg/ml	Intrinsic interfering substance, CLSI EP7-A02
3	Hemoglobin	Sigma, H7379	4 mg/ml	Intrinsic interfering substance, CLSI EP7-A02
4	Bilirubin	Sigma, F4021	5 mg/ml	Intrinsic interfering substance, CLSI EP7-A02
5	mucin	sigma M2378	1.0 %	Intrinsic interfering substance, CLSI EP7-A02
6	Whole blood	Trina SN0001	1.0 %	Intrinsic interfering substance, CLSI EP7-A02
7	Phenylephrine hydrochloride	Sigma, PHR1017	10 mg/ml	Nasal spray, Drugs.com
8	Dexamethasone	Sigma, D4902	0.6 mg/ml	Nasal steroid, CLSI EP7-A02
9	Flunisolide	Sigma, F5021	2.5 mg/ml	Nasal steroid, Drugs.com
10	Budesonide	Sigma, B7777	1 mg/ml	Nasal steroid, Drugs.com
11	Benzocaine	Sigma, E1501	5 mg/ml	Throat candy, anesthetic drug, DRUGBANK, Canadian Institutes of Health Research
12	Menthol	Sigma,M2772	40 mg/ml	Throat candy, anesthetic drug, DRUGBANK, Canadian Institutes of Health Research
13	Zanamivir	Sigma,SML0492	10 mg/ml	Antiviral agent, Drugs.com
14	Tobramycin	Sigma, T4014	20 mg/ml	Antibiotics, DRUGBANK, Canadian Institutes of Health Research
15	Tamiflu (Oseltamivir)	Sigma, SML1606	6 mg/ml	Antiviral agent, Drugs.com

16	Acetaminophen	sigma A7083	10 mg/ml	Anti-inflammatory medication, Drugs.com
17	Ibuprofen	sigma I4883	5 mg/ml	Anti-inflammatory medication, Drugs.com
18	Aspirin	sigma A2093	2 mg/mL	Anti-inflammatory medication, Drugs.com

6.3 Test date : Mar. 30, 2020

6.4 Tested by : Soyoung Park / Dept. of R&D
Confirmed by : Eunkyung Kim / Dept. of R&D

6.5 Results
Test result of interfering substances data is summarized at Table 11.

Table 11. The result of interference test

No	Interfering Substance	specimen	Result		
			1st	2nd	3rd
1	Albumin	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
2	Glucose	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
3	Hemoglobin	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
4	Bilirubin	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
5	Phenylephrine hydrochloride	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
6	Dexamethasone	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
7	Flunisolide	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-

8	Budesonide	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
9	Benzocaine	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
10	Menthol	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
11	Zanamivir	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
12	Tobramycin	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
13	Tamiflu (Oseltamivir)	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
14	mucin	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
15	Whole blood	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
16	Acetaminophen	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
17	Ibuprofen	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
18	Aspirin	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-
19	No Interference	CAGP-02	+	+	+
		CAGP-03	+	+	+
		CAGN-01	-	-	-

6.6 Conclusion

The results showed that the SGTi-flex COVID-19 Ag had no interference by the potential interfering substances above which may exist in specimen, such as drugs, chemical and biological analytes.

7. Test Results – High dose hook effect

7.1 Test device

Table 12. Test device

Product Name	SGTi-flex COVID-19 Ag
Lot No.	CAGT20901
Manufacturing date	Mar. 16, 2020

7.2 Test Materials

(1) Normal human nasopharyngeal swab and oropharyngeal swab in extraction buffer is used as a basic matrix.
(2) The dilutions of certified reference material, Heat inactivated SARS-CoV-2 virus culture fluid (ATCC, VR-1986HK, 2019-nCoV/USAWA1/2020) and commercial antigen, recombinant SARS-CoV-2 nucleoprotein (2019-nCoV Nucelocapsid protein, Novoprotein, DRA31) were prepared by serial dilution in each matrix.
(3) One batch is used for the testing and each testing is to be performed 20 times repeatedly.

7.3 Test date : Aug. 04, 2020

7.4 Tested by : Soyoung Park / Dept. of R&D
Confirmed by : Eunkyung Kim / Dept. of R&D

7.5 Results

Table 13. Test result of high dose hook effect for SGTi-flex COVID-19 Ag (Recombinant nucleocapsid protein)

	Result			
Matrix	Nasopharyngeal swab in buffer		Oropharyngeal swab in buffer	
Concentration (ng/mL)	Number of Positive/all	% Positive rate	Number of Positive/all	% Positive rate
1,000,000	5/5	100	5/5	100
100,000	5/5	100	5/5	100

10,000	5/5	100	5/5	100
1000	5/5	100	5/5	100
0	0/5	0	0/5	0

Table 14. Test result of high dose hook effect for SGTi-flex COVID-19 Ag (Heat-inactivated SARS-CoV-2)

	Result			
Matrix	Nasopharyngeal swab in buffer		Oropharyngeal swab in buffer	
Concentration ($TCID_{50}$/mL)	Number of Positive/all	% Positive rate	Number of Positive/all	% Positive rate
$8.0X10^4$	5/5	100	5/5	100
$8.0X10^3$	5/5	100	5/5	100
$8.0X10^2$	5/5	100	5/5	100
0	0/5	0	0/5	0

7.6 Conclusion

The results demonstrated that no hook effect was observed at high levels of SARS-CoV-2 recombinant nucleoprotein up to 1 mg/mL and heat-inactivated SARS-CoV-2 culture fluid up to $8.0X10^4$ $TCID_{50}$/mL.

8. Test Results – Precision/Reproducibility

8.1 Test device

Table 15. Test device

Product Name	SGTi-flex COVID-19 Ag	
Lot No.	CAGT20901	CAGT20902
Manufacturing date	Mar. 16, 2020	Mar. 19, 2020

8.2 Test Materials

The negative reference material (CAGN-01) and a positive reference materials (CAGP-01,02,03) manufactured according to SGTi-flex COVID-19 IgM Standard Material Manufacture and Maintenance (SOP-QC-223) were used.

8.3 Test date : Mar. 30, 2020 ~ Apr. 03, 2020

8.4 Tested by : Soyoung Park, Jinsup Kim / Dept. of R&D
Confirmed by : Eunkyung Kim / Dept. of R&D

8.5 Result

The repeatability performance data is summarized at Table 16.
The reproducibility performance data is summarized at Table 17.

Table 16. Test result of repeatability performance

Day	Run	Repeat testing	Lot: CAGT20901			
			CAGP-01	CAGP-02	CAGP-03	CAGN-01
Day 1 (2020.03.30)	Run 1	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
	Run 2	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
Day 2 (2020.03.31)	Run 1	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
	Run 2	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
Day 3 (2020.04.01)	Run 1	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
	Run 2	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
Day 4 (2020.04.02)	Run 1	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-

	Run 2	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
Day 5 (2020.04.03)	Run 1	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-
	Run 2	1st	+	+	+	-
		2nd	+	+	+	-
		3rd	+	+	+	-

Table 17. Test result of reproducibility performance

Site, Tested by	Day	Run	Repeat testing	Lot: CAGT20901				Lot: CAGT20902			
				CAGP-01	CAGP-02	CAGP-03	CAGN-01	CAGP-01	CAGP-02	CAGP-03	CAGN-01
Site 1 Person 1	Day 1 (2020.03.30)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 2 (2020.03.31)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 3 (2020.04.01)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
			1st	+	+	+	-	+	+	+	-

		Run 2	2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 4 (2020.04.02)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 5 (2020.04.03)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
Site 2 Person 2	Day 1 (2020.03.30)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 2 (2020.03.31)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 3 (2020.04.01)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-

		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 4 (2020. 04.02)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
	Day 5 (2020. 04.03)	Run 1	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-
		Run 2	1st	+	+	+	-	+	+	+	-
			2nd	+	+	+	-	+	+	+	-
			3rd	+	+	+	-	+	+	+	-

8.6 Conclusion

The results showed that the reproducibility of the SGTi-flex COVID-19 Ag was acceptable. Within-run, Between-run, Batch-to-batch, Day-to-day, and Between site performance results meet 100% of the acceptance criteria.