

# Test Report

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 Doc. ID: R-LA1-326-04
 

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 Revision: 04
 

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 Date: Jul. 04, 2022
 

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Title:	<b>Impact of variants on performance</b>
Product:	SGTi-flex COVID-19 Ag
Date:	Jul. 04, 2022

## Protocol No. P-LA1-326-04

Revision History		
Rev.0	Apr. 05, 2021	First study after design
Rev.1	Jan.10, 2022	Addition of the Omicron variant
Rev.2	Jan. 24, 2022	Addition of Contrived sample test of SARS-CoV-2 variants
Rev.3	Mar.29, 2022	Addition of Clinical sample test of SARS-CoV-2 variants
Rev. 4	Jul. 04, 2022	Addition of the Omicron variant

Prepared by/ date	Reviewed by/ date	Approved by/ date
Sunhee Lee		Seungbum Yoo
 Jul. 04, 2022		 Jul. 04, 2022

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## 1. Purpose

It is a study to evaluate the impact of the variants of SARS-CoV-2 on performance of SGTi-flex COVID-19 Ag.

## 2. Test location and duration

2.1 Test location: Sugentech, Inc. Daejeon, Rep.of Korea.

2.2 Test duration:

1) Apr. 01, 2021

2) Jan.10, 2022

3) Jan.21, 2022

4) Mar. 06. 2022

5) Jul. 01, 2022

6) Jul. 04, 2022

## 3. Responsibilities

3.1 Study Coordinator: Sunhee Lee / Preparation of test protocol & test report

3.2 Overall Supervisor: Seunbum Yoo / Final review and approval

3.3 Researcher: Soyoung Park / Performance of testing

## 4. In-Silico analysis for variants of SARS-CoV-2

### 4.1. Information of Antibody epitope sites

Test kit name	Target (s)	Epitope position	Aminoacid sequence
SGTi-flex COVID-19 Ag	Nucleo capid protein	44-175	GLPNNTASWFTALTQHGKEDLKFPRGQG VPINTNSSPDDQIGYYRRATRRIRGGDGK MKDLSRWYFYLLGTGPEAGLPYGANKD GIIWVATEGALNTPKDHIGTRNPANNAIV LQLPQGTTLPKGFYAEG

### 4.2. The amino acid sequence information of Nucleocapsid of various SARS-CoV-2 variants

	Virus subtype	First Identified	WHO label	Mutation at NP

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1	Original SARS-CoV-2	China	-	-
2	B.1.1.7	UK	Alpha	D3L, R203K, G204R, , S235F
3	B.1.351	South Africa	Beta	T205I
4	P.1	Brazil	Gamma	P80R, R203K, G204R
5	B.1.617	India		R203K, D377Y
6	B.1.617.1	India	Kappa	R203M,D377Y
7	B.1.617.2	India	Delta	D63G, D377Y,R203M
8	B.1.617.3	India		P67S,D377Y,R203M
9	*B.1.427/ B.1.429*	USA	Epsilon	T205I
10	B.1.1.529/ BA.1**	South Africa	Omicron	P13L, del31/33, R203K, G204R
11	BA.2/BA.3/ BA.5***	South Africa	Omicron	P13L, del31/33, R203K, G204R, S413R
12	BA.4	South Africa	Omicron	P13L, del31/33,P151S R203K, G204R, S413R

\* B.1.427 and B.1.429 have the same mutation site, at T205I of Nucleocapsid protein.

\*\* B1.1.529 and BA.1(B.1.1.529.1) which is subtype of Omicron, have the same mutation site at P13L, DEL31/33, R203K, G204R of Nucleocapsid protein.

\*\*\* BA.2, BA3 and BA.5 which are subtype of Omicron, have the same mutation site at P13L, DEL31/33, R203K, G204R and S413R of Nucleocapsid protein.

## 4.3 Results of the alignment on Nucleocapsid protein of SARS-CoV-2 Variants and Antibody epitope site (44-175 aa)

### -Original SARS-CoV-2

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(717)	7e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGQGVPIINTNSSPDDQIGYRRATRRI RGGDGKMKD				60
Sbjct 44	.....				103
Query 61	LSPRWYFYLLGTGPEAGLPYGANKDGI I WVATEGALNTPKDHI GTRNPANNAAI VLQLPQ				120
Sbjct 104	.....				163
Query 121	GTTLPKGFYAEG	132			
Sbjct 164	.....	175			

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## - B.1.1.7 (Alpha)

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(717)	7e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1		GLPNNTASWFTALTQHGKEDLKFP	INTNSSPDDQIGYYRRATRRI	RGGDGKMKD	60
Sbjct 44		.....	.....	.....	103
Query 61		LSPRWYFYVLGTGPEAGLPYGANKDGI	IWVATEGALNTPKDHI	GTRNPANNAI	120
Sbjct 104		.....	.....	.....	163
Query 121		GTTLPKGFYAEG	132		
Sbjct 164		.....	175		

## - B.1.351 (Beta)

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(717)	7e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1		GLPNNTASWFTALTQHGKEDLKFP	INTNSSPDDQIGYYRRATRRI	RGGDGKMKD	60
Sbjct 44		.....	.....	.....	103
Query 61		LSPRWYFYVLGTGPEAGLPYGANKDGI	IWVATEGALNTPKDHI	GTRNPANNAI	120
Sbjct 104		.....	.....	.....	163
Query 121		GTTLPKGFYAEG	132		
Sbjct 164		.....	175		

## - P.1 (Gamma)

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
277 bits(709)	1e-98	Compositional matrix adjust.	131/132(99%)	131/132(99%)	0/132(0%)
Query 1		GLPNNTASWFTALTQHGKEDLKFP	INTNSSPDDQIGYYRRATRRI	RGGDGKMKD	60
<b>Sbjct</b> 44		.....	..... <b>.R</b> .....	.....	103
Query 61		LSPRWYFYVLGTGPEAGLPYGANKDGI	IWVATEGALNTPKDHI	GTRNPANNAI	120
Sbjct 104		.....	.....	.....	163
Query 121		GTTLPKGFYAEG	132		
Sbjct 164		.....	175		

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## - B.1.617

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(716)	9e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGGQGVPI	NTNSSPDDQI	GYRRATRRI	RGDGKMKD	60
Sbjct 44	.....	.....	.....	.....	103
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
Sbjct 104	.....	.....	.....	.....	163
Query 121	GTTLPKGFYAE	132			
Sbjct 164	.....	175			

## - B.1.617.1 (Kappa)

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(716)	9e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGGQGVPI	NTNSSPDDQI	GYRRATRRI	RGDGKMKD	60
Sbjct 44	.....	.....	.....	.....	103
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
Sbjct 104	.....	.....	.....	.....	163
Query 121	GTTLPKGFYAE	132			
Sbjct 164	.....	175			

## - B.1.617.2 (Delta)

Range 1: 44 to 175 [GenPept](#) [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
277 bits(708)	1e-98	Compositional matrix adjust.	131/132(99%)	131/132(99%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGGQGVPI	NTNSSPDDQI	GYRRATRRI	RGDGKMKD	60
<b>Sbjct</b> 44	..... <b>.G</b> .....	.....	.....	.....	103
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
Sbjct 104	.....	.....	.....	.....	163
Query 121	GTTLPKGFYAE	132			
Sbjct 164	.....	175			

## - B.1.617.3

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
277 bits(709)	9e-99	Compositional matrix adjust.	131/132(99%)	131/132(99%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGGQGVPI	NTNSSPDDQI	GYRRATRRI	RGDGKMKD	60
<b>Sbjct</b> 44	..... <b>.S</b> .....	.....	.....	.....	103
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
Sbjct 104	.....	.....	.....	.....	163
Query 121	GTTLPKGFYAE	132			
Sbjct 164	.....	175			

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## - B.1.427/ B.1.429 (Epsilon)

Range 1: 44 to 175 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(717)	7e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGQGVPI	NTNSSPDDQI	GYRRATRRIRGGDGKMKD	60	
Sbjct 44	.....	.....	.....	103	
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
Sbjct 104	.....	.....	.....	.....	.....
Query 121	GTTLPKGFYAEG	132			
Sbjct 164	.....	175			

## - B.1.1.529 (Omicron including BA.1)

Range 1: 41 to 172 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(717)	5e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGQGVPI	NTNSSPDDQI	GYRRATRRIRGGDGKMKD	60	
Sbjct 41	.....	.....	.....	100	
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
Sbjct 101	.....	.....	.....	.....	.....
Query 121	GTTLPKGFYAEG	132			
Sbjct 161	.....	172			

## - BA.2, BA.3, BA.5

Range 1: 41 to 172 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
280 bits(717)	5e-100	Compositional matrix adjust.	132/132(100%)	132/132(100%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGQGVPI	NTNSSPDDQI	GYRRATRRIRGGDGKMKD	60	
Sbjct 41	.....	.....	.....	100	
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
Sbjct 101	.....	.....	.....	.....	.....
Query 121	GTTLPKGFYAEG	132			
Sbjct 161	.....	172			

## - BA.4

Range 1: 41 to 172 [Graphics](#)

[▼ Next Match](#) [▲ Previous Match](#)

Score	Expect	Method	Identities	Positives	Gaps
278 bits(710)	6e-99	Compositional matrix adjust.	131/132(99%)	131/132(99%)	0/132(0%)
Query 1	GLPNNTASWFTALTQHGKEDLKFRGQGVPI	NTNSSPDDQI	GYRRATRRIRGGDGKMKD	60	
Sbjct 41	.....	.....	.....	100	
Query 61	LSPRWYFYVLTGTGPEAGLPYGANKDGI	I	WVATEGALNTPKDHI	GTRNPANNAI	VLQLPQ
<b>Sbjct</b> 101	.....	.....	.....	<b>S</b> .....	.....
Query 121	GTTLPKGFYAEG	132			
Sbjct 161	.....	172			

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## 5. Recombinant Nucleocapsid protein test for SARS-CoV-2 and variants

### 5.1 Test device

Product Name	SGTi-flex COVID-19 Ag
Lot No.	CAGT20104
Manufacturing date	Dec. 21, 2020

### 5.2 Test procedure

- (1) The each of commercial recombinant SARS-CoV-2 nucleocapsid protein is prepared by serial dilution at 1 ng/mL (low positive), 5 ng/mL (moderate positive), 25 ng/mL (high positive) in the negative matrix.
- (2) 50  $\mu$ L of each dilution sample is spiked to swab.
- (3) One batch of devices is used for the testing and each test is according to instructions for use. The device is validated by negative and positive Control Materials (SGTi-flex COVID-19 Ag Control)
- (4) Each testing is to be performed 5 times repeatedly by visual reading.
- (5) The test results are displayed according to the degree of color development of the lines as follows.

Display	Degree of line intensity
++++	Line intensity is similar to C line.
+++	Line intensity is lower than C line, but clearly identified.
++	Line intensity is less than half of C line.
+	Line intensity is weak, but it is confirmed that there is a line.
-	There is no line.

- (6) The results are recorded in the form, F-LA-401-00.

5.3 Tested by : Soyoung Park / Dept. of R&D

Confirmed by : Sunhee Lee / Dept. of R&D

Test date : Apr. 01, 2021, Jan.10, 2022, Jul.04, 2022

### 5.4 Test Results

Table 1. Test result of Original SARS-CoV-2

Type of Variant	Sample concentration (ng/mL)	Number of repetitions				
		1	2	3	4	5
	25 (High)	+++	+++	+++	+++	+++



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Original SARS-CoV-2	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
	0 (Negative)	-	-	-	-	-
B1.1.7 variant	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
B1.351 variant	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
P.1	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
B.1.617	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
B.1.617.1	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
B.1.617.2	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
B.1.617.3	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
B.1.427/ B.1.429	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
B.1.1.529 BA.1	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
	0 (Negative)	-	-	-	-	-
	25 (High)	+++	+++	+++	+++	+++

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BA.2 /BA.3/ BA.5	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
BA.5	0 (Negative)	-	-	-	-	-
BA.4	25 (High)	+++	+++	+++	+++	+++
	5 (Moderate)	++	++	++	++	++
	1 (Low)	+	+	+	+	+
	0 (Negative)	-	-	-	-	-

## 6. Contrived virus sample test for SARS-CoV-2 and variants

### 6.1 Test device

Product Name	SGTi-flex COVID-19 Ag
Lot No.	CAGT20104
Manufacturing date	Dec. 21, 2020

### 6.2 Test procedure

- (1) Pooled normal human nasopharyngeal swab in PBS is used as a basic matrix.
- (2) The each of SARS-CoV-2 or variants is prepared by serial dilution at  $7.0 \times 10^2$  TCID<sub>50</sub>/mL (as equivalent to 2xLoD),  $1.75 \times 10^3$  TCID<sub>50</sub>/mL (equivalent to 5xLoD) in the negative matrix.

#### <Test materials\_ Inactivated virus>

	Virus subtype	Resource/ Product Number	Stock Conc. (TCID <sub>50</sub> /mL)	WHO lineage
1	Original SARS-CoV-2	BEI resource NR-52287	$2.80 \times 10^6$	
2	Original SARS-CoV-2	Zeptomatrix 0810587CFHI	$3.16 \times 10^6$	
3	B.1.1.7	Zeptomatrix 0810614CFHI	$1.05 \times 10^6$	Alpha
4	B.1.351	Zeptomatrix 0810613CFHI	$4.57 \times 10^6$	Beta
5	P.1	Zeptomatrix 0810616CFHI	$1.26 \times 10^6$	Gamma
6	B.1.617.2	Zeptomatrix 0810624UV	$1.51 \times 10^6$	Delta
7	B.1.1.529	BEI resource	$1.51 \times 10^7$	Omicron

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		NR-56495		
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- (3) 50  $\mu$ L of each dilution sample is spiked to swab.
- (4) One batch of devices is used for the testing and each test is according to instructions for use. The device is validated by negative and positive Control Materials (SGTi-flex COVID-19 Ag Control)
- (5) Each testing is to be performed 5 times repeatedly by visual reading.
- (6) The test results are displayed according to the degree of color development of the lines as follows.

Display	Degree of line intensity
++++	Line intensity is similar to C line.
+++	Line intensity is lower than C line, but clearly identified.
++	Line intensity is less than half of C line.
+	Line intensity is weak, but it is confirmed that there is a line.
-	There is no line.

- (7) The results are recorded in the form, F-LA-401-00.

6.3 Test date : Jan. 21, 2022, Jul.04, 2022

6.4 Tested by : Soyoung Park / Dept. of R&D  
Confirmed by : Sunhee Lee / Dept. of R&D

## 6.5 Test Results

Table 2. Test results of Contrived sample of SARS-CoV-2 and variants

Type of Variant	Sample concentration TCID <sub>50</sub> /mL	Number of repetitions				
		1	2	3	4	5
Original SARS-CoV-2	1.75x10 <sup>3</sup>	++	++	++	++	++
	7.0x10 <sup>2</sup>	+	+	+	+	+
	0	-	-	-	-	-
B1.1.7	1.75x10 <sup>3</sup>	++	++	++	++	++
	7.0x10 <sup>2</sup>	+	+	+	+	+
	0	-	-	-	-	-
B1.351	1.75x10 <sup>3</sup>	++	++	++	++	++
	7.0x10 <sup>2</sup>	+	+	+	+	+
	0	-	-	-	-	-
P.1	1.75x10 <sup>3</sup>	++	++	++	++	++

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	7.0x10 <sup>2</sup>	+	+	+	+	+
	0	-	-	-	-	-
B.1.617.2	1.75x10 <sup>3</sup>	++	++	++	++	++
	7.0x10 <sup>2</sup>	+	+	+	+	+
	0	-	-	-	-	-
B.1.1.529	1.75x10 <sup>3</sup>	++	++	++	++	++
	7.0x10 <sup>2</sup>	+	+	+	+	+
	0	-	-	-	-	-

## 7. Clinical Study for Omicron variant

### 7.1 Test device (Candidate device)

Product Name	Manufacture	Lot No.
SGTi-flex COVID-19 Ag	Sugentech, Inc.	CAGT22901

### 7.2 Reference method

- Real time RT-PCR : STANDARD™ M nCoV Real-Time Detection kit (Manufacturer: SD Biosensor, Inc.), Allplex™ SARS-CoV-2 Assay (Manufacturer: Seegene, Inc.) and Real-Q 2019-nCoV Detection Kit (Manufacturer: BioSewoom, Inc.)

### 7.3 Test Sample

#### (1) Omicron specimen

- 45 Positive frozen nasopharyngeal swab specimens in VTM were provided by The National Biobank of Korea (NBK).
- Positive nasopharyngeal swabs were collected in VTM and were diagnosed by the real time RT-PCR method in National Biobank of Korea (NBK).
- The specimens were confirmed as the omicron variant by S- gene sequencing by Korea Disease control and Prevention Agency (KDCA)

#### (2) Delta specimen

- 45 Positive frozen nasopharyngeal swab specimens in VTM were provided by The National Biobank of Korea (NBK).
- Positive nasopharyngeal swabs were collected in VTM and were diagnosed by the real time RT-PCR method in National Biobank of Korea (NBK).
- The specimens were confirmed as the Delta variant by S- gene sequencing by Korea Disease control and Prevention Agency (KDCA)

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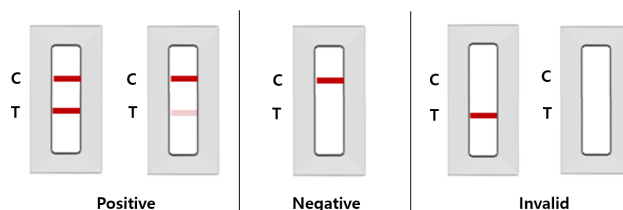
## 7.4. Test procedure

### 7.4.1 Swab in Viral Transport Media Test Procedure

- (1) Open the pouch and take out the Test Cassette. Place it on a flat, dry and clean surface.
- (2) Mix the specimen in VTM by vortexing.
- (3) Using micro pipette, transfer 300 µL of sample in VTM to the sample extraction buffer tube.
- (4) Press the Dropping Cap onto the Extraction Buffer tube containing the processed sample.
- (5) Invert the Extraction Buffer tube and add 3 drops of processed sample into the sample well on the Test Cassette.
- (6) After dispensing the sample, Read the results by user's eyes in 15 minutes according to the instruction for use. Some positive results may appear faster right after the reaction. The result after 30 minutes is invalid.

### 7.4.2 Interpretation of test results

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



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

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		Reference method
		Positive
Test device	Positive	a
	Negative	c
	Total	a+c

- Positive percent agreement (PPA) =  $100 \times a / (a+c)$

7.5 Test date : Mar. 17, 2022, Jul. 01, 2022

7.6 Tested by : Soyoung Park / Dept. of R&D  
Confirmed by : Sunhee Lee / Dept. of R&D

## 7.7 Test Results

Table 3. Test result of SARS-CoV-2 Omicron Variant samples

NO	COVID19_ID	Type of SARS CoV-2	Age	Sex	RT-PCR				Test results
					Manufacture	E	RdRP	N	
1	COVID19-1871	Omicron	3	F	Seegene	20.44	20.71	20.13	+
2	COVID19-1908	Omicron	3	M	Seegene	28.43	29.48	29.14	-
3	COVID19-1937	Omicron	2	M	Seegene	18.89	19.41	18.40	+
4	COVID19-1954	Omicron	2	F	Seegene	18.30	22.05	17.22	+
5	COVID19-2034	Omicron	2	M	BioSewoom	28.98	30.12	N/D	-
6	COVID19-2037	Omicron	3	M	BioSewoom	18.10	18.56	N/D	+
7	COVID19-2071	Omicron	3	F	Seegene	15.70	17.19	14.38	+
8	COVID19-2096	Omicron	2	M	Seegene	19.55	20.68	18.34	+
9	COVID19-2132	Omicron	2	M	Seegene	19.93	20.24	18.25	+
10	COVID19-2161	Omicron	3	M	Seegene	17.78	17.98	17.14	+
11	COVID19-2202	Omicron	3	M	BioSewoom	16.03	16.47	N/D	+
12	COVID19-2247	Omicron	3	M	Seegene	26.20	27.35	25.44	+
13	COVID19-2288	Omicron	5	M	Seegene	18.22	18.63	17.48	+
14	COVID19-2314	Omicron	4	F	Seegene	27.45	29.17	25.82	-
15	COVID19-2331	Omicron	5	M	Seegene	18.71	19.56	17.78	+
16	COVID19-2353	Omicron	5	F	Seegene	20.29	21.56	18.47	+
17	COVID19-2355	Omicron	7	M	Seegene	23.57	24.89	23.41	+
18	COVID19-2397	Omicron	4	F	Seegene	29.01	29.90	29.15	-
19	COVID19-2403	Omicron	2	F	Seegene	19.21	20.26	17.82	+
20	COVID19-2431	Omicron	3	M	BioSewoom	16.82	17.35	N/D	+
21	COVID19-2432	Omicron	2	F	BioSewoom	11.99	12.34	N/D	+
22	COVID19-2461	Omicron	6	F	BioSewoom	15.74	15.98	N/D	+
23	COVID19-2503	Omicron	3	M	Seegene	23.21	24.00	23.11	+

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24	COVID19-2512	Omicron	5	M	Seegene	21.15	21.91	19.89	+
25	COVID19-2521	Omicron	4	M	BioSewoom	25.88	25.67	N/D	+
26	COVID19-2526	Omicron	3	F	Seegene	24.49	24.85	24.52	+
27	COVID19-2550	Omicron	4	M	Seegene	23.79	24.13	23.48	+
28	COVID19-2568	Omicron	3	F	BioSewoom	28.20	26.48	N/D	+
29	COVID19-2601	Omicron	3	F	BioSewoom	20.53	20.00	N/D	+
30	COVID19-2638	Omicron	6	M	BioSewoom	15.32	14.63	N/D	+
31	COVID19-2681	Omicron	3	M	BioSewoom	15.41	14.40	N/D	+
32	COVID19-2828	Omicron	3	F	SD Biosensor	20.54	19.94	N/D	+
33	COVID19-647	Omicron	2	F	SD Biosensor	18.00	15.30	N/D	+
34	COVID19-651	Omicron	5	F	SD Biosensor	17.7	20.66	N/D	+
35	COVID19-669	Omicron	3	F	SD Biosensor	16.6	18.44	N/D	+
36	COVID19-695	Omicron	3	M	SD Biosensor	24.97	22.06	N/D	+
37	COVID19-696	Omicron	5	F	SD Biosensor	18.90	16.40	N/D	+
38	COVID19-701	Omicron	3	F	SD Biosensor	17.60	21.20	N/D	+
39	COVID19-719	Omicron	3	F	Seegene	24.22	24.72	23.31	+
40	COVID19-762	Omicron	2	F	Seegene	19.29	19.39	19.42	+
41	COVID19-770	Omicron	2	F	Seegene	19.79	20.12	19.91	+
42	COVID19-778	Omicron	2	M	Seegene	22.22	23.17	22.67	+
43	COVID19-801	Omicron	2	M	Seegene	15.83	17.05	14.75	+
44	COVID19-802	Omicron	6	F	Seegene	16.46	17.88	14.84	+
45	COVID19-810	Omicron	2	F	BioSewoom	19.36	14.41	N/D	+

Table 4. Test result of SARS-CoV-2 Delta specimen

NO	COVID19_ID	Type of SARS CoV-2	Age	Sex	RT-PCR				Test results
					Manufacture	E	RdRP	N	
1	COVID19-246	Delta	3	F	Seegene	25.14	25.8	25.08	+
2	COVID19-249	Delta	5	M	Seegene	23.38	24.12	22.24	+
3	COVID19-278	Delta	7	F	SD Biosensors	15.52	15.67	N/D	+
4	COVID19-280	Delta	6	M	SD Biosensors	12.26	11.62	N/D	+
5	COVID19-289	Delta	5	M	Seegene	17.64	18.67	15.84	+
6	COVID19-293	Delta	5	F	Seegene	26.39	26.99	24.89	+
7	COVID19-304	Delta	4	M	Seegene	21.71	23.31	17.8	+
8	COVID19-325	Delta	6	M	Seegene	17.37	17.91	15.84	+
9	COVID19-330	Delta	8	F	Seegene	24.7	24.96	23.72	+
10	COVID19-352	Delta	6	F	Seegene	19.38	21.14	16.98	+
11	COVID19-359	Delta	6	F	SD Biosensors	18.11	17.34	N/D	+
12	COVID19-374	Delta	5	F	Seegene	21.96	15.02	15.28	+
13	COVID19-382	Delta	2	M	Seegene	34.05	34.4	31.2	-

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14	COVID19-404	Delta	4	M	Seegene	19.1	20.21	16.54	+
15	COVID19-424	Delta	4	F	Seegene	21.24	21.36	19.21	+
16	COVID19-431	Delta	3	M	Seegene	22.06	23.13	19.49	+
17	COVID19-438	Delta	6	F	Seegene	21.81	21.92	21.6	+
18	COVID19-451	Delta	3	M	Seegene	20.5	21.57	18.83	+
19	COVID19-468	Delta	6	F	Seegene	25.71	26.18	25.72	+
20	COVID19-482	Delta	6	M	Seegene	20.33	20.9	20.34	+
21	COVID19-489	Delta	4	M	Seegene	17.72	17.59	17.61	+
22	COVID19-494	Delta	2	M	Kogen	18.13	16.62	N/D	+
23	COVID19-506	Delta	7	F	Kogen	19.47	18.19	N/D	+
24	COVID19-514	Delta	5	F	BioSewoom	24.18	23.55	N/D	+
25	COVID19-515	Delta	7	M	BioSewoom	15.28	14.41	N/D	+
26	COVID19-516	Delta	4	F	Seegene	18.4	19.18	17.7	+
27	COVID19-520	Delta	2	F	Seegene	21.75	22.31	21.53	+
28	COVID19-534	Delta	6	M	BioSewoom	12.77	13.48	N/D	+
29	COVID19-595	Delta	3	F	Seegene	21.71	22.72	18.89	+
30	COVID19-604	Delta	6	F	BioSewoom	20.87	19.69	N/D	+
31	COVID19-847	Delta	4	F	Labgenomics	7.88	8.3	N/D	+
32	COVID19-905	Delta	5	M	Labgenomics	31.98	31.88	N/D	-
33	COVID19-987	Delta	5	F	Labgenomics	10.59	11.54	N/D	+
34	COVID19-1082	Delta	3	F	Seegene	18.27	15.85	16.93	+
35	COVID19-1300	Delta	6	F	Seegene	20.7	19.53	19.79	+
36	COVID19-1369	Delta	4	F	Labgenomics	11.68	10.39	N/D	+
37	COVID19-1389	Delta	2	F	Seegene	21.23	18.11	19.36	+
38	COVID19-1514	Delta	4	F	Labgenomics	11.23	11.6	N/D	+
39	COVID19-1522	Delta	2	M	Seegene	26.61	26.12	26.19	+
40	COVID19-1526	Delta	5	F	Seegene	29.67	26.92	28.53	+
41	COVID19-1543	Delta	3	M	Seegene	18.84	15.27	17.29	+
42	COVID19-1675	Delta	4	F	Labgenomics	13.92	15.46	N/D	+
43	COVID19-1704	Delta	6	M	Seegene	31.83	31.63	N/D	-
44	COVID19-1727	Delta	2	F	Seegene	21.79	17.31	20.28	+
45	COVID19-1801	Delta	3	F	Seegene	19.89	16.68	19.43	+



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## 7.8 Results interpretation

Table 5. Clinical Performance analysis for Omicron variant specimen

		Reference method : RT-PCR for SARS-CoV-2		
		Positive	Negative	Total
Test device : SGTi-flex COVID-19 Ag	Positive	41	0	41
	Negative	4	0	4
	Total	45	0	45
		Positive percent agreement (PPA)		
PPA of Total Results		91.11% (95% CI : 79.27%~96.49%, 41/45)		
PPA at Ct value ≤25		100.0% (95% CI : 90.82%~100.00%, 38/38)		
PPA at Ct value >25		42.86% (95% CI : 15.82%~96.14%, 3/7)		

Table 6. Clinical Performance analysis for Delta variant specimen

		Reference method : RT-PCR for SARS-CoV-2		
		Positive	Negative	Total
Test device : SGTi-flex COVID-19 Ag	Positive	42	0	42
	Negative	3	0	3
	Total	45	0	45
		Positive percent agreement (PPA)		
PPA of Total Results		93.33% (95% CI : 82.14%~97.71%, 42/45)		
PPA at Ct value ≤25		100.0% (95% CI : 90.59%~100.00%, 37/37)		
PPA at Ct value >25		62.5% (95% CI : 30.57%~86.32%, 5/8)		

## 8. Conclusion

From the in-silico analysis results of the eight variants, it can be expected that the 11 variants (B.1.1.7, B.1.351, B.1.617, B.1.617.1, B.1.427/B.1.429, B.1.1.529/BA.1, BA.2/BA.3/BA.5) do not affect our product. P.1, B.1.617.2, B.1.617.3 and BA.4 variants have each one mutated sequence at the epitope site of the antibody used in our product but the 99% sequences are identical.

The line intensity of the SGTi-flex COVID-19 Ag obtained from the recombinant nucleocapsid protein or contrived virus sample of the original SARS-CoV-2 or the

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variants were all similar at same concentration. The SGTi-flex COVID-19 Ag was able to successfully detect the nucleocapsid protein of the SARS-CoV-2 variants (B.1.1.7, B.1.351, P.1., B.1.617, B.1.617.1, B.1.617.2, B.1.617.3, B.1.618, B.1.427/B.1.429, B.1.1.529/BA.1, BA.2/BA.3/BA.5, BA.4) and also it successfully detects the inactivated SARS-CoV-2 variants (B.1.1.7, B.1.351, P.1, B.1.617.2, B.1.1.529).

In the clinical sample study, the SGTi-flex COVID-19 Ag was able to successfully detect the clinical specimens of the omicron variant as results in 91.11% and the Delta variant as results in 93.33% positive agreement with RT-PCR.

Through the test results of various approaches, including in-silico analysis, recombinant nucleocapsid protein test, contrived viral sample test and omicron clinical sample test, it can be inferred that SGTi-flex COVID-19 Ag is virtually unaffected by various variants including 5 VOCs (alpha, beta, gamma, delta and omicron).