

Issue number: BA200-20211129-QA2

November 29, 2021

Subject : Notification of internal test results for SARS-CoV-2 variants (Version 6.00)

Dear valued customers,

We, SD Biosensor, Inc., would like to inform you that STANDARD™ Q products for SARS-CoV-2 diagnostic are not affected by **“Alpha(B.1.1.7), Beta(B.1.351), Gamma(P.1), Delta(B.1.617.2), Kappa(B.1.617.1), Epsilon(B.1.429), Iota(B.1.526), Lambda(C.37), Zeta(P.2), Omicron(B.1.1.529) SARS-CoV-2 variants”**. The list of applicable STANDARD™ Q products is as follows.

No.	Product Name	Reference No.
1	STANDARD™ Q COVID-19 Ag Test	Q-NCOV-01G
2	STANDARD™ Q COVID-19 Ag Home Test	Q-NCOV-03G
3	STANDARD™ Q COVID-19 Ag Nasal Test	Q-NCOV-04G
4	STANDARD™ Q COVID/Flu Ag Combo Test	Q-CVFL-01C
5	STANDARD™ Q COVID-19 Ag Saliva Test	Q-NCOV-02G
6	STANDARD™ i-Q COVID-19 Ag Test	EQ-NCOV-01G
7	STANDARD™ i-Q COVID-19 Ag Home Test	EQ-NCOV-03G
8	STANDARD™ Q COVID-19 Ag Test 2.0	Q-NCOV-07G

We verified this through internal test, and detailed information about it is below.

## 1. Analytical sensitivity

### 1.1 Purpose of test

The purpose of this test is to verify that the sensitivity of STANDARD™ Q products is not affected by SARS-CoV-2 variants by using synthetic recombinant proteins.

### 1.2 Sample of test

#### 1) Specimen (Positive)

Since STANDARD™ Q products target nucleocapsid protein (hereafter, N protein), recombinant N protein of 27 variants were synthesized and used as positive specimen.

#	Pango lineage	GISAID ACCESSION ID. EPI_ISL	WHO label
1-1	B	402125	N/A
1-2	B.1.1.7	835226	**Alpha
1-3	B.1.351	660190	Beta
1-4	P.1	792680	Gamma
1-5	B.1.617.1	1360306	**Kappa
1-6	B.1.617.1	1789542	**Kappa
1-7	B.1.617.1	1620161	**Kappa
1-8	B.1.617.1	1545312	**Kappa
1-9	B.1.617.1	1823120	**Kappa
1-10	B.1.617.1	1904467	**Kappa
1-11	B.1.617.1	1660436	**Kappa
1-12	B.1.617.1	1913208	**Kappa
1-13	B.1.617.1	1969991	**Kappa
1-14	B.1.617.2	1970310	Delta
1-15	B.1.617.2	1660458	Delta
1-16	B.1.617.2	1807318	Delta
1-17	B.1.617.2	1913205	Delta
1-18	A.23.1	925892	**Not yet assigned
1-19	B.1.429	1771435	**Epsilon
1-20	B.1.526.2	1080752	**Not yet assigned
1-21	B.1.526	1227165	**Iota

1-22	B.1.617.3	1704494	**Not yet assigned
1-23	C.36	1936140	*Not yet assigned
1-24	C.37	1111296	Lambda
1-25	P.2	1182578	**Zeta
1-26	B.1.616	1239370	**Not yet assigned
1-27	C.1.2	3164100	*Not yet assigned

\*Variants under monitoring

\*\*De-escalated variants

## 2) Specimen (Negative)

ID	PCR result
*Negative human swab	Negative

\*Negative human swabs were collected from healthy donors and were confirmed to be negative by PCR (US FDA EUA approved, STANDARD M nCoV Real-Time Detection kit, CFX96).

## 3) Test strip

3 lots of test strips were used for the test.

## 1.3 Method of test

- 1) Each of the recombinant N proteins was diluted in successive concentrations.
- 2) The dilutions were spiked with a swab.
- 3) The spiked swab was tested in the same method as the IFU.
- 4) Dilutions of the recombinant N proteins were tested repeatedly 20 times for each lot of test strips.

## 1.4 Result of test

The recombinant N protein of 27 variants showed a similar limit of detection (0.0156  $\mu\text{g}/\text{mL}$ ) to the Wuhan-Hu-1 recombinant N protein (#1-1) used as a positive control. Therefore, it was confirmed that the sensitivity of the STANDARD™ Q product was not affected by the 27 variants.

## 2. In-silico analysis

## 2.1 Purpose of test

The purpose of this test is to theoretically verify that STANDARD™ Q products are not affected by SARS-CoV-2 variants.

## 2.2 Method of test

- 1) Compare the region where the variant was mutated (hereinafter, mutation site) with the region that STANDARD™ Q targets to detect SARS-CoV-2 (hereinafter, epitope region).
- 2) If the mutation site corresponds to the epitope region, it is predicted that there is a possibility of affecting the STANDARD™ Q product, and the evaluation result is marked with 'P'.
- 3) If the mutation site does not correspond to the epitope region, it is predicted that there is no possibility of affecting the STANDARD™ Q product, and the evaluation result is marked with 'N'.

## 2.3 Result of test

As a result of in-silico analysis of 42 variants, the mutation sites of 2 variants (#2-14: 1239370, #2-31: 1969991) corresponded to the epitope region. However, it was confirmed that #2-14 and #2-31 did not affect the sensitivity of STANDARD™ Q products through the test for analytical sensitivity (#1-26 and #1-13).

#	Pango lineage	GISAID ACCESSION ID. EPI_ISL	Dominant Mutation site (amino acid number)	Result (P or N)
2-1	B	402125	N/A (as standard)	N/A
2-2	A.23.1	925892	202	N
2-3	AT.1	2385327	67, 203, 204	N
2-4	AT.1	1259283	203, 204	N
2-5	B.1.1.7	835226	3, 203, 204, 235	N
2-6	B.1.351	660190	205	N
2-7	B.1.427	1060793	205	N

2-8	B.1.429	1771435	205, 234	N
2-9	B.1.429	1194304	205	N
2-10	B.1.525	2432518	2, 12, 205	N
2-11	B.1.526.1	2204920	205, 234	N
2-12	B.1.526.2	1080752	13, 202	N
2-13	B.1.526	1227165	199, 234	N
2-14	B.1.616	1239370	325	P
2-15	B.1.617.1	1360306	203, 377	N
2-16	B.1.617.2	1508996	63, 203, 215, 377	N
2-17	B.1.617.3	1704494	67, 203, 377	N
2-18	B.1.621	1582980	205	N
2-19	C.36	1936140	203, 204, 212	N
2-20	C.37	1111296	13, 203, 204, 214, 366	N
2-21	P.1	792680	80, 203, 204	N
2-22	P.2	1182578	119, 203, 204, 234	N
2-23	P.3	1213573	203, 204	N
2-24	B.1.617.1	1789542	203, 377, 385	N
2-25	B.1.617.1	1620161	3, 203, 377	N
2-26	B.1.617.1	1545312	203, 204	N
2-27	B.1.617.1	1823120	203, 236, 377	N
2-28	B.1.617.1	1904467	3, 13, 203, 243, 377	N
2-29	B.1.617.1	1660436	3, 63, 203, 377	N
2-30	B.1.617.1	1913208	30, 203, 377	N
2-31	B.1.617.1	1969991	203, 310, 377	P
2-32	B.1.617.2	1970310	63, 203, 377, 385	N
2-33	B.1.617.2	1660458	63, 203, 377	N
2-34	B.1.617.2	1807318	63, 203, 204, 205, 206, 207, 208, 377, 385	N
2-35	B.1.617.2	1913205	63, 203, 215, 377	N
2-36	AY.1	3244751	63, 203, 215, 377	N
2-37	AY.2	3123565	63, 203, 377	N
2-38	AY.3	3352221	63, 203, 215, 377	N
2-39	AY.3.1	2920875	63, 203, 215, 377	N
2-40	B.1.621	3477571	205	N
2-41	C.1.2	2695610	13, 204, 384, 203	N
2-42	B.1.1.529	6640917	13, 31(deletion), 32(deletion), 33(deletion), 203, 204	N

### 3. Final conclusion of the test

As a result of analytical sensitivity and In-silico analysis, it is verified that STANDARD™ Q products are not affected by Alpha(B.1.1.7), Beta(B.1.351), Gamma(P.1), Delta(B.1.617.2), Kappa(B.1.617.1), Epsilon(B.1.429), Iota(B.1.526), Lambda(C.37), Zeta(P.2), Omicron(B.1.1.529) SARS-CoV-2 variants.

We will continue our efforts to comply with high quality management standards and to maintain a consistent high quality management system to ensure customer's satisfaction and product safety. If you have any questions, please contact our sales representative.

Sincerely,  
Geun-Kuk Song  
QMR  
SD BIOSENSOR, Inc.

