SD BIOSENSOR

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Subject : Notification of internal test results for SARS-CoV-2 variants (Version 4.04)

Dear valued customers,

We, SD Biosensor, Inc., would like to inform you that STANDARD™ Q products for SARS-CoV-2 diagnostic are mostly 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) 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	9902-NCOV-02G

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 17 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

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).*

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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 17 variants showed a similar limit of detection (0.0156 ㎍/㎖) 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 17 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 35 variants, the mutation sites of 2 variants (#2-14: 1239370, #2-31: 1969991) corresponded to the epitope region. However, it was confirmed that #2-31 did not affect the sensitivity of STANDARD™ Q products through the test for analytical sensitivity (#1-13). We plan to confirm the analytical sensitivity of #2-14 through additional testing.

#	Pango lineage	GISAID ACCESSION ID. EPI_ISL	Dominant Mutation site (amio 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

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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

3. Final conclusion of the test

As a result of analytical sensitivity and In-silico analysis, it is verified that STANDARD™ Q products are mostly 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) SARS-CoV-2 variants. In addition, we plan to complete additional testing on 'GISAID ACCESSION ID. EPI_ISL 1239370 (#2-14)' by July 2021. We will communicate by issuing an official notice as soon as additional testing is completed.

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.