SD BIOSENSOR

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Subject : Notification of internal test results for SARS-CoV-2 variants (Version 7.00)

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), Mu(B.1.621), Omicron(B.1.1.529, BA.1, BA.2, BA.3, BA.4, BA.5) 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.
Mutations commonly found in the 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(BA.1, BA.2, BA.3) variants as well as the variants listed in part 1, analytical sensitivity, have been wet-lab tested using recombinant proteins, in the combinations indicated in the table in part 1 and no impact was observed in test performance. The mutations commonly found in the respective strains and in the Omicron(B.1.1.529, BA.4, BA.5) variant *(see the table in part 2, in-silico analysis)* have been analyzed in-silico, and no impact on performance is expected.

0. Monitoring information

0.1 Circulating mutations in nucleocapsid (N) protein

On a monthly basis, viral genomic sequences of the circulating strains will be gathered using GISAID. The most recent 2000 complete and high coverage entries will be analyzed at least monthly against the reference sequence (Wuhan-Hu-1/2019), and all non-synonymous mutations in the N protein will be identified. The percentage of single mutations and mutation combinations in the N protein will be analyzed. All mutations present in > 5% of the circulating isolates will be defined as "Relevant Mutations".

0.2 Variants of Concern/Interest globally

Additionally, Variants of Concern (VoCs) and Variants of Interest (VoIs) by the WHO and the European Centre for Disease Prevention and Control (ECDC), as well as Variants Being Monitored (VBMs), VOIs, VOCs and Variants of High Consequence (VOHCs) by the US CDC will be monitored regularly. Isolates from all variants listed above will be monitored on GISAID. The most recent 2000 complete and high coverage entries per variant will be analyzed against the reference sequence (Wuhan-Hu-1/2019), and all non-synonymous mutations in the N protein will be identified. The percentage of single mutations and mutation combinations in the N protein will be analyzed. All mutations present in > 5% of the variant will be defined as "Relevant Mutations" as well.

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 Specimen of test

1) Specimen (Positive)

Since STANDARD™ Q products target nucleocapsid protein (hereafter, N protein), recombinant N protein of 29 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

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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	N/A
1-19	B.1.429	1771435	**Epsilon
1-20	B.1.526.2	1080752	N/A
1-21	B.1.526	1227165	**Iota
1-22	B.1.617.3	1704494	N/A
1-23	C.36	1936140	N/A
1-24	C.37	1111296	**Lambda
1-25	P.2	1182578	**Zeta
1-26	B.1.616	1239370	N/A
1-27	C.1.2	3164100	***N/A
1-28	BA.1	6640917	Omicron
1-29	BA.2※	7190366	Omicron

※ *In the case of BA.3 variant, wet-testing is omitted since the mutation sites of N protein are same as BA.2.*

** Previously circulating Variants of Concerns*

*** Previously circulating Variants of Interest*

**** Formerly Monitored 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 29 variants showed a similar limit of detection 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 29 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 57 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

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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 (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
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	6647959	13, 31(deletion), 32(deletion), 33(deletion), 203, 204	N
2-43	BA.1 (B.1.1.529.1)	6640917	13, 31(deletion), 32(deletion), 33(deletion), 203, 204	N
2-44	BA.2 (B.1.1.529.2)	7190366	13, 31(deletion), 32(deletion), 33(deletion), 203, 204, 413	N
2-45	BA.3 (B.1.1.529.3)	7526186	13, 31(deletion), 32(deletion), 33(deletion), 203, 204, 413	N
2-46	B.1.640.1	6700813	63, 205, 378	N
2-47	B.1.640.2	7181977	22, 205	N
2-48	XD** (Delta and BA.1)	9879437	63, 203, 215, 377	N
2-49	XE** (BA.1 and BA.2)	9177743	13, 31(deletion), 32(deletion), 33(deletion), 203, 204 204, 413	N
2-50	XF** (Delta and BA.1)	8894978	13, 31(deletion), 32(deletion), 33(deletion), 203, 204	N
2-51	BA.1.1	9754508	P13L, E31(deletion),	N

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			R32(deletion), S33(deletion), R203K, G204R	
2-52	BA.2.2	12417574	P13L, E31(deletion), R32(deletion), S33(deletion), R203K, G204R, S413R	N
2-53	BA.2.12	10842022	P13L, E31(deletion), R32(deletion), S33(deletion), R203K, G204R, S413R	N
2-54	BA.2.12.1	11490263	P13L, E31(deletion), R32(deletion), S33(deletion), R203K, G204R, S413R	N
2-55	BA.4	12043292	P13L, E31(deletion), R32(deletion), S33(deletion), P151S, R203K, G204R, S413R	N
2-56	BA.5	11903045	P13L, E31(deletion), R32(deletion), S33(deletion), R203K, G204R, S413R	N
2-57	BA.5	12307612※	P13L, E31(deletion), R32(deletion), S33(deletion), E136D, R203K, G204R, S413R	N

** The identical mutation as found as the dominant mutation in this variant was already tested for #2-6*

*** XD, XE, XF are characterized by combining with the other two lineages (Delta + Omicron) by considering all mutation site including both spike protein and nucleocapsid protein. However, if only the sequence of nucleocapsid protein is considered, a single lineage can be characterized.*

※ Accession number of 12307612 is BA.5 sub lineage with very small portion (7.86 by GISAID, 2022.06.16.)

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(BA.1, BA.2, BA.3) SARS-CoV-2 variants". In addition, as a result of In-silico analysis, it is verified that STANDARD™ Q products are not affected by "Mu(B.1.621), Omicron(B.1.1.529, BA.4, BA.5) SARS-CoV-2 variants".

Additionally, based on the United States Food and Drug Administration (FDA) recommendation, variants BA.2, BA.4 and BA.5 will be wet tested for potential changes in assay performance.

4. Interpretation of test result

The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

4.1 Negative test result

A negative test result means that it is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you suspect that you have an infection, contact you doctor/primary care physician.

4.2 Positive test result

A positive test result means that it is very likely that you have COVID-19. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a PCR test to confirm the result.

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.