We will thrive by manufacturing the best IVD products

SD BIOSENSOR

To : Valued customer

C.C : -

Subject : **Notification of internal test results for SARS-CoV-2 variants (Version 7.19)**

1. We, SD Biosensor, Inc., wish you happiness and success.

2. We, SD Biosensor, Inc., would like to inform you that STANDARD™ F 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.4.1, BA.5, BA.2.75, BF.7, BF.14, BJ.1, BQ.1.1, BA.4.6, BA.2.75.2, BA.2.12.1, BA.5.1, BA.5.2, BA.2.3.20, XBB, BA.2.10, BM.1.1.1, BS.1, BQ.1, BA.4.4, BA.5.2.6, BN.1, CH.1.1, CJ.1, XBF, XBB.1, XBB.1.5, XBC, XBB.1.16, XBB.1.9.1, XBB.1.16.1, XBB.1.9.2, XBB.2.3, EG.5.1, BA.2.86, GW.5.1.1, FW.1.1, JN.1, GE.1.2.1, JN.1.1, JD.1.1, BA.2.86.1, JG.3, EG.5.1.6, HV.1, GS.4.1, XBB.1.16.15, FL.1.5.1, EG.5.1.3, GE.1, JN.6, JN.2, JN.3, HK.6, EG.5.1.1, JF.1, EG.10.1, XBB.1.16.6, XBB.1.16.11, HK.3, BA.2.87.1, JN.1.18, JN.1.22, JN.1.4, JN.1.7, JN.1.8, KP.2, KP.3, KP.1.1, XDQ, JN.1.7.1, JN.1.11.1, XDK, JN.1.16, LB.1, KP.2.3, JN.1.18.3, KP.2.2, KP.3.1, KP.3.1.1, KP.3.1.4, KP.3.2.3, KP.3.2.4, KP.3.3, KP.4.1, LB.1.3, KP.2.6, KP.3.2.2, JN.1.7.1, JN.1.7.2, JN.1.7.4, JN.1.7.5, KP.2.1, KP.2.10, KP.2.15, KP.3.2, JN.1.18.1, JN.1.18.2, JN.1.18.4, LQ.1.1, LB.1.1, LB.1.2, LB.1.4, LB.1.7, KS.1, JN.1.7.3, XEC, MC.1, JN.1.16.1, JN.1.18.6, JN.1.40, MC.2, MC.3, MC.2.1, MC.4, KP.2.3.3, LY.1, MA.1, LB.1.3.1 and KS.1.1, JN.1.7.8, KP.2.19, MC.16, MC.13, MC.24, LP.8.1, LP.8.1.1, XEC.8, XEC.2, XEC.14, XEC.2.2, XEC.2.1, LF.7, MC.10.1, NB.1.8.1, XFG, XFC, and LF.7.9) SARS-CoV-2 variants"**. The list of applicable STANDARD™ F products is as follows.

No.	Product Name	Reference No.
1	STANDARD™ F COVID-19 Ag FIA	F-NCOV-01G
2	STANDARD™ F COVID/Flu Ag Combo FIA	F-CVFL-01C
3	STANDARD™ F COVID/Flu Ag FIA	F-CVFL-02C

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, BA.4.1, BA.5, BF.7, BJ.1) 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.2.75, BF.7, BF.14, BJ.1, BQ.1.1, BA.4.6, BA.2.75.2, BA.2.12.1, BA.5.1, BA.5.2, BA.2.3.20, XBB, BA.2.10, BM.1.1.1, BQ.1, BA.4.4, BA.5.2.6, BN.1, CH.1.1, CJ.1, XBF, XBB.1, XBB.1.5 XBC, XBB.1.16, XBB.1.9.1, XBB.1.16.1, XBB.1.9.2, XBB.2.3, EG.5.1, BA.2.86, GW.5.1.1, FW.1.1, JN.1, GE.1.2.1, JN.1.1, JD.1.1, BA.2.86.1, JG.3, EG.5.1.6, HV.1, GS.4.1, XBB.1.16.15, FL.1.5.1, EG.5.1.3, GE.1, JN.6, JN.2, JN.3, HK.6, EG.5.1.1, JF.1, EG.10.1, XBB.1.16.6, XBB.1.16.11, HK.3, BA.2.87.1, JN.1.18, JN.1.22, JN.1.4, JN.1.7, JN.1.8, KP.2, KP.3, KP.1.1, XDQ, JN.1.7.1, JN.1.11.1, XDK, JN.1.16, LB.1, KP.2.3, JN.1.18.3, KP.2.2, KP.3.1, KP.3.1.1, KP.3.1.4, KP.3.2.3, KP.3.2.4, KP.3.3, KP.4.1, LB.1.3, KP.2.6, KP.3.2.2, JN.1.7.1, JN.1.7.2, JN.1.7.4, JN.1.7.5, KP.2.1, KP.2.10, KP.2.15, KP.3.2, JN.1.18.1, JN.1.18.2, JN.1.18.4, LQ.1.1, LB.1.1, LB.1.2, LB.1.4, LB.1.7, KS.1, JN.1.7.3, XEC, MC.1, JN.1.16.1, JN.1.18.6, JN.1.40, MC.2, MC.3, MC.2.1, MC.4, KP.2.3.3, LY.1, MA.1, LB.1.3.1 and KS.1.1, JN.1.7.8, KP.2.19, MC.16, MC.13, MC.24, LP.8.1, LP.8.1.1, XEC.8, XEC.2, XEC.14, XEC.2.2, XEC.2.1, LF.7, MC.10.1, NB.1.8.1, XFG, XFC, and LF.7.9) 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™ F products is not affected by SARS-CoV-2 variants by using synthetic recombinant proteins.

1.2 Specimen of test

1) Specimen (Positive)

Since STANDARD™ F products target nucleocapsid protein (hereafter, N protein), recombinant N protein of 34 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	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[1)]	7190366	Omicron
1-30	BA.4.1[2)]	12043292	Omicron
1-31	BA.5	11903045	Omicron
1-32	BA.5.3.1[3)]	12307612[a)]	Omicron
1-33	BF.7	12810243	Omicron
1-34	BJ.1	14167044	Omicron

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

2) BA.4.1 (hCoV-19/South Africa/NCV1112/2022) was first designated as BA.4 on April 14, 2022, and re-designated on May 22, 2022 (from pango-designation issue #548).

3) BA.5.3.1 is rearranged from BA.5 (12307612). Its prevalence is 0.39% for last 6 months (2022.07.18-2023.01.12) from covspectrum (Cov spectrum.org)

a) Accession number of 12307612 is BA.5 sub-lineage with very small portion (7.93% by GISAID, 2022.07.29)

** 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 34 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™ F product was not affected by the 34 variants.

2. In-silico analysis

2.1 Purpose of test

The purpose of this test is to theoretically verify that STANDARD™ F 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™ F 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™ F 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™ F product, and the evaluation result is marked with 'N'.

2.3 Result of test

As a result of in-silico analysis of 185 variants, the mutation sites of 3 variants (#2-14: 1239370, #2-31: 1969991, #2-62: 14167044) corresponded to the epitope region. However, it was confirmed that #2-14 and #2-31, #2-62 did not affect the sensitivity of STANDARD™ F products through the test for analytical sensitivity (#1-26 and #1-13, #1-34).

Additionally, 2 amino acid mutations (#2-140, #2-172) were investigated. However, the major variants of SARS-CoV-2, variants with such amino acid mutations are extremely rare, and their prevalence has not been reported. Continuous monitoring of SARS-CoV-2 variants is ongoing, and if any variants with these amino acid mutations are identified, the in-silico analysis of the variants will be updated in the report.

#	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	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, 31del, 32del, 33del, 203, 204	N
	2-43	BA.1 (B.1.1.529.1)	6640917	13, 31del, 32del, 33del, 203, 204	N
	2-44	BA.2 (B.1.1.529.2)	7190366	13, 31del, 32del, 33del, 203, 204, 413	N
	2-45	BA.3 (B.1.1.529.3)	7526186	13, 31del, 32del, 33del, 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, 31del, 32del, 33del, 203, 204 204, 413	N
	2-50	XF** (Delta and BA.1)	8894978	13, 31del, 32del, 33del, 203, 204	N
	2-51	BA.1.1	9754508	P13L, E31del, R32del, S33del, R203K, G204R	N
	2-52	BA.2.2	12417574	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
	2-53	BA.2.12	10842022	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
	2-54	BA.2.12.1	11490263	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
	2-55	BA.4.1[a)]	12043292	P13L, E31del, R32del, S33del, P151S, R203K, G204R, S413R	N
	2-56	BA.5	11903045	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
	2-57	BA.5.3.1[b)]	12307612**	P13L, E31del, R32del, S33del, E136D, R203K, G204R, S413R	N
	2-58	BA.2.75	13826295***	P13L E31del, R32del, S33del, R203K, G204R, S413R	N
	2-59	BA.2.75	13711333***	P13L, G204R, R203K, S413R	N
	2-60	BF.7	12810243	P13L, G30del, E31del, R32del, S33F, R203K, G204R, S413R	N
	2-61	BF.14	13490388	P13L, E31del, R32del, S33del, R203K, G204R S413R	N
	2-62	BJ.1	14167044	P13L, E31del, R32del, S33del, R203K, G204R, T282I, S413R	P

2-63	BQ.1.1[c)]	15155651	P13L, E31del, R32del, S33del, E136D, R203K, G204R, S413R	N
2-64	BA.4.6	12475182	P13L, E31del, R32del, S33del, P151S, R203K, G204R, S413R	N
2-65	BA.2.75.2	14290506	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-66	BA.2.12.1	9801346	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-67	BA.5.1	11941796	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-68	BA.5.2	11763535	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-69	BA.2.3.20	15031190	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-70	XBB	14891630	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-71	BA.2.10	8092783.2	P13L, E31del, R32del, S33del, R203K, G204R S413R	N
2-72	BM.1.1.1	13949278	P13L, E31del, R32del, S33del, R203K, G204R S413R	N
2-73	BS.1[d)]	14853841	P13L, E31del, R32del, S33del, T135I, R203K, G204R	N
2-74	BQ.1	14294806	P13L, E31del, R32del, S33del, E163D, R203K, G204R, S413R	N
2-75	BA.4.4	12012915	P13L, E31del, R32del, S33del, P151S, R203K, G204R, S413R	N
2-76	BA.5.2.6	12845553	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-77	BN.1[1]	15027018	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-78	CH.1.1	15316879	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-79	CJ.1	15157635	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-80	XBF	15414358	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-81	XBB.1	14917652	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-82	XBB.1.5	15687648	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-83	XBC	15057246	D63G, R203M, D377Y	N
2-84	XBB.1.16	16835403	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-85	XBB.1.9.1	17300463	P13L, E31del, R32del, S33del, R203K, G204R, T362I, S413R	N
2-86	XBB.1.9.1[2]	16093023	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-87	XBB.1.16.1	17206435	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-88	XBB.1.9.2	16508753	P13L, E31del, R32del, S33del, R203K, G204R, L219F (10.22%), S413R	N
2-89	XBB.2.3	16382405	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-90	EG.5.1	17308785	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-91	BA.2.86	18125259	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-92	GW.5.1.1	18543379	P13L, E31del, R32del, S33del, P80S, R203K, G204R, S413R	N
2-93	FW.1.1	18536082	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N

2-94	JN.1	18659732	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N	
2-95	GE.1.2.1	18756527	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-96	JN.1.1	18853765	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N	
2-97	JD.1.1	18854003	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-98	BA.2.86.1	18857718	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N	
2-99	JG.3	18854004	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-100	EG.5.1.6	18839472	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-101	HV.1	18852130	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-102	GS.4.1	18782653	P13L, G30del, E31del, R32del, S33A, R203K, G204R, S413R	N	
2-103	XBB.1.16.15	18851465	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-104	FL.1.5.1	18850174	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-105	EG.5.1.3	18851485	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-106	GE.1	18860090	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-107	JN.6	18849705	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N	
2-108	JN.2	18842882	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N	
2-109	JN.3	18853544	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N	
2-110	HK.6	18840974	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-111	EG.5.1.1	18852843	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-114	XBB.1.16.6	18847872	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-115	XBB.1.16.11	18851629	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-116	HK.3	18860010	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N	
2-117	BA.2.87.1	18849988	P13L, E31del, R32del, S33del, T148A, G178D, R203K, G204R, S413R	N	
2-118		18849985	P13L, E31del, R32del, S33del, T148A, R203K, G204R, S413R	N	
2-119		18849986	P13L, E31del, R32del, S33del, T148A, R203K, G204R, S413R	N	
2-120		18849990	P13L, E31del, R32del, S33del, T148A, R203K, G204R, S413R	N	
2-121		18849987	P13L, E31del, R32del, S33del, T148A, G178D, R203K, G204R	N	
2-122		18849989	P13L, E31del, R32del, S33del, Q43H, T148A, R203K, G204R, S413R	N	
2-123		18849991	P13L, E31del, R32del, S33del, T148A, R203K, G204R, S413R	N	
2-124		18849984	P13L, E31del, R32del, S33del, T148A, G178D, R203K, G204R, S413R	N	
2-125		18845398	P13L, G30del, E31del, R32del, S33D, T148A, R203K, G204R, S413R	N	
2-126	JN.1.18	19013232	P13L, E31del, R32del, S33del, R203K,	N	

			G204R, Q229K, S413R	
2-127	JN.1.22	18661795	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-128	JN.1.4	18848538	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-129	JN.1.7	18900863	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-130	JN.1.8	18607284	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-131	KP.2	19150387	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-132	KP.3	19150395	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-133	KP.3	19150366	P13L, E31del, R32del, S33del, R203K, G204P(10.63%), Q229K, S413R	N
2-134	KP.1.1	19150383	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-135	XDQ	19178922	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-136	JN.1.7.1	19176764	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-137	JN.1.11.1	19032226	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-138	XDK	19056040	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-139	JN.1.16	19188775	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-140	N/A	N/A	S23P, A35T, L39F, A50V, R68P, G204P, A218S, G243C, T366I, P368S, R385K, S412N	N
2-141	LB.1	19280900	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-142	KP.2.3	19280924	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-143	JN.1.18.3	19308882	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-144	KP.2.2	19308969	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-145	KP.3.1	19308987	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-146	KP.3.1.1	19308984	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-147	KP.3.1.4	19309252	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-148	KP.3.2.3	19308646	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-149	KP.3.2.4	19309896	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-150	KP.3.3	19311121	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-151	KP.4.1	19310969	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-152	LB.1.3	19311039	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-153	KP.2.6	19311074	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-154	KP.3.2.2	19309868	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-155	JN.1.7.1	19316552	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-156	JN.1.7.2	19314356	P13L, E31del, R32del, S33del, R203K,	N

			G204R, Q229K, S413R		
	2-157	JN.1.7.4	19316766	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-158	JN.1.7.5	19314342	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-159	KP.2.1	19317179	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-160	KP.2.10	19311924	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-161	KP.2.15	19318987	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-162	KP.3.2	19319091	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-163	JN.1.18.1	19297384	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-164	JN.1.18.2	19317120	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-165	JN.1.18.4	19317135	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-166	LQ.1.1	19318973	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-167	LB.1.1	19318965	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-168	LB.1.2	19318818	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-169	LB.1.4	19317358	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-170	LB.1.7	19318941	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-171	KS.1	19350160	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-172	N/A	N/A	Q241H	N
	2-173	JN.1.7.3	19314079	P13L, E31del, R32del, S33del, L139F, R203K, G204R, Q229K, S413R	N
	2-174	XEC	19283881	P13L, E31del, R32del, S33del, R203K, G204P, Q229K, S413R	N
	2-175	MC.1	19411171	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-176	JN.1.16.1	19515337	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-177	JN.1.18.6	19515738	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-178	JN.1.40	19515377	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-179	MC.2	19446205	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-180	MC.3	19523998	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-181	MC.2.1	19499240	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-182	MC.4	19256890	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-183	KP.2.3.3	19586058	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-184	LY.1	19585519	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-185	MA.1	19578603	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
	2-186	LB.1.3.1	19546489	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, T379I, S413R	N
	2-187	KS.1.1	19524128	P13L, T24I, E31del, R32del, S33del,	N

			R203K, G204R, Q229K, T379I, S413R	
2-188	JN.1.7.8	19721712	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, P365L, S413R	N
2-189	KP.2.19	19758200	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-190	MC.16	19778727	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-191	MC.13	19781478	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-192	MC.24	19782165	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-193	LP.8.1	19782915	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-194	LP.8.1.1	19782172	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-195	XEC.8	19783063	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-196	XEC.2	19782890	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-197	XEC.14	19782885	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-198	XEC.2.2	19782847	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-199	XEC.2.1	19781968	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-200	LF.7	19780361	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-201	MC.10.1	19782924	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-202	NB.1.8.1	19862356	P13L, E31del, R32del, S33del, R203K, G204R, S413R	N
2-203	XFG	19897301	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, T379I, S413R	N
2-204	XFC	19904719	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, S413R	N
2-205	LF.7.9	19905084	P13L, E31del, R32del, S33del, R203K, G204R, Q229K, 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.)

**** E31, R32 and S33 amino acid deletions of BA.2.75 occur in 74.15%, 74.15% and 72.79% respectively (Cov-spectrum.org, 2022.07.22).*

a) BA.4.1 (hCoV-19/South Africa/NCV1112/2022) was first designated as BA.4 on April 14, 2022, and re-designated on May 22, 2022 (from pango-designation issue #548).

b) BA.5.3.1 is rearranged from BA.5 (12307612). Its prevalence is 0.39% for last 6 months (2022.07.18-2023.01.12) from covspectrum (Cov spectrum.org).

c) BQ.1 was included to BQ.1.1 (cov-lineages/ pango-designation on GitHub)

d) The prevalence of BS.1 was 0.00% (Cov-spectrum.org, 2022.10.21), there were only 106 sequences in the database.

1) BN.1 belongs to BA.1 in the phylogenetic classification, but the sequence of N protein is same to BA.2.

2) XBB.1.9.1 was not designated in Covspectrum and GISAID on 4th April (rev.13), so we searched for XBB.1.9.1 based on cov-lineages/pango-designation, issue #1819. But, issue #1819 was closed as not planed issue. The information of XBB.1.9.1 was corrected based on Covspectrum, GISAID and cov-lineages/pango-designation, issue #1704 (https://github.com/cov-lineages/pango-designation/issues/1704)

3. Final conclusion of the test

As a result of analytical sensitivity and In-silico analysis, it is verified that STANDARD™ F 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, BA.4.1, BA.5, BF.7, BJ.1) SARS-CoV-2 variants”. In addition, as a result of In-silico analysis, it is verified that STANDARD™ F products are not affected by “Mu(B.1.621), Omicron(B.1.1.529, BA.2.75, BF.14, BQ.1.1, BA.4.6, BA.2.75.2, BA.2.12.1, BA.5.1, BA.5.2, BA.2.3.20, XBB, BA.2.10, BM.1.1.1, BS.1, BQ.1, BA.4.4, BA.5.2.6, BN.1, CH.1.1, CJ.1, XBF, XBB.1, XBB.1.5, XBC, XBB.1.16, XBB.1.9.1, XBB.1.16.1, XBB.1.9.2, XBB.2.3,EG.5.1, BA.2.86, GW.5.1.1, FW.1.1, JN.1, GE.1.2.1, JN.1.1, JD.1.1, BA.2.86.1, JG.3, EG.5.1.6, HV.1, GS.4.1, XBB.1.16.15, FL.1.5.1, EG.5.1.3, GE.1, JN.6, JN.2, JN.3, HK.6, EG.5.1.1, JF.1, EG.10.1, XBB.1.16.6, XBB.1.16.11, HK.3, BA.2.87.1, JN.1.18, JN.1.22, JN.1.4, JN.1.7, JN.1.8, KP.2, KP.3, KP.1.1, XDQ, JN.1.7.1, JN.1.11.1, XDK, JN.1.16, LB.1, KP.2.3, JN.1.18.3, KP.2.2, KP.3.1, KP.3.1.1, KP.3.1.4, KP.3.2.3, KP.3.2.4, KP.3.3, KP.4.1, LB.1.3, KP.2.6, KP.3.2.2, JN.1.7.1, JN.1.7.2, JN.1.7.4, JN.1.7.5, KP.2.1, KP.2.10, KP.2.15, KP.3.2, JN.1.18.1, JN.1.18.2, JN.1.18.4, LQ.1.1, LB.1.1, LB.1.2, LB.1.4, LB.1.7, KS.1, JN.1.7.3, XEC, MC.1, JN.1.16.1, JN.1.18.6, JN.1.40, MC.2, MC.3, MC.2.1, MC.4, KP.2.3.3, LY.1, MA.1, LB.1.3.1, KS.1.1, JN.1.7.8, KP.2.19, MC.16, MC.13, MC.24, LP.8.1, LP.8.1.1, XEC.8, XEC.2, XEC.14, XEC.2.2, XEC.2.1, LF.7, MC.10.1, NB.1.8.1, XFG, XFC, and LF.7.9) SARS-CoV-2 variants”.

In Ver.7.19, the N protein sequences of 3 variants were investigated: XFG (19897301), XFC (19904719) and LF.7.9 (19905084).

All of them are very similar to the N-protein sequence of BA.2 (7190366). (Homology 99.52-99.76%).

The mutation sites of in the 3 variants are not expected to affect test performance because they are not located in the epitope region

Additionally, the performance of the test kit is unaffected by 13 amino acid mutations (S23P, A35T, L39F, A50V, R68P, G204P, A218S, G243C, T366I, P368S, R385K, S412N, Q241H). Among the major variants of SARS-CoV-2, variants with such amino acid mutations are extremely rare, and their prevalence has not been reported. Continuous monitoring of SARS-CoV-2 variants is ongoing, and if any variants with these amino acid mutations are identified, the in-silico analysis of the variants will be updated in the report.

4. Interpretation of test result

A negative result may occur if the concentration of antigen in a specimen is below the limit of detection of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by molecular assay.

Result	COI(Cutoff index) value	SARS-CoV-2 Ag
Positive	COI ≥ 1.0	Positive for SARS-CoV-2 Ag
Negative	COI < 1.0	Negative for SARS-CoV-2 Ag
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient’s specimen.

3. 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.

Sincerely,

SD Biosensor, Inc.

Writer	: Mi-ho Hwang	**Reviewer**	: Kyu-Hee Lim	**QMR**	: Kyu-Hee Lim	**Factory Manager**	: Yoon-Seok Jin
REF No.	: BA200-20251001-QA2			**Date**	: 2025.10.01.		
Address (Head office)	: C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA			**Address** (Manufacturing site)	: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA		
Website	: www.sdbiosensor.com			**Tel**	: (Tel) +82-80-970-9700, (Fax) +82-31-300-0499		