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To : Valued customers

C.C : N/A

Subject : **Notification of Inclusivity test results for Influenza A/B, RSV and SARS-CoV-2 variants of STANDARD™ M10 Flu/RSV/SARS-CoV-2**

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

2. In-silico analysis and wet-testing of nucleotide sequence homology was conducted to theoretically verify that primer/probe of STANDARD™ M10 Flu/RSV/SARS-CoV-2 is not affected by 15 Influenza A virus subtypes, 3 Influenza B virus lineages, 2 RSV subtypes and 119 SARS-CoV-2 variants

2.1. We would like to inform you that the 15 Influenza A subtypes collected during up to "2025.06.16" are not affected detection. We verified through internal testing, and detailed information about it is as follows.

No.	Subtypes	Impact	Analysis method	Reference seq. ID (GISAID)
1	H1N1	Not affected	Wet testing, In-silico analysis	EPI_ISL_3652187
2	H1N2	Not affected	In-silico analysis	EPI_ISL_407777
3	H2N2	Not affected	In-silico analysis	EPI_ISL_17044
4	H3N2	Not affected	Wet testing, In-silico analysis	EPI_ISL_3684961
5	H5N1	Not affected	In-silico analysis	EPI_ISL_642539
6	H5N6	Not affected	In-silico analysis	EPI_ISL_3279878
7	H5N8	Not affected	In-silico analysis	EPI_ISL_1846964
8	H7N2	Not affected	In-silico analysis	EPI_ISL_154164
9	H7N3	Not affected	In-silico analysis	EPI_ISL_393391
10	H7N4	Not affected	In-silico analysis	EPI_ISL_1139780
11	H7N7	Not affected	In-silico analysis	EPI_ISL_560343
12	H7N9	Not affected	In-silico analysis	EPI_ISL_926812
13	H9N2	Not affected	In-silico analysis	EPI_ISL_3852391
14	H10N3	Not affected	In-silico analysis	EPI_ISL_4385576
15	H10N8	Not affected	In-silico analysis	EPI_ISL_530445

Based on the in-silico analysis, detection of the H3N2 Subclade K was confirmed to be possible.

Subtypes	Target gene	Coverage (%)
H3N2 Subclade K	M	1669/1675 (99.64%)
	PB2	1628/1648 (99.09%)

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2.2. We would like to inform you that the 3 Influenza B lineages collected during up to "2025.06.16" are not affected detection. We verified through internal testing, and detailed information about it is as follows.

No.	Lineage	Impact	Analysis method	Reference seq. ID (GISAID)
1	Victoria	Not affected	Wet testing, In-silico analysis	EPI_ISL_19891206
2	Yamagata	Not affected	Wet testing, In-silico analysis	EPI_ISL_430780
3	unknown	Not affected	In-silico analysis	EPI_ISL_17516384

2.3. We would like to inform you that the 2 RSV subtypes collected during up to "2025.06.16" are not affected detection. We verified through internal testing, and detailed information about it is as follows.

No.	subtype	Impact	Analysis method	Reference seq. ID (GISAID)
1	A	Not affected	Wet testing, In-silico analysis	EPI_ISL_19662923
2	B	Not affected	Wet testing, In-silico analysis	EPI_ISL_19159677

2.4. We would like to inform you that the 119 SARS-CoV-2 variants collected during "2019.07.01 ~ 2025.05.22" are not affected detection of "AY.1, B.1.1.529, B.1.1.7, B.1.351, B.1.427, B.1.429, B.1.525, B.1.526, B.1.617.1, B.1.617.2, B.1.621, BA.1, BA.2, BA.2.10, BA.2.12.1, BA.2.3.20, BA.2.75, BA.2.75.2, BA.4, BA.4.1, BA.4.4, BA.4.6, BA.5, BA.5.1, BA.5.2, BA.5.2.6, BF.14, BF.7, BN.1, BQ.1, BQ.1.1, BQ.1.8, C.37, CH.1.1, CH.1.1.1, CH.1.1.2, DV.7.1, EG.5.1, EG.5.1.1, EG.5.1.3, EG.5.1.4, EG.5.1.6, EG.6.1, FL.1.5.1, FU.1, FU.2, GE.1, HK.3, HV.1, JN.1, JN.1.18, JN.1.22, JN.1.4, JN.1.7, KP.1.1, KP.2, P.1, P.2, XBB, XBB.1, XBB.1.16, XBB.1.16.1, XBB.1.16.11, XBB.1.16.15, XBB.1.16.2, XBB.1.16.6, XBB.1.16.9, XBB.1.5, XBB.1.5.11, XBB.1.5.72, XBB.1.9.1, XBB.1.9.2, XBB.2, XBB.2.3, XBF, XE, KP.3.1.1, XEC, KP.2.3, KP.3.3, LP.8.1.1, KP.3.1, MC.1, MC.16, MC.24, KP.2.2, MC.13, LB.1, XEC.2, KP.1.1.3, LP.8.1, LB.1.7, KP.3.3.3, KP.3, XDV.1, KP.3.2.3, LB.1.3, MC.11, XEC.8, KP.3.2, LB.1.3.1, XEC.4, MC.10.1, BA.1.1, KP.3.1.4, MC.10, LP.8.1.4, MC.6, KS.1, XEC.9, LP.1, MC.9, B.1.2, KP.1.1.1, JN.16.1, MC.2, LF.7.1.3, XEK, LF.7.2.1". We verified through internal testing, and detailed information about it is as follows.

No.	Variants	Impact	Analysis method	Reference seq. ID (GISAID)
1	AY.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_13460389
2	B.1.1.529	Not affected	Wet testing, In-silico analysis	EPI_ISL_13577830
3	B.1.1.7	Not affected	Wet testing, In-silico analysis	EPI_ISL_2790408
4	B.1.351	Not affected	Wet testing, In-silico analysis	EPI_ISL_2784424
5	B.1.427	Not affected	In-silico analysis	EPI_ISL_2785301
6	B.1.429	Not affected	In-silico analysis	EPI_ISL_2775813
7	B.1.525	Not affected	In-silico analysis	EPI_ISL_2790926
8	B.1.526	Not affected	Wet testing, In-silico analysis	EPI_ISL_2785204

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9	B.1.617.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_2775113
10	B.1.617.2	Not affected	Wet testing, In-silico analysis	EPI_ISL_13578933
11	B.1.621	Not affected	In-silico analysis	EPI_ISL_13560255
12	BA.1	Not affected	In-silico analysis	EPI_ISL_13577829
13	BA.2	Not affected	In-silico analysis	EPI_ISL_13582157
14	BA.2.10	Not affected	In-silico analysis	EPI_ISL_13583072
15	BA.2.12.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_13583384
16	BA.2.3.20	Not affected	In-silico analysis	EPI_ISL_17858894
17	BA.2.75	Not affected	In-silico analysis	EPI_ISL_18936094
18	BA.2.75.2	Not affected	In-silico analysis	EPI_ISL_17858778
19	BA.4	Not affected	In-silico analysis	EPI_ISL_17956663
20	BA.4.1	Not affected	In-silico analysis	EPI_ISL_17950032
21	BA.4.4	Not affected	In-silico analysis	EPI_ISL_17950002
22	BA.4.6	Not affected	Wet testing, In-silico analysis	EPI_ISL_17956414
23	BA.5	Not affected	Wet testing, In-silico analysis	EPI_ISL_17956660
24	BA.5.1	Not affected	In-silico analysis	EPI_ISL_17948388
25	BA.5.2	Not affected	In-silico analysis	EPI_ISL_17948352
26	BA.5.2.6	Not affected	Wet testing, In-silico analysis	EPI_ISL_17948369
27	BF.14	Not affected	In-silico analysis	EPI_ISL_17948360
28	BF.7	Not affected	Wet testing, In-silico analysis	EPI_ISL_17948403
29	BN.1	Not affected	In-silico analysis	EPI_ISL_17956491
30	BQ.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_17956505
31	BQ.1.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_17956496
32	BQ.1.8	Not affected	In-silico analysis	EPI_ISL_17886136
33	C.37	Not affected	In-silico analysis	EPI_ISL_13522162
34	CH.1.1	Not affected	In-silico analysis	EPI_ISL_17948456
35	CH.1.1.1	Not affected	In-silico analysis	EPI_ISL_17952025
36	CH.1.1.2	Not affected	In-silico analysis	EPI_ISL_17882522
37	DV.7.1	Not affected	In-silico analysis	EPI_ISL_19218686
38	EG.5.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_19222462
39	EG.5.1.1	Not affected	In-silico analysis	EPI_ISL_19222520
40	EG.5.1.3	Not affected	In-silico analysis	EPI_ISL_19222623
41	EG.5.1.4	Not affected	In-silico analysis	EPI_ISL_19222546
42	EG.5.1.6	Not affected	In-silico analysis	EPI_ISL_19222459
43	EG.6.1	Not affected	In-silico analysis	EPI_ISL_19222513
44	FL.1.5.1	Not affected	In-silico analysis	EPI_ISL_19222547
45	FU.1	Not affected	In-silico analysis	EPI_ISL_19222532
46	FU.2	Not affected	In-silico analysis	EPI_ISL_19222452
47	GE.1	Not affected	In-silico analysis	EPI_ISL_19163952
48	HK.3	Not affected	In-silico analysis	EPI_ISL_19220003

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49	HV.1	Not affected	In-silico analysis	EPI_ISL_19222587
50	JN.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_19224524
51	JN.1.18	Not affected	In-silico analysis	EPI_ISL_19225060
52	JN.1.22	Not affected	In-silico analysis	EPI_ISL_19223401
53	JN.1.4	Not affected	Wet testing, In-silico analysis	EPI_ISL_19224520
54	JN.1.7	Not affected	In-silico analysis	EPI_ISL_19225193
55	KP.1.1	Not affected	In-silico analysis	EPI_ISL_19225223
56	KP.2	Not affected	In-silico analysis	EPI_ISL_19225243
57	P.1	Not affected	Wet testing, In-silico analysis	EPI_ISL_13564425
58	P.2	Not affected	Wet testing, In-silico analysis	EPI_ISL_2775491
59	XBB	Not affected	Wet testing, In-silico analysis	EPI_ISL_17937838
60	XBB.1	Not affected	In-silico analysis	EPI_ISL_18073652
61	XBB.1.16	Not affected	In-silico analysis	EPI_ISL_19222542
62	XBB.1.16.1	Not affected	In-silico analysis	EPI_ISL_19190014
63	XBB.1.16.11	Not affected	In-silico analysis	EPI_ISL_19222586
64	XBB.1.16.15	Not affected	In-silico analysis	EPI_ISL_19222539
65	XBB.1.16.2	Not affected	In-silico analysis	EPI_ISL_17952028
66	XBB.1.16.6	Not affected	In-silico analysis	EPI_ISL_19222522
67	XBB.1.16.9	Not affected	In-silico analysis	EPI_ISL_19163957
68	XBB.1.5	Not affected	Wet testing, In-silico analysis	EPI_ISL_17952046
69	XBB.1.5.11	Not affected	In-silico analysis	EPI_ISL_18073351
70	XBB.1.5.72	Not affected	In-silico analysis	EPI_ISL_19222463
71	XBB.1.9.1	Not affected	In-silico analysis	EPI_ISL_17951657
72	XBB.1.9.2	Not affected	In-silico analysis	EPI_ISL_17951981
73	XBB.2	Not affected	In-silico analysis	EPI_ISL_18936147
74	XBB.2.3	Not affected	In-silico analysis	EPI_ISL_17951983
75	XBF	Not affected	In-silico analysis	EPI_ISL_17948287
76	XE	Not affected	In-silico analysis	EPI_ISL_13587265
77	KP.3.1.1	Not affected	In-silico analysis	EPI_ISL_19879380
78	XEC	Not affected	In-silico analysis	EPI_ISL_19879348
79	KP.2.3	Not affected	In-silico analysis	EPI_ISL_19872038
80	KP.3.3	Not affected	In-silico analysis	EPI_ISL_19878476
81	LP.8.1.1	Not affected	In-silico analysis	EPI_ISL_19879460
82	KP.3.1	Not affected	In-silico analysis	EPI_ISL_19874944
83	MC.1	Not affected	In-silico analysis	EPI_ISL_19879357
84	MC.16	Not affected	In-silico analysis	EPI_ISL_19876739
85	MC.24	Not affected	In-silico analysis	EPI_ISL_19879329
86	KP.2.2	Not affected	In-silico analysis	EPI_ISL_19864958
87	MC.13	Not affected	In-silico analysis	EPI_ISL_19879353
88	LB.1	Not affected	In-silico analysis	EPI_ISL_19864960

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89	XEC.2	Not affected	In-silico analysis	EPI_ISL_19878285
90	KP.1.1.3	Not affected	In-silico analysis	EPI_ISL_19872103
91	LP.8.1	Not affected	In-silico analysis	EPI_ISL_19878187
92	LB.1.7	Not affected	In-silico analysis	EPI_ISL_19878543
93	KP.3.3.3	Not affected	In-silico analysis	EPI_ISL_19877199
94	KP.3	Not affected	In-silico analysis	EPI_ISL_19872057
95	XDV.1	Not affected	In-silico analysis	EPI_ISL_19864860
96	KP.3.2.3	Not affected	In-silico analysis	EPI_ISL_19864806
97	LB.1.3	Not affected	In-silico analysis	EPI_ISL_19879349
98	MC.11	Not affected	In-silico analysis	EPI_ISL_19879377
99	XEC.8	Not affected	In-silico analysis	EPI_ISL_19878186
100	KP.3.2	Not affected	In-silico analysis	EPI_ISL_19877243
101	LB.1.3.1	Not affected	In-silico analysis	EPI_ISL_19878537
102	XEC.4	Not affected	In-silico analysis	EPI_ISL_19879150
103	MC.10.1	Not affected	In-silico analysis	EPI_ISL_19878257
104	BA.1.1	Not affected	In-silico analysis	EPI_ISL_19879018
105	KP.3.1.4	Not affected	In-silico analysis	EPI_ISL_19858057
106	MC.10	Not affected	In-silico analysis	EPI_ISL_19876719
107	LP.8.1.4	Not affected	In-silico analysis	EPI_ISL_19879469
108	MC.6	Not affected	In-silico analysis	EPI_ISL_19864968
109	KS.1	Not affected	In-silico analysis	EPI_ISL_19845778
110	XEC.9	Not affected	In-silico analysis	EPI_ISL_19877564
111	LP.1	Not affected	In-silico analysis	EPI_ISL_19865144
112	MC.9	Not affected	In-silico analysis	EPI_ISL_19875910
113	B.1.2	Not affected	In-silico analysis	EPI_ISL_19849689
114	KP.1.1.1	Not affected	In-silico analysis	EPI_ISL_19864822
115	JN.1.16.1	Not affected	In-silico analysis	EPI_ISL_19879457
116	MC.2	Not affected	In-silico analysis	EPI_ISL_19877252
117	LF.7.1.3	Not affected	In-silico analysis	EPI_ISL_19875508
118	XEK	Not affected	In-silico analysis	EPI_ISL_19878298
119	LF.7.2.1	Not affected	In-silico analysis	EPI_ISL_19878791

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,

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SD Biosensor, Inc.



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