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Issue number: BA200-20210507-QA4

May 7, 2021

Subject : SD Biosensor's STANDARD™ Q products for SARS-CoV-2 diagnostic are not affected by **"India, Brazil, South Africa and UK variants".**

Dear valued customers,

We, SD Biosensor, Inc., verified that STANDARD™ Q products for SARS-CoV-2 diagnostic are not affected by India(B.1.617, B.1), Brazil(B.1.1.248), South Africa(B.1.351) and UK(B.1.1.7) variants through internal test. 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 Home Test Saliva	Q-NCOV-05G
4	STANDARD™ Q COVID-19 Ag Nasal Test	Q-NCOV-04G
5	STANDARD™ Q COVID-19 Ag/Ab Total Test	Q-NCOV-01T
6	STANDARD™ Q COVID/Flu Ag Combo Test	Q-CVFL-01C
7	STANDARD™ Q COVID-19 Ag Saliva Test	Q-NCOV-02G
8	STANDARD™ i-Q COVID-19 Ag Test	EQ-NCOV-01G
9	STANDARD™ i-Q COVID-19 Ag Saliva Test	EQ-NCOV-04G
10	STANDARD™ i-Q COVID-19 Ag Saliva Home Test	EQ-NCOV-02G
11	STANDARD™ i-Q COVID-19 Ag Home Test	EQ-NCOV-03G

Please refer to the following for details on the test, including procedures and conclusions.

1. Purpose of test

The purpose of this test is to verify that STANDARD™ Q products are not affected by India, Brazil, South Africa and UK variants.

2. Item of test

- Analytical sensitivity
- In-silico analysis

3. Sample of test

3.1 Specimen (Positive)

Outbreak country	Variant	Synonym	Sample type	Target
China	Wuhan-Hu-1	N/A	Recombinant protein	*N protein
United Kingdom	B.1.1.7	VUI 202012/01, VOC-202012/01, 20B/501Y.V1, 501.V1	Recombinant protein	*N protein
South Africa	B.1.351	501.V2, 20C/501Y.V2	Recombinant protein	*N protein
Brazil (Reported from Japan)	B.1.1.248	20J/501Y.V3, P.1	Recombinant protein	*N protein
India	B.1.617	VUI-10	Recombinant protein	*N protein
India	B.1	VUI-11	Recombinant protein	*N protein

**SARS-CoV-2 variants were synthesized to be recombinant nucleocapsid protein (Hereinafter, N protein) due to the target protein of STANDARD™ Q products is N protein.*

3.2 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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3.3 Test strip

3 lots of test strips(STANDARD™ Q COVID-19 Ag Test) were used for the test.

4. Method of test

4.1 Each of the recombinant N proteins was diluted in successive concentrations.

4.2 The dilutions were spiked with a normal swab.

4.3 The spiked swab was tested in the same method as the IFU.

4.4 Dilutions of the recombinant N proteins were tested repeatedly 20 times for each lot of test strips.

5. Result of test

Variants recombinant N protein had similar limit of detection to Wuhan-Hu-1 recombinant N protein used as a positive control. Therefore the sensitivity of STANDARD™ Q products was not affected by variants.

Outbreak country	Variant	Concentration of limit of detection (㎍/㎖)
China	Wuhan-Hu-1	0.0156
United Kingdom	B.1.1.7	0.0156
South Africa	B.1.351	0.0156
Brazil (Reported from Japan)	B.1.1.248	0.0156
India	B.1.617	0.0156
India	B.1	0.0156

Further in-silico analysis show that each variant has high homology comparing with Wuhan-Hu-1 as shown in the table below.

Outbreak country	Variant	Homology comparing with Wuhan-Hu-1
United Kingdom	B.1.1.7	99.52%
South Africa	B.1.351	99.76%
Brazil (Reported from Japan)	B.1.1.248	99.28%
India	B.1.617	99.52%
India	B.1	99.52%

6. Conclusion of test

In conclusion we verified that performance of STANDARD™ Q products is not affected by India, Brazil, South Africa and UK variants.

We will promptly communicate any updates regarding COVID-19 products. In addition, 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.

SD BIO SENSOR, Inc.