SD BIOSENSOR

C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

(Tel) +82-31-300-0400, (Fax) +82-31-300-0499
www.sdbiosensor.com

Issue number: BA200-20210504-QA3

May 3, 2021

Subject : Performance of SD Biosensor's SARS-CoV-2 diagnostic products are theoretically not be affected by newly discovered India variants(B.1.617 and B.1).

Dear valued customers,

We, SD Biosensor, Inc., would like to inform you that our SARS-CoV-2 diagnostic products remain suitable for the detection of SARS-CoV-2 antigens even in the emergence of newly discovered India variants.

According to our investigation, the India variants are divided into B.1.617 and B.1. The sites where the nucleocapsid proteins of B.1.617 and B.1 were mutated were the same as 203 and 377 of amino acid position. Since the recognition site of the raw materials used in our antigen test are different from mutation sites, we expect our products are theoretically able to detect India variants.

To conclude our theory, we are planning to conduct an evaluation by using recombinant nucleocapsid proteins expressing those site mutations. We expect this evaluation will be finished by May 2021.

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 BIOSENSOR

C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

(Tel) +82-31-300-0400, (Fax) +82-31-300-0499
www.sdbiosensor.com

Issue number: BA200-20210202-QA4

February 2, 2021

Subject : Performance of STANDARD™ Q COVID-19 Ag Test is not be affected by UK, South Africa and Brazil variants

Dear valued customers,

We, SD Biosensor, Inc., verified that the STANDARD™ Q COVID-19 Ag Test is suitable for detecting SARS-CoV-2 variants found in UK, South Africa and Brazil through internal test. 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 the STANDARD™ Q COVID-19 Ag Test detects SARS-CoV-2 variants.

2. Item of test

- Analytical sensitivity
- In-silico analysis

3. Sample of test

3.1 Specimen (Positive)

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

**SARS-CoV-2 variant strains were synthesized to be recombinant nucleocapsid protein (Hereinafter, N protein) due to the target protein of STANDARD™ Q COVID-19 Ag Test is N protein.*

3.2 Specimen (Negative)

ID	Source	PCR result
Negative human nasopharyngeal swab	BioNote,Inc	Negative

**Negative human nasopharyngeal 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).*

3.3 Test strip

3 lots of test strips 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 nasopharyngeal swab.
4.3 The spiked swab was tested in the same method as the IFU of the STANDARD™ Q COVID-19 Ag Test.
4.4 Dilutions of the recombinant N proteins were tested repeatedly 20 times for each lot of test strips.

SD BIOSENSOR
C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
(Tel) +82-31-300-0400, (Fax) +82-31-300-0499
www.sdbiosensor.com

5. Result of test

STANDARD™ Q COVID-19 Ag Test detected 3 types of variant recombinant N protein(UK, SA and BR) with same limit of detection as recombinant N protein of Wuhan-Hu-1 used as a positive control. That concentration of limit of detection was 0.0156 ㎍/㎖. Therefore the sensitivity of STANDARD™ Q COVID-19 Ag Test was not affected by mutant B.1.1.7, B.1.351 and B.1.1.248.

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

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

6. Conclusion of test

In conclusion performance of STANDARD™ Q COVID-19 Ag Test is not be affected by UK, South Africa and Brazil variants.

We are planning further study using real UK, South African and Brazil mutant viruses, not recombinant. We expect this study will be finished by the end of February 2021, but this may be delayed due to the domestic regulations for prevention of infectious disease. We will notify you of an update letter as soon as further study 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.