

S2 Covid-19 Rapid Antigen Test Kit

ERCSSO5340

Recognition performance report of mutant viruses

Study Summary

This study tested the reliability of the S2 Covid-19 Rapid Antigen Test Kit by spiking the nucleocapsid protein, spiker protein and SARS-CoV-2 strain of the SARS-CoV-2 mutant virus into the tested samples.

1.Purpose

The purpose of this test is to evaluate the reliability of the S2 Covid-19 Rapid Antigen Test Kit under the presence of nucleocapsid protein, spiker protein and SARS-CoV-2 strain of the SARS-CoV-2 mutant virus.

The eligibility standard of the product is: When the SARS-CoV-2 Ag rapid detection kit is used to detect a pre-diluted $10\times\text{LoD}$ positive sample, and the positive rate is still $\geq 95\%$, it can be determined that the performance of the product is not significantly affected in this mutant virus strain.

2.Reference

The study was performed according to the technology specification of the S2 Covid-19 Rapid Antigen Test Kit.

3.Method

Spike a healthy Nasal swab sample, NP swab sample and a healthy OP swab sample into saline water, respectively. Prepare the supernatant for subsequent use. Spiked different kind of nucleocapsid protein of SARS-CoV-2 mutant virus (50 pg/mL). And in supernatant described above, respectively. Each supernatant are tested 50 times.

Spike a healthy Nasal swab sample, NP swab sample and a healthy OP swab sample into saline water, respectively. Prepare the supernatant for subsequent use. Spiked different kind of spiker protein of SARS-CoV-2 mutant virus (200 pg/mL). And in supernatant described above, respectively. Each supernatant are tested 50 times.

Spike a healthy Nasal swab sample, NP swab sample and a healthy OP swab sample into saline water, respectively. Prepare the supernatant for subsequent use. Spiked different kind of SARS-CoV-2 mutant strain (6.9×10^2 TCID₅₀/mL). And in supernatant described above, respectively. Each supernatant are tested 50 times.

4.Result

N-protein of mutant virus	Nasal Swab Sample	NP Swab Sample	OP Swab Sample
Alpha (B.1.1.7)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Beta (B.1.351)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Gamma (P.1)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Delta (B.1.617.2)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Eta (B.1.525)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Lota (B.1.526)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Kappa (B.1.617.1)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Lambda (C.37)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Mu (B.1.621)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Omicron (B.1.1.529)	50/50 (100%)	50/50 (100%)	50/50 (100%)
C.1.2	50/50 (100%)	50/50 (100%)	50/50 (100%)
B.1.618	50/50 (100%)	50/50 (100%)	50/50 (100%)
P.2	50/50 (100%)	50/50 (100%)	50/50 (100%)
D614G	50/50 (100%)	50/50 (100%)	50/50 (100%)
501Y.V2	50/50 (100%)	50/50 (100%)	50/50 (100%)

S-protein of mutant virus	Nasal Swab Sample	NP Swab Sample	OP Swab Sample
Alpha (B.1.1.7)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Beta (B.1.351)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Gamma (P.1)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Delta (B.1.617.2)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Eta (B.1.525)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Lota (B.1.526)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Kappa (B.1.617.1)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Lambda (C.37)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Mu (B.1.621)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Omicron (B.1.1.529)	50/50 (100%)	50/50 (100%)	50/50 (100%)
C.1.2	50/50 (100%)	50/50 (100%)	50/50 (100%)
B.1.618	50/50 (100%)	50/50 (100%)	50/50 (100%)
P.2	50/50 (100%)	50/50 (100%)	50/50 (100%)
D614G	50/50 (100%)	50/50 (100%)	50/50 (100%)
501Y.V2	50/50 (100%)	50/50 (100%)	50/50 (100%)

SARS-CoV-2 mutant strain	Nasal Swab Sample	NP Swab Sample	OP Swab Sample
Alpha (B.1.1.7)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Beta (B.1.351)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Gamma (P.1)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Delta (B.1.617.2)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Eta (B.1.525)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Lota (B.1.526)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Kappa (B.1.617.1)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Lambda (C.37)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Mu (B.1.621)	50/50 (100%)	50/50 (100%)	50/50 (100%)
Omicron (B.1.1.529)	50/50 (100%)	50/50 (100%)	50/50 (100%)
C.1.2	50/50 (100%)	50/50 (100%)	50/50 (100%)
B.1.618	50/50 (100%)	50/50 (100%)	50/50 (100%)
P.2	50/50 (100%)	50/50 (100%)	50/50 (100%)
D614G	50/50 (100%)	50/50 (100%)	50/50 (100%)
501Y.V2	50/50 (100%)	50/50 (100%)	50/50 (100%)

According to the test results, the detection performance of S2 Covid-19 Rapid Antigen Test Kit is suitable for a variety of SARS-CoV-2 mutant virus strains.

5. Conclusion

The S2 Covid-19 Rapid Antigen Test Kit shows good recognition performance report of mutant viruses.

Sensing Self Pte. Ltd. Singapore

December 2, 2021