

Declaration Letter

June 30, 2022

Dear customers,

This letter is served to notify you that the Bioperfectus Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit and Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit (Self-test) show no drop off in sensitivity and specificity in face of SARS-CoV-2 variants (known as B.1.1.7, B.1.351, P.1, B.1.617.2, B.1.427, B.1.429, P.2, B.1.525, P.3, B.1.526, B.1.617.1, C.37, B.1.621, B.1.1.529, BA.2, BA.3, BA.4, BA.5 and B.1.640.2, BA.1xAY.4 recombinant).

Although the reported variants have mutation sites on the Nucleocapsid Protein of SARS-CoV-2 (listed in Table 1), our antibodies used in the Bioperfectus Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit and Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit (Self-test) bind to the conserved region of the Nucleocapsid Protein. Therefore, our kits effectively avoid the region of current reported mutants and the **PERFORMANCE WILL NOT BE AFFECTED BY THE MENTIONED MUTATIONS.**

Table 1. Mutation Profile of SARS-CoV-2 Variants

Variant	Label	Mutation site of Nucleocapsid Protein
BA.1xAY.4 recombinant	XD	D63G+D377Y+R203M
B.1.640.2	IHU	D22Y+T205I
B.1.1.529/BA.2/BA.3/BA.5	Omicron	P13L+DEL31/33+R203K+G204R+S413R
BA.4	Omicron	P13L+DEL31/33+P151S+ R203K+G204R+S413R
B.1.1.7	Alpha	D3L+S235F+RG203KR
B.1.351	Beta	T205I
P.1	Gamma	P80R+RG203KR
B.1.617.2	Delta	D63G+D377Y+R203M
B.1.427/B.1.429	Epsilon	T205I
P.2	Zeta	A119S+M234I+RG203KR
B.1.525	Eta	A12G+T205I
P.3	Theta	RG203KR
B.1.526	Iota	M234I+P199L
B.1.617.1	Kappa	R203M+D377Y
C.37	Lambda	P13L+R203K+G204R+G214C
B.1.621	Mu	T205I

References:

1. <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html>

2. <https://nextstrain.org/ncov/global>
3. <https://www.ecdc.europa.eu/en/covid-19/variants-concern>
4. <https://outbreak.info/situation-reports>

We thank you for your continued support and understanding. Any questions, please kindly contact our sales representatives or send e-mail to info@bioperfectus.com for more information.

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