

In silico analysis of Impact of SARS-CoV-2 Variants

to Flowflex SARS-CoV-2 Antigen Rapid Test

The product Flowflex SARS-CoV-2 Antigen Rapid Test was designed to detect the nucleocapsid protein antigen from SARS-CoV-2 in human nasal and nasopharyngeal swab specimens. Using the available information on the GISAID website, the current variants of concern and variants under investigation have several mutations in the spike protein and a few mutations in the nucleocapsid protein. The mutation on the nucleocapsid protein for each variant is listed below:

No.	Variant designation	Mutation on the nucleocapsid protein
1	Alpha (B.1.1.7)	D3L, S235F
2	Beta (B.1.351) / Mu (B.1.621)	T205I
3	Gamma (P.1)	P80R
4	B.1.617	R203K+D377Y
5	Kappa (B.1.617.1)	R203M+D377Y
6	Delta (B.1.617.2)	D63G+D377Y+R203M
7	B.1.617.3	P67S+D377Y+R203M
8	B.1.618	A119S, A217S, E367Q, G18S, M234I
9	Epsilon (B.1.427/B.1.429)	T205I
10	Zeta (P.2)	A119S+M234I+RG203KR
11	Eta (B.1.525)	A12G+T205I
12	Theta (P.3)	RG203KR

13	Iota (B.1.526)	M234I+P199L
14	B.1.616	T325I
15	A.23.1	S202N
16	Lambda (C.37)	P13L+R203K+G204R+G214C
17	Delta Plus	D63G, R203M, G215C, D377Y
18	Omicron (B1.1.529)	P13L, E31-, R32-,S33-, R203K, G204R

The antibodies used in Flowflex SARS-CoV-2 Antigen Rapid Test is target to the region of 209 – 232aa of the nucleocapsid protein. Base on the sequence alignments, there is not any mutation in this range for above variants, except variants B. 1.618, Lambda (C.37) and Delta Plus. These three variants have only one mutation site in this range. Base on the sequence alignments in silico analysis, we do not anticipate that nucleocapsid protein mutations out of the region of 209 – 232aa will have any effect on test performance.

In additional, the wet analysis studies were conducted with recombination nucleocapsid proteins for all the variants, except the latest variant of Omicron (B1.1.529). No obvious difference observed when testing with different recombination nucleocapsid protein of different variants of SARS-CoV-2.

And we will conduct a wet analysis study as soon as we get the recombination nucleocapsid protein for Omicron (B1.1.529).