Technical Bulletin

SARS-CoV-2 Variant Detection

A study was performed to determine detection of various SARS-CoV-2 recombinant mutations across the on-market Quidel antigen assays.

Each recombinant mutation, as specified by the proposed variants and mutations to the nucleoprotein, was diluted to an initial target concentration and tested on the Sofia® SARS Antigen FIA to verify that it was detectable. Once detected, serial dilutions of each recombinant mutation were subsequently formulated and tested with each of the Quidel antigen assays listed in the table below. Each level was tested with a total number of three (3) replicates. Sofia SARS Antigen FIA, Sofia Flu + SARS Antigen FIA, QuickVue® SARS Antigen Test and QuickVue At-Home OTC COVID-19 Test remain unaffected by the variants identified below.

Variant Strain	CDC Description	Place of Origin	NP Mutation	NP Mutations Tested	Status
a. 201/501Y.V1, VOC202012/01, or B.1.1.7	Alpha	UK	N_S235F N_R203K N_D3L N_G204R	D3L/S235F D3L, R203K, S235F R203K/G204R; S194L	not affected
b. 20H/501Y.V2 or B.1.351	Beta	South Africa	N_T205I N_T362I N_P13S	T205I D3L/T205I/S235F P13L	not affected
c. 20J/501Y.V3 or P.1	Gamma	Brazil	N_P80R N_G204R N_R203K	I292T; A119S/R203K/G204R/ M234I	not affected
d. CAL.20C or B.1.429	Epsilon	California	N_T205I N_M234I N_D377Y	D144H/T391I/S413I D377Y	not affected
e. B.1.427	Epsilon	California	N_T205I N_M234I N_D377Y	D144H/T391I/S413I D377Y	not affected
f. B.1.617. B.1.617.1, B.1.617.2 and B.1.617.3	Delta	India	N_R203M N_D377Y N_D63G	R203K, P13L/S194L/D377Y	not affected

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