

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. All eight (8) recombinant mutations were detected by each of the Quidel antigen assays.

| Variant Strain | Place of Origin | NP Mutation | Sofia SARS Antigen | Sofia 2 Flu + SARS Antigen | QuickVue® SARS Antigen | QuickVue At-Home COVID-19 |
|---------------------|--------------------|----------------------------|-----------------------|-------------------------------|---------------------------|---------------------------------|
| Wild type | Wuhan | N/A | \checkmark | \checkmark | \checkmark | \checkmark |
| B.1.1.7 | UK | D3L, S235F | \checkmark | ~ | \checkmark | ✓ |
| B.1.1.7 | UK | D3L, R203K, S235F | ~ | ~ | \checkmark | ✓ |
| 501Y.V2 | South Africa | T205I | ~ | ~ | ✓ | \checkmark |
| B.1.1.7, 501Y.V2 | UK/South Africa | D3L/T205I/ S235F | ~ | ~ | \checkmark | \checkmark |
| P.1 (501Y.V3) | Brazil | R203K, G204R | \checkmark | ~ | \checkmark | ✓ |
| P.1 (501Y.V3) | Brazil | I292T | ~ | ~ | √ | \checkmark |
| P.1 (501Y.V3) | Brazil | A119S-R203K- G204R-M234 | ~ | ~ | \checkmark | \checkmark |

If you have any questions regarding the use of this product or to report a product problem, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or <u>technicalsupport@quidel.com</u>. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidel.com** to see more options for Support.

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