

The TaqCheck™ SARS-CoV-2 Fast PCR Assay Kit contains a set of TaqMan® RT-PCR assays for use in research for the qualitative detection and characterization of SARS-CoV-2 RNA. The kit includes two assays that target SARS-CoV-2 genes and one positive control assay that targets the human RNase P RPP30 gene.

Based on in-silico mutation analysis performed on November 18th 2022, the mutations associated with the Omicron variant, its sublineages, and the recombinant lineages listed below (WHO label) should not interfere with overall test inclusivity.

- BA.1
- BA.2
- BA.3
- BA.4
- BA.5 (including BQ.1 and BQ.1.1)
- BA.2.75
- BJ.1
- BA.4.6
- BA.2.3.20
- XE recombinant
- XBB recombinant, including XBB.1.5

*The spike (S) gene 69-70del mutation found in Omicron is predicted, according to in-silico analysis, to impact the S gene assay but not the N gene assay. Due to 2-gene redundancy built into the protocol, this single-gene effect is predicted to have no impact on overall test performance. The S gene deletion can be found in the following sublineages of Omicron:

BA.1	BA.2	BA.3	BA.4	BA.5	BA.2.75	BJ.1	BA.4.6	BA.2.3.20
Yes	No	Yes	Yes	Yes	No	No	Yes	No

In summary, to date, the lineage variants noted in Table 1 have not been found to interfere with overall TaqCheck™ SARS-CoV-2 Fast PCR Assay Kit results. Furthermore, at this time, there are no documented mutations or variants that would require adaptations to the test or changes in use. However, we will continue to monitor emerging variants and their potential impact on our assays.

Kindest Regards,

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