

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 three assays that target SARS-CoV-2 genes and one positive control assay that targets the human RNase P RPP30 gene.

As part of our Post-Market Surveillance policy, we regularly monitor emerging variants and public database updates to assess the potential impact of the latest variants on the detection of the SARS-CoV-2 genes targeted by the TaqCheck™ SARS-CoV-2 Fast PCR Assay Kit.

Based on in-silico mutation analysis performed on April 12th 2022, the mutations associated with the variants listed below should not interfere with overall test sensitivity.

- Delta (B.1.617.2 and AY lineages)
- Omicron (BA.1, BA.2, BA.3, BA.4, BA.5 and descendent lineages)*
- Mu (B.1.621, B.1.621.1)
- Lambda (C.37)
- Gamma (P.1 and descendent lineages)
- Eta (B.1.525)
- Beta (B.1.351)
- Alpha (B.1.1.7)

*The spike (S) gene 69-70del mutation found in Alpha, Omicron, and other variants 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 (incl. BA.2.12.1)	BA.3	BA.4	BA.5
Yes	No	Yes	Yes	Yes

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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