

## Diagnosing SARS-CoV-2 New Variants Lineages

Through genomic surveillance of SARS-CoV-2, multiple new variants of concern (VOC) and variants under investigation (VUI) have arisen independently at multiple locations. Latest data reveals that, until this moment (April 2021), there are 4 variants of concern and 7 variants under investigation, and all these variants have multiple mutations inside S gene (Spike proteins). These mutations may reduce the efficacy of current RT-qPCR molecular diagnostic tests that target the spike glycoprotein's gene S of SARS-CoV-2.

## How do these mutations affect diagnostic coronavirus RT-PCR assays?

The SARS-CoV-2 RNA transcript encodes the replicase complex ORF1ab, the spike protein (S), viral envelope (E), membrane (M), and the nucleocapsid proteins (N). The deletion 69-70 in the spike protein of the variant of the predominant UK variant called VOC-20DEC-01 (B.1.1.7 lineage) has been reported to cause a negative result using RT-qPCR assays that target the S-gene. Moreover, the South African variant called VOC-20DEC-02 (B.1.351 lineage), the Brazilian variant called VUI-21JAN-01 (P.2 lineage) and the India variant VUI-21APR-01 (B.1.617 lineage) also have multiple mutations in the spike protein.

## Do these mutations affect NZYTech's diagnostic coronavirus RT-qPCR assays?

The mutations in spike protein described above does not affect NZYTech RT-qPCR assay's ability to accurately detect SARS-CoV-2. NZYTech SARS-CoV-2 one-step RT-qPCR Kit, were designed to identify SARS-CoV-2 ORF1ab and N genes.

## What does this mean for diagnostic laboratories?

Laboratories using an RT-qPCR assay targeting the S-gene should review the performance of their results and closely watch for false-negative results caused by the variant.

## References:

COVID-19 Genomics UK Consortium. COG-UK update on SARS-CoV-2 Spike mutations of special interest: Report 1 (December 19, 2020). <https://www.ecdc.europa.eu/sites/default/files/documents/SARS-CoV-2-variant-multiple-spike-protein-mutations-United-Kingdom.pdf>

European Center for Disease Prevention and Control (2020) Rapid increase of a SARS-CoV-2 variant with multiple spike protein mutations observed in the United Kingdom. <https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>

Rambaut, A., et al. (Dec 20, 2020) Preliminary genomic characterisation of an emergent SARS-CoV-2 lineage in the UK defined by a novel set of spike mutations: COVID-19 genomics UK consortium. <https://virological.org/t/preliminary-genomic-characterisation-of-an-emergent-sars-cov-2-lineage-in-the-uk-defined-by-a-novel-set-of-spike-mutations/563>