

## SARS-CoV-2 Genetic Variants: Effects on COVID-19 assays January 2021

SARS-CoV-2 genetic variants can cause false negative results in some molecular assays. Assays that target the Spike(S) gene of the SARS-CoV-2 virus are susceptible to false negative callouts. According to recent guidance provided by the FDA, molecular assays that have multiple gene targets for the SARS-CoV-2 virus are less susceptible to a false negative result.

Alverno Laboratories has consulted with our vendors to determine the effects of the SARS-CoV-2 UK variant on our COVID-19 assays. It has been determined that all Alverno **assays will not be impacted by the SARS-CoV-2 genetic variants** and will continue to call out COVID-19 positives with a genetic variant present. Alverno Laboratories performs three molecular COVID-19 detection assays that target the S gene. However, because they utilize multiple gene targets of the SARS-CoV-2 virus to detect COVID-19, manufacturers have assured us that the virus will still be detected if at least one or two of those gene targets are detected.

The manufacturers of our serological and antigen assays have also assured us that these assays will not be impacted by the presence of the SARS-CoV-2 genetic variant in a patient sample. Below is a list of our COVID-19 molecular assays and the gene targets utilized for COVID-19 detection.

Assay Vendor	Gene Targets
Cepheid GeneXpert	N <sub>2</sub> and E
Diasorin Mdx	ORF1ab and S
Abbott m2000 and Alinity m	RdRp and N
BioFire FilmArray	M and S
Thermo Fisher Quant Studio	ORF1ab, N, and S
Roche Liat	ORF1ab and N

