

Impact of Variant Mutations on COVID-19 Testing

Like all viruses, the SARS-CoV-2 virus mutates over time, resulting in new variants. The Centers for Disease Control (CDC) continues to identify, monitor and categorize all variants circulating within the U.S. At present, the two [Variants of Concern \(VOC\)](#) are B.1.617.2 (first detected in India), and more commonly known as the Delta variant, and the Omicron variant B.1.1.529 (first detected in South Africa). Variants previously designated as a [Variant of Interest \(VOI\)](#) or [Variant of Concern \(VOC\)](#) that are no longer detected or are circulating at very low levels in the U.S. have been moved to a new classification level designated [Variants Being Monitored \(VBM\)](#). There is a new classification level named [Variants of High Consequence \(VOHC\)](#) – to date, no variants of high consequence have been identified in the United States.

The CDC is also [tracking COVID-19 cases caused by variants](#) nationwide, though the data is based on a sample of sequenced specimens and may not be representative of the total number of cases circulating in the United States. As part of our ongoing commitment to our public health partners, ACLA members are currently working in close coordination with FDA, CDC and state and local public health labs to support research and sequencing efforts in response to these variants.

Will the sensitivity of ACLA member laboratory PCR tests be affected by these new variants?

While more research is needed to understand the public health impact of these mutations, the sensitivity of high-quality PCR assays for COVID-19, which test for multiple targets, is not expected to be affected. The [FDA has stated](#) that “molecular tests that use multiple genetic targets to determine a final result are less likely to be impacted by increased prevalence of genetic variants.”

The Variants of Concern (VOC) and Variants Being Monitored (VBM) currently listed by the CDC all contain mutations in the Spike (S) gene. Fortunately, high-quality PCR tests, such as those offered by ACLA members, use multiple targets to test for SARS-CoV-2 and are therefore protected from significant impact.

Even if a test does utilize an S-gene target, additional targets can be used to confirm the presence of SARS-CoV-2 in an infected individual. For example, if a patient is tested with an assay that has three viral genomic targets (including one S-gene target), and the remaining two viral targets are positive, then it’s not a concern if the S-gene drops or is inconclusive. In that scenario, the patient would expect to receive a positive result. ACLA members are confident in the accuracy of our PCR test results and will continue to lead with the science.

Are ACLA members using their expertise to help sequence coronavirus genomes, or contributing to other research on the variants?

Yes, some ACLA members are supporting this effort, working in close coordination with FDA, CDC and state and local public health labs. Genetic sequencing is being used to characterize and identify a particular SARS-CoV-2 strain to support public health response.