



Testing for COVID-19 Variants: Questions and Answers
Updated September 10, 2021

- 1. Will the current polymerase chain reaction (PCR) tests pick up the all the variants with the same sensitivity and specificity?**
The FDA recommends that test developers consider the impact of mutations on the performance of their IVD devices (<https://www.fda.gov/media/146171/download>). The FDA has a list of tests impacted by SARS-CoV-2 mutations: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests>.
- 2. Will the current antigen tests also do the same?**
There is less information on antigen tests as it pertains to detecting the variants. However, we assume that antigen tests would be more at risk for being impacted. We have heard that the FDA is going to require antigen test manufacturers to reevaluate their assays (tests) performance against the new variants but so far, we do not know if that has happened.
- 3. Do we or will we see an increase in testing because of the variants?**
If there is increasing case numbers due to increased transmissibility of the variants, then yes, we could see more testing. Currently, clinical testing is not routinely performed to distinguish which variant of SARS-CoV-2 is in each specimen.
- 4. How are these variants identified, and how can we predict if they might impact a test's performance?**
Sequencing SARS-CoV-2 in specimens collected from patients with COVID-19 is needed to identify new variants of the virus. This sequence data can then be compared to the RNA regions examined by the diagnostic tests. This will continue to be an iterative process as the virus continues to change.
- 5. Which tests are better at picking up the variants?**
Sequencing identifies variants. Routine tests performed in clinical laboratories should all detect the current circulating strains we know about now.

More in the purview of the Association of Public Health Laboratories and the Centers for Disease Control and Prevention, support for public health laboratories is necessary to perform sequencing of positive samples to track the number of variants circulating and detect new variants. Right now, there is no need for a patient to know if they are infected with a variant or not. Currently, this data is very important for epidemiology purposes but as yet isn't used for patient care. Therefore, this testing does not need to be performed in a clinical laboratory.
- 6. How do these variants affect proficiency testing (PT) if it does at all?**
The CAP includes viral variants in its PT for different respiratory viruses, and SARS-CoV-2 variants are likely to be included in routine PT samples.