

Cycle Threshold (Ct) Values in PCR Tests

The State Hygienic Laboratory (SHL) understands the public's interest in ensuring the accuracy and reliability of the testing methods it uses to detect the presence of the virus that causes COVID-19 in swab samples sent to it from across Iowa. SHL shares that concern and is committed to providing timely results that are as accurate as possible with the current equipment, well trained staff, and best science.

No testing protocol, whether for COVID-19, other viruses, cancer, or other illness, is 100 percent accurate all the time. Human error in the collection, storage, transportation, analysis, and data management of specimens does occasionally occur. Equipment sometimes fails or gives an inaccurate reading. To minimize those things from happening, SHL adheres to rigorous, nationally recognized standards governing the handling of specimens, the validation of the equipment used to process tests, daily quality control, and other quality management protocols for analyzing and reporting out results. That includes strictly following the testing procedures spelled out by the manufacturers of the lab equipment used by SHL.

One concern recently raised by members of the public, and a handful of researchers, is the Cycle Threshold (Ct) value used to determine whether a specimen is positive for the COVID-19 virus. Ct values are used in what are called polymerase chain reaction (PCR) tests. Specifically, it's been suggested that the threshold used by labs such as SHL to determine whether someone is positive is too high, resulting in "false positives." But the fact is that molecular biology is a complex science and attempting to link specific Ct values to particular results can be misleading. The Ct value above or below the threshold does not alone directly correlate to a positive or negative result; it's only one portion of the analysis of the results. SHL, for instance, also looks at the slope of the PCR curve depicted in the results to indicate how the amplification of the DNA is occurring.

SHL has never tracked or aggregated Ct values as part of its reporting process because it is not a recommended practice or even considered useful by national testing standards. Notably, the Association of Public Health Laboratories, Centers for Disease Control, and the College of American Pathologists have all clearly stated that Ct values should not be reported because of variations in sample collection and testing. The point will soon be moot as SHL is shifting to the Thermo Fisher Scientific TaqPath reagents for all COVID-19 testing in the near future. This product does not provide the lab analyst with any Ct values, but only the interpretation of the Ct values based on the manufacturer's calibration and software analysis. Hence, patient results are reported as positive, negative, or inconclusive. (In the latter case, the recommendation is to collect another swab from the patient.)

From SHL's perspective, this approach to COVID-19 testing is preferable because it reduces the risk of human error and standardizes the interpretation of the data.

You may find these resources helpful for better understanding the role of Ct values in COVID-19 testing:

- [Interpreting Results of Diagnostic Tests](#), from Centers for Disease Control's Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories (Serology)
- [Ct Values: What They Are and How They Can be Used](#), by the Association of Public Health Laboratories (November 9, 2020)
- [College of American Pathologists \(CAP\) Microbiology Committee Perspective: Caution Must Be Used in Interpreting the Cycle Threshold \(Ct\) Value](#), by the Infectious Disease Society of America