

# SARS-CoV-2/COVID-19 virus PCR Ct Cutoff Values

October 5, 2020

The Kansas Health and Environmental Laboratories (KHEL) use real-time PCR (RT-PCR) to look for the genetic material (nucleic acid) of the SARS-CoV-2 virus in patient samples. Our most commonly performed RT-PCR assay (aka test) has a Ct cutoff of 42 and is the most sensitive assay currently available. All assays are rigorously and critically evaluated for accuracy prior to use on patient specimens.

- Ct stands for 'cycle threshold.' The higher the Ct number, the lower the amount of virus detected in the specimen.
- Not all RT-PCR tests use the same Ct cutoff. Each test is different, with different sensitivities based on things like how the test was designed.
- Any specimen that has a Ct below the cutoff for the test is most likely a true positive. Ct cutoffs are established by test manufacturers through evaluation of known positive and negative samples and are approved as a part of the FDA's Emergency Use Authorization process. Clinical laboratories, including KHEL, are federally regulated and always perform rigorous in-house evaluation and validation of each new assay before using it to test patient samples. This involves testing known positive and negative samples to ensure the assay is working properly and not producing false results.
- SARS-CoV-2 diagnostic RT-PCR assays are qualitative (yes or no) tests. They are not designed to determine the amount of virus present in the specimen (viral load) because many external factors can influence these results. Ct values can differ immensely between a poorly collected specimen to a well-collected specimen. A common reason for false negatives is poor specimen collection. Other factors that can impact Ct values include proper (or improper) specimen transport, specimen storage temperatures, how many times the specimen has been frozen, and the instrument on which testing is performed.
- Viral loads can vary by body site and the stage of infection. Early during infection virus is easiest to detect in the upper respiratory tract with a swab. Later during infection as the virus migrates, the virus may be harder to detect in the upper respiratory tract but testing of lower respiratory tract samples may be more likely to detect the virus.
- The amount of virus present in a person can vary during the course of their illness. A specimen may have a higher Ct value (low viral load) if the patient is early in their infection and the virus is still increasing in their body or later in infection when the viral load is decreasing. In both of these examples the high Ct still represents a true positive with SARS-CoV-2 nucleic acid detected.

- For SARS-CoV-2, it is still unknown how much virus is needed to transmit virus from person to person and cause new infections. This is one of the many areas of ongoing research.
- RT-PCR tests are the “gold standard” for SARS-CoV-2 testing worldwide, not just in the U.S, with the highest sensitivity and specificity of any known diagnostic test for this disease.

