FAQs about CT Values from COVID-19 PCR Tests: A Response for LTCFs

RESOURCE

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Intended Audience: Long-Term Care Facilities (LTCFs)

Purpose: To provide information to LTCFs on frequently asked questions (FAQs) about Cycle Threshold (CT) values from COVID-19 PCR tests.

1. What is a CT value?
   CT stands for “Cycle Threshold” and indicates how many times a machine needed to try to copy a particular virus’s genetic material before being able to detect that material on a particular test called a Polymerase Chain Reaction (PCR) test. The CT value can be looked at as an indirect indicator of the amount of viral genetic material detected from a particular specimen on a particular test at a particular time. In general, a lower CT value indicates a higher viral load in that specimen, and a higher CT value indicates a lower viral load.

2. What factors can affect a CT value?
   While a CT value may reflect the amount of viral genetic material in a particular specimen at the time a test is run, several other factors may also impact the CT value result. That means that the CT value cannot be used to tell how sick a person is or will become or what treatment should or should not be offered. Factors that can affect the CT value may include:
   - How much SARS-CoV-2 virus a patient was shedding when the sample was collected (which may be related to how contagious the patient was at the time of collection),
   - Whether the virus was truly present (rarely, some other substances can look similar enough to cause a positive result at a very high CT value),
   - When the sample was collected with respect to exposure, symptom onset, or overall course of infection,
   - How or how well the sample was collected,
   - What type of sample was collected (nares, nasopharyngeal, saliva, etc.),
   - Other substances in the sample such as mucus or other body fluids,
   - What type of test or “assay” was utilized,
   - How long ago the sample was collected before the test was run, or
   - How the sample was stored prior to running the test.

3. Does a COVID-19 or SARS-CoV-2 test always give a CT value?
   There are many types of COVID-19 tests, but only PCR tests ever give a CT value. If a person is tested using an antigen test (looking for viral proteins) or antibody test
(looking for human antibodies to the virus), there will usually be no CT value associated. However, some PCR tests do not report out a CT value even to the laboratory, whereas others may report the result to the laboratory, but the laboratory does not share this result with the ordering provider and reports only whether the result was above or below the threshold to be considered a positive result.

4. Can a laboratory give a CT value result to a facility/submitter? *(see Note 1 below)*
   Most FDA Emergency Use Authorization (EUA) PCR assays are not written to provide CT values to submitters and providers because the tests are qualitative, meaning results are intended to be provided only as positive or negative.

5. Can a CT value predict how infectious an individual with COVID-19 is?
   A CT value is one of several components used to 1) interpret a positive SARS—CoV-2 PCR test in asymptomatic fully vaccinated people, and 2) carry out decisions on isolation, quarantine, work exclusion, and response testing. For situations requiring complex interpretation (for example, the decision to isolate/re-isolate an asymptomatic fully vaccinated person, with a positive PCR test, in a residential congregate care setting) and where infection control measures are required, such as Response-Driven Testing (RDT), work exclusion, or instituting isolation, CT values are one of several variables that can be reviewed and taken into account for infection prevention (IP) decision-making.

6. Do CT values have clinical significance?
   A CT value alone does not have clinical significance. It can be used, in conjunction with an individual’s exposure history, symptom and vaccination status, and history of previous positive COVID-19 PCR tests, to guide IP decision-making.

7. What can CT values tell us?
   Samples with CT values <32 generally contain sufficient genetic material for WGS and are more likely to contain replication competent virus. Although there are limitations in the use of CT values, they are one factor to consider when evaluating molecular test results and can be useful in assessing the trend in the viral load. If there is high suspicion of a new infection, laboratories may attempt WGS on samples with CT value <32.

8. Where can I find more information about CT values?
   a. The Centers for Disease Control and Prevention (CDC) has useful information on CT values and PCR tests here:
      [Frequently Asked Questions about COVID-19 for Laboratories]
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b. The California COVID-19 Testing Task Force has a useful handout that explains PCR (including CT values from PCR tests), Antigen, and Serology Testing here: Testing for COVID-19: PCR, Antigen, and Serology 8-6-20

For additional questions about the management of asymptomatic fully vaccinated people in healthcare settings who have a positive molecular test positive for SARS-CoV-2, please contact the CDPH HAI Program at: covHAI@cdph.ca.gov

*Note 1 (from the FDA website here):

**Can laboratories report CT values for authorized molecular diagnostic COVID-19 tests?**

Yes. Laboratories performing molecular diagnostic COVID-19 tests for the qualitative detection of SARS-CoV-2 report test results as being positive or negative. Under the molecular diagnostic emergency use authorizations (EUAs), laboratories can also report cycle threshold (CT) values for authorized molecular diagnostic COVID-19 tests they perform. CT values indicate the number of amplification cycles needed to reach the threshold at which a molecular diagnostic test can detect a positive signal. CT values are not comparable between tests and may not be comparable between different lots of the same test, as they are dependent on various factors such as the specimen collection, storage, transport, time from collection, nucleic acid target, primers and probes, extraction method, amplification method, instruments used, etc. Therefore, if the same sample from an individual is tested with two different tests, or even the same test from different lots, they are likely to return different CT values, even if both tests return a “positive” test result.

While a low CT value is generally considered to indicate a higher viral load in a patient specimen (i.e., less amplification is needed to detect a positive), and a high CT value is generally considered to indicate a lower viral load in a patient specimen (i.e., more amplification is needed to detect a positive), currently there is no consensus as to whether or not particular CT values correlate with a person being or not being infectious or risk level for disease severity. So, appropriate care should be taken with interpretation of CT values.
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**References:**