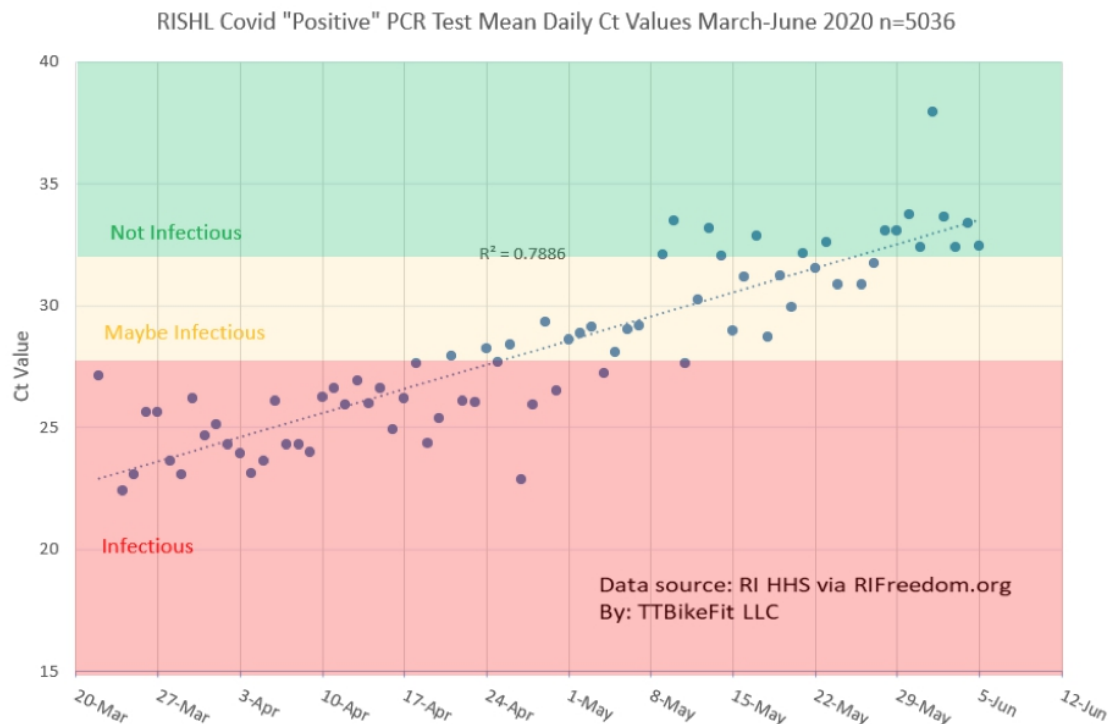


COVID-19 PCR Testing: Cycle threshold values are the missing piece of the pandemic puzzle – until now

in COVID-19 01/08/2021

<https://rationalground.com/covid-19-pcr-testing-cycle-threshold-values-are-the-missing-piece-of-the-pandemic-puzzle-until-now/>



ANALYSIS

BY TODD KENYON, PhD, CFA

Most folks by now have heard that the great majority of COVID-19 tests are PCR (Polymerase Chain Reaction) tests. And you may have heard that there are potential problems with interpreting the results of these tests. New data obtained from a Freedom of Information Act (FOIA) request in the State of RI confirms that there is much more information contained in PCR testing than a simple “positive/negative for COVID” result. Yet until now this information has been withheld.

First, a quick review of the PCR test. Originally developed to detect the presence of DNA and RNA in biological samples, even its Nobel Prize-winning inventor Kary Mullis declared that PCR was never intended to diagnose a disease. It simply detects the presence of specific genetic material, which may or may not indicate infection.

With every other disease, clinical symptoms are required for diagnosis. The vaccine trials require specific symptoms along with a positive test to flag someone as a COVID-19 “case”.

Yet we are running millions of PCR tests worldwide on asymptomatic folks and quarantining them (this includes essential health care workers) if they test “positive” – no symptoms required.

As Dr. Mullis put it, the PCR technique can find almost anything in anybody. The PCR test uses amplification cycles to find viral RNA. The sample is repeatedly chemically amplified to increase the RNA copies until they can be detected. Each “cycle” of amplification doubles the number of molecules in a sample. If you run enough cycles, you can effectively find a single molecule of any substance.

But is this clinically significant? Not according to many studies that confirm PCR results by culturing virus from the samples (a technique not practical for wide-spread testing). These studies indicate that if the machine must run more than 25 to 35 cycles to get the sample to the test’s Limit of Detection, there isn’t enough virus in the sample to matter clinically – i.e., no live virus can be cultured. Yet data we have obtained indicates that most labs run more than 35 cycles, and some run as many as 45! Since each cycle doubles the RNA copies, 40 cycles means ONE TRILLION-fold amplification (2 to the 40^{th} power)!

The number of cycles required for the machine to flag the sample positive, known as the CYCLE THRESHOLD or Ct, is proportional to the original viral load in the sample. Higher viral load = more infection. Fewer cycles required to detect the virus (Lower Ct) = more infection. Once you get to ~30+ cycles, the likelihood that the subject is infectious becomes very small. This Ct number is a crucial part of the PCR test result!

Except that officials don’t seem to think so. If you get a positive PCR test result, good luck getting your Ct value. It is simply not reported. This is akin to taking a cholesterol test and getting a yes/no answer. You are “positive” for high cholesterol, but no information is given on LDL and HDL levels and how far out of normal range they are. That would be ridiculous, yet this is what the world is doing with PCR tests for COVID-19.

On top of the Ct issue is that tests don’t look for the complete RNA strand. Instead, they test for one, two, or three [gene sequences](#). Tests that look for only one sequence are less accurate than those that use two or three, and even if the Ct value is reported, that value is often the average of the values for the different gene sequences instead of the number of cycles needed to detect each sequence. If the number of cycles for detecting different sequences varies widely, that may be an indication that there is a problem with the test, and averaging the values can hide that.

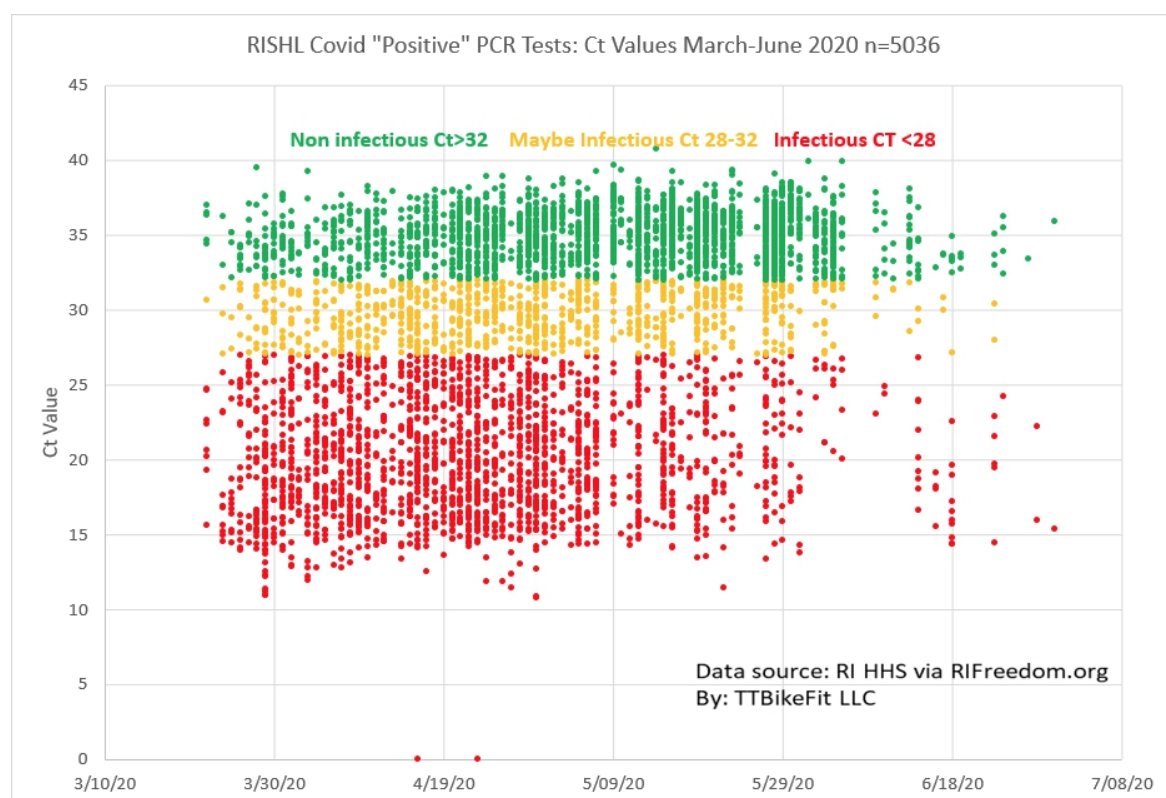
If you get a positive result, you have no idea “how positive” you are. Are you infectious? Likely to become ill? There’s no way to know without the Ct score – but go and quarantine anyway! Not only does this result in huge amounts of needless quarantines, it also serves to drive fear and panic. Overly sensitive tests with no Ct “score” are used to inflate “case” counts.

Also, everyone who shows up at a hospital for any reason is tested, with no Ct information, and if “positive” they are counted as a “COVID hospitalization”. Even fatalities are inflated, as many jurisdictions only require a “positive” test any time in the 1-2 months before death to flag someone as a COVID fatality.

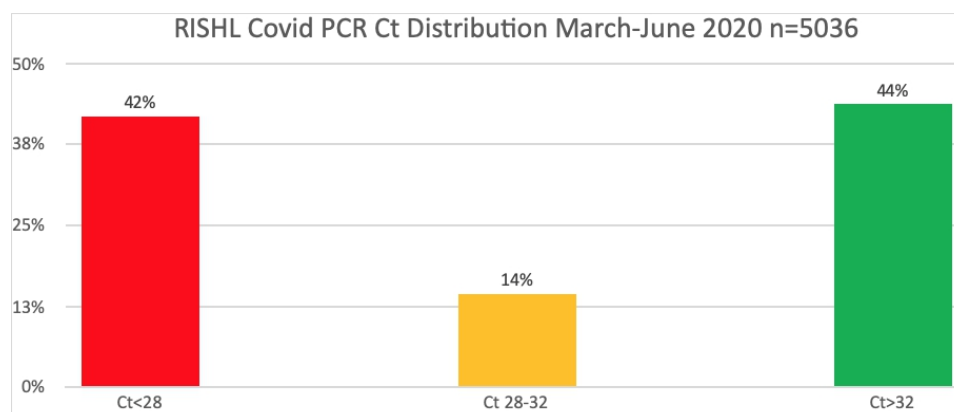
So a binary “positive/negative” PCR test regime with no quantitative information inflates COVID numbers from cases to hospitalizations to deaths.

Ct data is simply not reported, and many labs claim they don't even keep them. It took a FOIA request from an intrepid member of RIFreedom.org to finally uncover data from the RI State Health Laboratory (RISHL) spanning March-June 2020. If this Rhode Island data is at all representative, there is a lot to be learned from PCR test Ct scores.

First we take a look at each individual positive test, plotted as Ct score versus date of test. The pandemic hit RI hard in early spring, and these data cover that period. Note the color code that indicates which of these "positive" tests may have been truly infectious versus not infectious, or "cold positives". One can argue where exactly to draw these zones, but the point is clear that a great number of the positive tests represented "cold"/non-infectious individuals.

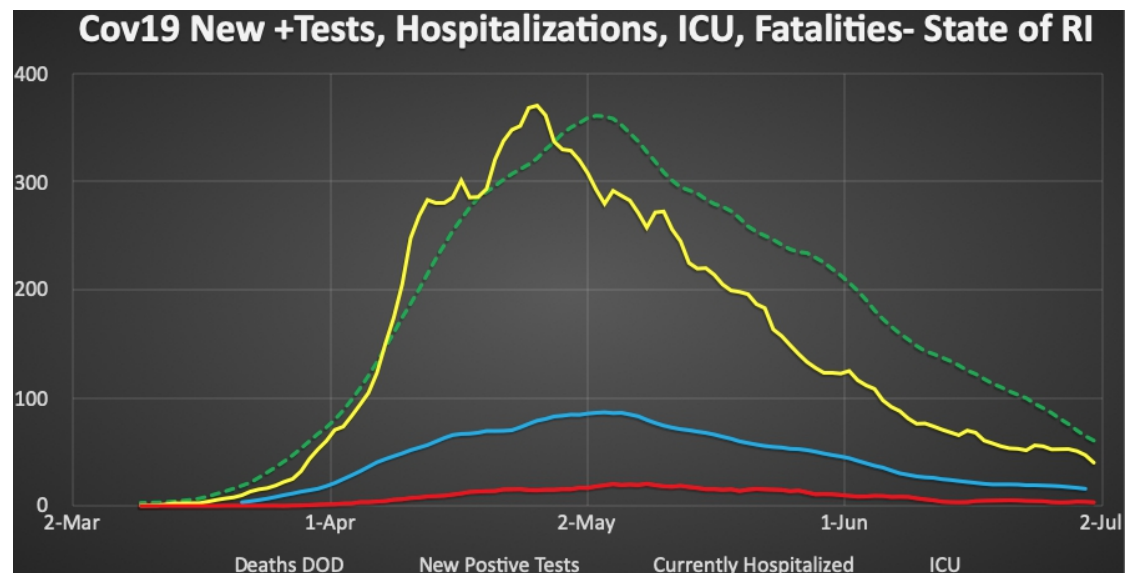


Next we look at the relative numbers of tests in each category, by Ct value.

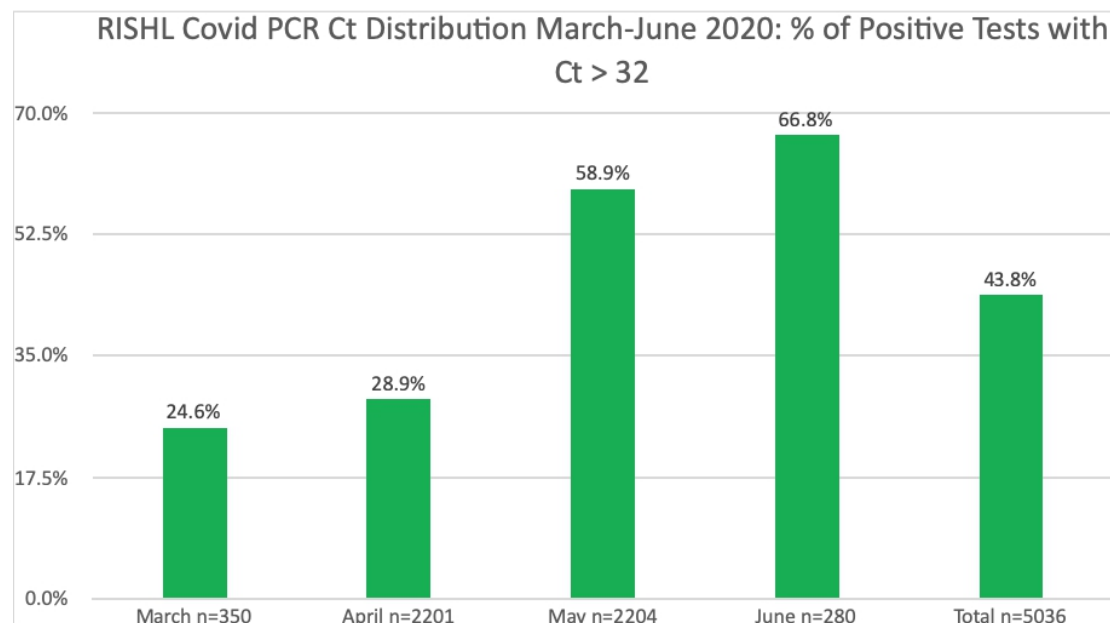


Data source: RI HHS via RIFreedom.org
By: TTBikeFit LLC

We can see that nearly half of the positive tests had Ct scores of greater than 32 – meaning they were probably not infectious. Only 42% were likely infectious, and this is during a time when RI was smack in the middle of the spring pandemic, AND when they were mainly testing symptomatic people!



We can analyze the data further by looking at what percentage of Ct scores were above 32 (likely not infectious) by month. As the Spring progresses, we see more tests with higher Ct values = more people with lower viral loads, to the point where 2/3 of tests in June were likely not infectious.

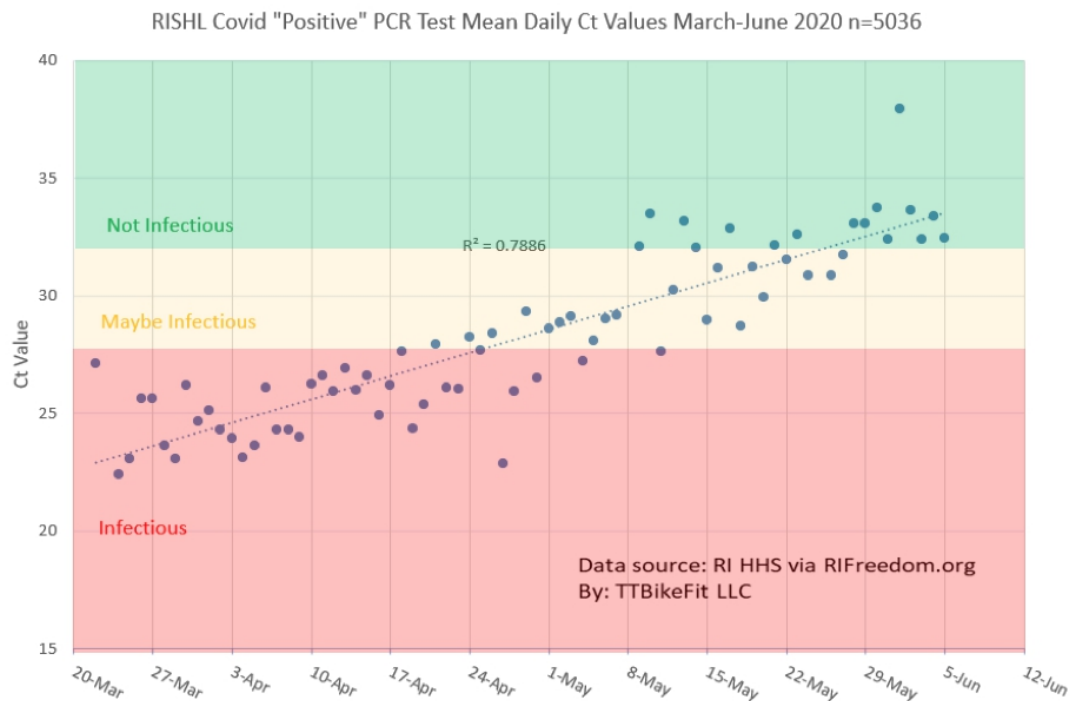


Data source: RI HHS via RIFreedom.org

By: TTBikeFit LLC

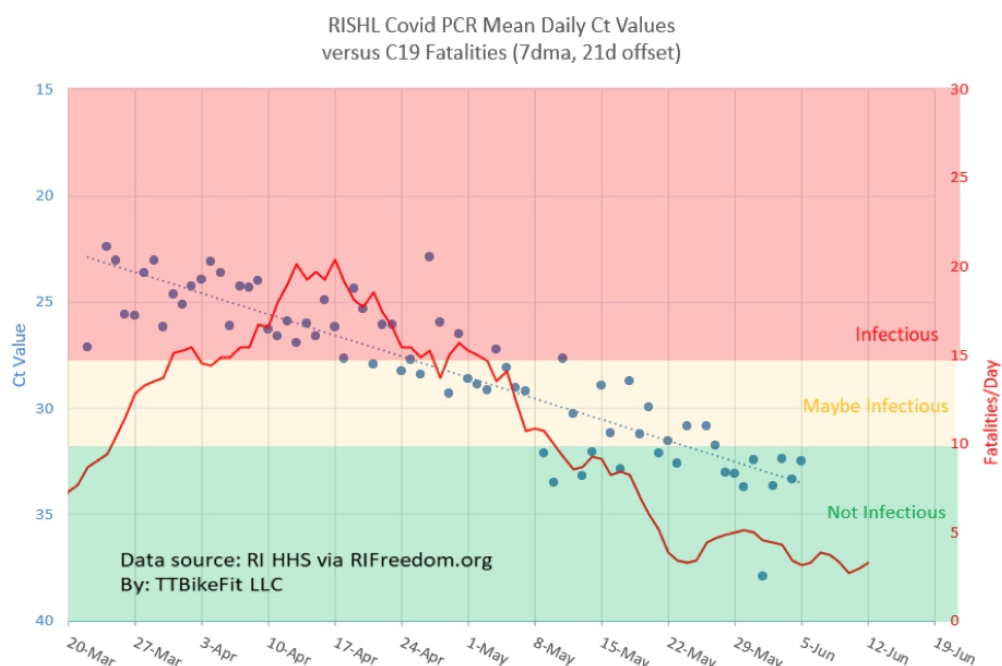
Note that RI's case/hospitalization/death metrics peaked right near the end of April – which corresponds to the large jump in non-infectious Ct scores in May vs April!

Now it gets even more interesting. Let's look at the daily mean Ct scores by date.



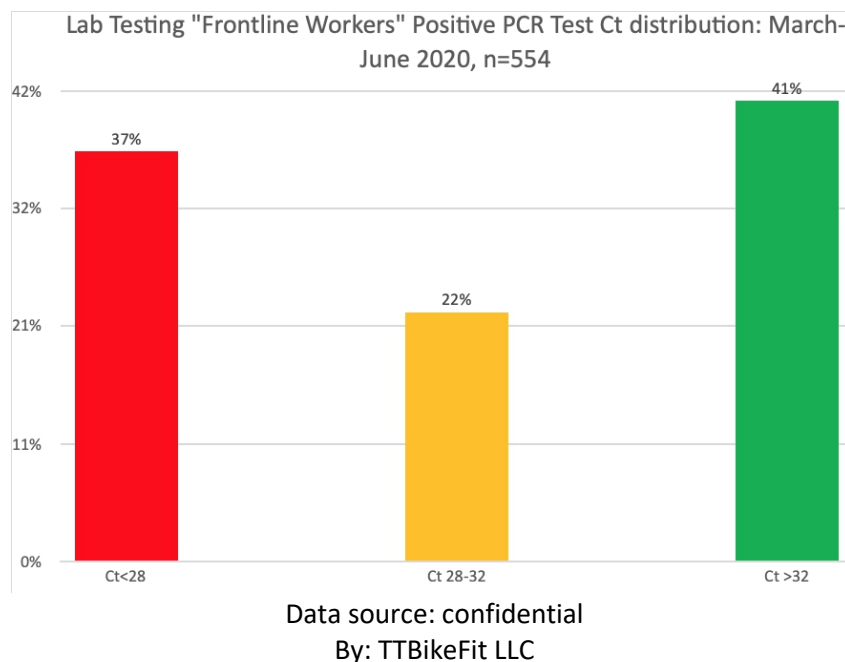
As May approaches, the average Ct score of positive tests rises linearly through the “maybe infectious” zone into the “not infectious” zone, again showing clearly that viral loads were decreasing (fewer people were actually sick).

Finally, if we overlay fatalities, we can clearly see the potential predictive effect of Ct score trends relative to pandemic severity. In the graph below, daily fatalities have been offset by 21 days (shifted 21 days earlier than actual date of death) to better align with infection date.



Here I inverted the Ct scale to represent viral load. As viral load is decreasing (Ct score increasing), we see that fatalities (21 days later) follow. As average Ct scores pass through the yellow into the green zone, fatalities wane. So the Ct score clearly has predictive power! As it should, since it represents viral load, and higher viral load = more severe illness. It is quite possible that by May-June most of the positive tests were picking up non-viable RNA – dead virus.

Perhaps one might object that this is just one data set (sadly), so maybe this is a fluke. Well, we did manage to procure a second small data set from a lab on the U.S. west coast, also from the spring. And voila, the Ct score distributions are remarkably similar to those in RI.



It is frankly negligent that officials and “experts” on both sides of pandemic policy are ignoring or cannot access this data. Labs simply don’t provide them, apparently because they are not required to do so. Beyond informing a tested individual regarding the severity of infection (or if there is even an infection at all), the distribution of Ct scores in any given time period provides information that clearly has predictive value in gauging pandemic severity. Yet Ct values are nearly impossible to obtain. To date, only the state of Florida has moved to [require reporting of Ct scores](#), though it’s unclear what the level of public disclosure will be (if any). PCR testing is used as a blunt instrument to whip up reporting of “cases,” hospitalizations, and deaths, while crucial insights from Ct scores are ignored.

Worse than draconian lockdown policies are lockdowns based on faulty and incomplete data. How can rational policy be set based on metrics that are corrupted through improper use of PCR testing? Every individual receiving a test should receive their associated Ct score. Furthermore, all states should require Ct scores to be reported along with “cases.” Until then, we are driving blind.