

## January 15, 2021

## **Bottomline**

- The US is using a PCR with 40 cycles
  - At 40 cycles 90-97% of all positives are false positives
    - The C.D.C.'s own calculations suggest that it is extremely difficult to detect any live virus in a sample above a threshold of 33 cycles.
- The PCR test can return a positive result if the person has the flu or other bacterial or viral pathogens.
- More than 9 in 10 people who are told they have Covid based on the PCR test do not.

### What does the PCR test do?

The PCR (Polymerase Chain Reaction) test is designed to detect a specific sequence of nucleotides. Nucleotides are the building blocks of genomes, and the idea is that if you can detect a string of nucleotides that is specific for a certain virus, then that proves the organism is present at the sample site. One thing that's important to understand at this point is that PCR is only detecting sequences of the viral genome, it is **not able to detect whole viral particles, so it is not able to tell you whether what you are finding is live virus**, or just non-infectious fragments of viral genome. It is also not able to tell you if you are finding the virus or a relative of that virus since it is only looking at a portion of its necleotides. In English the test can't tell the difference between Covid and other Coronavirus (e.g. the flu). Even the CDC has stated "**This test cannot rule out diseases caused by other bacterial or viral pathogens**." See pages 39 and 40 of <u>this report</u>. This means that the test can return a positive result for the flu or other viruses.

The PCR test works by repeating a series of chemical reactions over and over. If the sequence of nucleotides that is sought is present in the sample, then each time the reaction is repeated, the number of copies of the sequence will double, so that more and more copies accrue. The reason you do this repeated cycle of doubling, is that once you get enough copies of the sequence you're looking for, then you can use other technologies to detect it. For example, you can add molecules to the sample that visibly light up if enough copies of the sequence are present. So if enough copies are present in the sample, then they can be detected, and you get a positive test.

We have been told, but haven't confirmed, that the current threshold for a positive Covid test is 18 million copies.

To put this in numbers, if you start with one copy of the nucleotide sequence, then after one cycle you will have two copies. After two cycles you will have four copies. And so on. The fact that each cycle doubles the number of copies means that the numbers quickly build to massive levels.

Most PCR test in the US use 40 cycles. Most tests in Asia use 25 cycles. The number of cycles used to get a positive result is actually a pretty important number, because it tells you how much virus is in the sample. The lower the number of cycles required, the more virus is in the sample. The higher the number of cycles, the more likely that the result is a false positive, caused perhaps by having a tiny amount of inactive virus in the respiratory tract, or by contamination of the sample in the lab.

It has also been noted that PCR tests with thresholds above 30 are so high that they may detect not just live virus but also genetic fragments, leftovers from infection that pose no particular risk — akin to finding a hair in a room long after a person has left.

In a perfect world, if you get a positive PCR test you would then perform a viral culture to ensure that the result was not a false positive. What this means is that you take the sample, add it to respiratory cells in a petri dish, and see if you can get those cells to start producing new virus particles. If they do, then you know you have a true positive result. However, this method is rarely used in clinical practice, which means most US diagnoses are made based entirely on the PCR test.



Let me take a minute to make the numbers clear: If you have 1 virus (living or dead) or part of the virus in the sample you will have the following results:

- after 10 cycles (2^9) 512 viruses
- after 20 cycles (2^19) 524,288 virus
- after 25 cycles (2^24) 16.8 million
- after 30 cycles (2^29) 538 million
- after 40 cycles (2^39) 550 billion

So anyone with as little as 1 live, dead or partial virus will test positive at the 40 cycle level. Doctors and medical experts are aware of this issue but are not addressing it.

### Studies on the 40 cycle threshold:

- A <u>paper</u> published on September 28 by the Oxford University Press for the Infectious Diseases Society of America noted that, based on the scientific consensus of more than 100 studies, the cycle threshold should be no more than 30 cycles. Going further, the researchers tested 3,790 positive tests in which they knew the cycle values. They found they could culture (i.e., they found viable virus in) 70 percent of positive samples at a cycle threshold of 25. That percentage dropped to 20 percent of positive samples at the research consensus of 30 cycles. Above 35 cycles, only 3 percent of positive samples could be cultured. Said a different way above 35 cycles 97% of the positive test would be false positives.
- The C.D.C.'s own calculations suggest that it is extremely difficult to detect any live virus in a sample above a threshold of 33 cycles. (Article)
- A September 29, 2020 paper that did a <u>systematic review looking at the ability to culture live virus after a positive</u> <u>PCR test</u> found that the probability of a false positive result increased hugely with each additional cycle after 24 cycles. After 35 cycles, none of the studies included in that review were able to culture any live virus.

### Comments by healthcare people on the 40 cycle threshold

- Officials at the Wadsworth Center, New York's state lab, have access to C.T. values from tests they have processed, and analyzed their numbers at NY Times's request. In July, the lab identified 872 positive tests, based on a threshold of 40 cycles. With a cutoff of 30, about 63 percent of those tests would no longer qualify as positive.
- In Massachusetts, from **85** to **90** percent of people who tested positive in July with a cycle threshold of **40** would have been deemed negative if the threshold were **30** cycles, Dr. Michael Mina, an epidemiologist at the Harvard T.H. Chan School of Public Health, said. "I would say that none of those people should be contacttraced, not one."
- "I'm really shocked that it could be that high the proportion of people with high C.T. value results," said Dr. Ashish Jha, director of the Harvard Global Health Institute. "Boy, does it really change the way we need to be thinking about testing."
- Any test with a cycle threshold above 35 is too sensitive, agreed Juliet Morrison, a virologist at the University of California, Riverside. "I'm shocked that people would think that 40 could represent a positive," she said.

# As noted, it is relatively easy to get a false positive test using the PCR test. But how big is this problem?

To calculate the percentage of False Positives we first need to understand two important terms. Those terms are sensitivity and specificity, and they are critical for all diagnostic tests used in medicine, because they tell you how good a test is.

*Sensitivity* is the probability that a disease will be detected if the person actually has the disease. For example, a test with a sensitivity of 90% will detect the disease correctly 90% of the time and miss it 10%. Said a different way 9 out of 10 patients with the disease will correctly be told that they have the disease. 1 of 10 with the disease will be incorrectly told that they don't have it.



*Specificity* is the opposite of sensitivity. It is the probability that a person who doesn't have the disease will be told that they don't have the disease. So, a specificity of 90% means that 9 out of 10 people who don't have it will be correctly told that they don't have it. 1 out of 10 people who don't have it will be incorrectly told that they do have it (FALSE **POSITIVE**)

A perfect test will have a sensitivity and specificity of 100%, which would mean that it catches everyone who has the disease, and doesn't tell anyone they have the disease if they don't. No such test exists. In general, sensitivity and specificity are in conflict with each other - if you push one up, the other will go down.

### So what is the Sensitivity and Specificity for the PCR test?

In a published review of 38 studies of PCR tests, the overall sensitivity was determined to be 88% while the overall specificity was 94% (between 88% and 100% in all the studies). On a side note, studies of the antibody tests have found similar numbers.

### What does this mean in practical terms?

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Let's say we test 1,000 people in a group that has 10% Covid sickness (100 have it and 900 don't).

- Of the 100 who have Covid, the test will successfully pick up 88 (100 x .88).
  - Of the 900 who don't have Covid, the test will correctly tell 846 that they don't have it (900 x .94), • but it will also tell 54 healthy people that they do have covid (900 x .06) - FALSE POSITVES
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- So, in total 142 people out of 1,000 are told that they have Covid (88 correctly and 54 False Positives).
  Of those 142 people, 62% actually have the disease, and 38% are False Positives.

That's not great as 4 in 10 people are being told that they have it when they actually don't.

10% of the population having a disease at any one time is rather high. So now lets try a more realistic example of 1%

If we test 1,000 people in a group that has 1% Covid sickness (10 have it and 990 don't) the results are

- Of the 10 who have covid, the test will successfully pick up  $9(10 \times .88)$ 
  - Of the 990 who don't have it, 931 will be correctly told that they don't have it,
    - But it will also tell 59 healthy people that they have Covid (990\*.06) FALSE POSITVES
    - All of the False Positives by definition will be symptom free
- So, in total, 68 people will be told that they have covid.
  - But only 9 out of 68 will actually have the disease.
  - To put it another way 87% of positive results will be false positives (basically 9 in 10)
  - Note all of the False Positives by definition will be symptom free

This issue with false positives happens with all tests. The reason it is not usually an issue is with other tests we don't test people who are symptom free.

When you only test people who have symptoms or are being tested because of a doctors order the false positives will be a much smaller percentage of the total because the group being tested has a very high percentage of people who are sick.



However, for Covid we are testing anyone and everyone who wants to be tested. This means that the percentage of people with the disease who are getting tested is very low. As shown in the example above this leads to an enormous False Positive issue where nearly 9 in 10 of the positive test results are false positives.

When you add that to the over cycling issue of the PCR test you can see that upwards of 95% of all positive Covid test could be FALSE positives.

This could explain why there are so many asymptomatic cases and why our healthcare and contact tracing people can not find their transmission method. It is because they don't actually have Covid, not because it is spreading via asymptomatic transmission.

Recognizing this problem, the CDC has recently changed its guidance and now suggests most testing should be diagnostic: "Considerations for who should get tested: People who have symptoms of COVID-19, people who have had close contact with someone with confirmed COVID-19, people who have been asked or referred to get testing by their healthcare provider, or state health department. Not everyone needs to be tested."

#### Legal rulings

An appeals court in Portugal has ruled that the PCR process is not a reliable test for Covid 19, and therefore any *enforced quarantine based on those test results is unlawful.* You can read about it at <u>Portugal Appeals Court Ruling.</u>

#### Please let us know what else we can do for you.

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