



Episode 1,765: The PCR Testing Fiasco

Guest: Kevin McKernan

WOODS: I want you to tell people exactly why your opinion on this matters. Tell us about your background.

MCKERNAN: Okay, so from 1996 to 2000, I ran the research and development team at MIT for Eric Lander on the Human Genome Project. This was not the only lab in the world. A lot of labs contributed, but there was a really sizable contribution coming out of Cambridge. And so I built a robotic pipeline that did millions and millions of PCRs. So I'm very familiar with robotics and liquid handling and the parts of the automated process that might contribute to contamination, and also where PCR falls apart. And right now, a lot of that is really not technical, it's communication, and hopefully we'll touch on that a bit.

WOODS: All right, let's start with the most basic thing. What does PCR stand for and what is it?

MCKERNAN: So it stands for polymerase chain reaction, and it is a way of amplifying a single molecule of DNA into millions of copies of DNA in a couple hours, usually probably under 90 minutes this can be done. And in the process of amplifying it, you can get a better measurement on how much of it is you have around. So you can count molecules this way, and that's often a version of PCR that we have in COVID testing known as quantitative PCR. These are ones that have some fluorescent dyes involved so that you can monitor the course of PCR in real time and you can see and calculate how much is in the sample, what the initial number of molecules are in the sample.

It's very specific, so it's very, very good at differentiating one virus from another. And sometimes that's its downfall. I think you may have heard probably some critiques of PCR in the news lately from its inventor, Kary Mullis, whom I've known. He's passed, sadly, and I wish he were around to help defend these things, but some of his criticisms about it were not necessarily related to COVID. They were related to his doubt that HIV actually was the only virus involved in AIDS. I don't think we have that conflation going on in COVID at the moment.

WOODS: All right, so let's talk about then, indeed, what we've been reading, we layman, have been reading about this if we've been paying attention, I think the most high-profile thing on it was that *New York Times* article probably five, six weeks ago now. And the headline was something like, "Was your coronavirus test positive? Maybe it shouldn't have been," something like that.

MCKERNAN: Yes.

WOODS: And that was saying that in some jurisdictions around the United States, that the testing was so sensitive that people were getting results that, for all practical purposes, were really not useful for anything. So what's going on with that?

MCKERNAN: So I think, the main problem we have is the news is basically speaking about this problem like earthquakes while hiding the Richter scale. So it's very hard to have a coherent discussion, because the values in these tests aren't being shared. They're turning what is a very quantitative test into a plus-minus answer. And that's the biggest problem we've got. We've got to get the CQ values, or the cycle threshold values, public.

This is something that, it's a test that has linear dynamic range over six orders of magnitude. It's an incredibly valuable test, because you can measure a single molecule or a million molecules with the same test. However, they're hiding that data. That data is getting omitted, and so you just get a positive-negative result and you're left questioning: well, did I have a single copy of the virus, or did I have a million copies of the virus? I'd kind of like to know. If you have a single copy, odds are you're probably not infectious and you shouldn't be quarantined. If you have a million, you probably should be. But this is getting distilled into a black-and-white answer.

I think on the conservative side that if you find a single molecule, you still quarantine people. And there's some weaknesses there. There are some weaknesses that I think that *New York Times* article was speaking to, is that many of the fragments at the later stage of the infection are, in fact, non-infective. You can pick up RNA from a virus that's not inside the virus shell, if you will. Most of these viruses have a protein coat, and your audience may have heard of a spike protein that's on that coat that helps it get into the cell through the H2 receptor. Well, when that's not there, the virus is just RNA, and your body will dispose of it and degrade it over time. But PCR can still pick that up. It can still pick up single molecules of RNA that don't have a protein coat on them, and therefore, they're not infectious. And a large part of the testing window of a patient who has COVID is in this viral clearance phase, this phase where they are shedding dead virus and there's more dead virus than live virus, and it's therefore not a viable virus.

And there are some publications I'll hopefully be able to point you to and the literature on this that speak to people correlating their quantitative PCR results to how these viruses behave when you put them into cells and whether they actually infect, whether they're still infectious or not. There's a paper from JAAFAR, who did this work in Didier Raoult's lab. Raoult's known for his hydroxychloroquine work, but he's also done a very, very prolific work on qPCR and quantitating how effective certain qPCR values are. And their assay's coming in around 33. 33, 35. After that, the CQ value is no longer predictive of infective virus. Now, that number is probably different for every single test that's out there, and that's what I think is complicating the communication on this.

WOODS: Ah, okay, all right, because I had been hearing people saying that anything higher than 30 was already suspect. And then I even heard that there are some European sources that have cranked it up as high as 45.

MCKERNAN: That I think is actually – they may be liable for that. If that is past their limit of detection, a class action lawsuit will probably hold them accountable, mainly because when

you validate a PCR test like this, there are several bodies out there that can help bring a consensus along as to what are the best practices for doing it. AOAC is one of them, and we work with them closely for building these viral tests in the cannabis industry.

But they will always have you do a limit of detection assay to validate this. And what that does is you take the target molecule that you're trying to amplify and you serially dilute it all the way down to a single molecule. And then you run your test and you record, can I pick this up down at a single molecule, or does my assay fall apart at 50 molecules or 100 molecules? Most of the COVID testers have no capacity to detect past 50 molecules. They just don't have the sensitivity. It's hard to get RNA to amplify. They're not as sensitive as DNA-based tests, and so the crap out of 50 copies. Someone who's pushing it out to 45 is probably detecting past their limit of detection, and they shouldn't be calling patients in that zone, because your assay clearly doesn't have the detection capability to pick them up there.

Now, you will also see this further confused in the news, in that some of these people will claim, the manufacturers will claim that my test does not pick up anything in the negative control out to 45. And that we need to be careful of that. That doesn't mean that they're necessarily calling somebody out of 44; they're just promising the people who use their tests that they've run the test to ensure that if you add water to the test, we don't get any background signal all the way out to 45 cycles. And that's actually a good bragging point for a lot of tests, so you want to make sure that the vendor, you're not mixing up what they're bragging about that – *Hey, my step my test stays really clean after 45 cycles* – with I'm making calls out at 44. Because the latter is probably clinically negligent, and the former is actually good practice.

WOODS: What are the consequences of this problem? I suppose the primary one is that a lot of people – who knows how many? – have been forced to quarantine for really no reason, for effectively no reason, and that this is profoundly disruptive to society when it just keeps happening, and all of a sudden, arbitrarily this is disrupted and that's disrupted and people's lives are thrown into turmoil. Am I getting what the main issue is here, or is there more?

MCKERNAN: You're nailing it on the head, and I put out a bit of a tweet storm on this because I'm concerned that the longer the tail end window of positivity exists – like if we have really, really sensitive tests, and we're picking up noninfectious people and the majority of the lifecycle of the disease is that long tail of lowering your infectivity, every time you capture somebody with a positive test in that long tail, you create a chain reaction of five or ten more tests, because then your household has to get tested and then your contact map should probably get tested. And that creates what I call a testing R naught, not which is the R naught of how much one positive test chain reacts into how many more tests. If that R naught is higher than the origin of the virus, this pandemic won't end.

So I think we really need to draw attention to that, get these CQ values public and get people talking about it, and perhaps putting a little bit more research toward the direction of how viable is this and what numbers should cut off be? I mean, 30 was brought up in the *New York Times* article, and that's probably the right number for the assay that they were using. We have lots of assays in the marketplace, and I do not want to be advocating for us to all standardize on a single assay, because we tried that with the CDC and we ended up with no assays or contaminated assays. So I like competition in the marketplace, but with that requires consumers to be a little bit more aware of some of the different attributes and to ask more questions and get more specifications on how these things differ.

My main concern and what precipitated me writing that tweet storm was that I went to a COVID testing center recently, and in asking the clerks and the nurses there what was the false positive rate of the test, they couldn't answer it. What was the false negative rate of the test? They had no answer. I asked them, what was the positivity of the test? Like how many people were you getting positive per day? They didn't know. And I asked, well, who gets this information? Is it going to get reported to the public health department in my town? Am I going to get harassed to be in my home? *So we only report the positive tests.* I'm like, well, if you only report the positive tests, you have no denominator. How do you know the percent positivity? How do you know if the pandemic's ending? You have to report both to the state, don't you? And effectively, I have less confidence in getting COVID tests than I might have like with a bud tender at a dispensary.

WOODS: Yeah. Well, I mean, it would be like inventing a new currency, the tom, toms, and then saying, Well, this drum set cost 500 toms, but you don't know what that – maybe that's cheap, maybe that's expensive. I have nothing to compare that to, because this is just an isolated number with no context.

Now, beyond that, it seems to me the other key thing here is that, obviously, the number of so-called cases out there is inflated by some factor we can't know because of this problem. And then of course, the inflation of that number leads politicians to take more draconian measures. So you would think there would be more people – now, there are some, but you'd think there'd be more people saying, oh, wait a minute, before we jump and panic here, we should realize that a lot of these are going to be, by the nature of these tests, at least functional false positives. And yet I have not heard Dr. Fauci address this at all. It's like it's not even happening. And I remember him specifically saying, As we head into flu season I really don't like to see the case count per day at 40,000. I'd rather see it at like 10 or something. But maybe it is at 10. Like maybe, because of this problem, maybe you've already got your wish, and it's not even coming up.

MCKERNAN: Yeah, there's a couple points there. For it not to be spoken about, it's almost like it's getting brushed under the rug, because you can have an increased positivity because kids go back to school. And that's a different age demographic that we shouldn't be worried about if the positivity goes up, because the viral load's probably lower. And this is one reason why I've been trying to really push for CQs getting out, because the viral load is believed to be at a lower rate in the patients that are less affected by this. So you might actually see that the viral load's going down while the positivity is going up, but we can't see that right now. And we shouldn't be worried about kids having a higher positivity rate, because as – you had Martin Kulldorff on here. As he eloquently pointed out, there's a thousand-fold difference in risk according to age. All right, so this shouldn't ring any alarm bells.

And then the false positive rate is not really known jurisdiction to jurisdiction unless you do a lot of digging. Like I happen to know what the positivity rates are here in Cambridge because we've got a business here and we keep track of these things. And Northeastern University is about a 1 in 2000 positivity rate. That's really low. In fact, that's so low, I suspect most of those positives are probably false positives, because it's getting really close to the false-positive rates that are reported on some of these tests in their emergency use authorizations. I've also heard from a group in Melbourne, Australia, who's going through a horrendous lockdown, that the last like 54,000 tests they ran were all negative. So that's really impressive. That means their false-negative rate has got to be at least lower than that, yet they're still locked down.

And then I've heard in the UK and other places people estimating these things as high as 1%. Well, if it's at 1% and the disease prevalence goes down to 1%, you're not going to know which one of your positive – you have a 50/50 chance that your positives are going to be false or true, and you won't know which ones they are. So the disease prevalence plays an important role. When your disease prevalence gets low like it is now, your false positive rate needs to be even lower, tenfold, maybe a hundred-fold lower so that you have the confidence that the positives you're calling are a real risk to society. So that's one issue on the false positives.

And I think the second issue we touched on already, which is these positive tests do not correlate necessarily with symptoms, because we're not differentiating live virus from infectious virus, or I should say dead virus from infectious viruses. And there are some ways to do that. I point people to the tweetstorm I put out as to how people can do that, because it's a bit involved and it needs some diagrams. But that is technology that is available today. It's quite old-school technology, but I don't think there's a motivation to implement it, because this long tail of infectivity is driving a massive testing boom. Billions and billions of dollars in testing revenue is on the table right now. Nobody wants to tighten down that dial.

WOODS: Ah. Okay, well, that was actually going to be my next question, was what alternatives do we have? Is there any other way of assessing whether somebody is actually in a condition where he's infectious or not? And of course, on the show notes page, I'm going to link to – when you say this tweet storm, it's a series of tweets, and then I found a place where they took all your tweets and made it into one, big, easily read post. So I'll link to that at TomWoods.com/1765 so people can look at it for themselves. By the way, I did not know – I swear to you I did not know – because I first looked at this on Twitter, and I was just trying to follow your argument and read all this technical stuff. I didn't get down to the part – or at least I guess I did. I didn't realize it – I think I saw the thing involving me separately, and I didn't realize it was part of this whole tweet storm.

MCKERNAN: Oh, yeah.

WOODS: But you actually included my video from the Jekyll Island conference, and I thought –

MCKERNAN: Yeah, the cherry on top. I have a way of trying to trap people toward your videos.

WOODS: Well, then I wrote to you, and *then* I saw that you had included my video. And I thought, oh, he must think I'm some kind of ego case, that I reach out to people because they tweet my videos.

MCKERNAN: Oh, no.

WOODS: But it was honestly because the level of analysis you had was so significant. All right, so here we are in this situation, then, that according to you, there is not likely to be a resolution of this problem. Yet it's a major problem, and it is not only inconveniencing and really throwing a lot of people's lives into all kinds of disarray because of arbitrary quarantine, but also it is fueling the whole case-demic problem because of the numbers that

these types of tests are yielding. Geez. Well, I mean, is there any sign of hope here? I hate to leave people like this.

MCKERNAN: I'm very much worried about it, because it is creating a lot of public distrust, and if we ever do have a resurgence — I am a little bit skeptical that we're going to have a massive resurgence because coronaviruses don't do this. The history of them is they cycle two to four years, and so I'm somewhat suspect that second waves are coming. But we are going to be blind to it as a society because nobody trusts these things.

And it's not because PCR is effective. It's really the most effective tool for the job here. It's that we're just simply failing to communicate the most valuable data from the test, which is the log scale that it runs on. And as I mentioned earlier, it's literally like trying to have debates on how to manage earthquakes without the Richter scale. I'm stunned that this data is not being put forward, considering all the other data that's available on COVID. I mean, you can go to a lot of these testing sites, and they'll have the percent positivity on the site, they'll have the number of tests per day. They do wonderful jobs putting all this other data public, but the one thing that really matters is the only thing that's not there.

So I would just encourage people to continue to demand for it, ask for it, push for home testing as well, because there is a massive risk with all of this data being centralized that we don't really know how the numbers are being crunched. And really, the world we should be looking for is home testing, where you can test in the privacy of your home and make a decision, just like pregnancy testing where you want to go and what you want to do with this. And even though these tests may be a hundred- to a thousand-fold less sensitive, that's okay, because you can afford to take them twice, a couple hours apart or a couple days apart, and that gives you information of the virus load going up or down when you have two time points like that.

So I think the FDA is in the way of that right now. They don't want to allow home testing unless home testing is as sensitive as qPCR —

WOODS: Yeah.

MCKERNAN: And it shouldn't be — you just need enough to know whether you're moving into this really high rate of viral shedding and viral load, which you have in the acute period where you're sick, but you don't really need to be picking up the long tail. And if they're cheap and fast, you can do them twice, which is the most valuable thing you can do, because it will eliminate false positives by doing them twice, and you'll also get time points to know whether it's growing or shrinking in your system. So the home testing is I think the win, just because it fits with personal liberty. It fits with my data and my time. I don't need the town health department telling me what to be doing with this data, when they themselves don't even know what a false positive is. So I've been kind of a strong advocate on that front, because I think it resonates with personalized medicine. And where we're headed with all this is a surveillance state on qPCR, and that's not personalized medicine and never will be.

WOODS: I remember seeing, probably two months ago, Boris Johnson over in the UK saying that what they were hoping to shoot for was a kind of test that would be rapid on a large scale that could be given to, let's say, spectators at a theater event as they arrive, so that maybe they have to arrive early, but they can test and be sure that the production can go on

safely, even with a full audience because everybody in the audience has tested negative. Do you know about such a test? Is it conceivable to have such a test?

MCKERNAN: There is Cheng Zhang, who is well known for his work in the CRISPR fields, he's out of the Broad Institute, has built a CRISPR-based test like that that's probably 15 or 20 minutes. It's either getting commercialized through Sherlock or through Mammoth. Those are two to keep your eyes on. They recently just got a tremendous amount of grant money, however. I say that tongue-in-cheek in that I've lived through a lot of government grants, and oftentimes the grant money poisons the success, because you end up responding to the reviewers as opposed to the marketplace. But that's probably a topic for another cast. But he's one to follow.

But these tests are probably 10- to 20-minute tests. They often use a technology called LAMP. We have some of that technology on our website, as well. We do use some of these tests in the cannabis industry to figure out the sex of a plant and whether or not it's infected with certain viruses. They're very effective, and they're simple and colorimetric, and you can get the answer with like the hardware on your phone. You don't need like a sophisticated qPCR instrument. But the biggest hurdle there is FDA. And the technologies work; it's just the FDA blessing it to work, given the lower sensitivity of those tests.

WOODS: Okay. It's incredible to me that – at this point, you would think Woods here, of all people, should not be surprised at things like this. But there's nobody at the FDA that sees the opposite problem of an excessively sensitive test? I mean, really, none of them see the problem?

MCKERNAN: You know, it's – well, you've probably had a few guests on have spoken about death by regulation. What is her name again, Mary –

WOODS: Mary Ruwart.

MCKERNAN: Yes, yeah, let's get her on to talk about it [laughing].

WOODS: Yeah. I mean, it's just crazy. It's just crazy. This is obviously a problem. And especially when I think there are places in the world where they're being more reasonable with the testing –

MCKERNAN: Absolutely.

WOODS: – that would laugh at us if they saw what was going on.

MCKERNAN: Well, I mean, if you just look at the history of this, books will be written about it. South Korea got testing up and running faster than we did, and PCR was invented by Kary Mullis in California, and it's been off patent for several years. It's not like this is some new bleeding-edge technology. It's quite generic now. But why did South Korea get it running before we did? A lot of that – I've been on another cast with Brittney Shaffer about this, but the a lot of that is just due to the regulations we have here, that the CDC declared a monopoly on this, so no company like ours would bother getting into the space because it's going to be run by the CDC. They drop the ball, they fumble it, they then say, fine, everyone can do it. Then the next hurdle you have to get through is an emergency use authorization by

the FDA. I mean, just the logic of this is like, when there's an emergency, here's some additional paperwork for you to fill out before you break the glass. Right? It makes no sense. Like in case of fire, break glass. No, no in case of emergency –

WOODS: Yeah, but yet on the other hand, you get the sense that when it comes to vaccines, they really have pulled out all the stops to just fast-track things.

MCKERNAN: They have, yes. And I do think there's an active – whether it's intentional or not, the money that flows through all that system don't favor generics. And so the whole hydroxychloroquine system has been just wrecked because there's no really pharmaceutical company that has a marketing budget that's going to help push that through. And so instead, you get companies that have patented compounds like Remdesivir who are setting up studies to actually try to destroy hydroxychloroquine, to kill the generics so that they can elevate Remdesivir in light of it. So you get all of these weird incentive structures.

WOODS: Yeah. Remdesivir just had a very unfortunate paper published against it, I understand.

MCKERNAN: Yes, ironically, after it was deemed – I think it was just approved.

WOODS: Yeah. And it was the – I forget the exact wording Dr. Fauci used. It would be the standard of care, and then they found that there turned out to be no benefit from it.

MCKERNAN: Yeah. Yeah, and the paper continued to fly on hydroxychloroquine having some benefit. I mean, it's by no means a black-and-white story, but I think if you go to C19 – I'll have to forward you a link. All the HCQ studies are now collected on one website, and they're something like 70% green. Like 30% say no benefit, and 70% say that there are. But a lot of the ones that showed no benefit, they gave them toxic levels of the drug. So yeah, so there's a certain bias in our FDA system for drugs that have no owners. If it's a generic drug, if it's a natural medicine like cannabis, all of these things are going to get piled on and suppressed in favor of something that has a patent on it, because the patented compounds have the marketing budgets behind them that can get through the cost of the FDA. And I think a lot of that's going on with the vaccines, too. There's all types of liability waivers in the vaccines. There's billions of dollars being funneled into them. Vitamin D is probably more effective right now.

WOODS: Yeah, it's interesting that, again, maybe two months ago, it sort of became mainstream to point out that a lot of people who struggle in particular with COVID have vitamin D deficiency. And we even have Dr. Fauci saying, Yeah, I take vitamin D regularly. And he even, I believe, said that it's probably a good idea for people to take, given the current circumstances. But I remember when saying you should have vitamin D – and I'm not even an alternative health sort of guy. I'm just a spectator when it comes to that. I don't know enough to have an opinion. I just remember people saying you probably should be taking some vitamin D, and everybody's saying, *Oh, you crazy quack. No way.* And now it's sort of like, well, yeah, we all knew that. No, no, you didn't actually. Nope. You're not allowed to get away with that. No.

MCKERNAN: [laughing] You made fun of the osteopath, and we're coming after you for it.

WOODS: [laughing] That's right. So tell me, what sources do you look at? Because you obviously have a really good handle on a very important piece of this overall puzzle, but nobody can be an expert on everything, and I'm sure you're as curious day to day as I am about what's going on and what the political response is and what the trends are. Where do you look for your information?

MCKERNAN: So I try first to really look at what people's funding sources are, because I find that predominantly motivates their bias. It's been exasperating COVID. I mean, the political fights that you see on Twitter right now, they are so clearly polarized. You see Biden versus Trump scientists, those people I just pass by. If their funding sources coming from the government, the Gates Foundation, they tend to be more lockdown-y than others. So I have been looking mostly at scientists that are in the free market and are looking at this because they're seeing the economy implode upon them, and if they don't get involved then they end their business. And these folks seem to be a little bit more aware of the economics issues. I mean, one group I've been paying close attention to is this PANDA group that, I think you had Nick Hudson on very recently, didn't you?

WOODS: Yes, yes.

MCKERNAN: Yeah. So he's got a great circle of people that are from all over the world that are not united by any type of employment contract, but are just united in their curiosity of trying to get to the bottom of this. And they seem to have less conflicts, and I get a cleaner story from them. So if folks are looking to – I think there's some statisticians there, and they may even have a donation page. I'd point your attention to them, because I think they are they're doing good work, and they have good modeling going on. And we need something other than the constant Ferguson models being thrown at us. And the reason we're getting those Ferguson models is that Gates and other people are funding the narrative.

And I've seen this story in the cannabis industry. We have NIDA, which is the National Institute of Drug Abuse, funded by the federal government to predominantly make negative information about cannabis. Yet no one's ever died from this drug. And so there's an entire institution that's there to create propaganda. And that's going on I think in a lot of these epidemiology centers, is they are predominantly funded through government, and the more alarmist they become, the more money they get. And so you have got to get rid of that noise out of your thread and find folks that don't have those financial motivations. It's not always easy, but PANDA is a good place to start.

WOODS: Yeah, so obviously I second that, given that I had Nick on the show. So we'll put this stuff up also on the show notes page, TomWoods.com/1765. Any parting words? Anything of your own that you'd like me to direct people to, or any final words?

MCKERNAN: So we do a lot of work of testing viruses in the cannabis field, so if anyone's in that marketplace and needs genomic expertise, that's what we do at Medicinal Genomics. We make tests that pick up the pathogens on cannabis. And we also make DNA snip arrays for people to do molecular breeding with cannabis. So we're in the genomic space. We're just focusing in on the world's most productive and valuable crop, as opposed to focusing in the healthcare system. We were in the healthcare system before, but after the AMA came out, it just wrecked the reimbursement in that space and made it very complicated to operate doing human genetics. And so we pivoted into the cannabis field, where there seems to be less of that, surprisingly. The partially illegal industry is less regulated than healthcare.

WOODS: Yeah, how about that? All right, so everything that we've talked about, I'll put up at TomWoods.com/1765. All right, I think I have captured the exact amount of time that I planned to. I appreciate you doing this in such short notice. But when I saw what you had written on this, and then I saw we followed each other on Twitter, and then I went my email and I saw we had corresponded before, I thought, yeah, okay, I'm getting this guy on the show. And I'm glad I did. Thanks so much.

MCKERNAN: Hey, thanks. I'm going to look forward to the Tom Woods bump, because I know it's big.

WOODS: Yeah, that's right. Yeah, you can expect it. Thanks again.

MCKERNAN: Cheers.