# Diagnosing COVID-19 - Advice from UW Pathologists on Ramping Up Testing Capacity

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**Julie McDowell:**

Seattle experienced the COVID-19 pandemic's first wave in the US. UW Medicine's Dr. Jeffrey Baird, Acting Chair of Laboratory Medicine, was at the forefront confronting significant challenges related to diagnosing patients with this virus. In this kaka, Dr. Baird discusses lessons learned from testing and personnel challenges when ramping up testing capacity.

In addition, Dr. Suzanne Dintzis, associate professor of pathology at UW School of Medicine and current president of the Washington State Society of Pathologists, weighs in on Current Autopsy Protocol. Dr. Baird, can you begin by giving us some background on how your lab began COVID-19 testing and how you ramped up your capacity? What was your initial daily volume and where are you right now?

**Dr. Baird:**

So our laboratory started this whole adventure in our division of virology with the two laboratory directors there, the division head, Dr. Keith Jerome, and an assistant professor, and really the lead on this, Dr. Alex Greninger. Those two virologists were just monitoring the situation in China I think like we all were in this business and were interested in it. Alex has been interested in virology since his medical school training specifically was interested in what's called viral metagenomics. So sort of studies of many viruses all at one time using techniques like genome sequencing and next generation sequencing. So he did his resident here in that and then we hired him as faculty and he's been interested in developing viral diagnostics. When he and Keith were thinking about this, I have heard from Keith now that he really didn't think that this would come to much from Wuhan and it would be maybe like SARS or MERS, which had a little bit of a flare but didn't really end up going anywhere after that.

And that of course didn't happen. But just because Alex's interest in this, sometime I think around in January he developed a test similar to what we're doing right now, an RTPCR test, and began using it as a research basis. So not as a clinical test, but using it on a research basis to study discarded respiratory samples that we were doing just to see if it performed. And as things became more out of hand in China, he began to recognize that there was a sense of urgency and began an advocacy campaign really to try to get us to be allowed to use this test clinically. But at the time, there were a variety of regulations that required the test to be approved by various governmental agencies. And when testing came through in the very first cases, so patient number one in the United States, and I believe the first death in the United States happened here in the greater Seattle area, he really wanted to start using this test, but it really wasn't allowed and we were still having to send testing through the public health and CDC system.

Eventually, the way that he tells the story, he needed to get samples that were positive to validate his test, eventually was able to get inactivated virus, I believe from Texas or somewhere else because that's a safe sample to ship. They shipped that to him. And then we had our first case here that came in from a patient who eventually, I believe, I'm not exactly sure, but I believe was the first patient to have died from it. And so we had our positive sample for our validation at that time. And we had had many discussions earlier about how would we validate this test without a positive sample. And as Alex likes to say, the virus beat FedEx by just simply spreading in our community. That was, I think on a Friday, that Saturday February 29th, the FDA made an allowance that allowed the test to go on. Sunday we accepted samples and then on Monday we went live with about a hundred test capacity.

We ramped over the next two weeks to being able to do about 1800 tests a day. And our volume exponentially grew to that 1800 to the point where we were getting well over 2000 samples a day from all of the communities, hospitals and such that we serve in our reference laboratory capacity here at the University of Washington. We were getting mostly regional samples, state samples, but some national samples. And we've since had to slow that down and focus mostly on the state of Washington and our hospitalized patients, the sickest of our patients and healthcare workers and first responders as now thankfully other laboratory capacity is growing. Our current capacity is about 3000 tests a day and we have plans to relatively quickly ramp to about 5,000. The commercial laboratories are now ramping up to perhaps several fold more than that, but there's only a few of them in their national capacity. Probably doesn't serve enough to test all those who require to be tested in the United States. So I think that tells you where we've come from and where we are right now.

**Julie McDowell:**

What would you say were the key challenges you faced when ramping up volume and capacity?

**Dr. Baird:**

Number one, at the beginning, clearly there was a regulatory problem. Since then, the FDA I think has been quite understanding and Commissioner Hahn has issued an allowance that lets states regulate this, which has been very helpful for us. So we've gone that route and our testing strategies are now approved by the state of Washington, and I believe other states are doing similar things. New York State early on had that approval, but other states didn't until about Monday this week.

And then there were some logistics problems also. We have a rather large reference laboratory that serves predominantly the region of the Pacific Northwest, and for some tests, national or international clients, but we are not of the scope of a large commercial lab like a Quest or LabCorp. So getting flooded with 2000 samples for one specific test, many of whom are not actually registered patients or electronically interfaced to us created an enormous amount of manual work. And the day that we popped over our test capacity, we had a giant backlog. And in fact, we have a backlog today too, simply because of logistics. We have basically gone from being a regional reference lab to a national reference lab for one test, and that's actually quite challenging to accommodate.

Next issue that has made it difficult is money. In the first two weeks of this, I spent $10 million plus of the departmental reserves on bringing this capacity and faced essentially bankrupting the future of the department. It was not a difficult decision to make, but it nonetheless just goes to the show that it is an expensive thing. If you figure that it costs me about $10 million to do the first 10,000 tests, that's a thousand dollars a test it cost at the beginning. Not very many places have that amount of resources.

And then the last issue I would say is now supply chain. Everybody in the country wants to do this, and one of the reasons it's cost so much money is that I've had to invest in three or four, about three and a half because of the way that the test works, but three to four different platforms to continue doing the test because inevitably we will run out of supplies for one or more of them, and I'm just hoping we don't run out of three or four of them at once. So that's been actually quite difficult too with supply chain.

I don't think there's a really good answer for that. Some of the large vendors are, I think rationally allocating supplies to those who can do the most testing like the large national laboratories. But really for a place like Seattle, which is rather isolated in the Pacific Northwest and a large population center but far away from other population centers, it's difficult to get a reasonable turnaround time for the decisions that need to be made on inpatients if you do that testing and have to mail it to California or to New Jersey or to North Carolina or something like that. So it's really important that each population center has at least one place that can do the test with a reasonable turnaround time.

Now, that's not been realized in most population centers, but I think what we're seeing now in New York City, they've brought on testing live now and have now found out, "Oh geez, that's actually where most of the cases are." And the only reason that it's not because they all of a sudden got a lot of cases, it's because there've been cases there for quite some time. They just couldn't test quite fast enough.

**Julie McDowell:**

So looking back at how you expanded capacity, what are some lessons learned that you can share with other pathologists, particularly those who are in the early stages of ramping up their lab to meet anticipated demand?

**Dr. Baird:**

I would say all the things that I just said, it's going to be expensive. And so you're going to need to get your hospital administration to understand that this is a financial emergency. All hospital systems in the country are going to undergo insane amounts of financial stress. For example, many of the hospital systems have canceled elective surgeries, and that will probably sink most surgical subspecialties because they'll have a lot of infrastructure waiting but no cases to be done. And so money will be tight, but money needs to be spent on this. The supply chain cannot be emphasized enough. Simply waiting for your favorite vendor or the vendor whose instrument you already have to come online with the test isn't really probably going to work very well, at least not in the early stages right now in the upswing of this epidemic because the supplies just aren't there for some of these things.

People have gotten approvals for various different kits, testing kits, gotten emergency youth authorization to sell these kits, but there's 350 million people in the country, many of whom are scared and probably want to test, maybe don't need a test if you're well and worried. But if you're sick, it would make sense perhaps to get a test with a doctor's evaluation or for the public health interest. But we don't have that ability right now. And so it'll be very difficult to conceive of how everyone will get all the supplies they want to test all the people that should be tested soon enough.

So I don't have a crystal ball or magic wand to see how that could actually get done, but it is something that should be paid attention to. One is not resource limited and everyone is resource limited, but if one has enough resources, one piece of advice might be to invest in more than one testing platform, knowing that probably any one of them will run out of supplies arbitrarily. I wake up every morning and wonder what's the next crisis going to be that day.

**Julie McDowell:**

So let's talk a little bit about personnel. Based on your experience, what are some things that pathologists should keep in mind in terms of managing laboratory personnel during this time in the midst of a pandemic?

**Dr. Baird:**

So one thing is that as a lot of procedures have been canceled, actually volumes in the rest of our laboratory have gone way down. And so we may actually have staff in areas that are not as necessary, largely because we're focusing a lot of effort on Covid testing. And so we have the ability perhaps to shift work from places where there isn't as much volume to places that might need it. Now, not all places are going to scale up to have a 3000 tests per day COVID testing laboratory, but just understanding that volumes might drop and there might be an opportunity to redeploy is important. For us, some of the pain points have been literally in taking a mostly day shift laboratory, turning it into an overnight 24/7 laboratory, which we did last week was a staffing issue. And we just had a lot of people that just understand the mission and people who are day shift, people just staying 18, 24 hours and working themselves.

Self-care of the workers has been important. It's not a large part of my budget, but I spent a lot of money on food simply just providing meals and just basic needs and care and a little something nice to someone who's been working all day every day and sending some people home when they're looking really haggard and looking exhausted is important. And that goes for the faculty as well as the staff. That's another thing. Specimen processing for us has been incredibly busy simply because we're getting several thousand of a single test that may be coming from a place that we don't have electronic interfaces with. So there's a lot of work to be done there too. And then the last thing that we've, thank God, not yet been facing, but I will say is a when not an if is what happens when the lab members get ill with either Covid or something that's difficult to tell that is not Covid. It's also flu season right now.

And so we are developing a mitigation plans for what happens when the lab either has a member who gets sick or, God forbid, the entire lab gets sick. And that's something that is a potential thing. We're all practicing social distancing and doing what we can when we're not at work and also at work teleworking, et cetera. But the people who work in the lab need to come and work at unfortunately fairly close quarters, and they're sort of sacrificing themselves. They're risking being close to a lot of other people right now in the service of their community and their state. It's noble, but it's also something that puts them at a risk.

**Julie McDowell:**

So Dr. Dintzis, can you tell us about current autopsy protocols for Covid patients or suspected Covid patients, please?

**Dr. Dintzis:**

Yeah, these things are changing very quickly, actually day to day. The current status for Covid positive or a suspected Covid death is actually we do not perform a full autopsy here at the University of Washington Medical Center. We do what we call a swab only autopsy, which is swabbing either the nasopharynx or the oropharynx and then sending the body to the King County medical examiner. The medical examiner here has done, I think nine or 10 autopsies to date on Covid known positive patients. There's some consideration whether that's going to continue. Now that they have those samples, the thought is maybe not, since they do have quite a bit of samples to work with.

**Julie McDowell:**

What about the ability for pathologists and laboratorians to render diagnoses from remote i.e. Non CLIA certified sites in case they're quarantined or remote for another reason?

**Dr. Dintzis:**

Yeah, that's probably the most active area of advocacy right now for pathologists in different states. So you're talking about using what's called the 1135 waiver, which was the waiver in place because of the emergency declaration, which allows possible modification of Medicare, Medicaid, and chip requirements during the emergency declaration period. So there have been a number of successful 1135 waivers that have been issued in the state of Washington, also in Massachusetts and Florida, I believe, but none of them to date has addressed the particular clear requirement, which is in place for telepathology or telelaboratory medicine, which means rendering of diagnoses in locations that are not currently CLIA certified.

So the Washington State Society of Pathologists that I'm actually president of that society, we are working with lobbyists right now in Olympia. And I know that the University of Washington Government Affairs office is pretty much camped out in Olympia right now, and we're trying to put together a waiver. I know that also the Association of Psychology chairs, APC, has put out quite a bit of information on a listserv, so they're attacking this as helping to get a number of states to put together waivers like this that can be approved on a state by state basis.

**Julie McDowell:**

Any final thoughts you both want to share with your pathologist colleagues, not just in the US but really all over the world about the outlook and their role in this pandemic? Dr. Dintzis, can we start with you?

**Dr. Dintzis:**

Well, I think for anatomic pathologist, Dr. Baird has already said that actually a lot of our work is decreasing. Our general service work largely revolves around cancer and other diseases, which by the way, they're still continuing but are being a little bit overshadowed by Covid. But because a lot of the surgeries and the clinic visits have been understandably stopped, our volumes are decreasing. The big question for our workforce is what happens as Dr. Baird has indicated when, not if, but when we get sick. So contingency planning for shift work and having some kind of strategy for covering services either in-house with people that are available or outside working on the 115 waiver to allow people who are either quarantined or perhaps but can work to do their work from home.

**Dr. Jeff Chang:**

And this is Jeff. What I would say, I would echo that and add a little bit that I've learned some things in biomedical ethics in the last couple of weeks that I hadn't really spent as much time thinking about in a long time since I last took about a biomedical ethics class. But there's such a thing called a crisis standard of care, which is still a standard of care, but it's a standard of care that's different than we're all used to. And that involves things like rationing and using resources to those who might derive the most benefit from it. And that's not just a discussion about using ventilators or ICU beds, that comes to the laboratory too, and laboratory testing resources.

I think if I were to tell other pathologists and lab directors who were still contemplating this coming, and there may be only a few cases in their community, number one, if you only see a few cases in your community, that's probably because you're not testing enough and there's probably an awful lot. We've tested about 20,000 people now and found about 1300 cases just in the Seattle area. And we're not a large metropolitan area compared to a place like New York or Chicago or something.

So there's probably a lot there. It's going to get worse, there will be more cases. And so I think that it is absolutely necessary that today, if you're listening to this podcast, turn off the podcast pretty soon and go and make sure that every laboratory division that you have, the hematology lab, the micro lab, the anatomic pathology, histology lab, all of them have mitigation plans right now for a 10, 20, 50, 75% drop in workforce. And you have to decide what testing are you going to be doing from simply delaying the turnaround time for some assays that might be routine or outpatient types of things to simply worst case scenario where you might just be doing the most critically lifesaving types of tests like blood cell counseling, blood gases and things like that.

So those plans need to be in place today, or better yet last week because that's where we're at right now. And I fully expect that we're going to use some version of those plans in our system here. We were early in the wave that is now washing across the country. People have said we're at the epicenter. I don't think we're at the epicenter. I think we're just sort of at the first wave and it will go over at some point.

Another thing that I'm thinking about too is that we need to be prepared to help our colleagues. I've been as helpful as I can, but as the wave washes over us and maybe there's a [inaudible] wall where cases start receding and our social distancing types of activities work, I'm fully preparing to help all the other places that are going to have the crisis just like we're having it right now. So be prepared for the worst because some version of that could very well happen and be ready to help.

And the last thing I'll say is I've said this a lot to other folks too who have said other tips and tricks, say thank you a lot. You're going to need a lot of help in this. And always tell people thank you. And so along those lines, I would thank you for allowing us this opportunity to participate in this advocacy and tell the story and help give this information to others.

**Julie McDowell:**

Well, thank you Dr. Baird, and thank you Dr. Dintzis. Visit cap.org for the latest CAP information on COVID-19. Thank you for listening to this CAPcast. Be sure to listen to our other CAPcasts from the CAP on our SoundCloud channel by downloading the SoundCloud app on your mobile device. And we're also on Apple Podcast and the Stitcher app. To find this podcast, search for the word CAPcast on these apps. Once you find our podcast, be sure to click the subscribe button so you don't miss new CAPcast episodes.