# Infectious Disease Program: Continuously Evolving to Bolster Public Health

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**Lisa Tomcko:**

Welcome to the latest edition of the College of American Pathologist CAPcast. I'm Lisa Tomcko, content specialist with the CAP.

In 1989, 40 years after first launching its proficiency testing survey program, the CAP added infectious disease testing to its PT catalog. Since that time, the CAP has led the way in developing new programs to ensure the quality and accuracy of laboratory testing for infectious diseases, including SARS-CoV-2, Zika testing, and testing for molecular microbiology multiplex panels. In this CAPcast episode, I'm joined by Dr. Christina Wojewoda and Dr. Daniel Rhoads, who are chair and vice chair respectively of the CAP'S Microbiology Committee. We'll be delving into how the Infectious Disease Testing Survey program has evolved over the years, its impact on public health, including the COVID-19 pandemic, and what future directions the program is focusing on to ensure that patients continue to receive accurate infectious disease test results. This episode is part of a CAPcast series highlighting the CAP's proficiency testing program, which is celebrating its 75th anniversary in 2024.

A big welcome to both of you and let's do a quick round of introductions. Dr. Wojewoda, would you like to start us off?

**Dr. Christina Wojewoda:**

I'm Christi Wojewoda. I'm the director of the Clinical Microbiology Laboratory at the University of Vermont Medical Center and a professor in the Department of Pathology and Laboratory Medicine at the Robert Larner College of Medicine.

**Lisa Tomcko:**

Great. Thank you. And Dr. Rhoads?

**Dr. Daniel Rhoads:**

Hi, Dan Rhoads. I'm section head of microbiology at the Cleveland Clinic's main campus in Cleveland, Ohio, and I'm an assistant professor at Case Western Reserve University.

**Lisa Tomcko:**

Excellent. Happy to have you both here and with no further ado, I'll let you take it away.

**Dr. Daniel Rhoads:**

Great. Thanks so much. Alright, Dr. Wojewoda, can you just give us an overview of infectious disease or microbiology proficiency testing program? How would you characterize the role of these surveys among the other types of PT programs that are offered by the CAP?

**Dr. Christina Wojewoda:**

In microbiology, we like to think we're special, and in this case we really are. In the CLIA Regulations, they did something which I think was actually quite smart. They regulate microbiology at the subspecialty level, and so we don't have to do a proficiency testing product for every catalyst indole oxidase that we do in the laboratory. We have to do a proficiency testing product for the subspecialties of bacteriology, mycology, mycobacteriology, parasitology, and virology. That means our proficiency testing offerings are a little bit different. The other reason why we're a little bit special or different than other areas of the laboratory is that the scope of service for microbiology laboratories is really quite variable. If you go into a chemistry laboratory, everybody's probably running a sodium potassium bicarb on their patients, but for microbiology, small laboratories might just be doing a gram stain all the way up to a laboratory like yours, Dan, who's doing full identification and susceptibility testing on different organism types at the mass spec level, sequencing level. Some laboratories are even utilizing artificial intelligence now to help identify parasites in stool. So we have to have proficiency testing products to cover the full spectrum of laboratories in microbiology and that will be suitable for each laboratory to satisfy their CLIA requirement.

**Dr. Daniel Rhoads:**

Yeah, a lot breadth of menu. It's very real. So over the last 30 years, infectious disease testing has evolved and changed. Can you describe your perspective on how it's changed over the last three decades, the practice of clinical microbiology and also how the CAP'S proficiency testing program has kept up with those changes?

**Dr. Christina Wojewoda:**

Yeah, so interestingly enough, neither one of us has been in microbiology for 30 years quite yet, but—

**Dr. Daniel Rhoads:**

Noted. Make sure that makes it in the notes.

**Dr. Christina Wojewoda:**

The technology has changed tremendously in the past 30 years. I mean, back in the day, 30, 40 years ago, API strips and automated biochemical identifications were the new hippest technology, and now we're working with MALDI-TOF mass specs sequencing, total lab automation, even AI, and so our proficiency testing programs have to keep up with that variety in technology. At the top of the episode was mentioned multiplex panels to detect multiple different organisms in one sample, and so building proficiency testing that's suitable for different manufacturers, similar panels to make sure that they can be utilized for all of the different laboratories is important. And then I always like to say that the bugs outsmart us and in just our short tenure on the microbiology committee, we've had to do three mid-year program launches for emerging infectious agents, Zika, COVID-19 and Mpox, and I don't see that slowing down at all. Dan, how about, what do you think? What are your thoughts on how the program has evolved over its history?

**Dr. Daniel Rhoads:**

I see the same trends that you described. I mean, it's definitely more molecular, more syndromic. The pace of change is not slowing down. It feels like things are changing so quickly, but in my mind, if not my heart, I know that things are only going to continue to change faster. There has been and will continue to be more evolution of microbial resistance to antimicrobials, emerging pathogens we have, and we'll continue to look for ways to build syndromic panels so we can test more quickly.

How has the CAP'S proficiency testing program, how has it been able to quickly pivot to address emerging public health threats like Zika and very recently COVID? How is the structure of the program that enables CAP to keep pace with these emerging pathogens and offer these surveys with a short turnaround time?

**Dr. Christina Wojewoda:**

That's a great question. So usually the process takes two to three years for us to get a new proficiency testing product to the market. We usually start with just figuring out who's doing different types of assays, so is there a market for it? Then we have to find somebody who can make the material for us. I think it's a common misconception that CAP actually makes the PT material. We work with vendors to create the material and then we have to make sure that it works with different assay types. We don't want to build a proficiency testing survey that is just suitable for one assay if other labs wouldn't then be able to use it. We tested it in different laboratories and then we put it in the proficiency testing catalog so people know that it's there and all of this takes, again, two to three years.

For Zika and COVID, we really sped up that process due to the public health crisis. Thankfully, there was material available for both viruses as usually that's our rate limiting step is finding suitable material, either whole organism or plasmid or something that could be utilized for testing. We were able to get material for both of those viruses and get those up and running in under a year, which was great. Additionally, we haven't mentioned, but Mpox, we also did a mid-year launch due to the public health concern, and again, it was really just kind of getting all parties to work together in one pathway to get things moving a little bit more quickly.

Dr. Rhoads, you were really instrumental in developing the COVID PT products. Can you discuss the role of CAP PT in this pandemic, not just in the US but globally?

**Dr. Daniel Rhoads:**

As you remember, and probably those listening. Remember, the early days of the COVID pandemic were really painfully busy and stressful, and quality management is one component of making sure we have a good laboratory that's doing good work, and so I was appreciative that the CAP took the time and effort to put together PT for SARS-CoV-2 so quickly because that was essentially one less thing I needed to worry about. I didn't have to put together alternative testing or trade samples with the laboratory. The one thing that could stay the same, even if everything else changed, was our proficiency testing process where we get the survey from the CAP and we're able to perform the testing and report the results back and then compare ourselves to peers. I was impressed with how widely adopted the survey was. Thousands of laboratories in the US and abroad subscribed to the survey, and I know all of those laboratories also had that same reassurance that they were getting a good product and this was one less thing they need to worry about during the pandemic was putting together alternative proficiency testing.

So we were also able to, as a committee, take advantage of the large sample size of data that was generated through the proficiency testing survey. There has been and continues to be, although at a lesser extent, interest in CT values or viral loads or however you want to describe how much viral RNA is in those samples. I appreciated the CAP and the committee's willingness and work to try to share the information that we had in a useful way to infectious disease epidemiologists, microbiologists, to let them know how the different assays were performing compared to each other, but also to provide a word of caution not to interpret these results as we try to figure out together throughout the pandemic what all this means in terms of the level of RNA in a sample.

**Dr. Christina Wojewoda:**

I just remember being at, it was end of February, I was representing CAP at the USCAP meeting and having multiple people come up and say, "Hey, so are we going to have to make PT for this?" And thinking, "No, it'll just go away." Silly me, but again, you really were steadfast in "This is coming. It's coming quickly, and let's get PT ready for it." And CAP did the right thing in pursuing this, even though it was a little bit risky at the time, we didn't know a whole lot about SARS-CoV-2 at that point in time, let alone if we should ship it across the country or across the world or if it was going to pan out to be anything but CAP and those involved really worked hard to get that material out. As you described, Dan, many assays were developed really quickly and some were really good assays and some might not have been so great of assays, and I think our PT helped shake out which assays were performing as expected and which assays were not.

Your point about the CT values I think is really important just to hit home that we were able to publish based on our proficiency testing data, that even though we sent the same PT material out to different laboratories using different assays, even laboratories that were using the same assay got a spread of CT values, and so when the same material was sent across the world, everybody got a little bit of a different answer even though people really wanted to hang their hat on a CT cutoff of 30, for example, to be infectious, and the assays just weren't dialed in enough to really have reproducible results for CT values.

**Dr. Daniel Rhoads:**

Yeah, something else we did, I mean, it's been four years ago now. It's kind of crazy since the emergence of the virus in the us, but there was a period when there was alpha and delta and we're now in the Omicron era, but the CAP did a good job sourcing material to keep up with it because there's s gene target failures and all these variable performance of the assays based on the variant that was circulating du jour almost, but I appreciate the CAP was willing to source and keep current with the variance that we're circulating because that impacts the assay's performance potentially. That was another caveat that we worked through together.

**Dr. Christina Wojewoda:**

So as you mentioned Dr. Rhoads, the pace of change just keeps increasing, keeps speeding up. How do you see the infectious disease PT programs evolving in the future?

**Dr. Daniel Rhoads:**

Something that we haven't had to do yet, but I expect we'll have to do at some point is come up with a metagenomic or some kind of agnostic input to the sample as more and more laboratories develop metagenomic approaches to pathogen detection. These are still very much lab developed tests and everybody does it a little differently for different indications, different specimen types, but I expect that within the next 30 years. How about that? Within the next 30 years, we'll need to have something like that available because it'll be routinely used in testing. There's also a continual push, and I like this push to do testing closer to the patient, whether that's a unsupervised self-collected specimen or point of care testing. I'm not sure exactly how that's going to impact the proficiency testing development, but that's something I think about when thinking about trying to control for the whole test process. As the pre-analytic process becomes more complex, we'll need to continue to think about how to use proficiency testing to help to ensure that the quality is maintained with those changes in the specimen collection.

What do you think?

**Dr. Christina Wojewoda:**

In thinking about this, something that we've worked on as a committee is making sure that our laboratories are able to detect antimicrobial resistance, and so making sure that our proficiency testing offerings are keeping pace with antimicrobial resistance, that we're challenging laboratories to detect those really bad bugs in order to allow physicians to treat patients appropriately, I think is going to be a focus, keeping our eyes open for newly emerging infectious agents where we're never going to be able to take a break from that one. And then something that we talked about a lot at our committee meetings around proficiency testing is balancing an a la carte menu, if you will, for a one size fits all, and so not every manufacturer's syndromic panel is the same, or I might have a standalone assay for one of the components of a syndromic panel and making sure that we have PT offerings that serve every level of laboratory and we don't box them into this big panel for PT that they might only see their one or two targets once or twice in a year trying to figure out the best way to package our PT material that makes it useful for every laboratory.

**Lisa Tomcko:**

Well, thank you both so much for sharing all the great insights on the Infectious Disease Testing Survey program from its inception to its more recent endeavors and also giving us a look into where it's headed.

**Dr. Rhoads:**

Thanks for having us.

**Dr. Christina Wojewoda:**

Thank you so much!

**Lisa Tomcko:**

And thank you all for listening. Stay tuned for more episodes in our 75 years of proficiency testing and external quality assessment series, and learn more about the CAP'S proficiency testing program and its offerings via the link in the show notes. For more information about the CAP visit cap.org.