Customer case study | North America
Dan LaFlamme, Sr. Field Application Scientist

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Facing daunting challenges, a new testing lab found a hero and friend in a Thermo Fisher FAS leader and the analytical validation team

Introduction

In 2020, new and existing labs were confronted with numerous challenges: from incorporating new instrumentation, software, and techniques into existing workflows to quickly meeting stringent requirements. In the US, labs can demonstrate adherence to rigorous lab operations standards with accreditation from the College of American Pathologists (CAP).

Dan LaFlamme, senior field application scientist (FAS) supervisor for Thermo Fisher Scientific, points out that meeting these requirements presents a daunting challenge since newer lab testing methods are often dramatically different from the methods scientists already know.

"Because these solutions are unfamiliar, labs often need assistance in choosing strategies to satisfy requirements with regard to control materials," LaFlamme explains.

LaFlamme earned his PhD in biochemistry and molecular biology from the University of Maine, and worked in genetics research and testing labs for 19 years before joining Thermo Fisher in 2014. He describes his role in Global Services and Support as a player–coach for Thermo Fisher's genetic testing solutions FAS team.

As labs perform the analytical validation experiments required for them to begin testing samples, LaFlamme's team provides key technical training and consulting services to help labs get up to speed. This includes a validation plan template, protocol templates, controls, data analysis consultation, final report template, and summary documentation templates so customers can easily input their own study designs, as well as continuous on-site support.

"We offer the customer-laboratories support," he says, "so that they can complete the required studies quickly and efficiently and get on with the business of serving their customers." LaFlamme points out that the relationships built through these engagements serve to reinforce customer trust in Thermo Fisher Scientific—and the high level of satisfaction gauged in customer feedback for the team supports his point.

Not only does the genetic testing solutions team earn high marks from customers, but LaFlamme himself was recently singled out by Catalyst Diagnostic—a Michigan-based clinical laboratory—as having gone above and beyond. Because of feedback like this, LaFlamme is being recognized as a "Guardian of Your Science" within Thermo Fisher Global Services and Support.

Thermo Fisher recently spoke with Heather Wood, MSc, technical laboratory director at Catalyst Diagnostic, to find out how LaFlamme consulted the lab with their analytical validation process, and to learn about the qualities that truly make him a guardian of their science.

Can you let us know a bit about yourself and your lab?

I received a master's degree in cell and molecular biology and have been working in the clinical field for many years. I worked with another clinical laboratory doing newborn screening at the state laboratory here in Michigan for 12 years. I took the leap to come into private industry in 2020, and, for me, jumping into private industry and working with a brand-new lab starting from the grassroots was incredible but daunting.

I joined Catalyst in September of 2020, and we hit the ground running. We wanted to start with COVID-19 testing, but we also had plans to do a lot of other types of testing utilizing Thermo Fisher's analytical [consulting] services. Having the support of Thermo Fisher and the team truly made it happen for us.

Why did you decide to seek out consulting services for your analytical validation process?

I've done a lot of validations in my years, and I knew that time was a big factor for us. Being able to dedicate that time is a luxury, which is not something that you have in a private industry. There was just one other person and me. And we're like, "OK, so we gotta do this," and we really appreciated the services that Thermo Fisher offered with [validation consulting, field service, etc.].

Can you elaborate on why you chose Thermo Fisher specifically?

When I first arrived at this lab, the decisions about instrumentation had already been made, but I was very familiar with the company. I've worked in a forensics lab and done sequencing, STRs, and so forth. I've used Thermo Fisher's products like Applied Biosystems™ QuantStudio™ systems, Applied Biosystems™ 7900HT Fast Real-Time PCR systems, and others for many years. Everyone in the life sciences knows Thermo Fisher, right? Thermo Fisher is a giant in science. I've worked with Thermo Fisher reagents and instruments for years, virtually my entire career. I think there's a trust factor involved—versus finding someone that you may not know.

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This is a scary time. There are all kinds of kits out there now. They're popping up all over the place. Who do you go to? Go to someone you trust, right? I think that played a large part in the decision. Also, the Applied Biosystems™ QuantStudio™ 12K Flex Real-Time PCR System—which is what we use in the lab—is very flexible. We can do open arrays. We can do 384-well or 96-well assays. Having that flexibility and knowing that we're going to be utilizing the instruments for multiple test types played a huge role. That's our main workhorse, along with Thermo Scientific™ KingFisher™ sample purification systems.

And when we started reaching out to colleagues in 2020—this is when the virus was still new—and asked, "Who are you using for COVID-19 testing? What kits are you using?" A lot of people were using Thermo Fisher's kits. There's a lot of trust in them. So we chose to go with the Applied Biosystems™ TaqPath™ COVID-19 Combo Kit.

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What was your experience with Dan LaFlamme like?

Dan is a pivotal person who came in at a pivotal time for us. We started working with him and the rest of the analytical validation team when we were first getting the lab up and functioning. And that meant coming into a lab that was virtually empty! I'm going to set the stage for you of where we were: we're brand new, and I'm a newcomer to private industry. There's a whole lot on our plate. Stress is high. We don't even have chairs in the lab yet. That's not an exaggeration.

I mean, we had purchased the instruments; I had written the quality manuals and brought some supplies in—but they were minimal, and Dan just rolled with it. He came in totally easygoing, very low stress, and just took things as they came. He was extremely patient and helped [us with our planning]. I had been feeling like, "Oh my God, this is crazy," and he just rolled with our craziness. He was great. I can't imagine what it was like to come into our high-stress environment.

Dan was like, "Yeah, no big deal, let's do this." I thought it was great. He's very knowledgeable, has a fantastic personality, is very easy to work with, and is always available for any follow-up questions, emails, and calls. And having the service and support, and [helping us with the plan]—it was really gold, especially with the time factor.

Can you tell us more about what he and his team did for you?

There's just so much that's really involved in doing a validation; a lot of studies are needed to clinically validate something to use within a laboratory. And every year we had to go through a special inspection process because we wanted to achieve additional accreditation through CAP.

Dan came to the lab to do the initial training for COVID-19 testing and open arrays. We had different formats of open array, so it was either Dan or another field service person who came out when Dan wasn't available. Whenever we were getting ready to validate a new format, they would send someone out to work with us to make sure that everything was going fine and we could then proceed with the studies. That was where they had to put in the most time and effort with the data analysis [consultation]. It saved a huge amount of time having that support.

We didn't have to go in and search for or figure out what controls we needed—our panels are ginormous, so it would have taken weeks. I think weeks were saved by having [these consulting services]. I'm sure you probably hear this often from other people who have utilized your service, but it expedited our ability—as a brand-new company—to start testing.

The promise of our analytical validation service is that it can potentially reduce the overall time to launch by up to 75%—does that ring true to you?

Without a doubt. Absolutely, yes.

How did Thermo Fisher's consulting services help prepare you to meet compliance requirements?

When we had our first CAP inspection, they were extremely impressed with the reports because they included all the parts and pieces that we need. You do all these different studies to look at precision, accuracy, reproducibility, sensitivity—all of that.

Not only that, but [Thermo Fisher actually also has the ability to help] supply the controls and all of the different organisms that you have on your panel. So, say we're looking at a panel that has 56 organisms, right? That's a whole lot of controls that you'd have to find and purchase to validate or verify analytical specificity. Whereas with the Thermo Fisher analytical services, they're able to use the plasmids that are already generated through, for example, the Invitrogen™ GeneArt™ service. So they're doing a lot of that initial groundwork that would take a lot of time—the planning part. It's incredible. The inspectors were really impressed with how concise and comprehensive our reports were. They cover all the checks that you're looking for. You know, CAP inspectors have certain checklists of things that they're looking for, right? That's how it works, so they were able to easily go through the plan and checkmark those. As a matter of fact, one of the inspectors still reaches out to me for consultation with the open array work—she's asked me on a couple of occasions to share an example summary, so she can show other labs what they should look like.

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Did you feel confident when you faced an inspection? Did you feel less nervous about it?

Oh yeah, very confident. You can literally just hand it right to the inspector—signed off and everything—and you don't have to worry about it. It really removes a lot of stress and, like I said, the biggest thing is time.

You sound very satisfied. Would you recommend this service to other labs?

I would recommend it. I would use Thermo Fisher's validation services over and over, given how well it went. Dan and his whole team came in, [helped us plan, and this] made everything possible for us. There's no doubt in my mind that the service saved us time and was well worth the cost.

But it wasn't just the timeliness of the services. It was also the ability and willingness of Dan and his team to deal with any troubleshooting issues we had: their graciousness and personability. By the end of it, I felt like it was not just a service, but that we were all friends, like they were truly part of our team. And it made such a huge difference.

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