Case study | North Carolina, USA
Featured field service engineer: Danielle Wells



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Services and support

## A Thermo Fisher Scientific FSE helped with instrument qualification services essential to a state lab renovation



Danielle Wells
Field Service Engineer
Thermo Fisher Scientific

For North Carolina's Department of Public Health, a planned major renovation of their molecular laboratory was uncharted territory. It meant moving six Applied Biosystems™ 7500 Fast Dx Real-Time PCR Systems into a temporary location. With the help of a Thermo Fisher Scientific Field Service Engineer (FSE) managing the physical relocation of the equipment, the department also recognized the need for instrument qualification services post-move and re-installation. FSE Danielle Wells was up for the challenge. She was able to not only help in the physical move of the equipment but also facilitate the instrument calibration and qualification, in addition to handling pricing and consultation seamlessly.

The lab's supervisor in charge of the project, Shadia Rath, had absolute confidence in Danielle, who went to great lengths to ensure that the transition was smooth, and the lab was quickly up and running after the move.

For going above and beyond to get their molecular laboratory operating again in just two days, Danielle has been honored with the Thermo Fisher Global Support Services Guardians of Your Science award. We connected with Shadia Rath to learn more about Danielle's exceptional support of her lab.

## Can you tell us about yourself, your work, and the challenges you faced in renovating your lab?

**Shadia:** For 26 years, I've been a part of the North Carolina State Lab, navigating through various departments. It was with the creation of the molecular epidemiology lab that I discovered my true place, stepping in as the lab's supervisor—a role I've had for 15 years. In my role, I coordinate many of the project management services, including contacting FSEs and troubleshooting projects.

We had planned a major renovation of all five rooms of our molecular suite, including our amplification room, which houses our instruments from Thermo Fisher. Due to the high volume of molecular testing that we do, we had limited time and couldn't afford to be offline. We had to get back up and running as quickly as possible.

#### At the time, what service plan were you on and did you add services for the move?

**Shadia:** We were and still are on a basic service plan that provides planned maintenance and qualification twice a year. This was outside that scope of service so we did have to add on.

Danielle was instrumental and amazing as always in helping to coordinate that. There were additional quotes and purchases required, and she was great. She went above and beyond in helping me get quotes and making sure I had everything the lab needed. That, in my opinion, is way more than what an FSE will normally do.

"Although we've never done a full qualification on our own, I would say it would take us at least twice as long without Danielle's help."





Shadia Rath, MS

Supervisor, Molecular Diagnostics and Molecular Epidemiology Unit, State Laboratory of Public Health, Division of Public Health, North Carolina Department of Health and Human Services

## Can you tell us more about the move and how Danielle helped?

**Shadia:** She helped move everything, which was quite a task. I know she had help with physically moving some of the instruments, but she almost single-handedly helped get them up and running. Then, of course, we had to have them moved back to their original location and she assisted with that.

She was amazing in getting us back up and running as quickly as possible and worked with me on prioritizing which instruments to bring back online at which time because different groups used different instruments—and that way we could get at least one instrument up and running for every test.

#### And how long did the instrument qualifications take?

**Shadia:** Because we had six instruments, she performed three qualifications on one day and three the next. The entire lab was back up and running in two days. Danielle did all the troubleshooting, making sure we had what we needed to get the instruments back online. Some of our instruments are getting older, so she helped us get the parts we needed to get them performing optimally.

"She provides complete, thorough, and timely documentation. Although we fall under CLIA and are inspected twice every two years, technically they can come in at any time and ask for anything. So, it's good to know that I have everything I need and don't have to worry about it."



## Could you tell us about the documentation that was provided?

Shadia: Other than the physical relocation, the service she provided during the move was similar to a normal service. She ran all the dyes and calibrations that were required, the Applied Biosystems™ TaqMan™ RNase P Instrument Verification Plate, the backgrounds, and all the other things. She provided essentially the same documentation as a normal service. There was one additional report for the physical move, but everything else was the usual documentation that we get with regular service. She's very good about getting those turned around quickly.

The forms are very extensive and If we didn't have help with that documentation, we would have to basically spell out in depth what was done ourselves, which is extremely time-consuming. If Danielle didn't do it, we would have to take the screenshots and printouts of the spectra of the calibration document to show that backgrounds were checked. We would have to document all the steps that data auditors look at, such as heat block temperature. Without the reports from Thermo Fisher, I don't know how we could do all that.

"I can't imagine trying to maintain this level of technical equipment, conduct testing, achieve the turnaround times, and meet the expectations placed on us if we didn't have our service coverage and the ability to call Thermo Fisher tech support..." What can you share about the uptime that you experienced using Thermo Fisher's instrument qualification services, and the time and cost you saved by not having your team do qualifications yourselves?

**Shadia:** I don't even want to begin to think of my team doing qualifications without Danielle. I think we would still be trying to get the instruments up and running.

I like to close things up as quickly as possible and don't like to leave anything hanging. So she's great about getting those reports back to me on time. There have been a couple times where there might be a discrepancy. She's great at getting them corrected and getting me the updated service reports that I need to make sure that the documentation on our side is right.

Although we've never done a full qualification on our own, I would say it would take us at least twice as long without Danielle's help.

As for cost, I was once able to point out on the service report to the assistant director of operations what it would've cost if the qualifications were not covered by a service agreement.

I was able to show, "Just one minor thing going wrong could cost over half of what a year's service coverage is, so it's absolutely imperative to have that service plan and to be able to contact our FSE at any time."

If an instrument goes down, to have to get a quote and then go through our purchasing process is not a quick thing on our end. We would be down at least a month before we could get Thermo Fisher in here. That's huge. I can't imagine trying to maintain this level of technical equipment, conduct testing, achieve the turnaround times, and meet the expectations placed on us if we didn't have our service coverage and the ability to call Thermo Fisher tech support and say, "here is our problem, please dispatch somebody out here right away."

#### What can you tell us about Danielle's impact on your compliance process?

Shadia: She provides complete, thorough, and timely documentation. Although we fall under CLIA [Clinical Laboratory Improvement Amendments] and are inspected twice every two years, technically they can come in at any time and ask for anything. It's good to know that I have everything I need and don't have to worry about it. She's great with keeping up with stuff. If I ever need anything, I just reach out and say, "I think I'm missing this one." Especially with the move—because there were six instruments at a time and reports required for the move and the qualification—she made sure that we had everything we needed and were good to go before she was done with us.

#### What else can you tell us about Danielle?

Shadia: Around 2009, during H1N1, we got our first 7500 system and had an excellent FSE. When we found out he got another position and was going to be leaving us, we were devastated. But he promised us he was leaving us in good hands, and he did because he left us in Danielle's hands. She is not only amazing at her job, but also personable and friendly.

Above and beyond any engineer I've ever worked with, Danielle is so willing to help; when we text her randomly with a problem, she will call, FaceTime, or email us, or send us a colleague to act on a case until they can reassign it to her. So as much as I hated to lose our previous FSE, I have to say I could not have been happier with who we got in his place. In fact, I don't think any of us here at the lab could be happier. We are lucky to have Danielle assigned to us. Honestly, I don't know if our instruments would be functioning if it weren't for the service that we get from her and her colleagues.

And that brings up another reason why she is wonderful: if for any reason she ever gets called away or is unavailable, she makes sure to leave us in good hands. She has always made sure to provide me with contact information for her great colleagues.

I am honored to be able to speak to what an amazing person Danielle is, and she is truly deserving of this award.