Customer case study | India
Featured Field Service Engineer: Dibyendu Nath

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Services and support

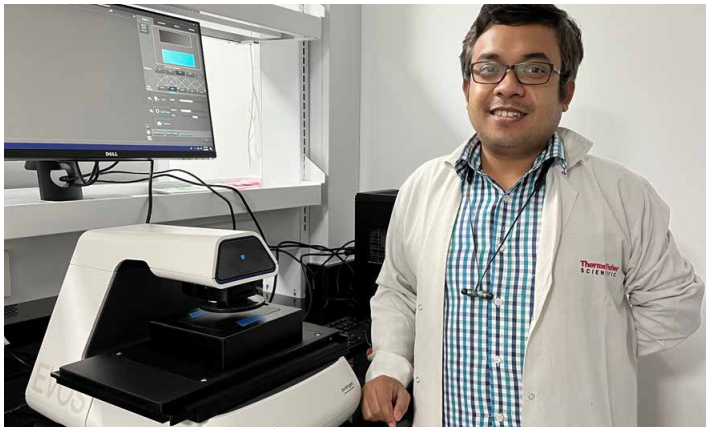
A lab in South India manages a crisis-driven shift to high-throughput PCR, thanks to help from a dedicated field service engineer

When COVID-19 hit, everything changed. The molecular biology lab of the Shri Dharmasthala Manjunatheshwara (SDM) College of Medical Sciences and Hospital located in Karnataka, India, had been using low-throughput PCR, running no more than a dozen samples at a time, to detect *Mycobacterium tuberculosis* and the hepatitis C virus (HCV). Then in early 2020, the nation's prime minister sounded the alarm: labs throughout the country were needed to immediately shift to COVID-19 testing. The SDM molecular biology lab didn't even have a high-throughput instrument—let alone a system approved for diagnostic use.

"It was a situation of panic because we didn't know what was going on or what we were dealing with," says the lab's technical manager, Dr. Sughosh Kulkarni. "We'd never faced such a huge sample load. A high-throughput instrument had just never even been considered."

Fortunately, downstairs in the hospital's medical college, an Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System had been installed a year prior. As the main PCR research workhorse of the Central Research Laboratory (CRL), the instrument was not approved for diagnostic purposes—but Dr. Kulkarni knew it could handle a high-throughput workflow. With the system located three floors down from the molecular biology lab, and with research staff literally at home on lockdown, it would be easy enough to access the instrument. But what would be involved in repurposing it for this urgent diagnostic purpose?

Dr. Kulkarni immediately reached out to the Thermo Fisher Scientific field application scientist (FAS) who had helped install the QuantStudio system in the research lab. The FAS referred him to Dibyendu Nath, the field service engineer (FSE) for sequencing, qPCR, and other large bioscience systems across the South India region. Nath informed Dr. Kulkarni about the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) process involved in achieving the National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation and Indian Council for Medical Research (ICMR) approval required for repurposing the instrument for COVID-19 testing. Nath also said he could help them do it.



Dibyendu Nath, field service engineer (FSE)

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In helping Dr. Kulkarni's lab navigate those rigorous protocols and get the approvals, Nath proved instrumental—additionally, he helped the lab overcome a critical challenge with its sample purification process. For his considerable effort on behalf of the SDM molecular biology lab, Thermo Fisher is recognizing Dibyendu Nath this month with our Guardian of Your Science Award.

Highlighting the hard work and dedication of our service heroes, the Guardians of Your Science program leverages feedback from our customers about Global Services and Support team members who go above and beyond in providing world-class support for their important projects. The program honors and rewards these outstanding individuals around the world for their tireless effort to advance science. To find out more about Nath's efforts and learn what makes him a true Guardian of Your Science, we connected with Dr. Kulkarni at his lab in Karnataka:

Dr. Sughosh Kulkarni
Technical Manager
SDM Molecular Biology Laboratory

Can you tell us about yourself and your lab at SDM?

I am Sughosh Kulkarni, an MD microbiologist, which means I specialize in medical microbiology. I completed my MD in microbiology in 2015 and have been working in this field for almost six years now. As the technical manager of the molecular biology lab at SDM, I oversee the technical aspects of the functioning of the lab, and I'm also in charge of the technicians. I do the reporting of lab activities, and I'm also the lab's signing authority.

We have four people on the team: the laboratory director, Dr. Raghavendra Kulkarni, who is a senior professor and head of the Department of Microbiology; Dr. G.S. Ajantha, quality manager for the laboratory; and Dr. Manjunath Hosamani, deputy quality manager for the laboratory. We also have four laboratory technicians who I oversee.

We're located in the Dharwad district of Karnataka state in the south of India. It's one of the largest districts in the state, and it serves a huge population. In this district we have only three real-time PCR laboratories approved by the ICMR: two are government laboratories, and one is a private laboratory, which is ours. Because SDM Medical College is a private college, we fall under the private laboratories category.

What was it like at SDM at the start of the COVID-19 pandemic?

When the government announced the lockdown, there was a lack of clarity, and the guidelines were frequently evolving and changing. For a hospital like ours, the first step was to implement infection prevention control strategies because we are a 1,200-bed hospital.

We serve the rural part of the region. Most of the people who come here are of a low socio-economic status and have a low literacy level. To convince them that they needed care, we had to do a lot of training of our doctors and nursing staff, as well as the senior residents and post-graduates studying medicine and surgery in different areas.

Protocols had been established for general infection prevention control, like for dealing with things like multidrug-resistant (MDR) organisms. But we were never trained to deal with a respiratory virus, so that training was a major challenge for us. We initiated cleaning and disinfection protocols, and then we initiated the triage of the patients coming into the hospital. Most of the doctors and nursing staff didn't even know how to don the complete personal protective equipment (PPE). We were used to using regular PPE, but when it comes to COVID-19, you need complete PPE for biosafety level 3. So we initiated all of those things.

What were the challenges for your lab of initiating COVID-19 testing?

Initially we did have a real-time PCR instrument here, but the limitation was that it was a low-throughput instrument, so we decided to shift the high-throughput QuantStudio 5 system from the research lab to our molecular biology laboratory.

It was a do-or-die situation. The QuantStudio 5 system is a standard instrument for testing COVID-19. We had two options. One was to buy a new instrument; two was use whatever instrument was there right now. With the nation on lockdown and nonmedical people forced to stay home from work, the researchers were not coming to the hospital anyway. So the CRL researchers were on board—"We will shift the instrument for the greater good."

There was also a lot of pressure from the government authorities because they wanted us to start functioning immediately. They said we should use it. In fact, that QuantStudio 5 system is under a government scheme—the government of Karnataka funded it as part of a student-training project. Since there were no students, there was no research activity going on, so shifting it to our laboratory made sense.

It was purchased for research, though, and not for diagnostic purposes. Unless and until we did the IQ/OQ/PQ, we were not supposed to do any COVID-19 testing or generate any reports. And because the instrument got shifted from the ground floor up to the third floor, that's technically a change of site of the instrument, right? So we also had to get it recalibrated.

With those qualifications done, we could get NABL accreditation—that is the authority in India that checks on the quality and quality management systems of the laboratory. Once they approve that you're meeting quality standards and you have NABL accreditation, you can then receive ICMR approval for COVID-19 testing.

Dibyendu Nath was the person who was instrumental in helping with that.

When you learned that Dibyendu was the guy you needed to get in touch with, and you first contacted him, what was your first impression?

He was quite a gentleman, a straightforward person. I told him, "Mr. Dibyendu, this instrument was installed in our institution for research purposes; how do we move ahead?"

He said, "Sir, you have to do the IQ/OQ/PQ. Send me an email request; I will immediately reply to you together with my sales team, who will also be involved." I did that, and the next day we got the quotation for the process. It was an emergency, so within a week's time, everything was set up, and Dibyendu was, of course, right in the middle of traveling to different sites.

"He was quite a gentleman, a straightforward person. I told him, 'Mr. Dibyendu, this instrument was installed in our institution for research purposes; how do we move ahead?'"

In Karnataka alone, we have around 300 laboratories, including private and government laboratories. Dibyendu had to travel to each place because most of the laboratories are equipped with Thermo Fisher instruments. Not only in Karnataka but other places in South India as well. He used to cover the entire South Indian region.

Nonetheless, he said, “Sir, I’ll be there, whatever it takes.”

I remember that first time he came to our institution to begin the process. After finishing an IQ/OQ/PQ session at a private laboratory in Bangalore around 11:00 p.m., he traveled early the next morning about 450 kilometers to Dharwad. That’s about six hours by car. He started out at 4:00 a.m. traveling by cab. We had arranged a room for him to freshen up in and get some rest before coming in to the lab. But he didn’t do that. He jumped directly on the instrument and started working on it. I really loved his commitment and dedication. That’s how he is. He does his job well.

When he completed the IQ/OQ/PQ and documentation processes at our lab, which were finished at around 5:30 p.m., he immediately took the same cab and traveled on to another district adjacent to Dharwad. Again, 400 kilometers away, where he had to do the same task again. He worked straight through.

It’s remarkable. He realized what was at stake, even at that time. How far into 2020 were you at that point?

Early 2020. We were under national lockdown. The police had established checkpoints. We were not supposed to travel at all, not even interdistrict, forget about interstate. It was a unique situation like India had never seen. So all of the institutions where he worked would write him a document that said, “To whomsoever it may concern, this person is traveling for COVID-19 laboratory purposes,” so he may be allowed to bypass all the checkpoints.”

It’s amazing when scientist-technicians are suddenly out there in this almost apocalyptic, virtually empty landscape, driving with special papers from state to state; they’re suddenly these heroic characters. They really stepped up.

Yes, and it is so important. Unless this person travels and does that job, that laboratory will not be validated and won’t be able to apply for any accreditation or get ICMR approval. The stakes are high, right? It’s all about the functioning of the laboratory. If the laboratory is going to function, this person has to come there and get the instrument ready for the diagnostic purposes, get the qualifications done, and all the documentation has to be correctly arranged. It’s a huge task.

Dibyendu told us that after the IQ/OQ/PQ process, you started running samples and ran into a technical problem. He said he worked almost a 48-hour shift for that repair. Can you tell us about how he supported you in that effort?

Yes, we did the documentation work, showed the protocols to the NABL. The NABL approved our process: “You are good enough. You have good quality standards.” Then the ICMR was notified and gave us their approval, and finally we had become an ICMR-approved laboratory.

The team at SDM Molecular Biology Laboratory

> “I really loved his commitment and dedication. That’s how he is. He does his job well.”

Once we got the approvals and started the testing, the lab was totally functioning. Then we got an order from the government that we needed to test at least 400 to 500 samples per day. That was a huge task for us considering that in India there is a shortage of manpower. As you know, we had only four technicians at that time, so we purchased and installed a Thermo Scientific™ KingFisher™ Duo Prime Purification System for automated extraction. It was running smoothly, but within a week, we experienced a mechanical problem. It was costing time and energy from our side, so I immediately contacted Dibyendu and asked him to please address it.

We were both working day and night then. He was working day and night traveling to laboratories, representing Thermo Fisher, traveling to laboratories and doing his job. And I was working day and night in our new COVID-19 laboratory. So, we had built a sort of bond. We used to frequently call each other.

Did he have to come back on-site to help you with that?

Yes, he had to come back on-site because it was a mechanical problem. First, he requested, before coming on-site, that I download software on my laptop, connect it to the purification system, and check whether the protocols were correct or not. He did that with the TeamViewer™ app, but could not solve the issue remotely. He said, "I think there's a mechanical problem, so I need to come there." The next day, he was here. He came with a colleague and they did a fantastic job.

I actually felt sympathy for Dibyendu at that time because he was traveling the entire state to address so many issues throughout so many labs. But he came to our hospital and worked all day and until late in the evening investigating and troubleshooting the issue, so he could address it.

He and his colleague tried their best, but there was a mechanical problem in the unit they couldn't immediately solve. Thermo Fisher immediately replaced the unit, and within a week we were up and running again. In the last two years, we processed around 60,000 samples. It was a lot.

Could you have done that without the qualification process and service that he provided for you?

Not at all. We could not have done it.

Dibyendu told us you're an admirer of Thermo Fisher product lines. Is there a reason why you trust the brand and products along with our service?

For the last year and a half, we have been using Thermo Fisher's Applied Biosystems™ real-time PCR kits for COVID-19. It's entirely a Thermo Fisher workflow: from extraction to all the reagents we use, to the final amplification process—everything is from Thermo Fisher.

We had been initially using a real-time PCR kit by a company based in Germany. But Thermo Fisher came up with a better diagnostic kit—the Applied Biosystems™ TaqPath™ COVID-19 Combo Kit*—and we were able to get these kits at a better price. This was huge because for India, price is huge. The cost of the test is as critical a parameter for us as the quality of the product.

"He came to our hospital and worked all day until late in the evening investigating and troubleshooting the issue, so he could address it."

Q: Could you have done that without the qualification process and service that he provided for you?

A: Not at all. We could not have done it.

So now we are using the Applied Biosystems™ CoviPath™ COVID-19 RT-PCR Kit, a Thermo Fisher product being produced here in India under the "Make in India" project, and which is for use only in India. That has helped keep our running cost low. And because of that, we are now able to offer the test to the public, to our patients, at a low price. That's wonderful.

We also did a validation comparing the CoviPath kit with other real-time PCR kits on the market—and let me tell you: the CoviPath kit performed way better; the running time was just one hour.

This is the advantage we have experienced with this kit. We're very happy with it, and we scored 100% in our interlaboratory comparison. What happens is, whatever test we are running, in a six-month period we need to send five positives and five negatives of the COVID samples to a referral laboratory. That referral laboratory will test them and provide grades. With the CoviPath kit, we have scored the highest grade: 100% concordance. So, yes, we are happy with Thermo Fisher products.

Have you maintained your contact with Dibyendu? Do you still have a relationship with him?

Yes, we are still in touch. The IQ/OQ/PQ was done in 2020, right? So, now the next calibration is due in 2022. I have contacted him again regarding how to go about it. He immediately sent a quotation for that. And our purchase department has already started the initiation. Coincidentally, the warranty on our instrument is expiring. So now we will be entering an annual maintenance contract (AMC); Dibyendu has also guided me in that process—what kind of AMC we need to get, for example.

What would you say distinguishes Dibyendu or makes him stand out, and why do you think it makes sense for our company to give him this honor?

Straight to the point: he's a humble person, a gentleman, and professional in his behavior. Only when we truly understand the problem that we are facing can we accept a solution from a technician. Sometimes, no matter what solution a person offers, if we can't understand it, we won't be able to accept it. Dibyendu makes each situation clear. Even if I keep asking him technical questions about something I don't understand, he makes it simple to understand. He explains the problem, the solution, and why it should be done a particular way. The way he explains things is crystal clear. His communication skills are great.

Overall, he's just a nice person to interact with.

"Dibyendu makes each situation clear. Even if I keep asking him technical questions about something I don't understand, he makes it simple to understand."

* Use of TaqPath assays with the QuantStudio 5 system is dependent upon regional regulatory requirements for COVID molecular products.