



Duke University Laboratory Leaders Deliver During the Pandemic

Clinical Laboratories at Duke University Health System quickly ramped up their testing capacity in the face of a surging pandemic, staying ahead of supply chain interruptions with transparent communication and helpful partnerships.

Laboratory leaders' response to the crisis helped them forge a stronger relationship with health system leaders and afforded themselves greater leadership opportunities while improving the system's overall perception of laboratory medicine. Their handling also prompted a fundamental shift in how the health system responds to disasters.

Duke Health Clinical Laboratories, directed by pathologist Michael Datto, MD, PhD, FCAP, Associate Vice President and Medical Director, Duke Health Clinical Laboratories; Associate Professor and Vice Chair of Clinical Pathology, Department of Pathology, Duke University, turned on a dime to create the laboratory COVID incident-response team. This team was composed of long-standing operations directors and seasoned laboratory leaders. Each team member had clear roles, responsibilities and independent authority in their delegated operations, clinical and financial tasks. Central to the success of this team and the Duke COVID response was pathologist Diana M. Cardona, MD, FCAP, Associate Director for Duke Health Clinical Laboratories and Director and Vice Chair for Anatomic Pathology. Dr. Cardona's role was to lead high-level strategic planning for Duke's mid- to long-term COVID response. While the rest of the team focused on tomorrow and next week, Dr. Cardona's primary charge was to take what was happening today and focus on next month and even next year.



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Diana M. Cardona, MD, FCAP

Associate Professor of Pathology;
Associate Director, Duke Health Clinical Laboratories; Vice Chair and Director, Anatomic Pathology Clinical Laboratories, Duke University Medical Center

that turned out to be a critical role in our response," Dr. Cardona said.

Such entrustment allowed laboratory staff to work nimbly and safely, revising strategy daily as the demand for tests reached extraordinary highs. In moments, the health system's ability to provide care depended on the laboratory's ability to test.

"Health systems around the world got a small glimpse of what the world would look like if a crucial test — a key part of practicing medicine — wasn't available," said Dr. Datto. "Without it, the practice of medicine shuts down. We can't do elective or non-emergent surgeries. Clinics close and routine preventive and maintenance health care stops. We needed COVID testing to ensure the safety of our patients and providers and to continue to provide care. Without it, we could no longer practice medicine. That was an eye-opener for the world."

Outsmarting supply chain woes

Dr. Datto says the team's relentless focus on granular testing data and equipment supply enabled it to stay ahead of supply chain interruptions, ensuring that the system had tests when it needed them.

Fortunately, laboratory leaders had secured contracts with two large test vendors prior to the pandemic for high-throughput molecular platforms, which enable Duke Laboratories to conduct large volumes of tests rapidly. The laboratory had started with 60 daily tests in late March, which "was nowhere near where we needed to be," Dr. Cardona said.

Duke Laboratories quickly ramped up their testing capacity. Under the leadership of Dr. Christopher Polage, MD, MAS, FCAP, Associate Professor and Director for Duke Health Clinical Microbiology, the laboratories added new testing platforms weekly until staff worked across seven different testing platforms at once. Laboratory staff also validated tests in record time, completing validations in a matter of weeks or even days that traditionally would have taken up to 10 months. This showed the health system what high-complexity tests really require, Dr. Cardona said, and proved how well the laboratory team could deliver when times were tough.

Drs. Datto and Cardona's team currently conduct >1,000 tests a day, with the capacity to handle 3,000 tests a day if needed.

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Supporting staff

Staff monitored daily turnaround times for in-house and outsourced tests. They distinguished what incoming COVID-19 tests were destined for inpatients, outpatients or employees, and further identified whether recipients were symptomatic so they could monitor positivity trends. Such tracking also enabled laboratory leaders to better manage supply.



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 Medical Director and Associate Vice President, Duke Health Clinical Laboratories; Associate Professor and Vice Chair for Clinical Pathology, Department of Pathology, Duke University Medical Center

In the thick of the pandemic, all 900 of Duke's laboratory staff worked to support ramping up COVID testing, test kit assembly, and front-end process and handling, while maintaining normal laboratory operations. In doing so, many faced uncertainty and fear about the risk of contracting COVID-19. Drs. Datto and Cardona communicated daily with staff to alleviate fears and were transparent about "everything that we knew at the time" related to the virus, Dr. Datto said.

They also developed a split-shift approach and allowed staff to work remotely to limit exposure, and at the same time guaranteed all staff a continued 40-hour week, even if a staff member was asked to stay home.

"It was hard because [lab] employees had to work when everyone else took a breather," he said. "Supporting them through that was another lesson in leadership."

New approaches to leadership

Dr. Datto says the pandemic changed the way Duke laboratory leaders thought about disaster planning. In addition to incessantly tracking equipment supply and managing test flow, the team had to constantly reassess what supplies were essential.

"Now we ask ourselves, 'What could I live without? What could I send out? What would I do if a key piece broke?'" Dr. Datto said. "We absolutely need troponins, so we created redundancy around [them]. There are certain supplies that we must deliver rapidly. In the past, if we had a critical system failure, we could always outsource. During the pandemic, we didn't have that option."

In addition to supply-focused discussions every evening, laboratory leaders amped up talks with health system leaders, communicating daily about testing, positivity rates and hospitalized patients.

While Duke's laboratory leaders always have had regular contact with the rest of the health system, "In this setting, we not only were sitting at the leadership table, but we also drove discussions on what the health system was and wasn't able to do," Dr. Datto said. "'Yes, we can open elective surgeries tomorrow. No, we can't test people who need colonoscopies.' It was an array of decisions where the health system turned to our laboratories and said, 'What's the best path?'"

Turning trust into action

Laboratory leaders' transparent communication and use of granular data were essential in enabling all health system leaders to make decisions, reinforcing the laboratory leaders' trustworthiness and governance skills, and the value of their work.

Duke senior leadership demonstrated this trust by approving Dr. Cardona's plan to expand Duke's microbiology laboratory in 2020, a big request during a financially challenging year. Like many other health systems, Duke had to postpone elective procedures because of pandemic constraints. Yet system leaders approved the \$2.8 million project, which has helped laboratory staff to consolidate and streamline testing, ultimately saving the system money.

Dr. Datto says that he, Dr. Cardona, and other laboratory leaders also established trust



Duke Laboratories' Response to the Pandemic

Through the following means, Duke laboratory leaders turned a crisis into an opportunity for growth. They took the following steps to meet extraordinary testing demand while staying ahead of supply chain interruptions, keeping staff safe and even saving the health system money.

- Leaders developed a laboratory-specific, incident-management team with defined areas of responsibility.
- They identified risks and assets, and developed response visibility across key stakeholders.
- They learned to be nimble without exhausting staff.
- They created transparent communication channels among laboratory leaders, staff and health system leaders.
- Finally, they celebrated their successes, and parlayed goodwill from hospital leaders into new strategies and partnerships.

over the years by creating efficiencies and working with providers to develop the highest-quality, safest and most cost-effective care through laboratory medicine. Over the years, the laboratories have brought on new tests to decrease length of stay through rapid diagnosis of infections in hospital patients. The laboratories have led the way on rapid assessment of cardiac ischemia in the ED through the implementation of high-sensitivity troponin testing. They have worked with vendors to develop best-in-class, high-complexity molecular genetics tests for cancer patients and patients with inherited diseases or predisposition to diseases, and educated providers on how and where to use these tests. The laboratories have even developed software for real-time decision support around comprehensive genomic profiling for cancer patients. Dr. Datto said that our goal is to help providers order fewer, higher impact tests and make the right decisions with those results. This drive to high-quality care has created trust. This trust was critical in our success during COVID.

Dr. Cardona also developed a business plan for the implementation of fecal immunochemical tests to screen for colon cancer, which can improve outcomes and save the system money. Dr. Cardona worked with a student from the Fuqua Business School to develop the business case and is working with key stakeholders across the health system to formalize Duke's screening algorithm with the goal of detecting colorectal cancer early or require less-invasive means to detect it. This effort should continue to improve Duke's overall performance, Dr. Cardona said, which then boosts its bottom line.

"[Test efficiencies are] not just about generating revenue simply because we're performing a different or a new test. It's the downstream impact of that test, which ideally improves population health outcomes, resource utilization and revenue," Dr. Cardona said of the screening.

Dr. Datto said that even before the pandemic, laboratory staff helped hospital leaders in their work by identifying efficiencies and shortening lengths of stay. Laboratorians "are willing to step up and lead" no matter what, he added.

The pandemic reminded leaders about the importance of laboratory medicine, Dr. Datto said. It gave lab leaders a unique opportunity to take the reins.

"We were the only people who could address COVID-19," Dr. Datto said. "The responsibility was ours and uniquely ours. And it was one we could not delegate."

During the pandemic, "the whole world for a little bit rotated around [lab leaders]," Dr. Datto said, and they should not give up their hard-earned seats at the table. "Laboratorians bring unique perspectives that most providers don't have, and administrators should take note."

"If you haven't tapped the leaders in your laboratory for larger leadership conversations around your health system, you're missing an extraordinarily valuable resource," he said.



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