



Laboratory Insights Amidst COVID-19

WHEN THE PANDEMIC HIT, ONE HEALTH SYSTEM ACTED QUICKLY TO MEET ITS OWN PATIENTS' NEEDS, THEN SHARED ITS TESTING CAPACITY WITH THE COMMUNITY

The novel coronavirus global pandemic upended hospital laboratories when it first emerged in the US in early 2020 and spread in waves throughout the country. Health care providers urgently moved to reengineer operations to meet the demands of testing, triaging, and caring for patients with COVID-19. Laboratories found their workloads shift as their focus moved from routine to COVID-19 testing. As University of Chicago Medicine swiftly implemented safety and quality control measures for clinical care, its medical laboratories found ways to quickly deliver accurate diagnostic-testing results for its own patients and those in the wider community.



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KATHLEEN G. BEAVIS, MD, FCAP

Medical Director of Microbiology &
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Director of Laboratory Quality

University of Chicago Medicine, an integrated academic and community health system, includes the medical center complex on the university campus and dozens of outpatient clinics throughout the Chicago area. Its laboratory services department supports 4.5 million billable tests each year. With more than 330 employees and 50 faculty members, the department provides reference laboratory-testing services to entities within the health system and to nonaffiliated hospitals, managed care organizations, and outpatient clinics.

The laboratory’s COVID-19 journey began long before most Americans had learned of the new coronavirus. Kathleen G. Beavis, MD, FCAP, medical director of microbiology and immunology laboratories and medical director of laboratory quality, had taught in Wuhan, China, a few years earlier and reached out to her former colleagues for insight in late December 2019 when she heard news reports about the fast-spreading disease. On January 6, her laboratory started to reengineer processes and workflows to protect staff who would be working with specimens, and large orders of respiratory panels and other supplies were placed. By January 24, a hospital incident-command structure had been established.

With collection devices in short supply, the medical center’s supply chain outlet sought alternatives for Beavis’ laboratory to review. “We tested more than 20 transport media and more than 10 swab types, most of which, but not all, we found satisfactory,” she said.

On March 15, the laboratory went live with automated testing and is using four platforms for testing. In late spring, the medical center reached beyond its walls to provide diagnostic testing—results in 24 to 48 hours—for more than a dozen nonaffiliated community hospitals, Federally Qualified Health Centers (FQHCs), and nursing homes that were struggling to meet COVID-19 testing demands.

Pooling Specimens for COVID-19 Testing

Pooling samples—mixing several samples together in a batch or pooled sample—allows multiple samples to be processed with a single diagnostic test. If the pooled sample yields a positive result, each specimen of the pool is tested individually to identify the one that is positive. This approach is particularly attractive when resources are limited, but it comes with drawbacks. In pooling, samples are diluted, which could result in less viral genetic material available to detect, increasing the likelihood of false negative results.

Pooling samples works well when there is a low prevalence of cases, meaning more negative results are expected than positive results, according to the Food and Drug Administration. Beavis found this to be true when she used pooled testing for HIV, where prevalence of acute infection was low and the high viral loads associated with acute infection meant all of acute infections could be detected.

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As the need for COVID-19 tests increased and reagent shortages lingered, her team had to decide: Should they limit testing based on symptoms and risk factors, as some institutions have done, or test as many patient specimens as possible and mitigate the risk of a false negative result?

Limiting testing based on symptoms and risk factors does not make sense for COVID-19 because there are so many asymptomatic people who are spreading the disease. But widespread pooling was not a good option because the infection prevalence rate—15% to 20% at some points—was so high that many pooled samples would have required the second step of testing each specimen individually. Thus, the laboratory’s protocol, implemented in July 2020, uses pooling only for specimens from asymptomatic patients who are having pre-procedure screenings.

Pooling required new processes which, in turn, required staff members and technology support. These included:

- Before analysis, specimens need to be sorted into those that could be pooled and those that required individual testing.
- After analysis, results from pooled specimens need to be reported to the electronic health records of individual patients. When it became clear that the existing computer programming did not support that, technologists in the microbiology laboratory devised a procedure using barcode scanners and Excel spreadsheets to report individual results from pooled specimens.
- Transparency is essential. When reporting results from pooled samples, the laboratory included a notification about the decreased sensitivity associated with pooling and the possible need for retesting because of it. This disclaimer was made in the hospital information system and in the patient portal so that patients were aware.

Staffing Issues During Pandemic

As the pandemic drags on, the toll on laboratory staff members is a growing concern. Managers worry about supporting workers who become ill, those who have children who attend school remotely and those facing other challenges associated with the public health emergency.

The laboratory services department sought support from the medical center’s human resources department to present, via Zoom, information about resilience techniques. It also distributed a pamphlet, developed by the health system’s employee-assistance program, that identifies opportunities to reduce the stress associated with pandemic fatigue. “We have an ongoing effort to try and address staff resilience during these very stressful times,” said Candis Kinkus, MBA, vice president of laboratory services.

Social distancing in busy laboratories presents a challenge. Spread across many buildings, University of Chicago laboratories are in various configurations, some of which were built out 40 or 50 years ago. “We have found that, for some

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laboratories, we’ve actually had to identify additional space that was being used for some other non-testing purpose, repurpose it, and reallocate our staff,” Kinkus said.

Strategies included:

- **New shift schedules.** In the health system’s histology laboratory, for example, the length and timing of work shifts were changed so that fewer staff were working in the space at any one time.
- **Space optimization.** Staff meetings are conducted via Zoom during the pandemic, allowing conference rooms to be repurposed as break rooms. Lesson learned: The number of chairs in a break room must correspond to the maximum capacity of the room that allows for social distancing. “We literally moved some chairs out of those spaces so that we could ensure compliance with the use of conference rooms in a socially distant manner on a 24/7 basis,” Kinkus said.

Serving the Community During an Emergency

As soon as the health system had the supplies and protocols in place to meet its patients’ needs, the leadership team provided access to testing to the residents in the greater South Chicago community.

Many nursing homes, community hospitals, and FQHCs had relationships with reference laboratories that could not accommodate the volume and turnaround time necessary for COVID-19 testing. To support their needs, the laboratory services department leveraged the infrastructure to support its long-standing outreach program. A third-party vendor provided middleware to connect University of Chicago Medicine’s laboratory information system with any software application that community providers use for ordering tests. “That essentially eliminated paper orders because we could stand up electronic orders, and it also got rid of paper results,” Kinkus said.

Because the laboratory had a stable inventory of supplies, it has been able to provide COVID-19 test results within 24-48 hours for community provider organizations.

KEYS TO SUCCESS

Good working relationships with the medical center's supply chain, information technology facilities, media, and other departments all have been essential to University of Chicago Medicine's successful COVID-19 testing program, said Candis Kinkus, MBA, vice president of laboratory services. "It's terrific for us in the laboratory to see how many departments are supporting us so that we can support patient care," she said.

Other success factors include:

- **Proactive planning.** When the laboratory services department arranged to do COVID-19 testing for community health care providers, the contracts allowed either party to terminate the contract with 30 days' written notice. This protected University of Chicago Medicine in the event that supply shortages made fulfilling the contracts impossible.
- **Transparency about protocols.** At the time University of Chicago Medicine began pooling samples for COVID-19 testing, the Food and Drug Administration required microbiology laboratories to submit an emergency-use authorization. Although that requirement has been dropped, Kathleen G. Beavis, MD, FCAP, medical director of microbiology and immunology laboratories and medical director of laboratory quality, sees that the rigorous approach benefited her laboratory. "It gave us confidence that we were quantifying the risk by determining how many low-prevalence infections we would miss," she said. "This allowed us to be transparent with physicians who ordered the tests and patients who reviewed their results. It also gave us confidence that our risk-mitigation strategies were appropriate."
- **Support for staff members.** Hospital and health system leaders must find ways to keep employees healthy—physically, mentally, and emotionally—and engaged during the most stressful period of their working lives. "We can have all the systems in the world, great information technology and fabulous platforms, but we need our people," Beavis said. "We need to value our people and figure out how to keep them going."

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