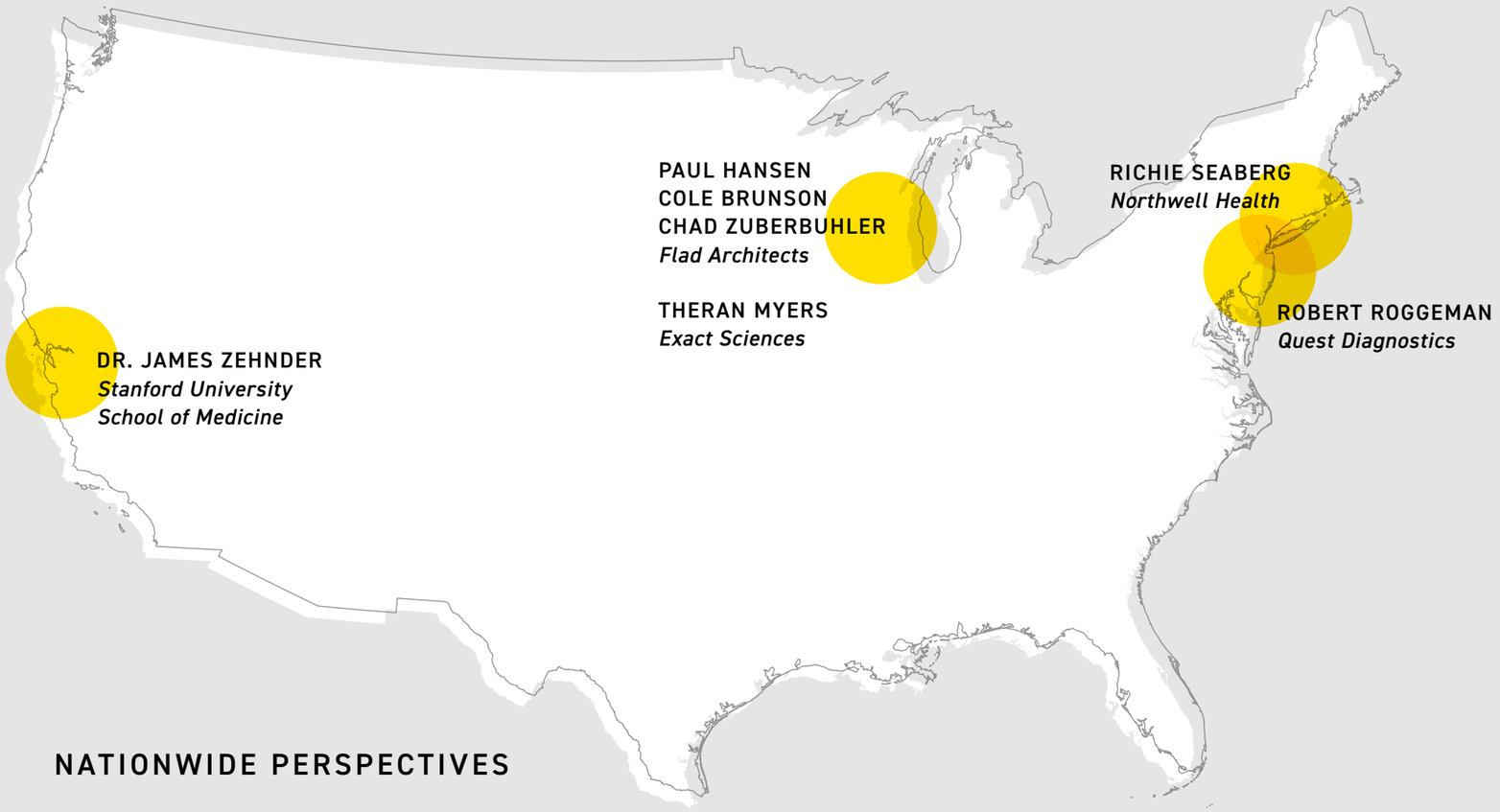
TESTING FOR LIFE

Lessons learned and emerging opportunities in clinical diagnostic laboratories

EXTRAORDINARY TIMES, EXTRAORDINARY MEASURES

When reflecting on the U.S. healthcare system during the COVID pandemic, we often think of healthcare providers as the frontline heroes supporting patient care. However, staff and leadership at clinical diagnostic testing lab organizations are heroes, too. They have responded with creative agility and resilience to supply shortages and increased demand for testing, devising innovative ways to optimize existing space, source supplies, and boost efficiency.

To hear multiple perspectives on insights gained from the pandemic and thoughts on the future of clinical diagnostic lab design, Flad Architects convened a panel of industry specialists, from around the U.S.



NATIONWIDE PERSPECTIVES

Panelists included Theran Myers, director of laboratory systems development for Exact Sciences; Robert Roggeman, executive director national lab operations at Quest Diagnostics; Richard “Richie” Seaberg, business services director and an administrative director with Northwell Health; Dr. James Zehnder with Stanford University School of Medicine; and Cole Brunson and Chad Zuberbuhler, principal science planners at Flad Architects. The virtual seminar was hosted by Flad Architects and moderated by Paul Hansen, a principal at the firm.

They discussed topics including designing and operating for real-time scalability, planning for increased automation and high throughput, overcoming supply challenges, and accommodating IT infrastructure. Highlights of the discussion follow below and the **full recording is available here >**

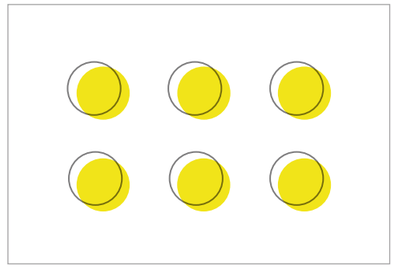
TOPICS

FLEXIBILITY AND REAL-TIME SCALABILITY ARE ABSOLUTELY KEY FOR ANY LAB OF THE FUTURE."

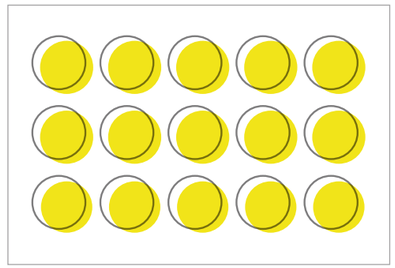
– ROBERT ROGGEMAN, QUEST DIAGNOSTICS

OPERATIONAL CHALLENGES AND EMERGENT OPPORTUNITIES

Panelists agreed that the pandemic has reinforced the need for flexible, adaptable spaces to respond to unforeseen challenges. To demonstrate the importance of flexibility within his organization, Richie Seaberg shared that Northwell Health's lab network was able to rapidly expand from six molecular diagnostic units at the start of the pandemic to 15 in the same space; Northwell staff were initially running 1,000 PCR COVID tests per day, which grew to 17,000 as of October 2021 and has since accommodated additional increases as needed. He credited the rapid in-place expansion to flexible lab solutions such as overhead utility distribution, mobile benches, and careful space planning that accommodated staff, equipment, supplies, waste flow, and adjacencies.



CURRENT CAPACITY



SURGE RESPONSE

1,000

17,000

PCR COVID TESTS PER DAY

FLEXIBLE SPACE AND EMERGENT CLINICAL TESTING PLATFORMS, INSTRUMENTATION, AND EQUIPMENT

Thoughtfully designed and placed lab casework, lab utilities, and equipment are essential, and panelists stressed the need to think even more broadly to truly plan and build for future flexibility. In lab functions that are highly impacted by planned or unforeseen change, the concept of pre-investment involves incorporating lab and environmental infrastructure that is needed in the future to accommodate additional equipment, automated testing platforms, sample and specimen processing throughput, and preparedness for surge testing.

Cole Brunson provided examples of pre-investment strategies ranging from simple to complex, stressing the importance of considering the flow of specimens and samples, material, personnel, and waste. An example of a smart strategy on the simple end of the spectrum is incorporating supplemental lab support shelving space adjacent to a lab. The shelving may not have an immediate use, but it is conveniently located to accommodate future needs. Additionally, a cost-plus, pre-investment is to construct expansion surge space by finishing the walls, floors, and ceilings in advance of the program demand. Only minimal modifications will then be needed, such as installing lab fixtures and casework, to make the space fully operational for future testing. Finally, the most flexible option would be to construct unfinished lab space with overhead service panels for utilities and a plumbing drain grid; also partially fit-out with fixtures and furnishings. Although this option is initially more costly, it also offers the most possibilities for future expansion and lab surge with minimal disruption to ongoing regulated testing operations.

Similar strategic facility and operational approaches can also be leveraged from an infrastructure standpoint. For instance, mechanical rooms can be designed in a modular fashion so that supplemental equipment can be added with ease, increasing capacity for future loads.

Panelists agreed that a significant lesson learned is the need to plan for lab waste drains. In the context of validated and regulated lab environments, saw cutting floors is highly disruptive to operations. The density, location, and modularity of lab waste drains is a key macro-planning consideration and a pre-investment strategy that should not be overlooked.

ENTERPRISE DIGITAL INTEGRATION AND ITS INFLUENCE ON HEALTHCARE AND CLINICAL DIAGNOSTICS TESTING

Panelists also agreed that informatics are key to clinical diagnostic testing labs' efficiency of function today and into the future. Improved and robust data flows will lead to benefits such as improved sample and specimen tracking, faster specimen and specimen turnaround times, and improved pre- and post-analytics techniques for sequencing and imaging. Those benefits, though, will only come with software improvements, integration with the supply chain, and better strategies for overcoming the space challenges associated with IT infrastructure.

"PATHOLOGY REALLY IS BECOMING A DIGITAL ENTERPRISE."

– DR. JAMES ZEHNDER, STANFORD UNIVERSITY SCHOOL OF MEDICINE

Richie Seaberg related Northwell's reliance on Information Technology (IT) from the micro- to the macro-scale during the pandemic. Fundamentally, lab testing needed to track every step in the process since long before COVID, but tracking components became unusually challenging when, due to supply shortages early in the pandemic, the labs were 3D printing their own swabs and saline tubes. IT stepped up to ensure that all components had lot numbers. On a much larger scale, IT was also crucial on the results side. Northwell's IT professionals devised a system that allowed patients to be tracked as they were transferred around the hospitals to load balance, and they also developed systems to rapidly relay reports to state, city, and county health agencies.

James Zehnder spoke to the growth of molecular testing technologies like next-generation sequencing, coupled with mass spectroscopy platforms and initiatives, that are leading to collaboration between the sciences and the computer science departments at Stanford.

Although these technologies show great promise, implementation challenges include allocating space for automation and IT infrastructure, as well as sharing information across systems.

SUPPLY CHAIN CHALLENGES AND FACILITY PLANNING FOR THE FUTURE

Even with the most advanced IT systems and adaptable spaces, a lab's operations may be decremented if it lacks the necessary supplies and equipment to support its operations. In addition to Seaberg's 3D printing anecdote, other panelists recounted struggles with supply chain shortages and the heroic efforts made to overcome them.

The problem with those heroic efforts, though, is that they are not sustainable long-term. Panelists agreed that better industry-wide strategies need to be implemented to overcome the shortcomings with lean supply chain manufacture and just-in-time strategies that came to light during the pandemic. After all, the scarcity mindset can negatively impact decision-making and lead to hoarding, stockpiling, and other tactics that make sense in the short term yet challenge the overall industry over the long term.

Given that a reliable, national system-wide supply chain solution may be years or even decades away, panelists discussed their entities' current strategies for supply storage. Myers shared that Exact Sciences' approach has always been as lean as possible, with just-in-time supply of material delivered daily to the labs. Exact Sciences has invested heavily in logistics assets and automation to transport supplies efficiently and provide the labs with all the materials they need for each shift. Roggeman shared that Quest also has a central warehouse, but the strategy has introduced logistical challenges. Seaberg said that, when the pandemic struck, Northwell was able to leverage common consumables, reagents, and existing assays, and quickly transition them to COVID testing pathways. With 23 individual hospitals, multiple outpatient service centers, and other health facilities throughout the New York metropolitan area, Northwell relies on a hub-and-spoke model, receiving supplies in a central facility and distributing them to each site based on testing volume.

THE FUTURE OF CLINICAL DIAGNOSTICS SYSTEM DESIGN

As the conversation turned toward clinical diagnostic testing labs of the future, panelists shared that they expect to see more continued growth in molecular testing, precision cancer diagnostics, and other novel testing platforms. They also anticipate analyzers getting smaller, with the possibility for increased throughput and more automation. More point-of-care testing and at-home test collection is expected as well.

Zuberbuhler summed up the panelists' views of an ideal future-state by speaking to the desire for smart labs that integrate directly with healthcare providers, vendors, supply warehouses, and even to various stations within the lab itself to operate more efficiently and deliver rapid, reliable results for providers and their patients.

APPLYING TODAY'S LESSONS TO TOMORROW'S LAB DESIGN

The future will undoubtedly bring new challenges and opportunities. The unsung healthcare heroes working within the intelligently designed clinical diagnostic facilities will help meet them.

VIEW THE FULL WEBINAR FOR MORE INSIGHTS >

DESPITE DAUNTING ODDS, STAFF AND LEADERSHIP AT DIAGNOSTIC TESTING LABS HAVE KEPT PATIENTS AND HEALTHCARE PROVIDERS INFORMED DURING THE PANDEMIC," SAID MODERATOR PAUL HANSEN. "AS DESIGN PROFESSIONALS AND LAB PLANNERS LEARN FROM THEIR TEAMWORK AND INGENUITY, WE'RE FINDING OPPORTUNITIES TO IMPROVE EXISTING SYSTEMS AND HELP FUTURE-PROOF THE INDUSTRY."

PANELIST PROFILES

THERAN MYERS

ROBERT ROGGEMAN

RICHIE SEABERG

DR. JAMES ZEHNDER

PAUL HANSEN

COLE BRUNSON

CHAD ZUBERBUHLER

THERAN MYERS

Director of Laboratory Systems Development

Exact Sciences

Trained as a microbiologist and immunologist, Theran has worked in clinical labs for 20 years. He joined Exact Sciences to support laboratory testing for the Cologuard clinical trial, and he has since been involved in designing and optimizing the clinical labs that have scaled Cologuard from zero to millions of reported results per year. He continues to support process optimization as well as new test deployment and optimization at Exact Sciences Laboratories.

RICHIE SEABERG

Director of Business Services/ Administrative Director

Northwell Health

Richie is a dedicated laboratorian focused on developing new facilities, incorporating new hardware, and developing new methods that will enhance the patient and associate experience. He firmly believes that achieving these goals requires maintaining a strong vision of the future, embracing advancements in IT, preparing for potential contingencies, and working collaboratively within teams.

ROBERT ROGGEMAN

Executive Director National Lab Operations

Quest Diagnostics

Robert is a licensed medical technologist at Quest Diagnostics, where he has been the program director for managing the design, construction, fit-out, and start-up of Quest's new "Lab of the Future" in Clifton NJ. In this role, Robert coordinated the activities of multiple project streams to ensure the laboratory opened on schedule despite the impact of the COVID-19 pandemic. Prior to Quest, Robert served as CEO and vice president of testing for the American Red Cross, where he participated in multiple lab build-out and redesign efforts and coordinated the consolidation of laboratory operations into two of the largest blood screening laboratories in the United States.

DR. JAMES ZEHNDER

Professor of Pathology and Medicine (Hematology), Director of Clinical Pathology, Department of Pathology

Stanford University School of Medicine

Trained in internal medicine, hematology and oncology, James joined the pathology department at Stanford University as director of the coagulation lab in 1994. At the time, Factor V Leiden, the most common inherited mutation causing blood clotting risk, was discovered, which prompted the launch of Stanford's molecular pathology laboratory. Since 2016, James has served as the director of clinical pathology. In addition, he continues to see hematology patients in clinic and attends on the hospital hematology consult service.

PAUL HANSEN

Principal, Flad Architects

Event Moderator

Paul's years of leading and managing projects that support science discovery, development, and manufacturing have given him unique insights into the questions asked by clients. Understanding their methods, he can find the ways in which their business objectives align with the solutions crafted by the design team. A project leader and client advocate with extensive experience on both sides of the fence, he's a calming influence – listening, providing counsel, and delineating solutions that enable business, helping advance conversations to positive outcomes.

CHAD ZUBERBUHLER

Principal, Science Planner
Flad Architects

A planner who works with project teams to support the development of facility design and program solutions, Chad contributes to program conception and planning of laboratories, including mechanically intensive support areas, initial development and drawing of plans/elevations, facility process flows, and coordination of details and documentation. He knows that, above all, laboratory spaces need to function well, so his primary goal is to understand how the design team can help facilitate the client's mission and optimize the lab space.

COLE BRUNSON

Principal, Science Planner
Flad Architects

As an architect and lab planner, Cole has worked on large, complex projects including pharmaceutical, process manufacturing, and research laboratories, always with an eye toward spaces that are functional, flexible, efficient, and safe. Adept at solving the puzzles inherent in laboratory planning, he's also a good listener, a vital skill in the process of understanding a client's challenges so that options can be developed, presented, and recommended.

Jodi Mulcahy
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