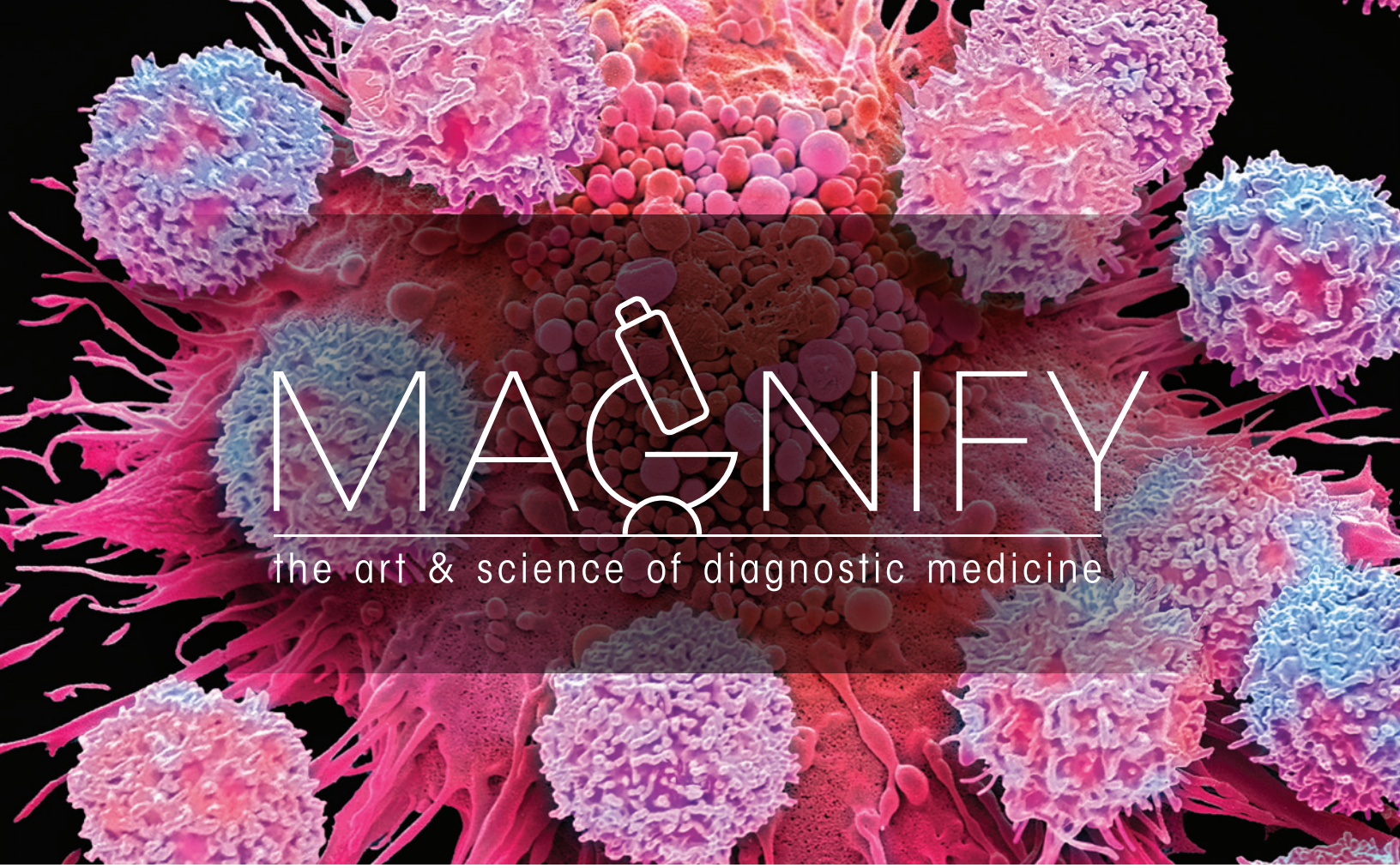

Spring 2024

Celebrating 40 Years of Putting the Patient First

40th Year Commemorative Edition
ARUP LABORATORIES
40 Years
TIME TESTED, FUTURE FOCUSED.

In Magnify, we share stories that bring laboratory medicine to life.

MAGNIFY

the art & science of diagnostic medicine

Contents

Contributors

Writers: Lisa Carricaburu, Kellie Carrigan, Heather Stewart, Bonnie Stray, Alice To

Graphic Designers: Athena Ho, D'Arcy Monforte, Mary Paul, Nikole Thayne, Natalia Wilkins-Tyler

Photographer: Corrin Rausch

Web Designer: Amy Davis

Editors: Kate Button, Lisa Carricaburu, Elizabeth Carver, Kristen Deem, Dora Lockhart, Kari Morandi, Heather Stewart

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Watch CEO Andy Theurer's video message here:

A Message From the CEO

As ARUP Laboratories celebrates its 40th anniversary in June 2024, I want to personally thank each of our employees. Their commitment to patient care has enabled ARUP to reach this important milestone.

For a company to survive and thrive for four decades is rare, and the history of our company is rich. In this special edition of Magnify: The Art and Science of Diagnostic Medicine, we will share stories of the determination and grit that launched ARUP from a tiny, high-risk startup into one of the nation's four largest clinical reference laboratories.

I want to acknowledge the founding pathologists and the 100 employees who joined them in surrendering their jobs and taking great personal risk to join this endeavor. Our 4,500 employees now provide the best in laboratory medicine to hospitals and health systems in all 50 states.

Most importantly, though, as we remember the journey that brought us here, I want to recognize everyone who has ever worked at ARUP and express my sincere appreciation for the shared purpose, friendship, and support we have shown and will continue to show one another.

Ours is a story of outstanding business success that I am proud to share. We have created something very special at ARUP Laboratories. Let's celebrate!

Andy Theurer
CEO

1973

Lloyd Martin

Ernst J. Eichwald, MD, chair of the University of Utah Department of Pathology, hires Lloyd Martin as a business manager. Martin plants the seeds of a new idea: pathologists owning, operating, and expanding a reference laboratory.

1983

John M. Matsen, III, MD, incorporates Associated Regional and University Pathologists Inc. and becomes ARUP's first chief executive officer (CEO).

1984

ARUP Laboratories launches. Lab staffers receive pink slips from the University of Utah Hospital and immediately join the new company at 390 Wakara Way in Research Park.

ARUP Marks the Milestones of Its 40-Year History

June 1984

Associated Regional and University Pathologists Inc. formally launched on June 15, 1984, the day lab employees received pink slips from the University of Utah Hospital that a lab secretary filled out by hand.

"The way it was presented was as such an opportunity, such a journey, and such a great experience that I don't know if I was as nervous about it as I should have been at the time, but I was one of the lucky ones to get that pink slip," said Leslie Hamilton, MT(ASCP)SM, former senior vice president of Technical Operations.

The group of about 100 immediately joined a new company now known as ARUP Laboratories, but the idea was born more than a decade earlier when Lloyd Martin became the business manager for the university's Department of Pathology. He promoted the concept of pathologists owning and operating a reference laboratory. Within a year of Martin's hiring, John M. Matsen, III, MD, would return to his native Utah to accept a professorship in pathology and pediatrics at the U School of Medicine and to direct the U's clinical laboratories. Matsen would become the driving force to persuade the faculty to embrace the unique business

1989

Intermountain Healthcare becomes an ARUP client.

ARUP moves to 500 Chipeta Way. Designed by Russ Haymond and Charles DeWitt, the 75,000-square-foot building is constructed in 10 months.

1992

Matsen becomes University of Utah vice president of health sciences, and Carl R. Kjeldsberg, MD, is named president and CEO of ARUP.

Carl R. Kjeldsberg, MD

1993

Ronald Weiss, MD, MBA, is named director of laboratories. He helps translate ARUP's vision and mission statements into The Five Pillars of ARUP Culture.

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"Without John Matsen, we would never have [had] an ARUP. … He was so important, so brave, and was a real driver."

Carl R. Kjeldsberg, MD,
Retired CEO

Key figures from ARUP reflect on the past 40 years and look toward the future in a special video. **Watch now.**

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ARUP employees pose for a photo.

venture, which was not an easy sell. He had to convince career state employees with attractive retirement packages, job security, and little business experience to join a for-profit testing lab.

"All of our employees were scared to death. They were going to lose their regular insurance, and they didn't know what was going to happen with their retirement through the University of Utah, but John Matsen was convinced ARUP would succeed," Harry R. Hill, MD, an ARUP founder, reminisced.

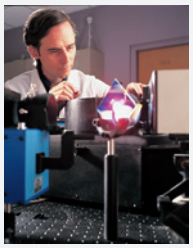
Matsen also needed the hospital's support, which was an easier sell, thanks in part to new federal regulations capping lab fees. The administrators saw the practical side of the lab splitting off from the hospital, especially given their anxiety over potential shortfalls from lab fees.

The small startup moved out of the U Hospital in August 1984 and into an old Occupational Safety and Health Administration (OSHA) lab at 390 Wakara Way in Research Park, complete with turrets, like a castle.

Caravans of moving vans and pickup trucks transported each lab's equipment over

1994

Responsibility for operational logistics shifts from medical directors to technical operations managers. Labs are staffed 24/7/365 to better meet patients' and clients' needs.



Carl T. Wittwer, MD, PhD

Carl T. Wittwer, MD, PhD, and K. Owen Ash, PhD, lead ARUP as it offers the first polymerase chain reaction (PCR) test and jumps into molecular pathology.

1995

Building 2 is added. Kjeldsberg, Matsen, and University of Utah President Arthur K. Smith, PhD, cut the ribbon.

John M. Matsen, III, MD, in his office.

Matsen's mint-green trailer.

three days, but it would take months to complete the move. During that time, not a single item was damaged or lost, and no tests were interrupted.

"We kind of predicted, those of us who started with ARUP, that within a couple of years we'd probably be moving back, so we didn't worry, and things just continued to grow. I would have never imagined we would be in the position we are today," said Nancy Andes, MBA, MT(ASCP), former senior vice president of Marketing.

Space was tight in the 25,000-square-foot building in those early years, and employees developed a sense of humor and of family. Several office romances developed, 59 of them resulting in marriage. Employees wore many hats. They shoveled snow in the winter, mowed the lawns and trimmed trees in the summer, and used their own cars to transport specimens.

"We had a dream when we started it. It was a little bitty lab in a little bitty building. People were very concerned about moving away from the university, but we survived, and we worked hard and took chances. We had fun doing it," Hill said.

1989: Intermountain Healthcare Becomes a Client

ARUP did not have a model to guide its growth and overcame many hurdles in the first few years, including merging academia with business, learning to keep pace with the competition, and convincing clients outside the Intermountain Region that it could handle sophisticated tests. As ARUP's first president, Matsen encouraged his staff to expand and often took to the road himself to sell ARUP's unique services to clients, many times after an all-nighter in

1996

The ARUP Institute for Clinical and Experimental Pathology® is founded under the direction of Harry R. Hill, MD.

1998

William L. "Bill" Roberts, MD, PhD, joins ARUP. He is instrumental in forming the Children's Health Improvement through Laboratory Diagnostics (CHILDx™) program and initiating ARUP's pediatric reference interval study.

1999

ARUP exits the corporate drug testing business.

Lab stewardship is introduced with the Analyzing Test Ordering Patterns™ (ATOP®) report.

the lab. His colleagues said he either slept on the plane or in his mint-green trailer parked behind the hospital.

ARUP's selling points far outweighed its weaknesses. As a medical school lab with sophisticated technology capable of providing high-quality, cost-competitive, full-service esoteric testing, ARUP openly shared its knowledge, technology, and expertise.

"Our focus was to help our clients," Hill said. "If they wanted to bring on a test that we were doing, we would help them set it up."

"If you look at what we did in helping others, sometimes it was detrimental to our growth because we helped them make their labs successful. It played into our values, our mission, and our goals as an educational facility as well as a reference laboratory," Andes said.

ARUP won the business of several academic medical centers, including the University of Minnesota and the University of Washington. Their endorsements paved the way to more growth and proved that ARUP was a legitimate player in the reference laboratory business. But perhaps one of the biggest shots in the arm came in 1989, when Intermountain Healthcare signed a 10-year contract with ARUP. Intermountain's flagship facility, LDS Hospital, was already using ARUP for routine testing. The head of pathology there had given approval for the hospital and its renowned Primary Children's Hospital to send some testing to ARUP in previous years.

CEO Andy Theurer said it was a sought-after contract, but a tricky one. "We are part of the University of Utah, yet we are going to try to service one of the university's biggest competitors. It worked out beautifully because it gave us the amount of work we needed to develop very sophisticated testing, and from that moment we really moved from a regional lab to a national one."

Eventually, Intermountain became one of ARUP's largest clients, nearly every hospital in Utah came to rely on ARUP, and "regional" in ARUP's name no longer applied to the company. ARUP had clients, including academic medical centers, pediatric hospitals, and teaching hospitals, in all 50 states, making it a national reference laboratory.

1992: Matsen Leaves To Become U VP, Kjeldsberg Takes Over

Matsen pushed his staff and managers hard to ensure ARUP's success. He is famous for pointing his index finger in a way that (he said) meant emphasis. Those working with him knew the pointing finger meant, "Just get it done."

"Without John Matsen, we would never have [had] an ARUP. … He was so important, so brave, and was a real driver," said retired CEO Carl R. Kjeldsberg, MD.

Matsen's absolute commitment, high expectations, willingness to work with others, generosity, and mentorship shaped what ARUP is today.

"He was a teacher at heart," Hamilton said. "He wanted the very best from all of us and spent a lot of time in the lab before he became so busy. He was always focused on quality."

In November 1992, Matsen stepped down as ARUP CEO and

2000

Building 3 is added and gives ARUP an additional 72,000 square feet of space. ARUP acquires a nucleic acid sequencer, which enables the development of the original Hepatitis C Virus Genotype test.

2001

ARUP obtains tax-exempt status.

ARUP's Institute for Learning is established to provide educational opportunities to employees and clients.

2002

Kjeldsberg and University of Utah President Bernie Machen, DDS, MS, PhD, shake on a deal that ARUP is not for sale. Within months, their deal falls apart when Machen seriously entertains a bid from Sorenson Capital.

U Department of Pathology chairman to become the U's vice president of health sciences. Kjeldsberg took over leadership at ARUP with his own unique style and profoundly influenced ARUP culture.

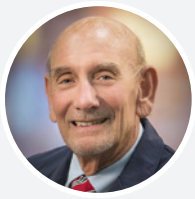
"Carl was a big proponent of work-life balance. In the early years, he used to take Wednesday afternoons off during the ski season, and he would hold a board meeting at Snowbird, on skis—a board meeting," said Ronald Weiss, MD, MBA, former president and chief operating officer.

Kjeldsberg's philosophy was, "Hire the best, treat them well, and they will treat the customers well." He is famous for "walkabouts" around the labs and Wednesday walks in Red Butte Garden with employees for exercise and conversation.

"I practiced management by walking around. I did not want to isolate myself in the office. That is how a CEO fails. I needed to go into the trenches to see what [was] happening, and I would often hear things that I would have never heard if I was sitting in my office," Kjeldsberg said. "I also emphasized that employees needed a balanced lifestyle."

Kjeldsberg challenged ARUP to start a daycare, to provide excellent tuition and health benefits, and to create an on-site health clinic for employees and their families, all of which continue today.

Matsen (left) and Carl R. Kjeldsberg, MD (right), shake hands during ARUP's 10th anniversary celebration.



"Our focus was to help our clients. If they wanted to bring on a test that we were doing, we would help them set it up."

Harry R. Hill, MD, an ARUP Founder

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2002

ARUP volunteers use of its lab facilities to the doping control lab of the University of California, Los Angeles (UCLA), which performs athlete drug testing during the Winter Olympics in Salt Lake City.

2003

The deal with Sorenson Capital is called off. Kjeldsberg agrees to give the university more control over ARUP and 5% of annual revenue.

ARUP launches a year-long initiative to expand newborn screening under Utah state law by utilizing a new mass spectrometry method that allows for simultaneous analysis for multiple newborn diseases.

ARUP's Building 1.5 opens with the world's largest lab specimen freezer, a two-story, 7,000-square-foot unit that can hold 2.2 million specimens and has fully robotic storage and retrieval capabilities.

Weiss becomes company president and chief operating officer.

The Five Pillars of ARUP Culture are prominently displayed.

Kjeldsberg (center) and ARUP employees out for a Wednesday walk.

The 5 Pillars of ARUP Culture

ARUP first articulated its core values in writing as part of the strategic planning that led to its expansion in the early 1980s and eventual evolution into a nationwide reference lab, Weiss said. He was among the leaders who translated ARUP's vision and mission statements into the Five Pillars, which he described as an effort to crystalize and codify ARUP's culture into bullet points that people could recognize in what they were doing and use as a guidepost. Those bullet points, now known as The Five Pillars of ARUP Culture, include:

I. Provide excellent patient care by supporting clients.
II. Create a good working environment.
III. Do the right thing.
IV. Improve continuously.
V. Act responsibly.

"Each one of them was important in supporting the overall mission of quality healthcare, research, and education, but primarily a focus on patient care," Weiss said. "As long as we act in the interests of patients and employees, continue to improve individually and as an organization, and we're fiscally responsible, that is still a formula for success."

The Five Pillars have stood the test of time and guide the decisions that leaders at ARUP make, said Sherrie L. Perkins, MD, PhD, who served as CEO from 2017 to 2021. "Academics and trying to do the right thing drive so much of what we do. The Five Pillars distill core values that make sense from a business and an ethical perspective." The mission is clear, and the company's actions align with it.

ARUP has a reputation among employees and others as one of the best places to work in Utah and is ranked among Forbes magazine's Best Employers by State. Utah Business magazine has honored ARUP with a "Best Companies to Work For Award" every year since 2018. The award measures employee satisfaction related to culture, benefit offerings, and compensation.

"One of the most important things that we do here is treat our workforce well, so they can turn around and forward that

2004

Charles D. Hawker, PhD, MBA, spearheads implementation of a new lab automation system that can transport and sort up to 4,000 specimens an hour.

2006

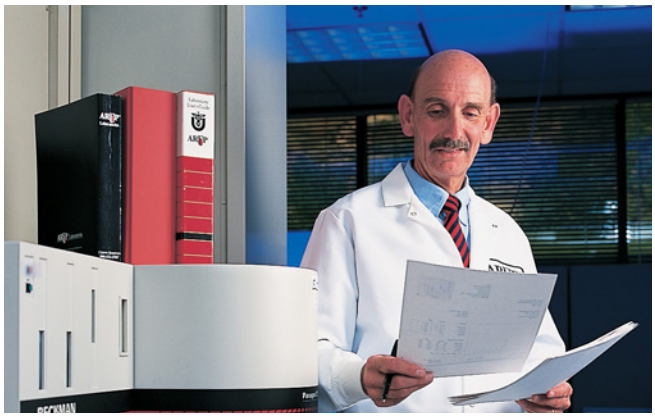
ARUP Consult® launches as a clinician test selection guide to share expertise beyond the lab. It was originally designed for Palm Pilots.

2007

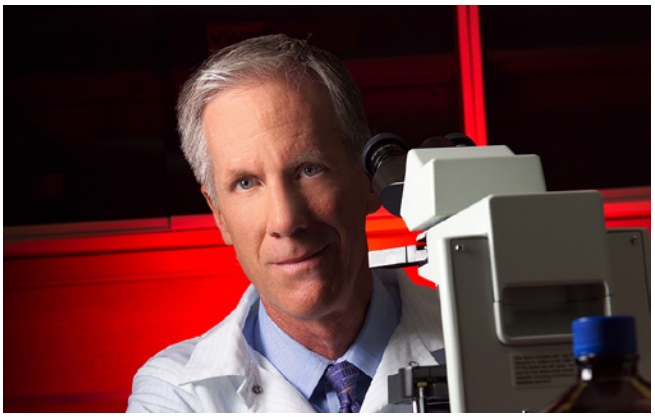
ARUP opens an on-site childcare center.

2008

ARUP Consultative Services begins offering market opportunity assessments, outreach infrastructure evaluation, and outreach business planning.



Harry R. Hill, MD, founded the ARUP Institute for Clinical and Experimental Pathology® in 1994.



Ronald Weiss, MD, MBA, former president and chief operating officer, is credited with distilling ARUP's core values into The Five Pillars of ARUP Culture.

treatment on to the patients and the doctors," said Theurer, the CEO.

1994: Medical Directors Freed From Responsibility for Lab Operations

By the mid-1990s, ARUP's business was thriving. Nearly two-thirds of the nation's academic health centers were sending samples to ARUP, including Stanford, University of Pennsylvania, and Harvard, and the company was focused on growth after four years of substantial profitability. Then came some bad news—an $800,000 loss in March 1994. Theurer, who was the assistant controller at the time, said, "We had hired too many people too quickly. We still didn't know how to operate a profitable business."

ARUP officers gathered the technical operations managers and ordered them to develop standards for lab and department staff sizes, as well as staff titles, and to implement new efficiencies. The result was a historic power shift that moved operational logistics from the medical directors to the technical operations managers, and a quick return to black ink.

"So many people see this as a watershed moment for ARUP. The medical directors were moved into areas of expertise where they were absolutely needed and out of the day-to-day running of the company. We developed a lot of processes that decreased costs and were good for all the labs," Hamilton said.

Hill, seeing a need to support the medical directors, founded the ARUP Institute for Clinical and Experimental Pathology® to help maintain an emphasis on publishing research, developing new tests, and embracing emerging technologies.

"Harry was probably the one individual who has had the biggest impact on preserving the academic nature of ARUP. He consolidated research and development into one unit.

2008

ARUP purchases a building at 560 Arapeen Drive. The Transportation Department moves to a new airport facility.

2009

ARUP Blood Services opens a 15,000-square-foot facility in Sandy, Utah. Kjeldsberg retires. Edward R. "Ed" Ashwood, MD, becomes ARUP's president and third CEO.

2011

ARUP expands its no-cost employee clinic into a fully staffed Family Health Clinic.

2012

ARUP assumes testing oversight for the University of Utah community clinics and South Jordan laboratories.

"One of the most important things that we do here is treat our workforce well, so they can turn around and forward that treatment on to the patients and the doctors."

Andy Theurer, CEO

Key figures from ARUP reflect on the past 40 years and look toward the future in a special video. **Watch now.**

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R&D is central to what we do as a reference lab. You need to look at the future, develop tests, get them into production in our clinical laboratories, and provide them for the people we serve across the country," said Peter Jensen, MD, chairman of the U Department of Pathology and the ARUP Board of Directors.

Around this same time, a sendout supervisor at a Texas hospital complained about ARUP's downtime and said that ARUP needed to move to 24/7 operations to compete with the "big boys." ARUP employees mostly went home in the late evenings and on weekends, but hospitals were under increasing pressure to keep patient stays to a minimum, meaning they needed lab results fast. Another physician in California complained that no one at ARUP was answering the phone on July 24.

"The head of Marketing, Don Wood, picked up the phone, and there was an angry voice saying, 'Why are you not answering the phone? I've been calling for almost a half-hour.' Wood said it was Pioneer Day (a Utah state holiday), and the physician said, 'We don't have Pioneer Day here, and unless you guys get your act together, I'm not going to send any specimens to ARUP.' From that day on, we worked every day," Kjeldsberg said.

1999: ARUP Exits the Corporate Drug Testing Business

Throughout the years, although some business ventures worked well, leaders eventually decided that others did not fit ARUP's commitment to put patients first. In 1985, ARUP embarked on workplace drug testing for an oil-drilling company that wanted its employees tested for marijuana, and other sectors were becoming interested in drug testing as President Ronald Reagan's "War on Drugs" was taking off. ARUP was certified to test federal employees for drug use in 1989 and was the 35th lab in the nation to be given this status. Despite performing thousands of tests every month, ARUP's profit margins on drug testing were small, and its core mission centered on patients' health, not the corporate world. Ten years after it was created, ARUP would turn over its corporate drug testing business to Northwest Toxicology and refocus on clinical testing.

2015

Under Hawker's guidance, ARUP implements the MagneMover LITE automation track system to move specimens through the lab at 2 meters per second, which enables ARUP to manage 7,000 specimens an hour.

Dean Li, MD, PhD, serves as ARUP's interim CEO.

2016

Edgar Braendle, MD, PhD, becomes CEO.

2017

Sherrie L. Perkins, MD, PhD, is named CEO and becomes the first woman CEO of a major reference laboratory in the United States. Andy Theurer is named president after serving as chief financial officer (CFO).

Don Wood, head of Marketing (seated on right), confers with Kjeldsberg.

This image and tagline were used on ARUP's drug testing brochure.

ARUP was also briefly in the veterinary testing business, but the lab work was difficult. First, veterinarians wanted more detailed analyses of cultures for their horse, cattle, and canine specimens than hospitals were requiring for humans. Second, most of ARUP's lab instruments were not designed for animal specimens. Finally, the samples came in all shapes and sizes.

"A bird would die, and they would send us the whole bird," said Peggy Ahlin, former senior vice president, director of Quality and Compliance. "There was a diarrhea outbreak at Hogle Zoo. We got buckets of samples." Eventually, the animal testing was discontinued.

Andy Theurer in 2001.

2001: ARUP Obtains Tax-Exempt Status

ARUP was founded as a for-profit entity, and for the first 16 years, paid taxes. In 1997, the Utah Tax Commission audited the lab, found that ARUP suppliers were not charging sales tax on out-of-state purchases, and said the lab owed $1.3 million from the previous four years.

"We did not have money. We were borrowing money to make payroll," said Theurer, who was ARUP's controller at the time and was tasked with fixing the tax bill. Theurer worked with a tax consultant named

2017

ARUP earns International Organization for Standardization (ISO) 15189 status from the College of American Pathologists (CAP). Hawker coauthors a report detailing ARUP's 25-year journey toward achieving the prestigious Six Sigma score for lost specimens.

2018

ARUP partners with Techcyte Inc. to develop the world's first artificial intelligence (AI)-augmented ova and parasite detection tool, which sets the stage for expansion of digital diagnostics.

2020

On March 12, ARUP begins molecular diagnostic testing for COVID-19 under the leadership of Chief Medical Officer (CMO) Julio Delgado, MD. In September, Delgado transitions into an executive vice president role, and Tracy George, MD, is named CMO. On November 7, ARUP verifies its 1 millionth COVID-19 result.

Glenn Bartholomew, who after six months of research, found a little-known provision in the federal tax code permitting companies to claim a federal income tax-exempt status if they provided an essential government function. Theurer saw an opportunity that aligned with ARUP's academic research role, teaching mission, and financial commitment to the university, but he had to convince the Executive Committee, whose members did not agree at first, and the university. Theurer eventually received permission to pursue the tax exemption, but it set up a three-year battle with the Internal Revenue Service.

"They sent out three teams of the top brass to shut this down, and every one of them agreed with our assessment. In April 2001, the Internal Revenue Service issued us a rare private letter ruling granting tax-exempt status, and that completely changed the financial complexion of ARUP," Theurer said.

"It was the start of a fantastic relationship that tied ARUP's success to the university's success. We take some of the money we would pay in tax and distribute it to the university," Theurer explained. "The model has served us well. I meet with the university president once a quarter, and as I tease him, I have several million reasons to meet with him because we give a quarterly distribution at that meeting."

2002: ARUP Averts a Plan to Sell the Company

Despite ARUP's nonprofit status and the promise of ongoing revenue to the U, the possibility that ARUP could be sold persisted. University President Bernie Machen, DDS, MS, PhD, considered a sale in late 2000 and hired consultants to determine ARUP's worth.

Kjeldsberg and U President Bernie Machen, DDS, MS, PhD, entered a memorandum of understanding in 2002 that ARUP was not for sale.

"For months, I was carrying this terrible secret. People in dark suits were touring the laboratory. I made them take off their jackets so at least it would not be so obvious to the employees," Kjeldsberg said.

The attractiveness of a sale lost its luster when the market cooled after the 9/11 terror attacks, and the price dropped 75%. To keep the U from selling ARUP, Kjeldsberg entered a five-year memorandum of understanding with Machen in 2002, giving the president $5 million annually for keeping the company within the university.

The sense of relief did not last long. By January 2003, the venture capital group, Sorenson Capital, was interested in ARUP, and Machen's legal counsel had determined that the memorandum was not a legally binding document. Kjeldsberg said he was incredibly angry.

"I couldn't believe it. We had just signed an agreement, and to make things worse, the proposal was loaded with financial

2021

Andy Theurer is named CEO after more than 30 years with the company. George is named president and continues in her role as CMO.

ARUP opens its newest building, Building 4. Every aspect of the new building has been carefully designed to optimize large-scale laboratory operations and position ARUP for future growth.

In 2018, Jensen, Perkins, and Theurer helped break ground for Building 4 using ceremonial gold shovels.

incentives for ARUP executives. They wanted to buy me and some of the other executives," Kjeldsberg said.

ARUP's mission was to advance laboratory medicine and put patients first, not necessarily to make money. The Executive Committee opposed the sale unanimously, and a very influential ARUP board member resigned in protest, Theurer said.

"Nobody on the Executive team was interested in personal gain on the backs of everybody who built ARUP. I remember having a frank conversation with then-CEO Carl Kjeldsberg, who said, 'Andy, we need to do everything we can to stop this deal. It is not good for ARUP, the workforce, our patients, the University of Utah, or the state,'" Theurer recalled.

Kjeldsberg and his team made an 11th-hour effort to derail the sale, offering loans and cash to the U. Meanwhile, Machen and the trustees were having second thoughts over the economics of the deal, which would plunge ARUP into debt, and eventually came to the decision that ARUP should be kept under the university's umbrella. The financial advantages of the tax-exempt status ARUP enjoyed as a university entity would have been lost in a sale.

In April 2003, Machen called Kjeldsberg to say the deal was off, but he wanted a bigger cut from ARUP. He wanted a flat-percent share of annual revenue, and Kjeldsberg reluctantly agreed to the new deal.

2008: Major Real Estate Purchases Secure Building 560 and Expansion of Central Facility

ARUP continued to grow during the early 2000s, adding Building 1.5 in 2003, which included a two-story freezer capable of storing more than 2 million specimens for up to one year. The freezer, still in operation, uses a robotic system and custom software to control access to specimens and their storage trays, reducing the incidence of handling errors and premature discards.

In the fall of 2008, needing even more laboratory space, ARUP purchased a building at 560 Arapeen Drive, moving administrative employees to the new space over the course of a year and freeing up prime lab space in the main facility. Buildings 585 and 606 were purchased around the same time, and ARUP leased what is known as the "Triangle Parking Lot" long term. Theurer said the transactions were strategic, gave the company bargaining power to also purchase the buildings that made up the central facility, and allowed for further expansion.

2022

Jonathan Genzen, MD, PhD, is named CMO, and Adam Barker, PhD, becomes chief operations officer (COO). Consultative Services is rebranded as ARUP Healthcare Advisory Services.

2023

The ARUP Institute for Research and Innovation in Diagnostic and Precision Medicine™ (R&I Institute) is formed under the direction of George, chief scientific officer and president of the Innovation Business Unit.

ARUP earns FDA approval for AAV5 DetectCDx™, a first-ever companion diagnostic immunoassay for a gene therapy.

2024

ARUP's University Business Unit is created, led by President Dan Albertson, MD.

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Ed Ashwood, MD

Dean Li, MD, PhD

Edgar Braendle, MD, PhD

Sherrie Perkins, MD, PhD

Edward R. "Ed" Ashwood served as ARUP's third CEO until 2015. Dean Li was the interim CEO until Edgar Braendle took the leadership role in August 2016. Sherrie Perkins was chosen for the CEO role in 2017.

> ***"When COVID first hit, our testing volumes went down by over 65%. My main mission was to keep the company together and not have to let anyone go."***
>
> Sherrie Perkins, MD, PhD,
> Former CEO

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"In the beginning, we were leasing from a local developer, and that relationship was great. Years later, the buildings were sold to a real estate investment trust, and every time we needed to make changes or remodel labs, which was often, the rent would go up. I built a plan to move the entire campus down to the plot where the Triangle Lot is now—and leaked it. Suddenly, the trust wanted to sell, and now we do not answer to a landlord," Theurer said. "That also gave us undeveloped land for what became Building 4, and land for future growth."

4 CEOs in 4 Years

Kjeldsberg retired as CEO in 2009 after more than 16 years as the head of ARUP. Edward R. "Ed" Ashwood, MD, served as president and ARUP's third CEO until 2015. Then, Dean Li, MD, PhD, stepped into the role as interim CEO until Edgar Braendle, MD, PhD, took over in August 2016. Since ARUP is owned by the U, leaders there had tremendous influence on the leadership at the company.

Vivian Lee, MD, PhD, MBA, the U's senior vice president of health sciences from 2011 to 2017, wanted a different trajectory for ARUP and chose Braendle, whose background was in the pharmaceutical industry and who had little experience with laboratory testing, to focus beyond lab tests and on medical device creation. Lee also wanted ARUP to consider collaborating with Theranos, the then-darling of Silicon Valley that promised a perfect marriage between technology and healthcare. The now-defunct company claimed it could run hundreds of blood tests from a single, tiny sample, and Elizabeth Holmes, the former CEO, is serving time in prison for fraud.

Lee resigned from the U not long after Braendle's arrival, and ARUP's board decided the leader of the company should have extensive experience in laboratory medicine. They chose Perkins, a renowned hematopathologist and already a member of ARUP's Executive Committee, as CEO, and she wanted a partner at her side.

"I chose Andy Theurer to help me because I didn't have a lot of business

background. I had been an academic my whole life, with a career focused on research, teaching, clinical work, and some administration," Perkins said. "He and I were able to build a very solid team that did great clinical medicine and combined it with academics and business."

Perkins was the first woman to serve as CEO of any major reference laboratory. ARUP has since been honored as one of 100 Utah Companies Championing Women, and Forbes magazine included ARUP on its list of the nation's Best Employers for Women.

2020: COVID-19 Pandemic Changes Everything

In December 2019, a cluster of patients in China experienced the symptoms of a pneumonia-like illness that did not respond well to standard treatments. ARUP closely followed the developments and started working on a test. Under the leadership of ARUP's chief medical officer at the time, Julio Delgado, MD, MS, ARUP's medical director of Molecular Infectious Diseases, David R. Hillyard, MD, was instrumental in validating one of the first high-throughput COVID-19 diagnostic tests in the country. Hillyard and his colleagues in R&D validated the test in three days and opened testing on March 12, fast-tracking the normal six- to 12-month validation process.

"Without the expertise of the R&D staff, their familiarity with the process, and their adaptability, validating a test at this speed would not have been possible," Hillyard said.

"Our quality is extremely important to us. Within two days, the demand from our customers was so high, we could not meet it," Jensen said. ARUP had to shut down testing, find lab equipment, knock down walls to create space for new labs, and hire staff to deal with the rapidly increasing volume of COVID-19 test orders. Jensen said the experience benefited the company.

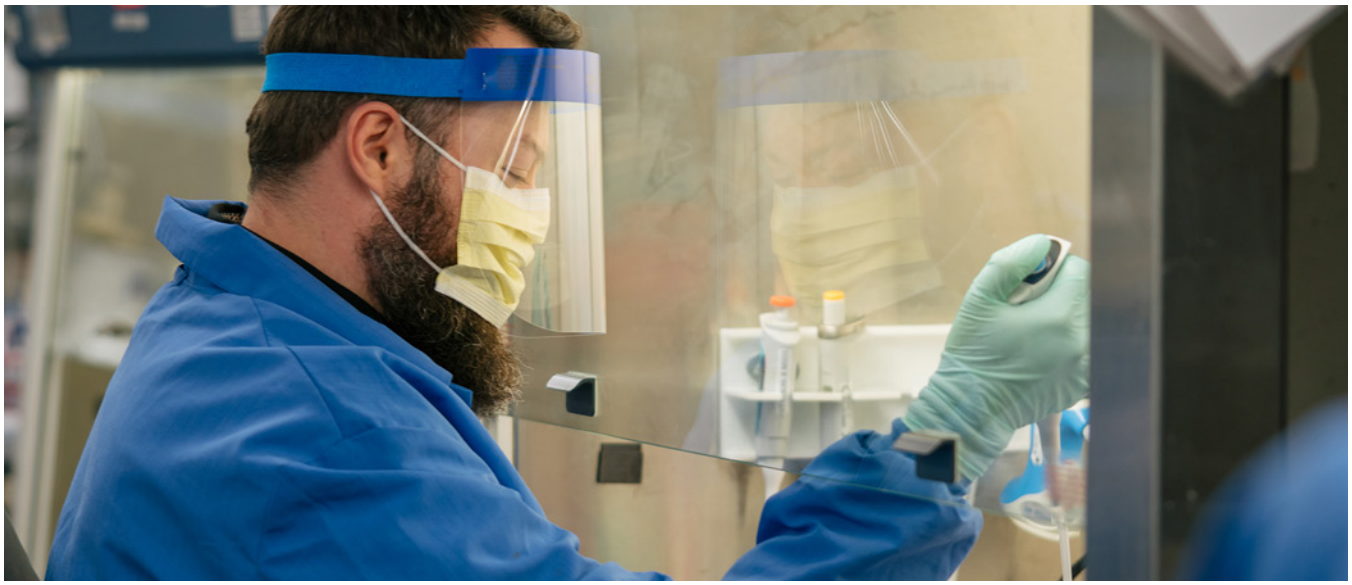
"We learned that we can be nimble, that we can do things rapidly and still do them well," he said.

By March 11, more than 4,200 people worldwide were reported to have died due to COVID-19, and the World Health Organization declared COVID-19 a pandemic. That same day, Utah Jazz center Rudy Gobert tested positive, and the NBA suspended the season. Within days, states across the country began to implement shutdowns, and Utah was no exception. Gary Herbert, then governor of Utah, called for public schools to close for two weeks on March 16, but they would remain closed through the end of the school year.

"When COVID first hit, our testing volumes went down by over 65%. My main mission was to keep the company together and not have to let anyone go. Our employees are number one. The executives decided to take salary cuts to make sure that ARUP's workforce and the company were intact when life returned to normal," Perkins said. People united in the mission to serve patients and keep ARUP going. Many employees also offered to take pay cuts and fill in wherever they were needed.

ARUP faced many challenges in early 2020, including how to ensure the health and safety of employees required to be on-site, how to navigate the uncertainties of childcare, and

A woman producing saliva for a COVID-19 test. An ARUP and University of Utah study determined that saliva specimens were as effective for detecting the SARS-CoV-2 virus as the deep nasopharyngeal swabs.



Jeremy Klein, BS, MB(ASCP)^{CM}, group manager of Technical Operations in Integrated Oncology and Genetics, performs a COVID-19 test.

how to keep morale up. "Trying to support our employees as much as possible was really the primary focus of the Executive team through much of COVID," Perkins said.

On March 15, the first ARUP employee was diagnosed with COVID-19. Immediately, the ARUP Family Health Clinic, which provides primary care for more than 12,000 patients, shifted toward telemedicine as much as possible. The clinic worked closely with Corporate Safety and Information Technology teams to develop a COVID-19 reporting tool to track and organize employee cases and to moderate risk and exposure. As cases increased, the clinic partnered with the Facilities Department to build an on-campus specimen collection site for employees and their families, keeping the labs and facilities safely staffed.

Delgado, now ARUP executive vice president and the vice chair and chief of the Division of Clinical Pathology at the U, recalled vividly the mission to protect the workforce's health and their jobs.

"I remember with so much gratitude how quickly ARUP was able to identify the tools to prevent any type of risk of exposure, how quickly we were able to offer the vaccine to individuals, and making the important decision to not lay anyone off," Delgado said. "I am very proud of how we acted."

On March 18, a 5.7-magnitude earthquake rocked Salt Lake City shortly after 7 a.m. while ARUP executives were meeting to discuss the COVID-19 response.

"Everybody immediately ran for cover under my desk. Eight or ten of us were cheek to cheek, wondering what was happening, and I was thinking, 'On top of everything, now we have to deal with an earthquake?' The gravity of the situation had us all nervously laughing," said Delgado.

ARUP struggled with supply shortages but used research and innovation to create its own solutions. When a shortage of the media needed to transport specimens in test collection kits occurred, ARUP's Reagent Lab moved quickly to formulate a saline transport media for COVID-19 testing. They also developed their own media, ARUP Transport Media™, to use as an alternative to universal transport media (UTM) when the world's only supplier of UTM was unable to meet global demand.

ARUP also utilized the expertise of its researchers to identify solutions. An ARUP and University of Utah study determined that saliva specimens were as effective for

From left to right, Jonathan Genzen, MD, PhD, chief medical officer, Perkins, Theurer, and Jensen cut the ribbon opening Building 4.

detecting SARS-CoV-2 as the deep nasal swab specimens that were used initially. This research made it possible for ARUP to develop and launch a COVID-19 test that used saliva specimens, rather than hard-to-acquire nasopharyngeal swab specimens.

ARUP was sharing knowledge and sharing supplies. Adam Barker, PhD, then director of R&D, said he and Michael Bevan, vice president of supply chain and manufacturing operations, were driving around at night dropping off testing kits and reagents to hospitals because they had run out.

"Our focus was and is patient care. We were basically making sure that all labs, no matter who it was, were running, so everyone's patients could get the testing they needed," Barker said. Once ARUP scaled up testing, was in a groove with hybrid work, and had navigated the impact of COVID-19 on the bottom line, Perkins put the focus on making testing the most effective possible with automation and a state-of-the-art new building.

2021: Building 4 Opens

ARUP's newest 220,000-square-foot building opened in 2021 and increased the company's square footage by 45%. Seeing the need for continued growth, Perkins reactivated plans for the space shortly after accepting the CEO role and saw the project through to completion. The new building includes the

"We are looking five and 10 years down the road to develop partnerships, technologies, and laboratory tests that will benefit patients and healthcare systems."

Tracy George, MD, Chief Scientific Officer and Innovation Business Unit President

Key figures from ARUP reflect on the past 40 years and look toward the future in a special video. **Watch now.**

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> ***We have seen how other reference laboratories that are spread out across the country are fraught with problems involving lost specimens."***
>
> Andy Theurer, CEO

Key figures from ARUP reflect on the past 40 years and look toward the future in a special video. **Watch now.**

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Mountainside Café, Specimen Receiving (SR) and Specimen Processing operations, Mass Spectrometry Labs, automated Chemistry and Immunology Labs, and an entirely new track automation system.

The automation system allows for groups of 20 specimens to be transported in a single rack. The previous system moved one specimen along the automated track at a time. Automation also improved workflow and decreased turnaround times in the expanded Automated Core Lab, bringing manual touches down from 26 to eight. All areas of SR are centralized on the fourth floor, creating efficiencies.

"Our advanced automation has already allowed us to achieve Six Sigma standards, particularly in the area of number of lost specimens," said former Operations Director Clint Wilcox, who oversaw the automation project.

Hidden above ceilings, tucked into floors, and even in a tunnel are mechanical, electrical, piping, and other flexible systems that also allow for scaling up and adaptation. To ensure laboratories can operate 24/7 without disruption, redundancies are built into the electrical, heating, ventilation, and air conditioning systems. The sophisticated ventilation system exchanges the air within the labs with fresh air up to 14 times an hour to ensure specimen viability and for the benefit of laboratorians. A total of 18,500 square feet of windows allows for plenty of natural light and mountain views.

"In designing this building, we absolutely aimed to create an environment that would increase happiness and satisfaction among our employees," said Jonathan Genzen, MD, PhD, chief medical officer. "If our staff is happy, we collectively accomplish great things."

The Mass Spectrometry Labs include three separate chemical control areas to ensure safe use of chemicals and include 120 mass spectrometers, which demand an enormous amount of power. A custom exhaust system extracts heat from the equipment, providing for more accurate and reliable testing for patients.

Today, ARUP owns eight buildings in Research Park that include more than 65 labs and encompass 750,000 square feet of physical space. ARUP has intentionally kept most of its nearly 4,300 employees and labs centralized.

"We have seen how other reference laboratories that are spread out across the country are fraught with problems involving lost specimens," Theurer said. "It is a competitive advantage to have testing in one place, and it also allows for in-person collaboration among our experts."

**Six Sigma quality is a method to identify defects in a process and eliminate them to get as close to zero as possible. A typical Six Sigma goal is 3.4 defects per million opportunities.*

Dan Albertson, MD, is the president of the University Business Unit and division chief of Anatomic Pathology and Solid Tumor Molecular Pathology.

2023 and 2024: New Business Units Formed

ARUP has seen tremendous growth during the past 40 years and has expanded from about 100 employees to more than 4,300, from just a few tests to more than 3,000, and from one building to eight. The company has started to adopt a new multidivisional corporate structure to respond strategically to its growth. Part of its strategy involves creating new business units to ensure focus on innovation and the university, from which the company began.

The ARUP Institute for Research and Innovation in Diagnostic and Precision Medicine™ (R&I Institute) was formed in 2023 to accelerate groundbreaking diagnostic and prognostic technologies to drive life-changing innovation.

"Their whole task is to partner with other companies developing cutting-edge technologies so we can develop those technologies and bring them right into healthcare systems," Theurer said.

Led by Innovation Business Unit (IBU) President Tracy George, MD, who is also ARUP's chief scientific officer, the unit includes R&D, the R&I Institute, the Clinical Trials group, and the PharmaDX group, which is focused on development of companion diagnostic tests to accompany novel pharmaceuticals. One such test is AAV5 DetectCDx™, the first FDA-approved companion diagnostic immunoassay.

The Clinical Trials group provides clinical research organizations, pharmaceutical and biotechnology companies, in vitro diagnostics (IVDs) manufacturers, and clinical and academic trials and projects with access to ARUP's broad clinical test menu.

Tracy George, MD, is the chief scientific officer and president of the Innovation Business Unit.

The Hamiltons celebrated Thanksgiving in 2022 with their grandchildren, two months before Frank passed away. From left to right, Lily, age 6, Frank Hamilton, Evie, age 2, Luke, age 6, Leslie Hamilton, and Beau, age 4.

The History of ARUP's Logo

John M. Matsen, III, MD, went to the University of Utah's Graphic Arts Department for help with the ARUP logo in March 1984. Within days, designers Steve Engen, son of legendary ski industry pioneer Sverre Engen (brother of Alf Engen), and Jamie Omer came up with the blood-red, test tube U—a design that has stood for four decades with very little evolution.

Then

ARUP® Laboratories

Now

ARUP® LABORATORIES

The establishment of the R&I Institute as an entity dedicated to innovation signaled a new era as ARUP moved to intensify its efforts to accelerate invention and discovery.

"We are looking five and 10 years down the road to develop partnerships, technologies, and laboratory tests that will benefit patients and healthcare systems. My team is smaller and hyperfocused on the long game, and that allows us to be extremely nimble. We know we will have some failures, but we will move on quickly and find many successes," George said.

ARUP's University Business Unit was formed in April 2024 and is led by President Dan Albertson, MD, who is also division chief of Anatomic Pathology and Solid Tumor Molecular Pathology. It is made up of all ARUP laboratory operations within the University of Utah Health system, as well as ARUP Blood Services. Albertson said the unit's goal is continuous improvement both in patient care and in operational efficiencies.

"It is important for me personally to approach every leadership position with service to others at the forefront," Albertson said. "As I help lead this new business unit, providing the highest quality laboratory testing to U patients will be the primary focus."

Work Worth Doing

Patients have been ARUP's focus from the beginning. With more than 20 million specimens now being tested annually, ARUP is impacting the care of nearly 17 million people every year. They include patients such as Hamilton's late husband, who was diagnosed with melanoma shortly after her retirement. Hamilton said next generation sequencing (NGS), performed at ARUP, pinpointed his cancer's genotype, and as his disease progressed and the medicine improved, clinicians could direct targeted therapy.

"My husband passed away after seven years, which is a tremendous time to survive with stage IV melanoma. It was because of the tests, the people behind the tests, and understanding what was working and not working," Hamilton said. "The work that we do here is important. It's work worth doing."

As ARUP looks ahead, there are plans for growth, including additional buildings, and a sense of gratitude in Theurer. "Not many companies last 40 years. It's worth marking the moment because ARUP is thriving. Some of the most brilliant minds in the world are right here, and with them, our success is ensured. I'm honored to be part of it."

Bonnie Stray, bonnie.stray@aruplab.com

Equipped with a wealth of knowledge and experience in diagnostic medicine and an abundance of problem-solving ingenuity, the visionary leaders of the Innovation Business Unit (IBU) will advance diagnostic medicine through strategic collaboration. Pictured (from left to right): Tracy George, MD; Robert Ohgami, MD, PhD, FCAP; Jay Patel, MD, MBA; Kristi Smock, MD; and Paul Osmundson.

Creating Ecosystems That Amplify Impact: ARUP's Innovation Business Unit Is Fast-Tracking Diagnostic Solutions Through Partnerships

In September 2023, ARUP Laboratories founded its Institute for Research and Innovation in Diagnostic and Precision Medicine™ (R&I Institute) as part of the creation of a newly formed, wider division, the Innovation Business Unit (IBU), that will lead focused efforts in diagnostic technology innovation.

Tracy George, MD, ARUP chief scientific officer and president of the IBU, spearheaded the formation of the new entity.

"We've created a division that is dynamic, nimble, and fast-paced to accelerate innovative developments in laboratory medicine, ultimately to benefit patients and improve patient care," George said. "We're focused on collaborating with like-minded partners who share our sense of purpose."

> ***"We have created a dynamic team of experts who bring deep expertise to accelerate innovations that have significant potential to meaningfully impact patient care."***
>
> Tracy George, MD, Chief Scientific Officer and President of the Innovation Business Unit

Within the IBU, the R&I Institute investigates emerging technology that has significant potential to alter the future of diagnostic medicine, even though it may be years away from use in clinical settings.

Robert Ohgami, MD, PhD, FCAP, vice president of the R&I Institute, explained that the institute is "creating ecosystems that foster innovation, break down barriers, and magnify patient impact."

Since its formation, the R&I Institute has established key partnerships with industry leaders, including an ongoing partnership with Tasso, a provider of blood collection solutions. Their novel blood collection device enables remote blood collection to support clinical trial recruitment. As part of this collaboration, ARUP has validated several assays for samples obtained by the device, which collects a smaller volume of blood than traditional blood draws. ARUP's teams will continue to validate more specimens for additional assays.

The IBU also includes ARUP's PharmaDx and Clinical Trials groups, which are led by Jay Patel, MD, MBA, vice president.

Through the efforts of Patel's team, ARUP Laboratories' companion diagnostic test, AAV5 DetectCDx™, received FDA approval, becoming the first companion diagnostic immunoassay approved for a gene therapy on June 29, 2023.

The milestone represents the culmination of nearly a decade of dedicated effort by the members of the PharmaDx group, whose perseverance and expertise have proven essential to develop a high-quality assay that meets the rigorous regulatory requirements of both the FDA and the European Commission and is scalable for clinical use globally.

"PharmaDx exists to meet the unique need that biotech and pharma companies have for companion diagnostic devices, especially in rare diseases," Patel said. "Due to our strong values and dedication to patient needs, ARUP is well positioned to address the need for companion diagnostics."

The ARUP Institute for Clinical and Experimental Pathology® (R&D) forms the final piece of the strategic approach. Led by Kristi Smock, MD, R&D concentrates on the development of new tests that have established clinical utility. R&D also supports ARUP's 70-plus laboratories to ensure continued efficiency and quality.

"ARUP is known as a high-quality laboratory, and R&D plays a significant role in maintaining the quality of the tests on our test menu. We have a whole team that maintains, updates, improves, and develops new tests," Smock said.

For example, as a result of R&D's efforts, ARUP has recently launched its Rapid Acute Myeloid Leukemia Targeted Therapy Mutation Panel. The panel provides a tool to rapidly assess mutations and identify prognostic markers so that effective targeted therapies can be started promptly.

R&D celebrated 25 years in operation in 2021.

The IBU combines the right experts with ARUP's exceptional operational proficiency to push the boundaries of diagnostic medicine.

Tracy George is ARUP chief scientific officer and president of the Innovation Business Unit.

"We have created a dynamic team of experts who bring deep expertise to accelerate innovations that have significant potential to meaningfully impact patient care," George said.

Tracy George, MD: Visionary Who Leads Transformative Breakthroughs

Tracy George, MD, joined ARUP Laboratories in 2018 as the director of PharmaDx and Clinical Trials. Under her leadership, PharmaDx and Clinical Trials experienced substantial growth. Later, she served as chief medical officer, leading ARUP's labs through COVID-19. Now, George has spearheaded a more concentrated effort to drive innovation. She has played a key role in the formation of ARUP's Innovation Business Unit (IBU), and now serves as president of the IBU and as ARUP's chief scientific officer.

Which experiences in your life led you to become a pathologist? An innovator?

George: I met a pathologist, Susan Atwater, MD, while working as part of a summer honors program at the Lawrence Livermore National Laboratory at the University of California, Berkeley (UC Berkeley). Dr. Atwater invited me to do a rotation with her in medical school at the University of California, San Francisco (UCSF) that further led me to explore pathology and laboratory medicine as a potential career. Years later, I worked with Dr. Atwater as a colleague at Stanford University in the Department of Pathology.

I have participated in biomedical research since I was in college and particularly enjoyed working on translational research that bridges basic scientific research with clinical medical practice. I worked on a project that used fluorescence in situ hybridization (FISH), a novel technique at the time, to detect chromosomal abnormalities in bladder cancer. I remember speaking to one of my professors at UC Berkeley about the potential of FISH. He did not think that the technology was useful, but I disagreed. Now, FISH is routinely used in many areas of medicine, including the detection of chromosomal abnormalities in various neoplasms.

I also consulted for various startups during my time as a faculty member at Stanford, which further cemented my interest in innovation.

Which accomplishments are you most proud of at this point in your career?

George: I have held many roles that have allowed me

to influence the development of new therapies and technologies to further improve patient care, through my own research and through various leadership opportunities. I've continued to engage in translational research, including a seven-year, international, multi-institutional clinical trial that culminated in the development of a new therapy for systemic mastocytosis (SM), [the results of which were] published in the New England Journal of Medicine. I've participated in many other clinical trials for new therapies for SM. At ARUP, I was appointed chief medical officer during COVID-19 and led ARUP's medical directors as we navigated the challenges the pandemic posed. Now, I serve as chief scientific officer and president of the newly formed IBU.

Why have you chosen to focus on innovation?

George: Innovation is fun! I find it deeply satisfying to brainstorm problems with our exceptional team members and to find solutions through new technologies and tools. Innovation is fundamental to develop advancements in medicine.

Which aspects of your expertise and experience do you believe will contribute most to the success of the Innovation Business Unit?

George: Working at different institutions with different people has allowed me to have a great deal of experience in medicine that spans a wide range of laboratory settings. I have led individual clinical laboratories at academic hospitals, including Stanford and Lucile Packard Children's Hospital (LCPH); the Genetics and Cytometry Laboratories at TriCore, a regional reference laboratory; and I have served as the chief medical officer at ARUP, a national reference laboratory. In addition, I've gained business experience while sitting on the board of directors of a family-run business for many years and through consulting with startups while working in the Bay Area. I've developed an approach to leadership that will contribute most to the success of our IBU: First, choose the right people. Second, create a leadership structure that makes sense with your leaders. Third, give leaders responsibility, authority, and resources to do their job. Fourth, allow your leaders to lead (don't micromanage). Fifth, share the success and learn from opportunities for improvement.

Which opportunities for innovation in laboratory medicine are you most excited about, and why?

George: I am most excited about applied artificial intelligence (AI) and its potential to solve targeted problems in pathology and laboratory medicine. AI will provide new tools to solve existing problems, and, in terms of opportunities for improvement, the sky is the limit!

From your perspective, which obstacles do innovators in laboratory medicine face? How is ARUP positioned to help address those challenges? How will you use your expertise and experience to help address those challenges?

George: There are many challenges in laboratory medicine for innovators, including technical, regulatory, funding, and staffing challenges, and challenges of access to subject matter expertise. ARUP has significant experience in all of these areas, with outstanding staff members who can aid our partners in overcoming those challenges. Collaborations between industry and academia serve as a great way to expand expertise, combine resources, and thrive together.

Why should industry partners choose to collaborate with ARUP?

George: We have amazing physicians and scientists here at ARUP, and we all agree that our mission is to improve patient care. Our track record demonstrates ARUP's capability to

"ARUP is known as a high-quality laboratory, and R&D plays a significant role in maintaining the quality of the tests on our test menu. We have a whole team that maintains, updates, improves, and develops new tests."

Kristi Smock, MD, Vice President of the ARUP Institute for Clinical and Experimental Pathology®

Robert Ohgami (center) converses with fellow founding members of the R&I Institute, Erica Clyde (left) and Hunter Best, PhD, FACMG (right).

innovate and collaborate with industry partners. We are the number one laboratory of choice for those who are looking for the highest quality and most innovative reference lab.

Robert Ohgami, MD, PhD, FCAP: Fearless Innovator To Magnify Patient Impact

Robert Ohgami, MD, PhD, FCAP, serves as the vice president for the ARUP Institute for Research and Innovation in Diagnostic and Precision Medicine™ (R&I Institute). Ohgami has spent his career dedicated to translational research, including important breakthroughs in the development of next generation sequencing, such as targeted sequencing for myeloid neoplasms and diagnosis of lymphomas and leukemias.

Which experiences in your life led you to become a pathologist? An innovator?

Ohgami: In 2000, I began medical and graduate school training, intending to become a pediatrician. However, my interactions with pathologists, who were also my teachers and mentors, led me to rethink this path and ultimately choose pathology. I was captivated by its unique integration of science, clinical practice, research, and innovation. During graduate school, I worked with Mark Fleming, MD, DPhil, in his lab at Boston Children's Hospital. Dr. Fleming, an expert in hematopathology and iron metabolism research, seamlessly integrated clinical responsibilities, education, and research. Observing him make complex diagnoses

> ***"[The institute is] creating ecosystems that foster innovation, break down barriers, and magnify patient impact."***

Robert Ohgami, MD, PhD, FCAP, Vice President of the R&I Institute

and teach fellows, then rush back to the lab, solidified my decision to pursue hematopathology. He exemplified a fearless, curious mindset, embracing innovation. His advice, "Ignore what people say you ought to do; follow your own path," has been a guiding principle in my career.

Which accomplishments are you most proud of at this point in your career?

Ohgami: At this point in my career, I am most proud of the development and success of my students and mentees, our significant contributions to diagnostic pathology through translational research, and the synergy between these two areas. Leading the R&I Institute resonates deeply with me, as it embodies both groundbreaking translational research and an environment that emphasizes teaching and mentoring. The institute thrives on mutual learning and collaboration, extending from our internal team to our industry and academic partners, fostering the development of innovative diagnostics, and sharing knowledge through international presentations and publications.

In addition, my scientific and clinical contributions have elucidated the cellular origins of Castleman disease, genetic and environmental factors in blastic plasmacytoid dendritic cell neoplasm (BPDCN), mutational subtypes in pediatric lymphomas, and the immunophenotypic characteristics of indolent T-lymphoblastic proliferations.

Why have you chosen to focus on innovation?

Ohgami: My dedication to innovation stems from my dual role as a translational researcher and a practicing pathologist. Innovating has been a central theme throughout my career. I find my greatest sense of flow—a state of deep engagement and fulfillment—in creating and developing new technologies, and novel diagnostic approaches and insights, that are adopted and used by others. This process of discovery and creation is not just professionally rewarding but also deeply meaningful to me. Furthermore, ARUP Laboratories' commitment to magnifying patient impact resonates with my own values to prioritize innovative solutions to enhance patient care, which makes it the perfect environment.

Which aspects of your expertise and experience do you believe will contribute most to the success of the Innovation Business Unit?

Ohgami: The foundation of my contribution to the Innovation Business Unit (IBU) lies in my extensive experience in scientific research, diagnostic pathology, and leadership. My academic and practical journey, from graduate studies to leading translational research labs as a clinician scientist, has equipped me with valuable insights and skills. This experience, combined with my ongoing work in diagnostic pathology, ensures a relentless commitment to patient-centric innovation. Leadership roles at Stanford, University of California, San Francisco (UCSF), and ARUP have refined my ability to navigate complex organizational structures, teaching me the importance of knowing when to lead, how to lead with other leaders, and when to collaboratively follow.

Which opportunities for innovation in laboratory medicine are you most excited about, and why?

Ohgami: There are three opportunities for innovation in laboratory medicine that excite me: applied artificial intelligence (AI), big data, and genomic medicine. I am particularly excited about the potential of applied AI in laboratory medicine. This technology can revolutionize diagnostics by enhancing accuracy, efficiency, and consistency. At ARUP, we are already using simple forms of AI to rapidly diagnose myeloid malignancies and patients with inherited disorders via genomic sequencing. AI algorithms can analyze complex datasets faster and more accurately than traditional approaches, leading to fast and reliable diagnoses. The integration of big data in laboratory medicine presents a significant opportunity for innovation. With the vast amounts of data generated in laboratory medicine, big data analytics can uncover patterns and trends that were previously unnoticed. This can lead to breakthroughs in understanding diseases, developing new diagnostic tests, and improving patient care. My excitement about genomic medicine stems from its capacity to transform patient care through advanced diagnostic techniques, ultimately enabling personalized treatment plans.

From your perspective, which obstacles do innovators in laboratory medicine face? How is ARUP positioned to help address those challenges? How will you use your expertise and experience to help address those challenges?

Ohgami: Innovators in laboratory medicine face significant obstacles, including resource scarcity and the pressure of time constraints. These challenges necessitate the development of cost-effective and time-efficient solutions to enhance patient care and laboratory operations. ARUP is uniquely positioned to address these challenges through its strategic investment in research and innovation, coupled with its strong partnerships. This approach not only mitigates resource limitations but also accelerates the development and implementation of innovative solutions. Leveraging my expertise in collaborative research and

resource optimization, I will contribute to transforming these challenges into opportunities for advancement. My experience in strategic planning and implementation equips me to lead initiatives that efficiently manage time constraints to ensure rapid innovation and the adoption of new technologies. Furthermore, I am committed to advancing ARUP's capabilities in applied AI, big data analytics, and molecular medicine, areas where my research background aligns with the company's vision for leading innovation in laboratory medicine.

Why should industry partners choose to collaborate with ARUP?

Ohgami: Industry partners should choose to collaborate with ARUP due to our strong reputation for quality service, which forms the foundation of all our partnerships. However, true synergistic collaboration extends beyond just delivering quality service; it requires alignment on four critical levels: mission, sense of urgency, long-term strategic vision, and culture. Partners align with us on our mission to significantly impact patient outcomes through innovation. Our white-glove service, combined with a sense of urgency, ensures efficiency and timely deliverables. Our long-term strategic vision attracts partners looking for sustainable success, whereas our compatible cultures enable seamless collaboration.

Paul Osmundson: Building Synergy To Foster Successful Collaborations

Paul Osmundson is the vice president of Business Development in the Innovation Business Unit (IBU). Osmundson joined ARUP in 2023. He has extensive leadership experience in diagnostic sales, business development, marketing, payer relations, and strategy.

Which experiences in your life led you to become involved in business development in the innovation space?

Osmundson: As with most of us, I've felt the impact of family challenges and loss due to undiagnosed or misdiagnosed conditions, or poor outcomes that result from avoiding healthcare. Those experiences have given me purpose and drive to be involved in the development of new technologies, deliverables, and payment models that can positively impact the human condition.

Paul Osmundson is the vice president of Business Development in the Innovation Business Unit.

My career started in anatomic pathology and that led to molecular pathology and eventually clinical pathology. As I've witnessed advancement in medicine improve the treatment of medical conditions, it's inspired me to be part of the efforts that drive clinical findings, lead to early diagnosis, and provide better therapies to improve patient lives.

Which accomplishments are you most proud of at this point in your career?

Osmundson: The most rewarding aspect of my work is hearing how projects, partnerships, and technology have directly impacted the quality of life, and even sustained life, for patients throughout their healthcare journey.

At one point in my career, I overheard a physician speaking with a patient going through the diagnosis process. The physician mentioned that the lab he was using was best in class and it would provide the necessary information to make the best decisions specifically for that patient.

As I listened to this example of how diagnostic solutions can empower physicians with the right tools to make decisions and provide care, I was honored to play a role in the development of those solutions.

Why have you chosen to focus on innovation?

Osmundson: I have found that leading technologic advancements is extremely rewarding, especially as we

realize solutions that can amplify patient impact when they are scaled and commercialized.

Which aspects of your expertise and experience do you believe will contribute most to the success of the Innovation Business Unit?

Osmundson: I excel at identifying individual synergies to move through seamless negotiations, as well as finding the right cultural and strategic fit to generate successful collaborations.

Which opportunities for innovation in laboratory medicine are you most excited about, and why?

Osmundson: First, advancements in neurology, and especially Alzheimer's disease, where we have a huge opportunity to impact patient lives with early detection and treatment. Second, the potential of genetics testing to identify predispositions for disease that may lead to predictive interventions. Third, digital solutions such as digital pathology, applied artificial intelligence (AI), and machine learning (ML) that will drive the future of medicine. The IBU is exploring many other technologies, strategies, and collaborations to advance medicine.

From your perspective, which obstacles do innovators in laboratory medicine face? How is ARUP positioned to help address those challenges? How will you use your expertise and experience to help address those challenges?

Osmundson: There is so much technology coming from all different sources. The tech industry has entered the healthcare space with exciting solutions, but they will need to navigate the rigid regulatory environment to ensure patient safety.

As academic subject matter experts, our team members can help guide our collaborators and industry partners through consultation, collaboration, and goal alignment.

Why should industry partners choose to collaborate with ARUP?

Osmundson: For those that require the highest standards that will truly impact a patient and those who manage their care, ARUP is clearly the best choice.

Jay Patel, MD, MBA: Building Dynamic Teams To Broadly Impact Diagnostic Medicine

Jay Patel, MD, MBA, is the vice president of PharmaDx and Clinical Trials at ARUP. After completing a hematopathology fellowship at Stanford University, Patel joined ARUP in 2014 as a medical director of Hematopathology. His leadership has led to key expansions in PharmaDx and Clinical Trials, as well as achievements such as obtaining FDA approval for ARUP's companion diagnostic, AAV5 DetectCDx™.

Which experiences in your life led you to become a pathologist? An innovator?

Patel: The revolution in molecular biology took place when I was a young student and sparked my interest in the underlying basis of disease. I'll always remember using a polymerase chain reaction (PCR) technique on our first day of freshman biology lab! This eventually led me to become a pathologist with a clinical focus on molecular diagnostics. I enjoy clinical practice but was drawn to work with ARUP's PharmaDx and Clinical Trials groups, now part of the Innovation Business Unit (IBU), because of the potential

"Due to our strong values and dedication to patient needs, ARUP is well positioned to address the need for companion diagnostics."

Jay Patel, MD, MBA, Vice President of PharmaDx and Clinical Trials

to improve the lives of large numbers of patients through innovation in diagnostics.

Which accomplishments are you most proud of at this point in your career?

Patel: I'm most proud of my role in building a strong and dynamic team that continues to learn, grow, and execute on behalf of the patients and clients we serve.

Why have you chosen to focus on innovation?

Patel: I love doing this work because we have the potential to broadly impact disease states and entire patient populations through innovation in laboratory medicine. There is an excitement that comes with doing work that is new and inherently difficult, which motivates me.

Which aspects of your expertise and experience do you believe will contribute most to the success of the Innovation Business Unit?

Patel: Through leadership of our PharmaDx and Clinical Trials groups, I have gained experience in leading high-stakes collaborations with biopharma companies of all sizes. These are complex, long-term engagements that bring great opportunity along with unique challenges. To position these partnerships for success and drive programs forward, our team brings a depth of expertise to bear across various functional areas, including project management, technical and laboratory operations, quality and regulatory affairs, as well as business development.

Which opportunities for innovation in laboratory medicine are you most excited about, and why?

Patel: The promise of precision medicine is slowly but surely being fulfilled, and laboratory medicine plays a key role. Diagnostic tools enable the precision medicine paradigm—the right therapy for the right patient at the right time—to become reality. As scientific advances drive progress in precision medicine, I am confident that laboratory medicine will continue to be a crucial piece of this puzzle.

From your perspective, which obstacles do innovators in laboratory medicine face? How is ARUP positioned to help address those challenges? How will you use your expertise and experience to help address those challenges?

Patel: The economic considerations at play in laboratory medicine are real and represent a formidable obstacle to laboratory medicine reaching its full potential. Through collaboration with multiple stakeholder groups, including payers, patient advocacy organizations, therapeutic companies, and in vitro medical device manufacturers, laboratory medicine providers can work to overcome these challenges.

Jay Patel (center) consults with fellow hematopathologists Robert Ohgami (left) and Madhu Menon, MD, PhD, FCAP (right).

Why should industry partners choose to collaborate with ARUP?

Patel: ARUP is an ideal partner for industry because our mission and values align well with the goals of most prospective innovative industry partners. We bring broad medical, operational, regulatory, and tactical experience to the table and can collaborate with partners in ways that other reference laboratories cannot.

Kristi Smock, MD: Driven To Improve Patient Care

Kristi Smock, MD, is the vice president overseeing the ARUP Institute for Clinical and Experimental Pathology® (R&D). She is a medical director of ARUP's Hemostasis/Thrombosis Laboratory and is active in the hemostasis/thrombosis professional community. Smock is the recipient of the Bill Roberts Award for Clinical Excellence in Laboratory Medicine and the Outstanding Teaching Award in Clinical Pathology at the University of Utah, and she was named a 40 Under

Kristi Smock is the vice president of the ARUP Institute for Clinical and Experimental Pathology®.

Forty honoree by the American Society for Clinical Pathology (ASCP).

Which experiences in your life led you to become a pathologist? An innovator?

Smock: I have always been motivated to understand how things work. In medical school, I came to understand pathology as the specialty that incorporates knowledge about mechanisms of disease with diagnostic applications in patient care. Through innovation, we can continuously advance our knowledge and applications to benefit patients.

Which accomplishments are you most proud of at this point in your career?

Smock: Through my role as an ARUP medical director in the Hemostasis/Thrombosis Laboratory and my involvement in the leadership of several national and international professional organizations, I'm proud to have provided excellent patient care for patients with bleeding and thrombotic disorders.

Why have you chosen to focus on innovation?

Smock: My primary goal is always to continuously improve patient care and outcomes, and innovation makes that possible.

Which aspects of your expertise and experience do you believe will contribute most to the success of the Innovation Business Unit?

Smock: I have worked at ARUP since starting my pathology residency in 2003. I have extensive experience as an ARUP medical director and University of Utah academic faculty member and have strong working relationships with individuals across the company and university. This institutional knowledge helps me facilitate the collaborations necessary to help R&D bring on impactful new tests and support ARUP's existing test menu.

Which opportunities for innovation in laboratory medicine are you most excited about, and why?

Smock: I'm most excited about the opportunity to develop laboratory testing that drives medicine to become more personalized for individual patients and addresses how disease manifestations and response to treatment vary from patient to patient. I see opportunities for this across diverse areas of laboratory medicine.

From your perspective, which obstacles do innovators in laboratory medicine face? How is ARUP positioned to help address those challenges? How will you use your expertise and experience to help address those challenges?

Smock: The ultimate goal for innovators in laboratory medicine is to implement new technologies and applications in clinical laboratories for the benefit of patients. To accomplish that, innovators need to consider how and when to incorporate new tests into the clinical practice landscape. For example, there needs to be clinical acceptance and consensus about how to interpret and act on the results. Reimbursement can also prove challenging in the early phase of a new test, when clinical uses are still emerging. The expertise present at ARUP, along with our excellent reputation in the field, enables us to navigate these challenges and to provide impetus in the medical community by disseminating our technical and clinical knowledge.

Why should industry partners choose to collaborate with ARUP?

Smock: Collaborating with ARUP has many benefits for our partners. We offer deep scientific and medical knowledge across laboratory medicine, and we know how to move the right technologies and tests from investigational stages to operationalized tests that meet rigorous quality and regulatory standards.

Kellie Carrigan, kellie.carrigan@aruplab.com

ARUP Alumni: 40 Years of Training the Best and Brightest

David G. Grenache, PhD, D(ABCC), MT(ASCP), Chief Scientific Officer and Laboratory Director of the Core Laboratory, TriCore Reference Laboratories; Clinical Professor of Pathology, University of New Mexico; ARUP Medical Director of Special Chemistry Lab: 2007–2017

Challenge Yourself and You Will Grow

David Grenache, PhD, D(ABCC), MT(ASCP), was working as an associate medical director at the University of North Carolina at Chapel Hill hospital laboratory in 2007 when he received a call. On the line was William L. "Bill" Roberts, MD, PhD, section chief of Chemistry and medical director of the Automated Core Lab at ARUP, a man whom Grenache knew only by his reputation in clinical pathology.

Grenache didn't know much about ARUP and wasn't looking for a job, but he was intrigued when Roberts told him about an opportunity to run the Special Chemistry Lab as its new medical director. When he told his then-partner that night about speaking with Roberts, his partner asked, "Are you going to go?" Grenache replied, "Of course not! We can't live in Utah. They don't let gay people in Utah." His partner encouraged him to give it a chance. "Well, don't you think that you should see it before you judge it?"

The visit to ARUP left Grenache highly impressed by the lab operations. With his partner, he decided to take the leap and pursue the opportunity. He saw it as a challenge professionally and personally, and has always tried to live his life with this personal philosophy: Challenge yourself and you will grow.

Now, years later, when Grenache looks back at this moment, he calls it the best career decision he ever made, thanks to the people at ARUP who influenced his career and allowed him to blossom: Roberts, Ed Ashwood (ARUP CEO from 2009 to 2015), and Carl R. Kjeldsberg, MD (ARUP CEO from 1992 to 2009), among many others.

> ***"Despite the often intense and serious nature of the work we did at ARUP, one could still always find a way to laugh and have fun."***
>
> **David G. Grenache, PhD, D(ABCC), MT(ASCP), Chief Scientific Officer and Laboratory Director of the Core Laboratory, TriCore Reference Laboratories**

In 2017, Grenache left ARUP for a new challenge as chief scientific officer of TriCore Reference Laboratories, a regional clinical lab serving the state of New Mexico.

When he reflects on his time at ARUP, Grenache remembers the feeling of being part of a community that rallied behind a single mission and vision, working toward continuous improvement and offering high-quality lab services.

"Despite the often intense and serious nature of the work we did at ARUP, one could still always find a way to laugh and have fun," he said.

Brian Shirts, MD, PhD, Director of the Institute for Public Health Genetics and Associate Professor in the Department of Laboratory Medicine and Pathology, University of Washington; ARUP Clinical Pathology Residency: 2008–2012; ARUP Molecular Genetic Pathology Fellowship: 2010–2011; ARUP Assistant Medical Director of Informatics: 2009–2012

> ***"In the best interest of patient care, healthcare providers are obliged to better communicate about hereditary cancer risk and family outreach."***
>
> Brian Shirts, MD, PhD, Director of the Institute for Public Health Genetics and Associate Professor in the Department of Laboratory Medicine and Pathology, University of Washington

The Perfect Combination

In 2008, Brian Shirts, MD, PhD, had just received his doctoral degree in human genetics from the University of Pittsburgh and was looking for a clinical pathology residency. ARUP Laboratories kept coming up again and again.

Shirts was no stranger to Utah. He had grown up in the state and earned a bachelor's degree in biology from the University of Utah. This combination of familiarity and the opportunity to train at one of the top laboratories in the country made the decision to accept a residency obvious.

Once at ARUP, he worked with Medical Director Brian Jackson, MD, MS, in informatics and laboratory test utilization management. The projects that had the most impact on Shirts were about how laboratory test results, including genetic test findings, can best be communicated to physicians and patients.

The principles he learned from Jackson inform his current work in familial cascade testing at the University of Washington. If an individual tests positive for a genetic condition, best practice calls for the individual to inform relatives so they also can be tested. This is cascade testing.

In reality, however, cascade testing doesn't always happen, so people who could benefit from the information aren't informed.

"In the best interest of patient care, healthcare providers are obliged to better communicate about hereditary cancer risk and family outreach," Shirts said.

This conviction led him to start a research project called ConnectMyVariant, which is based on the idea that if two people have the same pathogenic variant, they have a 90% chance of a common ancestor. Shirts' project is now a nonprofit and helps individuals with variants understand how to expand the outreach to connect with others who may need testing. He credits his time at ARUP for providing him with a productive, exciting, and interesting combination of academic and high-throughput reference laboratory work that he hasn't found anywhere else in the country.

"I really appreciated there was the culture [at ARUP] of patients first, and doing things that are right for the patient."

Alice To, alice.to@aruplab.com

Christopher Garcia, MS, MD, Medical Director, Division of Computational Pathology and AI, Mayo Clinic; ARUP Informatics Residency: 2013–2014; ARUP Assistant Medical Director of Informatics: 2012–2014

Implementing Clinical Artificial Intelligence With a Patient-First Focus

Christopher Garcia, MS, MD, now medical director of Mayo Clinic's Division of Computational Pathology and AI, took an unexpected turn toward medicine after he volunteered at a hospital emergency room (ER) in 2004. He had planned to build a career in web development and graphic design before his ER experience reshaped his priorities and inspired him to pursue a career in medicine long term. He remembers how good he felt at the end of each day he volunteered, knowing that he had helped someone.

Shortly after Garcia started medical school at the University of Illinois College of Medicine, he realized that he could combine his passion for web development with his desire to help patients by pursuing a career in health informatics.

In 2013, Garcia had the opportunity to study and practice health informatics at ARUP as a resident. While at ARUP, he worked with Medical Director Brian Jackson, MD, MS, on many applications, including Analyzing Test Ordering Patterns™ (ATOP®), a custom reporting tool designed to help clients use patient data to enhance lab test utilization and patient care, and ARUP Consult®, a clinician's guide to diagnostic testing.

As part of a student project at ARUP funded by the University of Utah Department of Pathology, Garcia developed a digital pathology platform that clinicians and students could use to upload deidentified slides and collaborate. This platform has been used globally, and as the primary contact to field user questions, Garcia received inquiries from people all around the world about the platform well after he left ARUP.

Garcia has since held positions at ARUP, Philips, Labcorp, and Mayo Clinic and said that ARUP played a vital role in cementing his patient-first values. "High quality and putting the patient first have colored the rest of my career. I bring that with me everywhere I go," he said. "It's helped me be a strong patient and physician advocate out in corporate America."

At Mayo Clinic, Garcia leads teams that are developing and implementing artificial intelligence (AI) in the clinical laboratory. As a medical director, he vets incoming projects, provides guidance, and offers solutions. His teams are expanding and taking on a variety of AI/machine learning (ML) projects.

Applications of AI/ML in medicine are far reaching and rapidly growing. Predictive AI analytics for cancer diagnosis and interpretation of the composition of kidney stones are some examples, Garcia explained. With each project, his team works hard to ensure that all solutions mitigate bias and are safe, high quality, and appropriately managed. He is excited about how AI/ML can be used to help patients, and is happy to have carried the knowledge and ethical awareness he acquired at ARUP to other healthcare companies.

> ***"High quality and putting the patient first have colored the rest of my career. I bring that with me everywhere I go."***
>
> Christopher Garcia, MS, MD, Medical Director, Division of Computational Pathology and AI, Mayo Clinic

Ryan Craig, MD, PhD, Residency Program Director and Assistant Professor, Tulane University School of Medicine; ARUP Anatomic/Clinical Pathology Residency: 2014–2018; ARUP Hematopathology Fellowship: 2018–2019

Paying It Forward: From ARUP Resident to Tulane Residency Director

In 2008, Ryan Craig, MD, PhD, now Tulane University School of Medicine residency program director and assistant professor, took a long camping trip through many of Utah's national parks. As someone from Louisiana, he had never seen anything like them. "I fell in love with the geography and the scenery, coming from Louisiana, where there's no snow, no mountains, none of that stuff," he said.

When he went back home and began missing the mountains, Craig knew he had to return. As a medical student at Louisiana State University, he knew the most efficient way to move to Utah would be to find a residency or fellowship program in the state and continue his education. After researching medical schools in Utah, he decided to apply for a residency at ARUP.

Beyond its proximity to natural beauty, ARUP offered Craig the opportunity to learn the ropes of pathology and conduct his own research with the help of expert medical directors. He also knew that pathology would be the best route for him because he could "be involved with patient care while pushing the frontiers of medicine through research and clinical trials."

Quickly after starting his residency, he knew he was in the right place. "I felt lucky that I was able to train somewhere that has such an extensive test menu, case volume, and talented faculty members with lots of specializations. It was an encouraging place to be."

Craig appreciates ARUP's focus on leadership training for its residents and fellows and attributes his successful career progression to this training. He learned how to collaborate with others and lead teams in a way that he had not learned through any other schooling. After returning to Louisiana and accepting a faculty role at Tulane, he quickly rose to a leadership position. Now, he holds multiple appointments at Tulane, including as director of its residency program.

His daily responsibilities include assisting with immunology research and counseling residents. He remembers his time as a resident fondly, and his favorite part of his job is showing the same support to his residents that he received at ARUP.

media@aruplab.com

> ***"I felt lucky that I was able to train somewhere that has such an extensive test menu, case volume, and talented faculty members with lots of specializations. It was an encouraging place to be."***
>
> Ryan Craig, MD, PhD, Residency Program Director and Assistant Professor, Tulane University School of Medicine

ARUP Laboratories Hosts Informational Webinar on the FDA's Rule To Regulate Lab-Developed Tests

ARUP Laboratories hosted an informational a webinar on May 23, 2024, for clients, members of the media, and others to discuss the FDA's rule to regulate laboratory-developed tests (LDTs) as medical devices. Jonathan Genzen, MD, PhD, ARUP's chief medical officer and senior director of governmental affairs, and Jonathan Carr, JD, chief compliance officer, summarized the details of the final rule and discussed the anticipated challenges for labs, patients, and providers.

The FDA released the final rule on April 29, 2024, without incorporating many concerns raised by ARUP Laboratories and other members of the clinical laboratory community. ARUP's stance on the rule has not changed, CEO Andy Theurer said. ARUP believes the FDA does not have statutory authority over LDTs and maintains that the rule will limit access to essential testing services, stifle innovation, and increase healthcare costs.

Jonathan Genzen, MD, PhD (left), chief medical officer and senior director of governmental affairs, and Jonathan Carr, JD (right), chief compliance officer, hosted an informational webinar on the FDA's rule to regulate lab-developed tests.

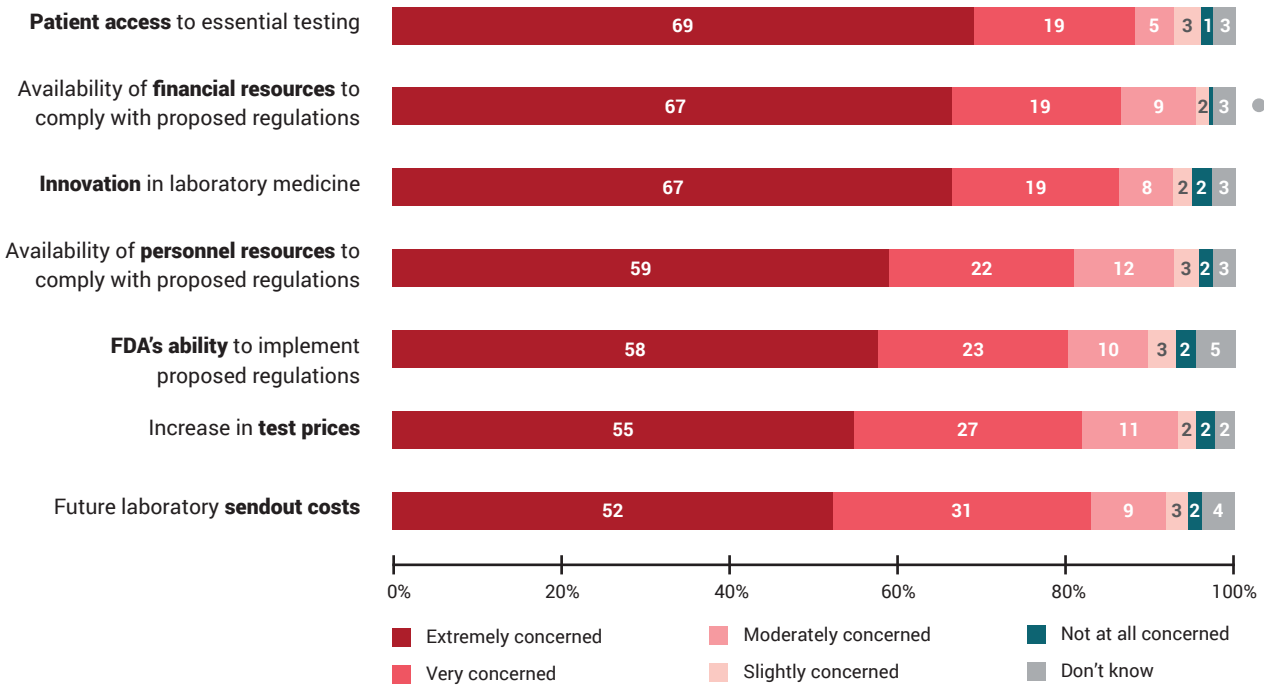
"ARUP is evaluating and reviewing the final rule, including any changes, internally and with our industry partners," Theurer said. "Our focus remains on supporting our patients and our clients to ensure they do not lose access to the essential services we provide."

"ARUP is committed to maintaining our extensive test menu and advocating at the national level on behalf of the clinical laboratory community and the patients we serve," Genzen added.

The final rule differs from the FDA's proposed rule published in October in that it permits enforcement discretion in some instances, such as for LDTs currently on the market and for those approved by the New York State Clinical Laboratory Evaluation Program (CLEP). Labs will have to comply with new record-keeping and labeling requirements for many of those tests.

The rule will be phased in over the next four years. In the first year, by May 6, 2025, laboratories that offer LDTs will be required to file medical device reports with the FDA. Year two adds requirements for registering and listing LDTs with the FDA. By year three, clinical laboratories will need to begin applying FDA quality system requirements (QSRs), and by year three and a half, clinical laboratories will be required to submit premarket approvals for high-risk LDTs. Current FDA user fees can be as high as $483,000 for each premarket

88% of respondents expressed strong concern regarding the proposed rule and patient access to essential testing.



Only 3% reported having sufficient financial resources to pay FDA user fees.

Support for FDA Proposal

Yes **8.2%**

No **71.6%**

Don't know **13.7%**

No opinion **6.6%**

Of 503 respondents, only 8% support the FDA's proposed rule.

Negatively Impacted by Rule

Yes **83.9%**

No **3.4%**

Don't know **12.7%**

Of respondents whose laboratories perform LDTs, nearly 84% believe the rule will negatively impact their laboratories.

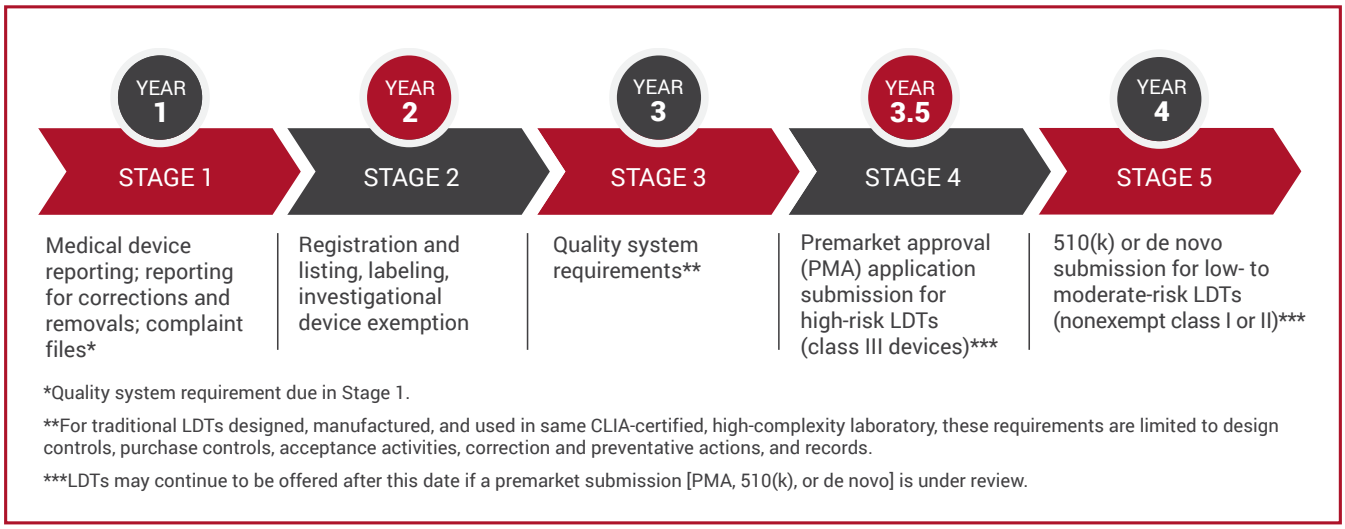
Remove Tests From Menu

Yes **60.9%**

No **5.9%**

Don't know **33.2%**

The majority of laboratories believe they will have to remove tests from their menus.



Access informational resources, including ARUP's statement in response to the final rule, results of ARUP's survey of the lab community's sentiments regarding the rule, and ARUP's public comment on this page:

aruplab.com/fda-ldt

authorization submission. The final stage, at year 4, adds premarket notification requirements for low- and moderate-risk LDTs.

In a November 28, 2023, public comment on the FDA's proposed rule, ARUP urged the FDA to withdraw the proposal, citing negative impacts to patient care and innovation. ARUP believes the FDA used exaggerated estimates of the number of LDTs ordered and flawed data about their performance. LDTs address a vital need and have an excellent performance record in ARUP's laboratories and in external proficiency testing.

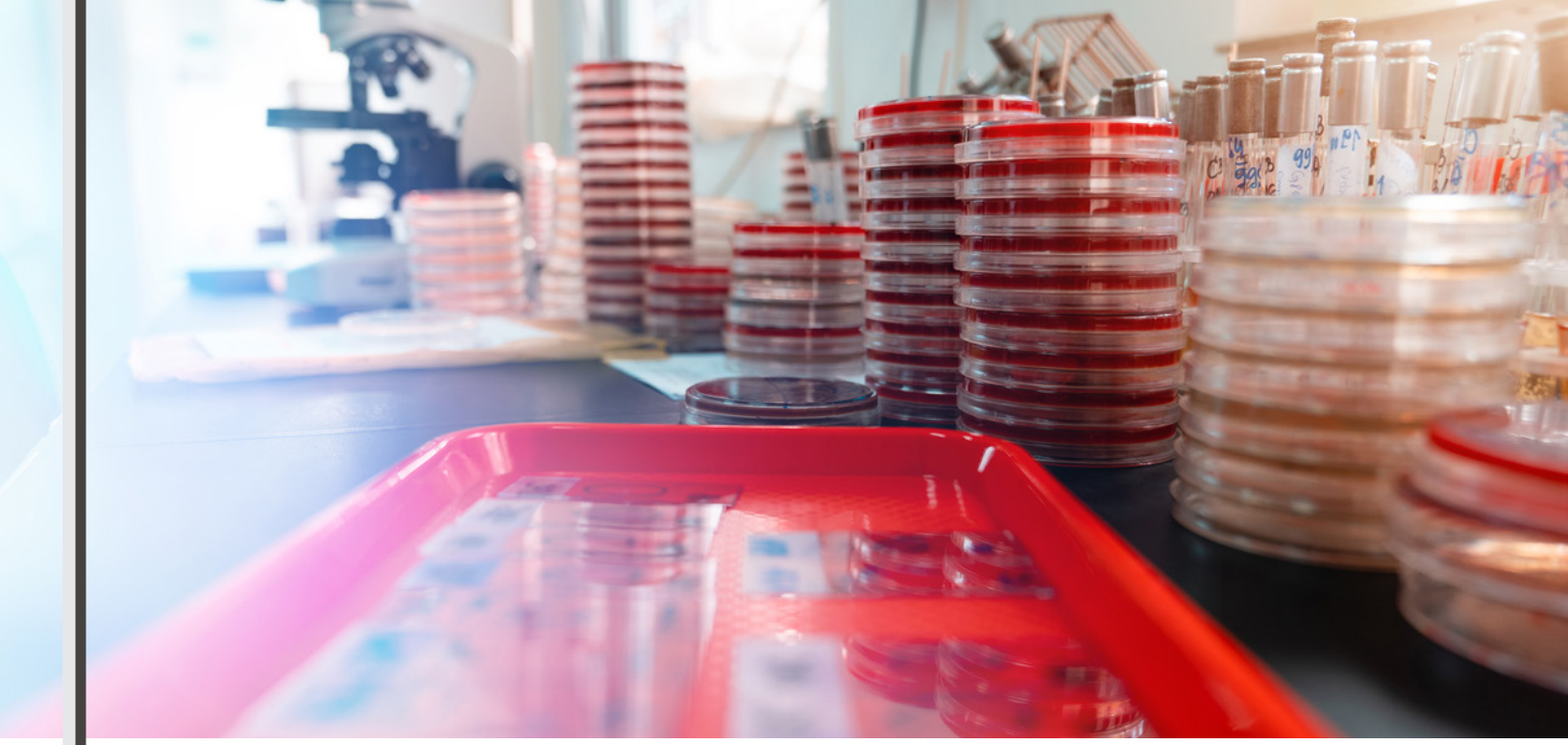
ARUP also challenged the agency's regulatory authority over laboratory-developed testing services. Congress gave the FDA authority to regulate medical devices, but if Congress had intended the FDA to regulate laboratory-developed testing services as medical devices, lawmakers would have included this concept in the text of the Medical Device Amendments of 1976 (MDA), and did not.

This past spring, ARUP conducted the largest survey to date assessing the impact of the proposed rule on clinical laboratories. Nearly 85% of respondents indicated the rule would hurt their laboratories and, ultimately, patient care. Of the 503 respondents, only 41 (8.2%) supported the FDA's proposal, and of those whose labs perform LDTs, more than 60% said they would have to remove tests from their menus. A third indicated they did not know if they would need to remove tests. ARUP's webinar sought to educate industry professionals so that labs can determine their next steps.

As an alternative to FDA regulation of LDTs, ARUP has advocated for a collaborative process to update existing regulations that now govern clinical laboratories under the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments. Genzen said a collaborative legislative approach would be a better option.

"We are disappointed that the FDA enacted the rule, denying many stakeholders the opportunity to collaborate on an oversight framework aligned with clinical laboratory expertise and resources in order to better protect patients and future innovation," Genzen said.

Bonnie Stray, bonnie.stray@aruplab.com



How ARUP Consultants Helped a Client Adjust to Unexpected Order Volumes and Prepare for Future Growth

For more than 25 years, ARUP Healthcare Advisory Services has partnered with clinical laboratories to help them demonstrate their long-term value to their health systems. With an expansive portfolio of customizable offerings, our team of healthcare consultants is focused on clients' success in terms of sustainable revenue growth, high-quality patient care, and cost-saving operational efficiencies. Our consultants are seasoned lab leaders and data analysts who empower laboratories with adaptive solutions that enable healthcare leaders to deliver on the promise of value-based care.

Here, we take an in-depth look at how ARUP Healthcare Advisory Services helped one client absorb an unexpected and unprecedented amount of new lab outreach business. Look for more client success stories in future issues of Magnify as we highlight the real-world impact of our expert consultants.

ARUP Healthcare Advisory Services consultants recommended layout adjustments to a client's specimen processing area, helping to eliminate bottlenecks and streamline workflows.

Solving a Logistical Challenge

A large academic-based health system operating out of the Midwest won a significant amount of new laboratory outreach business after a commercial lab acquired a nearby regional reference laboratory.

Seeking an alternative to the large commercial lab, many hospitals in the region transitioned their reference testing to the health system laboratory, an ARUP client. This influx of testing greatly benefited the health system laboratory's growing outreach program, but it presented logistical challenges. The laboratory experienced higher dwell times, order errors, and large daily pending logs, all while struggling with employee turnover in key positions.

The health system sought the expertise of ARUP Healthcare Advisory Services to manage the challenges from the increased outreach volumes and to plan a course for future growth.

Recommendations

After conducting a thorough review of the health system's laboratory and outreach operations through stakeholder interviews and observations, ARUP Healthcare Advisory Services noted several improvement opportunities.

Layout Adjustments to Specimen Processing Area

ARUP's healthcare consultants observed several bottlenecks in the health system's specimen processing layout. To reduce inefficiencies, ARUP recommended reorganizing the courier pickup and drop-off locations, pneumatic tube stations, and specimen processing stations. The consultants provided three alternative plans for the client to choose from, offering the health system flexibility in making the improvements.

Client Demographics

- 24/7 operations
- 30+ laboratory locations
- 35+ expert pathologists
- ~20M tests/year
- 650+ laboratory professionals

Career Ladder Positions

Given the influx of new testing and a continued labor shortage, the health system experienced high employee turnover and difficulty filling new positions. ARUP recommended the addition of career ladders for many positions within the lab to increase retention and allow experienced employees to take on additional responsibilities. The healthcare consultants also suggested the creation of a new specialist position in specimen processing to help streamline workflows. The addition of this role would enable processors to escalate outlier cases, allotting them more time to focus on routine orders. Together, these changes would help with recruiting efforts, reduce errors, and minimize staffing stress.

Revised Issue Resolution Management

Many of the 22,000-plus samples on the client's pending log were unnecessary duplications. Processors routinely canceled these orders without a review process. Although this approach was appropriate for managing inpatient testing, it resulted in significant delays, unnecessary cancelations, and customer dissatisfaction when applied to outreach specimens. ARUP recommended a structured review and resolution process for all samples and orders, including suspected duplicates.

Outcomes and Next Steps

The health system implemented many of ARUP's operational recommendations at its main laboratory location, including the reconfiguration of the specimen processing area, the addition of new career ladder positions, and the introduction of a structured review process for pending specimens and order cancelation.

With a new specimen processing layout, new specialized roles, and a revised order review approach, the client cut daily pending logs from more than 22,000 samples to approximately 3,000 samples. The health system also reduced the number of unnecessary cancelations to near zero.

Given their main laboratory's successful implementation of these changes, other laboratory locations within the health system are now making similar modifications. The client continues to pursue new outreach business opportunities with the confidence that its laboratory is well positioned to handle growth.

Heather Stewart, heather.stewart@aruplab.com

Daily pending log reduced by more than 19,000 samples

Unnecessary cancelations reduced to near zero

Shorter dwell times with streamlined processing space

Lower turnover and improved employee satisfaction with career ladder positions

ARUP LABORATORIES
500 Chipeta Way
Salt Lake City, UT 84108-1221
Phone: 800-522-2787
Fax: 801-583-2712
aruplab.com

ARUP is a nonprofit enterprise of the University of Utah and its Department of Pathology.