## the art & science of diagnostic medicine AR P LABORATORIES SUMMER 2019 Information in this publication is current as of July 2019. All content is subject to change. Please contact ARUP Client Services at (800) 522-2787 with any questions or concerns.



### Magnify

### The Art and Science of Diagnostic Medicine

Have you ever approached a Claude Monet painting, stopping only when you are inches from the canvas? The whole becomes the sum of its parts: a brush stroke, minuscule touches of color, the interplay of shapes. In diagnostic medicine, pathologists approach the patient in a similar way, zooming in and magnifying the infinitesimal details that make up the patient—a blood cell, the spiral of a DNA strand, a gene variant, a foreign bacteria or a virus.

Through these microscopic clues, pathology experts assist in the detection, diagnosis, treatment, and management of human diseases and conditions.

Approximately 70 percent of patient-care decisions are based on in vitro diagnostic test results produced by a clinical laboratory.

Magnify focuses on ARUP Laboratories' current role in diagnostic medicine, as well as its drive to propel knowledge and discoveries forward. As the country's largest nonprofit, national reference laboratory, ARUP has entrepreneurial roots and strong ties to academic medicine that guide its unique business approach. (It is a nonprofit enterprise of the University of Utah and its Department of Pathology.)

This approach includes emphasis on education, strict adherence to evidence-based knowledge, and an environment that promotes collaboration and thus accelerates innovation. The stories among these pages will allow readers to see for themselves, zooming in and back out, ARUP's patient-focused and market-facing dynamics at work.

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### When Ethics Is the Business Strategy

In healthcare, we take our altruistic motives for granted. "First, do no harm" is our mantra. We put the patient first.

Yet even the most committed and selfless among us recognizes some naiveté in that assumption. In this era of consolidation aimed at cutting costs and improving efficiency, a profit motive that too often translates to price gouging and limitations on service can put healthcare businesses at odds with medical and scientific ethics.

It doesn't have to be that way, though. In fact, it can't be that way if the goal is success for the long term, according to Brian Jackson, MD, MS, ARUP medical director of business development, information technology (IT), and support services. He believes healthcare in general and the diagnostics industry in particular can build on principles ARUP views as central to its business strategy to make money while also staying true to healthcare's core values.

"So much of modern business gets distracted by value extraction, which is an unsustainable goal," said Jackson, who lectures on the topic of ethics as a business strategy at ARUP and to lab industry groups. "But if we focus on value creation instead, it brings us back to our clinical and scientific roots."

Make no mistake—money matters to laboratories, as it does to all businesses.

Jackson, though, believes laboratories can produce gains for owners or investors while also satisfying the needs of patients, clients, employees, suppliers, regulators, and even the communities in which they reside. He is a proponent of stakeholder capitalism, which asserts that no company can thrive into the future without the active engagement of all involved. It calls on businesses to actively pursue moneymaking opportunities while also actively practicing ethics, and not to treat one as a tradeoff for the other.

"We sometimes hear companies say they're giving up being as successful as they could be because they want to do the right thing, but they shouldn't view it like that," Jackson said. "Doing the right thing can be the centerpiece of your strategy."

More companies across industries, from Dignity Health to Nike to hedge funds manager BlackRock, are embracing the notion that answering to a higher purpose creates business value.

ARUP Leads a Growing Number of Companies That Are **Building Their** Strategies Around Core Values



"Profits are in no way inconsistent with purpose—in fact, profits and purpose are inextricably linked," Blackrock chairman and CEO Larry Fink wrote in this year's letter to shareholders. "Profits are essential if a company is to effectively serve all of its stakeholders over time—not only shareholders, but also employees, customers, and communities."

"Purpose guides culture," Fink wrote. It provides a framework for consistent decision-making, and, ultimately, helps sustain long-term financial returns for shareholders.

"There is a large body of evidence that if we do the best we can to deliver to a variety of stakeholders in a fair and just manner, with transparency, integrity, and honesty, then the bottom line ends up healthy as well," said Abe Bakhsheshy, PhD, a professor of organizational behavior at the University of Utah's David Eccles School of Business.

ARUP's founders understood this, and the company has benefitted from the University of Utah's commitment to manage ARUP for the future, Jackson said. "It is an important part of the ARUP story," he added. "Our leadership [both internally and at the U of U] has always been driven by medical values. They've managed for the long-term, not short-term, financial targets."

It Can't Be All Talk and No Action

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, said Ronald Weiss, MD, a retired professor and staff hematopathologist who was the company's president and chief operating officer from 2003 to 2009.

Weiss was among leaders who later 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 include:

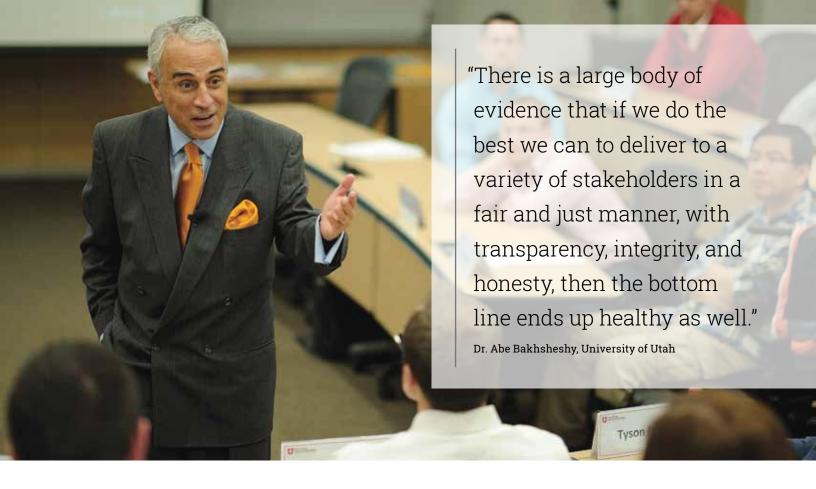
- I. Provide excellent patient care by supporting clients.
- II. Create a good working environment.
- III. Do the right thing.
- IV. Improve continuously.
- V. Act responsibly.

"The brilliance of the Five Pillars is that they distill core values that make sense from a business and an ethical perspective," said ARUP CEO Sherrie Perkins, MD, PhD. "We filter every decision we make through the Five Pillars, and if it goes against one or more of them, we seriously look at what that decision entails and whether it's the right decision."

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Dr. Sherrie Perkins, ARUP CEO





Weiss added that competitors sometimes seek to gain a quicker, stronger position by trying to "do well while leaving the good to someone else." At times, it makes things difficult, but as Weiss said, "We always come back to this belief that as long as we act in the interests of patients and employees, continue to improve ourselves individually and as an organization, and we're fiscally responsible, that is still a formula for success."

It can't be all talk and no action.

Bakhsheshy used the example of Enron Corp. to assert that companies must demonstrate they do more than talk about values. Enron developed a 45-page code of conduct that it clearly ignored before spiraling into the most costly corporate bankruptcy in U.S. history amid widespread corruption and accounting fraud.

Enron CEO Jeffrey Skilling left the impression he was doing God's work, Bakhsheshy said. "Enron wanted everyone to believe it was on the side of the angels, but which angel were they talking about? Lucifer?"

It's hard not to be cynical when you recall such examples, Jackson said, but he emphasized that values articulated in internal codes of ethics such as the Five Pillars can translate into action in numerous ways. In the diagnostics industry, labs that value transparency make certain they validate new tests and verify their clinical utility before marketing them aggressively, he said. They ask whether the way they manage patents unjustly limits patients' and scientists' access to advancements in healthcare.

They also seek transparency from suppliers. How do reagent vendors treat lot-to-lot variation, for example? Do other suppliers care about and take action to support environmental sustainability?

"There's so much consolidation going on that some healthcare organizations are huge, giving them enormous purchasing power," Jackson said. "They can use that purchasing power to influence the behavior of their suppliers."

Labs with medical and scientific ethics at their core work to strengthen accreditation systems, he said. They recognize that regulation that seeks to require accreditation and transparency can complement voluntary efforts toward improvement.

In short, they practice good medicine by putting the patient first.



### Provide Excellent Patient Care

### Create a Good Working Environment

### Do the Right Thing

### Improve Continuously

### Act Responsibly

Ι

Put the patient first.

Support our clients.

Openly share experience and expertise with others and support and applaud success.

Ш

Treat people with mutual respect and support, both inside and outside the organization.

Set high expectations for ourselves and others

Show compassion, appreciation, courtesy, and civility.

Whenever possible, make decisions through consensus.

Develop and reward individuals and teams.

Delegate, empower, develop trust, and make people feel important.

Create a safe, satisfying work environment for employees.

Emphasize balance in life: work, wellness, and family.

Be fair in all dealings.

Do the right thing —not necessarily the easiest or most popular.

Be honest and lead with integrity.

Comply with the law.

Set challenging but achievable objectives for ourselves and our departments.

Keep professionally current and educate others.

Take initiative and ownership of issues; be available, responsive, and accountable; provide service to others before self; admit mistakes; and, expeditiously take corrective action.

Engage in ongoing research to further medical science and the mission of ARUP, the Department of Pathology, and the University of Utah.

Take calculated risks and be innovative in managing change.

Regularly seek to improve human relations skills.

Publish and present results and findings.

Practice fiscal responsibility.

Commit to high quality and professional excellence.

Protect the reputation of the University of Utah by acting conservatively.

Balance the business needs of ARUP with the educational and academic mission of the University of Utah.

Hire the best applicants, train them, and support them.



### Whoa. How Does This Work?

Julie Altwies, chief business development officer, recalls an experience that impressed her when she first joined ARUP in 2010.

She remembers visiting a client, and listening as the account executive (AE) recommended that the client either insource vitamin D testing, which generated significant revenue for ARUP, or consider having clinicians put patients on vitamin D supplements without testing them at all. Why? Such testing, if deemed necessary, is more cost-effective and results are more timely when performed closer to the patient.

"I remember walking out of there and thinking to myself, 'Whoa. How does this work?'" Altwies said. "But it does work. We lost vitamin D testing revenue, but we solidified a relationship. There were other esoteric tests the client needed.

"If we do the right thing, there will always be a need for the type of medicine we practice," she said. "Part of that is keeping the interests of health systems first, and filling the niche for those esoteric tests they can't do."

Jackson added that satisfying the needs of patients and all other stakeholders takes continuous effort, especially as companies grow. It requires vigilance and a recognition that no company will be perfect every day.

"If you want to excel, you must always go back to your roots and remember who your primary stakeholders are," Bakhsheshy said, and Weiss agreed.

"You have to step back every once in a while to assess whether your values have changed, and whether they've changed consciously or they've evolved unconsciously and you're no longer happy with where you've gotten to," he said.

Perkins is confident in the Five Pillars' staying power. "Even as our culture evolves a little, it still has a basis that remains very true to itself," she said.

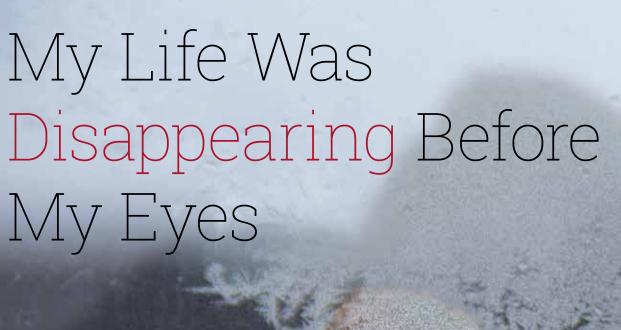
Jackson emphasized that ARUP's Five Pillars work because the company's many stakeholders are well represented by them.

"They articulate a firmly held belief that good business and good ethics are compatible," he said. "You can build ethics into your business strategy, and it only strengthens your success over the long term."

"We sometimes hear companies say they're giving up being as successful as they could be because they want to do the right thing, but they shouldn't view it like that. Doing the right thing can be the centerpiece of your strategy."

Dr. Brian Jackson, ARUP







The fatigue lingered after Chris caught strep throat. He reasoned that it was a combination of the exhaustion that comes with having a new baby and the effect of Minnesota's bleak. winter days. Yet his weakness intensified. His arms trembled as he lifted his newborn daughter, so he compromised, lying on the floor with her.

By spring he was seeing double, short of breath, and his hands tingled. He started using a cane and wheelchair to get around. Still, no one knew what was wrong.

While Chris and his wife Alicia watched their newborn daughter, Taylor, gain weight and reach milestones, Chris's lean, athletic build withered.

"Don't sit on Dad," Alicia would tell their 4-year-old son, Justin. "Don't ask Dad to do it." Justin would tug at his dad and plead, "Teach me how to ride a bike."

"It was heartbreaking," recalled Alicia. "He didn't want to be remembered as the dad who lay around on the couch all day."

Before the strep, Chris's trajectory was enviable: 26 years old, he was fresh out of college, undertaking a brand new job as a medical technologist at the Mayo Clinic, and had a blossoming family. Then he got sick. And sicker. He took medical leave from his job. His intense pain kept him up at night, so he sometimes had only one or two hours of sleep. Walking exhausted him. His days consisted of moving from the couch to the bedroom or bathroom and back. Going outside was difficult. "Even the sun hurt," Chris remembered.

### A Medical Wild-Goose Chase

Over the next 18 months, a medical odyssey involving all kinds of diagnostic tests and well-intentioned specialists would challenge Chris and Alicia's grip on hope. One physician ran tests and an MRI to check for multiple sclerosis. When Chris experienced what felt like a panic attack and rapid heart palpitations, a cardiologist ordered a cardiac panel and multiple other tests to check for heart issues. When he lost 10 pounds and then developed a distended belly, the physician ordered diagnostic and imaging tests, looking for cancer or tumors. When he experienced hot flashes and swollen lymph nodes, an infectious disease specialist ran more tests. They proved nothing.

A neurologist ran a battery of tests and concluded that the illness was in Chris's head: He was depressed. A psychiatrist diagnosed him with agoraphobia, general anxiety disorder, and depression, although Chris disagreed with all three diagnoses. To address the loss of mobility, doctors prescribed physical therapy. He "failed out" three times, nearly fainting from the exertion the therapy required. Eventually, Chris's medical record would run 300 pages in length and include results from hundreds of lab tests.

The thermoregulatory sweat test, which Chris dubbed "the Easy-Bake Oven test," involved being coated in gold-colored powder from head to toe and heated up in an enclosed space. Everywhere he sweated, he would turn blue. "I looked like a Smurf," recalled Chris. This test can diagnose certain neurologic and autonomic disorders. Still nothing.

Chris scheduled his appointments two to three weeks apart, packing several into one day because the effort of undergoing them exhausted him. Every time he did anything that involved physical, mental, or emotional stress, he would crash and feel wiped out for several weeks.

"My life was disappearing before my eyes," said Chris, a soft-spoken man who is more likely to listen than to be the one talking in a conversation. "Here I was, surrounded by the best, but no one could figure out what was wrong."



"Sometimes people's bodies don't react the way a textbook says they should react. And often, patients have a phenomenal sense of what is going on with them. As physicians, our job is to really listen and be open to learning what else might be going on, then formulate that information into an actionable plan."

Dr. Kathryn A. Gibson, ARUP Family Health Clinic

He and Alicia spent their time scouring PubMed and Google, digging into medical literature, and searching for answers. "We didn't watch TV at night or go out. Ever. We would put the kids to bed, and then we would go to work," recalled Alicia, who was also working part time and caring for their children. "I felt like my whole future was collapsing in front of me." She realized she might have to care for Chris long term and provide for her family on her own, so she began studying for the law school aptitute test (LSAT) in order to apply to law schools.

After 12 months of testing, Chris received a final diagnosis: chronic fatigue syndrome and fibromyalgia. There would be no more tests. He was prescribed cognitive behavioral therapy.

"I felt like they were throwing in the towel, giving up on me," remembered Chris. "I knew this was a diagnosis widely used when physicians can't figure out what's wrong." Despite his deep discouragement, Chris chose resolve. "I knew I would have to be the one to figure it out."

### A Stroke of Luck

Almost 12 months after his bout with strep throat, a friend offered to fly Chris out to Utah to meet with Danny Purser, MD, a family physician who had a hunch after hearing

about Chris's condition. At one point, Purser had also been diagnosed with chronic fatigue syndrome. "I was desperate and running out of hope at that point," recalled Chris. So he flew west.

Purser ran the same panel of endocrine tests that Chris had undergone six months into his illness. "I wanted to do the test but control some of the variables in hopes of a purer result," said Purser. This required asking Chris to fast for 48 hours, stop taking current medications, and refrain from any activity.

The results showed that a hormone, insulin-like growth factor 1 (IGF-1), was on the low end of the normal range (the same results as the earlier test). IGF-1 is a primary mediator of human growth hormone (HGH). Purser suggested that Chris investigate this further and sent him back home with instructions to seek out a well-known endocrinologist at the Mayo Clinic and request an insulin-tolerance test. The test would help clinicians see whether his hormones were working properly.

The endocrinologist reran the endocrine panel with the same results. He told Chris that he did not think the insulin-tolerance test was necessary. Chris pressed him for it, indicating that he would go elsewhere for the test if necessary. Performed in

10

### What's Normal in Hormone Testing?

Some lab tests provide a simple negative or positive answer (e.g., you either test positive or negative for strep throat). Other tests, like those used to detect hormones (endocrine tests), provide a numerical range that defines a normal value for that test. This is called a reference range or interval.

Different laboratories often determine their own reference ranges, so endocrine test results might be reported as normal from one lab and abnormal from another lab.

"Reference intervals show us what results can be expected from a healthy population for a specific hormone," explained Joely Straseski, PhD, MS, ARUP medical director of endocrinology. Reference ranges help describe what is typical for a particular group of people based on age, sex, pregnancy, body mass index (BMI), and many other possible factors.

The upper and lower limits of the interval are based on the most frequent results observed within that population, providing a reference for comparison. However, if someone's hormone levels fall just outside the normal range, it does not necessarily mean there is a problem.

### Treat the Patient, Not the Results

"I advise clinicians that even if a value is within the reference interval, there could still be a clinically relevant change going on in a patient. The reverse is also true: Values just outside of the reference interval might not have clinical implications," explained Straseski, who is also an associate professor of pathology at the University of Utah School of Medicine. "Results should always be interpreted within the context of the patient's clinical history." For example, if a patient's testosterone level suddenly drops from 700 ng/dL to 300 ng/dL, it might be a red flag for this particular patient even though the value falls within the reference range.

The ranges for test results in healthy people and those with illnesses often overlap; there isn't always a clear dividing line. Because of this, the reference range is a guide and not a rigid definition of normality.

Another variable to consider is how dynamic our bodies are—not unlike a boat on moving water, the human body

is constantly trying to find equilibrium. "Your body works super hard every day, every minute, to regulate itself, and if you test it at one moment in time, the results could look inappropriately normal or abnormal," explained Straseski.

### There Is No "One" Hormone Test

When physicians suspect an issue with the endocrine system, one of the areas they investigate may be pituitary function. The pituitary gland is the catalyst for most of the hormonal processes and pathways that take place elsewhere in our bodies. It lies at the base of the brain, just behind the bridge of the nose, and can wreak such havoc that it is routine to test patients after brain surgeries to make sure that the gland was not damaged.

"Hormones regulate a wide variety of functions within our bodies," said Straseski. "We have lab tests to investigate the individual steps in these pathways because every step is relevant." Usually, a pituitary issue affects multiple processes, not just one.

In the Automated Endocrinology Laboratory—one of several ARUP labs that perform endocrine testing—laboratorians work around the clock testing serum samples to analyze hormones such as insulin-like growth factor 1 (IGF-1), human growth hormone (HGH), and one of the major IGF binding proteins, IGF-BP3 (insulin-like growth factor binding protein 3).

"The test results generated by our laboratory help physicians determine if HGH is being adequately secreted or if it is suppressed," said lab supervisor Pete Middleton. "HGH concentrations are susceptible to variation throughout the day and are affected by exercise, stress, and other influences." For this reason, IGF-1 or IGF-BP3 can provide a clearer picture of HGH production than HGH levels themselves.

While many pediatric endocrine test specimens come to ARUP, ARUP has developed HGH and IGF-1 reference ranges that apply to patients well into adulthood. As Middleton added, "HGH isn't just important for our initial development, it is important throughout our entire lifespan."



only a few places around the country, the insulin-tolerance test can be risky and requires an inpatient setting.

A week later, Chris lay in a clinic bed and received an injection of insulin. Over the next two hours, his glucose levels were monitored every five minutes, with blood draws every half hour. When his levels dipped below 45 mg/dL, nurses insisted he drink some juice, repeatedly asking him if he was okay. Typical glucose levels hover around 100 mg/dL, and hypoglycemia symptoms start to become apparent when levels drop below approximately 50 mg/dL. "This is how I always feel," said Chris. His levels would eventually bottom out at 22 mg/dL.

Insulin helps move glucose from the blood into the cells. A low blood glucose state triggers a stress response in the body, making it release hormones that raise glucose levels, such as growth hormone, cortisol, and adrenocorticotropic hormone (ACTH).

A graph showing these responses usually resembles an elongated bell curve. Chris's graph had only downward-sloping lines, symbolizing the inactivity of cortisol and growth hormone. "My body was not making hormones when under stress," said Chris. "We now knew that something was going on in connection with my pituitary gland."

Pea-sized and tucked at the base of the brain, behind the nose, the pituitary gland is the master of all hormones. Imagine it as the first domino in a Rube Goldberg machine, setting off a complex, multipath chain reaction throughout the body.

"The pituitary gland is responsible for a cascade of hormonal processes that are connected to many different functions in our bodies, from bone growth to blood pressure to thyroid function, to name a few," said Joely Straseski, PhD, MS, medical director of endocrinology at ARUP. The many different hormonal processes contribute to the complexity of endocrine testing.

However, for Chris, more was at play than just the function of his pituitary gland.

Chris started treatment to correct his low cortisol levels, but it made him feel worse. After a month, he stopped taking it. Then the endocrinologist suggested he try HGH treatment for a year. This required Chris to inject himself with a synthetic growth hormone each night before bed.

"The doctor didn't have a lot of faith that this would make much of a difference," recalled Chris. But within one week, he could walk around the house without assistance. Within one month, he was running a mile. "It was like I was being given a new life."

After 18 months of searching for answers, Chris's final diagnosis was adult-onset idiopathic pituitary dysfunction. "Basically, we know something is wrong with my pituitary gland, but there is no diagnosis as to exactly what or why," said Chris.

### In the End, a Blessing in Disguise

To catch up on life and to regain his strength, Chris started setting physical goals, including off-road triathlons and a marathon. He returned to work with





plans to pursue a master's degree in laboratory medicine and biomedical technology. His case caught the interest of medical colleagues, who asked him to present to medical students. A professor who taught laboratory medicine and pathology classes changed her curriculum based on Chris's experience. He and his family returned to Salt Lake City, where Chris took a job with ARUP Laboratories.

Life was blossoming once more for the Allens. On January 11, 2013, Alicia and Chris welcomed their third child into the world. Baby Nicole arrived weighing 7 pounds, 14 ounces. But at 3 months, she started slipping down the growth and weight charts, and her health continued to decline over the course of her first year. "She was lethargic and had problems sleeping and was irritable," recalled Alicia. Nicole also exhibited unusual symptoms, turning blue in a warm bathtub and shivering uncontrollably.

"I just knew she was in pain," said Chris, who, along with his wife, began to suspect that Nicole had the same hormone deficiency as Chris. Endocrinology testing confirmed that she lacked the ability to produce HGH. Because of her father's long journey to diagnosis, clinicians were able to arrive much more quickly at answers in Nicole's case.

Now, each evening at the Allen household in a suburb of Salt Lake City, Alicia and Chris announce, "It's bedtime! Come get your vitamins and medicine." All four children (Ryan arrived in 2015) receive their vitamins, and 6-year-old Nicole receives an HGH shot, which is sometimes administered by her sister Taylor. If you ask her why she needs a shot, she'll exclaim, "Because I'm special, like Daddy." (Flu shots are a walk in the park for her.) Chris also takes his shot at night because that is when the human body naturally releases HGH—hence the saying, "Go to sleep so you can grow taller."

At the ARUP Family Health Clinic, family physician Katherine Gibson, MD, monitors Chris and Nicole closely with regular endocrine testing to check their growth hormone levels, as well as levels of other hormones produced by the thyroid and pituitary glands. She said, "The slightest imbalance in these hormones can have a potent effect on the body."

Although Chris and Nicole finally received a correct diagnosis, there are still unanswered questions. If a strep infection triggered the HGH dysfunction, as Chris suspects, then what triggered it in Nicole? What is the specific genetic variation responsible for the condition? Could the cause be an environmental exposure of some sort?

Chris, whose master's thesis focused on HGH and chronic fatigue syndrome, believes epigenetics played a role. "I think it is a genetic trait that gets triggered by a stressor. Mine was strep. For my daughter, maybe it was the trauma of being born." He is not aware of anyone else in his family who struggled with hormone deficiency or a mysterious illness.

While for Chris, this medical odyssey was both maddening and painful, there is a sense of relief, too. "I'm so glad it was me and not my daughter that went through the struggle of figuring out what was wrong."

### It's Not Easy Being a Hospital Laboratory—We Get It!

Hospital laboratories are a unique entity within the hospital. Often, they are hidden. Often, they're the fall guy when something "test related" goes awry. Yet in-hospital laboratories are indispensable to patient care. As part of the University of Utah Health academic-medical system, ARUP runs labs in the U of U hospital and in the Huntsman Cancer Institute, and services 140+ outreach clinics (see box).

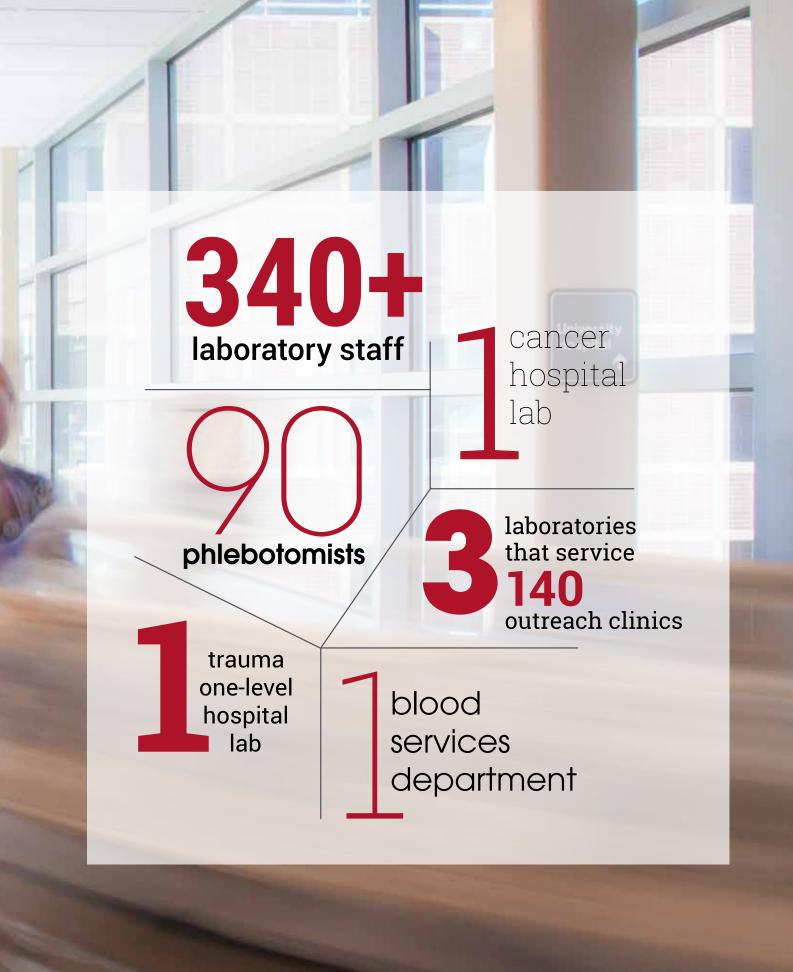
"We understand the challenges hospital laboratories face because we've faced them, too," says Jason Goodfellow, information technology (IT) manager of U of U Hospital labs. "We feel their pain."

Goodfellow draws on his own experience and expertise to consult with ARUP clients about hospital operations, IT, phlebotomy, process improvements, and specimen receiving. Issues that clients face related to Centers for Medicare and Medicaid Services (CMS) payments, overloaded emergency departments, communication, and space constraints are all similar to ARUP's own experiences in running a hospital laboratory.

"We also understand the challenges of communicating with the hospital so they can better discern the issues that the laboratory faces," says Jo D Fontenot, ARUP senior operations director for the U of U Hospital labs. She oversees phlebotomy and support services, client services, operations, clinical labs, and blood donor services. "We've had to learn how to advocate for the lab, solve problems, and collaborate in a system-wide approach, not in a vacuum."

With more than 60 years of experience between them, both Fontenot and Goodfellow know that all too often when things go wrong, fingers get pointed at the lab. Here, they discuss the issues they've faced, solutions they've found, and the work that still needs to be done.







### JG-Jason Goodfellow is ARUP's information technology (IT) manager of **University of Utah Hospital** labs. He has more than 27 years of experience and a degree in medical laboratory science. He began his career as a phlebotomist and then worked in pre- and post-analytical roles before transitioning to IT. He managed two large projects involving PathNet Millennium and Cerner PowerChart, which strengthened his acumen in healthcare IT and in finding solutions. "I love to solve puzzles that's why I'm engaged in my job." JF-Jo D Fontenot, MS, is ARUP's senior operations director for the University of Utah Hospital and the **Huntsman Cancer Institute.** She has more than 25 years of experience and is certified by the American **Society for Clinical** Pathology in medical technology. She attributes the strengths she brings to her job to her many years of experience as a generalist in a hospital laboratory and the leadership training she received in the military as an officer in the reserves. "Patience and dedicated, talented coworkers are key."

### How can a hospital lab avoid being a silo? What has ARUP done to overcome this?

JF—Become involved with hospital management. Reach out to nursing management and quality teams to collaborate on process-improvement opportunities. If the hospital has a patient safety committee, get involved. Committees like this are a great platform for others within the hospital to understand the challenges related to the hospital's lab.

JG—We've found that IT needs to be significantly involved in the clinical decision support team and the electronic health record (EHR) operations team within our hospital. Many institutions operate with a centralized IT department and this makes individual IT solutions improbable. On the laboratory side, we embed IT analysts in each department, which allows us to customize IT services.

JF—We did all this, and then we developed a Laboratory Process Improvement (LPI) committee that includes representation from nursing services and informatics, hospital quality, emergency department staff, IT, Epic super users, and patient safety.

This committee has helped people realize that, in many scenarios, the lab isn't really at fault, and that inefficiencies are a system-wide issue. For example, a provider may add a test to an order, but it is added incorrectly so the lab doesn't receive the add-on. Or laboratorians may end up with a sample but no order, or have a sample with a collection date and time that don't match the order. This is an interface issue between two different electronic systems, not solely a lab issue.

JG—As part of our LPI committee, IT representatives help address persistent process failures. We work with the hospital IT staff and quality teams to assess and fix issues. For example, if there is an inpatient location that has a high number of errors or complaints (e.g., incomplete labs, slow turnaround times), we'll go work directly with their staff to figure out what we can do as a team to improve outcomes.

The lab also provides training to medical staff on phlebotomy procedures and point-of-care (POC) testing. Our two laboratory liaisons work directly with nursing and clinic personnel to address questions or concerns in person. This goes a long way in bridging the lab-versus-hospital gap.

**JF**—We also provide tours of the laboratory to current and new nursing personnel. Otherwise, it's just a black box to them.

### What are some observations or misperceptions you can share regarding hospital labs?

JF—There's a real lack of appreciation regarding the complexity of laboratory testing and the preanalytic impact. Let's say a laboratorian recognizes a sample is compromised based on how it was collected and requests a recollection. Nursing personnel can become frustrated with this delay because they don't understand that the contamination may not be detected until the test is run.

Because hospital labs are often not visible, we forget that there are people working diligently behind the scenes

who care deeply about the patient's well-being. If lab staff recognizes a sample has been compromised, they'll reorder it because they don't want to risk inaccurate results that could affect the patient's care.

There is also a lack of understanding of nurses' and providers' roles in the delivery of timely and accurate patient results. This includes accurately placing and releasing orders, correctly collecting and labeling the specimens, and delivering the specimen to the laboratory in a timely manner.

We all need to be more aware of the complexities of our different roles by stepping up our communication efforts and being transparent.

### What are some of challenges we've faced in blood banking, and how have we improved?

**JF**—Blood transfusion is the most commonly performed procedure in the United States, and blood is a real scarcity. Our hospital, like many others, must maintain an inventory of blood so it is always available in case of a large-scale trauma.

We've put a lot of effort into reducing unnecessary transfusions and improving blood utilization. Right now we are focused on reducing unnecessary type and screen tests in newborns, decreasing blood waste in the operating room, and improving blood-ordering protocols for cardiac surgeries based on the type of procedure.

Our transfusion medical director and manager collaborate with clinical teams to minimize blood transfusions through improved management of patients with anemia and bleeding. They also consult and educate on transfusion protocols.

### What have we done to help phlebotomy services run more smoothly?

JG—We've moved away from traditional rounding—which involves drawing blood at intervals—to on-demand phlebotomy services. Implementing use of electronic handheld devices made this possible by transmitting and dispatching real-time orders rather than relying on scheduled rounds.



Phlebotomists: Isaac Chamberlain (left) and Alex Tew.

We've also implemented bedside labeling that instantly lets the laboratory know the patient's most current blood orders. This helps avoid unnecessary tests and decreases the risk of mislabeling or lost labels.

### How do we develop an engaged workforce?

**JF**—We've invested a lot of effort in this area. To help show appreciation, we require supervisors to spend at least two hours a month expressing gratitude to employees. This might entail writing thank you cards or taking an employee to lunch.

We're sticklers about making sure our leaders are good leaders who can model good behavior and focus on team building. We assign a mentor to new employees, and their manager follows up at the three-month mark to see how things are going.

All our departments have weekly huddles where the supervisor and/or employees recognize and thank each other for their efforts. These recognitions can show up in their performance reviews. In the huddles, employees can point out lab issues or potential areas of trouble and collaborate in finding a solution. Since we started the huddles, engagement scores have shot up.

**JG**— Another area that has helped with engagement is our Best in Class initiative, which empowers employees and gives them a sense of ownership. This initiative provides training and tools for the entire staff to improve processes and patient care. It encourages staff to not only identify issues, but also to be a part of finding the solutions. We believe this, too, has prompted the rise in our employee engagement scores.

### How have we improved collaboration efforts with the nursing staff?

JF—Nursing staff collects half of the samples sent to the lab, so strengthening the labs' communication and collaboration with nurses was key for us. With representation from multiple areas, including nursing, the LPI committee has helped address issues impacting patient testing and care. It has proven to be very successful in solving problems from a systems approach and helps medical staff see the bigger picture of what is going on and how they can help solve problems.

For example, the computer system may cancel a duplicate order and send out a "canceled" notification. But the provider assumes the lab has dropped the ball because it is not apparent in the provider's system that the computer, not the lab, canceled the test. With two different computer systems, issues like this come up. This is one reason why we are moving to Epic's Beaker system in order to provide more transparency in the medical record.

We also participate in quality meetings with nurses and have formal laboratory liaisons who train nursing personnel on sample processing. If we are getting an increase in specimen issues or complaints from one of our clinics or departments, one of our liaisons will retrain medical staff in that area.

We have to remember that medical staff speaks a different language than lab staff. It's important to speak their language when communicating concerns to nurses and avoid using too many laboratory-specific terms.

### Regarding ARUP's Huntsman Cancer Hospital labs, what have we learned to do better with regard to caring for patients with cancer?

**JF**—We are actively involved with the healthcare team in the delivery of care; this includes providing rapid testing, bone marrow support, and on-site and telepathology.

**JG**—The needs of this patient population are different from our traditional inpatient population. They may be coming in weekly for chemotherapy and their turnaround times (TATs) have to happen a lot faster. In order to improve, we had to reevaluate these patients' needs and backward engineer to meet those TATs. This led to establishing on-site laboratories for all the Huntsman healthcare system's infusion centers.

**JF**—We oversee on-site transfusion at each of the four Huntsman infusion centers. This proximity was key to keeping the coordination tight and the workflow quick. Pharmacists rely on the lab test results to know what chemo dosages patients will need within the hour.

Additionally, we have learned to work closely with nursing and pharmacy staff to ensure we are meeting the needs of patients who are receiving treatment. The area where this has been most challenging is in bone marrow collection, where too often we are not alerted in advance that our bone marrow techs will be needed. This is really about better

communication between the care team and the lab, and we are working on it.

**JG**—We've also brought on new testing unique to this patient population; some examples are tumor marker tests and a parathyroid hormone test for intraoperative cases.

### When consulting with our clients on site visits, what do they want to know?

JG—They want to know how we've tailored our laboratory information system (Cerner PathNet) to meet our needs and what implementation strategies are necessary to do this. We had to find some creative solutions to address common laboratory problems such as how to accommodate add-on testing and tools used for data mining. We share our solutions with our clients in hopes it will help them provide even better patient care.

They are also interested in how to improve lab communications with the hospital and our problem-resolution strategies. For example, they want to learn more about the Except system ARUP developed to allow us to document testing issues without interrupting the workflow.



How have ARUP's hospital laboratories attempted to resolve communication issues in order to improve efficiencies and avoid errors?

**JF**—We work with leadership from ARUP and U of U Health to support solutions that resolve problems. We noticed that pharmacy had a medicine safety committee that would report up to the hospital's safety committee. Yet we didn't have anything similar, even though labs come in second to pharmacy for being one of the areas where there are the most complaints or nonconformance issues.

Once we pointed this out and showed how integral laboratory services were in the whole hospital's healthcare system

and in patient care and satisfaction, hospital leadership was astonished. As a result, we created the LPI committee I mentioned earlier.

**JG**—Face-to-face interactions improve communication. We are present in a lot of quality management meetings—in nursing, the intensive care unit, newborn and delivery, and the emergency department, to name a few. We are there to answer questions, find solutions, and help them understand how their actions can impact the lab process.

Lab IT also works with U of U Health's patient safety reporting system to solve process problems and to improve workflows between the laboratory information system and the hospital's electronic medical record system.

**JF**—We've been able to jump over a lot of hurdles and find solutions that benefit everyone by focusing on communication, collaboration, and transparency.

"Once we showed how integral laboratory services were in the whole hospital's healthcare system and in patient care and satisfaction, hospital leadership was astonished."

Jo D Fontenot, ARUP



### What the C-Suite Doesn't Know: The Effects of the Lab on Downstream Costs

Lauren Pearson, DO, MPH, has one foot in the world of laboratorians and one foot in the world of clinicians. She provides technical oversight and quality management for the ARUP labs located within University of Utah Health's hospital and clinics. She also assists clinicians with medical decisions regarding test selection and result interpretation and has a role in systems quality and process improvement.

Poor quality can sink a ship. Beware of the iceberg effect, in which only a small portion of the costs of poor quality is visible, while much larger costs remain invisible below the surface.

Many of the difficult-to-quantify costs of poor quality in a lab intersect with other healthcare system processes. They represent opportunities for improvement in system processes that will enhance overall patient care, safety, and the patient experience.

To tap into these opportunities, laboratory leadership needs to be included in multidisciplinary teams along with other stakeholders to continuously evaluate system quality and drive process improvement efforts.



### How can the hospital and its lab leverage their strengths to improve patient care and decrease healthcare costs?

I think there are many opportunities for collaboration between labs and clinicians that can really provide improvements to patient care and enhance patient safety. When people and their areas exist as a silo, there are lost opportunities.

If hospital leadership really wants to amplify the work hospitals are doing to improve care, then they need to push for collaboration and give labs a seat at the table. When they do so, leaders will be surprised by how fast this drives change. All too often, the barrier for the lab is that people just don't think about including them. Let's face it, the lab itself is often out of sight and its laboratorians are not visible in typical patient scenarios, yet they are an integral piece of the puzzle in facilitating diagnoses and treatment.

These are lessons learned that our clients could benefit from. Granted, some clients are more resource limited than others, but that is even more of an impetus to effectively use their existing resources. Yes, some of the cost savings will come from utilization efforts, but the savings can be difficult to quantify: error prevention, risk mitigation, and process and workflow improvements. Healthcare organizations know the cost affiliated with failure is a high one.

### What do you think chief financial officers and CEOs may be unaware of when it comes to their hospital laboratories?

The lab is a rich source of data for a hospital. This data provides an opportunity to see what is or isn't working well in regard to quality systems, existing processes, or workflow, because a lot of the clinical processes in caring for patients interface with the lab in some way.

Labs collect massive amounts of data for things that go well and things that don't go well—it is a deep repository that can

show where the gaps are and where the threats to patient safety exist. The lab has information on where processes need to be improved to make things better, faster, and safer for the patients.

### ARUP runs several hospital and clinic labs. How does this make us different from other large national reference laboratories?

Being closer to where patient care is happening is always an advantage. And being closer to the provider makes us acutely aware of ever-evolving needs in the medical community, whether it's a need for new assays, improvements on current assays, or process improvements to better meet the needs of patients and providers.

Our close relationship with University of Utah Health is unique. It is beneficial from both an operations and a quality perspective. Our culture at ARUP is connected to a higher purpose, which is to provide quality patient care at all times. We think of specimens as patients. Because of our connection to the university, we are receiving continuous feedback on how our level of service aligns with the healthcare system and patients' needs. This also means we have to be flexible and agile and make changes when appropriate for patient care by offering new testing, extended hours of service, or reducing turnaround time.

The downside of making adjustments as needed to resolve issues or improve care is that it requires readily available resources. While another reference laboratory might say, "This is what we offer, take it or leave it," we look to make improvements. This differentiates us.

Putting patients at the center of what we do makes us continuously strive to improve the laboratory side of care. I think ARUP's connection with U of U Health and the university's medical school creates an interesting dynamic that funnels a strong sense of purpose back into the company's culture. It is not just about churning out lab results.

As our clients and other healthcare professionals struggle with current healthcare industry issues (e.g., emergency response, cost containment, etc.), they teach us the best ways to serve their needs. These stories demonstrate just a handful of ways that ARUP has been privileged to help clinicians as they navigate the system to care for their patients.



With hospitals in Texas, Puerto Rico, and Florida facing evacuation and natural disasters in 2017 and 2018, and serious fires ravaging the West Coast in recent years, some hospital staff members have dealt with crises that are well beyond the healthcare emergencies they expect to cope with each day.

As the deadliest wildfire in California history raged in the fall of 2018, several clinicians and patients from Feather River Hospital in Paradise, California, holed up for safety and to continue operations in a residential garage after their ambulance caught on fire.

74.7%
of ARUP clients have
Connect™ accounts

Feather River, an ARUP client, had a contingency plan—it had previously opted in to ARUP Connect™. This online system allows clients to access their lab test orders and records, order supplies, and otherwise interact with ARUP, regardless of where they are, using a simple laptop and password.

"All of this saved a huge amount of time. After all they'd gone through with the fires, being able to speed this along really made a difference."

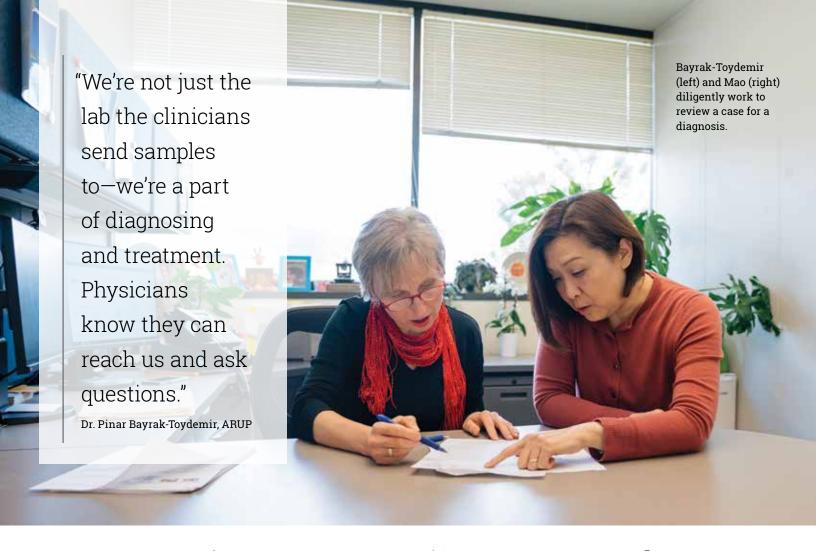
Matthew Baker, ARUP

As an established user of Connect, Feather River was able to give additional clinicians access to testing orders and results for patients who were transferred after Feather River moved its base of operations to a nearby hospital.

"All of this saved a huge amount of time," said Matthew Baker, technical supervisor in ARUP's Client Services. "After all they'd gone through with the fires, being able to speed this along really made a difference."

Among ARUP clients, 74.7 percent have Connect accounts.

If Feather River had been one of the 25.3 percent of clients that have yet to opt in, its providers would not have been able to access patient test records off-site via laptop, and vital work would have been delayed. ■



### Accessing Expertise Fast When a Baby Can't Breathe

The baby could not breathe on her own. Only days old, a machine kept her alive in the neonatal intensive care unit (NICU) at Primary Children's Hospital. Genetic testing was performed, and the child's specialist, part of a physician group regularly in touch with ARUP, asked Pinar Bayrak-Toydemir, MD, PhD, an ARUP medical director of molecular genetics and genomics, for input on the test results.

After taking a look at the genetic testing, Bayrak-Toydemir concluded that the child had a syndrome that affects the neuromuscular junction; a mutation in an important receptor meant that signals weren't being transmitted between neurons and muscle cells.

This discovery led to a treatment that could help—a medication that could prompt the muscles to work so the baby could begin breathing on her own. The clinicians no longer needed to look at the large collection of other genetic findings. They were able to start the child on the prescribed drug immediately, and the baby began to improve.

With access to genetic counselors and medical directors who provide expert review of genetic test results, health issues and treatments can be identified early.

Like most ARUP medical directors, Bayrak-Toydemir teaches in the University of Utah School of Medicine. "We're not just the lab the clinicians send samples to—we're a part of diagnosing and treatment," said Bayrak-Toydemir. "Physicians know they can reach us and ask questions."

Medical directors such as Bayrak-Toydemir and her colleague Rong Mao, MD, have built a rapport with clinicians after reviewing many cases to ensure a correct diagnosis. "The physician may say, 'Did you think about anemia having the same genetic phenotype,' and we might go back and look at that," said Bayrak-Toydemir. "It's a back-and-forth, and I think we're special in that perspective. It's not something larger laboratories can easily do." ■

### Accelerating the Answers



"When I started out in my work, I would do what I do with students—look at the list of possible lab tests first, then decide what to do next. Now, I often skip directly to the section that reviews final steps following a diagnosis."

Michael S. Robinson, NP, Revere Health

Standing with several nurse practitioners in training, Michael S. Robinson, NP, describes which tests to order when high levels of eosinophils show up in a patient. These disease-fighting white blood cells, when present in quantity, result in a condition called blood eosinophilia, he explained, using his phone to access a bookmarked link to ARUP Consult®, an online test selection and interpretation tool.

Robinson helps with orientation of trainees about to graduate from nurse practitioner programs as part of his work for Revere Health in Provo, Utah. He browses ARUP Consult's algorithms menu and selects step-by-step flow charts that offer testing strategies for a range of conditions. The Eosinophil-Related Disorders Testing Algorithm, for instance, notes that if eosinophils are present at 500–1,500 cells per microliter or higher, a clinician should screen for secondary causes of eosinophilia, including asthma, allergy drug reaction, infection, or new and abnormal tissue growths called neoplasms. In some cases, they should consider tissue biopsy.

"I especially love the algorithms for working with students; they're so helpful in guiding them through the process," said Robinson. He uses Consult on his own, too, especially for rarer conditions. "When I started out in my work, I would do what I do with students—look at the list of possible lab tests first, then decide what to do next. Now, I often skip directly to the section that reviews final steps following a diagnosis."

Dianna Tolen, MD, a pediatrician at Kids First Pediatric in Canfield, Ohio, goes to ARUP Consult with lab-specific questions. "For clinical information, there are plenty of websites I can check, but I go to Consult when I need academic information from the laboratory—that's exactly what I'm seeking."

When clinicians visit ARUP Consult, they gain access to information on nearly 300 disease-related topics and more than 70 testing algorithms to help them choose which tests to order. Medical experts at the U of U School of Medicine and ARUP coauthor and review all topics; regular updates reflect the latest medical advances and changes to the ARUP test menu.

Robinson isn't the only one drawn to the algorithms. Many algorithms, such as those for anemia, thyroid disorders, hypercalcemia, and newborn drug testing, are among the most visited content on ARUP Consult, says Lisa Carricaburu, managing editor of the ARUP Decision Support products.

## Will This Rare Disease Impact Your Children? Guiding Familial Genetic Testing

In the rare condition rhabdoid tumor predisposition syndrome (RTPS), aggressive tumors often start in the cerebellum, kidneys, or other soft tissues. RTPS occurs in infants and toddlers younger than 3 years old, affecting approximately one in a million children. After a California family's baby was found to have tumors, a genetic counselor affiliated with an out-of-state specialist advised family members to be tested. The parents and older sibling's genetic tests were negative. However, future children could still be at risk if the mutation that caused disease in the infant was present in a subset of sperm or eggs, a phenomenon called germline mosaicism.

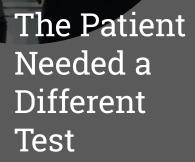
In late 2017, a blood specimen from the family's new baby arrived at ARUP with a request to test a certain region of a chromosome where the older sibling's mutation had occurred.

RTPS is usually caused by a random error in the DNA that is not inherited, but parents typically still want to rule out the condition in their other children. "After all, if it's a known mutation, you can enter a surveillance program with a pediatric oncologist to try to identify and treat tumors as early as possible," said ARUP genetic counselor Shelly Bosworth, MS, LCGC (shown left).

Bosworth recognized that a family member had already tested positive for RTPS at a different laboratory. To ensure continuity of test results, she coordinated family testing with that other lab using a residual (preserved) sample from the new baby. "There can be nuances in the methodology at different labs, unless it's a common test. So if you can send the testing back to the lab that performed the first family test, you help make sure methodology doesn't affect getting the correct result," said Bosworth.

To streamline the process, Bosworth was able to maintain the testing record in the ARUP financial system so that the test could be performed as a sendout and the family would not incur a separate bill for testing. Throughout the process, she kept in close contact with the client and the family's genetic counselor.

Fortunately, the new baby turned out not to have RTPS. However, Bosworth's intervention helped obtain results in a potentially serious situation. "When ruling out a condition in a young child who could be monitored or treated early, we want to go out of our way to make sure this is done right—even if it means advising different testing than what's ordered," noted Bosworth. "We never want to mislead parents into thinking a child's not at risk when they are."



When ARUP genetic counselor Marcia Jodah, MS, LCGC (shown right), received a test order to assess for pathogenic variants in genes that affect the mitochondria, she noted that standard clinical information was not included with it. Placing the test on hold, she asked the client to send that information.

In response, she received a patient history form stating the patient was a 29-year-old with hearing loss. Jodah flagged the test order, noting that mitochondrial DNA testing should not be the first test considered for individuals with hearing loss only.

After contacting the ordering provider, Jodah learned the desired test was mitochondrial antibody testing, which was associated with a different clinical diagnosis unrelated to the patient's hearing loss. "We saved several thousand dollars and ensured the correct test was performed for the patient," said Jodah.

### A Small Change Led to Big Savings

A regional medical center in the Midwest that is a level III stroke center is seeing benefits from implementing ARUP-advised changes in its electronic health record (EHR). Although the center is still measuring results, it's definitely seen a difference after an ARUP Consultative Services business review advised differentiating between two frequently confused tests for blood proteins that help control blood-clot formation (Protein C, Functional or Antigen; and Protein S, Functional or Antigen). "Docs were ordering the tests for patients with potential thrombosis or thrombophilia without realizing the difference between the tests," says Christine Richards, MT (ASCP), MSEM, laboratory director at Phelps Health, Rolla, Missouri.

Confusion over certain test orders is nothing new in hectic practices where clinicians must act fast to send in requests, and a number of studies reveal that 10 percent to 30 percent of laboratory tests performed in the United States are either unnecessary or inappropriate. In 2015, Jane Dickerson, PhD, DABCC, and Michael Astion, MD, PhD, published an article in Clinical Laboratory News about trying to clarify vitamin D testing for providers in their home institution, Seattle Children's Hospital. After trying four methods in two years, the pair felt cautiously optimistic about their ordering improvements and wrote about the need for industry-wide change.

"A very large number of laboratories struggle with physicians ordering the wrong test due to confusing test names, and I'd say that only a small proportion of labs have addressed it by clarifying and simplifying the test names in the physician order entry system," said medical director Andrew Fletcher, MD, CPE, MBA, who oversees ARUP's Consultative Services. "Many labs want to make that change, but don't have informatics resources. Simplifying test names is an example of something that works."

ARUP Consultative Services works with clients to monitor their test orders on an electronic dashboard and aims to review progress with them each year. For Phelps Health, around 45 tests are being tracked.

"We utilize information gleaned from ARUP Consultative Services business reviews and share it with our staff and providers. For instance, we're in the process of meeting with our pediatrics staff to switch to umbilical-cord drug screen testing instead of meconium—that will be more effective and more efficient. These are just a few of the many examples I can think of that we've used from our business review to initiate and educate staff on appropriate ordering panels," says Richards. "I love that ARUP points out any orders we are inappropriately underutilizing—or overutilizing."

"We utilize information gleaned from ARUP Consultative Services business reviews and share it with our staff and providers...I love that ARUP points out any orders we are inappropriately underutilizing—or overutilizing."

Christine Richards, Phelps Health



ARUP is building on 35 years of determination and purpose, harnessing its expertise to improve patient lives. From the beginning, the company has strived to learn what it doesn't know, advance and share what it does, and continuously seek new ways to add value—all the while operating with tenacity and compassion.

In 1984, a group of University of Utah pathologists made a gutsy move. They launched ARUP Laboratories to perform lab tests for regional hospitals to generate income for a budget-strapped university pathology department. Aptly named Associated Regional and University Pathologists (ARUP) at the time, the company would expand beyond its founders' wildest dreams, eventually outgrowing its name.

### Lean. Resourceful. Resilient.

These traits helped ARUP survive the "learning-curve" years while it established its niche. Colleagues shared desks, shoveled snow, and pulled overnighters. Some even married each other. In those days, the resonating clang of a cowbell would announce the "win" of a new client. Teamwork permeated the culture.

"It was a tough sell initially; we were considered the 'boondocks,'" said John Matsen, MD, ARUP's first president (1984–1992) and chairman of the U of U Department of Pathology. "People were skeptical that we could do anything as sophisticated as operate a pathology laboratory worthy of national consideration."

ARUP could not compete with the large corporate labs in the areas of volume and price. Instead, it choses to align as a partner with its clients, supporting their efforts to be the principal healthcare providers in the communities they serve by offering highly complex assays and accompanying consultative support. This approach, combined with sharing expertise rooted in academic medicine, inventive thinking, and a fierce commitment to patient care, began earning ARUP the confidence of clients outside the Intermountain West.

### Winning Them Over

"We knew if we could just get them to try us once, we could win them over," recalled Carl Kjeldsberg, MD, who led ARUP for 17 years (1992–2009). "To use ARUP once was to become a convert." Eventually, ARUP would serve more than half of the country's teaching and children's hospitals.

As ARUP expanded, it built a reliable courier service and began offering clients value-added services. Listening to clients has resulted in ARUP's increased focus on tools and services to show clients how to make labs more efficient and decrease downstream costs in their healthcare systems.

"Our academic roots help us to remain on the cutting edge of laboratory medicine and to provide excellent patient care," said Sherrie Perkins, MD, PhD, and CEO of ARUP. "Sharing our knowledge stems from these roots as well."

Today, ARUP has more than 4,000 employees, 100-plus medical directors, advanced automation, and will soon have a new building that will add 200,000 square feet of lab space. ■

ARUP is ready for the next 35 years.



"We're not just trying to drive value to the laboratory; we're trying to drive it to an entire healthcare system."

Dr. Andrew Fletcher, ARUP



This high cost makes infliximab a good candidate for therapeutic drug monitoring (TDM) to ensure that positive patient outcomes balance the expense to the patient, the insurer, and the healthcare system.

ARUP offers TDM tests for infliximab and other drugs. These tests analyze antibodies to determine whether a medication is active in the patient's bloodstream. If a patient isn't responding well to infliximab, for instance, medical providers can consider alternative medications and treatments.

Testing like TDM is an exciting opportunity, according to David Shiembob, senior healthcare consultant with ARUP Consultative Services. "It helps labs in medical centers demonstrate their value outside of the laboratory. This is a real way to quantify savings and improve treatment at the same time."

### **Multidisciplinary Patient Care**

Many aspects of patient care, such as drug therapy and diet, play key roles in both the need for a lab test and the interpretation of the test result.

Consider a patient being treated with the drug warfarin to prevent blood clotting or the development of existing clots: If that patient eats an unusually large amount of leafy greens at dinner, the international normalized ratio (INR) value—a standardized monitoring value for patients using blood thinners—will change. Providers need to know if the shift in their patient's INR value requires a different drug dosage or if the change resulted from a one-time shift in the patient's diet.

This is just one example of how communication between the lab, pharmacy, and other healthcare providers can improve patient care. Collaboration among the varied providers who care for each patient is crucial to the success of the treatment.

### **Eliminating Silos**

"Lab and pharmacy need to work together and not be siloed," said Danielle Kauffman, PharmD, MBA. Kauffman joined ARUP as a senior pharmacy consultant in the fall of 2018. As the first pharmacist consultant hired at ARUP, she is working to help clients use processes such as TDM and other pharmacological solutions to improve patient care. She also works closely with medical directors in ARUP's Toxicology and Pharmacogenetics departments to find efficient ways for labs and hospitals to collaborate.

"You don't want to waste the patients' time or compromise their health," said Kauffman. "And as pharmacies and laboratories work together more often, it will be easier for administrators to see that in addition to improving patient care, collaboration saves the health system money and time."

One area of interest is how the budgets in different hospital departments are related. For example, lab tests may be ordered to determine drug-therapy options, and more lab testing could result in more efficient dosing and choices of drug therapy. In that instance, the laboratory might overspend its budget, but the pharmacy's expenditures may actually decrease to an even greater degree, creating savings overall in the hospital.. When watchful hospital administrators are aware of the two departments' interplay, said Kauffman, they come to understand the cause and effect.

As collaboration becomes increasingly common, it may also be possible to resolve that most dreaded hospital conundrum: numerous blood draws. If lab and pharmacy experts are working together to closely monitor efficient dosing and related testing, then fewer blood draws are required. "In addition to providing better care, this could really affect patient satisfaction scores. If I were a patient, I'd want less blood taken." said Kauffman.

### **Tidying Electronic Records**

Kauffman is not just a pharmacist; she also has a computer programming background. At times, confusing information in hospital information systems (such as two similarly named forms of vitamin D) can lead to misordered tests. Kauffman notes that her work will include thinking about ways to make electronic health records (EHRs) "less messy and ensure that they display information more clearly."

"Danielle has a unique perspective: Her technology background makes her familiar with the intricacies of the electronic medical record," said Dr. Andrew Fletcher, MD, CPE, MBA, medical director for ARUP Consultative Services. He explains that ARUP is not just going to tell clients how they can improve their pharmacy stewardship; instead, ARUP will give them the tools to do so, as well as access to experts on staff who can share experiences about real-world implementation.

### **Bringing Genetics Into Health Predictions**

As scientists and healthcare practitioners learn more about the effect of genetics on lifelong health, having pharmacists working within a laboratory will be key. The growing field of pharmacogenetics focuses specifically on a people's genetic makeup and how well they will metabolize drugs.

"As pharmacies and laboratories work together more often, it will be easier for administrators to see that in addition to improving patient care, collaboration saves the health system money and time."

Dr. Danielle Kauffman, ARUP (right)



"In healthcare, we have traditionally treated patients in a reactive way. With the application of pharmacogenomics testing, we can proactively place the patient on the right drug and right dose at the right time to ensure a quicker therapeutic result," said Kauffman. With pharmacists in the lab, healthcare systems will be ahead of the curve.

Pharmacists have a place in laboratory medicine. "A pharmacist within a laboratory setting to guide development, implementation, and reimbursement is becoming ever more critical," said Diana Brixner, RPh, PhD, professor and executive director, Pharmacotherapy Outcomes Research Center, University of Utah.

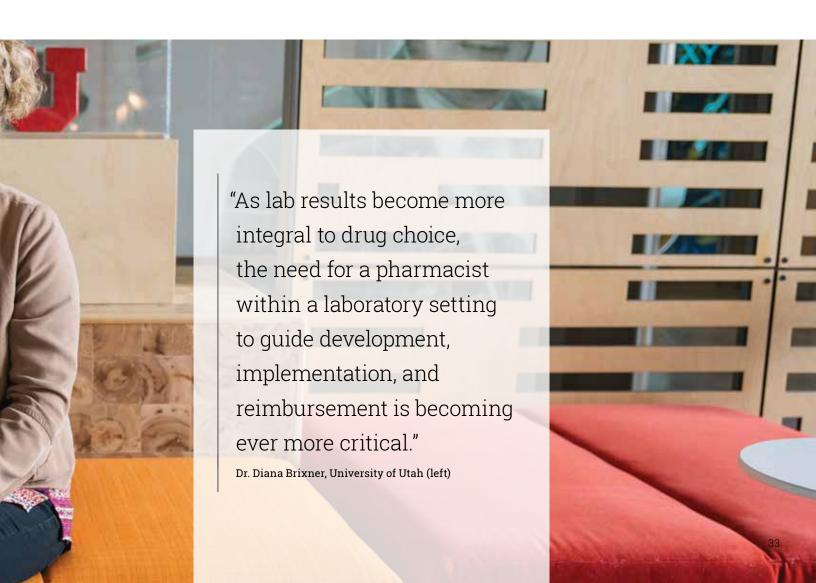
### Feeding the Laboratory With Fresh Ideas

ARUP's close connection with the U of U will come into play in Kauffman's role, too. She plans a laboratory rotation for U of U pharmacy students as well as a pharmacy internship in the lab so her students will have the benefit of experiencing an emerging area of study.

Kauffman expects ARUP's association with the U of U and her role as an adjunct associate instructor will enable her to continuously refresh her skills and knowledge of research, technology, and current industry topics. "Away from education, you can get caught up in what you do every day. But for us at ARUP, and our clients, there's the benefit of exposure to those fresh ideas and the latest information. We'll bring that value to clients."

### It's Our Business

Bringing pharmacy expertise into the lab shows a real commitment by ARUP to drive value. "We could just say, 'That's not laboratory; that's not our business,' but hiring a PharmD shows ARUP is in touch with our clients' realities. Their pain points are costs, and we're in tune with the needs of healthcare systems and the state of healthcare in the United States," explained Fletcher. "We're not just trying to drive value to the laboratory; we're trying to drive it to an entire healthcare system."



# Why Are Some Hospitals Moving Toward Universal Cord Collection?



At the University of Utah Hospital, moments after a baby comes into the world, a nurse quickly snips 8 inches off the umbilical cord. That portion of the cord is then labeled and stored in a designated refrigerator for one to two weeks. If the baby begins to show symptoms of drug withdrawal in the hours and days after birth, the preserved cord tissue could hold the key to the baby's treatment.

"If we have reason to suspect a baby was exposed to drugs in utero, then we will send the cord in for testing. Sometimes we may take cord tissue from a baby we don't realize is at risk and then discover during the hospital stay that mom used drugs during pregnancy that may affect the baby after delivery," said Julie Shakib, DO, MS, MPH, medical director of the U of U Hospital Well Baby and Intermediate Nurseries.

While meconium (the baby's first stool) has traditionally been the sample of choice to test for in utero drug exposure, successful cord tissue testing is convincing more and more clinicians to snip and store. The simple fact is that it's

convenient. Every baby arrives with a cord attached, there's plenty of specimen available, and cord storage can be done as a matter of policy, not judgment. No bias enters the equation if nursing staff automatically takes tissue from each baby's cord.

Meconium can be difficult to collect. The baby may pass it in utero, as happens in 10 percent of cases. It may be thrown away, sometimes purposely by a mother or family member who fears drug detection. For busy nurses, the logistics of checking every diaper can be tricky. For all these reasons, more health systems are choosing to collect cord tissue instead of meconium.



Just 8 inches of a newborn's umbilical cord provides ample tissue to test whether the infant was exposed to drugs in utero. Because drug residue is deposited consistently along the length of the cord, the Wharton jelly inside the cord can be tested at national reference laboratories such as ARUP.

"There is a push for universal cord collection—it's a very practical way to go," said Gwen McMillin, PhD, ARUP medical director of toxicology and pharmacogenetics. She pointed out that while both meconium and cord tissue testing volumes continue to increase at ARUP, the number of cord samples has grown at a faster rate. "We are now doing about equal amounts of cord and meconium testing."

### Identifying the Babies Most at Risk

"Often, we are aware of maternal drug use in advance [of childbirth]," said Shakib. "However, we are working on improving our screening efforts for both moms and babies in order to identify those babies at risk who otherwise would be missed." Signs that the mother may be using drugs include unexplained premature labor, a placental abruption, previous children in the foster care system, and little or no prenatal care, among other risk factors.

Opioid use during pregnancy commonly causes newborns to suffer withdrawal symptoms. If a mother has a history of opioid use during pregnancy, cord tissue will often be tested even before the infant begins to show withdrawal symptoms. Sometimes a discharged newborn ends up in the emergency room, at which point the cord tissue may be sent out for testing.

Shakib and her colleagues have instituted a neonatal opioid withdrawal syndrome (NOWS) care-process model at the U of U Hospital to

monitor and improve quality of care for newborns with NOWS. The process of caring for these babies involves a standardized scoring system for withdrawal and an algorithm to determine the most appropriate drugs and dosages to slowly wean babies from the opioids to which they were exposed in utero. While babies with NOWS can spend up to three weeks in the hospital, this standardized approach has been shown to reduce their length of stay, according to Shakib.

### Simpler, Faster Approach to Detect Drug Exposure

NOWS rates have increased dramatically in the United States. A 2016 report from the Centers for Disease Control and Prevention (CDC) estimated that about 24,000 drug-dependent babies were born in 2013, the last year with complete statistics. That is one baby every 20 minutes.

Women receive more opioid prescriptions than men, and according to the National Survey on Drug Use and Health, heroin use increased 100 percent among women from 2002–2013, compared with a 50 percent increase among men over the same period.

In infants, NOWS symptoms include tremors, respiratory issues, excessive crying, sleep and feeding issues, seizures, vomiting and diarrhea, and fever, among other ailments. Symptoms will vary depending on whether the infant was exposed to stimulants or depressants, and treatment varies as well.

ARUP was the second laboratory in the country to begin offering cord testing (starting in 2012) and continues to hone its expertise in this area. ARUP can now detect 46 drugs or drug metabolites in cord tissue, and most recently added gabapentin to the list. The most common drug ARUP's laboratorians identify is marijuana; the second most common class is opioids. Often there is a mix of illicit and prescription drugs.

"It's an area of testing that is evolving, and we are constantly learning more and improving," said McMillin, who is also a professor of pathology at the U of U School of Medicine. She pointed out that while both meconium and cord specimens are reliable for detecting drugs used in the last trimester of pregnancy, some drugs are better detected in one specimen than the other. However, the availability of the cord is perhaps the biggest advantage of using cord tissue over meconium for testing.

"There are fewer logistics," explained McMillin. "You only need one collector, to collect once, and turnaround time is quicker since it can be promptly sent to the lab." Cord collection also decreases the likelihood of labeling and handling mistakes because it happens in the delivery room. With meconium, there are potentially many collections being performed for children in a nursery or neonatal intensive care unit. A meconium specimen can also be incomplete or lost if a baby is transferred to another hospital, as commonly happens in rural areas. Multiple births can add to the confusion.

"With cord tissue screening, there is no missing piece. It's just more of a streamlined and reliable collection process for us," said Shannon Miles, BSN, RNC-MNN, who manages Perinatal Outreach & Ambulatory Services at Centra Healthcare in Lynchburg, Virginia. She recalled a time when the results from cord tissue testing proved that a new mother had successfully undergone treatment for addiction, which allowed her to keep custody of her child. "These cord screens are definitive and hold up in court."

For women already in labor on arrival, undergoing a cesarean delivery, or experiencing a placental abruption, urine or meconium collection may not be an option. "Sometimes that cord is the only thing we have to help us understand how to treat that baby," added Miles.



# Opportune Time to Help New Mothers

In the University of Utah Hospital Intermediate Care Nursery, it is quiet. There are no beeping machines and the lighting is muted. The medical team tries to perform all care duties within the same window of time so babies can rest and are not overstimulated. This nursery cares for babies who need oxygen support or fluids, or who are at risk of drug withdrawal.

Ideally, when the babies are not in this nursery, they are with their mothers. U of U Hospital is piloting a rooming-in program for mothers with opioid use disorders and their babies. Rooming-in helps the mother bond with her new baby while nurses and medical staff identify and treat neonatal opioid withdrawal syndrome (NOWS).

"We teach mom that swaddling the baby, lots of holding, and keeping a quiet environment helps the baby transition," said Marcela Smid, MD, MA, MS. Smid is clinical director of the SUPeRAD (Substance Use and Pregnancy—Recovery,

Addiction, Dependence) Clinic, a prenatal clinic for pregnant and postpartum women with substance use disorders. The type of care she describes, known as kangaroo care, has been shown to increase bonding between mothers and babies and may prevent the development of withdrawal symptoms or at least lessen their severity, decreasing the need for withdrawal drugs.

"Mom and other family members at the hospital are receiving a lot of interaction around education and support," added Smid, who is also an assistant professor in the Division of Maternal Fetal Medicine at U of U Health.

Smid explained that many of these mothers take methadone or buprenorphine to treat their opioid use disorders, and it is expected that about half of the babies exposed to these medications will develop NOWS and require treatment. "Successful treatment of the mom's opioid use disorder is the most important thing for both mom and her baby's health."

Pregnancy is a unique opportunity to identify and manage drug issues. For some mothers, pregnancy may be the only time they seek medical care and are forthcoming about drug use or addiction. "For these mothers, it can be a very emotional time, and they are full of worry for their new baby. Often, they are very receptive to the support and attention that is being offered," said Smid.

Many women affected by substance use disorders are in their childbearing years.

According to the American College of Obstetrics and Gynecology, more than 86 percent of pregnancies conceived by women with opioid disorders are unplanned.

For medical providers, establishing a relationship with the mother, creating a follow-up plan, and connecting the family with support measures after discharge is critical for the health of the child. The environment in which the child is raised can have long-term behavioral and developmental impact. This is why treatment of the mother's addiction is so important.

"Many of these women have experienced withdrawal themselves and don't want their babies to go through this," said Julie Shakib, DO, MS, MPH, who oversees the U of U's Well Baby and Intermediate Nurseries. "They want their babies to have happy, successful lives. So most moms work with us to help their child."

"For these mothers, it can be a very emotional time, and they are full of worry for their new baby. Often, they are very receptive to the support and attention that is being offered."

Dr. Marcela Smid, University of Utah Health



### Word on the Street:

# ARUP Is One of the Best Companies to Work For

Employee responses to "Why?" ranged from the very succinct, "I love it here. Period," to longer comments that provided glimpses into what they truly value as employees and what keeps them here. Purpose—helping patients—was one recurring theme.

"ARUP is a forwardthinking and great
company to work for,
as evidenced by the
survey," said CEO Sherrie
Perkins, MD, PhD. "It's
incredibly exciting that
ARUP has received this
honor, and everyone in
the company should
be proud to be a part of
making this company
what it is."

With the award, ARUP joins an impressive group of companies. Previous years' winners included O.C. Tanner, Domo, and Health Catalyst. ARUP was one of more than 100 companies that submitted entries last year. All companies were subject to a

rigorous examination of workplace characteristics such as benefits and pay, fairness and opportunities, corporate culture, and internal communication, as well as employee pride.

"It was gratifying to hear what our fellow ARUP employees had to say about working here and the significant role they played in having ARUP named as one of the 2018 best companies to work for," said ARUP President Andy Theurer, CPA. "Thanks. ARUP!"

Taking care of employees is a longtime philosophy held by ARUP and rooted in its 35-year history. ARUP founder Carl Kjeldsberg, MD, stated, "Focus on taking care of the employees, and the employees will take care of the business." Part of this focus always included an emphasis on employee health (physical and mental) and work-life balance.

Last year, more than 800 ARUP employees participated in a *Utah Business Magazine* survey and made the case as to why ARUP Laboratories should be considered one of Utah's best companies to work for in the magazine's annual competition.

# on-site fitness center



ARUP is employee centered and understands that a satisfied employee will provide superior client service. There are many ways in which the company strongly encourages wellness, employee support, employee empowerment, and fairness in the workplace. ARUP helps employees accommodate life's challenges.

You can be yourself—there is no discrimination in the way a person dresses, colors their hair, or if they have tattoos—they just hire nice people with a good work ethic.

I have never worked for a company that is such a champion for a work environment that people love coming to. I hear over and over from many employees how much they love coming to work. They feel they are valued, make important contributions, and have a voice to speak up about ideas and issues they have.

I have made many friends at work, and that makes it even more enjoyable to come to work every day. I feel respected and valued as an ARUP employee, not only by management, but by all my coworkers. We truly work as a team.

I've struggled for years to find a work-life balance that facilitated my ability to succeed at the university while working full time, and ARUP absolutely shines in this regard.

We work together to better the lives of the people we serve. Also, we work together to increase our knowledge through learning and collaboration.

ARUP has an incredible environment that focuses on the patients that we are running tests on. This caring for others rubs off on all of us. There is a strong culture of prioritizing scientific and medical ethics above everything else. Patients come first. We believe our customers have this same value system, so our business will benefit when we do the right thing.

The culture of ARUP is to "do the right thing," and everyone I know here really strives to do what is right to ensure quality patient care.

The fact that I don't have to pay 20% of my salary just to pay for insurance is enough for me to endlessly praise ARUP. I can't stress enough how good they are to their employees; they are always accommodating and give wonderful quarterly incentives that I've never received from any other company.

I feel like I'm surrounded by highly educated, friendly, enjoyable people that I love working with. The best of the best! I've wondered in the past if I should pursue my career goals somewhere else, but it's hard to get away from these amazing people!

# People Proud



Christopher Allen

Larissa Furtado



Jonathan Genzen



Allie Grossmann



Josh Klonoski









Tracy George



Yuan Ji



Mark Kushnir



Joely Straseski



Elizabeth Frank

Quality manager **Christopher Allen** spoke at the Frontiers in Lab Medicine conference on the topic "ISO 15189 as a structural support to a robust quality management system." The Birmingham, U.K., conference was organized by the Association for Clinical Biochemistry and Laboratory Medicine

medical director of molecular oncology, was a recipient of the 2018 40 Under Forty Award from the American Society for Clinical Pathology (ASCP). The award recognizes ASCP members whose work is "making an impact on pathology and

and The Dark Report.

Larissa Furtado, MD,

ARUP appointed Jonathan Genzen, MD,

laboratory medicine."

PhD, as chief operations officer on July 1, 2019. Since starting at ARUP in January 2013, he has served as chemistry section chief, as well as medical director for the Automated Core Laboratory, Laboratory Automation, and the Farmington Clinical Laboratory, among other responsibilities. His focus on process improvement has supported numerous ARUP solutions in standardization, scalability, and efficiency.

### Tracy George, MD,

hematopathology medical director and executive director of clinical trials and PharmaDx, is a founding member of American Initiative in Mast Cell Diseases (AIM). At AIM's annual conference, George co-chaired a session on classification,

pathology, and molecular biology, and she presented on bone marrow pathology in the diagnosis of mast cell disease. With team members, George applied for and was awarded a National Institutes of Health/ National Center for Advancing Translational Sciences R13 grant, which was used to fund the conference. She was a coinvestigator on the grant.

Allie Grossmann, MD, PhD, medical director of anatomic pathology and molecular oncology, was awarded an American Cancer Society Research Scholars Grant for the next four years to study "The Small GTPase ARF6 in Melanoma Progression and Metastasis."

Yuan Ji. PhD. medical director for the

Molecular Genetics and Genomics and Pharmacogenomics labs as well as noninvasive prenatal testing, was selected for the 2019 ACMG Foundation Genetic Leadership Society at the recent American College of Medical Genetics and Genomics (ACMG) annual meeting.

Josh Klonoski, MD, PhD, received the 2019 Paul E. Strandjord Young Investigator Award from the Academy of Clinical Laboratory Physicians and Scientists (ACLPS).

The abstract Free 25 hydroxy vitamin D by LC-MS/MS: reference intervals in healthy adults and observations in pre-/post-menopausal women received an American Association for Clinical Chemistry (AACC) Academy

Distinguished Abstract Award at the 2018 annual meeting. Its authors were Mark Kushnir, PhD, scientific director of mass spectrometry R&D; Sonia La'ulu, R&D scientific manager; and Joely Straseski, PhD, MS, MT(ASCP), DABCC, medical director of endocrinology and the Automated Core Laboratory.

The abstract Status of vitamin B6 sufficiency in the US pediatric and adult populations received a Second Place Abstract Award in the Nutrition Division at the AACC 2019 annual meeting. Its authors were Mark Kushnir, **PhD**, scientific director, mass spectrometry R&D, Jason Krantz, lab supervisor, Analytic Biochemistry; and Elizabeth Frank, PhD, DABCC, medical

At ARUP, our dynamic group of medical directors/pathologists and research scientists provides a steady supply of expertise, knowledge, and innovation. Each year, they publish hundreds of articles in leading journals, present at conferences around the world, and contribute to professional organizations. Here we recognize their accomplishments, as well as those of ARUP employees in many other areas of the company. We are proud that they are being acknowledged for their hard work and skill.



Joshua Hunsaker



Danielle LaGrave



Wendy Murphy



Taylor Snov



Erik Kish-Trier



Melinda Manion



Lis Schwarz



Kamisha Johnson-Davis



Gwen McMillin



Heather Reichman



Irene De Biase



Buck Lozier



Naphavanh Phengphong



Tatiana Yuzyuk

director, Analytic Biochemistry.

The abstract Comparison of disclosed smoking status to the presence of serum nicotine and metabolites in maternal quadruple screen specimens received an AACC Academy Distinguished Abstract Award at the 2019 annual meeting. Its authors were Jonathan Genzen, MD, PhD, ARUP chief operations officer; Joshua Hunsaker, R&D specialist; Kamisha Johnson-Davis PhD, **DABCC**. medical director of clinical toxicology; Danielle LaGrave, genetic counselor; Gwen McMillin, PhD, medical director of toxicology and pharmacogenetics; Wendy Murphy, medical laboratory scientist in the Electro Manual Endocrinology lab; Heather Reichman, lab supervisor of Clinical Toxicology; and **Taylor Snow**, R&D technician.

The abstract Quantitative analysis of long chain fatty acids (C12-C24) in packed red blood cells by gas chromatography-mass spectrometry received a Second Place Abstract Award in the nutrition division at the AACC 2019 annual meeting. Its authors were Irene De Biase, MD, PhD, FACMG, medical director of biochemical genetics and newborn screening; Erik Kish-Trier, R&D scientific manager; Buck Lozier, R&D scientist; Melinda Manion, medical laboratory scientist; Naphavanh Phengphong, senior medical laboratory scientist; Lis Schwarz, ARUP R&D investigator; Joely Straseski, PhD, MS,

MT(ASCP), DABCC, medical director of endocrinology and the Automated Core Laboratory; and Tatiana Yuzyuk, PhD,

FACMG, medical director of biochemical genetics and newborn screening.

The **ARUP Wellness Center** won two awards at the Utah Worksite Wellness Conference. The Platinum Healthy Worksite Award honors ARUP's efforts to link health promotion and business outcomes through the center's prevention services. The Innovation Award for Physical Wellbeing recognized the center's success in engaging employees and promoting wellness with an "Exercise with Executives" competition. The Innovation Award is based on company size and centered

on six areas of wellness: physical, social, occupational, emotional, financial, and community.

The CDC Division of Laboratory Systems nominated **ARUP** for a 2018 Center for Surveillance. Epidemiology, and Laboratory Services (CSELS) Honor Award in the Excellence in Partnering category for "exemplary communication tools fostering strong ties between the CDC and partners, resulting in effective dissemination." Lisa Carricaburu, managing editor of ARUP Consult®, represents ARUP as a member of the CSELS Laboratory Communicators Network.

**ARUP** was a finalist in two award categories at the 2019 Vizient Connections Business Summit: the Support Services Supplier of the Year Award and the Compliance and Integrity Award, and ultimately won the Support Services Supplier of the Year Award.

ARUP was named one of the 2018
Best Companies to Work For by Utah
Business Magazine in a December 2018 award ceremony. The win was based on a comparison of benefits and pay, fairness and opportunities, corporate culture, internal communication, and employee pride.



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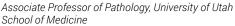
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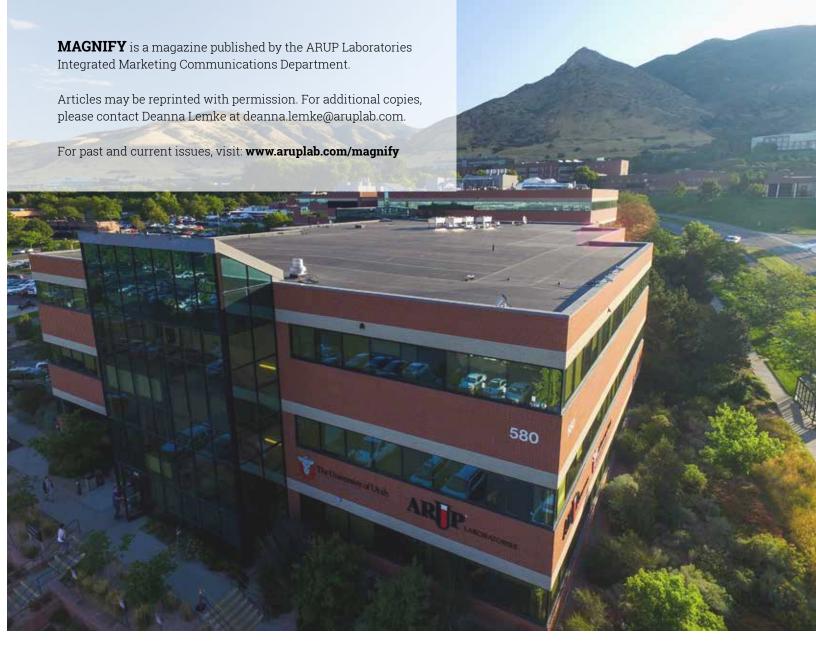
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