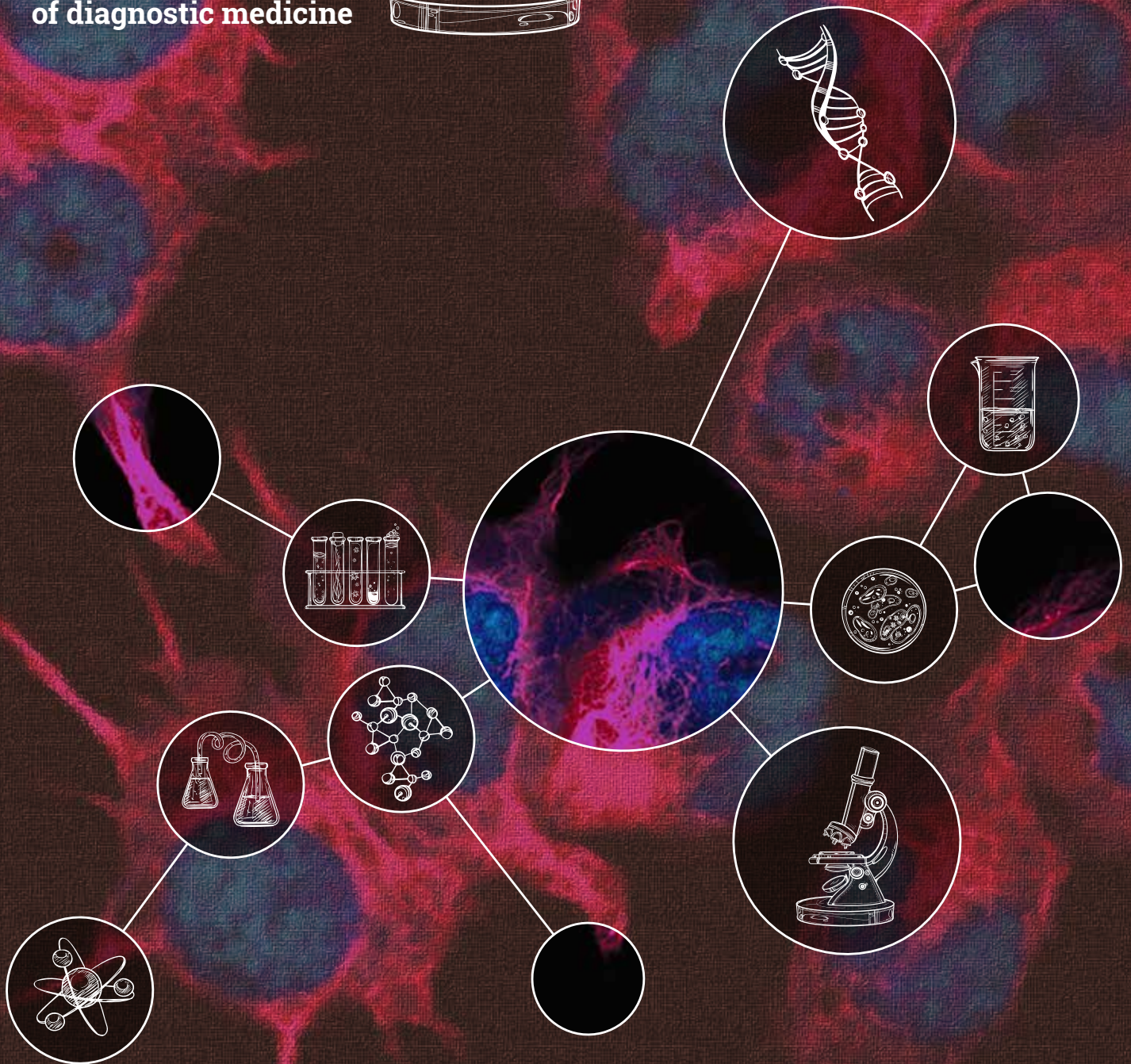
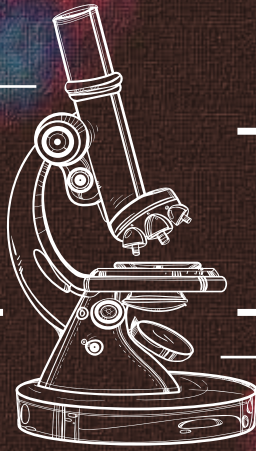
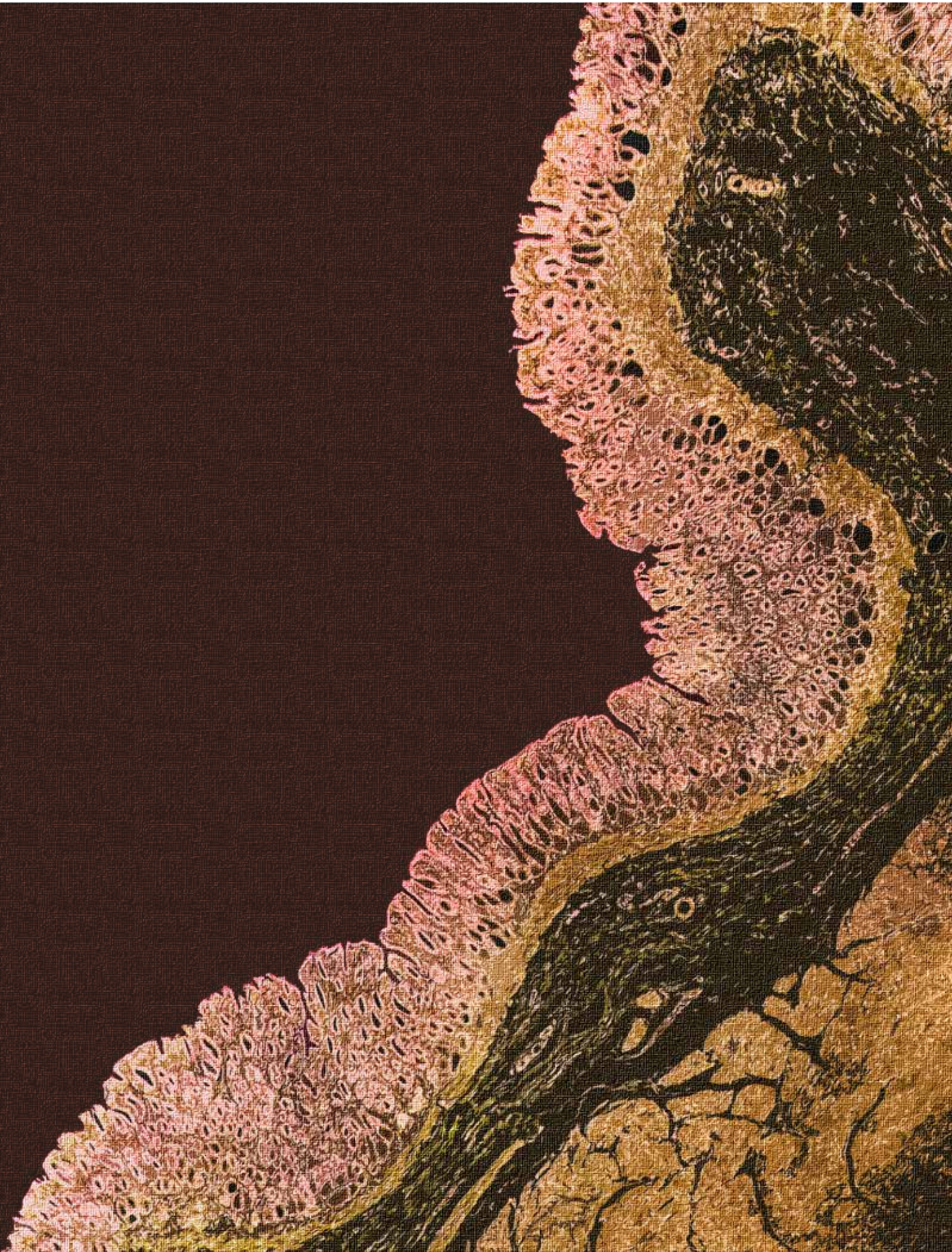


MANIFY

the art & science
of diagnostic medicine





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 medical 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 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 in on ARUP Laboratories' current role in diagnostic medicine, as well as its drive to push knowledge and discoveries forward. As one of the country's two largest nonprofit, national reference laboratories, ARUP has entrepreneurial roots and strong ties to academic medicine that guide its unique business approach.

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

On the cover: Neuron cells

Left: Cross section of a normal stomach showing pyloric mucosa

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New Leadership Infused with Hands-On Experience

This past August, not one, but two experienced ARUP veterans were selected to lead the company. Sherrie Perkins, MD, PhD, became the new CEO, and Andy Theurer, CPA, became the new president. With more than 50 years of ARUP experience between them, their breadth and depth of expertise runs significantly wide and deep, as does their loyalty to the company that they have watched grow and evolve through the years. In the following Q&A, they share their thoughts on ARUP, each other, and what's ahead, and in the process, reveal their leadership styles.



Andy Theurer, CPA

Chief Financial Officer;
Senior Vice President,
Finance; Secretary,
ARUP Laboratories
Board of Directors (17
years); author of articles
on laboratory economics

Sherrie Perkins, MD, PhD

Director of Hematopathology; Interim Department
Chair, Department of Pathology; Division Chief of
Clinical Pathology; Director of R&D Institute; member
of Executive Management Team (10 years); Tenured
Professor of Pathology, U of U; author of 200+ journal
articles and 70 book chapters on hematopathology

What does Andy bring to the table in his role as president?

S—Andy brings a wealth of experience; he’s been here for 27 years, just like I have. His deep knowledge of finance and business are indispensable, as is his thorough understanding of what makes ARUP unique as a business. While I certainly know medicine and technology, the business side of ARUP has not been a big focus of my past roles. I can really rely on Andy’s expertise.

And Sherrie, what does she bring as CEO?

A—At the heart of ARUP is medicine. Sherrie knows medicine and the lab industry. She is internationally known for her pathology expertise, has run the R&D department here, and has been the chief medical director. She knows academics and the importance of that differentiator for ARUP. Sherrie understands the synergies that are created by merging an academic and business enterprise, and she sees how to get the most out of it. While all these skills make her a great choice to lead this company, she also knows what she doesn’t know and will rely on the expertise of others.

Thoughts on being ARUP’s first female CEO?

S—I’ve always been at the forefront and cracked a lot of pink glass ceilings on the way up. But honestly, I don’t see myself so much as a woman in this role, but rather as someone who really cares about ARUP. I do think it is a really exciting opportunity. I have two daughters, and I want to be a role model for them and their friends—that means a lot to me. I’m really looking forward to the challenge.



“Sherrie understands the synergies that are created by merging an academic and business enterprise, and she sees how to get the most out of it. While all these skills make her a great choice to lead this company, she also knows what she doesn’t know and will rely on the expertise of others.”

What’s next?

S—We will continue to focus on being a partner in health systems and providing the best patient care through our testing and with other tools we innovate. This will keep us at the leading edge of lab medicine. We’ve learned a lot over the last four to five years with our changes in leadership, and we’re ready to move on and continue growing.

A—We’ve been able to study what’s really driving our growth. We’ve grown 30 percent over the last three years, and that growth is continuing and gaining even more traction. Our competitors have not experienced that kind of growth; they grow through acquisitions of other companies. When you tease out the acquisitions, their organic growth has been flat.



Can you speak to ARUP’s growth and its challenges?

A—Our growth will continue to come from new tests and developments in our core business: chemistry, immunology, and infectious disease. If we can successfully help to make our clients’ jobs easier, they will reward ARUP with their loyalty. Both quality testing and exceptional service are part of our roots.

S—Our focus is on maintaining and strengthening the core. We realize we’re going to come under tremendous price pressures as our clients deal with regulation changes such as PAMA [Protecting Access to Medicare Act] and other factors. With reimbursement cuts, we need to figure out how to strengthen our core and be more efficient so that we can partner with clients to provide them with lower prices, which will make health systems healthier.

A— Strengthening the core means standardizing and automating wherever we can. This concept is not new to ARUP. The Core Lab and specimen handling and storage system areas are good examples. Now we are working on standardizing and automating within the laboratory itself to strengthen our core areas. This will allow us a much higher capacity so we can manage the increasing workload. It will also free up our employees from mundane tasks, allowing them to focus on more sophisticated processes. This should make their jobs more meaningful and rewarding; they won’t get stuck doing the repetitive components that automation can do.

S—Automation and standardization will also cement the high quality ARUP is known for; it’s much easier to be consistent when you have very standardized practices and one way of doing things.

This is our focus for the next three to five years. It’s a very large initiative, and other platforms will come in under this. The plan is for all of this to coalesce with the new building that we’re adding to accommodate growth.

A—Focusing on the core will produce healthy margins, which can then be used for innovation efforts—for example, next generation sequencing (NGS). PCR and mass spectrometry are part of ARUP’s core testing, but years ago, they were cutting edge. NGS is on the cutting edge now.

S—So now we’ll invest in an NGS genetic lab and really focus on keeping ARUP at the forefront of esoteric testing. As a company, we need to embrace a balance between pursuing cutting-edge developments and sticking to our core.

How is our academic connection important?

S—It’s essential. It’s one of our differentiating factors both in helping us to understand what our clients are going through [ARUP operates several of the hospital’s labs] and provides for collaboration in academics. It helps us to really remain on the cutting edge of science.

A—Let’s not forget that we emerged out of the University Hospital and the Department of Pathology. The hospital continues to be a sister company and a perfect incubator for us to try new developments, such as in utilization management, before taking them to our other clients.



“We know that the laboratory drives the rest of medical care. While lab costs account for only about 3 percent in medicine, laboratory test results influence more than 70 percent of medical decisions. Using the right test, for the right patient, at the right time can help reduce downstream costs.”



Can you talk about collaborations with the University of Utah? What about the Huntsman Cancer Institute (HCI)?

S—Many of our medical directors are involved in HCI research and patient care, attending tumor boards and interacting with clinicians daily. The technologies we have here at ARUP help drive the research. Being a part of this research keeps us on the leading edge in cancer developments. For example, we've been asked to look at doing next generation sequencing to identify some new targets [cancer biomarkers] and working more closely with people in HCI's hematology section. There are also multiple interactions that are going on with the anatomic pathologists in the areas of breast cancer and other neoplasms.

Some of the collaborations happening in other areas of the University involve the Scientific Computing Institute, the Utah Genome Project, and the Engineering and Business schools. This cross-pollination helps us to tap into the newest things happening in these fields, as well as interact closely with experts not available to many other people in the industry. Again, this differentiates us from other labs.

A—We've also collaborated with the Department of Engineering in the past to help us build some of our automation and track systems. We continue to interact with bioinformatics in hopes of finding better ways to integrate information into the EMR [electronic medical record]. The business school has talked to us about different models of thinking about innovation, institutional organization, and a variety of topics that have helped shape us.

Tell us about next generation sequencing at ARUP.

S—If you look at all the reference labs and academic labs across the United States and Europe, NGS is going to be playing an essential role in patient care. ARUP is positioning

“We've always been about education and sharing our expertise in lab medicine. We can share knowledge with our clients to help them understand industry changes and how to become more efficient.”

itself within a market that has not been particularly well established, but moving forward will be essential for remaining at the leading edge of patient care, particularly in the area of genetic disorders, as well as cancer.

We're building the NGS [Genomics] lab out in multiple ways. First of all, we are developing test panels that allow us to use a standardized approach, no matter what the specific genes. These panels will focus on cancer and genetic abnormalities in hereditary disorders. These NGS panels will allow for more standardized workflows because everything will be done in the same way. Right now, we have 60 NGS tests, and every single one is done in a slightly different way, and that makes for a lot of challenges.

A—This is driving our strategy. While there are many small companies built around one test, ARUP will be able to offer specific tests with these NGS panels while maintaining standardization. In other words, clients can set up a specific panel to meet their needs, and ARUP will not have to change our process for each panel. We will run one standard “uber panel,” greatly minimizing complexity. And that is something we can scale.

The new NGS lab is being built on a very automated line, including extraction and amplification tasks; there are going to be minimum touches. This will allow our medical experts to focus on interpreting tests rather than worrying about how things are being run.

Who was an important mentor?

S—Without question, Carl Kjeldsberg [ARUP's cofounder and former CEO]. I originally came to Utah from Washington University in St. Louis to do a fellowship with Carl at the University of Utah. I wanted to stay on just because it was such a great opportunity to work with a giant of

hematopathology, and we've maintained close mentoring ties throughout the evolution of his career.

He taught me the importance of work-life balance. I remember one weekend working on a paper, and he came by and said, “Sherrie, go home and be with your daughters and husband. This will still be here when you come in on Monday.” He also instilled in me a love for medicine, especially hematopathology, and the importance of people. He taught me that if you take care of people, the people will take care of the business.

And your mentor, Andy?

A—Carl mentored me as well. For eight years, I was his CFO [chief finance officer], and that relationship has continued. He taught me to not take myself too seriously. He could be so focused, yet have a sense that everything would work out. I remember being in a pretty intense meeting, and he leaned over and asked me how my water skiing was coming along—a passion of mine. It not only lightened things up, but it showed that he was interested in me as a person. He was always interested in people at ARUP and learning about them. That's one of the things that I've taken away from Carl: Get to know the people here better because they make this company work day in and day out.

He is still my mentor. In this new role, I've asked him to continue mentoring me. He's already done his own 360 degree analysis of me and has been quite frank about how I can improve.

S—Continual improvement is part of the culture here that he really instilled. It was always about continued innovation and thinking about what's next and how to do better and better.

Can you discuss anticipated challenges ahead?

S—One of the major challenges that I think is coming to the entire healthcare industry, and particularly the lab industry, is the issue of reimbursement. We see this particularly in Medicare, which will drive the third-party reimbursement, with PAMA and other cuts. Over the next three years, the industry is looking at cuts of up to 30 percent of reimbursements.

This is really going to severely impact many of our clients because the margins are so fine, so we have to support them by looking at ways to do our testing better, faster, and more efficiently so that we can cut costs without

compromising quality. We can help our clients become more efficient through utilization management efforts.

We know that the laboratory drives the rest of medical care. While lab costs account for only about 3 percent in medicine, laboratory test results influence more than 70 percent of medical decisions. Using the right test, for the right patient, at the right time can help reduce downstream costs in the healthcare system, such as by reducing the length of stay in the hospital or eliminating a medication that the patient is not responding to.

A—Another challenge is attracting good talent and keeping them in a strong economy. With our growth, we are looking at new ways to attract and retain employees that include analyzing our benefits package, reworking the compensation package, and focusing on keeping our people healthy and happy, just to name a few.

How can we support our clients for the future?

S—We've always been about education and sharing our expertise in lab medicine. We can share knowledge with our clients to help them understand industry changes and learn how to become more efficient—continuing to partner with our clients and provide new UM [utilization management] guidance on how to provide the best care in the most cost-effective ways. The Illumicare ribbon is an example of a recent tool that will help our clients in this area. Our aim is to drive excellence in healthcare with all of our clients.

A—We believe healthcare is best delivered closest to the patient, so we pursued partnerships with our clients to support their efforts to be the principal healthcare providers in the communities they serve. We helped our clients better service physician office labs in their communities and enabled them to refer tests to us that they couldn't do.



How will ARUP be quicker, more nimble, in the marketplace?

A—The way to become quicker and more nimble is to keep processes simpler, which means standardizing. We're doing this and it will be our focus for the next few years. As we continue to grow, this will be an important accomplishment for ARUP because the bigger you get, the harder it is to be nimble without standardizing and simplifying our processes.

Does the academic element inhibit the ability to act fast?

S—Yes. On the one hand, our academic ties may make us less agile, but they are also what keep us on the leading edge of what we do. It is this balance between academics and our business mission that has made us so successful.

A—ARUP's founding fathers realized that there needed to be more agility than what you typically find in a completely

“The reputation and reach of ARUP has changed. I remember going on a couple of sales calls early on, and people would act like, ‘Utah? Do planes go there?’ Now, ARUP has become well known and incredibly respected coast to coast.”

academic setting. This is the “enterprise” part of ARUP as it developed out of the U of U's Department of Pathology. They realized business and strategy decisions needed to happen faster than what you'd find at a university.

You've been at ARUP a long time. What are some notable changes you've witnessed here?

A—The financial strength of ARUP. When I came here, we were operating on a financial thread. Every two weeks we borrowed the maximum amount possible just to make



payroll; we would take large vendor checks and put them in a drawer until we had enough money in the bank for them to clear. For a number of years, the financial condition was slim. Since then, we've grown the business by 20-fold. With that, we've become better and more efficient, which continues to drive our economic strength. Now we can make decisions quickly, knowing we have the financial backing to support those decisions.

S—The reputation and reach of ARUP has changed. I remember going on a couple of sales calls early on, and people would act like, “Utah? Do planes go there?” Now, ARUP has become well known and incredibly respected coast to coast. Our reputation for quality, our medical directors, and the U of U have really cemented us as a leader in this field.

What personally prepared you for this job?

A—The many challenges I've faced while working here at ARUP—from turning early-stage tax audits and assessments into our current nonprofit status, to navigating complicated business and political issues—have helped shape me and my understanding of what is best for ARUP. Working with the people here has made me realize that we can do great things and solve very complex problems as a team.

S—Throughout my career, I've always had my family's support behind me, encouraging me to go for it. I've had great mentors who were willing to let me try and do things that weren't really accepted when I first came here, and there were very few women in leadership positions at the University. I also think the strong teams we've been able to build here influenced me—helped give me the confidence that we can figure out hard problems together. ■



ARUP rests along the foothills of Salt Lake City, where employees can break away for a mountain bike ride or a trail run—a few even take to the trail on their unicycles. With access to in-house yoga, pilates, a fully equipped gym, a health-focused cafeteria, and a family health clinic, employees are encouraged to take care of themselves—a philosophy nurtured by ARUP's cofounder and past CEO, Carl Kjeldsberg. His belief that, “If you take care of the people, the people will take care of the business,” has become part of ARUP's culture.

From Your Sister with Love— the Gift of Life

When Kylie Sharp slides open her closet door, you're greeted by a blush of bridesmaid's dresses lining the far side. A navy blue one hangs among the pink ones—all silky remnants of unattended weddings, or those she almost didn't make. As Kylie's close college friends walked down aisles to exchange vows, her life was riddled with doctors' appointments and hospital stays. "It's not a good thing when everyone in the ER knows your name," quips Kylie.

Nine years ago, Kylie was diagnosed with autoimmune hepatitis. She was 17 years old. At first, her family thought the fatigue was from her busy high school schedule. A competitive gymnast, Kylie was training five hours a day, five days a week. Then the jaundice kicked in and she learned of her diagnosis. Her doctor informed her that she would eventually need a new liver. Kylie was added to the national waiting list, which gives the sickest patients priority, but she also had a backup plan. "When I first heard the news, I just knew that if I was a match, I would donate part of my liver," says Chelsie, Kylie's older sister by two-and-a-half years.

Waiting to live is not part of Kylie's DNA, as is evident in her blog, "LiverDie." This young woman, who describes herself as "shy...except in the gym," with striking long, auburn hair and a wide-open smile, set off for Seattle, where she was attending the University of Washington on a full gymnastic scholarship.

In her freshman year, a physical required of all school athletes revealed that Kylie had developed primary sclerosing cholangitis, a chronic condition that damages the bile ducts and eventually compromises the health of the liver. This reaffirmed the need for a new liver.

Kylie fought through her fatigue and any thoughts of quitting, continuing with her rigorous training schedule. "I was always tired, but I just dealt with it because that was always how I felt." While earning a degree in anthropology, Kylie headed to the Bahamas on a school service trip and studied abroad in Tahiti.

She settled in Seattle after college, but every few months she would get sick and end up returning home for care. Then University of Utah Health announced its new Living Donor Program for liver transplants, and Kylie qualified. She called her older sister, Chelsie, and gave her the update—she was moving home and gearing up for a new liver. Chelsie was ready. Her sentiments had not changed.

"She keeps me calm, and I make sure she stays brave."

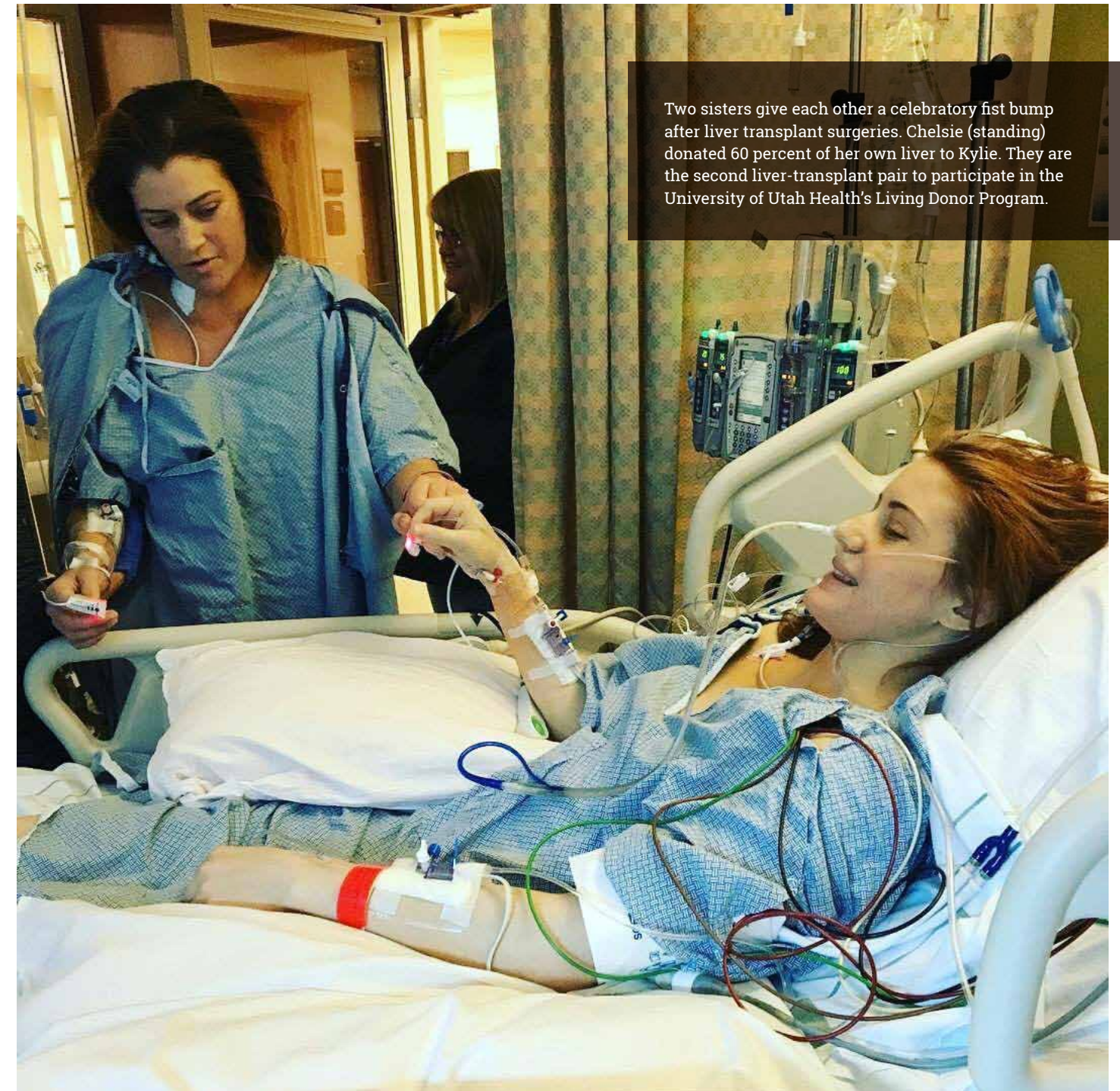
—Chelsie Sharp

"It just naturally felt like my role—it was like a reflex," says Chelsie. They would be the second liver-transplant pair to participate in the Living Donor Program. For the past decade, the program had focused only on kidney transplants—about seven times more patients are waiting for kidneys than livers, according to the United Network for Organ Sharing (UNOS).

"This program meant I wouldn't have to get even sicker before I became eligible for a transplant. It's better if you can be stronger when you go through it," says Kylie.

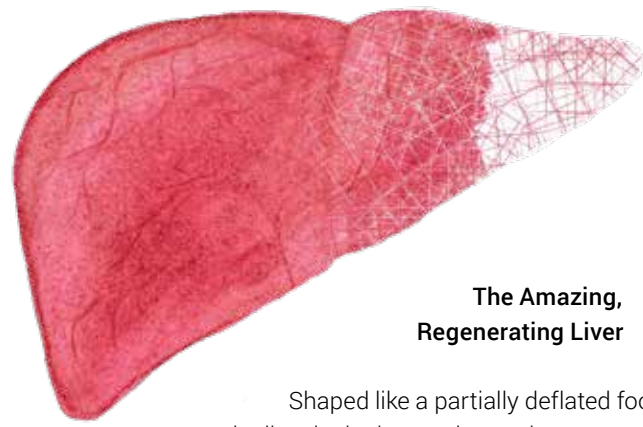
"Hello, beautiful human... The last eight years of my life have led me to a profound knowing that life is a precious gift... How we spend our time is how we spend our life, so wake up and live! Live every day, live every moment, live through every smile and live through the tears... We are never sure where this journey leads or where it ends."

— Excerpt from Kylie Sharp's blog, www.LiverDie.net. Her instagram account: [liv_er_die](https://www.instagram.com/liv_er_die).



Two sisters give each other a celebratory fist bump after liver transplant surgeries. Chelsie (standing) donated 60 percent of her own liver to Kylie. They are the second liver-transplant pair to participate in the University of Utah Health's Living Donor Program.

Photo credit: Felipe Fogolin



The Amazing, Regenerating Liver

Shaped like a partially deflated football, the liver is the largest internal organ, weighing two to three pounds in adults. It is vital. We can't live without it. The liver helps us process what we eat and drink into energy and nutrients for our bodies. It is the main detoxifying organ in the body, removing harmful substances from our blood.

Unlike any other internal organ, the liver can substantially regenerate and grow to just the right size for the body it inhabits. Even if only 25 percent of the original liver mass is present, it can regenerate and return to its full size.

The prospect of liver regeneration was introduced in the early 19th century, but the concept is captured in the story of Prometheus, the Greek god whose immortal liver was feasted on day after day by Zeus's eagle. Each night, Prometheus' liver miraculously regenerated. Of course, this is myth, not medical literature.

The regeneration process begins immediately after surgery. In three months, the donor's liver will have grown to 90 percent of its original size. The recipient's liver typically grows more slowly but will grow to the size required for normal liver function.

Before surgery, 3-D imaging is used to calculate the size and volume of the donor's liver and guide surgeons on how much to remove. "We know how much will be left for the donor and the actual volume that is being given to the recipient. This ensures that both will have sufficient liver to function if growth were not to happen—which is highly unlikely," says

Robin Kim, MD, surgical director of liver transplantation and chief of the Division of Transplantation and Advanced Hepatobiliary Surgery at the University of Utah. While a person can live with as little as 25 percent of her liver, Kim emphasizes that their patients have far more than that.

The option of securing an organ from a living donor helps bypass the national waiting list for an organ. According to the Organ Procurement and Transplantation Network, every 10 minutes, someone is added to this list, and an average of 22 people die each day waiting for a transplant. Even though one organ donor can save up to eight lives, the need far outpaces the demand. This is why every donor—whose body harbors multiple organs—is so precious.



Dr. Robin Kim (right). Photo credit: U of U Health

"Without the doing, the dreaming is useless. We can wake up every morning and daydream about the life that we want to live, or we can choose to make that life our reality. I don't know about you, but I want my dreams to be my reality. So, here's to getting out there and exploring every chance that I get to create a life that I can't wait to share."

— Excerpt from Kylie Sharp's blog, www.LiverDie.net. Her instagram account: [liv_er_die](https://www.instagram.com/liv_er_die).

Matchmaking

Before Chelsie could donate part of her liver to her sister, both were scrutinized in different ways. Was Chelsie truly ready and committed to this decision? Was her own liver healthy enough? Were Chelsie and Kylie's bodies free of infections and viruses?

"The rigor they put you through to ensure you are up for being a donor is intense. You go through months of seeing if you are a good fit," says Chelsie. A team of people were involved, including doctors, social workers, a psychiatrist,

While the transplant process involves a multidisciplinary team all working closely together, pathologists are involved in the entire arc of care, from before to after the transplant surgery. Sometimes, they monitor patients for years after a transplant.

and a dietician, among others. Questions ran the gamut: How does your family feel about this? Is your workplace supportive? Financially, how will you be affected? Whose idea was this? "It was like a series of tough job interviews," recalls Chelsie, who didn't budge in her decision. "It had been made."

While the transplant process involves a multidisciplinary team all working closely together, pathologists are involved in the entire arc of care, from before to after the transplant surgery. Sometimes, they monitor patients for years after a transplant. Pathologists are more often found in the lab than at the patient's bedside, and their expertise is in analyzing a patient's blood and tissue biopsies on slides beneath a microscope.

Pathologists determine blood types, antibody status, and how well an organ is functioning. They are able to check for infections and the presence of autoimmune or inherited

How Can a Transplant Trigger Lymphoma Cancer?

The Epstein-Barr virus (EBV) is a common herpes-type virus that infects about 95 percent of adults. At the time of initial infection, EBV may lead to the disease called mononucleosis or "mono," or it may cause no symptoms at all. Once we are infected with EBV, the virus remains with us for life. Alternatively, some patients may never have been exposed to EBV before a transplant, and it is possible to acquire the infection through a transplanted organ if the donor was previously infected.

EBV resides in blood cells called B lymphocytes in a resting or latent state. In the latent state, the virus changes the way its genes and proteins are expressed so that it can evade the immune system and remain in the B cells of our bodies undetected. The genes and proteins of latent EBV also stimulate B cells to proliferate or divide and make more copies. The virus then gets passed along in these cell divisions.

Some of the rapidly proliferating or dividing B cells may turn into cancer cells. When the immune system is normal and healthy, it keeps abnormal B-cell proliferation in check. When the immune system is weakened by medications after a transplant, uncontrolled B-cell proliferation can turn into cancer (e.g., lymphoma).

The main treatment for EBV-driven lymphoproliferative disease is a reduction in the immunosuppressive drugs. The hope is that this will allow the immune



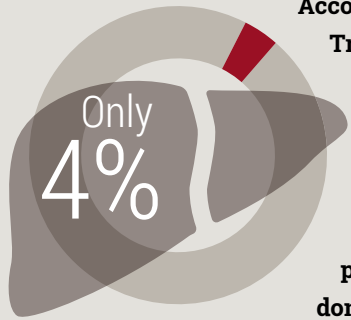
system to help fight the abnormal B-cell proliferation. If that does not work or the disease advances to cancer, then treatment entails chemotherapy.

Living Donor Programs

Last year, University of Utah Health launched its Living Donor Liver Transplant Program, one of only 20 such programs in the country. So far, five people have successfully received a living liver transplant; Kylie and Chelsie Sharp (see main article) were the second pair to participate in the program.

Living donor transplantation, in which a part (liver) or whole (kidney) organ is donated by a living person—often a family member or friend—increases the availability of healthy organs for transplants so that recipients can undergo a transplant before they become increasingly sick or die as a result of organ failure.

According to the American Transplant Foundation, in 2015, only 359 liver transplants (or about 4 percent of all liver transplants performed that year) were made possible by living donation.



Living donor kidney transplant programs are more common, with some 230 across the United States. The U of U Health's own program started in 1966 and has provided 950 kidney transplants, with over a 98 percent patient survival rate.

"This disparity in numbers of living donor kidney versus liver programs is due to multiple factors, including the increased complexity of the surgery and the later inception of living donor liver transplantation," says Robin Kim, MD, surgical director of liver transplantation and chief of the Division of Transplantation and Advanced Hepatobiliary Surgery at the University of Utah.

Living donor programs have a positive ripple effect, giving others on donor transplant waiting lists a better chance of becoming a recipient of a deceased donor. According to the American Liver Foundation, currently some 17,000 children and adults are waiting for donated livers. The waiting list grows every year.

diseases in both the donor and recipient. "These diagnostics help us determine if transplantation is a good idea or not," says Kim.

To avoid transplant rejection, Kylie and Chelsie's blood is carefully studied, as well as their liver tissue, which needs to match as closely as possible. If Kylie's body detects something foreign—antigens from Chelsie's liver—her body might attack her new liver. (Antigens are perceived as a foreign substance in the body and trigger an immune response.)

Sometimes the donor's history is unknown or incomplete, especially in the case of donors who have passed away. The liver is screened for inherent liver disease, hepatitis, scarring, fatty infiltration, liver spots, or anything else that might indicate disease. "The pathologist will help us determine what the disease is and how far along it is," says Kim, who notes that lab results are just one of the guiding factors used to determine whether a transplant is a good idea. "It's a go about 50 percent of the time."

"In the pretransplant stage, we're looking for what infections the donor and the recipient may have been exposed to in the past," explains Kim Hanson, MD, MHS, section chief of Clinical Microbiology at ARUP. She is also at the bedside, caring for patients. Hanson explains that many of us have been exposed to and harbor asymptomatic infections in our bodies, such as the herpes viruses or tuberculosis.

"These can wake up after a transplant and cause major problems for the recipient. Lab testing is done to screen both the donor and the recipient. We then use the results to develop infection prevention and/or monitoring strategies for the recipient," says Hanson, who is also the head of Immunocompromised Host Infectious Diseases Services at the University of Utah Hospital and Huntsman Cancer Center. The risk of infection varies based on the type of transplant.

Sometimes, midsurgery, the surgical team will come across something suspicious (e.g., a mass, an enlarged lymph node), and they will biopsy it and wait for a pathologist to analyze the tissue. "They need to know more about it before they proceed. Is it cancerous or not?" says Allie Grossman, MD, PhD, medical director of Surgical Pathology and Molecular Oncology at ARUP. She and her colleagues may have only 20 minutes to obtain the patient's tissue, mount it, section it, stain it, and interpret it in order to provide a diagnosis. If the tissue is cancerous, the transplant is halted.

If this complex matchmaking process goes well, and the donor's organ proves healthy, then the next milestone is the actual transplant.



"Every day may not be good, but there is something good in every day. If there is one thing this whole process has taught me, it is to count my blessings every day and take full advantage of the days that I am feeling healthy. I always try to remind all of you to wake up and live every day of your life, but trust me, I have to constantly remind myself as well. Life is definitely a glorious mess, but amongst this chaos it is also a beautiful adventure."

— Excerpt from Kylie Sharp's blog, www.LiverDie.net. Her Instagram account: [liv_er_die](https://www.instagram.com/liv_er_die).

A Bit of History...

At the University of Utah, a shortlist of well-known individuals have played notable roles in artificial organ and transplant organ advancements—for example, William Kolff, MD, in the area of kidneys, and William DeVries, MD, and Robert Jarvik, MD, in the area of the heart. Part of such pioneering work can be attributed to **Ernst Eichwald, MD, a former professor of pathology and the chair of the U of U's**



Department of Pathology (1967–79).

Eichwald's work focused on tissue transplantation and research on genetic factors that influence the rejection of the transplanted organ. While studying cancer in the 1940s, he described the

male-specific antigen, an identifying factor allowing doctors to see if the patient's immune system was accepting the transplant or not. This finding helped establish the foundations of transplantation immunology.

"Ernst was always very curious about the pathophysiology of tissue transplantation and worked relentlessly—early morning to late at night and weekends. He did this into his 80s," recalls Carl Kjeldsberg, MD, who worked for Eichwald in the '70s and would go on to cofound and run ARUP. "In meetings, he would challenge you with pointed questions. He was critical and demanding but always fair."

Eichwald organized the first International Transplantation Conference, sponsored by the National Institutes of Health, and founded the journal that would become known as *Transplantation*. His research played an important role in the development of successful protocols for organ transplantation in patients.

Kjeldsberg adds, "Ernst was what Germans call a Mensch—a great human being."

When I Woke Up

Seven years after Kylie learned she would eventually need a new liver, she and her sister were being prepped for surgery in the U of U's surgical transplant unit. It was 7 a.m., and their family was gathered around Chelsie's hospital bed.

"I remember everyone being nervous," says Kylie. A nurse was inserting an IV tube into Chelsie's arm, and she had to be poked twice. Chelsie hates needles; she passed out on her very first blood draw during the matching process. "You sure you want to do this?" teased Kylie. "When you wake up, there are going to be a lot more of these around you."

Four hours later, it was Kylie's turn to leave her mom's side. "I love you," said her mom, Toynet Sharp. "You're going to feel really good when you wake up, and I'll be here waiting for you." She wouldn't see Kylie until 10 p.m. Chelsie woke up at 3 p.m.

"It was hard to sit there and wonder," recalls Toynet. "What kept us going was the steady stream of updates we got on each of the girls throughout the surgeries. It was really reassuring." Coincidentally, the day also marked Toynet and her husband's 30th wedding anniversary. The surgeries were not the "extra special thing" they had planned on, but when they found out the date, it seemed like a good fit. "One daughter helping save the life of our other daughter was about as extra special as it gets."

Kylie recalls: "When I woke up, I was crying, I was so happy to see my mom." She immediately asked, "How's Chelsie? Is she OK?" She could see Chelsie through the door in the adjoining ICU room. Kylie attempted three steps to go see her sister, but had to lie back down.

"When I woke up, my first concern was my mom—her whole world is her three children," remembers Chelsie. "And two of us were in surgery." Once Chelsie was able to stand with the care team's help, she shuffled over to her sister. With Chelsie leaning on Kylie's bed, the two sisters, with two groggy smiles, gave each other a wobbly, we-did-it fist bump.

A team of 10 doctors and nurses transplanted 60 percent of Chelsie's liver into Kylie, and completely removed Kylie's weakened liver. Because the liver is a highly vascular organ, the process is slow and meticulous work, about a four- to five-hour operation for each surgery. Within a few days of surgery, Kylie's jaundice began to disappear, the clotting abilities of her blood improved, and she began thinking more clearly. "My body just felt better," says Kylie.

Then for the next milestone: Kylie's body needed to accept the new liver.

"I tell my patients that transplantation is about second chances and that many with end-stage organ disease don't get that chance... Yes, there are going to be ups and downs, but at the end of this process is the opportunity to lead a normal and healthy life."

—Robin Kim, MD

"I Thought, This Time, What Can I Give Her?"

Kylie began receiving high doses of immunosuppressant drugs just hours before the transplant. Immunosuppressant drugs cast a sleepy spell over the cellular warriors in the body that fight foreign invaders, preventing them from attacking the new liver, mistaking it for an intruder.

However, when these warriors are subdued, they can't fight off the real threats of viruses, germs, and bacteria. "It is a really delicate balance on how much to give," admits Kim Evason, ARUP medical director of Anatomic Pathology. "If you don't provide enough of the immunosuppressant drug, then you risk rejection; if too much, the patient may develop an infection." Evason analyzes more than 500 slides a week looking for clues that will help guide doctors toward the best treatment for their patients. "We look at the slides and the patient's chart and then start puzzling it over together."

Last August, only five months after her transplant, Kylie was diagnosed with posttransplant lymphoma, a cancer resulting from an accelerated growth of white blood cells in the body's immune system. "I thought, this time, what can I give her?" says Chelsie. The Epstein-Barr virus (EBV) is often the underlying culprit that triggers this type of lymphoma; most likely Chelsie had been exposed to this virus and it woke up from a latent or dormant state once it was introduced into Kylie's body. EBV-driven cancer is relatively rare, developing in approximately 1–2 percent of patients within the first five years after a liver transplant. (To learn more about the pathophysiology, see sidebar on page 13).

While a team of medical specialists guided Kylie through her treatment, it required a deluge of doctors' appointments, unexpected hospital stays, and days of feeling "ugh." "She spent more days in the hospital than she did in her own bed last year," recalls Chelsie.

It was the year that many of her close friends were marrying, and Kylie never knew, until the last minute, whether she was going to make their weddings or not. It depended on her health. Despite the frustrations, Kylie focused on the good days. "If Kylie can, she is totally out living life," says Chelsie. "Her attitude is: Be alive while you can."

"When I feel good, I want to go out and play and do what it is I love. I try not to think about what is holding me back," says Kylie, who loves dogs, rock climbing, and hiking. "You were just in the hospital yesterday, what are you doing out hiking today?" I get that question all the time."

Maybe it was all that time spent balancing—walking, leaping, dancing—along the unforgivingly narrow path of a gymnast's beam that has helped Kylie develop her grit for counterbalancing her trials with positivity—admittedly, an emotionally taxing balancing act at times. Managing emotions is an art, and a discipline she is passing on to young gymnasts as a coach.

Now when Kylie slides open her closet door, a long, pink chiffon dress is mixed in with the other pink bridesmaid's dresses. This past September, when Kylie watched her sister Chelsie walk down the aisle to exchange vows, she wore this dress, feeling healthy and happy for everyone. ■



No way was she going to miss this wedding. Kylie with her sister and bride-to-be, Chelsie.

Our Experts Are Your Experts—A Consulting Team That Talks Shop with Clients



Dave Rogers and three other ARUP employees were on a shuttle bus headed to the Fort Lauderdale airport. They had just finished up visits to five hospital labs over two and a half days for a client. Despite the humidity and long days, Rogers and his colleagues—Leslie Hamilton, Clint Wilcox, and Jerri Turner-Jacyno—were bantering back and forth, excited.

“We were amazed by all that we were able to do,” recalls Rogers, group manager over several support areas at the time. “So many efficiency improvements came out of the visit.”

They brainstormed: Why don’t we do this for other clients? What would this team look like? What other areas of expertise could ARUP share that would directly help a laboratory improve?

What started as a trip five years ago to woo a struggling client, one that ARUP was at risk of losing, set in motion what would become a well-crafted consulting team that today invigorates the laboratory processes of a half dozen of ARUP’s clients each year. The Consultative Services department pulls people in from other areas of the company to create these teams.

Members of the team are chosen based on what a client needs—often these needs are pain points that ARUP’s account executives have homed in on while working with their clients. Perhaps a client has requested someone to advise them on specimen tracking or courier/transportation or microbiology processes. “Their needs can be quite different, so how we can help them is very customized,” says Kevin Swallow, Client Relations Division manager.

“These visits deepen the relationship with our clients,” adds Leigh Huynh, MBA, senior healthcare consultant at ARUP, who oversees these visits. “They really begin to see us more as a partner who can help them solve problems.”

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Why don’t we do this for other clients? What would this team look like? What other areas of expertise could ARUP share that would directly help a laboratory improve?

Questions Help Home in on Solutions

Admittedly, it can be unnerving when a handful of strangers walk into your lab, watch you work, and ask a bunch of questions, all the while jotting down notes. Moments that might make you sweat.

“As soon as the staff knows we’re not there to cut jobs or take over or steal their business, they are welcoming,” says Huynh, with a laugh.

“Help might even be showing them how to bring more tests in-house,” says Jason Goodfellow, who oversees IT support for the University of Utah Hospital’s laboratory. “Sometimes we get incredulous looks, but there will always be reference tests that they will need, and they can send those to us.”

The Consultative Services team talks to as many people as they can who are at the bench and doing the hands-on work. Managers step away, so employees will talk more freely. By the end, the ARUP team knows the lab staff well.



“These visits deepen the relationship with our clients,” says Leigh Huynh, MBA, senior healthcare consultant. “They really begin to see us more as a partner who can help them solve problems.”

Examples of the types of questions asked include: What takes up the most time in your day? What is the task that you most dread? What is your daily workflow, and why is it that way? What suggestions do you have? What would you change?

“Often, what we find is that everybody is doing things differently even though everybody thinks they are doing things the same,” says Huynh. Oftentimes, there are multiple ways to perform the same tasks. The Consultative Services team guides clients toward best practices.

A broad range of input and perspectives are gleaned from those in the lab and those using the lab—and about the impact of the lab and its practices on patient care. Along with laboratorians, the consultative team also talks to pathologists, hospitalists, ER physicians, and directors, among others. If needed, team members will attend 4 a.m. morning rounds with phlebotomists or come in at night to observe the night shift lab operations.

“It’s all about matching what their needs are with all the expertise and depth of experience we have here.”

—Sandy Richman, Director, Consultative Services

At the Medical University of South Carolina (MUSC), ARUP was hired to provide consulting for a lab remodel. “They spent four days here analyzing all the labs—all the front end operations. They weren’t only focused on mapping floor plans, but were also watching the interactions between labs,” says Lori Gauld, director of operations for Pathology and Laboratory Medicine at MUSC. “The recommendations we received were not just regarding space issues, but also suggested things we could work on prior to remodeling.”

The Teacher Is the Student; the Student Is the Teacher

Clients receive robust reports, averaging around 35–40 recommendations. This tangible, third-party input is sometimes all a client needs to sway leadership to take action on laboratory concerns that have been simmering on the back burner.

This was helpful for MUSC, who had been pushing for a laboratory remodel for their central processing. “We were able to take a plan to our space committee and get permission to move forward,” says Gauld. “ARUP helped us articulate our needs and get them all on paper—when you see them on paper, you understand where all the inefficiencies are.”

“We were able to take a plan to our space committee and get permission to move forward... ARUP helped us articulate our needs and get them all on paper—when you see them on paper, you understand where all the inefficiencies are.”

—Lori Gauld, Director of Operations, Pathology and Laboratory Medicine, Medical University of South Carolina

Rogers explains that, primarily, three areas are covered in the consulting outreach: removing interferences, improving efficiencies, and improving quality. Rogers, who oversees the Specimen Processing department at ARUP’s central facility, developed a scoring system for clients, allowing the clients to rank the “ease” and “impact” involved in implementing recommendations.

This visual scorecard helps clients prioritize and decide whether or not to act on a recommendation. For example, if a laboratory can’t handle incoming calls, a recommendation might be to implement a client relations management program—a hefty investment. On a scale from one to three, this is a “one,” meaning it’s difficult to implement. However, the impact of such a program would be a “three,” the highest ranking. Add the two scores together for a final score of four. “If the final score is a ‘five’ or a ‘six’, then we’ll suggest they move forward with the recommendation,” says Rogers.

“The scorecard showed us some low hanging fruit and validated for us that we were on the right path with changes we wanted to make,” says Laura Bubla, director of Laboratory Services for SSM Health in Janesville, Wisconsin. Her company was especially interested in exploring ways to improve employee scheduling. “We wanted to hear from ARUP what they had seen work well and what combination would work best for us,” adds Bubla, whose laboratory has begun using block scheduling this fall. “Change is hard, but these recommendations helped us move this forward.”

ARUP team members, selected based on client requests, take time out of their already busy roles at ARUP to help. It is a voluntary effort with no additional pay; they do it because they get something out of it, too.

“By immersing myself in our clients’ world, I gain a better understanding of what their needs are and how they work,” says Dave Layton, an industrial engineer supervisor. “I also learn a tremendous amount from the rest of the team. All this helps me do my job here better.”

“It goes two ways,” says Rhonda Hensley, who sometimes returns with new ideas to implement. Hensley specializes in microbiology laboratory testing.

“We have a lot of experience and robust departments here with the freedom to innovate and come up with ideas to solve our own internal issues,” says Goodfellow. “And then we get to go out and share these solutions with other labs.” ■

Sharing Our Solutions

Tailored Consulting Teams Match Clients’ Needs

What started as a trip to woo a struggling client more than five years ago set in motion what would become a well-crafted consulting team that today invigorates the laboratory processes of a half dozen of ARUP’s clients each year.



Dave Layton, Supervisor, Industrial Engineer

Specialty areas: process improvement, floor design/redesign, industrial engineering, Lean and Six Sigma, value stream mapping

“We go in and take a look at a client’s current strategies and then offer workflow recommendations and identify areas where they can reduce waste and error. One client had three different drop-off points for incoming specimens. We consolidated it to one drop-off area to reduce confusion

and duplication of resources. We share ideas about introducing Lean into the lab, often by value stream mapping a client’s processes. For example, if an assay has a technician going between three different benches, we find ways to reduce it.”



Ken Curtis, Supervisor, Technical Support

Specialty areas: client services, exception handling

“I spent nine years in a clinical lab setting so

that comes in handy too in helping clients with processing and support in a hospital laboratory. We’ll work with clients on how to build a call center within a hospital lab or how to manage calls better with their existing staff. We break it down into steps—really getting into the specifics. We can help with managing and tracking specimen issues; for example, a recommendation might be to electronically tag a problem specimen so it won’t sit too long or be forgotten about when a shift change happens.”



Chris Sorensen, National Transportation Manager

Specialty areas: logistics/couriers operations, IATA & DOT shipping, regulations, specimen tracking, process improvement, driver safety

“I help with streamlining the movement of specimens from outreach, internal departments, or outside facilities into the lab. Past experience overseeing phlebotomy, specimen processing, and referral testing helps me have an overall view of workflow from the patient to the testing lab. For one client, I worked with their courier team on delivery logistics. Their pickup/drop-off times made

sense to them, but these times didn't support turnaround times in the lab. We recommended how they could get more specimens per run, decrease turnaround by avoiding specimens sitting overnight or coming in late.”



Kevin Swallow, Client Relations Division Manager

Specialty areas: outreach connectivity solutions, process improvement, client supply, training/logistics, business development

“We provide the analysis for complete hospital connectivity to doctors, or just for certain components. One client had us look at their utilization management, business

development, lab operations, and transportation—they wanted full integration of all these areas.”



Rhonda Hensley, AVP, Group Manager, Classic Infectious Disease

Specialty areas: microbiology laboratory testing, procedure knowledge

“One client wanted us to look for inefficiencies in their microbiology department, so our recommendations primarily focused on ways that would save time and rid processes of unnecessary steps. We provided more than 40 recommendations. We suggested a faster method for

identification of yeast that didn't cost a cent but improved turnaround by 24 hours. We pointed out where they could eliminate some steps in culture reads and provided an easier way to process ova and parasites.”



Jason Goodfellow, University Hospital Lab Technical Supervisor/IT Support

Specialty areas: hospital operations, IT, lab and hospital information systems design, phlebotomy, process improvement, specimen receiving

“My expertise is in my experience. Often, I can quickly understand the issue a hospital lab is facing because we've had that same challenge and had to come up with

solutions. For example, one client was being overwhelmed with a lengthy registration process for outpatients needing lab work. We recommended a self-service kiosk that integrates with the hospital systems to move that front-end stress off of the lab employees and also provide a smoother process for outpatients.”



Dave Rogers, Group Manager, Support Services/Specimen Processing

Specialty areas: specimen receiving, laboratory automation, laboratory informatics, referral testing, process improvement, courier management

“Most everything we do falls into three main

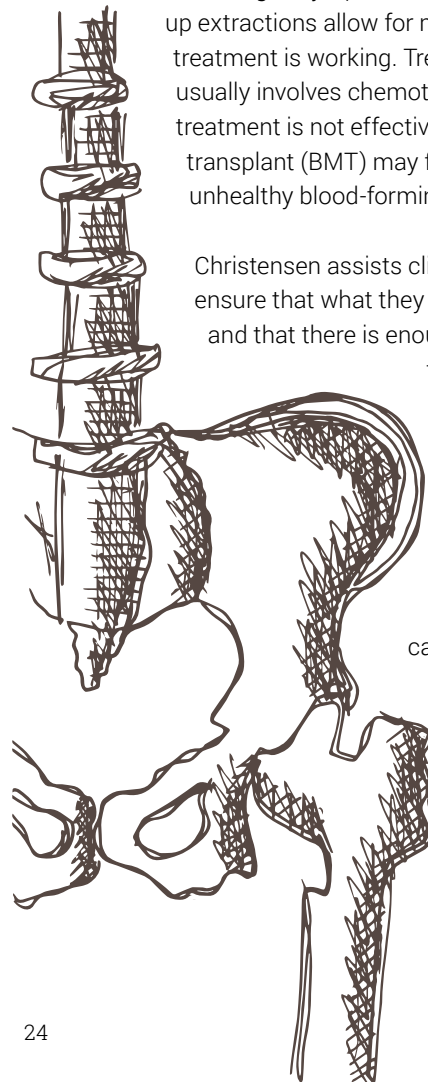
categories: removing interferences, improving efficiencies, and improving quality. We'll show clients how to improve their processes, like how to build in daily quality controls such as function checks for their freezer and refrigerators. Daily, someone needs to record the temperatures in their system to make sure they are within the correct range. If temps are outside this range, then the employee needs to document what they did to address the issue. The capturing and required review of this information can be automated to help a client improve patient care and meet regulatory requirements.” ■

Bone Deep—Tapping the **Lifeblood** of Marrow for Transplant Patients

Whenever Lauren Christensen gets a Frosty at Wendy's, she thinks of one of her patients. "After each bone marrow extraction, she always treats herself to a Frosty," says Christensen, an ARUP technician who specializes in bone marrow extraction and biopsies at Huntsman Cancer Hospital for patients with blood cancers.

"I've known some of these patients for years; it's why I love my job. You get to know about their kids, pets, how school is going," says Christensen, who hopes the conversation helps distract patients from the procedure.

The extracted bone marrow or a bone biopsy helps pathologists identify the type of cancer (e.g., Hodgkin/non-Hodgkin lymphoma, leukemia, myeloma). Follow-up extractions allow for monitoring to see if the treatment is working. Treatment for these patients usually involves chemotherapy or radiation. If the treatment is not effective, then a bone marrow transplant (BMT) may follow, which aims to replace unhealthy blood-forming cells with healthy ones.



Christensen assists clinicians, guiding them to ensure that what they extract is bone marrow and that there is enough of it for sufficient

testing—usually about two teaspoons. Marrow is the soft tissue inside bones that produces more than 200 billion new blood-forming cells daily—cells that will grow into red blood cells (oxygen carriers), white blood cells (infection fighters), and platelets (for clotting and repair). Marrow is the seedbed of our blood.

A deep red, and more viscous than blood,

marrow is filled with tiny bone spicules that look like grains of sand. Before it clots, Christensen will immediately plop marrow droplets onto slides. Then blood from a quick finger prick is put on a slide as well. This allows the pathologist to compare the circulating blood to the bone marrow slides to see how the two compare.

After pathologists identify the type of disease, then they look for clues to indicate risk factors for that particular patient, such as genetic variations, blood cell count, plasma counts, and chromosome variation. All these results play into a scoring system that will guide the doctor to move forward with a transplant or choose another treatment approach.

In the lab, these slides will be analyzed by a pathologist such as Mohamed Salama, MD, ARUP's chief of Hematopathology. "When I look at a patient's blood sample through the microscope, I determine the tests we are going to need to do from that point forward to get more specific info—with each test, results may indicate a need for another test, until we've narrowed the differential diagnosis down to a very specific diagnosis."

Dr. Lazar-Molnar is part of the continuum of care for patients who need a bone marrow transplant. This includes identifying a specific diagnosis, helping patients find a good match, and monitoring a patient's health after the transplant.

Sincere thanks to our neighbor, the Natural History Museum of Utah, for the beautiful photo backdrop.

After pathologists identify the type of disease (e.g., type of leukemia), then they look for clues to indicate risk factors for that particular patient, such as genetic variations, blood cell count, plasma counts, and chromosome variation. All these results play into a scoring system that will guide the managing doctor to move forward with a transplant or choose another treatment approach. "We provide the doctor with a very detailed story of what is going on based on all these clues," says Salama.

The Heart and Science of Matching

There are two different types of bone marrow transplants: one involves transplanting the patient's own cells back into the body; this is an autologous transplant. These blood stem cells are taken from the blood before chemotherapy and then transfused back in after the treatment. Transplants that use another person's cells are known as allogeneic transplants and require finding the right match.

The search to find the right match can be quite extensive, generally starting with siblings and parents, then extended relatives, and then eventually reaching out to nonrelated people or donor registries. This process can take an

average of three months (to day of transplant) and can be longer for minorities and mixed ethnicities, who may face more challenges in finding a match because the potential matching donor population pool is smaller.

A sibling who has the same biological parents as the recipient has a 25 percent (1 in 4) chance of being a match. However, 70 percent of patients will not have a match in their family. Many patients are looking for matches; every three minutes in the United States a person is diagnosed with blood cancer, according to Cheekswab, an organization that urges minorities to become donors.

What needs to match up between a donor and recipient are the human leukocyte antigens (HLAs), which are specific proteins on the surface of white blood cells and other cells that make each person's tissue type unique. Blood tests can show if a person's HLA is a good match for a patient—the better matched, the less likelihood of complications.

"These HLA molecules are inherited from your parents, one set [known as a haplotype] from each. If you have siblings, there is a 25 percent chance that you will have an HLA identical sibling—the best match for a transplant—and a



The patient becomes a chimera, with DNA from another being.

25 percent chance that you share none at all, in which case a transplant is not possible," explains Eszter Lazar-Molnar, PhD, ARUP's medical director of Immunology. "These molecules show a strong linkage to racial and ethnic background."

For those who can't find a match within their family, it is crucial that bone marrow registries, like the National Marrow Donor Program, are available and have a large pool of donors. "By registering to be a donor, you can literally save someone's life by donating once," says Lazar-Molnar, who also oversees the University of Utah's Histocompatibility and Immunogenetics Laboratory. Her team reconfirms that the blood typing is accurate for those who find a match through registries.

Lazar-Molnar explains that while a perfect HLA match is best, sometimes this is not possible, and patients must settle for mismatches in which only some but not all of the HLA molecules are matched, which may increase the risk of rejection and other complications. There is a 50 percent chance of sharing one haplotype with your siblings, and with each of your parents—therefore, the chance of finding a donor with one haplotype match is usually much easier. Haplo-transplants raise other issues: mainly, how will recipients react to the mismatched HLA molecules being introduced into their bodies via the donors' bone marrow or stem cells? In short, can everyone play well in the sandbox together?

Laboratory tests can be used to detect whether the recipient has antibodies that will react to the donor's HLA and help monitor and manage these interactions. Such antibodies could potentially interfere with the body accepting the new cells, and could end up injuring the donor cells by triggering an immune response. "Not everyone has antibodies that strike against HLA, but previous transfusions, transplants, or pregnancy may lead to sensitization and the development of HLA antibodies," says Lazar-Molnar.

Donors can now donate either through peripheral blood draws, or by having a bone marrow extraction. For

collection of stem cells from peripheral blood, donors take medication that increases the number of blood-forming cells in the blood stream, which then can be collected by passing the blood through a machine that separates them. Transplant involves injecting these cells into the recipient's body, and the cells find their niche—migrating to the recipient's bone marrow—and go to work generating healthy blood cells.

"The match testing is happening while the doctor is preparing the patient for a transplant—eradicating the disease or decreasing the bulk of it through chemotherapy or other disease protocols," explains Salama. Pathologists are an integral part of the medical team to help identify when a patient is at the best point for a transplant to begin.

To Reject or Accept: A Delicate Balance

Right after a transplant, the doctor will check the transplant recipient's blood counts weekly to see if new blood cells are starting to grow in the bone marrow. Pathologists are able to identify which cells are from the donor (by markers in the DNA) and which are the recipient's cells in order to determine if the transplant (graft) is working and if there is any impending rejection or recurrence. The patient becomes a chimera, with DNA from another being. (A chimera is the Greek mythological beast composed of parts from different animals.)



Lauren Christensen, who specializes in bone marrow extraction, may see some patients over a period of years. The best part? Connecting with patients and seeing them get healthier.

If there are more of the donor's blood cells (DNA), this indicates success and less possibility of graft rejection. If there are more of the recipient's blood cells, then this may indicate a relapse or rejection. A very serious concern is a complication called graft-versus-host disease (GVHD), in which the donor's cells identify recipient's cells as foreign and start attacking not just the recipient's unhealthy bone marrow cells, which is good, but also start attacking other parts of the body.

"Imagine an army of praying mantises swarming a rose bush and eating away the aphids that are killing the roses, but after depleting the aphids, they turn on the roses themselves," says Nahla Heikal, MD, who analyzes posttransplant chimerism blood testing. She is a medical director of Immunology and Hemostasis/Thrombosis at ARUP.

She must closely monitor patients to make sure their immune systems are suppressed enough to accept the proliferation of donor T cells, but not suppressed so much that GVHD develops. "It's a very fine line to keep in control," admits Heikal. T cells, a type of white blood cell, are fundamental to our immune system; they are like soldiers that search out and destroy the targeted invaders (pathogens).

If the patient's health is improving, then the blood tests become less frequent. If there is still concern, then testing will continue, sometimes for many months or years. Testing can reveal how certain cell subsets are doing (e.g., myeloid cells, T cells, B cells, natural killer cells). "These can provide us with different messages," explains Heikal. "For example, if there is a high percentage of donor T cells on day 14 after the transplant, then this reassures us that things are going well." Looking at these subsets can also provide early warning signs of an impending rejection or recurrence, alerting the clinician of the need for early treatment.

"As I do calculations to understand and interpret the results, I'm very conscious of the person who is at the other end of these tests," expresses Heikal. She knows doctors will be looking for a progression in the results to determine if the patient is doing better. "I know how meaningful these numbers are for determining the best treatment and what they will mean for that patient." ■



The Gift of Life, Twice: Cord Blood Donations

When a baby enters the world, the gift of life can be magnified if the umbilical cord blood is donated to a public cord blood bank. Cord blood can be used to treat more than 80 diseases, including blood cancers like leukemia and lymphoma. The need is intense. According to the National Marrow Donor Program (NMDP), every three minutes, someone is diagnosed with blood cancer in the United States.

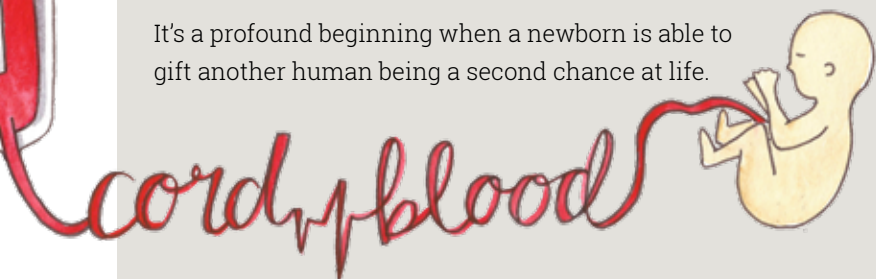
Studies show that cord blood does not need to match as closely as bone marrow or peripheral (circulating) blood for a successful transplant. For transplant patients who don't have a matched donor in their family, this increases the likelihood of finding a match—a process that can take more time than a patient might have.

Typically, the umbilical cord and placenta are discarded after a baby is born. Some people make arrangements to have their child's stem cells—from the cord and placenta—collected and stored in a private cord blood bank in case of health issues later in the baby's life or to secure the cells for a biological sibling who has a diagnosed medical need. To be clear, these stem cells are not taken from an embryo, and no blood is taken from the baby.

Sometimes finding a match is more difficult for those of different ethnic backgrounds (including interracial) because they have a smaller pool to draw matches from than Caucasian (white) donor seekers. In 2015, about 10 times more African-American patients could not find a match compared to 3 percent of Caucasians, according to NMDP, which operates Be The Match, the world's largest and most diverse donor registry. Donating cord blood increases the likelihood that a match can be found.

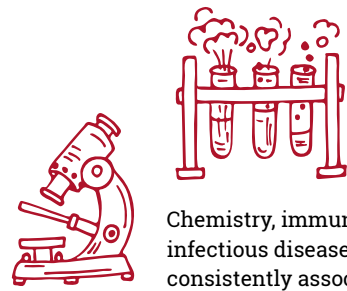
While only certain U.S. hospitals collect cord blood for donation to public cord banks, NMDP can send a cord blood donation kit to anyone who requests one. Donating is free and safe for both the baby and mother.

It's a profound beginning when a newborn is able to gift another human being a second chance at life.





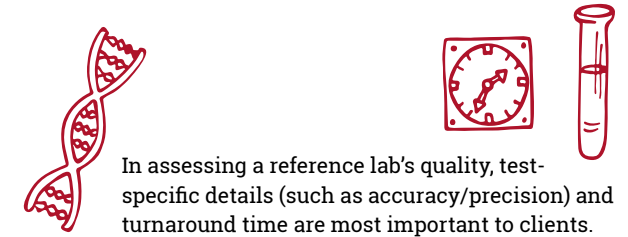
Nine in 10 respondents say that it is easy to do business with ARUP; only 2 percent say doing business with ARUP is difficult.



Chemistry, immunology, and infectious disease are the testing areas consistently associated with ARUP.



In assessing the best lab, clients tend to pick ARUP for customer service, interface services, scope of test menu, and price.



In assessing a reference lab's quality, test-specific details (such as accuracy/precision) and turnaround time are most important to clients.

The Results Are In—Clients Provide Excellent Feedback

"ARUP has wonderful customer service. They look at what is best for the client. It's like shopping at Macy's at Christmas as seen in the movie *Miracle on 34th Street*."

This was one of the more creative comments provided by the 1,200-plus clients who provided feedback in the 2017 Client Satisfaction Survey. Many comments praised interactions with our Client Services department. SRS San Diego Main Lab stated, "I wish ARUP could teach classes on customer service and respect to all companies who employ human beings."

"We've continued to improve steadily with each survey," says Kaarin Nisbet, assistant vice president and group

"ARUP has proven that it cares about quality. Customer service is definitely a priority. ARUP has convinced me that there are labs that actually care about quality results and not just the money. I proudly recommend ARUP to anyone who asks."

—Doylestown Hospital (Pennsylvania)

manager of Client Services. She points to three surveys conducted in the last five years.

On this most recent survey, clients put a great deal of importance on test-specific details (e.g., accuracy and precision) and turnaround time. More than half of the respondents rated the following as ARUP's strengths: utilization management, price, academic affiliation, and our efforts to support their goals to be the principal healthcare providers in their communities. "Results are very encouraging; these are the most positive results we have seen since Market Research took over this survey in 2013," says Daniel James, one of ARUP's senior market research analysts.

Overall, ARUP achieved a net promoter score (NPS) of 64

"Excellent quality and service. Our partner, NOT our competitor!"

—Adventist Hinsdale Hospital (Illinois)

percent. Companies with a comparable score are Facebook and Google. Amazon scores 71 percent. (An NPS is based on a respondent's likelihood to recommend ARUP to colleagues.) NPS rankings were highest among children's

"ARUP always has knowledgeable people working the phones. I can always get through without waiting; they get back to me when they say they will, and I can always trust what they are telling me. Not every lab is like that and I appreciate that in your company."

—Children's Hospital and Medical Center (Nebraska)



The majority of respondents (52 percent) indicated that they use a reference lab to perform molecular oncology or genetic sequencing tests, whereas 35 percent indicated they send this testing to a boutique lab.



ARUP achieved a net promoter score* (NPS) of 64 percent. Companies with a comparable score are Facebook and Google. Amazon scores 71 percent.



The highest NPS belong to children's hospitals and pathology groups or clinics (79 percent for each).

63%

63 percent say that ARUP is the best lab in terms of price.

hospitals and pathology groups or clinics, while reference labs received the lowest NPS (40 percent)—not surprising, as these are also ARUP’s competitors. The greater the respondent’s level of responsibility in deciding which reference lab to use, the higher ARUP’s NPS.

Chemistry, immunology, and infectious disease are the testing areas consistently associated with ARUP. The majority of respondents (52 percent) indicated that they use a reference lab to perform molecular oncology or genetic sequencing tests, whereas 35 percent indicated they send this testing to a boutique lab.

“ARUP continues to have an outstanding reputation and has always provided testing at a fair and reasonable price. The organization conducts itself with integrity, as seen through their work to improve laboratory test utilization. No other company is willing to share that a hospital laboratory could perform testing themselves at a more reasonable price; most labs would promote themselves as the only way to go.”

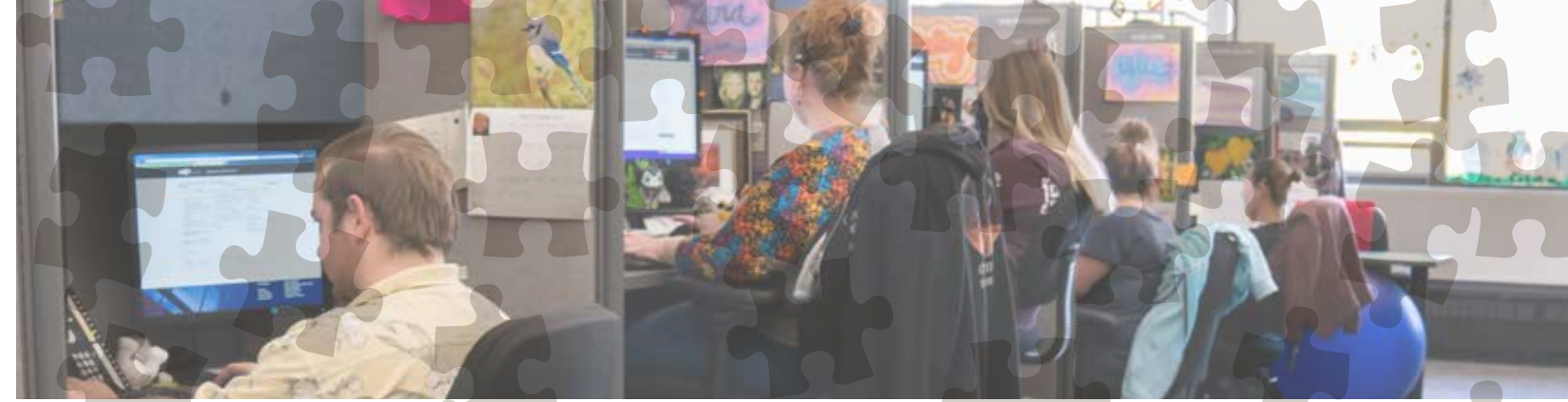
—Bristol Regional Medical Center (Tennessee)

“ARUP has by far THE most courteous, helpful, and friendly staff I have ever had the experience of speaking to. And since I need to speak to them daily, never have I left our conversation feeling that my concerns were not addressed or dealt with appropriately. I have never experienced an unpleasant person within their call staff, which to me is incredibly important. Feeling confident that my questions and inquiries are handled appropriately and effectively is paramount to our relationship with any reference laboratories.”

—Hennepin County Medical Center (Minnesota)

When asked which reference lab has the best customer service, interface services, scope of test menu, and price, ARUP dominated all four categories, particularly in customer service and interface services.

“ARUP is more competitive on price than we previously thought,” says James. Only 8 percent describe price as a weakness for ARUP. Over half (63 percent) say that ARUP is the best lab in terms of price. ■

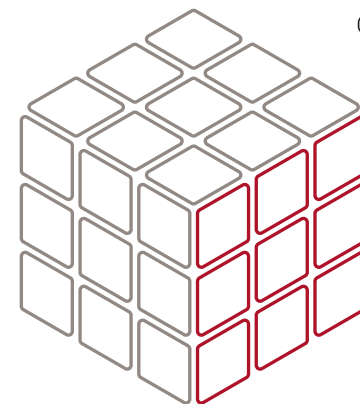


Puzzle Solvers: ARUP Client Services Reps in Action

Near a pin that says, “I saved a patient today. Ask me how,” is a row of intricately folded origami creations, puzzle gadgets, and a Rubik’s Cube, all of which line the top of April Richey’s computer. All hint at a talent she depends on daily in her job as a Client Services rep: She’s a whiz at figuring things out, finding answers for inquiries that run the gamut from the basic to the more esoteric.

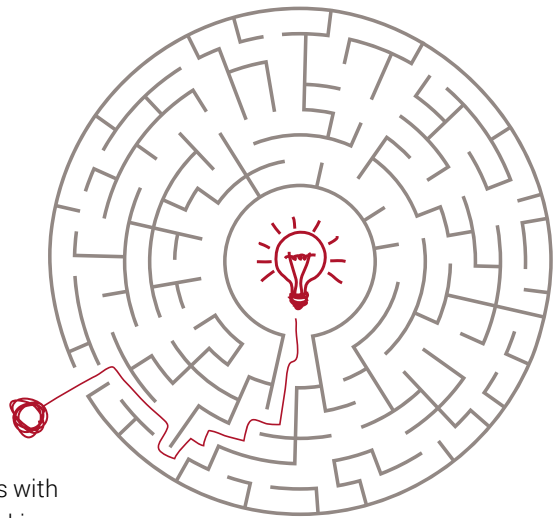
Clients call her with “puzzles.” What’s the turnaround time on this test? Do you have any free testosterone tests that measure the exact level and not just a range? Where is a patient’s specimen right now? Do you have an amphetamines test that specifically will give a quantitation for lisdexamfetamine? How much does a vitamin D test cost?

Richey zips from one open window to another on her computer—some 18 icons run along the bottom of her screen—as she checks, matches, and finds information for a client from Indiana, then one from Iowa, then South Carolina, then New York.



Clients with different accents, in different time zones, in different moods, call in daily from across the country. Within 20 seconds of the phone ringing, one of ARUP’s team of 120 Client Services reps picks up with a, “Hello, how can I help you today?”

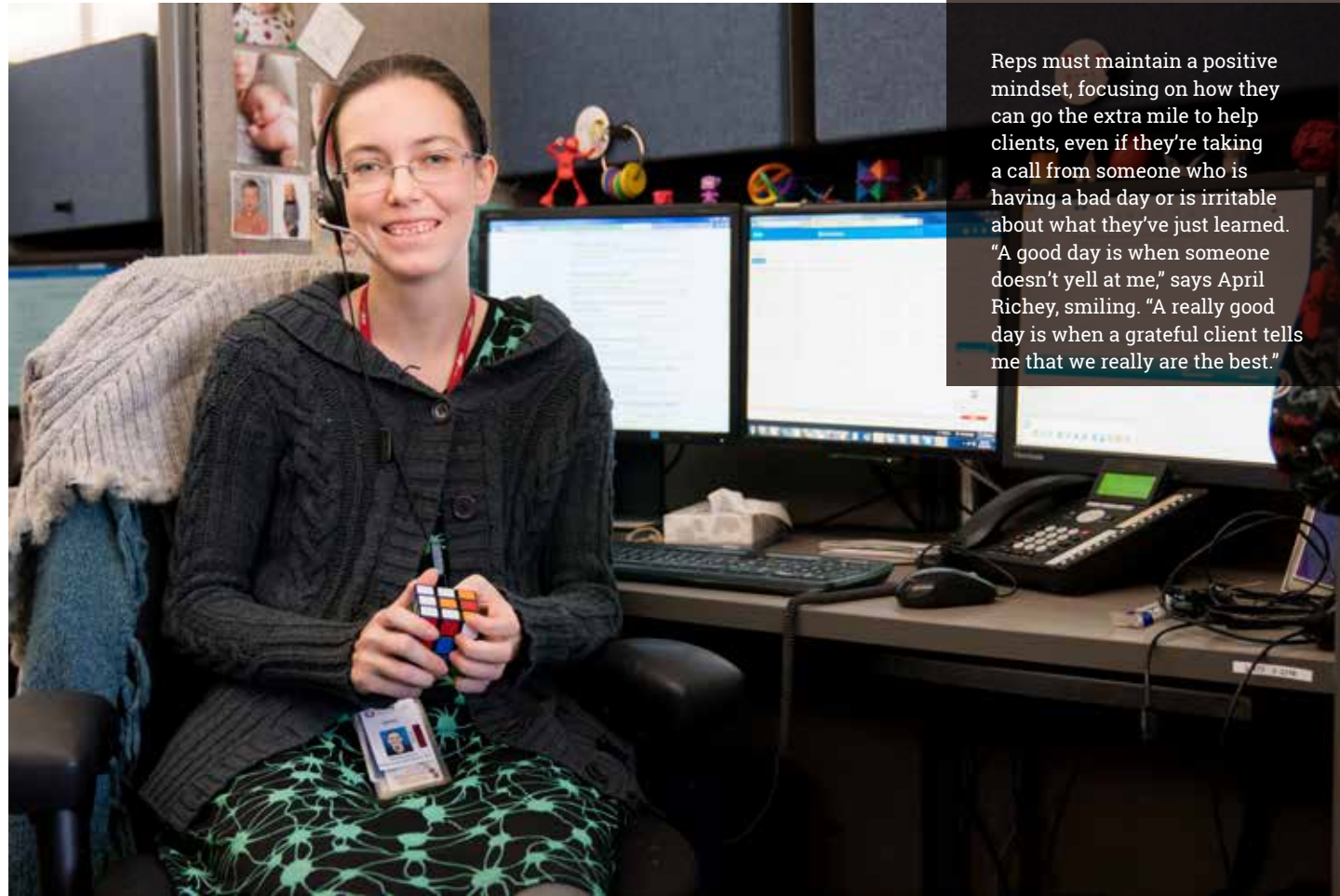
Nine experienced medical technologists are embedded in the Client Services team, supporting reps with some of the trickier technical inquiries and with clarification and communication.



For those who would rather not call, a new online chat option is available. A client with a hearing impairment recently expressed how grateful he was for this new feature.

Client Services is the liaison between ARUP’s own labs and the clients. When there is a change in one of ARUP’s own laboratories, the ripple effect of that change must be considered. First of all, reps need to be aware of it, understand it, and be able to communicate it clearly to ARUP clients. Often, reps are the first to know how a shift, tweak, or change impacts our clients because the phones are ringing.

“Our laboratory folks here have become really committed to keeping us in the loop and understand how changes need to be incorporated into our tools, and ultimately what that messaging is going to look and feel like for the client,” says Matt Baker, a Support Services technical supervisor.



Reps must maintain a positive mindset, focusing on how they can go the extra mile to help clients, even if they're taking a call from someone who is having a bad day or is irritable about what they've just learned. "A good day is when someone doesn't yell at me," says April Richey, smiling. "A really good day is when a grateful client tells me that we really are the best."

Remember Nothing; Know How to Find Everything

"We tell our employees: remember nothing," quips Kaarin Nisbet, who oversees ARUP's Client Services. "Every day changes happen—new information, new processes and updates. Our approach is providing our employees with the tools they need and how to use those tools rather than trying to remember the data."

Training is the foundation of what keeps Client Services strong. "It used to be more informal, a sort of learn-as-you-go approach, but now it's much more structured and solid," says Nisbet.

New employees go through a month of classroom training prior to any customer contact, fielding mock calls and learning to use their tools. "We notice trends on the floor and do monthly trainings to address them. We also might cover a new process or do a refresher course," says Brian Gardner, a Client Services trainer. On this day, he is sitting near six new employees fresh out of their month-long training; some have an experienced rep sitting right next to them to help with coaching if needed.

"Some days it is back-to-back calls, other days it's slower; there's no rhyme or reason to the pace," adds Gardner, who has worked in other call centers in the past. "We're not selling credit cards here. I feel like I'm making a difference because everything we do connects back to a patient."

To ensure quality is maintained, all calls and screen activity are recorded. This aids the Client Services reps, for example, if they need to double check a detail or add something to the caller notes. Other employees, called quality monitors, review reps' calls and provide feedback. "This continuous feedback loop combined with the training really makes a difference in quality," says Nisbet.

The management staff seeks feedback as well; an electronic suggestion box is used often by employees to share ideas or concerns. "We get continuous feedback from the floor that we act on," says Nisbet. "Responding and listening are priorities for us, as is being consistent and fair." Once reps are well versed in their customer service skills, there is the option to work from home some days.



(Top) Brian Gardner, Client Services trainer, works with new hire Randy Keepers (left). (Middle) After 10 years helping clients, senior agent Kara Finlayson is a pro at finding the answers. (Bottom) Client Services trainers Jessica Stevens (front right) and Gardner (back left) work with new hires Lorie Peterson and Trent Aagard, respectively.

Fielding calls all day (and night, the department is 24/7) can be tough. Reps must maintain a positive mindset, focusing on how they can go the extra mile to help clients, even if they're taking a call from someone who is having a bad day or is irritable about what they've have just learned.

Clients with different accents, in different time zones, in different moods, call in daily from across the country. Within 20 seconds of the phone ringing, one of ARUP's team of 120 Client Services reps picks up with a, "Hello, how can I help you today?"

"A good day is when someone doesn't yell at me," says Richey with a smile. "A really good day is when a grateful client tells us that we really are the best."

Aimee Brewster tries to find some common ground or a connection to make the exchange more enjoyable. "If the caller is in Boise, I might ask, 'Hey, how's the weather in Boise today?'" says Brewster. "If I can make callers laugh or relax, then it makes their day better and mine too. It's just about treating people like people," adds Brewster, who admits her job requires patience, tenacity, and a sense of humor.

Customer service isn't limited to just Client Services. It extends to any employee interacting with ARUP's clients. This can include genetic counselors and pathologists, as well as those in the Exception Handling department, which includes eight different groups, each specializing in a specific area.

The investigative path that reps take to find answers and solutions for their callers introduces them to the many moving parts and expertise of this large, national reference laboratory. It's hard not to learn something new every day. "I've learned more about medical testing than my brother-in-law, who is in medical school," chimes in Alexis Jensen, who sits next to Richey. It seems camaraderie is part of the job too. ■

Avoiding the Diagnostic Quandaries of Pneumonia

A New Test Uses New Technology

Five-year-old Jacob's parents rushed him to the hospital. He was struggling to breathe, his small lips and fingernails were bluish, and he was too weak to respond to his mother's voice. She was scared. The doctors were worried. Jacob had also been battling leukemia and was in the midst of undergoing chemotherapy. In the intensive care unit, Jacob was immediately intubated to help him with his breathing.

Based on his symptoms, Jacob likely had developed severe pneumonia. To derail its virulent advance on his lungs, doctors needed to know what was causing the pneumonia—what type of bacteria, fungus, or virus had triggered the infection. Knowing this would help doctors determine which medicine would work best to help Jacob's body fight the pneumonia.

Typically, this might mean a series of tests—and waiting to find out the results—to eventually identify the most effective treatment (medication). But for a child as sick as Jacob, waiting was risky.

Patients like Jacob may benefit from a recently developed test known as Explify™ Respiratory. This next generation sequencing (NGS) test for respiratory infections detects more than 200 common and rare bacterial, fungal, and viral respiratory pathogens with a single test. Many respiratory pathogens can cause similar clinical symptoms, but treatment is different for each, and rapid identification is important.

This test may reduce the risk of inappropriate antibiotic treatment, which could potentially have harmful effects, especially for immunocompromised patients. It can also avoid sequential testing that eats up precious time and may extend hospital stays. Diagnosing patients—particularly critically ill patients and immunosuppressed patients—with suspected pneumonia can potentially require up to a dozen tests (including test panels) to determine the culprit pathogen.

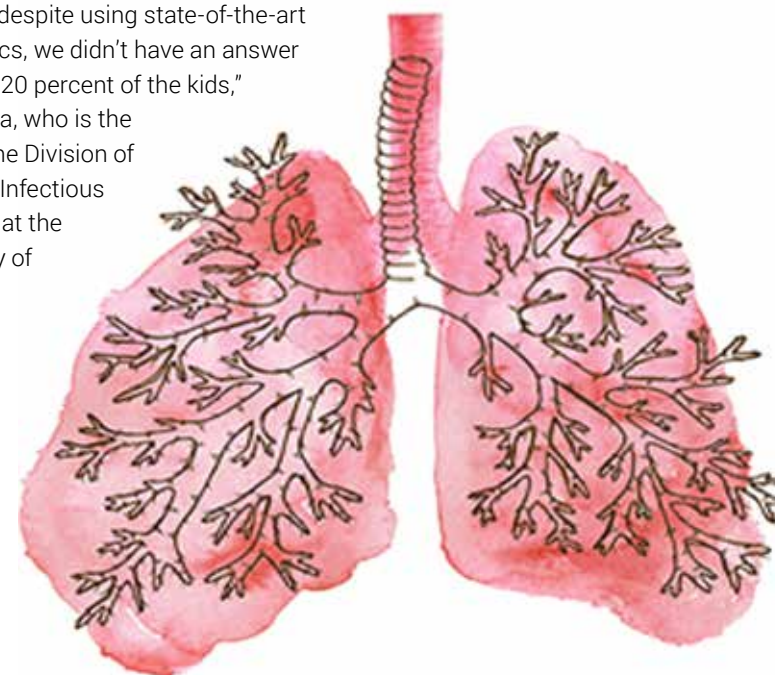
Explify is also helpful for scenarios in which very ill patients have tested negative (nothing is detected) using conventional testing and the physician suspects a missed

infection. It can also identify patients who are infected with numerous and diverse pathogens.

In two recent Centers for Disease Control and Prevention studies (both published in the *New England Journal of Medicine*), conventional testing failed to identify a potential cause of respiratory infections in about 20 percent of children and 60 percent of adult patients with community-acquired pneumonia. This is frustrating to clinicians because it may lead to excessive treatment or poor outcomes for patients and increased costs to the healthcare system.

Pediatric infectious specialist and study coauthor Andrew Pavia, MD, explained that in children, the study showed viral pathogens were much more common than bacteria causes, and that typical pneumonia-causing bacteria were less common than in earlier years, likely due to highly effective vaccines for *Streptococcus pneumoniae* and *Haemophilus influenzae* type b.

"This was an important finding, but not a complete surprise. What was a surprise was that despite using state-of-the-art diagnostics, we didn't have an answer for some 20 percent of the kids," says Pavia, who is the chief of the Division of Pediatric Infectious Diseases at the University of Utah.



The NGS technology ended up identifying pathogens missed by conventional laboratory tests in 30 percent of hospitalized children being treated for pneumonia. In a separate study, this same technology identified missed pathogens in approximately 40 percent of test-negative, immunocompromised children being treated in the intensive care unit for pneumonia.

Using similar NGS technology to Explify, Robert Schlaberg, MD, Dr Med, MPH, a specialist in molecular infectious disease testing at ARUP, then led a study looking at these children in whom no pneumonia-causing pathogens were identified. The NGS technology ended up identifying pathogens missed by conventional laboratory tests in 30 percent of hospitalized children being treated for pneumonia. (This study was published in *Journal of Infectious Diseases*.) In a separate study, this same technology identified missed pathogens in approximately 40 percent of test-negative, immunocompromised children being treated in the intensive care unit for pneumonia.

Future NGS studies will home in on the adult population—in more than half of adults with pneumonia, a cause can't be detected with current tests.

"Current diagnostic techniques rely heavily on testing for suspected pathogens, which can be inconclusive and time consuming," says Dr. Schlaberg. "This technology can test for a very large number of pathogens at once, whether they are expected or not. A doctor doesn't have to suspect the cause of a patient's infection to direct the test ordering, but can instead simply ask, 'What is my patient infected with?'"

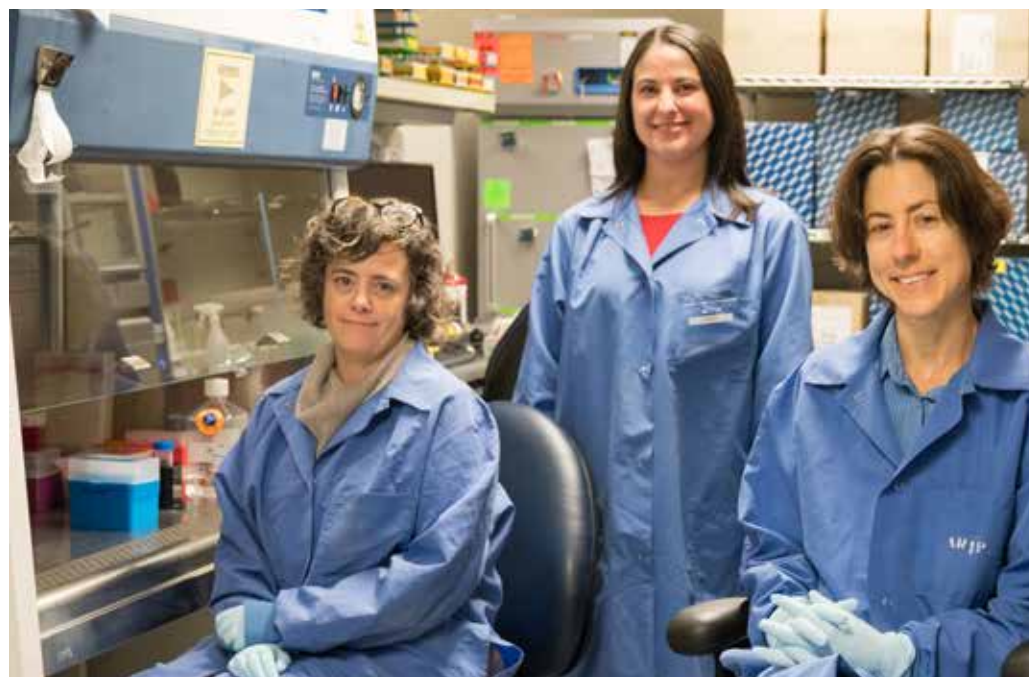
The Explify test is another tool for physicians to rely on in diagnosing and treating patients with respiratory disease. The test is powered by Taxonomer, an ultra-fast metagenomics search engine that can mine information from the vast amounts of genomic information extracted from DNA. This DNA is found in the pathogens located in a patient specimen; in the case of respiratory issues, the sample is fluid collected from the lung (bronchoalveolar lavage fluid). Taxonomer and the Explify test were developed by ARUP Laboratories and IDbyDNA, a Silicon Valley metagenomics company, in a collaboration to improve infectious disease diagnostics.

“Metagenomic testing is a paradigm shift in our approach to infectious disease diagnosis,” says Carrie Byington, MD, an expert in pediatric infectious diseases and an IDbyDNA advisor. “Compared with traditional testing modalities, the comprehensive nature of metagenomic testing will open new opportunities for identifying and understanding infectious pathogens and the roles they play in human health and disease,” says Dr. Byington, who is also dean of the Texas A&M College of Medicine.

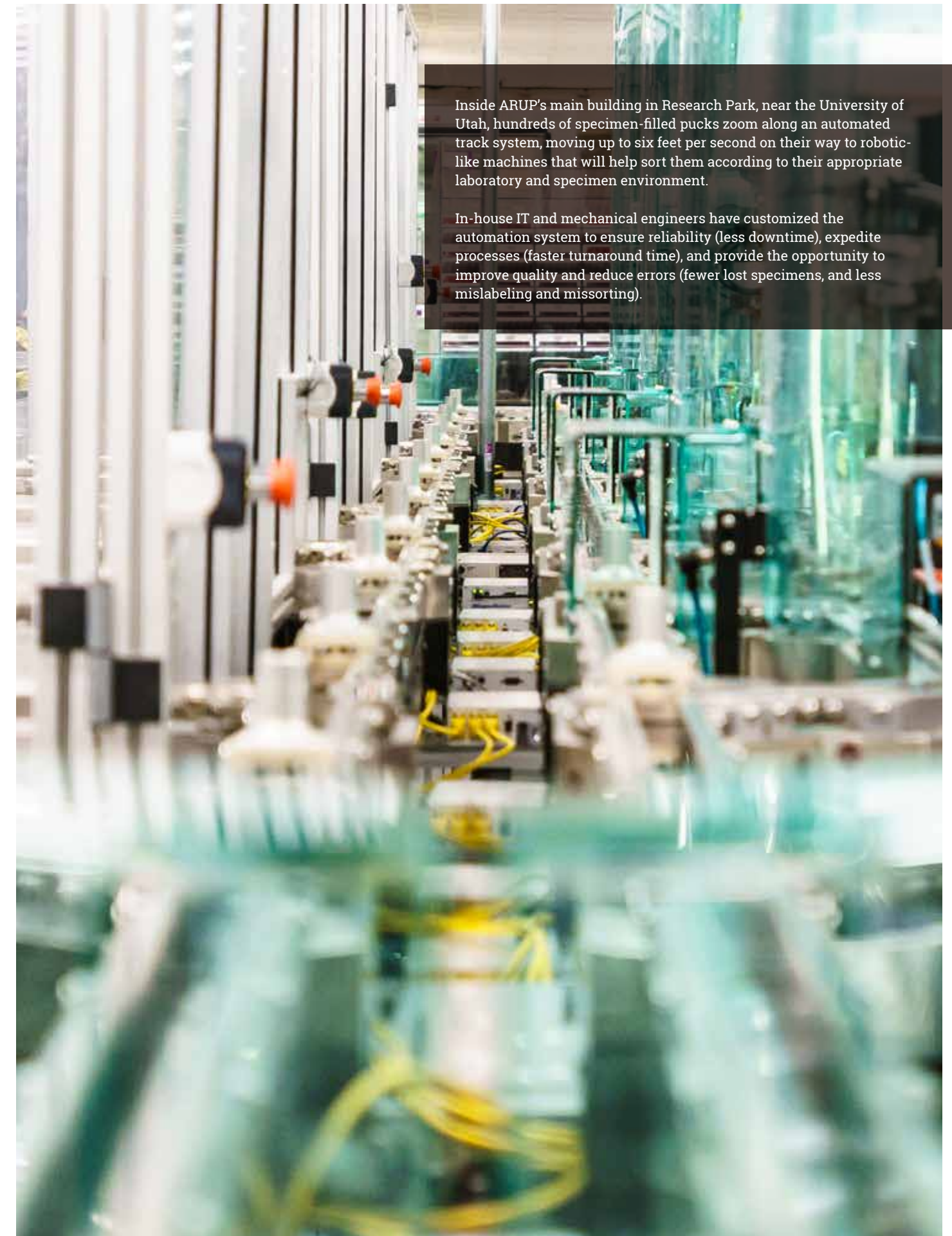
Most everyone knows someone who has battled pneumonia. Each year in the United States, about one million people have to be hospitalized for pneumonia—it is one of the leading causes of hospitalization for children under 5 and one of the leading infectious causes of hospitalization and death among adults in the United States, according to a 2015 study published in the *New England Journal of Medicine*. Some 50,000 people die annually from the disease.

Most everyone knows someone who has battled pneumonia. Each year in the United States, about one million people have to be hospitalized for pneumonia—it is one of the leading causes of hospitalization for children under 5 and one of the leading infectious causes of hospitalization and death among adults in the United States.

Daily around the country, physicians experience difficulty in diagnosing and treating patients with pneumonia and other respiratory diseases. Explify can help solve these diagnostic quandaries, particularly for patients with compromised immune systems, like Jacob. ■



Program manager Jenna Rychert helped oversee the implementation of Explify—also referred to as Respiratory Pathogens by Next Generation Sequencing. She worked with technical supervisor Brandy Serrano (center) and lead technologist Amy Cockerham (right) in the Infectious Disease Sequencing Laboratory to set this new test in motion. In the clinical lab, this required everything from training staff to performing validations and preparing procedures. This lab also does genotyping for HIV, hepatitis B and C, and influenza A, as well as sequence-based drug resistance testing for HIV, CMV, influenza A, *M. tuberculosis*, candida, and hepatitis C.



Inside ARUP's main building in Research Park, near the University of Utah, hundreds of specimen-filled pucks zoom along an automated track system, moving up to six feet per second on their way to robotic-like machines that will help sort them according to their appropriate laboratory and specimen environment.

In-house IT and mechanical engineers have customized the automation system to ensure reliability (less downtime), expedite processes (faster turnaround time), and provide the opportunity to improve quality and reduce errors (fewer lost specimens, and less mislabeling and missorting).

Achieving Six Sigma Levels in the Laboratory: Here's What We Learned

Wouldn't you love to fly on an airline that loses fewer than four pieces of luggage for every million pieces it transports? Not bad odds. In the field of quality, this level of performance is considered "world-class quality," and the Six Sigma quality method seeks to achieve error rates of no more than 3.4 defects per million opportunities.

This past July, ARUP Laboratories published a report detailing its 25-year journey toward achievement of this prestigious Six Sigma score for lost specimens.

"We found that to achieve this level, a laboratory needs automation," says Charles Hawker, PhD, MBA, who coauthored the article in the July 2017 issue of *Journal of Applied Laboratory Medicine* (JALM).

"To my knowledge, ARUP is the first clinical laboratory in the country to achieve Six Sigma quality for any metric," adds Hawker. For nearly two decades, Hawker has helped develop ARUP's highly sophisticated automation system, which has earned him respect worldwide for his expertise in this area.

While the ultimate goal is perfection, particularly in healthcare, making incremental progress toward this goal is the focus of ARUP's continuous improvement system. In clinical laboratories, mistakes in the analytic area are generally minor contributors to poor laboratory quality and diagnostic errors. The majority of mistakes—including lost or misplaced specimens—happen in the nonanalytic processes.

Some 55,000 specimens, destined for testing in 70 specialized laboratories, are processed daily at ARUP, so tracking the precise location of a single specimen is a herculean task. From time to time, one of these samples may lose its way.

The JALM article addresses lost-sample solutions that involve automation and human behavior controls, but the corporate culture is another important consideration. "It's a patient-centric culture here; each specimen is a patient," says David Rogers, who oversees specimen processing

and also coauthored the article. Every specimen arriving at ARUP passes through the hands of Rogers' team members.

"We want this report to show other laboratories that they too can strive for this level of quality," emphasizes Hawker. Readers learn how the automation of nonanalytic processes decreases the number of lost specimens. In addition, the article covers a variety of engineering and behavioral controls, which relate to how humans work, that have played a role in this remarkable achievement.

"Every time a human touches a sample, it creates an opportunity for error," explains Bonnie Messinger, ARUP's process improvement manager and the article's lead author. She estimates that a specimen could be handled 20 or more times from the point it leaves the client until it is discarded.

Automation Improvements

Using data spanning the 25-year period, the authors show the correlation between lost specimens and the implementation dates for eight major phases of automation, along with 16 process improvements and engineering controls. While implementation of process improvements, engineering controls, and automation all contributed to overall reduction in the lost-specimen rate, the data shows that automation was the most significant contributor.

"We want to share with other labs ideas that will help them improve their own processes and quality... This is at the heart of this report and is a core part of what ARUP does."

—David Rogers, Group Manager, Support Services/Specimen Processing

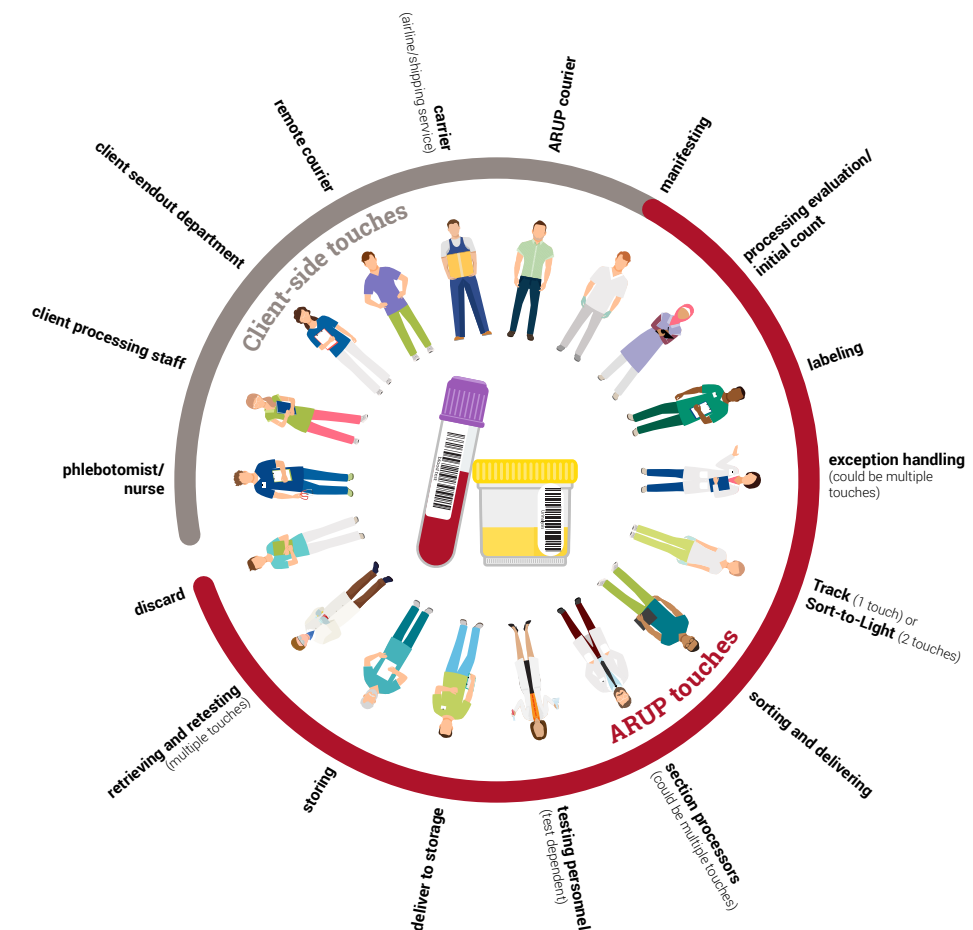
Examples of automation improvements include the addition of a Sort-to-Light System (S2L) in 2009–10, an automated specimen sorting system for manually managed specimens (15–18 percent of ARUP's specimens). Prior to implementing, technicians were required to read an abbreviated destination printed on the specimen label and sort these specimens by hand. As might be expected, specimens were occasionally missorted, leading to a higher potential for loss (and were compromised when sorted for storage at incorrect temperatures). The S2L system had an immediate and significant effect on the lost-specimen metric, cutting the number of errors per million samples by half.

Another improvement was the installation of a two-story freezer in 2003, which holds more than two million specimens. It uses a robotic system and custom software to control access to the specimens and their storage trays, reducing the incidence of handling errors and premature discards.

"Every time a human touches a sample, it creates an opportunity for error... A specimen could be handled an estimated 20 or more times from the point it leaves the client until it is discarded."

—Bonnie Messinger, Process Improvement Manager

The Human Touch: Following the Handling Path of a Specimen





“We found that to achieve this level [Six Sigma], a laboratory needs automation,” says Charles Hawker, who helped develop ARUP’s highly sophisticated automation system. Over time, with each automation enhancement, lost-specimen rates decreased.

Prior to installation, trays were stacked several layers deep on shelves, and specimens sometimes fell through and under the shelving. The manual process for discarding trays was likewise prone to error—trays were, on occasion, discarded prematurely.

In the centralized freezer, a robotic system loads and unloads trays from storage shelves, and a Motoman robot retrieves requested tubes from trays. In order to retrieve specimens, employees have to scan their IDs, providing a tracking history.

ARUP’s automation kicked off in 1998, as demand and growth accelerated. “This growth would not have been possible without automation,” says Hawker, who was tracking various metrics at that time.

With each automation enhancement, lost-specimen rates decreased. It did not happen immediately, but over the succeeding months, each new level of automation led to improvement. Because the automation stages and various process improvements overlapped, it was not possible to look at any particular stage or process enhancement in isolation, but collectively, the various changes have produced a nearly 100-fold improvement in the lost-sample Six Sigma metric.

Error-Proofing and Human Behavior Management

Human behaviors are influenced by process and engineering controls. In collaboration with ARUP’s in-house engineering team, zeroing in on relatively small modifications to the work environment proved to be quite effective.

For example, to prevent test tubes from rolling off the work surface, raised edges were implemented on all workbenches and workstations. In addition, to keep specimens from being accidentally discarded with the transport bag, all waste receptacles were moved away from the primary work area and fitted with rounded covers that included narrow, diagonal openings, so any item placed into them had to be put there intentionally.

“We have 18 different behavioral management strategies—ways of encouraging certain behaviors and preventing others,” says Messinger. Such changes can be very simple, such as encouraging people to keep their work areas uncluttered or establishing a lost-sample checklist.

Messinger explains that in the past, each section had a haphazard method of looking for missing samples. Now, many labs have their own custom checklists that detail specific locations to be searched. Every time a sample

The article attributes the remarkable decrease in the frequency of lost specimens not to a single intervention, but to a multifaceted, cumulative approach. “Our results demonstrate that two approaches—automation and designed behavioral controls—working together, can yield remarkable results.”

—Bonnie Messinger, Process Improvement Manager

is found in a new location, the checklist is reviewed and updated if necessary.

Another improvement that influenced human behavior and reduced error involved lighting. While looking for causes of labeling errors, employees were videotaped placing labels on specimens at different stations. An improvement team noticed that the lighting intensity differed from one space to the next throughout the receiving area. Lighting was adjusted to eliminate shadows and reduce the likelihood of a misplaced specimen.

A Bite-Size Backstory: Six Sigma

A Six Sigma level of performance is known as “world-class quality.” The Six Sigma method originated with Motorola in 1986 and was later adopted by General Electric and other well-established manufacturing companies.

Theoretically, performance expectations are set and then evaluated as a sigma metric, with six-sigma performance as the goal. In practice, the sigma level of quality for a given output or process is better understood as defects per million opportunities (DPMO). To achieve this world-class quality, there must be an error rate of no more than 3.4 DPMO.

The notion of applying Six Sigma quality improvement measurement models to healthcare remains controversial because “the target performance for healthcare is zero error—3.4 healthcare defects per million opportunities is not good enough,” explains Bonnie Messenger, ARUP’s process improvement manager. However, using the Six Sigma metric to compare performance across disciplines and organizations is a recognized way to normalize data and establish comparable benchmarks.

Rogers also noted another improvement that was not included in the article, but was piloted in the Specimen Processing area. Management in Specimen Processing and employees in other areas use video recording equipment to enhance the lab’s ability to critically review processes and identify key improvement opportunities. “This also helps staff to detect areas where specimens may be misplaced,” explains Rogers. “Many process improvements have been implemented as a result of lessons learned from observing staff perform routine duties when quality issues arise.”

Sharing with Others

The article attributes the remarkable decrease in the frequency of lost specimens not to a single intervention, but to a multifaceted, cumulative approach. “Our results demonstrate that two approaches—automation and designed behavioral controls—working together, can yield remarkable results,” says Messinger.

The article’s coauthors emphasize that even if a laboratory doesn’t have the same level of automation as ARUP, any degree of automation that replaces an error-prone process will help reduce error. They also emphasize that the main purpose of the article is to share stories of success and spread healthcare improvement ideas.

“We want to share with other labs ideas that will help them improve their own processes and quality,” says Rogers, who regularly visits other laboratories as part of an ARUP consultative team. “This is at the heart of this report and is a core part of what ARUP does.” ■

ARUP[®] LABORATORIES

JOURNEY OF A SPECIMEN

It's a bit of a mystery. You pee in a cup. Your blood gets drawn. A swish of saliva is swabbed. Something that dwells in your body is labeled and then disappears from your sight. Where does it go? What happens to it? That bit of you can harbor some pretty important information—clues that will help your doctor decide on the best treatment for you. So what happens between this small bodily “donation” and the return of the laboratory test results?

A new series of six videos show you the path a specimen takes as it makes its way to one of ARUP's 65 laboratories centralized in Salt Lake City, Utah, where more than 3,000 tests are performed. As the sample comes through the doors, chugs along the tracks, and passes through various hands into specialized labs, employees never lose sight of the fact that it represents a patient. As a matter of fact, that's why most of our laboratorians dig their jobs: Their efforts are making a difference in someone's life.



Pack Your Bags: Transportation

“Our couriers will pick up specimens and package them for air shipment on the fastest available routing to ARUP. One of the ways in which ARUP stands out from our competition is in the design of our shipping containers, which protect and maintain necessary temperatures to keep specimens viable.”



Chris Sorenson,
National Transportation Manager



Climb on Board: Automation

“The track system is really a single piece flow. Meaning once it's finished being processed, that individual unit can travel on the track directly to the sorter and be available to the lab in a matter of minutes, rather than hours.”



Clint Wilcox,
Group Manager,
Support Services



Meet Your Laboratorians: Inside the Lab

“We instill in our staff to remember that each specimen represents a person. It could be themselves, it could be a family member, but it represents a human being waiting for us to do the quality job that we're here to do.”



Martha Bale,
Director of Technical
Operations



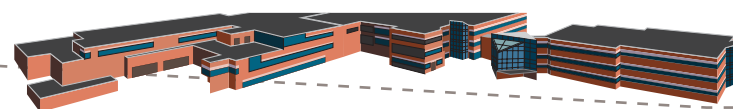
Navigating the Data: Biocomputing

What happens to all the information collected from the processing?

“The data itself in the raw state or in an aggregated state provides our medical directorship the ability to look at trends, look across patient history, and provide the patient a better overall picture view of their diagnosis.”



Erica Cuttitta,
NGS Informatics
Supervisor



Welcome to ARUP: Specimen Receiving

“Once specimens arrive at ARUP, we immediately triage them. We make sure that specimen integrity has been maintained while en route to ARUP... all work is assigned to a group of employees so we can process the work as quickly and accurately as possible and get it to the lab so testing can be performed.”



Dave Rogers,
Group Manager, Support
Services/Specimen Processing



Experience the Expertise: Medical Directors

“Having so many specialized medical directors allows us to provide accurate test results that can be used for the best medical care of the patients, but also allows for the best consultation service for physicians when there is a question about a test result.”



Julio Delgado, MD,
Director of Laboratories

If the journey intrigues you, check out the Journey of a Specimen videos on the ARUP Laboratories website.

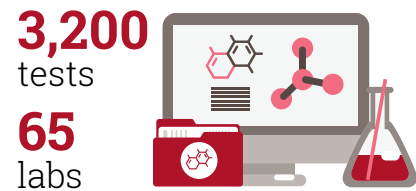
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WOW Factor

Since 1984, ARUP has worked quietly behind the scenes to support patient care—so quietly, in fact, that people don't realize the extensive role ARUP plays in diagnostic medicine. So we've decided to speak up and share some extraordinary facts with you.

ARUP performs more than 3,200 different tests and test combinations, relying on the expertise, care, and commitment of those working in one of its 65 centralized labs located along the foothills of Salt Lake City.

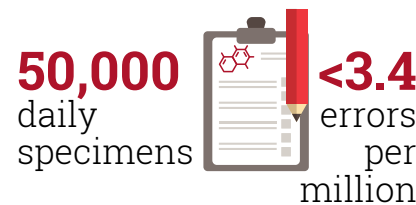


3,200 tests
65 labs

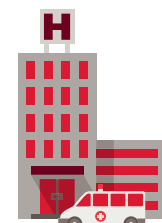


In a 2017 client survey, when clients were asked which reference lab has the best customer service, interface services, scope of test menu, and price, ARUP dominated all four categories.

More than 50,000 specimens arrive daily for testing, so ARUP's achievement of a Six Sigma level for lost specimens is a herculean task. This world-class rating aims for error rates of no more than 3.4 defects per million.



50,000 daily specimens
<3.4 errors per million



50% of university, pediatric, & teaching hospitals

More than 50 percent of the nation's university medical centers, pediatric hospitals, and teaching hospitals choose to send their testing to ARUP.

In the most recent quarter, more than 76,000 users worldwide visited ARUP Consult®, a free online test selection and interpretation tool for clinicians. Consult is organized into nearly 300 disease-related topics, which ARUP medical directors author or review for accuracy.

76,000 visitors in 3 months

16 genetic counselors



Our team of 16 genetic counselors play an integral role, supporting more than 330 genetic tests. They are involved in the entire continuum of genetic testing, from the early step of providing guidance on what test is needed all the way through to helping clients and physicians understand test results.

People Proud

Knowledge fuels the engines here at ARUP, and it is our dynamic cadre of research scientists who provide the know-how and expertise. Each year, they publish hundreds of articles in leading journals, present at conferences around the world, and contribute to professional organizations. We are proud that they are being recognized for their hard work and expertise.



Yuan Ji, PhD, medical director for Molecular Genetics and Genomics, as well as Pharmacogenomics, received the award for Top-Rated Abstract, 2017 ACMG Annual Meeting for the abstract "Comparative Analysis of Clinical Whole Exome Sequencing (WES) with Targeted Genotyping Identified Areas for Improving Accuracy of WES-based Pharmacogenetic Profiling." She also became a member of the board of the University of Utah Faculty Club.



Elaine Lyon, PhD, medical director for Molecular Genetics and Genomics, as well as Pharmacogenomics, became a member of the board of the American College of Medical Genetics and Genomics (ACMG).



Blaine Mathison, medical technologist specialist in the Parasitology and Fecal Testing (PAFT) Laboratory, received the Scherago-Rubin Award from the American Society of Microbiologists. The award recognizes "outstanding, bench-level clinical microbiologists" involved in routine diagnostic work rather than research, having distinguished themselves "with excellent performance in the clinical laboratory," according to the award website.



Xinjie Xu, PhD, medical director for Cytogenetics and Genomic Microarray, as well as Molecular Hematopathology/Oncology, was elected as a member of the Board of Directors for the Cancer Genomics Consortium in August 2017.

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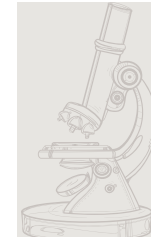
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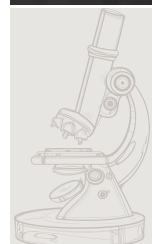
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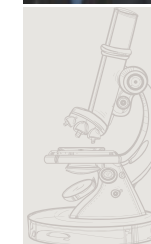
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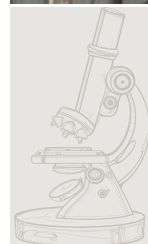
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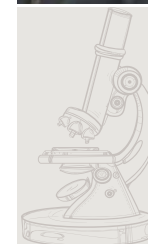
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MAGNIFY is a magazine published by the ARUP Laboratories Integrated Marketing Communications Department.

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BD-CC-016, Rev 0, December 2017