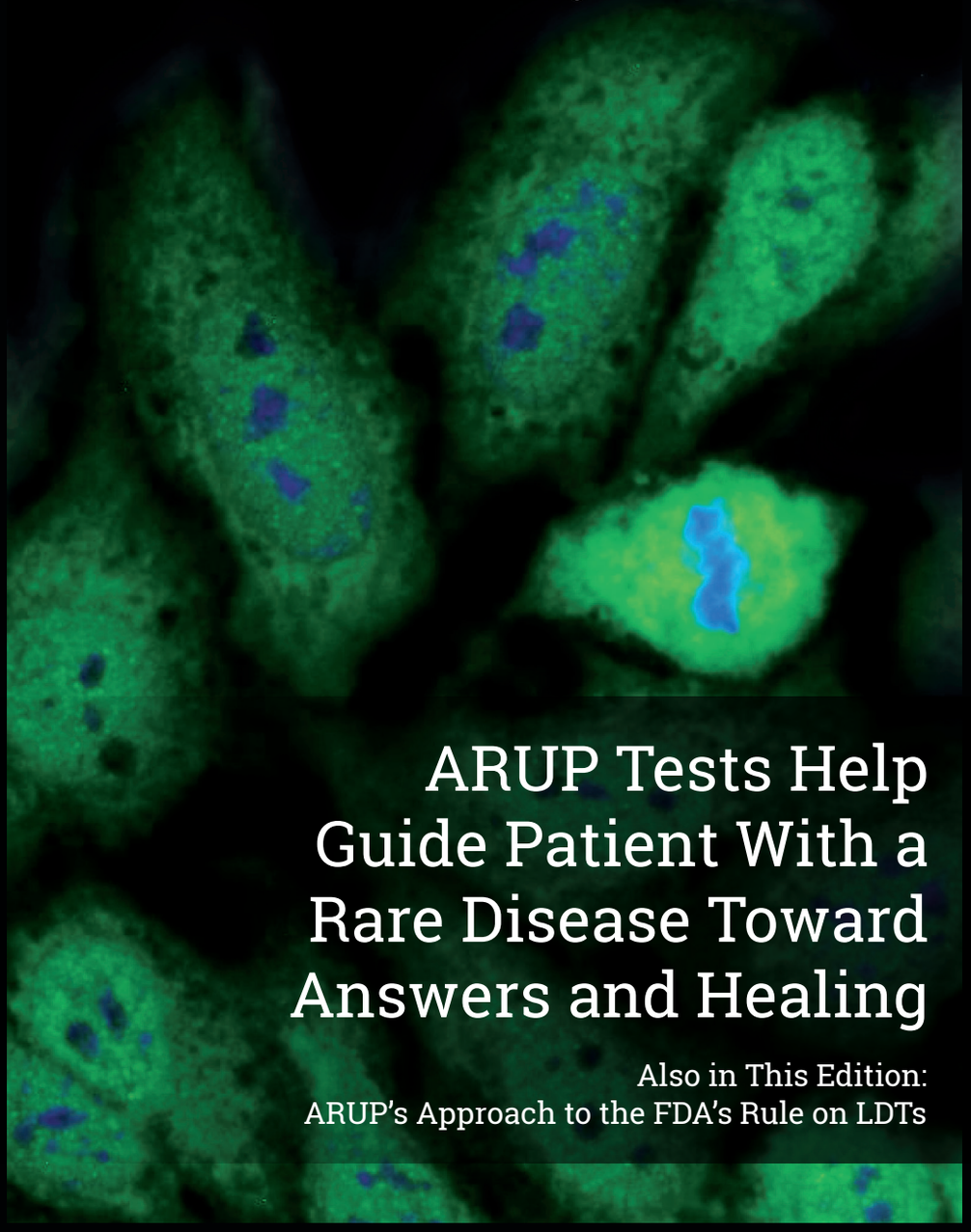
MAGNIFY

the art & science of diagnostic medicine

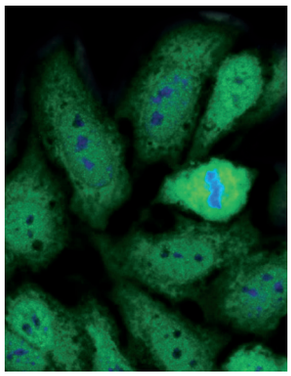


ARUP Tests Help Guide Patient With a Rare Disease Toward Answers and Healing

Also in This Edition:
ARUP's Approach to the FDA's Rule on LDTs

ARUP LABORATORIES

FALL 2024



About the Cover

The cover depicts the detection of antinuclear antibodies (ANAs) by indirect immunofluorescence. ANAs, which are malfunctioning antibodies that mistakenly attack the body's own cells, play a role in autoimmune conditions such as myositis.

MAGNIFY

the art & science of diagnostic medicine

Contents

Contributors

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

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

Photographer: Corrin Rausch

Web Designer: Amy Davis

Editors: Kate Button, Lisa Carricaburu, Kristen Deem, Dora Lockhart, Kari Morandi

To share these stories and see our videos, visit **aruplab.com/magnify-fall24**

Jonathan Genzen, MD, PhD, MBA, ARUP chief medical officer and senior director of governmental affairs (right), helps build my understanding of the new FDA rule regulating laboratory-developed tests (LDTs), as he has for everyone with whom he shares information about the rule and its implications for clinical labs.

"Hospitals and health systems that partner with ARUP know they can count on us to support them in any way possible so that they can support their patients."

Andy Theurer, CEO

A Message From the CEO

At ARUP Laboratories, we pride ourselves on discovering and sharing solutions to the myriad challenges our hospital and health system partners face.

So it should come as no surprise that when the FDA earlier this year published its long-anticipated and far-reaching new rule regulating laboratory-developed tests (LDTs) as medical devices, ARUP was at the forefront, unraveling the contents and implications of the 500-page rule so that we can help our clients thoughtfully and strategically adopt the new regulation while continuing to prioritize patient care.

Fortunately, ARUP's chief medical officer and senior director of governmental affairs, Jonathan Genzen, MD, PhD, MBA, has spent the past decade gaining substantial expertise and understanding of attempts by the FDA and the U.S. Congress to place new regulation on LDTs. Dr. Genzen has earned well-deserved respect in the clinical laboratory industry, not only as a knowledgeable and generous educator, but as an impassioned advocate for the tens of thousands of laboratory scientists who have committed their careers to the practice of high-quality, caring laboratory medicine.

You will hear Dr. Genzen's voice throughout this edition of Magnify, which aims to help make sense of the new FDA rule. He has published research, written articles, and appeared on numerous webinars and in podcasts that are available at aruplab.com. In the pages of this issue, you will find a link to his carefully crafted and continually updated matrix of the requirements that labs will have to comply with, as well as a timeline that spells out each stage of the rule's implementation in the coming years (see page 10). Drawing on Dr. Genzen's expertise, ARUP will continue to share knowledge and guidance when or if the landscape around the new rule shifts. Many of you know, for example, that a lawsuit challenging the FDA's authority to regulate LDTs is wending its way through the courts even as the new Trump administration may act to rescind the rule.

Hospitals and health systems that partner with ARUP know they can count on us to support them in any way possible so that they can support their patients. We'll continue to make good on that promise.

Andy Theurer
CEO

ARUP will support clients in whatever form they need as they adapt to the FDA's rule regulating lab-developed tests. Watch ARUP's leaders describe how else ARUP is aiding and advocating for labs.

Scan to watch video.

ARUP's Message to Clients Amid a Shifting Regulatory Environment: We'll Continue To Support Our Clients So They Can Support Their Patients

Never has a change more significantly affected the clinical laboratory industry than that brought about by the FDA's final rule regulating laboratory-developed tests (LDTs) as medical devices. In more than 500 highly detailed pages, the rule spells out daunting new requirements, a number of which are largely open to interpretation. Six months after the rule's May 6, 2024, publication date, many labs that offer LDTs remain understandably overwhelmed and anxious.

The November 5 election of Donald Trump to a second term as president added yet another layer of uncertainty. Should labs proceed with preparations to comply with the rule knowing that a new Trump administration may initiate the process to rescind it? And what happens if a pending federal lawsuit challenging the FDA's authority to regulate LDTs is successful?

ARUP Laboratories is asking the same questions in a fast-changing regulatory environment. For now, though, the rule remains in effect, with a May 6, 2025, deadline to comply with Stage 1 requirements looming. No one can predict when or how the new administration and Congress may act or what the court will conclude, so it is still prudent to prepare for Stage 1 requirements while closely monitoring how the landscape evolves, said Jonathan Genzen, MD, PhD, MBA. Genzen is ARUP's chief medical officer, senior director of governmental affairs, and a leader of ARUP's response to the rule, along with Julio Delgado, MD, MS, ARUP executive vice president, Adam Barker, PhD, ARUP chief operations officer, and Kristi Smock, MD, vice president of the ARUP Institute for Clinical and Experimental Pathology® (Research and Development).

From the day the new FDA rule regulating LDTs as medical devices was announced, ARUP has been at the forefront of education about the rule. Educational webinars such as the one featuring Chief Medical Officer Jonathan Genzen, MD, PhD, MBA (left), and Chief Compliance Officer Jonathan Carr, JD (right), pictured here speaking about the rule, are an example of ARUP's educational efforts.

> ***"Being engaged is incredibly important right now for all clinical laboratorians and anyone who cares about this issue so that regulators, legislators, and the FDA better understand unintended impacts of their proposals."***
>
> Jonathan Genzen, MD, PhD, MBA, ARUP Chief Medical Officer and Senior Director of Governmental Affairs

Regardless of what happens, ARUP's message to both clients and employees is unwavering: "Our eye will be on doing what we do best, which is supporting our clients, whatever happens, so they can best support their patients," Chief Business Development Officer Julie Altwies said.

For more than a decade, ARUP has closely followed and actively engaged in the lead-up to the new rule and in every other effort to change the way clinical laboratories are regulated, Genzen said.

Quality testing is and always has been paramount at ARUP, and each review of operations prompted by the specter of regulatory change produces the same result, Barker said. "We know exactly how to make safe, effective tests that provide accurate answers for patients. None of that has changed."

"We're very proud of what we're doing and where we're at," he said. "We already have an exceptionally high-quality lab run by professionals who have dedicated their lives to the practice of laboratory medicine."

He joined Delgado and Genzen in urging caution against overreaction as the clinical lab industry navigates uncertainty surrounding the rule.

By remaining flexible and staying informed, hospitals and health systems can be more thoughtful and strategic in how they're going to adapt in a shifting regulatory environment while continuing to prioritize patient care, Genzen said.

Educating, Advocating on Labs' Behalf

Key to ARUP's partnership promise to its clients is its commitment to remain at the forefront of education related to the new FDA rule and any proposed changes to regulations affecting clinical labs. As an academic reference laboratory and a nonprofit enterprise of the University of Utah's Spencer Fox Eccles School of Medicine and its Department of Pathology, ARUP shares knowledge and information as an essential part of its mission.

ARUP's expertise on lab regulation manifests in webinars, LabMind podcast episodes, articles, professional society presentations, and numerous other resources that its medical directors have created and made available to help build understanding. (See the next page for Resources on the FDA's New Rule Regulating LDTs.)

Advocacy efforts that ARUP continues to lead are also important, Genzen said. "We want to make sure that the needs of all clinical laboratories, not just our customers, are reflected in any regulations that exist, be they part of the

FDA final rule, or maybe legislative efforts going forward," he said. "Being engaged is incredibly important right now for all clinical laboratorians and anyone who cares about this issue so that regulators, legislators, and the FDA better understand unintended impacts of their proposals."

Sustaining a Robust Menu Amid Change

Critical to any discussion of the impact of the FDA rule and any future regulation is a reminder that ARUP's expansive test menu remains intact. ARUP offers hundreds of LDTs, and any that were on the market before May 6, 2024, are exempt in their current form from FDA premarket submission requirements.

Even before the rule was published, ARUP had begun evaluating new tests in its pipeline and its planned updates to existing LDTs to decide how best to prioritize tests under the new regulatory framework that the FDA plans to phase in over five years. ARUP already submits tests through the New York Clinical Laboratory Evaluation Program (NY CLEP), one pathway allowed under the FDA rule. ARUP knows the NY CLEP pathway well and has developed strong relationships with New York regulators as a longtime NY CLEP-approved lab, Barker said.

Delgado, Genzen, and Smock oversee the prioritization of submissions for NY CLEP approval. "We prioritize tests by what's best for the patient first, followed by what's best for lab operations and efficiency, and only then by whether we see a market opportunity," Delgado said.

Simultaneously, work is well underway to understand and enable compliance with Stage 1 reporting required in year 1 and Stage 2 labeling required in year 2, as well as all future requirements if necessary. (Refer to the Requirements Matrix at www.aruplab.com/fda-ldt-final-rule, and the Timeline for Implementation on page 10).

In every action related to the new rule or any other regulation, "We are being thoughtful, meticulous, careful, and also strategic," Genzen said. "We will sustain our robust menu while also continuing to dedicate resources toward innovation and new test development. That's incredibly important."

Shifting Regulatory Environment

Following the presidential election, industry groups representing clinical labs acted quickly to urge the new Trump administration to rescind the FDA rule.

Resources on the FDA's New Rule Regulating LDTs

ARUP maintains and continually updates a free resource library of webinars, podcast episodes, articles, and other materials to help lend understanding to the FDA rule regulating LDTs as medical devices.

Resources include:

- September 2024 LabMind podcast episode in which Jonathan Genzen, MD, PhD, MBA, chief medical officer and senior director of governmental affairs, answers common questions submitted by clinical laboratorians about the FDA rule
- June 2024 webinar in which Genzen and Chief Compliance Officer Jonathan Carr, JD, provide an overview of the rule's requirements and how they differ across settings and types of tests
- Timeline for Implementation (see page 10)
- Requirements Matrix
- Frequently Asked Questions (FAQs)

View all resources here: www.aruplab.com/fda-ldt-final-rule.

Legal Challenges to the FDA Rule

American Clinical Laboratory Association (ACLA) Lawsuit

- Filed on May 29, 2024, in U.S. District Court for the Eastern District of Texas
- Challenges the FDA's authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act. ACLA advocates for a collaborative legislative approach to additional regulation as an alternative.
- ARUP filed a declaration in support of the ACLA lawsuit on May 29, 2024.

Association for Molecular Pathology (AMP) Lawsuit

- Filed on August 19, 2024, in U.S. District Court for the Southern District of Texas
- Challenges the FDA's authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act, citing the potential impact of the rule on molecular diagnostics and precision medicine

Status: On September 20, 2024, an order was signed consolidating the two cases in U.S. District Court for the Eastern District of Texas. A motion for summary judgment initiated by ACLA is pending, with final court filings in response to that motion due by December 23, 2024.

Scan to learn more about the ACLA lawsuit.

Scan to learn more about the AMP lawsuit.

As clinical laboratories have begun working to implement the new FDA rule regulating laboratory-developed tests (LDTs) as medical devices, they have questions about what the FDA will require when they validate tests for a new specimen type or an automated process. This photo shows ARUP's Automated Core Lab.

In a November 12 letter, American Society for Clinical Pathology (ASCP) President Greg Sossaman, MD, MASCP, urged members of the Trump transition team to act. The letter reminded transition team cochairs Linda McMahon and Howard Lutnick that the previous Trump administration prevented the FDA from regulating LDTs. In 2020, then U.S. Health and Human Services Secretary Alex Azar blocked FDA regulation of LDTs, basing his decision on a legal opinion drafted by the general counsel of the Department of Health and Human Services (DHHS) that the FDA lacked statutory authority to regulate LDTs.

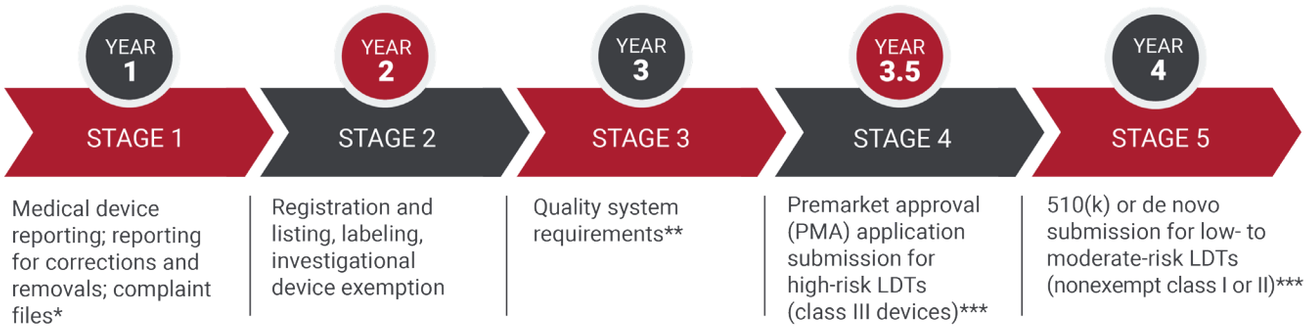
ARUP has many ASCP members among its workforce, and ARUP is a laboratory member of the American Clinical Laboratory Association (ACLA), which has also been in contact with the Trump transition team, asking that President-elect Trump move to delay implementation of the rule and signal an intention to rescind it, a process that would take time.

Rescission of the rule would require that the FDA follow its established notice-and-comment rulemaking process, which, even if initiated early in President-elect Trump's term, would take several months or longer.

Meanwhile, the lawsuit continues to wend its way through the court. The challenge started as two lawsuits, one filed by ACLA and the other filed by the Association for Molecular Pathology (AMP). They were consolidated in September in the U.S. District Court for the Eastern District of Texas. The lawsuits' challenge is based on the belief that the FDA lacks legal authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act, said Jonathan Carr, JD, ARUP's chief compliance officer.

In June, the U.S. Supreme Court handed down a decision in the landmark *Loper Bright Enterprises v. Raimondo* case that is generally viewed as favorable to ACLA and AMP in their challenge to the FDA because the decision overturned the so-called Chevron doctrine. That 40-year-old legal precedent previously instructed courts to defer to federal agencies' authority in reasonable interpretations of ambiguous laws.

The FDA has until December 23 to file its brief in response to the plaintiffs' motion for summary judgment in the case. The judge could request a hearing on the motion in early 2025, and a decision on the motion would follow.



Timeline for Implementation of the final FDA rule.

If the lawsuit is successful and the FDA under the new administration opts not to appeal, the rule will be terminated.

Even if the rule is rescinded or a court ruling leads to its demise, however, legislative attempts to further regulate labs may eventually follow, Genzen said.

The latest version of the Verifying Accurate Leading-edge IVCT Development (VALID) Act, which aims to add new regulation for LDTs, was reintroduced in the U.S. House of Representatives earlier this year, although Genzen said the future of the bill first introduced in 2020 will not be clear until after the new Congress begins.

Genzen said ARUP ultimately favors a solution that could result from collaboration between clinical labs, their trade associations, legislators, and regulators, all united in an effort to update existing quality standards for laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) while also doing what's best for patients and what's feasible for clinical labs.

He favors a compromise that would add transparency to LDTs currently offered by labs and keep beneficial aspects of test oversight under the CLIA framework while also potentially giving the FDA oversight for select high-risk tests, but not by simply lumping them in with conventional medical devices.

"There are some core principles that easily could be adapted for any future legislative or regulatory efforts, but it would require agencies that are willing to work collaboratively with the clinical laboratory community because it is in the interest of patient care," Genzen said. "It shouldn't be hard, and I'm still optimistic we can get there."

For now, ARUP will continue to act as a resource and as an advocate for its hospital and health system clients and for the entire clinical laboratory industry, he said.

"There are more than 100,000 clinical laboratorians in the U.S. who go to work every day to conduct testing to take care of people in their moments of greatest need. This is their career effort, their contribution. What drives them to work is helping people," Genzen said. "We obviously care about quality. We care about patient care. We care about transparency.

"We're committed to finding the right solution. I think there is a right solution if we all work together."

Lisa Carricaburu, lisa.carricaburu@aruplab.com

ARUP Healthcare Advisory Services Offers Tools To Help Labs Meet Requirements of FDA Rule

"We have a sense that a lot of clients have questions, and we want to help as many as possible."

David Shiembob, MBA, C(ASCP)[CM], Manager, ARUP Healthcare Advisory Services

ARUP Healthcare Advisory Services stands ready to help clients navigate the requirements that must be met to comply with the FDA's final rule on laboratory-developed tests (LDTs). ARUP's consultants have compiled a rich set of tools, resources, and templates to help clients get started on the steps necessary during the first two stages of the rule's five-stage timeline.

"We have a sense that a lot of clients have questions, and we want to help as many as possible," said David Shiembob, MBA, C(ASCP)[CM], manager, ARUP Healthcare Advisory Services. "That's why we've taken this approach to providing information and guidance."

The LDT guidance created by Healthcare Advisory Services covers:

- Health system and hospital responsibilities
- Requirements for the first two stages
- Quality management system requirements and best practices
- Action steps
- Additional resources

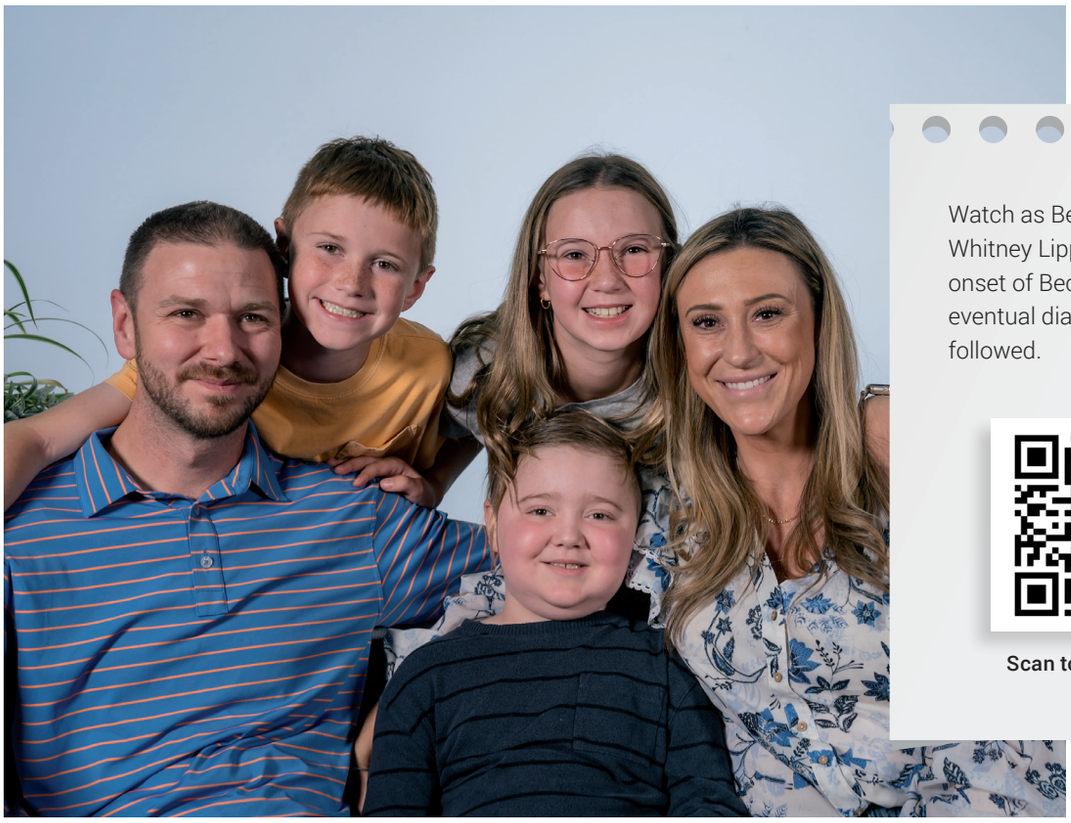
"There's still some uncertainty, and we know change and additional FDA guidance are coming," said Rick Panning, MBA, MLS(ASCP)[CM], ARUP senior healthcare consultant. "But we're trying to provide guidance and direction to clients about the steps they need to be taking right now. We're already several months into the first implementation phase, so no one should sit back and wait."

Healthcare Advisory Services is uniquely positioned to help health systems and laboratories contend with the final FDA rule on LDTs, Shiembob said. "ARUP is navigating these issues along with our clients. We have a robust menu of laboratory-developed tests that we intend to continue offering in an FDA-compliant manner."

Additionally, ARUP is committed to helping clients maintain their laboratories and test menus. "We believe in partnership with our clients, and we want our clients to be able to keep testing close to the patient when appropriate," Shiembob said.

Heather Stewart, heather.stewart@aruplab.com

Scan to request LDT resources from Healthcare Advisory Services.



Watch as Beckett, Zack, and Whitney Lippincott discuss the onset of Beckett's illness, its eventual diagnosis, and what followed.

Scan to watch video.

The Lippincotts pose for a family photo. Front row, left to right: Zack, Beckett, and Whitney Lippincott. Back row, left to right: Hudson and Kensington Lippincott.

Beckett's Journey: Overcoming the Challenges of Rare Disease Diagnosis With Help From ARUP Autoimmune Disease Testing

Beckett's Diagnostic Odyssey

On June 13, 2024, Whitney Lippincott walked into the emergency department of Intermountain Primary Children's Hospital in Salt Lake City and refused to leave until her 6-year-old son, Beckett, was admitted. In just two weeks, Beckett had transformed from an active, healthy boy who loved sports into one who struggled with basic daily tasks, such as climbing stairs, lifting silverware, and getting out of the bathtub.

During those two weeks, the Lippincotts rotated in and out of urgent care facilities and emergency departments in their search for answers. Each time, they were told that Beckett's symptoms were likely caused by a viral infection.

"They were telling me to go home and wait, but I had this motherly intuition that something was really wrong," Whitney said.

After he was admitted to Primary Children's, Beckett spent another week enduring test after test, including a difficult bone marrow biopsy to investigate whether he had leukemia.

Beckett weathered the procedure with astonishing fortitude, with the help of a trusted companion—his blanket. "The nurses were so kind to let Blanky go through the procedure with him," Whitney said.

"When an illness happens, you believe that doctors are superhuman and they will be able to figure it out right away," Whitney said. "We kept hearing, over and over again, 'This is weird. This is odd. His blood looks odd.'"

For patients who are suffering from rare diseases, as Beckett turned out to be, the journey to diagnosis can be onerous, stress inducing, and filled with unknowns. Arriving at the right diagnosis is challenging and, in Beckett's case, required a joint effort from persistent family members and knowledgeable physicians, as well as access to reliable and fast lab testing.

"It's like finding the right needle in a stack of needles," Whitney said.

Lisa Peterson, PhD, D(ABMLI), a medical director of Immunology, has played a key role in the development of autoimmune and myositis testing at ARUP.

Rare Disease Diagnosis: Juvenile Dermatomyositis

Eventually, Beckett's case reached Karen James, MD, MSCE, a pediatric rheumatologist at Primary Children's and an instructor at the University of Utah Spencer Fox Eccles School of Medicine.

"This case was particularly hard because it looked like a bad viral illness in the beginning. Our initial recommendation was to wait and see what happens. During that time, repeat labs showed worsening muscle inflammation and cytopenia [abnormally low levels of red or white blood cells or platelets]," James said. "He had this atypical presentation, and we weren't entirely sure what was happening."

As Beckett's symptoms worsened, James began to suspect an autoimmune disease. She ordered laboratory testing, which was performed at ARUP Laboratories, to measure the concentration of certain enzymes that can leak from muscles when they are inflamed or injured, including creatine kinase (CK), alanine transaminase (ALT), aspartate transaminase (AST), lactate dehydrogenase (LDH), and low-density lipoprotein (LDL).

According to James, elevated enzyme levels detected by just two of these tests would be sufficient for an autoimmune diagnosis, but Beckett's lab results showed that all five were elevated.

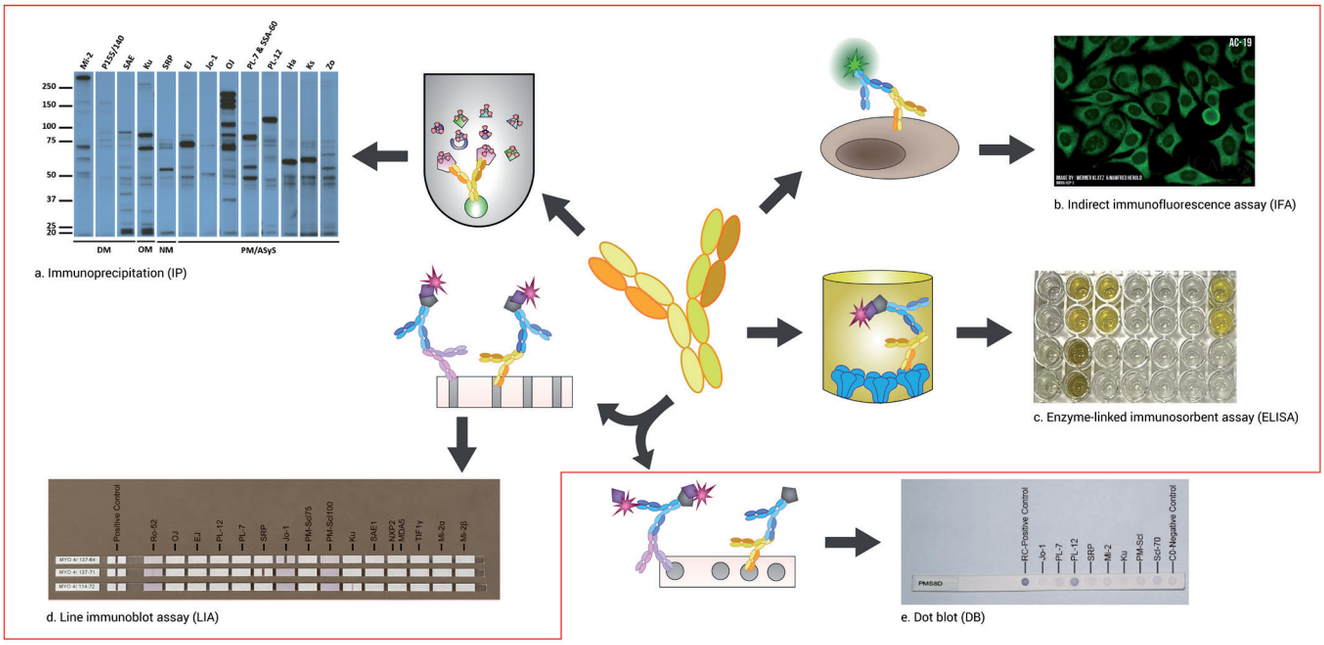
James also ordered testing to detect antinuclear antibodies (ANAs), which are strongly associated with connective tissue diseases, and von Willebrand factor, a marker associated with endothelial cell activation. Beckett's ANA test was positive. The von Willebrand factor result was initially in the normal range but increased to abnormal as his disease progressed.

"It's so important that we get those results back quickly to begin treatment," James said. "When I started working [at Primary Children's], I was thrilled to learn about ARUP. It's so nice to have a national reference lab right down the street where we can get reliable lab results."

After receiving results, James diagnosed Beckett with juvenile dermatomyositis (JDM), a rare autoimmune condition that is characterized by skin rash and muscle inflammation. According to James, the most likely cause for the condition was a mononucleosis infection that occurred simultaneously with extensive sun exposure.

The Lippincotts had visited a splash pad on June 1 and noticed an unusual redness in Beckett's face shortly after.

JDM is a rare disease that affects only one in 1 million children. If left untreated, JDM can result in permanent



ARUP integrates results from multiple methods, including immunoprecipitation, in order to provide an accurate test result.

muscle atrophy, as well as damage to the lungs and gastrointestinal (GI) tract.

"We were so lucky with how quickly we were able to get lab results back and how quickly they were able to diagnose [Beckett]," Whitney said. "We started treatment right away, which saved him from long-term damage to his muscles."

The Vital Role of Laboratory Testing

Testing for autoantibodies provides important insights for clinicians, in addition to confirming diagnosis. Myositis-specific and myositis-associated autoantibodies can be helpful in determining treatment course and in predicting the disease course, James explained.

Antibodies play an important role in our immune systems because they identify and attack foreign cells, such as viruses. Autoantibodies are malfunctioning antibodies that mistakenly attack the body's own cells.

"The myositis-specific and, to some extent, myositis-associated antibodies give us some prognostic information," James said. "Certain antibodies are associated with the more chronic disease course, some are associated with having more skin disease, and some are associated with having more internal organ involvement, such as interstitial lung disease or GI ulcerations."

Lisa Peterson, PhD, D(ABMLI), is a medical director of Immunology at ARUP who oversees ARUP's myositis panel testing and is guiding the development of assays to detect additional antibodies associated with myositis.

She said there are multiple methods to detect the relevant autoantibodies, some of which are more accurate than others. One method, immunoblot, is relatively easy and involves using strips of membrane coated with target antigens to detect the presence of myositis-specific antibodies.

However, the gold standard method for detecting myositis-specific autoantibodies, immunoprecipitation, is more time consuming and more labor intensive. This method involves radioactively labeling proteins and allowing them to bind to antibodies in the sample, using an electric charge to separate bound proteins by their molecular weight across an electrophoresis gel, which then has to be incubated with a piece of film to amplify the radioactive signal until it can be developed and interpreted. The resulting bands are then compared with known molecular weights to identify which proteins are present.

Beckett Lippincott visits a park in his hometown of Heber City.

ARUP is one of only three labs in the country that offer a myositis panel by immunoprecipitation.

"There are numerous publications on issues with false positives and false negatives using the blots alone," Peterson said. "We try to take more of an integrated approach. We use the results from immunoblot in combination with the results from immunoprecipitation and other methods to interpret testing. It really requires an integration of multiple methods to provide accurate results."

According to Peterson, autoantibodies can give important indications about the progression of disease or the development of new symptoms. For example, melanoma differentiation-associated gene 5 (MDA5) antibodies can be associated with rapidly progressive interstitial lung disease. ARUP calls to alert clinicians when results of MDA5 tests are positive.

Other antibodies are associated with cancer, although that is more common in adults with dermatomyositis than it is in children.

"We depend on ARUP for our ANA testing and the autoantibodies [testing] because we find their results to be reliable and interpretable," James said.

Beckett's results for the myositis panel were negative, which is "likely reflective of the fact that we don't yet know all of the autoantibodies that are out there for myositis," James said. She wasn't surprised by the negative result, due to the atypical pattern of Beckett's disease symptoms.

Research in this field is ongoing, and ARUP regularly evaluates new antibodies for the panel. In early 2025, ARUP will add Ha, Ks, and Zo autoantibodies to its panel.

"The good news is that we have treatments. The bad news is that I can't predict the future for [Beckett]," James said. "Some kids will have this once. Other kids will have a more chronic course, and the disease is harder to get under control."

Beckett's Road to Recovery

Beckett was discharged from Primary Children's on June 21 to begin his long road to recovery. His routine now involves daily doses of medications, including an initial high dose of steroids, and he faces a two-year course of chemotherapy and, for a time, weekly intravenous infusions of antibodies.

"All that matters is that he's healthy and on the mend," Whitney said. "At the same time, we're mourning the loss of who he was two months ago and saying goodbye to that kid for a little while, until he is back to where he needs to be."

According to his mom, Beckett has become an expert at swallowing pills and taking shots. Beckett says the "needle feels like a cotton swab."

With treatment, Beckett is slowly regaining strength in his muscles. He was able to return to school, albeit with a few modifications. He now needs to apply sunscreen before recess to limit the effects of sun exposure. Depending on his symptoms, he may need grading exceptions because of his muscle weakness, which affects skills such as handwriting.

When asked what he was most concerned about, Beckett said, "That my friends won't recognize me."

Some of the medications have unfortunate drawbacks. The steroids have left him with a puffy face and weight gain.

Beckett looks forward to playing baseball and lacrosse again when his strength returns.

"Beckett has been our little superhero. He is so brave. I can honestly say that. I don't think I've seen one tear throughout this entire process," Whitney said. "He really tapped into this inner strength and understood that he needs to be strong."

The Lippincotts plan to host a fundraising walk next summer to raise awareness of JDM. Proceeds from the event will go to the Cure JM Foundation.

Kellie Carrigan, kellie.carrigan@aruplab.com

How ARUP Healthcare Advisory Services Helped Fairview Health Services Build a Robust Laboratory Stewardship Program

As a national reference laboratory, ARUP Laboratories has an innate and thorough understanding of complex lab operations. ARUP Healthcare Advisory Services draws on this knowledge to help clinical laboratories deliver value-based care and achieve long-term revenue goals for their health systems.

Healthcare Advisory Services consultants are seasoned lab leaders and data analysts who offer an expansive portfolio of customizable offerings in areas such as lab stewardship, outreach operations, analytics and reporting, lab/system alignment, and more.

Here, we take an in-depth look at how Healthcare Advisory Services helped a client develop an effective laboratory stewardship committee. In future issues of Magnify, we'll continue to feature client success stories that highlight Healthcare Advisory Service's impactful, tailored solutions.

Laying the Groundwork for Laboratory Stewardship

Fairview Health Services, a Midwestern health system with 13 hospitals and 142 overall locations, is committed to improving health and well-being in the communities it serves. With that mission in mind, Fairview sought to improve its laboratory ordering practices to support appropriate care while optimizing the use of valuable laboratory resources. The health system partnered with ARUP Healthcare Advisory Services to establish a dynamic, effective laboratory stewardship committee and to provide an integrated data source to inform and benchmark the committee's efforts.

Healthcare Advisory Services consultants helped Fairview develop a successful laboratory stewardship program by:

- Recommending a governance structure
- Delivering a comprehensive data solution
- Analyzing system data to identify opportunities
- Prioritizing interventions and identifying next steps
- Providing continuing support

Stewardship Governance

The first step in creating a laboratory stewardship program is developing a charter document that specifies objectives, stewardship committee membership, and processes. Healthcare Advisory Services consultants provided Fairview with charter suggestions and examples from other organizations. This helped Fairview develop a charter that best met its unique needs.

Laboratory stewardship committees need clear objectives to ensure their efforts are focused and efficacious. Eliminating waste and achieving cost savings are common objectives. "But we intentionally named ourselves a stewardship committee and not a utilization committee," said Klint Kjeldahl, CT(ASCP), vice president of Laboratory Services at Fairview Health Services and a member of the stewardship committee. "Our goals really help to guide us toward

St. John's Hospital in Maplewood, Minnesota, is one of Fairview Health Services' facilities. Fairview partnered with ARUP Healthcare Advisory Services to build an effective laboratory stewardship committee.

appropriate test utilization, which doesn't always mean that you're reducing the number of tests. It's truly [about] the more appropriate use."

Healthcare Advisory Services consultants recommended that the Fairview team establish a clinician-led rather than a laboratory-led committee. Clinicians are the end users of laboratory services, so their concerns and priorities need to drive stewardship efforts. Additionally, when clinicians are spearheading changes, they can champion those initiatives throughout a system's clinical community.

"It's not just problems we're seeing from a laboratory perspective. It's problems our entire system is seeing," Kjeldahl explained. "Yes, laboratorians still have strong influence on the committee, but clinicians help us see through different eyes the various problems, opportunities, and potential solutions."

Fairview took a multidisciplinary approach to creating its laboratory stewardship committee, seeking involvement from clinicians as well as pharmacy, quality, operations, finance, nursing, IT, and other departments. This broad representation enables Fairview's laboratory stewardship committee to better understand the systemwide implications of its work. It has also helped to bring new ideas to the team.

> ***"The key benefit of having ARUP in the stewardship process is really that high-level institutional perspective. ARUP consultants have seen it all."***
>
> Michelle Stoffel, MD, PhD, Associate Chief Medical Information Officer for Laboratory Medicine and Pathology, Fairview Health Services, and Stewardship Committee Member

Comprehensive Data

Not long after launching its laboratory stewardship program, Fairview committee members realized they didn't have the detailed data needed to identify ordering trends or misutilization. The committee chose to implement ARUP AnalyticsDx™ (ADx) Comprehensive to gather that crucial data and uncover ideas for stewardship projects.

ADx Comprehensive gathers disparate system data into one seamless database. Easy-to-use dashboards enable leaders to filter test orders in a variety of ways so that they can establish baselines and monitor the impact of interventions.

"Change is really difficult. Even making a small change can take an intense, coordinated effort, and we cannot afford to waste the limited resources we have to make change," said Michelle Stoffel, MD, PhD, associate chief medical information officer for Laboratory Medicine and Pathology at Fairview Health Services and a member of the stewardship committee. "Having even a small amount of meaningful data is much more important than having large amounts of useless data."

Fairview worked closely with ARUP to build new ADx Comprehensive dashboards that provided the data views Fairview most needed. "It was really helpful to partner with ARUP on the data mapping," Stoffel said. "We learned a lot about our own data, as well as how it could optimally be mapped into the ADx Comprehensive dashboards in a way that makes sense for the questions we wanted to ask."

The Fairview team has found that ADx Comprehensive is an important part of the lab's overall data analysis ecosystem, complementing other data tools while giving unique insights not provided by other tools. "We, like many laboratory systems, have several reporting options in our toolkit, including our native EHR [electronic health record] reporting and enterprise-level solutions. However, the ADx Comprehensive dashboards provide powerful visuals of clinical best practices applied to our data in a way that facilitates change conversations with stakeholders," Stoffel said.

As an example, Stoffel used the automated visuals provided by the ADx Comprehensive dashboards to demonstrate the need to improve daily lab utilization to Fairview's medical informatics leadership team. "The visuals helped to tell the story in a way clinicians could instantly connect with," she said. "Because we use the dashboard data to augment our other enterprise reporting data, which clinicians are already familiar with, our stakeholders can easily see how the stewardship-focused views fit into the bigger data picture."

Data Analysis and Opportunities

The ADx Comprehensive dashboards give the Fairview laboratory stewardship committee a high-level view of ordering trends. "They let us see those big ordering patterns emerge, and I'll be honest, we've had a few moments in our stewardship committee where we couldn't believe what we were seeing. But that leads us to go look at our EHR build and our ordering reports. And there have been several instances where we have uncovered workflows that can be optimized," Stoffel said.

For example, using the ADx Comprehensive dashboards, the Fairview laboratory stewardship committee discovered that some clinicians were still ordering a creatine kinase-muscle/brain (CK-MB) test to detect acute coronary syndrome (ACS). However, clinical guidelines call for a high-sensitivity cardiac troponin test to identify a superior biomarker for detection of ACS. To prevent this misutilization of the CK-MB test, the laboratory stewardship committee had it removed from Fairview's test formulary.

Shortly after Fairview implemented ADx Comprehensive, Healthcare Advisory Services completed a utilization analysis that encompassed 12 months of laboratory data such as daily labs, duplicate orders, continuity of care information, sepsis testing protocols, and more. This analysis helped Fairview identify areas of opportunity for improvement.

Prioritization and Next Steps

The Fairview laboratory stewardship committee has been active for three years now. As its work becomes more visible and impactful, stakeholders throughout the organization are beginning to come to the committee with ideas.

"We're at the point now where, happily, I'm getting pathology colleagues emailing me, referring their clinical colleagues who want to see a change or want to initiate a project," Stoffel said. "Having clinical engagement really helps fuel the work because it lends visibility—folks tell their friends and then they know where to find us through their laboratory colleagues."

The Fairview laboratory stewardship committee is in the process of launching a portal that will allow anyone in the organization to submit suggestions for stewardship projects or offer potential solutions to challenges.

Meanwhile, the committee must prioritize the initiatives that will make the greatest impact and keep the team focused on its overall objectives. Some of the current initiatives the Fairview stewardship committee is working on include:

Changes to daily lab ordering: Fairview's utilization analysis found that 70% of inpatients had CBC and metabolic panel (MP) testing every day of their stay. Furthermore, much of this testing was duplicative, with 90% of CBCs and 75% of MPs being collected within 12 hours of the previous tests. The committee is launching a project to design and implement EHR ordering constraints that will limit the number of occurrences a provider can request for ongoing daily labs.

Timed-draw workflow changes: Some tests, such as tests to assess drug levels, need to be performed within specific time frames. Tests performed outside of the time frame are essentially wasted and may require specimens to be redrawn. Fairview is working to update its handheld patient identification system to prevent such tests from displaying until it's the right time to order them. This initiative is an example of how broader stakeholder representation, in this case, from the pharmacy, has optimized the stewardship committee's work.

Continuity of care committee creation: When tests are ordered for patients shortly before discharge from acute care, the patients may not receive follow-up on their results. Fairview's utilization analysis found that over the course of a year, 99,277 test results (excluding cultures) arrived postdischarge. Fairview's laboratory stewardship committee began developing a continuity of care subcommittee to address that gap in care. However, the team realized the subcommittee's work would transcend the laboratory and touch on continuity between different care teams, scheduling teams, other departments, the EHR, and the laboratory. Although the concept of a continuity of care subcommittee originated with the laboratory stewardship committee, it has become a systemwide initiative.

Test code oversight: When creating new test codes, a test code process team at Fairview now consults with the laboratory stewardship committee to consider impacts on stewardship.

> ***"[The ADx Comprehensive dashboards] let us see those big ordering patterns emerge, and I'll be honest, we've had a few moments in our stewardship committee where we couldn't believe what we were seeing."***
>
> Michelle Stoffel, MD, PhD

Continuing Involvement

Healthcare Advisory Services consultants have remained highly engaged with the Fairview laboratory stewardship committee. The consultants attend the committee's monthly meetings, bringing a wider perspective and suggestions to its work.

"The key benefit of having ARUP in the stewardship process is really that high-level institutional perspective," Stoffel said. "ARUP consultants have seen it all."

She added, "Having ARUP consultants as partners provides stability and accountability. They've provided that consistent forward momentum that can be really difficult to otherwise achieve when committee members rotate or when daily challenges become overwhelming."

Through its continuing engagement with Healthcare Advisory Services, Fairview's laboratory stewardship committee has become a robust engine for positive change. "What's been most powerful is the ability to find those improvement sweet spots that are operationally valuable, as well as clinically meaningful to the patient," Stoffel said.

Heather Stewart, heather.stewart@aruplab.com

Fairview delivers quality care with compassion, serving Minnesotans through its 13 hospitals and 142 facilities.

Advice to Other Organizations

The Fairview laboratory stewardship committee has gone through the arduous work of building its structure, analyzing data, and launching initiatives. Based on that deep experience, committee members have some valuable advice for other organizations seeking to build or strengthen their own committees.

- Get the right people involved. Find people who are passionate about the work, advised Klint Kjeldahl, CT(ASCP), vice president of Laboratory Services. He pointed specifically to the effort and involvement of the stewardship committee's secretary, Brenda Tomanek, director of Laboratory Operations at Fairview, as key to keeping the committee organized and moving forward. "If we had two more people helping to organize like Brenda Tomanek, and two more people with the passion [Michelle] Stoffel [MD, PhD, associate chief medical information officer] has for the data, we would have an even more successful stewardship committee," he said.
- Establish your data source. "Getting our data house in order is something that our committee spent well over a year doing. It can seem like a really long time before you see the fruit of that labor, but without taking the time to do that, you can literally just be spinning your wheels forever," Stoffel said.
- Prioritize your efforts. Many ideas can bubble up from analyzing your data, but your committee will only have bandwidth for a few. "Everything can be improved, and it can be really easy to get distracted with great ideas and people who are passionate about them," Stoffel said. "Understand that you can't do everything at once. You have to prioritize."

Heather Stewart, heather.stewart@aruplab.com

From left to right, Adam Clayton, PhD, clinical variant scientist; Steven Friedman, PhD, group manager of the Clinical Analytics in Sequencing and Clinical Analytics Division; Anastasia Kellogg, senior bioinformatics scientist, and Philippe Szankasi, PhD, R&D scientist in Oncogenomics, in discussion.

ARUP's Myeloid Malignancy Mutation Panel Is First To Offer Both a Targeted Gene Approach and Genomewide Analysis

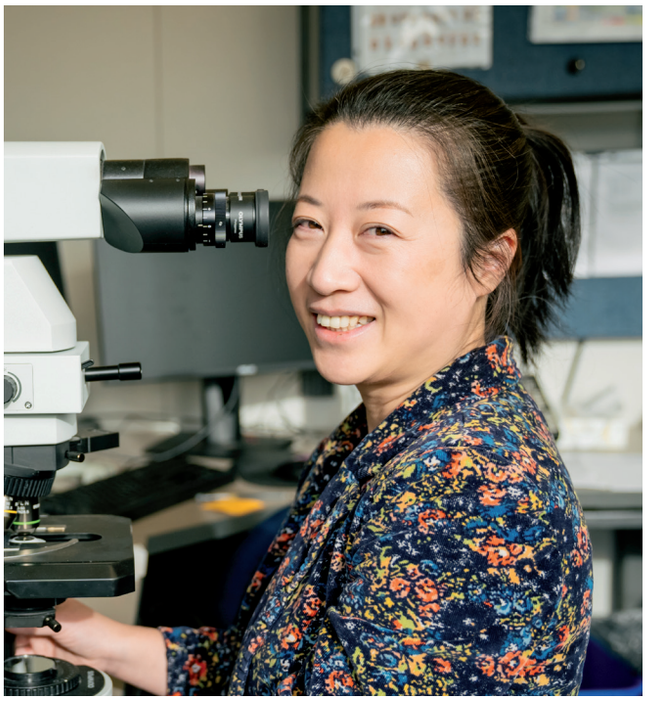
An ARUP-developed panel is the first of its kind to use next generation sequencing (NGS) to identify small, intermediate, and large structural abnormalities, including copy number variants (CNVs) and copy number-neutral loss of heterozygosity (CN-LOH), in a single assay.

The Myeloid Malignancies Mutation and Copy Number Variation Panel by Next Generation Sequencing (test number 3016621) offers a more comprehensive, cost-effective analysis of the genetic abnormalities involved in tumorigenesis that can inform the prognosis and treatment of acute myeloid leukemia (AML), myelodysplastic syndromes (MDSs), and other hematologic neoplasms.

ARUP is the only reference lab in the United States to offer this innovative test.

"By combining cytogenetic and NGS testing into one assay, this test offers integrated insights that can guide or optimize patient care decisions," said Peng Li, MD, PhD, medical director of Hematopathology at ARUP.

Li's recent research, which includes groundbreaking investigation of *DDX41*-associated myeloid neoplasms, has focused on the molecular etiology of myeloid and lymphoid malignancies and has identified novel germline and somatic mutations contributing to hematologic neoplasms. She



Peng Li, MD, PhD, medical director of Hematopathology, played an instrumental role in the development of the Myeloid Malignancies Mutation and Copy Number Variation Panel by Next Generation Sequencing.

> ***"This test will identify more disease-causing variants, providing patients with more conclusive results than traditional next generation sequencing or conventional cytogenic testing provide."***
>
> Peng Li, MD, PhD, Medical Director, Hematopathology, ARUP Laboratories

played an instrumental role in the development of ARUP's new myeloid malignancy panel.

CNV alterations, which are aberrations in the number of copies of a sequence of DNA, have been shown to contribute to cancer initiation and progression and to therapeutic resistance.

In 2022, the World Health Organization (WHO) and the International Consensus Classification (ICC) published updated guidelines regarding the classification of myeloid neoplasms and acute leukemias. Li said the new guidelines indicate that CNV information is essential for the diagnosis, subclassification, and risk stratification of hematologic malignancies.

Conventionally, two separate testing methods, sequencing and genomic microarray, are required to capture both small point mutations and larger structural variations.

"Panels that only include targeted genes offer a limited view. If we only look at point mutations, we miss something," said Philippe Szankasi, PhD, a scientist in Oncogenomics in the ARUP Institute for Clinical and Experimental Pathology® (Research and Development). Szankasi contributed to the validation of the panel, which ARUP began offering in October 2023. "We also need to know about the larger deletions/duplications that might remove a gene or triplicate it," he said.

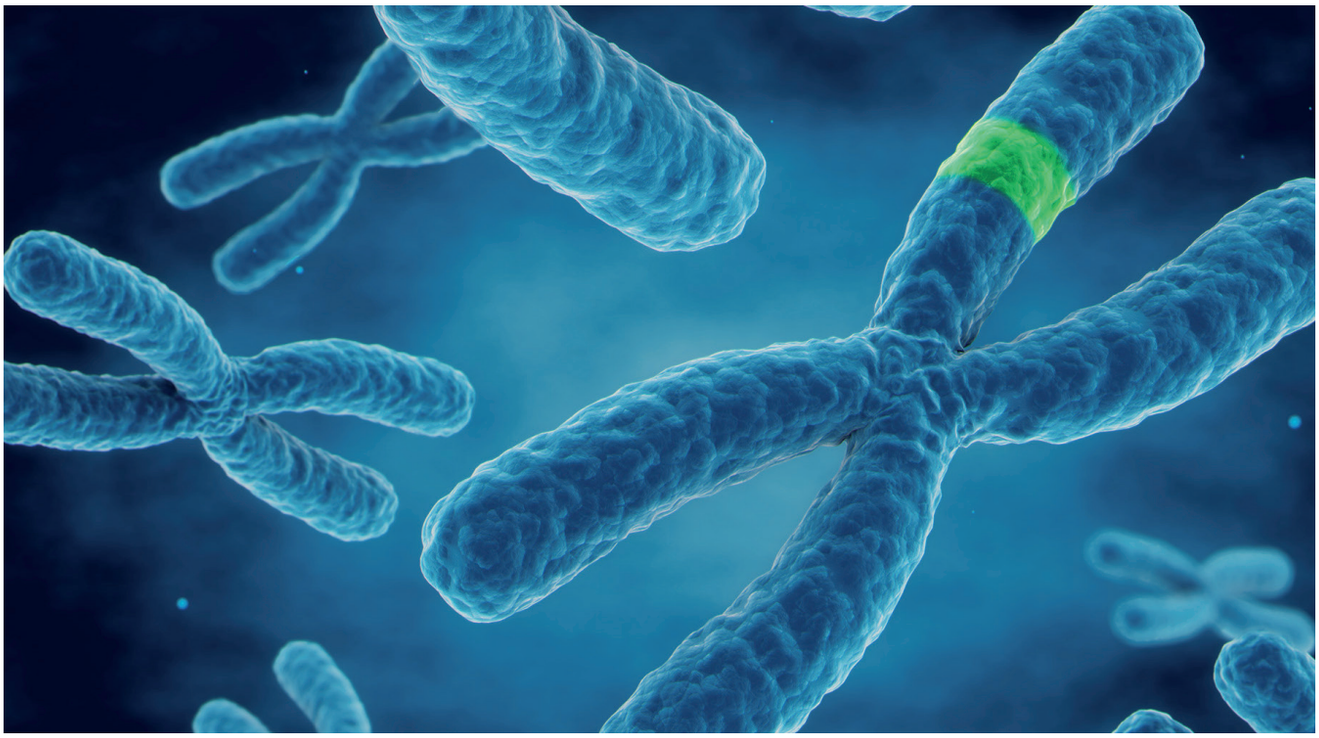
To identify CNVs, teams at ARUP designed the new panel to sequence segments of DNA throughout the entire genome in what they refer to as a backbone. According to Szankasi, 25% of the data captured from the assay is dedicated to this backbone. By sequencing across the entire genome, the data offer a broader picture of the alterations.

In addition to CNVs/CN-LOH, the assay also targets nearly 70 genes that are clinically relevant in myeloid malignancies.

"This test will identify more disease-causing variants, providing patients with more conclusive results than traditional next generation sequencing or conventional cytogenic testing provide," Li said. "The test's sensitivity in detecting CNVs at subgene or near-gene level … surpasses that of conventional karyotyping, FISH [fluorescence in situ hybridization], or array studies."

By combining what would normally be two assays—which use separate methods—into a single test, this panel provides a cost-effective option for comprehensive, integrated analysis.

As part of its design, the panel also has the capacity to identify CN-LOH. Regions of CN-LOH produce identical segments of DNA without altering the normal copy number of the chromosomes, which can lead to malignancy.



The inclusion of copy number variant (CNV)/copy number-neutral loss of heterozygosity (CN-LOH) in the Myeloid Malignancies Mutation and Copy Number Variation Panel by Next Generation Sequencing provides crucial information used to diagnose, subclassify, and determine prognosis for myeloid malignancies.

For example, CN-LOH can occur in the gene known as *TP53*—a gene that encodes the protein p53, a known tumor suppressor that controls cell division and cell death. When both copies of *TP53* are mutated, this imbalance can lead to the development of malignancy.

"*TP53* loss of heterozygosity may be missed by conventional testing," Li said.

To identify and report CN-LOH, ARUP teams had to develop their own software program with the capacity to recognize abnormal homozygous patterns and establish standard procedures for their analysis and reporting.

"It basically doubles the work per sample in terms of the analysis required. It's a new class of variant that required the team to write all new standard procedures," said Steven Friedman, PhD, group manager of the Clinical Analytics in Sequencing and Clinical Analytics Division.

The software, which has been dubbed "Sweet n LOH," analyzes variant allele frequency data to detect abnormalities.

"We have to determine what is normal versus abnormal from a mathematical perspective," said Anastasia Kellogg, senior bioinformatics scientist, who was key to the software's development.

The software identifies precise breakpoints where the abnormal (homozygous) sections of chromosome begin and end, compared to the normal (heterozygous) sections. The identification of those breakpoints enables the detection of CN-LOH.

"I credit our biocomputing team with building the software and tools, as well as working with ARUP's medical directors to establish a workflow that was clinically thorough, but also efficient," Friedman said.

More information about the panel is available in ARUP"s Laboratory Test Directory and on the aruplab.com Hematopathology page (aruplab.com/hematopathology).

Kellie Carrigan, kellie.carrigan@aruplab.com

Dan Albertson, MD, loves recreating in the mountains around Salt Lake City, seen here behind him through the windows of his office.

ARUP's University Business Unit President Has an Eye on What's Ahead as University of Utah Health Expands

When ARUP Laboratories formed 40 years ago as a tiny startup spun off from the University of Utah, few anticipated it would become one of the nation's four largest reference laboratories, with hospital and health system clients in all 50 states.

Since day one, however, ARUP has remembered its origins, and ARUP's new multidivisional organizational structure will ensure that the company can meet the needs of a growing local health system while also continuing to grow outside Utah.

In April 2024, ARUP named Dan Albertson, MD, as president of the newly created University Business Unit, which encompasses laboratory medicine at University of Utah Health and spans transfusion medicine, a blood donor center, university clinical labs, and anatomic pathology. Alberson has his eye on the future without losing focus on the present.

"We always need to be cognizant of the road ahead. When I think about ARUP and the University of Utah Health system, I'm thinking about what needs to be done in the next 12 to 18 months, the next two to five years, and beyond," Albertson said.

The health system is growing in complexity, with satellite facilities across the state. The number of patients who rely on it will continue to increase as more people discover the benefits of living and working in Utah. Albertson said part of his role involves preparing for the growth, expanding the laboratory footprint to meet patient needs, and improving efficiency.

One of Albertson's favorite activities is recreating with his children outside, four of whom are pictured here with their snowboards.

Albertson's children pose for a photo at Zion National Park.

"The focus on high-quality patient care must remain our priority, and I can't think of a better place to provide that sort of care than to our own community," he said.

ARUP is the sole provider of laboratory medicine and blood products for U of U Health and the Huntsman Cancer Institute, a role that has given ARUP an additional depth of clinical and laboratory expertise that can be shared with its clients across the country.

"If we can show that our own lab can benefit from a patient care standpoint and perhaps an operational or financial standpoint, that can bring value and be applicable to clients nationwide," Albertson said. He added that ARUP's medical directors provide excellent diagnostic expertise, and the partnership between ARUP and U of U Health results in a level of care that cannot be replicated in most institutions.

ARUP began transitioning to a multidivisional structure of distinct business units in July 2023 with the creation of the Innovation Business Unit, which is comprised of the ARUP Institute for Research and Innovation in Diagnostic and Precision Medicine™, the ARUP Institute for Clinical and Experimental Pathology®, and the company's Clinical Trials and PharmaDx groups. CEO Andy Theurer said the change allows business units to focus, ensures quality, and increases the level of service ARUP can provide, while also allowing for agility, something Albertson embraces.

"We have utilized digital pathology for many years at ARUP in a limited fashion, but we are on the cusp of utilizing it in a manner that spans all of cytopathology, surgical pathology, and molecular oncology in a way that enhances clinical sign-out, improves processes around archival storage and retrieval, promotes scholarship and research, and increases workforce flexibility," Albertson said.

Albertson does not view the digital transformation as a replacement for pathologists and laboratory personnel. "To date, there's not a robot than can replace human expertise at the bench or an artificial intelligence (AI) application that can accurately interpret one of many thousands of diagnoses made on hematoxylin and eosin (H&E) slides in the context of clinical history. Our present goal should be to utilize digital platforms and software applications that enhance what our experts do in the lab to improve operational efficiency and enhance patient care."

Albertson said he has full confidence in the ARUP workforce to tackle the challenges currently facing labs.

"Our teams are experts at what they do. I've worked with most of my colleagues for years. They come to work every day with the primary goal of providing excellent patient care," Albertson said. As he implements change and works toward increased cohesion in the University Business Unit, he cannot see the finish line, but he said, "I'm in it for as long

Albertson enjoys trail running, hiking, and all of Utah's outdoor beauty.

as I can actively contribute to our mission and provide value to the organization."

Albertson received a bachelor's degree from Xavier University in Cincinnati, Ohio, and an MD degree from the University of Nebraska, and then completed a residency in anatomic and clinical pathology at Creighton University in Omaha, Nebraska. He joined the Department of Pathology and ARUP as a fellow in 2012. He held multiple leadership positions in Anatomic Pathology before he was named division chief in 2022.

He had planned to stay in the Midwest following his education there, but that changed during his surgical pathology fellowship at ARUP and the U.

Albertson loves living in Utah and all of the outdoor activities available just outside the windows of his office, which look out on both the Wasatch Range and the Salt Lake Valley. He is an avid hiker, backpacker, trail runner, and snowboarder. On October 5, he participated in the DC Peaks 50, a 50-mile footrace that took him through the mountains in Davis County, Utah.

His approach to the race was like his approach to his new role as University Business Unit president.

"There are few things more difficult and simple at the same time," he said. "We all know where the finish line is, and the only way to get there is [to] start putting one foot in front of the other."

Bonnie Stray, bonnie.stray@aruplab.com

ARUP Alumni Feature: Eric Konnick, MD, MS, Reflects on Journey From Scientist to Medical Doctor

Eric Konnick, MD, MS, a pathologist at Fred Hutchinson Cancer Center and University of Washington (UW) Medical Center, started his healthcare career at ARUP Laboratories.

Eric Konnick, MD, MS, a pathologist at Fred Hutchinson Cancer Center and University of Washington (UW) Medical Center, started his healthcare career as a laboratorian at ARUP Laboratories. He finds his work as a pathologist fulfilling, but he had never considered a medical career before working at ARUP.

"It was really … my experiences in the laboratory and working with medical directors that got me interested in medicine," said Konnick, who is also an associate professor at UW and the associate director of UW Medicine's Genetics and Solid Tumor Lab.

In 1998, shortly after he earned his bachelor's degree in biology at the University of Utah, Konnick started working at ARUP as a scientist in the Molecular Pathology Laboratory. At the time, this laboratory performed all of ARUP's molecular infectious disease, genetic, and oncology testing. After working in the lab for six months, Konnick transferred to Research and Development, where he worked on developing tests and informatics interfaces.

Konnick continued to grow at ARUP while he worked toward his master's degree in laboratory science. After seven years in R&D as a scientist, he was ready for a new challenge.

"I understood the technology, and I understood the business piece of pathology. What I didn't understand was medicine, and eventually, I decided to apply to medical school," Konnick said. He started working toward his MD degree in 2006 at the University of Utah School of Medicine and continued to consult with ARUP part-time until he graduated.

While working in ARUP's R&D lab influenced Konnick's career path, it also shaped the values he still holds as a pathologist.

"We were encouraged to learn and improve. At the end of the day, it was always for the patients," Konnick said. "It established the framework that I work in now."

ARUP's leadership left a lasting impression on Konnick, now a leader himself. "When Dr. [Carl] Kjeldsberg was still CEO and chair, he would routinely walk through the laboratories and talk with staff," he said. "I was impressed that somebody who had a lot of responsibility took the time to interact with the folks who were generating the results."

Konnick loves to spend time outdoors and has enjoyed hiking in both Utah and Washington.

As Konnick pursued his medical degree and continued working in ARUP's R&D lab, his focus began to shift from infectious diseases to oncology.

"When I started, I was interested mostly in infectious diseases, and that's what I specialized in when I was in the R&D group," Konnick said. The adoption of precision oncology and precision diagnostics by the clinical laboratory is what initially piqued Konnick's interest in oncology toward the end of his time in medical school.

Konnick now specializes in oncology diagnostics in his current roles at UW. His lab runs preanalytic services to ensure that samples about to undergo testing are as high quality as possible and that patients receive timely and accurate results.

Although oncology is now his primary focus, Konnick still dabbles in infectious diseases testing.

"During the COVID pandemic, I was recruited to be one of the medical directors of the Seattle Flu Study. That was the public health outreach program run by a group here at the University of Washington to provide community-based testing," he said.

Konnick and other medical directors worked to provide rapid COVID-19 testing to the public during the peak of the pandemic. "We're the group that identified the first human transmission [of COVID-19] here in 2020."

One of Konnick's favorite parts of his job is knowing the impact he makes on patients every day. The advancements he has made in oncology, alongside other pathology researchers, have significantly improved the condition and prognosis of many patients with cancer.

"People who were on death's doorstep are now going out and running marathons and resuming their lives," Konnick said. "It's amazing to see those types of stories. To be a tiny part of it has been really rewarding."

Konnick added, "A lot of pathologists and laboratorians don't have that direct patient contact. But at the same time, we have the ability to touch virtually every patient who comes through a clinic door and gets a laboratory test or pathology diagnosis."

In addition to his work at UW, Konnick has been involved with the Association for Molecular Pathology (AMP) Professional Relations Committee (PRC) for eight years and has served as the chair of the committee since 2022. In this role, he participates in projects to advocate for both patients and pathologists through legislation and community outreach.

He recently received a Meritorious Service Award from AMP for his dedication to the organization and to the field of pathology. In a statement announcing the 2024 awards, AMP reported that Konnick "has helped lead AMP's ongoing efforts to establish a more efficient and effective regulatory framework for laboratory-developed testing procedures that would preserve innovation and protect patient access to essential medical services."

With AMP, Konnick and his colleagues interact with government agencies to help inform the development of policy to move the field of pathology forward. "The laboratory is critical to everything in healthcare, so I think having a role where we educate and advocate in the interest of patients from the laboratory perspective is important," he said.

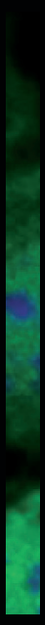
media@aruplab.com

Magnify is published by ARUP Laboratories.

For additional copies or for permission to reprint articles,

please contact Connie Porter, connie.porter@aruplab.com.

Visit aruplab.com/magnify to read past issues.



ARUP LABORATORIES

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

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

MKT-CRPCOM-COL-001