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Paradigm for collaboration: Legacy partners with QIAGEN to develop next generation sequencing

An interview with Yasmine K. Akkari, Ph.D., FACMG

Next-generation sequencing (NGS) is a breakthrough technology that makes decoding genetic information easier, faster and less expensive than conventional methods. When it comes to cancer, NGS enables the massive parallel analysis of genetic material — using gene panels to test for multiple genetic changes simultaneously rather than focusing on single genes or single mutations in tumors.

As a result, clinicians can not only better understand the molecular nature of a tumor more quickly and affordably, but also identify which treatments are effective in treating tumors harboring specific pathogenic variants.

“Validating genetic testing in tumors using NGS was important because we are increasingly aware that standard chemotherapy is not always effective. With NGS, we will have the tools to identify a targeted treatment proven to have a better chance of success,” explains Yasmine Akkari, Ph.D., FACMG, scientific director of cytogenetics, technical director of molecular pathology, and manager of genetics laboratories operations at Legacy Laboratory Services (LLS). “This personalized approach is the future of cancer care,” she adds.

Enter QIAGEN, a global leader in molecular diagnostic testing. Its GeneReader NGS System embodies the NGS technology Dr. Akkari

recognized as key to future molecular testing development at LLS.

“QIAGEN is a trusted vendor, and we already had a lot of their equipment in our laboratory,” Dr. Akkari says, noting that the company’s solutions for DNA manipulation are widely used and respected. “We figured that if they were

developing next-generation sequencing, their platform would be equally reliable and effective.

“So, when QIAGEN approached LLS last year about serving as a beta site for their new GeneReader NGS System, we felt it was a win-win,” she con-

tinues. “Through this partnership, we acquired state-of-the-art technology at an affordable price. QIAGEN benefits from the clinical data we generate during the validation process and the clinical testing of their platform.

“That’s the paradigm for collaboration: when both parties benefit,” she adds.

The year-long validation process has involved testing vetted specimens purchased from a national cell repository, as well as performing an inter-laboratory comparison on samples that had been previously tested at outside institutions.

“It’s how we verify the accuracy and precision of the system,” Dr. Akkari says. “All these steps

When it comes to cancer, next-generation sequencing enables massive parallel analysis of genetic material — using gene panels to test for multiple genetic changes simultaneously.

Collaboration: Ultimate aim is to benefit patients region-wide

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are checks and balances to ensure the test is appropriately validated and ready for clinical use. So far, the data looks very promising.”

Dr. Akkari anticipates that Legacy Laboratory Services will begin performing NGS testing on Legacy Health patients later this year. Testing will focus on the five most common and actionable cancers in the U.S.: breast, ovarian, colon, lung and melanoma.

“One of the great things about this system is that it’s an integrated and comprehensive workflow, not just a sequencer,” she says, noting that no other NGS system currently on the market offers this comprehensive functionality. “The QIAGEN GeneReader workflow does it all — from patient specimen and DNA extraction to producing an actionable report. In addition, the workflow offers a built-in bioinformatics pipeline. This latter resource has been invaluable in the success of our validations and has been vetted to improve clinical outcome. Not every lab has the capability to build that pipeline, and we’re able to use what QIAGEN has already developed.”

The ultimate value of this functionality is to benefit our patients.

“When we find a genetic signature, we can determine if it’s linked to a specific drug and, with an easy web page navigation, determine the location of the closest clinical trial offering that drug,” she says. “This is really ideal for serving patients, and enabling them to access the best possible care, close to home.



Yasmine K. Akkari, Ph.D., FACMG

“In today’s health care environment, resources are limited, but we were able to acquire this equipment in a fast, efficient and cost-effective way,” continues Dr. Akkari. “The goal is to advance cancer care and treatment for patients at Legacy Health and across the region.

“This NGS platform will not only be used for cancer. Our future direction is to use this technology to tailor diagnosis and treatment for seizures, developmental delay, inherited cancers and many other genetic-based ailments in our population.

“The ability to deliver this testing locally is a tremendous step forward in the development of molecular testing at Legacy Laboratory Services,” she adds. “It is important to note that this technology required focused education and training to develop the expertise required from our technical staff. It has been deeply rewarding to see our molecular lab scientists master this technology.”

Yasmine Akkari gains two appointments

Yasmine Akkari, Ph.D., FACMG, was elected to the Cancer Genomics Consortium Board of Directors and also the Association for Molecular Pathology’s Education Committee. These appointments allow Dr. Akkari to contribute to the development of policies, recommendations and education material for genetic testing on a national and international level.

Congratulations, Dr. Akkari, we admire your dedication and tenacity!

Autoconfirmations now available for MedManager Quick

MedManager™ Quick with Auto-Reflex is our newest testing option for health care providers managing patients with ongoing opioid therapy. This improved panel balances cost with the need to monitor patient compliance, prevent diversion and detect patients with substance abuse disorders.

The MedManager Quick Auto-Reflex panel provides rapid initial presumptive results. Confirmations for critical drug classes are then auto-reflexed, combining the cost-effectiveness of MedManager Quick with the convenience of reflexed confirmations.

Features and benefits

The MedManager Quick Auto Reflex panel:

- Includes nine of the most commonly abused drug classes (both prescription and illicit)
- Includes eight of the most commonly prescribed opioid classes

- Includes specimen validity testing, with tests for synthetic urine
- Offers rapid results
- Is cost-effective

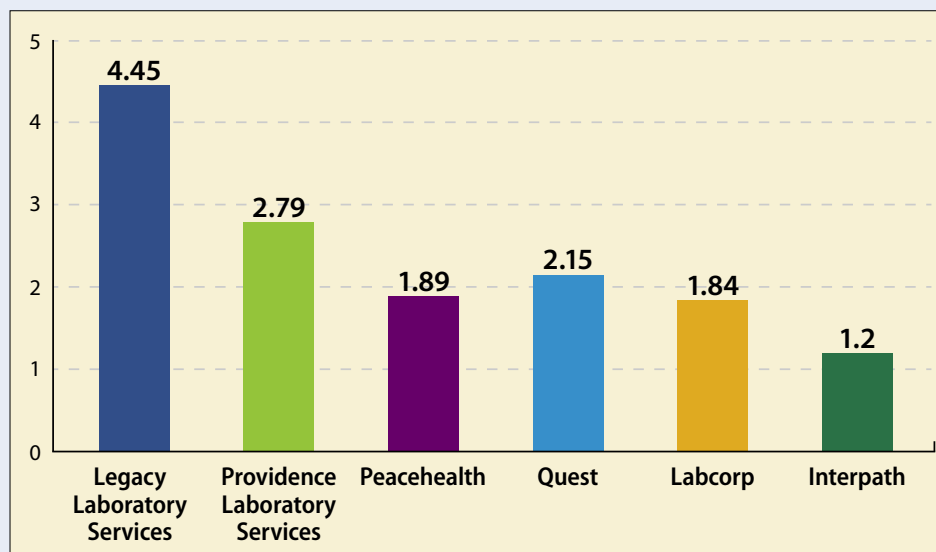
MedManager Quick includes automatic confirmation of these drug classes:

- Amphetamines
- Benzodiazepines
- Heroin
- MDMA (ecstasy)
- Opiates expanded
- Phencyclidine (PCP)

MedManager Quick with Auto-Reflex does not include interpretation.

For more information on pain medication panel testing, including pricing and payor information, please visit legacyhealth.org/labservices.

Survey: Legacy Lab first in overall performance



Ten key service attributes were surveyed: TAT, couriers, client services, professional staffing, EMR interfaces, website, billing, pricing and paper report.

Another national first for detecting synthetic urine

In 2009, our forensic toxicology laboratory developed the first-in-the-nation test for synthetic urine. Legacy Laboratory recently launched a second-generation test that aids in the detection of the more sophisticated synthetic urines now available on the internet. The launch was announced by David Roberts, Ph.D., manager of toxicology at Legacy Laboratory Services.

Specimens detected as fake are reported as invalid. For employment-related testing, we recommend immediate recollection under direct observation. That process allows the employee to produce a urine specimen under controlled conditions, and to essentially challenge the laboratory's finding that the first specimen was invalid.

Synthetic urine — Questions and answers

What is synthetic urine?

Synthetic or fake urines have the characteristics of human urine and, undetected, test as drug-free human urine. Individuals receiving long-term DEA-controlled opioids can even purchase specially designed fake urine that contains their prescribed drugs. The patient's motivation for this is to sell their prescription opioids for profit.

What is synthetic urine used for?

A quick search of the Internet reveals numerous products accompanied by claims that the buyer can use them to pass a urine drug screen — employment, pain medication monitoring or other drugs of abuse testing.

How is synthetic urine detected?

The most important lines of defense are personnel who are well-trained and experienced in specimen collection, along with protocols to detect substitution attempts. While temperature tests are a common practice, the synthetic urine packages often have instructions coaching the buyer in various ways to warm the specimen.

As synthetic products and donor behaviors become more sophisticated, objective identification through laboratory analysis becomes critical for the detection of drug aberrant behavior.

What happens if a fake is detected?

The specimen will be reported as invalid.

What are the implications of not detecting fake urine?

Any test is only as good as the specimen provided. If a laboratory has not developed the technology to detect synthetic urines, the employer or ordering provider will not receive accurate information regarding their applicant, employee or patient.

What do you expect in the future for synthetic urine?

Eventually companies will change to oral fluid for drugs of abuse testing because faking oral fluid is more difficult. Until that happens, Legacy Laboratory will continue to evolve our testing technology to detect these products and to provide accurate and useful information to our clients.

Central Laboratory marks 25 years of successes

By Don Toussaint, vice president, Legacy Laboratory Services

At Legacy Laboratory Services, we regularly set records and achieve milestones. We've recently reached another milestone with the 25th anniversary of the Legacy Central Laboratory. In July



Don Toussaint

1992, shortly after Legacy Health System was born, the first test results began to emerge from what was then termed MetroLab. Centralized laboratory services were sourced from the laboratory at Legacy Good Samaritan Hospital and also the basement of what is now the administration building at Legacy Emanuel Medical Center.

Things were different back in 1992. We had two Laboratory Information Systems: HBO ClinStar and Cerner PathNet. The Client Services Department consisted of two people answering phones, and we had five courier cars. There were also three different pathology groups at Legacy. Each of our laboratories used different types of instrumentation, and specimens couldn't be reliably routed between labs. HR and payroll rules were also different between the multiple Legacy facilities. Most of the physicians associated with the Legacy hospitals did not use our laboratory service. In 1992, we were not the preferred laboratory in the region, and we had our work cut out for us.

We've come a long way over the past 25 years. Today we have a single LIS that automates, manages and standardizes many aspects of our

laboratory operations. Our testing technologies, procedure manual and operating policies are standardized and automated. Cascade Pathology is a single professional group and a steadfast partner. Legacy Laboratory Services became one of the first to be accredited as a system laboratory and is an early adopter of the ISO 15189 standards. In 2008 Legacy Laboratory Services emerged as its own corporation under the Legacy Health umbrella. In 2015 we began moving into a new 63,000-square-foot Legacy Central Laboratory. From rudimentary beginnings 25 years ago, the Central Lab has become an essential resource for Legacy Health and for our region.

This 25-year track record of development and success toward becoming an integrated, high-quality laboratory service does not happen without the dedicated hard work of many people. Determined focus on a set of guiding principles is key to becoming a high-quality lab service that is preferred by customers throughout the region. Recent developments in our service area indicate that we are the preferred laboratory service, and the Central Lab has played a key part in that success.

Acknowledging the past helps us appreciate the present and set the continued course toward achieving our vision of being Innovative, Dedicated, Integrated and Preferred. Thank you for your part in making this happen.

Happy anniversary.

LATEST NEWS • LATEST NEWS • LATEST NEWS

FDA-approved high-risk HPV assay for ThinPrep and Surepath

Legacy Laboratory Services and Cascade Pathology Services are pleased to announce that the high-risk HPV assay using the FDA-approved Roche cobas 4800 PCR method has been FDA-approved and validated in our laboratory for both ThinPrep® and Surepath™ samples. ACOG guidelines support

co-testing and genotyping for HPV types 16 and 182.

Legacy Laboratory Services completed the verification studies of the Cobas® HPV test using the FDA-approved format for ThinPrep and Surepath collected samples.



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Legacy Central Laboratory is located at 1225 N.E. Second Ave. in Portland.

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