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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark

Founder & Publisher

Any Hope for Relief from PAMA Medicare Price Cuts?

IT IS A NOTABLE AND RARE SUCCESS for the clinical laboratory profession to convince the House and Senate to pass a law that is favorable to the interests of patients and the clinical laboratories that serve them.

Yet that is what happened when Congress passed the Laboratory Access for Beneficiaries (LAB) Act in December and President Trump signed it into law before the end of the year. *(See pages 3-6.)* This is evidence that a majority of representatives and senators are aware that access to local, high-quality medical laboratory testing must be maintained if Medicare beneficiaries and other patients are to be properly served by the U.S. healthcare system.

Now is when the oft-repeated adage of "the devil is in the details" will come into play. First, will the Medicare Payment Advisory Commission (MedPAC) deliver recommendations to the federal **Department of Health and Human Services** (HHS) and the **Centers for Medicare and Medicaid Services** (CMS) that truly address the flaws and biases in how CMS officials have interpreted the language of the Protecting Access to Medicare Act of 2014 (PAMA)? Will MedPac recommend proper fixes to the methods CMS has used to limit both the number and types of clinical labs required to report private payer lab test price data, as well as the formulas being used to analyze the data and set prices for the Clinical Laboratory Fee Schedule (CLFS)?

The second question plays off the first. Assume MedPAC recommends appropriate changes in how CMS conducts the private payer market study and uses that data to set Medicare CLFS prices, will CMS actually follow those recommendations? It can be credibly argued that actions taken by CMS officials since PAMA was enacted into law clearly conflict with both the intent of Congress and the language of the statute.

Even more to this point, that both houses of Congress felt the need to pass the LAB Act—which was written specifically to correct the flaws, bias, and problems created in how CMS officials are implementing the PAMA statute—is the most powerful fact supporting this assertion.

On one hand, pathologists and lab managers can see passage of the Lab Act as a positive step forward to fix a problem that threatens to undermine the clinical and financial stability of the nation's clinical laboratories. On the other hand, it remains to be seen whether officials at CMS will faithfully implement the recommendations that MedPAC will produce. TDR

33 Groups Cooperated to Get LAB Act Passed

ACLA, NILA, and other associations coordinated efforts to chart a path for reform of PAMA statute

CEO SUMMARY: At the end of 2019, the Laboratory Access for Beneficiaries (LAB) Act became law and addressed two of the three most onerous requirements in the Protecting Access to Medicare Act (PAMA) of 2014. It delays the data-reporting requirements under PAMA, and requires an independent advisory panel to review the methods federal officials used when implementing PAMA and to recommend revised data collection and rate-setting processes. It does not prevent the latest 10% cut in Medicare's lab payments.

IN A POSITIVE DEVELOPMENT FOR CLINICAL LABORATORIES, Congress passed the Laboratory Access for Beneficiaries (LAB) Act and President Trump signed it into law in the final days of 2019.

House and Senate passage of the LAB Act was the result of a year-long effort to explain to members of Congress the pressing need to address the serious problems clinical labs faced under the Protecting Access to Medicare Act (PAMA) of 2014, and how the implementation of PAMA was reducing beneficiaries' access to local clinical lab testing services.

Leading the effort to educate members of Congress about these issues were the **American Clinical Laboratory Association** (ACLA) and the **National Independent Laboratory Association** (NILA). ACLA and NILA worked with lab members of both associations and 31 other groups representing laboratories, nursing homes, physicians, and patients.

Their efforts involved meeting with and calling members of Congress to explain the detrimental effects PAMA has had on laboratories, nursing homes, Medicare patients, and physicians.

For clinical laboratories, the LAB Act addressed two of the three most onerous requirements of PAMA, which are:

- The reporting of lab test prices that commercial health insurers paid to clinical laboratories.
- The methodology CMS used to define which laboratories it would require to report the prices health insurers paid them for tests.
- The drastic cuts in payment under the Clinical Laboratory Fee Schedule that CMS implemented under PAMA.

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For the first onerous requirement, the LAB Act delayed until Jan. 1, 2021, the requirement that clinical labs must report the data—including prices—that private health insurers paid labs for hundreds of lab tests in what would have been the second reporting period.

Data Used to Cut Prices

After the first reporting period in 2017, CMS used that data to cut what it paid for tests in 2018, 2019, and 2020 on the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). *(See TDR, "PAMA Final Rule Issued, CMS Plans to Cut Rates by 5.6%," July 5, 2016; and "What Labs Can Expect from PAMA in 2019," May 20, 2019.)*

Laboratory directors and pathologists nationwide have leveled withering criticism against PAMA and the rules the federal **Centers for Medicare and Medicaid Services** (CMS) used when implementing the law regarding how clinical laboratories needed to collect data on the prices private health insurers paid for lab tests, the types of labs required to report that data, and the methodology CMS used to set CLFS payments.

Since 2015, when CMS proposed a draft rule to implement PAMA, clinical labs have said CMS was planning to impose an unfair system to collect and report data on what commercial health insurers paid for tests. The first data-collection effort resulted in deep cuts in what CMS paid for tests, causing some lab companies to close, to lay off staff, and to reduce the lab testing services they offered to Medicare beneficiaries and other patients.

Important Step Forward

The second onerous problem is the methology CMS is using to collect data, then use that data to set prices for Medicare Clinical Laboratory Fee Schedule (CLFS). The LAB Act requires an important step to address those problems CMS caused when it implemented PAMA's data-reporting and collection methodology, which the clinical laboratory industry characterized as deeply flawed.

The act requires the **Medicare Payment Advisory Commission** (MedPAC) to review the methodology and suggest an alternative that would allow CMS to collect payment data that reflects the actual market rates that insurers pay. MedPAC is a nonpartisan board that advises Congress. *(See sidebar, "Lab Directors Explain Problems with PAMA," page 5.)*

While delaying the reporting data and asking MedPAC to review the methodology are positive factors, the LAB Act did not prevent the third and most egregious part of PAMA from going into effect on Jan. 1 of this year: a third round of 10% cuts to the CLFS. This year is the third consecutive year that CMS has implemented cuts of 10% annually. Beginning next year (2021) and continuing for two more years (2022 and 2023), PAMA allows CMS to cut lab test payments by 15% annually.

Congress Intervenes

If Congress had failed to pass the LAB Act, clinical laboratories would have been required to report private market data through the same flawed data process used in 2017, ACLA said.

Payment cuts under PAMA remain in effect while a legal case proceeds in the U.S. Court of Appeals for the District of Columbia. In December 2017, ACLA brought that case against Alex Azar, the Secretary of the federal **Department of Health and Human Services**.

While that case continues and the deep cuts in Medicare lab payments remain in effect, the LAB Act has become one of the first positive developments for clinical labs in the six years since Congress passed PAMA.

NILA praised lawmakers' efforts, noting that the bill had 80 cosponsors in the U.S. House of Representatives, a strong sign that members of Congress wanted to address the flawed implementation

of PAMA. The bill was introduced in the Senate in mid-December by senators Richard Burr (R-North Carolina) and Sherrod Brown (D-Ohio) and had gained four additional cosponsors: Robert Menendez (D-N.J.), Pat Roberts (R-Kan.), Michael Bennet (D-Colo.) and Thom Tillis (R-N.C.).

More Time for Labs

The law gives laboratory associations time to pursue additional improvements to PAMA, said ACLA President Julie Khani. "Fortunately, Congress' decisive action puts us on the path to enact meaningful PAMA reforms that will protect seniors' access to essential laboratory testing services, as the law originally intended," Khani said in a news release.

Given these developments, understanding the role ACLA, NILA, and other lab and patient-care groups played in getting the law passed is useful for clinical lab directors and pathologists. The year-long process required extensive lobbying of members of the U.S. House and Senate, ACLA and NILA said. As part of that effort, lab directors and lab staff members played key roles.

A Year-Long Effort

"One reason we were successful in getting the LAB Act passed was that the laboratory community worked together," said Erin Will Morton, who represents NILA's interests in Congress and with CMS. "NILA worked closely with ACLA and other organizations representing labs, such as **AdvaMedDx**, the **Point of Care Testing Association**, and with the entire **Clinical Lab Coalition**.

"Even an important bill like the LAB Act won't move out of committee just because one organization wants it to," emphasized Morton. "It takes a collective effort of the entire clinical lab industry to pass legislation like the LAB Act and get it signed into law."

A key part of the effort for NILA, ACLA, and other lab groups was getting their members involved, said Morton, who also is Senior Vice President of **CRD Associates**, in Washington, D.C.

"NILA did a lot of grassroots organizing to encourage our members to make phone calls to their representatives in Congress and to ask them to cosponsor the bill," she commented. "We also met regularly with the staff of the relevant

Lab Directors Explain Problems with PAMA

IN PUSHING CONGRESS TO PASS THE LAB ACT, policymakers needed to hear how the Protecting Access to Medicare Act of 2014 is changing how clinical labs operate, said Erin Will Morton, who represents the **National Independent Laboratory Association** (NILA).

"It was important for us to explain that the business model that clinical laboratories have followed for many years is changing drastically and affecting patient care negatively," Morton added.

"NILA members were calling members of Congress to talk about the risk their businesses faced from the decrease in payment rates under PAMA," she explained. "The cuts in payment are having a negative effect on their ability to continue to serve their patients.

"Some NILA labs also talked about the layoffs they had to make and the implications that those layoffs were having on patient services," she said. "Several members said they were considering limiting or even eliminating their contracts with nursing homes."

Clinical laboratories have considered cutting those services because the payment was already so low, before the payment cuts under PAMA, that they barely covered labs' costs.

"Multiple lab companies told us that they had to cancel some nursing home contracts," she added. "NILA also encouraged nursing homes to call their members of Congress."

House and Senate committees so that we could keep the conversations moving.

"Getting a bill like the LAB Act passed in Congress requires both a grassroots effort—which we had from members of NILA, ACLA, and other groups—and close coordination with House and Senate committee staff to get the language included in a larger year-end bill.

"In addition, NILA members got involved at the state and Congressional District levels. "For that effort, NILA had regular conference calls with our members and sent out talking points and other materials to help facilitate effective communications with their members of Congress," Morton said.

Assessing PAMA's Impact

"Specifically, we wanted NILA members to talk about the impact that PAMA was having not only on clinical laboratories in their states and districts but also on patients," she added. "When lab owners talk about patients with members of Congress, it means they're talking about voters.

"That's why we stressed to NILA membership that it's so important for policymakers on the Hill to hear about the effect that bills will have on patients and their families," she commented. "A groundswell of activity is essential to moving something like this bill through Congress.

"We recognized that policymakers needed to hear from constituents about how PAMA affected patients in their districts and in their states," she said.

"Once we knew that clinical lab directors and other lab staff were calling members of Congress, then we could reinforce that message by following up with those same offices here in D.C. to reiterate the message and ask them to sponsor the bill," she added.

"In addition to grassroots activities over the past year, ACLA took the lead in scheduling hundreds of meetings in D.C. to explain the LAB Act to members of Congress," she said.

Thomas Sparkman, ACLA's Senior Vice President of Government Affairs and Policy, agreed that the groups representing labs, nursing homes, physicians, and patients worked together well.

PAMA's Implementation

"The work that ACLA and other stakeholders did to get the LAB Act across the finish line shows that there was a broad understanding that the implementation of PAMA did not go as Congress intended," he commented.

Also significant was support from two groups representing physicians: the **American Academy of Family Physicians** and the **Infectious Diseases Society of America**, he added.

"In addition, I was impressed that more laboratories from every sector of the clinical laboratory industry came forward in the past year saying they needed to stem the tide of payment cuts under PAMA," Sparkman said. "That includes large clinical labs, small and regional laboratories, hospital labs, and labs serving nursing homes. We even had some nursing home administrators supporting our efforts."

Now that the law is passed, the next steps involve working with MedPAC to ensure that the data-collection effort will represent the entire lab industry, Morton and Sparkman said.

MedPAC's Recommendations

Passage of the LAB Act is definitely a positive development for the clinical laboratory industry. However, it remains to be seen whether MedPAC will make recommendations that truly address the problems and flaws with how CMS is implementing PAMA, as well as whether CMS will then implement the MedPAC recommendations as MedPAC intended. TDR

—Joseph Burns

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Labs Get Less Revenue as Billing Shifts Offshore

Use of low-rate medical billers may cause labs and pathology groups to see sharp revenue declines

CEO SUMMARY: In an attempt to cut the cost of clinical laboratory test billing, a number of clinical labs and pathology groups are using offshore billing and collections companies. These companies charge about half of what U.S. billers charge, but along with the low rates may come a sharp drop in revenue of 30% to 40% or more because these offshore companies may not resubmit all rejected claims or go after small amounts that are difficult to collect, billing experts said.

SEEKING TO CUT THE COST OF LAB-TEST BILLING, a number of clinical laboratories and anatomic pathology groups have outsourced their billing and collections operations to offshore vendors.

This trend in the medical lab industry has not been reported widely. Thus, clinical labs and pathology groups using this collection strategy may be unaware that it could backfire by causing revenue to decline, according to medical billing experts.

Such companies outside of the United States charge 2% to 3% of the dollar amount they submit to healthcare payers. This rate is roughly half of the 5% to 7% that most billers in the United States charge, said Mick Raich, CEO of **Vachette Pathology**, in Sylvania, Ohio. The offshore companies are based in India, Indonesia, Pakistan, and the Philippines, among other countries.

Sharp Drop in Revenue

"Although these labs pay a low rate to their offshore vendors, they may see a sharp drop in revenue of 30% to 40% or more," added Raich. "That's because these offshore companies do not always pursue small amounts that are difficult to collect or resubmit all rejected lab test claims.

"I get calls at least once a month from a guy who says he has 600 people in some far-off place—such as in Bangladesh," Raich commented. "These guys will offer to do billing for us at about 3%. This happens all the time.

"When we've audited these companies, we typically find their operations to be a train wreck because you definitely get what you pay for," he added. "If your lab pays 3% or so of the amount an offshore billing vendor collects for you, most likely that company will do very little on the back-end to pursue difficult claims or the large number of lab test claims involving small amounts of money.

"The margin for these offshore companies is very, very thin," continued Raich. "This means they have less incentive to appeal denials for small amounts or resubmit rejected claims."

To be sure, Raich made an important distinction about offshore billing companies. "There are some very good billing firms who use some offshore services," he said. "Actually, operating in this way

is quite typical. Those billing firms that labs may want to avoid have no, or a very minor, presence here in the U.S."

Even at 6%, all medical billing companies operate on a thin profit margin, Raich added. "But in recent years, that margin became even thinner when healthcare providers—including labs and pathology groups—began sending much of their billing and collection work offshore in the pursuit of lower rates.

"One factor that encouraged labs to use offshore billing companies is consolidation in the billing industry," noted Raich. "Over the last five to 10 years, large billing companies have bought out privately-held and mom and pop billing companies. Many of the smaller companies were either sold or rolled up into larger billing companies. The end result was that a lot of the lab billing work was shifted offshore.

"Over the past 10 years, the number of medical billing companies in the United States dropped from 5,600 or so to only about 2,600 today," he said. "This move to offshore billing changed how much labs and pathologists pay for billing and collections to just 3% or even 2% in some cases." At such low payment rates, it's difficult for offshore billing companies to cover their costs when working on some claims, he added."

Less Claims Experience

Cyndee Weston, Executive Director of the **American Medical Billing Association**, confirmed Raich's comments.

"Offshore billing companies will charge 2%, 3%, or 4% where an American billing company has to charge at least 6%—because in the United States—billing companies must comply with U.S. laws," Weston said. "And U.S. companies will follow up on all the claims whereas the offshore companies don't have the personnel with the experience they need to pursue claims that get rejected or are difficult to collect.

"So, whenever a claim doesn't get paid, they just drop it," she added. "American billers don't do that. Instead, they'll follow up to find out why the claim wasn't paid, and then try to fix the problem so they can resubmit that claim."

Two other factors come into play when labs use billing companies. "First, while the lower rates are appealing, offshore companies may have a language barrier," Weston said. Second, these companies may not invest in ensuring that their personnel have adequate training to do the job properly, she added.

Billing Different Payers

Raich agreed, saying the staff at offshore companies may not be knowledgeable about the intricacies behind lab test billing and may not be familiar with the rules for billing different payers, such as Medicare, Medicaid, other government payers, or commercial insurers.

"It's not that the offshore companies are bad at what they do," Raich commented. "It's more that they're not venerable. By that I mean they don't have the people with 10 or 15 years of experience with clinical lab and pathology billing."

Staff training and experience are important factors for all billing companies, because over the past five to 10 years, billing for clinical lab and pathology tests has become more complex. In addition, payers frequently change their rules about payment—sometimes without informing labs or pathology groups. Or, if they do inform labs, notices come with little time for labs to adjust.

Offshore companies also tend to operate under different rules. "For small amounts of money, they just don't care," Raich commented. "Even for somewhat larger amounts, they may just let it go unpaid.

"We know from auditing different billers that they will have a benchmark to not pursue claims that are under certain amounts," he added. "They won't even work those claims, and that amount might be for every claim for certain clinical labs.

"For every lab and for every billing company there's a margin, and that margin is the point of diminishing returns," he explained. "That means that if an offshore

billing company is working on a $50 lab-test claim, and if they're paying their collections staff $2 an hour, the billing company may have exceeded the amount it spent to collect that money. Getting 2% on a $50 claim produces only $1 in revenue.

"Offshore billers in India, Indonesia, or the Philippines may pay their staff $2 an hour to file lab test claims," he added. "But paying so little means the offshore companies have even less incentive to pursue small claims."

Most labs know that to succeed at lab and pathology billing takes a dedicated staff with years of experience. Any turnover among the members of a lab's billing staff or at a billing company can mean a drop in revenue.

For Ann Lambrix, Vachette's Vice President of Client Services, large offshore billing companies often do not provide the customer service that labs and pathology groups need. "We continue to see problems when larger billing companies buy up smaller companies," she said. "The advantage of having a small billing operation, with maybe five or so clients, is that these companies pay more attention to those back-end denials and processes.

High Throughput Levels

"Smaller billing companies can have specific guidelines for each client," she added. "But the bigger billing companies operate at very high throughput levels and so use the same processes for dozens or hundreds of different clients.

"The larger companies must run very lean operations with high levels of automation," Lambrix commented. "When that happens, clinical labs and pathology groups don't get the individualized attention that is common with the smaller mom and pop billing operations here in the United States." TDR

—Joseph Burns

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Problems with Offshore Billing Companies

WHILE OFFSHORE BILLING COMPANIES OFFER LOWER RATES, they also can create problems for unwary clinical laboratories and pathology groups, said Cyndee Weston, Executive Director of the American Medical Billing Association, in Davis, Okla.

One of those problems is that many states prohibit Medicaid managed care plans from paying billing companies that are not based in the United States.

"In most states, the Medicaid provider enrollment agreements prohibit providers from using offshore billing companies," she said. "Or, at the least, the provider must notify the Medicaid department and request the use of an offshore biller. The Medicaid program then can deny that request.

"Most providers don't know that, and the billing companies don't always tell their clients about this regulation," she added. "That means the provider that contracts for offshore billing may not get paid.

"Seeking to collect payment, the provider may file a lawsuit, but in some foreign countries, legal cases can take decades to resolve," she commented.

In addition, offshore billing companies will often bill patients when payers reject claims, Weston noted.

"When claims get kicked back because the billing companies haven't filed them properly, many times offshore billing companies will just move on without any follow-up," she said. "Especially with low-cost claims, they'll often decide not to refile.

"Then, they may bill the patient for any unpaid amount," she explained. "That means those patients may get a surprise medical bill."

Balance billing some Medicare patients could be illegal.

Lab Acquisitions

NeoGenomics Spends $37M for Human Longevity's Oncology Division

This acquisition shows NeoGenomics going strong into next-gen gene sequencing for cancer patients

ONCE AGAIN, **Neogenomics, Inc.** is using an acquisition to build up its cancer-testing business. In a deal that closed on Jan. 10, the lab company acquired the Oncology Division of **Human Longevity**, based in San Diego.

Neogenomics said it paid $37 million for the division of Human Longevity that does next-generation sequencing services for pharmaceutical companies.

Last year, the Oncology Division generated approximately $10 million in revenue and ended the year with a backlog of approximately $15 million of signed contracts, NeoGenomics said in a press release. In addition to the added revenue, NeoGenomics gets the division's workforce as well, stated Douglas M. VanOort, the Chairman and CEO of NeoGenomics.

Germline, Exome, WGS

"We are delighted to add an experienced, specialized molecular workforce with strong next-generation sequencing expertise, particularly in servicing pharmaceutical customers," he said in the press release. The acquisition will expand NeoGenomics' ability to serve pharmaceutical companies with germline testing, as well as whole exome and whole genome sequencing, he added.

The acquisition expands Neogenomics' pharma division, which serves pharmaceutical companies doing clinical trials and drug development. This division represented 14.5% of the lab company's revenues in 2018. The bigger proportion of NeoGenomics' fast-growing clinical oncology testing business.

For the past five years, NeoGenomics has grown steadily by making significant acquisitions since 2015 when it spent $275.2 million to acquire **Clarient**, a unit of **GE Healthcare's Life Sciences**. Included in that was Clarient Diagnostic Services, which provides cancer diagnostic testing to hospitals, physicians, and pharmaceutical companies. *(See "NeoGenomics to Acquire Clarient for $275 Million," TDR, Oct. 26, 2015.)*

Acquired Genoptix in 2018

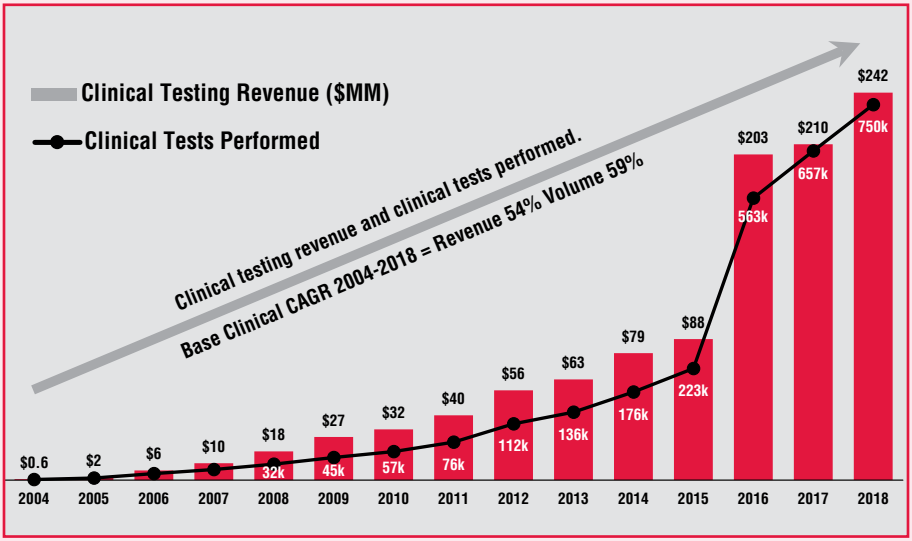
Three years later, NeoGenomics completed the acquisition of the clinical lab company **Genoptix** for $125 million in cash and one million shares of NeoGenomics' common stock. At the time, Genoptix was a clinical oncology lab, specializing in hematology and solid tumor testing. The deal expanded NeoGenomics' reach into oncology practices.

Because of its sustained, profitable growth, the share price of Neogenomics has skyrocketed. In June of 2018, its shares traded at about $8/share. Last week, its shares were priced at more than $32/share, according to company data.

For its part, Human Longevity said it will use the cash for working capital to supplement the $30 million of cash that it raised in a round of financing announced in November from biotech investors.

NeoGenomics Posts 16 Years of Strong Growth in Both Clinical Tests Performed and Revenue

FEW CLINICAL LABORATORY COMPANIES CAN MATCH NEOGENOMICS' RECORD OF SUSTAINED GROWTH IN ORGANIC TEST VOLUME, supplemented by several key acquisitions. The lab company acquired Clarient at the end of 2015 and Genoptix at the end of 2018. The chart below was presented by NeoGenomics at an investor conference in January 2020.



In a press release about the sale of the Oncology Division, Human Longevity President David Karow, MD, PhD, said, "The sale of this division allows us to focus entirely on longevity and extending the healthy, high-performance human lifespan."

Human Longevity's Problems

In December 2018, *The Wall Street Journal* (*WSJ*) reported that investors in Human Longevity had questions about the company's own longevity. Shortly after it was founded in 2014, the company had a valuation of $1.6 billion. But by the end of 2018, a new round of financing valued the company at about $310 million, a decline in value of about 80%, the *WSJ* reported.

Human Longevity did enjoy one major accomplishment. In 2016, the company published a study about what it found from its "high quality, in-depth sequencing (30X to 40X coverage) of 10,545 human genomes." In its press release about the study, Human Longevity said, "The team uncovered 150 million new single nucleotide genetic variants (SNVs), 82 million of which were novel." At the time, this was one of the world's largest database of whole human genomes.

J. Craig Venter, who helped sequence the first human genome, was one of the company's cofounders and served as Chief Executive Officer until he left that role early in 2017. By the end of the year, he had returned to the CEO position and then stepped down again in May 2018, the company said.

In July 2018, Human Longevity sued Venter's research institute in U.S. District Court in California, alleging misappropriation of trade secrets TDR

—Joseph Burns

CEO SUMMARY: The integrative diagnostics lab at the Vanderbilt University Medical Center aims to use sophisticated diagnostics to advance the use of precision medicine testing to improve patient care and to do so at an affordable cost. As part of these efforts, the lab staff seeks to predict how patients will metabolize medications and then provides that information in the form of clinical decision support to their treating physicians. By integrating clinical decision support into physicians' regular workflow, the laboratory is helping to improve patient outcomes.

Clin Lab 2.0 transition uses pharmacogenetics, formularies, and diagnostic management teams

Vanderbilt Lab Uses Predictive Medicine to Improve Care

As the healthcare system moves away from the fragmented, fee-for-service method of payment, clinical laboratories and anatomic pathology groups are paid for delivering value defined by improving patient outcomes and controlling costs.

In the United States, only a few clinical labs and pathology groups are operating in integrated healthcare systems under value-based payment arrangements. One of those is the lab at the **Vanderbilt University Medical Center** in Nashville. At VUMC, the clinical laboratory serves an integrated health network and delivers added value through a three-part clinical strategy.

The initial elements of this multi-part strategy were added in 2010, and since then, the team at VUMC has added innovative clinical services in a step-wise fashion, according to pathologist Mary M. Zutter, MD, VUMC's Vice President for Integrative Diagnostics. Zutter explained how the VUMC lab delivers added value during a presentation at The Dark Report's *Precision Medicine Institute* in New Orleans last spring.

The first of these initiatives was the predictive medicine and pharmacogenetics testing program that VUMC implemented 10 years ago to demonstrate the utility of prospective genotyping. In this program, the laboratory uses prescribing data from prospective genotyping as the basis for decision support for prescribing physicians. The lab staff adds the results of its prospective genotyping tests into decision-support tools built into the electronic health record (EHR) system.

The clinical decision support was developed by a team of clinicians, laboratorians, and informaticians. Prescribing physicians use those decision-support data to guide the selection and dosing of prescription medications for individual patients.

The second of these programs is diagnostic management teams. Working in DMTs, the lab staff—including pathologists and lab professionals—collaborate with treating physicians and other providers to improve diagnostic accuracy while cutting the average time physicians spend on diagnosis.

The third program is VUMC's laboratory test utilization program in which the lab uses a test formulary to eliminate unneeded tests. In an impressive example of the effectiveness of the formulary, the lab published data on how the formulary reduced orders for costly vitamin D2/D3 fractionated tests.

After introducing the formulary in 2014, the number of these test orders dropped from almost 600 each month in 2014 to zero by January 2016. Labs in every hospital and health system could use this same approach to generate substantial savings.

While each of these three lab initiatives is distinct, they are part of an integrated strategy to improve patient outcomes and control costs.

Note, for example, that the decision support system built into the EHR also supports the diagnostic management teams, and each DMT is useful in eliminating unnecessary tests. In turn, all three of the strategies support the lab's efforts to work with all clinicians to manage lab test utilization effectively.

In this way, the lab's strategies are consistent with the principles of the Clinical Lab 2.0 model. In this model of lab management, pathologists, lab directors, and clinical lab scientists use laboratory data to produce clinical insights to improve patient outcomes and support care delivered in value-based healthcare systems.

"Our laboratory's vision is to provide effective precision medicine at an affordable cost, and that vision transcends any specific disease or clinical domain," Zutter said. "That's the direction our clinical laboratory and our physicians are moving toward, and it's a powerful and unifying theme across all the different disciplines at VUMC. This also supports fuller integration of clinical care.

"Our laboratory has a team approach to care that begins by making a diagnosis of a patient's condition," she explained. "Then our laboratory and the treating clinicians follow that patient through therapy all the way to an assessment of that treatment."

LAB INITIATIVE ONE

Predictive Medicine and Pharmacogentic Testing

One of the most significant of the VUMC lab's three-legged strategies is the use of predictive medicine under a program called Pharmacogenomic Resource for Enhanced Decisions in Care and Treatment, or PREDICT. The members of the VUMC faculty who developed and implemented this program included Dan M. Roden, MD; Gordon R. Bernard, MD; and Josh F. Peterson, MD.

The aim of the PREDICT program is to assist clinicians in diagnosing a patient's condition, selecting an appropriate treatment for managing the patient's care, and then assessing the patient's response to treatment, explained Zutter.

"In our predictive medicine program, we use sophisticated diagnostics to predict how a patient will metabolize medications," she added. "Then we provide clinical decision support to allow the treating physicians to do what is best for the patient without the need to spend much time analyzing all of the possible options for each patient.

"Early on, we realized that one opportunity in diagnosis was for our lab team to better integrate our clinical decision support into the physician's regular workflow to help produce better outcomes for patients," she commented.

Prospective Genotyping

In 2010, when VUMC began its predictive medicine program, pharmacogenetics testing was not widely accepted, noted Zutter, who is also the Director of the Tumor-Host Interaction Program at the **Vanderbilt-Ingram Cancer Center** and the Louise B. McGavock Professor of Pathology, Microbiology, and Immunology.

"In September 2010, our PREDICT program launched its first initiative, and the VUMC team selected certain medications for at-risk heart patients," she said. "Our lab tests predicted how each patient would metabolize drugs and helped improve physicians' drug-dose selections.

"From the start of the PREDICT program, our lab was doing true predictive testing and the institution was not being reimbursed for this testing—in part because this program was an institutional initiative," she added. "Today, our lab does reactive, or indication, testing and most of our insurers reimburse for that work.

Medical Home Model of Care

"Since that launch back in 2010, we have followed more than 52,000 patients in a medical home model of care, and many of them receive a number of the drugs for which we test in our pharmacogenetics panels," Zutter added. "We use prospective genotyping to identify those patients in the high-risk group.

"When we do this testing, we don't test for a single drug-gene interaction (DGI)," she explained. "Instead, our lab does predictive testing with all of the drugs on our panel. That means we test for five DGIs at once to predict genetic risk."

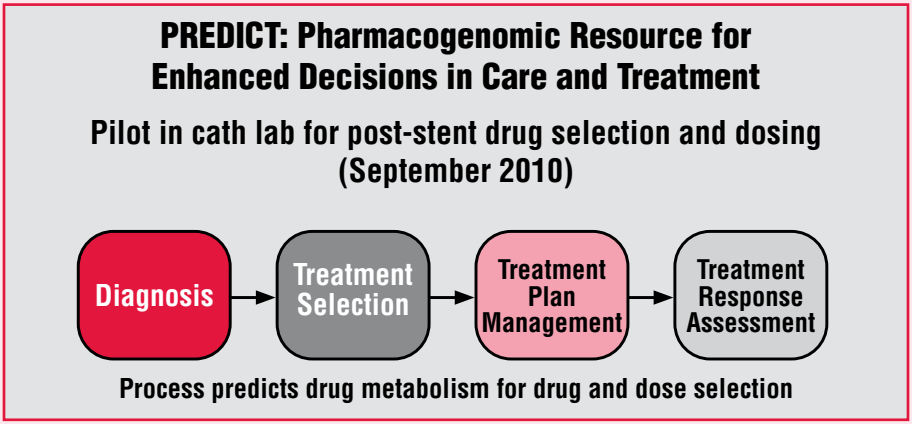
The five drugs and the corresponding genes being assessed are clopidogrel (for CYP2C19), simvastatin (for SLCO1B1), warfarin (for VKORC1 and CYP2C9), thiopurines (for TPMT), and tacrolimus (for CYP3A5).

"We found that 91% of these patients will have at least one of these risks," she reported. "In other words, almost all of those patients will take one of these drugs and have a drug-gene indication showing that clinicians would change how they treat those patients.

"Once we had data demonstrating that the pharmacogenomic test results indicated a need to change the course of treatment for those patients and that those patients had better outcomes, we decided over the past two years to expand the PREDICT program beyond those five drug-gene interactions," she added.

Vanderbilt University Med Center Laboratory Offers Pharmacogenomic (PGx) Testing Service

ADVANCES IN PHARMACOGENOMIC (PGx) TESTING allow innovative clinical laboratories to deliver greater value to referring physicians. In 2010, the laboratory team at the Vanderbilt University Medical Center launched the Pharmacogenomic Resource for Enhanced Decisions in Care and Treatment (PREDICT) program. In this initiative, the lab staff collaborated with physicians in four steps: diagnosis, treatment selection, treatment plan management, and treatment response assessment. Among the patients tested, 91% benefited from the PGx test results, the lab reported.



Source: Mary Zutter, MD, presentation at Precision Medicine Institute, New Orleans, May 3, 2019.

"Back when we launched the program we had PREDICT 1.0, which included only a few drug-gene pairs," Zutter said. "Now we have expanded that effort to the PREDICT 2.0 program, which is a rapid expansion to 10, and soon, 16 drug-gene interactions.

"Our lab is expanding—both to serve the interests of providers and customers, but also to identify more drug-gene interactions," she noted.

Adding Decision Support

"Our goal is to provide better clinical care, and we do that with clinical decision support, because if a patient is given instructions on a piece of paper and expected to take that paper the next time they go to their doctor, that system is destined to fail," Zutter explained.

"Instead, it's necessary to embed this information completely in the healthcare system—meaning in each patient's EHR—so that all physicians can see those instructions for their patients and follow them at the point of care.

"Part of that effort involves not just giving clinical decision support about which tests should be ordered, but also how to report that information back to providers and to patients," she said.

PREDICT Team Meetings

To expand the program, the PREDICT team members—including lab, clinical experts, pharmacologists, and informaticians—began meeting once or twice each month with large teams of clinicians, including pediatricians, cardiologists, and scientists.

One team would identify DGI pairs to add to the EHR and another would identify ways to expand the program to more clinicians throughout VUMC. "We

wanted these teams of clinicians to identify their priorities for decision support," Zutter said.

"At this time, we have focused on delivering a shorter turnaround time and lowering costs," she commented. "The VUMC HealthIT team has expanded clinical decision support so that it's available to every provider in our **Epic** EHR system, and also to every patient through the VUMC MyHealth portal.

"Therefore, treating physicians have the information and patients can take it back to their own providers," she added. "Having that information, patients can talk to their physicians about what they need and what they want.

"To accommodate testing for that number of new prescription drug starts, we scale up our lab processes so that we can get the right turnaround time," she explained. The goal is to reduce TAT from about five days to 24 hours."

LAB INITIATIVE TWO

Diagnostic Management and Decision Support

Not only does the lab need to manage more tests more quickly, it also needs to manage the vast volume of data these tests generate and deliver that data in a useful format to clinicians.

"As our laboratory starts putting data on functional and structural genetics, proteomics, and other effects of molecules into the decision-making matrix for every individual patient, whenever a provider needs to see that information, the amount of data can be overwhelming," Zutter commented.

"Because we can't overwhelm them with lab data, our lab team has made a huge effort to give them clinical decision support, which we define as an effort at integration.

"By that I mean, we aim to bring all of that information together, including information on the patient's symptoms, the results of the physical exam, the lab test data, and the drug therapy results," she explained. "Then, we put it all together in a summation developed by a team approach to care. In that way, our laboratory contributes to providing the best care to patients.

"This is where all of our efforts are leading us, and those efforts mimic what the diagnostic management teams do," noted Zutter.

Traditional Test Order Model

"For most lab testing, the traditional model of ordering tests and getting results assumes the clinician is the expert," she added. "In this model, the clinician orders the individual tests, the lab sends back results, and the clinician interprets those results. Then, the clinician may order more tests or prescribe drug therapy.

"This method is inefficient, costly, and yields limited quality results because clinicians cannot keep up-to-date on increasingly specialized tests and often are not ordering based on current evidence or guidelines," Zutter explained. "Getting advice from pathologists and lab specialists takes time and that is not feasible for clinicians in today's rapid-throughput patient care settings.

"At VUMC, the diagnostics management team is a collaborative effort among pathologists, clinicians, and biomedical informatics," she added. "Under this approach, we use standard test ordering algorithms to develop the correct pattern of diagnostic testing for each patient.

Decision Support Core

"The DMTs have system-supported care with decision support that ensures clinicians follow evidence-based practice because decision support comes on the front end before the lab runs any tests," she said. "Diagnostic experts in the decision-support core work between the clinician and the lab to ensure that all—and only—appropriate tests are ordered.

"In this front-end decision support approach, unnecessary tests are deleted, and essential tests are added, but only if needed," Zutter reported. "Then, the lab runs the tests and the decision-support core intervenes again when it receives the individual lab test results, interprets them, and issues comprehensive guidance to the clinician.

"Our approach to decision support helps the clinician and the patient understand the results of the testing," she said. "The benefits are increased quality of care for the patient, because the patient gets improved decision making, a faster test result, and reduced costs because we have eliminated unnecessary tests and avoided hospital admissions or shortened length of stay.

"In addition, we create a single, evidence-based and comprehensive report of integrated diagnostic data to guide therapy and disease monitoring," she added. "That process allows us to improve the algorithms iteratively as evidence-based practices evolve."

LAB INITIATIVE THREE

Lab Test Utilization

One of the goals of DMTs is to develop standard ordering practices that can be applied to a wide variety of tests, including next-generation sequencing for cancer. Thus, at VUMC, the lab can incorporate these guidelines to support effective laboratory test utilization.

"Using clinical decision support between the laboratory and the clinician, and by generating a comprehensive report that aggregates all of the data for clinicians and patients, we then wanted to know if we could scale this program to serve other clinicians in the medical center," Zutter said. "For example, can we apply the decision-support system to secondary testing standards for all hematologic malignancies? Right now we're working with oncologists for breast and gastrointestinal cancer.

Predictive Genotyping Improves Patient Care

IN 2010, THE CLINICAL LABORATORY TEAM at the Vanderbilt University Medical Center started a pharmacogenomics (PGx) testing program to evaluate patients for five drug-gene interactions (DGIs). In that program, called Pharmacogenomic Resource for Enhanced Decisions in Care and Treatment (or PREDICT), the VUMC lab used PGx testing on patients taking certain drugs.

The drugs and the corresponding genes being assessed with pharmacogenetic testing were:

- clopidogrel (for CYP2C19),
- simvastatin (for SLCO1B1,
- warfarin (for VKORC1 and CYP2C9),
- thiopurines (for TPMT), and,
- tacrolimus (for CYP3A5).

After the program began, the lab staff followed more than 52,000 patients who were covered under a medical home model of care. Many of those patients received a number of the drugs for which the lab was testing using pharmacogenetic panels, said Mary M. Zutter, MD, VUMC's Vice President for Integrative Diagnostics.

The lab used prospective genotyping testing to identify patients in the group who were at high risk by testing for all of the drugs on its panel. In this way, the lab tested for five DGIs simultaneously.

Almost all (91%) of the patients had at least one DGI risk, meaning the physicians caring for those patients would change the patients' treatment once they had the test results. By continuing to follow those patients, VUMC found that such testing improved patient outcomes.

Given that result, the VUMC lab has expanded the PREDICT program over the past two years by adding other drug-gene interactions, Zutter said. At first, the lab expanded testing to 10 DGIs, and soon that number will rise to 16 DGIs, she added.

"We know from a report published in the *American Journal of Clinical Pathology* (*AJCP*) in 2013 by Adam C. Seegmiller, MD, PhD, and others, that the use of a DMT review makes it possible to identify the optimal number of tests for patients who need bone-marrow testing. The research showed that optimal testing based on an evidence-based, interdisciplinary team approach could save the U.S. healthcare system about $500 million annually." Zutter said.

The Vice Chair for Clinical Pathology, Seegmiller also is Professor of Pathology, Microbiology and Immunology, and Director of Laboratory Medicine and Hematopathology.

Working with other members of the clinical team at Vanderbilt, Seegmiller and Zutter did the research and wrote the *AJCP* article, "Optimizing personalized bone marrow testing using an evidence-based, interdisciplinary team approach."

"From this work, we know we're helping patients and providers, which is one of the keys to success for an effective lab test utilization program," Zutter explained. "If your laboratory wants to get provider buy-in for what it's doing, your lab team must educate providers about how they and their patients will benefit.

"Anything that puts an additional burden on providers will fail. They can't handle any more work, because they already have too much to do," she commented. "That's why we show them how using the DMT system could save about 10 minutes per-patient-per-provider at the front end, and an additional five minutes per-patient-per-provider at the back end.

Right Diagnosis, More Time

"What's more, the providers then trust that they'll get the right diagnosis and have much more time either with their patients or more time with their families," she added.

"Another way we've improved lab test ordering is by developing a laboratory formulary committee," Zutter said. "This idea was approved in 2014 to protect patients from the costs and possible consequences of inappropriate or unnecessary laboratory testing, particularly for the many new and expensive clinical laboratory tests where the clinical utility is not clear-cut.

"The committee decided that a laboratory test should be ordered only when it is both medically necessary and likely to alter the diagnosis or treatment plan," she added. "Using this process, we've been able to save about $2 million a year for the Vanderbilt healthcare system."

Vanderbilt's lab test formulary has three categories. The first category is unrestricted tests which are automatically run or sent out. The second category is restricted tests that are conducted or sent out if certain prerequisites are met. The third category is non-formulary tests that are for research or investigational-use only. For these tests, the lab will offer an alternative formulary test or ask the provider to cancel the order and discard the sample.

Lab Tests with Clinical Utility

The tests VUMC targeted for lab-formulary review included all tests with no clinical utility, all outdated tests, all high utilization and high-cost reference tests, all high utilization in-house lab tests, and all overused tests.

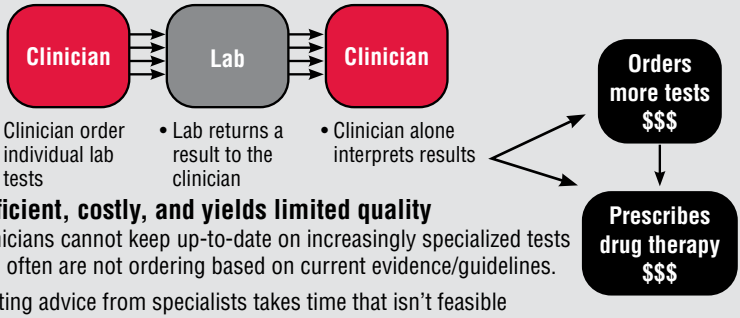
Under the lab's inpatient medical-necessity review, the staff limited inpatient ordering of tests when the TAT was expected to exceed the patient's length of stay because testing performed on inpatients should affect hospital care. Any test with a TAT of four to seven days requires an attestation of necessity (called a soft stop), and any test with a TAT of more than seven days requires the medical director's approval (a hard stop).

"In 2016, hard stops on 1,031 tests saved almost $260,000, and in that same year, soft stops on 4,567 tests saved almost $70,000," Zutter reported. Among the tests that are commonly canceled are those for platelet factor four, Sezary

How VUMC Lab's Decision Support Initiative Contributes to Improved Lab Test Utilization

MOST PHYSICIANS APPRECIATE A WELL-DESIGNED LAB TEST FORMULARY and access to laboratory professionals who assist in identifying the right test to order for each patient, helping to interpret the results, and in selecting the most appropriate therapy. Recognizing this opportunity, the lab at the Vanderbilt University Medical Center uses diagnostic management teams (DMTs) to change the traditional "expert model" approach to ordering in which the ordering physician is responsible for selecting lab tests and interpreting results.

Traditional "Expert Model" for Outpatient Testing and Treatment

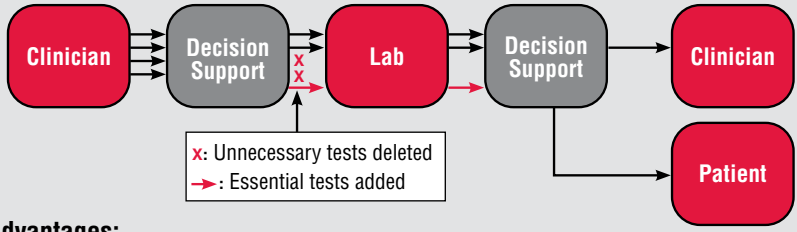


Inefficient, costly, and yields limited quality

- Clinicians cannot keep up-to-date on increasingly specialized tests and often are not ordering based on current evidence/guidelines.
- Getting advice from specialists takes time that isn't feasible in rapid-throughput the outpatient setting. Extra tests save time.
- Drugs routinely prescribed that are not indicated or poor choices.

TO HELP PHYSICIANS ORDER THE APPROPRIATE LAB TEST FOR EACH PATIENT, VUMC's lab staff worked with diagnostic management teams to develop a lab test formulary and a decision support system so that ordering physicians could collaborate with diagnostic experts to guide lab test ordering to improve patient care and eliminate unnecessary tests, as shown below.

Vanderbilt's System-supported Care with Decision Support Ensures Evidence-based Practice



Advantages:

- Diagnostic experts in the Decision Support Core work between the clinician and the lab to ensure only appropriate tests are ordered.
- The Decision Support Core receives the individual lab test results, interprets them and issues a comprehensive guidance online to the clinician.
- Benefits: increased quality to the patient (improved and more rapid decisions) and reduced cost (eliminating unnecessary tests, avoiding or shortening hospital admission).

Source: Mary Zutter, MD, presentation at Precision Medicine Institute, New Orleans, May 3, 2019.

preparation, urine hemosiderin, and red blood cell folate.

Many lab directors have found it challenging—and, at times, frustrating—to change physicians' lab test ordering patterns, particularly for vitamin D tests. VUMC's lab overcame those challenges after it introduced the formulary program late in 2014 and the number of such tests ordered each month dropped from almost 600 to zero by January 2016.

"We simply took the more expensive vitamin D tests off of the lab-ordering menu," Zutter explained. "We told the ordering physicians that we were planning to do so, and we thought when we did it that the endocrinologists and some of private primary care providers would complain. But no one ever complained.

$30,000 Saved in One Year

"In fact, no one seemed to notice that we eliminated all that testing, and that we saved about $30,000 over a year just for the vitamin D work," Zutter said. "Also, we replaced 23 reference tests with in-house alternatives.

"We continually review new tests that come online," she said. "This part is important because new tests require providers to make a decision on each one. Therefore, no new clinical laboratory tests are offered at VUMC without going through this formulary-review process.

"I should add that one key to the success of the lab test formulary is that it's not a lab-based process," she commented. "It's an institution-based process."

When implementing the formulary, Zutter said, two factors were critical to success. First, the committee's nine voting members were clinical leaders from throughout the medical center and, second, they used evidence-based data to decide which tests to restrict and which tests to add. "Committee members look hard at clinical utility," Zutter explained.

"Today, all genetic testing goes through the formulary-review process," she added. "That may be one reason a large proportion of our genetic testing is appropriate for our patients. Genetic counselors review all tests. And, for pediatric patients, we have a pediatric geneticist and a pediatric pathologist review those orders before we send them out."

Genetic Test Order Reviews

In 2016, of the 1,667 genetic test orders that were reviewed, 77% were sent as ordered, 18% were revised, and 5% were cancelled, Zutter reported.

"The whole laboratory test formulary process allows us to better define which tests should be done based on strong, published evidence and which lab vendors provide quality results," she said.

In conclusion, Zutter said that in all of these programs, VUMC's clinical laboratory uses the data it collects to improve care and to improve processes iteratively over time for all patients. "By pulling all of the data together, we know that the impact of our lab's efforts has been huge on cost savings to our parent medical center," she commented. "Next, we want to identify the effect we've had on clinical care."

Looking Forward for Labs

Now is a time when many clinical laboratory administrators and pathologists are looking for ways to offset deep cuts in lab test prices. For this reason, the multi-year experience of the clinical lab at Vanderbilt University Medical Center is a useful example of how a lab can evolve and thrive during healthcare's transition from disjointed care to fully-integrated clinical services.

As described in this intelligence briefing, although the VUMC lab developed three separate initatives that use lab testing to deliver more value, all three programs integrate seamlessly with VUMC's operational and clinical objectives. TDR

—Joseph Burns

Contact Mary Zutter at 615-322-5000 or mary.zutter@vanderbilt.edu.

Challenges of a Laboratory Test Formulary; Achieving Major Reduction of Vitamin D Tests

ONE SUCCESSFUL LAB STRATEGY WAS TO DEVELOP A LABORATORY FORMULARY COMMITTEE at Vanderbilt University Medical Center. This step was taken in 2014 and is now part of the integrated diagnostic solutions that include the PREDICT and the Diagnostic Management Team programs. The tables below explain how the the committee prioritizes tests that are appropriate to be included in the lab test formulary.

Prioritization for Lab Formulary Review

Current lab test menu

- ☐ **Tests with no clinical utility, outdated tests, etc.**
- ☐ **High utilization reference lab tests**
- ☐ **High-cost reference lab tests**
- ☐ High utilization in-house lab tests
- ☐ Over-utilized tests, by a department or group

All new lab test requests

- ☐ In-house testing
- ☐ **Send-out reference testing**

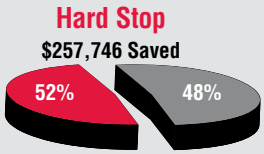
Lab Formulary: Restrict testing

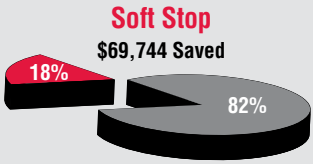
Inpatient medical necessity policy: limits inpatient ordering of tests with turn-around-time (TAT) expected to exceed length of stay (LOS)

Testing performed on inpatients should impact hospital care

TAT: 4-7 days: Require attestation of necessity ("Soft Stop")

TAT>7 days: Require Medical Director approval ("Hard Stop")





The graphic at left describes how the lab test formulary sets parameters for the inpatient medical necessity policy. In the data presented, savings from avoided lab test orders totaled $327,490.

Below is a table showing five lab tests with limited clinical utility that were eliminated from the lab test formulary. The big win was a reduction in Fractionated Vitamin D2/D3 test orders that fell to zero.

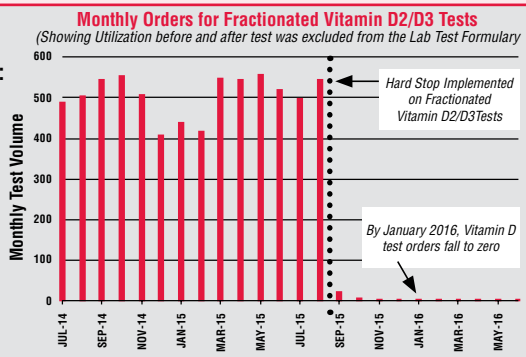
Formulary Priorities: Eliminate tests

☐ **Limited clinical utility/antiquated tests:**

- Platelet Factor 4
- Sezary Preparation
- Urine Hemosiderin
- Vitamin D2/D3 Fractionated
- Red Blood Cell (RBC) Folate

☐ **Duplicate tests/preferred vendor:**

- 23 reference tests replaced with in-house alternatives



Source: Mary Zutter, MD, presentation at Precision Medicine Institute, New Orleans, May 3, 2019.

Lab Marketplace

Two Collaborations: LabCorp-Thermo Fisher, Roche-Illumina

In deals related to the pursuit of companion diagnostics, two lab companies announced collaboration deals with companies that manufacture gene-sequencing equipment. The deals were announced on consecutive days earlier this month. Financial terms were not disclosed.

On Jan. 13, **Roche** said it formed a 15-year, non-exclusive partnership with **Illumina** to improve access to next-generation sequencing for clinical oncologists.

The next day on Jan. 14, **Laboratory Corporation of America** said it would adopt **Thermo Fisher Scientific's** Ion Torrent Genexus System and its Oncomine Precision Assay for research and development of companion diagnostics and applications for oncology and precision medicine. To adopt these technologies, LabCorp will leverage its participation in Thermo Fisher's Next-Generation Sequencing Companion Dx Center of Excellence Program.

About its deal with Illumina, Roche said the collaboration will help Roche build on its strategy to accelerate clinical research, streamline workflow, and expand test menus. In addition, the deal expands the reach of the work **Foundation Medicine** (a division of Roche) does to help patients get optimal cancer therapy through Foundation Medicine's data and clinical decision support tools, the companies said.

Under the agreement, Illumina will grant Roche the right to develop and distribute *in vitro* diagnostic tests on Illumina's NextSeq 550Dx System and on other diagnostic sequencing systems that Illumina will launch in the future.

For companion diagnostics (CDx), both companies will develop and pursue CDx tests for Roche's existing cancer therapies, as well as new therapies in the pipeline, Illumina will lead the development and regulatory approval processes and Roche will support that development and regulatory filings, the companies said.

Campanion Diagnostics Deal

Companion diagnostics also were a key to LabCorp's partnership with Thermo Fisher.

In its announcement of its partnership with Thermo Fisher, LabCorp said it will use the next-generation sequencing Genexus System and the Oncomine Precision Assay immediately for cancer research and to develop new tests.

Also, LabCorp will seek to find new applications for both the Genexus System and the assay. Currently, both assay and the Genexus System are used for research purposes only.

In the announcement, the companies described the Genexus System as the first fully-integrated NGS platform to deliver results in a single day. Using this NGS platform, labs can process small batches of samples for economical sequencing, the companies said.

LabCorp also said it expects the Genexus System to help LabCorp speed up access to NGS testing for clinical trials in LabCorp's specialty and drug development central laboratories. "If cleared or approved for diagnostic use, the system could be made available to smaller LabCorp laboratories, in addition to hospitals, and other LabCorp customers," LabCorp added. TDR

—Joseph Burns

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent weeks, the Supreme Court declined to consider an appeal in a case which challenged a lab company's patent on a clinical laboratory test. On Jan. 13, the justices rejected the appeal made by **Athena Diagnostics**, a division of **Quest Diagnostics**. In an earlier ruling, a lower court had ruled in favor of the plaintiff, the **Mayo Clinic**, that the patent on Athena's test to detect the presence of an autoimmune disease was invalid. In a story about the Supreme Court decision, *Bloomberg* reporter Susan Decker said the lower court found that "the test wasn't eligible for a patent because it merely covered a natural law—the correlation between the presence of an antibody and the disease."

MORE ON: *Patenting Lab Tests*

Bloomberg, in its coverage of the Mayo-Athena case, noted that "The U.S. Court of Appeals for the Federal Circuit in July split 7-5 on whether any medical diagnostic could be patented. The judges issued eight opinions over 80 pages lamenting the confusion over patenting diagnostic tests and its impact on patient care."

FOR ANIMALS: COMPANION DIAGNOSTICS ARE HERE!

Demand for cancer tests and associated cancer drugs for dogs, cats, and other animals is already substantial. Market research published by **Transparency Market Research** (TMR) of Albany, N.Y., estimated that the "global companion animal diagnostics market" totaled U.S. $2.3 billion in 2018. TMR predicts a compound annual growth rate for this sector globally of more than 9% from 2019 through 2027.

TRANSITIONS

- **Foundation Medicine** of Cambridge, Mass., a division of **Roche Holdings**, appointed Ritesh Khullar as its new Chief Commercial Officer. He came to Foundation from **Flatiron Health**, another Roche company. Previously, Khullar served at **Bristol-Myers Squibb,** and **Anderson Business Consulting**.
- **Bio-Rad Laboratories** announced the appointment of Dara Grantham Wright to the position of Executive Vice President and President of the Clinical Diagnostics Group. Wright held prior positions with **Thermo Fisher Scientific**, **Affymetrix**, **BD**, and **EMD Millipore**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, February 17, 2020.

SPECIAL SESSION

How and Why Innovative Hospital Labs Are Recapturing Outreach Market Share, Boosting Value

Jane Hermansen
Senior Administrative Director, Laboratory Services
Mayo Clinic, Rochester, Minn.

Protecting Network Access, Gaining New Clients and Creating New Sources of Specimens, Revenue

Hospital lab outreach programs are alive and thriving, despite the popular wisdom that says their day has come and gone. Be prepared for powerful evidence that shows how any hospital lab can succeed with an outreach lab business.

In her work with hospital and health system labs, Hermansen has the opportunity to interact with many successful hospital laboratory outreach programs in the nation. She will share the most effective strategies for marketing outreach testing services, winning effective managed care contracts, and delivering top service to physician-clients. You'll also learn how to gain support and resources from your hospital/health system administration.

This is essential knowledge for any lab manager, whether you are seeking to supercharge an existing lab outreach program or enter the outreach market for the first time. Bring your team and use these sessions as a strategic retreat. Register today and guarantee your place!

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UPCOMING...

- *Part Two in Northwell Health Lab's 10-Year Journey to Build Outreach Revenue and Deliver More Value.*
- *How Innovative Labs Use Autoverification to Free Up Medical Technologists for Higher-Value Tasks.*
- *Is Your Lab at Risk for EKRA Violations? Feds Successfully Prosecute Case Involving Lab Bribes.*