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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Special New Year's Report

Lab Execs Share Outlook for 2019

For an inside look at what may be in store for the clinical lab and pathology business this year, *Laboratory Economics* interviewed the top executives at a diverse group of 10 lab companies. Not surprisingly, our interviews revealed that commercial insurers are using Medicare's repricing of the CLFS as a pretext to cut their own rates. What is surprising (and alarming) is that some commercial insurers have demanded the full three-year phased-in ~30% CLFS reduction be applied to their rates upfront immediately. Labs are hoping to offset the pricing pressure by gaining economies of scale through geographic and test menu expansion. On the brighter side, the extreme pricing pressure that terrorized technical services for anatomic pathology for the past seven years seems to be over. Furthermore, molecular diagnostics and drugs-of-abuse testing continue to be high-growth markets.
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Quest Outlines Cost-Cutting and Efficiency Initiatives

At Quest Diagnostics' Investor's Day Conference on November 29, Jim Davis, Executive Vice President, General Diagnostics, outlined a number of cost-cutting and efficiency initiatives at Quest aimed at offsetting pricing pressure related to PAMA. Overall, Quest is seeking to trim 3% (i.e., $200 million) from its total annual operating costs each year going forward. *Continued on page 4.*

UnitedHealthcare Preferred Lab Network To Launch July 1

UnitedHealthcare has announced plans to create a "Preferred Lab Network" that is scheduled to go into effect July 1, 2019 (see UHC's December Network Bulletin). UHC says that it's begun reaching out to existing in-network independent labs, inviting them to apply to join its new Preferred Lab Network program. UHC says the Preferred Lab Network will feature labs that have met higher standards for access, cost, data, quality and service. "In the summer of 2019, we'll announce more information about the program, along with the labs that will be included in the Preferred Lab Network," according to the UHC bulletin.
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UnitedHealthcare Preferred Lab Network To Launch July 1 (*cont'd from p. 1*)

Details are scant, but *Laboratory Economics* thinks that UHC will offer "Preferred Lab Network" status to independent labs that accept lower rates in exchange for higher visibility on pop-up test order screens and marketing materials to physicians. UHC might also market the Preferred Lab Network to its members as the lowest-cost option for lab tests versus regular in-network and out-of-network labs.

UHC's creation of a Preferred Lab Network coincides with Quest Diagnostics joining LabCorp as a national in-network lab provider in 2019. Quest now has the opportunity to compete for 35 million UHC plan members in the United States. (Approximately eight million UHC members in HMO plans will continue under existing capitated lab agreements principally served by LabCorp.) Quest has stated a goal of gaining a 25% share of the available UHC membership by 2022.

What's New With BeaconLBS?

In late 2014, UHC rolled out a pilot lab benefit management program (LBMP) for approximately 430,000 of its fully-insured commercial members in Florida.

The program, which is being administered by LabCorp's BeaconLBS, includes a prior-notification requirement for some 80 high-volume lab and pathology tests. It also includes a "Laboratory of Choice" network managed by BeaconLBS. These labs are given prominence when physicians order lab tests for UHC's fully-insured members in Florida. In addition to LabCorp and all of its subsidiaries, there are currently 22 independent labs and pathology groups with the "Laboratory of Choice" designation.

UHC says that its LBMP has helped it lower costs and reduce unnecessary utilization. However, although it's been more than four years since roll out, UHC continues to label the Florida LBMP as a "pilot program." An attempt to expand the program to UHC's fully-insured commercial plan members in Texas was put on an indefinite hold following protest from physicians and labs (see *LE*, February 2017).

Meanwhile, UHC implemented prior authorization for certain genetic and molecular tests ordered for its commercial plans nationally in November 2017. LabCorp's BeaconLBS is managing the online intake process for these tests (see *LE*, September 2017).

However, Stephen Shivinsky, Vice President, Corporate Communications at UnitedHealthcare, says that BeaconLBS will not be managing UHC's new Preferred Lab Network.

Is UnitedHealthcare Reducing Its Lab Network?

And finally, *Laboratory Economics* asked UnitedHealthcare if it has been terminating contracts with some labs in its network to make room for Quest Diagnostics. "UnitedHealthcare expanded its free-standing lab network in 2018 with the addition of more than 25 contracts. Furthermore, to adapt to the ever-changing healthcare environment, and to innovate ways to improve it, UnitedHealthcare continually evolves the way we structure our services and our network. Right now, UnitedHealthcare currently has more than 300 independent, free-standing labs contracted through local, regional and national agreements," answered UHC's Shivinsky.

Gary Huff Out As CEO of LabCorp Diagnostics

Gary Huff, Chief Executive Officer of LabCorp Diagnostics, and LabCorp "agreed that Mr. Huff's employment with the company would terminate" December 31, according to a filing Friday with the U.S. Securities and Exchange Commission. LabCorp's Chairman and CEO Dave King will take over Huff's responsibilities as CEO of LabCorp Diagnostics on an interim basis. Huff had been the CEO of Labcorp Diagnostics since April 2017. He previously held various positions at the company, including Senior Vice President, Health Systems and Alliances.

Huff's departure follows LabCorp's announcement on November 30 that it was experiencing lower-than-expected volume growth at LabCorp Diagnostics. The company now expects that it will report revenue growth of 2.1% to 2.5% for LabCorp Diagnostics for 2018 versus prior guidance of 3% to 3.5%.

LabCorp Buys ACL In Atlanta Area

In separate news, LabCorp acquired American Clinical Laboratories (ACL—Stone Mountain, GA) effective December 3, 2018. ACL is a privately-held independent lab formed by its President and CEO Arun Khanna, PhD, in 1989.

LabCorp is acquiring the physician office client business of ACL, while service for its nursing home clients is expected to be taken over by Clinical Laboratory Services Inc. (Winder, GA).

ACL received $582,000 of Medicare Part B payments in 2016 (the latest available data). Overall annual revenue is estimated at roughly $2 million. In a letter announcing the sale to LabCorp, ACL anticipated the transition would bring its clients and patients improved electronic connectivity solutions for test ordering and result delivery and provide in-network status with more managed care plans.

OPKO Hires Former Quest Exec To Head BioReference Labs

OPKO Health has hired Jon Cohen, MD, as Executive Chairman of its BioReference Laboratories (Elmwood Park, NJ). Cohen, a vascular surgeon, was previously a senior executive at Quest Diagnostics for nearly 10 years. Most recently Cohen was Senior Vice President and Group Executive—Diagnostic Solutions.

Jon Cohen, MD

OPKO also announced the promotion of Geoff Monk to President of BioReference. Monk joined BioReference as General Manager in May 2018 and will report to Dr. Cohen. Monk was previously Managing Director of Quest's New York and New Jersey region (see *LE*, May 2018).

OPKO Chairman Settles With SEC

In separate news, Philip Frost, MD, Chairman and CEO of OPKO, has agreed to settle penny stock "pump-and-dump" charges with the Securities and Exchange Commission (SEC) by paying $5.5 million.

Frost, without admitting or denying the SEC allegations, agreed to pay about $5.5 million in penalty and repayment of alleged illegal gains. The settlement agreement also prohibits Frost, with certain exceptions, from trading in penny stocks. OPKO Health will pay a $100,000 fine.

"We have reached agreement with the SEC that will end a potentially expensive, contentious and time-consuming litigation and I am happy that we can focus on an exciting and productive 2019 for Opko Health," said Frost in a statement (see *Laboratory Economics*, September 2018).

Quest Diagnostics Outlines Cost-Cutting and Efficiency Initiatives (*cont'd from p. 1*)


Jim Davis

Below we've summarized a few of the cost-cutting/efficiency-gain plans that Quest Diagnostics is implementing, as outlined by Jim Davis, Executive Vice President, General Diagnostics.

Electronic Ordering

Davis estimated that Quest can reduce denied claims and save $120 million over five years through increased electronic ordering and improved patient collections. Paper requisitions currently account for 28% of all Quest's reqs. It costs Quest about $1 in labor for each paper req it receives to be re-entered into its computer. In addition, about 8% of paper reqs lack information needed for payment.

Quest is also pushing to have more patients pre-register on their own computers or tablets before visiting a Quest PSC. This allows Quest to gather patient insurance information and provide the patient with an emailed estimate of their co-pay or deductible responsibility before a specimen is drawn. This has the potential to eliminate the most common reason that patients don't pay their lab bills—disputes over their self-pay responsibility.

Immunoassay System Consolidation

Davis said that the company is using the PAMA Medicare rate cuts as leverage to negotiate price concessions from IVD vendors. "Every conversation begins with PAMA" and Quest is seeking at least 10% price reductions as IVD contracts come up for renewal, according to Davis.

For example, Quest recently issued an RFP with the goal of consolidating its number of immunoassay vendors from six down to two.

Quest operates a total of more than 500 immunoassay systems at 16 regional labs throughout the country that process approximately 128 million tests per year. The company currently uses seven immunoassay instrument systems from six suppliers. Current instruments include the Abbott ARCHITECT, the Beckman Coulter Unicel DxI-600, the DiaSorin LIASON-XL, the Ortho-Clinical Dx VITROS 3600, the Roche cobas e411, and Siemens' Advia Centaur and Immulite.

A decision on the two winning vendors is expected to be made within the next few months and the transition to new instrumentation will take place over a two-year period. "We're going to save a lot of money as we work the competitive nature of the deal that we put in front of these suppliers. And easily over five years, it'll save us about $50 million [$10 million per year]," said Davis.

Construction of New Mega-Laboratory in Northern New Jersey

Quest is aiming to break ground on the construction of a new 250,000-square-foot facility in Clifton, New Jersey this spring. Quest will invest $250 million to build and outfit the new facility, which is expected to open in early 2021. Quest selected the site (formerly occupied by Hoffmann-La Roche) after receiving $5.5 million in annual sales and use tax exemptions for 10 years from The New Jersey Economic Development Authority.

The new facility will employ some 1,100 people and consolidate roughly 85,000 in daily test volume from three existing Quest labs in Teterboro, NJ; Baltimore, MD; and Horsham, PA. Quest anticipates that the new laboratory will increase its capacity by more than 30% and improve productivity by >15% versus the three labs it will replace.

2019 Outlook For Labs: 10 Executive Perspectives (*cont'd from page 1*)

Colin Goldschmidt, MD, Worldwide CEO of Australia-based **Sonic Healthcare Ltd.**, says the company has no plans to consolidate or close practices at its U.S. operations, including the newly-acquired Aurora Diagnostics' practices. "This is not the reason for the acquisition. Instead, we do hope to expand further in both the CP and AP markets, particularly as we see ongoing convergence between the two."

Carl Goldschmidt, MD

"I remain deeply passionate about the important role of pathologists as the natural leaders in the lab and their vital contribution towards the elevation of lab standards and the optimization of patient care," says Goldschmidt (who is a pathologist himself).

Jerry Hussong, MD, was named CEO of Sonic Healthcare USA effective January 1. Hussong's appointment follows Steve Shumpert's decision to retire from the workforce at the end of 2018. Hussong had been Sonic's Chief Medical Officer in the United States since February 2017. Prior to that, he was Chief Medical Officer at ARUP Laboratories.

Goldschmidt says that Aurora's management team and staff will remain unchanged and will operate as a division of Sonic Healthcare USA under the leadership of Bruce Walton as President. Aurora's current Chairman and CEO Dan Crowley will resign following finalization of sale (expected by March 31).

Sonic's existing U.S. anatomic pathology practices are located at CBLPath (Ryebrook, NY), Sunrise Medical Laboratories (Long Island, NY) and Clinical Laboratories of Hawaii (Honolulu). Aurora will bring 220 pathologists at 32 practices spread out in 19 states. The acquisition of Aurora will boost Sonic's U.S. revenue to $1.1 billion per year (see *LE*, December 2018).

Douglas VanOort, Chairman and CEO of **NeoGenomics** (Fort Myers, FL), says that years of severe pricing pressure for anatomic pathology services seems to be abating. During the seven-year period from June 2011 through June 2018, NeoGenomics' average revenue per test declined by 44% to $318. However, the company's average revenue per test increased to $320 in third-quarter 2018.

Doug VanOort

Overall, NeoGenomics expects to report revenue of approximately $271 million for full-year 2018, up 13% from $240 million in 2017. VanOort says that the company's molecular oncology test panels are growing the fastest with year-over-year volume growth of 25% and an annual revenue run rate of $50 million. New tests introduced by NeoGenomics include an RNA-based next-generation sequencing lung cancer panel used to select patients for therapy with Bayer's new FDA-approved TRK inhibitor Vitrakvi (larotrectinib).

NeoGenomics completed its ~$140 million acquisition of Genoptix Inc. (Carlsbad, CA) on December 10 (see *LE*, November 2018). The combined company now has approximately 1,470 employees and annual revenue of $350 million.

VanOort says that NeoGenomics' initial focus is on integrating Genoptix's 35 sales reps with the goal of not losing a single client during the course of the wider integration of the companies (expected to take roughly one year).

VanOort says that the pathology lab insourcing trend at specialty groups (urology, gastroenterology and dermatology) is over. He says that the economics for insourcing are no longer compelling given the reimbursement cuts and difficulties in finding histology lab employees.

Finally, VanOort says that NeoGenomics is evaluating the new Eliminating Kickbacks in Recovery Act of 2019 (see *LE*, December 2018), which outlaws volume-based compensation for all laboratory sales reps. "We think there were some errors in the language of this law that are likely to be fixed and are waiting before we make changes to our sales force."

Peter Fisher, MD, President and CEO of **Health Network Laboratories** (Allentown, PA), says HNL's test volume grew by 9% last year to approximately 8 million billable tests. Approximately 55% of volume comes from non-hospital patient outreach testing, while 45% is from testing provided to the 12 hospital labs managed by HNL.


Peter Fisher, MD

Volume growth has been the fastest for toxicology testing (up 50+% year over year) and molecular/genetic testing (up 20+%), according to Fisher. HNL, which employs 35 pathologists, also saw 15% volume growth in anatomic pathology services in 2018.

HNL is an independent lab with 60 PSCs and about 1,000 employees that has several owners, including two hospitals in the Lehigh Valley Health Network (LVHN), as well as Good Shepherd Rehabilitation and Phoebe Ministries.

The growth of LVHN's physician practice, which currently has 750 physicians at 163 practices in the Allentown and Bethlehem areas, contributed to HNL's growth, as did the addition of inpatient lab management contracts with two LVHN hospitals in northeast Pennsylvania (Hazleton General Hospital and Pocono Medical Center) in mid-2018.

Roughly 20% to 25% of HNL's non-patient outreach testing revenue comes from the Medicare CLFS. Over the past 1-2 years, Fisher says that HNL renegotiated any commercial insurance contracts it had that were linked to future changes in the Medicare CLFS. "We're hopeful that with the addition of payment data from hospital outreach labs, the Medicare CLFS will reach equilibrium in 2021."

To increase efficiency, HNL continues to embrace new technology and invest in automation. The lab was among the first in the nation to install an automated chemistry line 20 years ago, and has since installed second and third generation full automation lines. In 2017, HNL became the first in the nation to install the world's largest ELISA automation system (EUROLab Workstation) at its central lab, and is currently planning the installation of a fully-automated microbiology system. Future plans call for the automation of toxicology panels as well as specimen preparation for molecular/genetic testing.

HNL provides testing services to approximately 300 clients in the post-acute care market, including nursing homes. Fisher says HNL is transitioning skilled nursing facility clients to electronic ordering and tightening up its requirements for STAT requests - now provided only if the test result has the potential to change a patient's treatment and improve outcome.

HNL's non-patient outreach service is currently concentrated throughout eastern and central Pennsylvania, including Allentown, Scranton, Harrisburg and Philadelphia. Fisher says HNL is licensed in 5 states and is currently pursuing a New York State Department of Health clinical laboratory permit for expansion into New York State.

In late December, HNL acquired Connective Tissue Gene Tests (CTGT - Allentown, PA), a privately held independent lab that specializes in molecular diagnostic testing for inherited genetic disorders. CTGT has 15 employees, including two MD-PhD's and two PhD cytogeneticists. The company was co-founded in 2004 by its CEO and Medical Director, James Hyland, MD, PhD, and its President and Director of Research, Leena Ala-Kokko, MD, PhD. Fisher says that the addition of CTGT will add constitutional genetics and pharmacogenetics to HNL's current capabilities in cancer and perinatal genetics, rounding out its comprehensive genomics portfolio.

CellNetix Pathology & Laboratories (Seattle, WA) expects to grow volumes by about 6% in 2019, which is consistent with growth over the past couple of years, says CEO **Kathleen Fondren**. Volume growth is being driven primarily by new clients, increased sales efforts and growth of health systems, she notes.

CellNetix, which merged with Puget Sound Institute of Pathology in 2017, processes about 230,000 surgical cases and 175,000 Pap smears annually. With more than 1,500 clients (physician groups),

the company serves parts of Washington, Oregon, Idaho and Alaska.


Kathleen Fondren

Though it has not been as hard hit by PAMA Medicare cuts as most clinical labs have, CellNetix expects the 19% cut to flow cytometry services (88185) in 2019 to have a negative impact on revenues. "We're looking at all our operations, including courier services and how we can get specimens into our core lab as quickly as we can to improve turnaround time," she says. "Everything is on the table. We would like to reduce cost-per-test by at least 5% in 2019."

One challenge faced by CellNetix is managing the various preauthorization requirements implemented by insurers. CellNetix has hired two additional staff just to deal with preauthorization requests, notes Fondren. "There are more and more tests that payers want prior authorization for," she says. "It's a burden on us because each payer is different and they're constantly changing the process."

An additional challenge is finding and retaining qualified personnel, especially since Seattle has such a competitive labor market. "We have Amazon and Google and lots of biomedical companies, so there's great competition for talent," notes Fondren.

TriCore Reference Laboratories (Albuquerque, NM) grew its non-hospital-patient commercial test volume by about 7% in 2018. However, revenue in that same business line declined by 3%, largely as a result of the reductions in Medicare payment for lab tests resulting from PAMA, according to CEO **Michael Crossey, MD, PhD**.


Michael Crossey, MD, PhD

TriCore is an independent, not-for-profit, clinical reference laboratory owned by Presbyterian Healthcare Services and University of New Mexico Health Sciences Center. As the largest laboratory in the state, TriCore serves over half the population of New Mexico, more than 60% of whom are on Medicare and/or Medicaid.

The Medicare cuts could have been much worse, but TriCore benefited from moving from a geographical fee schedule to a national fee schedule and actually received an increase in Medicare payment for some tests in 2018. However, Crossey expects to see an even bigger decline in Medicare revenues in 2019 and 2020.

"We included in our budget a 10% decrease in Medicare reimbursement for the commercial business line," Crossey explains. "Our commercial business line is 35% of our total business, so I can manage 2019, but I am really worried about 2020. We've been doing LEAN for years, so there's not much waste to drive out of the system."

To help offset these declines, TriCore plans to focus on reducing bad debt, which has increased significantly in the last five years, by at least 20% in 2019. The bad debt comes not only from patients in high-deductible plans who don't understand they are responsible for payment for some tests, but also from insurers who require pre-authorization for certain types of testing, especially higher-end genetic testing.

"Our front end can flag what needs prior authorization, but that's only if we draw the specimen," he explains. "If the specimen comes from a physician office, we have to go ahead and run it because of the stability of the specimen. Sometimes we don't get paid for the tests we run because the physician has not gotten a prior authorization or doesn't understand medical necessity."

Ultimately, TriCore relies on a diversified business model to offset the revenue cuts in its commercial testing, including hospital lab management services and a research institute that provides technical support for clinical trials. Additionally, as a part of its emerging Lab 2.0 initiative, TriCore has begun inking agreements with payers to provide insight based on laboratory data for managing certain health conditions, such as prenatal care and diabetes. Managed care organizations pay the lab based on per-member, per-month for these quality reports.

"Our corporate strategy in dealing with declining revenues is to diversify and offer new value, as op-

posed to hunkering down," says Crossey. "Nobody is going to survive the PAMA cuts by hunkering down."

Elazar Rabbani, PhD, Chairman and CEO of **Enzo Biochem** (New York City), says that the company is expanding its laboratory service area north into New England as well as south into the Mid-Atlantic. He says the company is scaling up in order to offset reimbursement pressure.

Elazar Rabbani, PhD

Enzo currently operates a central lab in Long Island, New York and 32 patient service centers throughout the New York City region. The company's clinical lab operations currently generate roughly $60 million of revenue per year.

Enzo recently obtained a license from the state of Connecticut and opened a new freestanding laboratory and PSC in Shelton (about 70 miles north of New York City). Enzo is hiring sales reps and plans to open more PSCs for expansion throughout New England, including Connecticut, Massachusetts, Vermont and Rhode Island. Rabbani says Enzo needed the new lab in order to obtain in-network status with regional payers that require a local lab presence.

In addition to geographic expansion, Rabbani says that Enzo has expanded its test menu, especially in women's health and STD testing, and begun marketing reference lab services to other independent labs and hospitals.

Enzo also has a life sciences division that offers a number of laboratory-developed molecular test reagents that work on commonly available open-instrument systems. Rabbani says Enzo's reagents offer savings of 30% to 50% versus those sold by the major IVD vendors for their closed-instrument systems. Test reagents offered by Enzo include real-time amplification for HBV, HCV, HIV and a women's health panel for 16 STDs (candida, chlamydia, gonorrhoeae, et al.).

Russell Watkins, General Manager at **Clinical Laboratory Services, Inc.** (Winder, GA), says that starting in late 2017, CLS began a combination of aggressive cost controls and geographic expansion of services to capture additional market share, thereby positioning it well for the anticipated 2018-2020 Medicare CLFS cuts.

"PAMA was a wakeup call for laboratories to run more efficiently and consolidate when possible. Consolidation of smaller independent lab operations will be necessary to maintain competitive services. Networks of smaller laboratories with limited market share will be unsustainable. We're already seeing some of these laboratories close or cut back services."

CLS is a full-service reference laboratory with 200+ employees servicing hundreds of long-term care facilities throughout the Southeast (Georgia, Tennessee, Alabama, Florida, and North and South Carolina). Approximately 70% of the company's testing is affected by the Medicare CLFS.

Watkins says that the Medicare CLFS rate reductions have opened the door for private insurance companies to reduce their lab payments, even as they maintain or increase their insurance premiums. He says that Medicare Advantage Plans were the quickest to follow the Medicare CLFS cuts.

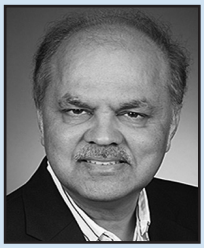
Watkins notes that many nursing home labs are small community-based labs or a combination of small failed labs managed with little resources or oversight. "Many nursing home labs used the 1990's laboratory mindset of taking any business they could because someone would buy them even though they were losing money. But Quest and LabCorp have not shown interest in the nursing home market." In addition, he believes that some nursing home labs have violated the Fair Labor Standards Act (FLSA) to lower their labor costs, payroll taxes and workmen's comp insurance. State and IRS enforcement of these laws combined with the PAMA reimbursement cuts will ultimately close most nursing home labs by 2020, predicts Watkins.

Watkins says that CLS reported its private-payer rates to CMS during the last reporting cycle in 2017 and will do so again as required by PAMA. "The reporting requirement is very labor intensive,

requiring staffing overtime with no revenue to offset cost. It's unsettling that some labs got a free pass."

Ultimately, Watkins believes the best solution to PAMA may be a Medicare-for-all health insurance program with responsibly established reimbursement schedules, which would force all labs to compete based on quality of care rather than insurance contracts that control referrals.

Atul Sharan, Co-Founder and CEO of **CellMax Life** (Sunnyvale, CA), says the company began processing patient blood samples for its colorectal cancer screening test at its CLIA-certified lab in northern California in November.



Atul Sharan

CellMax is receiving patient specimens from Stanford Medicine, Johns Hopkins, University of Southern California and the U.S. Department of Veterans Affairs Palo Alto Health Care System. CellMax plans to perform a clinical validation study on 500+ patient specimens and then begin commercialization of its test as an LDT (laboratory-developed test) at around mid-year.

The test, which is being branded as FirstSight^{CRC}, detects pre-cancer and cancer cells from a blood sample and is expected to have a price of less than $200.

Sharan says that ultimately the goal for the clinical study is 5000+ patients and submission of results to the Parallel Review Program for simultaneous approval from the FDA and a CMS national coverage determination.

A 737-patient study that took place at Chang Gung Memorial Hospital, the largest hospital in Taiwan, showed the test had a close to 90% accuracy for detecting pre-cancer while maintaining high accuracy (95%) for colorectal cancer. This was an expanded study; previous results were presented at The American Society of Clinical Oncology (ASCO) Gastrointestinal Symposium in January 2018 (see *LE*, May 2018). The expanded study results will be presented at the ASCO conference again this year on January 17-19.

Sharan notes that colonoscopy has high sensitivity for the detection of pre-cancers, but that patient compliance with colonoscopy screening guidelines is less than 40%. FirstSight^{CRC} offers a highly-sensitive non-invasive testing option to patients who are reluctant to undergo a colonoscopy, according to Sharan.

Raymond Kubacki, Chairman and CEO of **Psychemedics** (Acton, MA), which specializes in hair analysis for drugs of abuse, notes that the company is benefiting from growth in Brazil. A new law (Brazilian Federal Law No. 13.103) took effect in March 2016, requiring professional truck and bus drivers to pass a hair test for illegal drugs before obtaining or renewing their license. There are more than 10 million professional drivers in Brazil.

Raymond Kubacki

Hair testing is more expensive but can detect drug use that has occurred over a 90-day period versus only 2-3 days for urinalysis.

Kubacki notes that the Brazil market for hair testing will roughly double in size when professional drivers are required to renew their licenses every 2 1/2 years instead of the current 5 years. This expansion is by law and was scheduled to take effect late last year. However, implementation was temporarily delayed due to the elections in Brazil. Kubacki now expects that this market expansion will take place sometime this year.

Psychemedics performs all its testing for U.S. and international clients at its CLIA-certified and CAP-accredited laboratory in Culver City, California (Los Angeles metropolitan area).

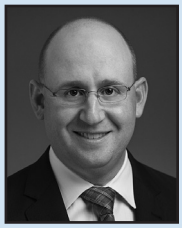
Other lab companies competing for hair testing business in Brazil include Quest Diagnostics, Omega Laboratories (Mogadore, OH) and ChromaTox Laboratorios (Sao Paulo, Brazil).

Psychemedics' revenue totaled $32.7 million in the nine months ended September 30, 2018, up 9% from $29.9 million for the same period a year earlier. This was primarily due to a 17% increase in volume, offset by a 6% negative impact from foreign currency exchange and a 2% decrease of average revenue per sample. The company's U.S. revenue was up 12.5% to $22.4 million in the nine-month period, while its Brazil revenue was up 2% to $10 million.

Meanwhile, *Laboratory Economics* notes that the U.S. Department of Transportation (USDOT) currently only permits urinalysis drug tests performed at laboratories that have been certified by the Department of Health and Human Services (HHS). However, HHS is currently developing federal hair testing guidelines for safety-sensitive transportation employees such as truck drivers. Once issued, it's possible that hair testing could replace urinalysis as the primary drug screening method for truck drivers in the United States.

Most U.S. trucking companies only require applicants to pass the USDOT-mandated urine test. However, some trucking companies have been hair testing their drivers for years, while also doing required urine testing. Federal approval of the hair alternative would decrease the costs for trucking companies that currently conduct both urine and hair sample tests, as they would be required to conduct just one of the tests.

Since its non-compete agreement with LabCorp ended in July 2017, **Wisconsin Diagnostic Laboratories** (WDL-Milwaukee) has expanded its business significantly, with both volumes and revenues increasing more than 10% in 2018, according to **Steve Serota**, Chief Operating Officer at WDL. For 2019, Serota anticipates additional volume growth of 10% to 15%, and revenue growth of approximately 9%.



Steve Serota

WDL (formerly United/Dynacare Laboratories) exited a joint-venture agreement with LabCorp in 2015, under which LabCorp had managed the independent physician outreach business, while WDL performed testing for the Froedtert Health System, along with a number of other hospitals. WDL now serves 30 hospitals, 900 long-term care facilities and 212 physician practices, and is continuing to expand, says Serota.

"We have grown pretty dramatically in the last year and a half since we were able to re-enter the outreach market competitively," he explains. "We have onboarded a number of physician practices, and we have a number of client-bill relationships, which has helped insulate us from some of the turbulence that exists in the marketplace in terms of reimbursement."

Although its Medicare reimbursement declined by about 7% in 2018, Serota says that WDL has been able to overcome that through expense reductions and a diversified payer mix. Medicare makes up about 18% of WDL's total revenues. Through automation, standardization and consolidation of platforms, the lab has been able to reduce operating expenses by 6.5% in 2018 and is projecting further savings of 6% to 8% in 2019.

"We think it's essential to get lean while still maintaining our value proposition," explains Serota. "We're looking at ways we can be smarter, better and more operationally efficient while still maintaining the maximum amount of patient touch and patient-centric service."

Working with the Medical College of Wisconsin, WDL is expanding its molecular genomics testing, particularly in the area of oncology, as a way of providing additional services to the Froedtert Cancer Center. The lab is also developing molecular tests to identify wound infections, is fortifying its toxicology testing and is looking at potential acquisitions and cooperative testing partnerships.

"Our biggest opportunities in the next year will be in growing regionally and expanding our footprint," says Serota. "We also think there there's an opportunity to highlight the expertise of our pathologists and for some of our niche offerings to look at a more national play, including an expansion of our consultative services. Our goal in 2019 is to really solidify our base in southeastern Wisconsin, to expand our service networks to the north and south and then set the stage for more growth and expansion moving into 2020."

Shutdown Delays ACLA Lawsuit Appeal Schedule

The federal government's partial shutdown means that appropriations to the U.S. Department of Justice have lapsed. And without appropriations, DOJ attorneys are prohibited from working, even on a voluntary basis, except in emergency circumstances. As a result, the DOJ, which is representing the Department of Health & Human Services, cannot file a brief responding to ACLA's opening appeal brief for its lawsuit challenging CMS's implementation of PAMA. As a result, the U.S. District Court of Appeals for the District of Columbia has revised its appeal briefing schedule and given DOJ/HHS an extra month to file their response (see *LE*, December 2018).

Revised Appeal Briefing Schedule

ACLA's Opening Brief	December 4, 2018
HHS/CMS's Response Brief	February 25, 2019
ACLA's Reply Brief	March 18, 2019
Oral arguments	not yet scheduled

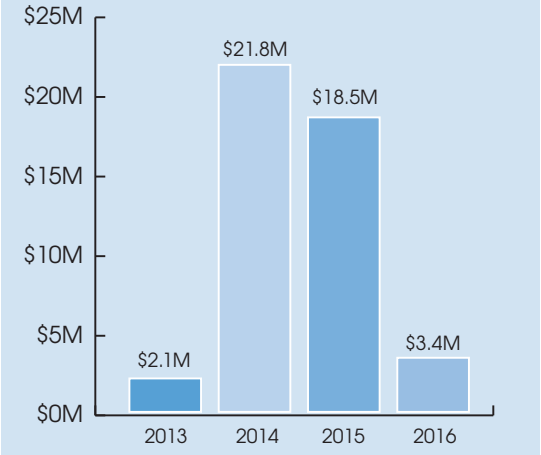
Vancouver Toxicology Lab Settles Kickback Allegations

Molecular Testing Labs (Vancouver, WA) has agreed to pay up to $1.778 million to settle allegations that it violated the False Claims Act by paying illegal kickbacks to local provider-owned labs in exchange for referrals of Medicare and Tricare patients for toxicology and molecular testing, the U.S. Attorney's Office in Seattle announced on December 19.

Molecular Testing Labs, which is a wholly owned subsidiary of Blackfly Investments LLC, was formed in 2012 by Adam Blackwell (Head of Laboratory Operations and R&D), Peter Flynn (Director of Laboratory Operations) and Steve Verschoor (Head of Sales and Business Development).

According to the settlement, the alleged kickback activity occurred between August 2014 and July 2015. Data from CMS shows that Molecular Testing Labs' revenue from Medicare Part B payments jumped from $2.1 million in 2013 to $21.8 million in 2014. The company billed for an average of 7.1 tests per Medicare patient in 2014 with an average payment of $1,102 per patient. Its most frequently billed tests in 2014 included cytochrome P450 gene analysis (CPT 81225, 81226 and 81227), coagulation gene analysis (CPT 81240 and 81241) plus a variety of toxicology tests for opiates, methadone, amphetamines, et al.

Medicare Part B Allowed Payments to Molecular Testing Labs



Source: CMS Provider Utilization Data, 2013-2016

Molecular Testing Labs remains in separate litigation with CMS concerning potential overpayment of claims. Depending on the outcome of that litigation, the ultimate settlement in this case could be between $180,000 and $1.778 million, according to the U.S. Attorney's Office.

The government was first alerted to the alleged wrongdoing, a U.S. Attorney's Office spokesperson said, through a complaint to a Department of Health and Human Services hotline: 1-800-HHS-TIPS (1-800-447-8477).

Molecular Testing Labs said that it disagrees with the government's findings and admits no wrongdoing, but agreed to a settlement to avoid continuing legal fees that had exceeded "hundreds of thousands of dollars."

Lab Stocks Up 28% In 2018

Eighteen lab stocks rose by an unweighted average of 28% in 2018. In comparison, the S&P 500 Index had a total return of -4.4% last year. The top-performing lab stocks in 2018 were CareDx, up 243%; Genomic Health, up 119%; and Foundation Medicine, up 101%. Shares of LabCorp were down 21%, while Quest Diagnostics was down 15%. Quest's total return (including dividends) was -13% in 2018.

Company (ticker)	Stock Price 12/31/18	Stock Price 12/29/17	2018 Price Change	Enterprise Value ($ millions)	Enterp Value/ Annual Revenue
Cancer Genetics Inc. (CGIX)	$0.24	$1.85	-87%	$19	0.7
Enzo Biochem (ENZ)	2.78	$8.15	-66%	79	0.8
Opko Health (OPK)	3.01	4.90	-39%	1,697	1.6
Psychemedics (PMD)	15.87	20.56	-23%	84	2.0
Interpace Diagnostics (IDXG)	0.80	1.02	-22%	15	0.7
LabCorp (LH)	126.36	159.51	-21%	18,317	1.6
Quest Diagnostics (DGX)	83.27	98.49	-15%	14,900	1.9
Myriad Genetics (MYGN)	29.07	34.35	-15%	2,264	2.8
Sonic Healthcare (SHL.AX)	22.11	21.40	3%	13,168	2.4
Exact Sciences (EXAS)	63.10	52.54	20%	7,246	18.2
Invitae (NVTA)	11.06	9.08	22%	758	5.9
NeoGenomics (NEO)	12.61	8.57	47%	1,184	4.2
Natera (NTRA)	13.96	8.99	55%	821	3.4
Veracyte (VCYT)	12.58	6.53	93%	457	5.3
Guardant Health (GH)	37.59	19.00	98%	2,952	38.0
Foundation Medicine (FMI)*	137.00	68.20	101%	5,350	26.5
Genomic Health (GHDX)	64.41	29.39	119%	2,143	5.7
CareDx (CDNA)	25.14	7.34	243%	1,013	15.4
Unweighted Averages			28%	$72,466	7.6

*Foundation Medicine was acquired by Roche for $137 per share on July 31, 2018.
Source: *Laboratory Economics* and Capital IQ

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