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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

LabCorp Buying DMC Outreach Lab

Tenet Healthcare Corp. (Dallas, TX), the parent company of Detroit Medical Center (DMC), has signed a definitive agreement under which LabCorp will acquire the outreach lab business from DMC University Labs. The deal only affects lab outreach services and not inpatient or outpatient testing performed at DMC's six hospital-based labs. The transaction is expected to close by April 1.

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Many Hospital Labs Still Don't Know They Must Report PAMA Data

On January 22, the Centers for Medicare & Medicaid Services (CMS) hosted a teleconference that focused on a new rule that requires nearly all hospital outreach labs to collect their private-payer payment data from January 1 to June 30, 2019, and report it to CMS in early 2020. This data, along with private-payer data from independent labs and physician office labs, will be used to set new rates for the Medicare CLFS in 2021. Although the new rule was published in early November (see *LE*, November 2018) and the data collection period is already underway, the teleconference Q&A showed that many hospital outreach labs are unaware that they are required to report. Broad participation from hospital outreach labs in the current data collection cycle is critical to stabilizing Medicare CLFS rates in 2021.

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UnitedHealthcare's New Preferred Lab Network Taking Aim At High-Cost Hospital Labs

UnitedHealthcare is planning to launch a new Preferred Lab Network on July 1, 2019 that aims to save money for both its health plans and members by shifting test volume away from higher-cost labs, especially hospital labs. Quest Diagnostics and LabCorp are expected to be the cornerstones of United's Preferred Lab Network, although some independent labs will be included as well. United says that hospital labs will be included only if they are willing to contract as a freestanding lab (i.e. independent lab) provider and meet certain cost and service criteria.

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UnitedHealthcare's New Preferred Lab Network *(cont'd from p. 1)*

United says that labs that are accepted into the Preferred Lab Network will continue to be reimbursed under their existing in-network participation agreements, except for hospital labs which must re-contract at the lower rates associated with freestanding lab contracts.

United says that labs that meet its criteria for pricing and service will be accepted into the Preferred Lab Network and will sign an amendment to their participation agreements. Labs that don't meet United's criteria will remain in United's network under their existing contracts.

United's Preferred Lab Network seems to be targeting lab test volumes currently being performed by hospital labs that bill through outpatient lab fee schedules, observes *Laboratory Economics*. Hospital outpatient lab fee schedules can often be set at rates that are 3-5 times higher than the ~50% of the Medicare CLFS rates offered by the national labs.

United's Preferred Lab Network Launch Timeline

Labs Invited	Started December 2018
Labs request an application	by Dec. 31, 2018
Labs return the application	by Jan. 31, 2019
Labs notified	by April 1, 2019
Services delivered as part of Preferred Lab Network	Starting July 1, 2019

Source: UnitedHealthcare

The volume of lab tests flowing to hospital labs has increased over the past seven years as health systems have expanded their reach by acquiring local physician groups. More than 40% of physicians are now employed by hospitals, up from 26% in 2012, according to the Physicians Advocacy Institute (PAI). When physicians are employed by hospitals or health systems, they perform and bill for more services through hospital outpatient fee schedules versus the lower fees offered at non-facility physician offices and independent labs.

In a Q&A session at the J.P. Morgan Healthcare Conference on January 10, Quest's CFO Mark Guinan shed some light on United's Preferred Lab Network:

> *So where hospitals have owned or affiliated physicians, it's been difficult to compete for that, but as we move forward with payers and especially with UnitedHealthcare, we've talked about a strategy where we actually work together and that's critical in order to bend that cost curve to move some of that volume out of the hospitals.… United is going to be working with us and other labs who are in that Preferred Lab Network. That's an opportunity. The bad news is that it won't come all at once, but the good news is that it's gonna be a multi-year tailwind in helping us grow.*

Stephen Shivinsky, Vice President, Corporate Communications at UnitedHealthcare, says the Preferred Lab Network will cover both clinical lab tests and pathology services. He says that United is reviewing applications and will announce which labs are in the new network prior to July 1. United will also describe the benefits that its members will receive from using the network prior to July 1, according to Shivinsky. *Laboratory Economics* believes that United's Preferred Lab Network may offer members waived or lowered coinsurance or copays versus regular in-network labs.

Aetna Highlights Cost Savings Offered By Big Labs

Aetna, which has 22 million health plan members nationwide, added LabCorp back into its network effective January 1. And the insurer has begun a big push to educate physicians on the cost savings that patients receive when their lab tests are performed by either Quest Diagnostics or LabCorp. The table below is a reproduction of a table contained in an educational brochure that Aetna recently sent to its contracted physicians. Although Aetna has contracts with dozens of other independent labs (BioReference Labs, Sonic Healthcare, Enzo, NeoGenomics, et al.), Quest Diagnostics and LabCorp get center stage in Aetna's lab brochures.

According to the Aetna table, patients that have not yet reached their deductible limit would pay $30 out of pocket for a hypothetical group of routine lab tests versus $45 for an in-network independent lab and $120 for an in-network hospital lab that bills through its outpatient lab fee schedule. Out-of-network labs are by far the most expensive at $300, according to Aetna.

Aetna's Comparison of Routine Lab Test Costs

	Quest Diagnostics & Labcorp	*In-network independent lab*	*In-network hospital lab***	*Out-of-network lab*
Cost of lab tests*	$30	$45	$120	$300
Patient's coinsurance/ copay	20%	20%	20%	40%
Patient pays	$6	$9	$24	$120

*Example of routine lab tests

**Data is not representative of hospitals that have a separately negotiated laboratory contract

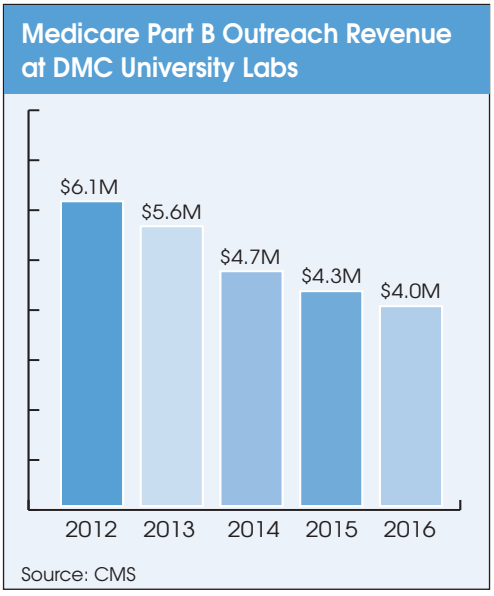
Source: Aetna (https://www.nafhealthplans.com/files/4215/4222/2069/All_In_-_Quest_LabCorp_Par_Non_Par_PDF__FINAL_tA22056_lab_brochure_hires_11.6.18.pdf)

LabCorp Buying DMC Outreach Lab *(cont'd from p. 1)*

"This transaction is a positive step in our continuing efforts to focus on the core of what we do at the DMC—delivering quality patient care that positively impacts the overall health and well-being of our community," according to a statement from DMC.

DMC University Labs employs several hundred lab employees at its six hospitals, but the sale to LabCorp will only affect roughly 90 employees. Its outreach lab operations include 12 patient service centers with a core lab based at DMC University Health Center. Following close of the transaction, LabCorp is expected to shift the acquired outreach test volume to its nearest regional laboratory in Dublin, Ohio.

DMC University Labs was formed in 1993 and performs more than six million tests per year, according to CLIA data. But its outreach lab testing business has been faltering in recent years. The latest available data from CMS shows that DMC University Labs Part B outreach testing revenue had fallen to $4 million in 2016, down from $6.1 million in 2012.



LabCorp Reports Full-Year 2018 Financial Results

LabCorp (Burlington, NC) reported net income of $883.7 million for the full-year 2018, down 28% from $1.227 billion in 2017. LabCorp's overall revenue increased by 9.9% to $11.3 billion in 2018.

LabCorp's traditional lab testing business increased its revenue by 2.5% to $7 billion in full-year 2018. Roughly half of the revenue growth was organic, while lab acquisitions (including PAML and its associated lab networks) accounted for the remainder.

On February 7, LabCorp held a conference call with analysts and investors. Here are some comments on a few key topics from CEO David King.

The Outlook for 2019 and Impact from PAMA

King said that the PAMA rate cuts will reduce the company's lab testing revenue by approximately 1.6% in 2019, consisting of lower Medicare CLFS payments of approximately $85 million plus $30 million of cuts from Medicaid plans, both fee-for-service and managed Medicaid, which are reducing their rates consistent with the Medicare reductions.

Walgreens PSCs

LabCorp has opened more than 25 PSCs in Walgreens stores since their partnership was announced in June 2017, including recent openings at nine stores in California. King said that LabCorp plans to have PSCs at 125 Walgreens locations by the end of 2019 and at least 600 locations within the next four years.

Gaining Access to BCBS of Florida

King said that LabCorp has begun discussions with BCBS of Florida (dba Florida Blue), which covers some 4.2 million members. Quest Diagnostics is currently the exclusive lab provider for all Florida Blue plans. "We have Walgreens-located patient service centers in the Florida market. So we're hopeful that we're going to see some progress there, but I can't give you a firm prediction about how it's going to turn out. We've been pleased with the fact that they've been willing to engage with us because we've been out of that contract for a good number of years," according to King.

Outlook for Acquisitions

LabCorp spent $118 million on lab acquisitions in 2018, making it a slow year for deals. But King said there is growing awareness among independent and hospital outreach labs about the true impact of the PAMA rate cuts. "This presents us with a number of attractive tuck-in lab acquisition opportunities, which typically deliver significant synergies and high return on invested capital," he said.

LabCorp Financial Summary ($ millions)

	2018	2017	% Chg
Total revenue	$11,333.4	$10,308.0	9.9%
LabCorp Diagnostics	7,030.7	6,858.2	2.5%
Covance Drug Development	4,313.1	3,451.6	25.0%
Operating cash flow	1,305.4	1,498.1	-12.9%
Capital expenditures	379.8	312.9	21.4%
Free cash flow	925.6	1,185.2	-21.9%
Pretax income	1,268.3	1,077.5	17.7%
Net income	883.7	1,227.1	-28.0%
Diluted EPS	8.61	11.81	-27.1%
Est'd number of requisitions	157.5	152.0	3.6%
Est'd revenue per requisition	$44.65	$45.12	-1.0%
# Lab employees	39,000	37,000	5.4%
Avg. revenue per lab employee	$180,274	$185,357	-2.7%

Source: LabCorp and *Laboratory Economics'* estimates for number of reqs and average revenue per req.

Many Hospital Labs Still Don't Know They Must Report *(cont'd from p. 1)*

The Final Medicare Physician Fee Schedule for 2019 states that hospital outreach labs that bill for their non-patient lab services using the hospital's national provider identifier (NPI) must now use Medicare revenues from the Form CMS-1450 14x Type of Bill to determine whether they meet the majority of Medicare revenues threshold and low expenditure threshold.

Under the Protecting Access to Medicare Act of 2014 (PAMA), applicable laboratories are required to report their private-payer rates for clinical lab tests to CMS so the data can be used to calculate Medicare CLFS rates.

During the teleconference, CMS confirmed that this will require most hospital outreach labs to collect and report their private-payer data.

Laboratory Economics notes that in simplest terms, the rule requires any hospital outreach lab that collects $12,500 or more in Medicare CLFS revenue during the first six months of 2019 to report their private-payer payment data to CMS. Of course, all independent labs and physician-office labs meeting the $12,500 threshold must also report.

Based on an analysis of Hospital Cost Report data from 2018, *Laboratory Economics* has identified more than 1,000 hospital outreach labs that will meet the $12,500 threshold and are therefore required to report.

The PAMA law authorizes CMS to impose civil monetary penalties of up to $10,000 per day on labs that are required to report, but fail to do so. However, CMS did not enforce this law during the first reporting cycle (2016-2017) and it has not threatened to do so in the current cycle.

The cost and complexity involved with collecting private-payer payment data combined with CMS's unwillingness to impose penalties on non-reporting labs lead *Laboratory Economics* to the unfortunate conclusion that most hospital outreach labs, as well as smaller independent labs and POLs, will dodge their reporting responsibility.

This likely scenario will have devastating long-term consequences for all laboratories. It means that lab test codes paid through the Medicare CLFS—already scheduled for three straight years (2018-2020) of 10% rate reductions—may suffer reductions of as much as 15% in 2021.

In addition, low reporting participation by hospital outreach labs may lead CMS to succumb to lobbying efforts by the American Hospital Association (AHA), which has argued that the cost of having hospital labs report outweighs any potential impact their data will have on CLFS rate calculations. In a statement, Roslyne Schulman, Director of Policy at AHA, told *Laboratory Economics:*

> *In comments to CMS, the AHA opposed the agency's proposal requiring hospitals to collect and report private-payer payment rates. We opposed the proposal due to the significant operational burden this data collection would impose on hospitals. The increased data reporting burden that would be imposed on hospital laboratories newly meeting the "applicable laboratory" definition would not be justified by what CMS itself expects to be a minimal impact on the clinical laboratory fee schedule rates. It is also our belief that Congress did not intend hospital outreach laboratories to qualify as applicable laboratories. We are continuing to help our members assess the impact of the rule.*

Low participation by hospital outreach labs in the current data collection cycle may lead CMS to excuse them from reporting in future data collection cycles.

Highlights From JPM Conference: LabCorp, Mayo, Exact, Myriad and Caris

Some of the largest publicly traded lab companies presented their goals and strategies for the New Year at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco, January 7-10. Here are highlights from some of the presentations:

LabCorp Chairman and CEO Dave King said, "I was a little surprised at the lack of deal flow in 2018. There were not a lot of PAMA-driven acquisitions. There was a lot of watching and waiting around the ACLA lawsuit and the potential for new legislation." King noted that the lawsuit is stalled because the U.S. Department of Justice cannot file briefs during the federal government shutdown. "The likelihood that we're going to get any near-term relief [from PAMA] is probably small," noted King. As a result, he expects more deals, including acquisitions and joint venture partnerships, with hospital outreach labs and independent labs to occur this year.

Regarding his recent takeover of the CEO responsibilities at LabCorp's diagnostic division, King said, "I felt we lost some focus and discipline in the diagnostics business….I haven't run the diagnostics business in a long time, but I still remember how from my time as Chief Operating Officer." He said LabCorp is currently looking for a long-term CEO for this division.

King also highlighted LabCorp's new direct-to-consumer testing initiative branded as Pixel. At Pixel.LabCorp.com, consumers can purchase fingerstick sample collection devices, then mail their samples to LabCorp for a small menu of tests that includes a wellness screen (lipid panel plus A1c for $69), heart health (lipid panel for $59) and diabetes check (A1c for $39). King said the service will be expanded to include more testing options and also be offered to health systems to serve their homebound geriatric patients.

Mayo Clinic (Rochester, MN) has a "strong focus" on artificial intelligence and big data, according to **Clark Otley, MD,** Medical Director. Otley said he sees a "humongous opportunity in this area" to use Mayo Clinic's curated big data and apply artificial intelligence and machine learning to it.

On the lab testing side, Otley said that Mayo Clinic Laboratories (formerly named Mayo Medical Laboratories) performed 25.5 million tests for 4,000 hospitals and other providers in 2018. MCL is a for-profit reference laboratory that operates as part of Mayo Clinic's Department of Laboratory Medicine and Pathology. *Laboratory Economics* estimates that MCL generated revenue of approximately $700 million in 2018.

Overall, Mayo Clinic recognized $12.5 billion in full-year 2018 revenue, up from $12 billion in 2017; operating income was $601 million versus $707 million.

Exact Sciences CEO Kevin Conroy anticipates reporting full-year 2018 revenue of between $454 million and $455 million, up 71% year over year. Cologuard test volume during 2018 was up 64% to approximately 934,000 tests.

Conroy expects that a marketing partnership with Pfizer (see *LE*, September 2018) will help the firm achieve significantly greater adoption of Cologuard in 2019. Further, he noted that Medicare coverage plus contracts with most commercial insurers mean that 94% of Cologuard patients have no out-of-pocket costs.

Exact spends more than $80 million per year on direct marketing, including approximately $1 million per month on TV advertising. The partnership with Pfizer will add another $45 million per year in advertising promotions, including TV, internet marketing and social media.

Conroy said that Exact will seek FDA approval to expand the label for Cologuard testing to include not only people that are between 50 and 85 and at average risk of getting colorectal cancer, but also those aged 45 to 49. That would increase the potential market for the test by 19 million people, he said.

Conroy said that Exact is exploring the development of blood tests for colorectal cancer screening. The company has also identified molecular biomarkers for indications other than colorectal cancer, including liver cancer, and would eventually like to develop a universal cancer panel.

At the end of the Q&A session, Conroy noted that 10 years ago when he first interviewed for the CEO job with Exact Sciences, his initial reaction about the company's colorectal cancer screening test (then called PreGen-Plus) was "there's no hope, there's no technology, the product has failed… why is the board keeping this alive?" Conroy said a subsequent meeting with Mayo Clinic's Dave Ahlquist, MD, who helped develop the testing technology, convinced him that DNA testing on stool samples was viable and he became Exact's CEO in April 2009.

Myriad Genetics' CEO Mark Capone said that Myriad plans a three-fold increase in the number of sales reps for its noninvasive prenatal tests (NIPT) this month as it pushes into the Ob/Gyn market, which he said is underpenetrated. Myriad entered the NIPT market through its $375 million acquisition of Counsyl Inc. (South San Francisco, CA) in July 2018.

Counsyl currently has about 80 sales reps and the increased sales force is being achieved by training Myriad's existing 225 women's health sales reps to sell Counsyl's two tests: Foresight Carrier Screen which allows would-be parents to discover if they're a carrier for certain genetic diseases, and Prequel Prenatal Screen tests for pregnant women to determine if their baby will be born with a chromosomal disorder such as Down syndrome.

Capone said that most other NIPT firms have focused on maternal fetal medicine clinics, since maternal fetal medicine specialists typically handle high-risk pregnancies for which NIPT is reimbursed. However, Capone said that NIPT for average-risk pregnancies is being increasingly accepted and some payers are covering it, noting that an anticipated endorsement by the American College of Obstetrics and Gynecologists sometime this year should help secure broader coverage.

Aside from Counsyl's tests, an important addition was the app Counsyl developed, Counsyl Complete, essentially a "one-stop shopping for [prenatal] tests to order by the Ob/Gyn," Capone said. "It automates the process from the time the patient comes into the office to the delivery of test results." Capone said that Myriad eventually plans to apply that app, which it will rebrand as Myriad Complete, to the company's entire portfolio of tests.

Meanwhile, Myriad still receives the majority of its ~$800 million in annual revenue from BRACAnalysis testing. Medicare rates for CPT 81162, the key code for BRACAnalysis, were cut by 10% to $2,253 in 2018, reduced by another 10% to $2,028 in 2019 and will be cut again by 10% to $1,825 in 2020. Capone said that commercial insurance rates for BRACAnalysis have been stable because the company has locked in long-term contracts with major insurers through 2020-2021.

Caris Life Sciences (Irving, TX) recently launched a new whole transcriptome sequencing test for tumor RNA analysis, according to **David Spetzler, PhD**, President and Chief Scientific Officer. In addition, he said that the company is expanding from solid tumors and into hematological cancers.

Currently, Caris offers a 592-gene sequencing panel, as well as a 53-gene fusion panel, and customized protein tests depending on the specific cancer lineage. It has analyzed more than 150,000 patient cases since it launched in 2009 and has more than 80,000 banked tissue samples and

20,000 tumor profiles with matched molecular and clinical outcomes data. Caris has also built a network of 25 institutions called the Precision Oncology Alliance in order to aggregate clinical outcome data.

In 2018, the firm profiled close to 30,000 patient tumors and its revenues grew to around $100 million from $68 million in 2017.

Lab Groups Challenge CMS Interpretation of NGS Coverage Decision

A number of clinical laboratory groups are urging CMS to revise what they believe is an overly broad interpretation of Medicare's national coverage determination (NCD) on next-generation sequencing (NGS) for beneficiaries with advanced cancer.

Under the NCD, which was finalized in March 2018, any diagnostic test using NGS that is approved or cleared by the Food and Drug Administration as a companion diagnostic for patients who meet the criteria for recurrent, relapsed, refractory, metastatic and advanced stages III or IV cancer would be covered nationally.

While the NCD was requested for a somatic-based test, CMS has instructed Medicare Administrative Contractors (MACs) to apply the terms of the NCD to both somatic and germline NGS-based testing for patients with cancer. This interpretation will restrict patients' access to medically necessary testing of germline mutations in cancer patients, say the groups in a Feb. 1 letter to CMS Administrator Seema Verma. The letter was signed by ACLA, CAP, the Association for Molecular Pathology and 60 more organizations.

MACs have implemented local coverage determinations (LCDs) that provide coverage for germline testing of cancer when supported by clinical guidelines, including NGS-based tests for germline mutations for breast and colon cancers, the groups note. This NCD will supersede existing LCDs that provide coverage for NGS-based testing for hereditary breast and ovarian cancer syndromes and Lynch syndrome in patients who do not have advanced cancer, they say.

"The implication of this interpretation is both germline and somatic NGS-based testing will become non-covered for Medicare beneficiaries with early-stage cancer," the groups write. "Our organizations believe that the inclusion of NGS-based testing for germline mutations represents significant policy overreach by CMS that will have unintended consequences on the care delivered to Medicare beneficiaries, particularly those who may have a genetic predisposition to cancer based on a family history or other relevant criteria."

Bruce Quinn, Principal at Bruce Quinn Associates, agrees that CMS's interpretation is overly broad, noting that the text of the NCD included remarks that germline testing was out of scope, plus a comment that the NCD did not apply to all types of testing. "However, some sentences of the NCD can be read in isolation—I would say out of context—to give a reading that it applies to all uses of NGS—whether microbiology, germline or anything else—all of which are non-covered."

"Germline testing is covered by any method (Sanger, PCR or NGS) by LCDs in every state," Quinn continues. "Only the NCD intervenes to say that NGS is non-covered. It is nonsensical to take the position that the same patient, with the same medical situation, reading the same gene, finding the same mutation is "medically necessary" if the base pair mutation is found by Sanger but not by NGS. This is especially true since the codes and prices are the same."

The lab groups are asking CMS to revise its current interpretation of the NCD by limiting it to somatic tumor testing and to communicate this change to the MACs.

Spotlight Interview With ARUP's Sherrie Perkins

Sherrie Perkins, MD, PhD

ARUP Laboratories (Salt Lake City, UT) offers more than 3,000 tests, ranging from routine screening tests to molecular and genetic assays. The lab has approximately 4,000 employees and is a nonprofit enterprise of the University of Utah and its Department of Pathology. *Laboratory Economics* recently spoke with Sherrie Perkins, MD, PhD, who became ARUP's Chief Executive Officer in August 2017.

Are volumes and revenues growing?
We process more than 55,000 patient specimens a day. Both volumes and revenues are consistently growing year to year. That's one of the reasons we're building a new facility. Currently, we are a one-site laboratory, but we have outgrown our facility. In September, we broke ground on a new 200,000-square-foot building that will house our specimen processing and highly-automated labs to absorb some of the volume. We're hoping to move into this new facility January of next year.

Tell me more about the standardization you are pursuing.
As an academic medical lab, we have quite a few lab-developed tests, so we've got a great deal of effort going into standardizing our processes, particularly in mass spec and next-generation sequencing, to put them on similar platforms in terms of pre-analytic processing. We think this will help improve efficiency, as well as increase cost savings. We're also hoping to do more automation, which will help with shortages in the med tech area.

Have you been affected by the PAMA Medicare cuts?
We see a little bit of effect, but we are focused on esoteric testing, which hasn't been hit as hard by these cuts as routine testing. However, we're active in terms of lobbying on this important issue.

Any other big initiatives planned for 2019?
We are working hard on an initiative to help our clients understand and communicate the value of lab medicine to healthcare. Many of our clients are facing financial pressures and are sometimes pressured to sell their lab. We've had several clients who have been at risk of being sold, and we've been able to analyze their financial data to prove that they are a profit center not a cost center and that selling the lab might not be beneficial to the owner. We have developed a value model to help our clients demonstrate to the C-suite their value to the health system and patient care.

We're also developing a lot of tools to help with utilization management. One is the IllumiCare Health Ribbon, which is a tool that overlies the electronic medical record that gives up-to-date testing interval and cost information. It also looks at pharmacy and radiology costs. In the places we've put this in, they've seen significant savings. The tool is being rolled out on a client-by-client basis.

Do you have any difficulty with pre-authorization requirements?
We don't have to deal with that a lot because the labs sending us specimens usually have gotten approval. But when we do receive testing that requires pre-authorization we have a team that works directly with payers.

Has the new law "Eliminating Kickbacks in Recovery Act of 2018" changed the way you compensate your sales reps?
We haven't made any changes at this time. However, we are closely monitoring this situation and are waiting to gain further clarification of the law.

What do you see as your greatest opportunity?
To demonstrate the value of being in a relationship with ARUP in terms of service, value and clinical support. We feel we have a good value-based offering that focuses on patient care. We would like lab testing to move away from being viewed as a commodity.

CardioDx Shuts Down Following Palmetto's Non-Coverage Decision

Private-equity-backed CardioDx Inc. (Redwood City, CA) has laid off its 110 employees and is auctioning off the lab equipment at its shiny 40,000-square-foot laboratory in Silicon Valley. CardioDx's closure comes after Palmetto's MolDx program issued a non-coverage policy for its Corus CAD test in early November 2018 and Medicare Part B contractors stopped paying for the test.

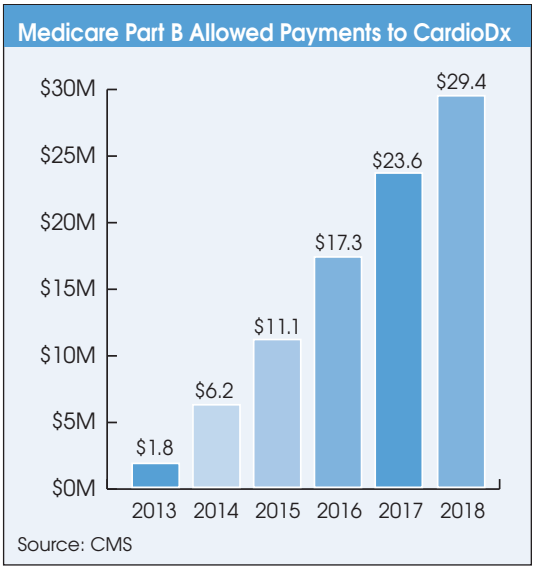
CardioDx's Corus CAD (Coronary Artery Disease) is a blood test that measures the activity of specific genes that changes when there is a significant narrowing or blockage in heart arteries. The test is supposed to help primary care physicians determine if patients with chest pain symptoms actually have CAD, or if their symptoms are caused by non-cardiac sources such as heartburn, muscle spasm, anxiety or lung-related conditions.

Palmetto had initially established coverage for the test in 2012 and Medicare reimbursement for the test (CPT 81493) was currently set at $1,050. Between 2012 and 2017, CardioDx received a total of $90 million in Medicare Part B payments for the test.

But late last year, Palmetto reversed its position and said that "Since initial coverage of the assay, the manufacturer has failed to demonstrate that testing resulted in improved patient outcomes or that testing changed physician management to result in improved patient outcomes."

Coverage decisions made by Palmetto's MolDx program are followed by four out of seven of the nation's Medicare Part B claims processors, including Noridian which processes Part B claims in CardioDx's home state of California. Its coverage decisions affect an estimated 85% to 90% of all molecular tests ordered for the nation's Medicare population.

Palmetto's coverage reversal may have been prompted by separate whistleblower lawsuits filed in federal court in San Francisco by two former CardioDx employees. One lawsuit was filed in 2015, while another was filed in February 2018. Both suits, filed under the False Claims Act, allege that the company defrauded Medicare out of tens of millions of dollars by selling a test that was medically unnecessary. The U.S. Department of Justice reviewed the lawsuits, but filed court papers in November saying it had decided not to pursue the claims.



CardioDx was founded in 2003 and had raised more than $300 million from venture capital firms. Its investors had included Artiman Ventures, GE Capital, Intel Capital, J.P. Morgan, Kleiner Perkins and Longitude Capital. CardioDx had filed papers with the Security Exchange Commission in 2013 for an initial public offering, but withdrew the filing in late 2014 citing unfavorable market conditions.

Miraca To Pay $63.5 Million To Settle False Claims Charges

Inform Diagnostics (Irving, TX), formerly named Miraca Life Sciences, has reached an agreement with the Department of Justice to resolve allegations that it violated the False Claims Act and Anti-Kickback laws by providing referring physicians with funding for EHR systems and services.

The alleged illegal activity took place while Miraca Life Sciences was owned by the Japanese laboratory company Miraca Holdings Inc. The DOJ settlement of $63.5 million is being paid by Miraca Holdings.

The settlement resolves three separate cases brought by different whistleblowers. All three cases were brought in the Middle District of Tennessee. The first was filed by former Miraca Life Sciences' Senior Vice President of Commercial Operations Paul Dorsa in September 2013; the second was brought by a company called LPF LLC in June 2016; and the third was brought in December 2016 by former Miraca Life Sciences' dermatopathologists Michael Heaphy, MD and Brian Hall, MD. In its press release DOJ said that the whistleblowers' share of the settlement had not yet been determined.

The whistleblower lawsuits alleged that, starting in 2012, Miraca gave physician clients discounts on new EHR systems and training on how to use them so long as they reciprocated with referrals. Miraca allegedly only targeted physicians who had a high potential to refer patients.

Miraca Life Sciences was sold to the private equity firm Avista Capital Partners for $177 million in November 2017. Avista has made a number of changes since the acquisition:

- ❑ The company changed its name from Miraca Life Sciences to Inform Diagnostics.
- ❑ A new group of senior executives and board members took over the management of the company and made compliance a top priority.
- ❑ Dana Simonds was hired as Chief Compliance Officer in April of 2018. Simonds reports to the board and manages a new team of compliance staff that includes nine employees.
- ❑ External consultants perform regular compliance and billing audits.

A spokesman for Inform Diagnostics says the company admitted no wrongdoing as part of the agreement with the DOJ and will not be subject to a Corporate Integrity Agreement.

Sonic Healthcare Finalizes Purchase Of Aurora Diagnostics

Sonic Healthcare has completed its previously announced acquisition (see *LE*, December 2018) of 100% of Aurora Diagnostics (Palm Beach Gardens, FL) for $540 million. Aurora has annual revenue of $310 million and operates 32 pathology practices with ~1,200 employees, including ~220 pathologists. Sonic has stated it has no plans to consolidate Aurora's practices.

Quest Completes Acquisition Of BBPL's Clinical Lab Business

Quest Diagnostics has completed its previously announced acquisition (see *LE*, December 2018) of the clinical laboratory services business of Boyce & Bynum Pathology Laboratories (Columbia, MO). Boyce and Bynum will keep control of its anatomic pathology division, Boyce and Bynum Pathology Professional Services Inc., and its nursing home lab division. The anatomic pathology services division, which includes 20 pathologists, will become the exclusive pathology provider for Quest Diagnostics clients in Missouri and a preferred pathology provider in the greater Midwestern region. Financial terms were not disclosed.

Lab Stocks Up 18% Year To Date

Seventeen lab stocks have risen by an unweighted average of 18% year to date through February 12. In comparison, the S&P 500 Index is up 9.5% so far this year. The top-performing lab stocks thus far in 2019 are Veracyte, up 45%; Exact Sciences, up 43%; and NeoGenomics, up 35%. Shares of LabCorp are up 16%, while Quest Diagnostics is up 7%.

Company (ticker)	Stock Price 2/12/19	Stock Price 12/31/18	2019 Price Change	Enterprise Value ($ millions)	Enterp Value/ Annual Revenue
LabCorp (LH)	$146.59	$126.36	16%	$20,340	1.8
Quest Diagnostics (DGX)	89.26	83.27	7%	15,840	2.0
Sonic Healthcare (SHL.AX)	23.65	22.11	7%	12,570	2.3
Exact Sciences (EXAS)	90.15	63.10	43%	10,580	26.5
Guardant Health (GH)	42.03	37.59	12%	3,880	49.8
Myriad Genetics (MYGN)	30.52	29.07	5%	2,372	2.9
Genomic Health (GHDX)	81.72	64.41	27%	2,770	7.3
Opko Health (OPK)	2.83	3.01	-6%	1,750	1.7
NeoGenomics (NEO)	17.00	12.61	35%	1,570	5.6
CareDx (CDNA)	24.44	25.14	-3%	908	13.8
Natera (NTRA)	15.44	13.96	11%	899	3.7
Invitae (NVTA)	14.55	11.06	32%	1,020	8.0
Veracyte (VCYT)	18.30	12.58	45%	684	8.0
Enzo Biochem (ENZ)	3.61	2.78	30%	118	1.2
Psychemedics (PMD)	18.64	15.87	17%	101	2.4
Cancer Genetics Inc. (CGIX)	0.26	0.24	11%	19	0.7
Interpace Diagnostics (IDXG)	0.96	0.80	20%	19	1.0
Unweighted Averages			18%	$75,441	8.2

Source: *Laboratory Economics* and Capital IQ

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