

# LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## PAMA Reporting Period Delay Is Welcome News For Labs

On December 20, President Trump signed into law a spending package that included provisions of The LAB Act. The legislation delays the PAMA private-payer data reporting schedule by one year, in order to give more time for all labs, especially hospital outreach labs, to gather and report data. The new schedule does not change the data collection period (Jan. 1 to June 30, 2019), but does delay the reporting of that data to CMS until Jan. 1 to March 31, 2021.

The reporting delay comes as a big relief to hospital outreach labs. Even the nation's more sophisticated hospital outreach labs were planning to devote substantial billing and IT staff to meet the original deadline. The delay should allow more labs to report more complete and accurate payment data.

Furthermore, the delay will give ACLA a fighting chance to get something out of its PAMA lawsuit with CMS, notes lab industry consultant Dennis Weissman. "The original reporting schedule might have rendered the lawsuit moot. Now it has more time to move through the courts," notes Weissman. *Continued on page 2.*

## Special New Year's Report: Lab Execs Share Outlook For 2020

For an inside look at what may be in store for the clinical lab industry this year, *Laboratory Economics* interviewed the top executives at a diverse group of 11 lab companies. Among the anecdotal trends detected are 1) strong volume growth is offsetting pricing pressure at the nation's largest hospital outreach labs; 2) an anticipated onslaught of hospital outreach lab divestitures has not materialized; 3) both commercial labs and hospital labs are looking for instrument and reagent suppliers to share the pain of PAMA rate cuts; 4) health systems continue to aggressively acquire physician groups to capture referrals, including lab test orders; and 5) several labs noted difficulty in finding qualified lab staff. *Continued on pages 3-8.*

## Some Pathology Groups Dropping Contracts With Anthem Blue Cross of California

Pathology groups and labs are struggling with the drastic rate cuts that Anthem Blue Cross of California put in place last summer. For example, the Anthem BC PPO plan in northern California cut its global rate for CPT 88305 from \$76.08 to \$42.34, while its global rate for 88342 was dropped from \$108.27 to \$44.64. "It's taken a huge financial toll on many labs here, some are terminating agreements with Anthem BC and moving out of network," says one pathology group executive from northern California, who wishes to remain anonymous. *Continued on page 10.*

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## PAMA Reporting Period Delay Is Welcome News For Labs *(cont'd from page 1)*

Julie Khani, President of the American Clinical Laboratory Assn., notes that there was broad bipartisan support for The LAB Act in both the House and Senate. In particular, she cites Rep. Scott Peters (D-CA), who introduced the House bill and raised The LAB Act with Energy & Commerce Committee Chair Frank Pallone (D-NJ) at a committee mark-up meeting earlier this year.

In addition to the delayed data reporting, The LAB Act directs the Medicare Payment Advisory Commission (MedPAC) to conduct a study to review how CMS has implemented the private-payer-based Clinical Lab Fee Schedule (CLFS) under PAMA. As part of this study, MedPAC is to consider the least disruptive ways for CMS to collect data from labs and the most accurate and representative methods to determine payments rates, including the use of statistical methods for estimating rates that are representative of the whole lab market. MedPAC must report its findings to CMS and Congressional committees no later than 18 months from the enactment of The LAB Act (i.e., by late June 2021).

MedPAC is an independent U.S. federal body comprised of 17 members appointed by the Comptroller General of the United States. MedPAC's Chair is Francis Crosson, MD, a former executive at the integrated managed care plan Kaiser Permanente. Its Vice Chair is Paul Ginsburg, PhD, a professor of health policy at the University of Southern California.

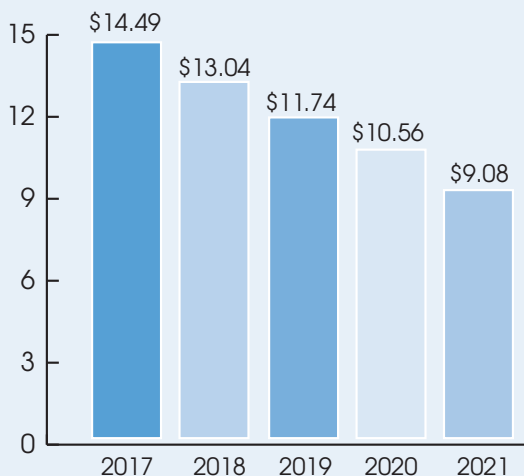
Of course there is no guarantee that MedPAC's study recommendations will be favorable or that they will be acted upon by CMS or Congress.

Furthermore, using statistical sampling methods to capture a representative share of all sectors of the lab market (independents, hospital outreach and POLs) may be extremely complicated, notes *Laboratory Economics*. That's because provider market share can vary widely for each of the 1,000+ CPT test codes on the CLFS.

### Delayed Reporting Guarantees a Fourth Year of Cuts in 2021

The one-year delay in reporting means that CMS will continue to use pricing data from the initial PAMA survey to formulate CLFS rates for 2021. This guarantees rate cuts averaging 10-15% for most high-volume tests next year when the max reduction cap becomes 15%.

#### Medicare Rates for Comprehensive Metabolic Panel (CPT 80053)



Source: CMS

As highlighted in the last issue of *Laboratory Economics*, three straight years of 10% annual rate cuts (2018-2020) have not fully lowered many high-volume lab tests down to the median CLFS rates set by the initial PAMA survey. For example, after three years of the max 10% annual rate reduction, the comprehensive metabolic panel (CPT 80053) will still need another 14% cut next year to reach the median rate determined by the initial PAMA survey.

Any potential benefit from delayed PAMA reporting and the inclusion of more hospital outreach labs won't occur until 2022.

## 2020 Outlook For Labs: 10 Executive Perspectives (*cont'd from page 1*)



**Steve Rusckowski**, Chairman and CEO at **Quest Diagnostics**, says passage of The LAB Act gives CMS an additional year to work with MedPAC and ACLA to recommend a less burdensome data collection process that better reflects commercial market rates, as consistent with the intent of Congress. “It’s important that we get this right, given the excessive cuts we’ve seen to date.”

He notes that the lab industry still faces reimbursement reductions of up to 10% this year and 15% in 2021-2023.

To offset the pricing pressure, Quest is targeting 3% in annual cost savings. For example, Quest is currently finalizing an RFP for its immunoassay platform with plans to move from six instrument vendors to one vendor. The consolidation is expected to save Quest \$35 million per year when fully implemented. “This is not just consolidating our purchases; this is an innovation in the platform where we can do multiple tasks on a single piece of equipment that previously were performed on separate pieces of equipment.”

In addition, Quest is consolidating three regional labs in the greater New York City area through construction of a new 250,000-square-foot flagship lab in northern New Jersey. The new lab, which is expected to raise productivity by 15% and increase capacity by 30%, is expected to become operational in early 2021.

Separately, Rusckowski notes that Quest continues to pursue buying hospital lab outreach businesses as well as contracts to help manage inpatient lab testing. “Conversations with hospital systems are getting broader. ...As a result of this complexity, proposed relationships take longer to develop.”

For full-year 2019, Quest expects to report an approximate 2.5% increase in revenue to \$7.72 billion.



**Tony Bull**, Executive Director of **AdventHealth Lab** (formerly Florida Hospital Laboratories), says AdventHealth’s outreach volume grew by 8% in 2019, while revenue was up 6%. He notes that the PAMA rate cuts are squeezing margins, especially for labs in Florida where Medicare recipients make up more than 20% of the state’s total population.

Over the past year, AdventHealth renegotiated all its lab service contracts with nursing homes. Contract changes included eliminating floating reimbursement rates and adding a la carte fees for stat test services. AdventHealth also put in place better systems to track the mileage of its nursing home phlebotomists and dropped a few contracts with distant nursing homes that were difficult to service, according to Bull.

He notes that AdventHealth’s lab outreach business has its own billing division—distinct from the hospital’s main billing department—giving it a very clear picture of lab outreach revenue, expenses and profitability. Nevertheless, he says that complying with PAMA’s reporting requirements will be a difficult task and that the one-year delay in reporting data to CMS is welcome news.

More good news came late last year when UnitedHealth ended its BeaconLBS Labs-of-Choice network in Florida effective August 31, 2019. AdventHealth looked into joining the Labs-of-Choice network but wasn’t able to agree to the terms with BeaconLBS, notes Bull.

AdventHealth’s lab outreach business serves about 300 physician practices in the Orlando region and is eyeing an expansion of its service area in 2020.

Other goals include establishing more EMR ordering interfaces; about 75% of AdventHealth’s physician clients are currently connected. In addition, Bull says that AdventHealth continues

to focus on improving the patient experience by reducing blood draw wait times, improving parking, and monitoring courtesy of service through patient surveys.

Despite the challenges, Bull says that lab outreach remains a great business for hospitals. “The key is having dedicated management that can consistently demonstrate the value of lab outreach to health system administration.”



**Scott Leighty**, Senior Vice President of Corporate Operations at **Atrium Health** (previously named Carolinas Healthcare System), says that Atrium’s freestanding 27,000 square-foot core labora-

tory is focused on providing reference tests to the health system’s acute care hospitals and outreach lab services to its 3,000 employed physicians. The core lab performed approximately 5.5 million tests in 2019 with 6% growth.

Atrium completed a strategic combination with Georgia-based Navicent Health in early 2019, and plans for a strategic partnership with Wake Forest Baptist Medical Center are being reviewed by the Federal Trade Commission.

Leighty says the PAMA rate cuts have resulted in some margin erosion, so Atrium Health is consolidating its suppliers (chemistry, hematology, reference testing, et al.) and seeking long-term contracts in exchange for lower pricing.

He notes that Atrium plans to have its PAMA data ready to meet the original reporting deadline. “We’re too far into the process to stop now.” He notes that Atrium’s core lab uses the main hospital billing system, but may eventually outsource its billing.

Leighty believes the one-year delay in PAMA reporting should increase overall hospital outreach lab participation.

Over the longer term, Leighty says the key for offsetting pricing pressure will be labs’ ability to perform population health studies and develop analytic tools that guide treatments.

**Adam Schechter** became **LabCorp’s** CEO effective November 1. In a presentation at the recent J.P. Morgan Healthcare Conference, Schechter noted that UnitedHealth recently began offering its Preferred Laboratory Network (PLN) to its self-funded health plan clients, which must decide if they want to add this benefit design change.



The PLN is comprised of LabCorp, Quest Diagnostics, BioReference Labs, Mayo Clinic Laboratory and Invitae. Health plan members that use a PLN lab have zero out-of-pocket payment responsibility. “If it works here, I’d imagine other payers will adopt similar types of programs,” noted Schechter.

“I’m optimistic that over time, as consumers play a larger role in their own healthcare, they will care more about how much money they’re spending,” Schechter said. “If they understand that they can have zero copays or if they use preferred labs they could reduce their costs, I think it could really work.”

On the topic of potential hospital lab outreach acquisitions, Schechter said, “We have a long list of potential opportunities. But it’s been surprising to me on how long it takes. There’s a lot of discussions, hospital by hospital, department by department, and trying to get people to move fast has been harder than I would have anticipated.”

Schechter said LabCorp is especially looking for local hospital outreach labs that can be folded into LabCorp’s existing infrastructure. “I would do as many of those as I could, where we can be accretive in the first year and return our cost of capital within two years typically. We can synergize them, bring them in and put them into our big machine.”

LabCorp expects to report that revenue at its Diagnostics Division declined by -1.5% to -0.5% to roughly \$7 billion in 2019.



Despite seeing PAMA cuts of \$6 million to \$7 million per year, **Sonora Quest Laboratories** (SQL - Phoenix) has been able to reduce costs by an equivalent amount through initiatives aimed

at improving productivity and reducing waste, says **Dave Dexter**, President and CEO. SQL, a joint venture between Banner Health and Quest Diagnostics, performs more than 60 million tests per year.

At any given time, the lab has 20 to 30 business excellence projects underway spanning the gamut from supply chain savings to robotics process automation, explains Dexter. Among one of SQL's most successful projects is its Actionable Insights Management (AIM), through which the lab provides data analytics to improve patient care and outcomes. The lab has partnered with Base Health, a predictive analytics company, to leverage lab data in conjunction with insurance claims data and published clinical research to prospectively identify population health risks, encourage clinical intervention and uncover risk adjustment revenue opportunities.

"We had one accountable care organization use our actionable insight last year to reduce the number of out-of-control diabetics from 11% to 3.5%," says Dexter. "We are close to signing three to four major contracts with payers for access to our data analytics."

Most recently, SQL has partnered with a tech company called uMETHOD Health to collect data on dementia and early onset Alzheimer's patients. Artificial intelligence is then used to interpret the data, and doctors use the findings to come up with personalized plans to manage the progression of the disease; more than 76% of patients show cognitive improvement. In addition, the lab has launched a pharmacogenomics pilot project designed to ensure patients are prescribed the correct drugs to demonstrate why insurers should pay for the PGx testing.

In 2019, SQL saw revenue growth of over 7% due in part to new contracts, but Dexter expects that figure to drop to around 5% in 2020. Growth is driven in part by the organization's direct-to-consumer testing division, which is expanding by about 15% per month.

SQL will move into a new, automated 200,000-square-foot lab in June. The lab will have its own power substation, water source and redundant generators to ensure that function is never compromised.

**Alverno Laboratories** (Hammond, IN) has seen volumes grow about 20% per year in recent years and expects 15% to 20% this year, according to CEO **Sam Terese**.



Revenues are not growing as fast, but still are expected to increase in the double digits. Alverno currently manages 34 hospital labs for the Franciscan Alliance and AMITA health systems in Illinois and Indiana, and has thousands of physician office clients in the Midwest.

"We have invested in custom technologies," says Terese. "Our next big move is robotic process automation. We are taking some traditionally more manual tasks and automating them. In fact, we just launched a pilot to have requisitions be read by machines. It's the next wave of automation."

Alverno is constantly adding new tests to its menu – more than 50 each year. The lab, which has full sequencing capabilities, recently launched a precision oncology program. In addition, Alverno performs toxicology testing for several behavioral health programs.

Digital pathology is also helping to drive growth. Alverno now uses digital pathology for primary diagnosis and reviews more than one million slides per year. "There's not only a cost benefit, but we see other benefits as well, such as assisted interpretations." For patients the biggest benefit just may be the reduction in turnaround time. Not only is the question of "is it cancer or not"

answered quicker, if the answer is “yes,” treatment options can be explored sooner as well. Terese believes that in the near future digital pathology will move into the realm of AI (Artificial Intelligence) which should help reduce turnaround times even more.

Terese does not anticipate any problems in collecting and reporting PAMA data to Medicare although Alverno is implementing a new billing system, which could create some challenges. Another challenge is a shortage in qualified workers, which is driving up wages, he notes.



In response to reimbursement pressure, **Wisconsin Diagnostic Laboratories** (WDL – Milwaukee) is working to improve efficiencies, using data to drive value and pursuing growth areas,

according to CEO **Steve Serota**. WDL serves more than 30 hospitals, 700 long-term care facilities and 250 outreach practices in Wisconsin and the Chicago area. WDL is also the sole laboratory provider for Froedtert Health and the Medical College of Wisconsin.

While WDL has seen about a 4.5% reduction in both federal and private reimbursement recently, the lab has experienced double-digit volume growth in each of the past three years, partly due to actively entering the outreach space. Since the laboratory is close to reaching saturation in the local market, WDL executives have begun looking at regional expansion.

As the lab industry moves from volume to value, WDL is embracing the role laboratory data can play in patient care. “It’s essential for healthcare organizations across the board to have a more data-centric, value-driven care plan model,” says Serota, who notes that WDL is working with its parent, Froedtert Health, to provide back-end data to providers that can be used to improve clinical care plan design and patient outcomes.

WDL also is bringing down operational costs by moving to full automation in chemistry and hematology. “We’ll be able to improve throughput and lower our variable cost per tests,” says Serota. “We’re in the midst of a lab renovation with Roche, and we expect to be live by the end of May.”

WDL’s growth areas include genomic medicine, where the lab is actively involved in informing interventions through a formulary-based approach. In addition, WDL is increasing its test offerings in specialty coagulation and is exploring partnerships and potential acquisitions in toxicology.

One of the biggest challenges WDL faces in the coming year is ensuring that it has the appropriate IT infrastructure and informatics it needs to capture and convert the massive quantity of data it has into usable, clinically relevant information. “We have a strong vision of where we need to go,” says Serota. “We are working to acquire the right resources and assets to bring that vision to life.”



Lab outreach test volume at **Stamford Hospital** in Connecticut is growing by approximately 2-3% per year and totaled more than two million tests in 2019, according to **Robert Babkowski, MD**,

Chair, Department of Pathology at Stamford Health. Growth in the hospital’s Stamford Health Medical Group (SHMG), which has added about 50 physicians in the past two years to reach 170, has contributed to volume growth at the outreach lab, notes Babkowski.

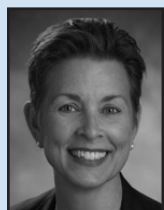
He says that Stamford began compiling its private-payer payment data for CMS more than a year ago and will have it ready under the original CMS schedule. “It was not an easy task, especially separating the hospital outpatient data from the nonpatient outreach data.”

Babkowski believes that the threat of large penalties for non-reporting labs is not being ignored by

hospital compliance departments and will motivate most hospitals to report their PAMA data. However, he also thinks that the nonpatient outreach lab fee schedules at many hospitals are competitive with national lab rates. As a result, he expects that the addition of hospital lab outreach prices won't have much effect on the next CLFS repricing.

Contrary to the expectations of most analysts, only a handful of hospital outreach labs have been sold to the national labs over the past few years. "Unless a hospital has a need for a short-term cash infusion, the sale of the long-term revenue stream from their outreach lab doesn't make sense." Furthermore, Babkowski says that outreach lab testing represents a valuable branding tool for hospitals seeking to expand other outpatient and ancillary services.

Babkowski says the Stamford outreach lab uses the main hospital billing, which does not pursue small lab test claims as aggressively as it should. "If we're going to expand outside of southwest Connecticut, we may need to consider outsourcing our billing."



**ACL Laboratories**, which performs more than 27 million tests per year for the Advocate Aurora Health Care System in Illinois and Wisconsin, has redesigned its outreach business model in response

to the Medicare cuts under PAMA, says President **Barbara Bigler**.

"We have adjusted our client base significantly," she says. "We have moved away from lower-volume clients, and we are requiring electronic orders, to ensure accuracy in our pre-analytical process and overall improved patient safety. We are also shifting toward client billing to mitigate the risk of PAMA. Some of our clients, such as nursing homes and home care agencies, are having trouble paying their bills because they also have been hit by PAMA."

To help offset the reimbursement reductions, ACL has focused on cost reductions through lab auto-

mation, standardization of platforms across the system and bringing most testing in-house. Since it was formed in 2000, ACL has saved \$1 billion by lowering operational costs.

This year, ACL will be transitioning to the Epic Beaker laboratory information system, which Bigler expects will bring increased efficiencies and additional cost savings, as well as an automated way to handle pre-authorization requests. The lab has planned for limited growth this year because of the conversion, but Bigler believes it will be in a better position for growth in future years.

"We're trying to build our client pipeline so we will be ready for growth in 2021," she says. "Last year we grew a little less than 5%. This year we expect 1% to 2%. Standard for ACL is 3% to 5% growth year over year. We follow the growth plan of Advocate Aurora Health Care. Wherever the system expands, we will expand our outreach business as well."

Besides declining reimbursement, one of the biggest challenges ACL faces is finding enough qualified technical staff. While ACL operates its own schools of histotechnology, medical technology and phlebotomy, it still is having difficulty filling positions simply because not enough students are entering the schools. "It's better than it was before we started the programs, but it's still not enough," says Bigler. "I don't know what we would do if we didn't have our own schools, as many universities are closing their med tech programs. There is a real awareness problem about the possibilities and opportunities available in this field."



**TriCore Reference Laboratories** (Albuquerque, NM) is diversifying its revenue stream to mitigate reimbursement pressures, including Medicare cuts under PAMA, says President and CEO **Michael**

**Crossey, MD, PhD**. "When PAMA went into effect, we didn't sit idly by," he notes. "We devel-

oped a diversification strategy to make us PAMA-resistant.”

For example, the TriCore Research Institute (TRI), assists IVD manufacturers with clinical trial testing of state-of-the-art equipment that has not been released to the industry as a whole. Not only does the research testing bring in a new revenue stream, but TriCore’s medical technologists have the opportunity to work with the next generation of testing platforms outside their day-to-day clinical work.

TriCore is also heavily invested in data analytics. In 2015, the lab acquired the Rhodes Group, a clinical IT software and services company. Rhodes technology provides the ability to mine data, analyze it and turn it into insights that can help health plans optimize diagnostic pathways and improve outcomes.

“Managed care providers pay for us for this insight on a per member, per month basis,” says Crossey. “It’s their own claims data, but we are able to provide timely insights in a way that’s useful to them. We have longitudinal records of patients, so we can actually tell them how an individual patient is trending.”

The PAMA cuts have hit TriCore “right between the eyes,” says Crossey. Medicare patients make up 20% of the lab’s market, and Medicaid patients are 35% of the market. While TriCore’s commercial market is shrinking, the lab has pushed back against managed care providers that have tried to tie contracts to a percent of Medicare.

“We can’t weather a hit like that,” notes Crossey. “We have renegotiated our contracts. We are transparent about our revenues with the payers. We’re a not-for-profit, but not a for-loss. The payers don’t want us to go out of business, so

they’ve been willing to work with us.”

For 2020, Crossey anticipates lab volume growth of around 5%, but related revenue growth is expected to be relatively flat. While automation has helped lower labor costs, labor is a big concern going forward. More and more med techs and clinical laboratory scientists are retiring and fewer are coming out of health science programs. “Even with our partnerships with strong laboratory education programs in New Mexico, staffing is definitely something I worry about,” he says.



**Mark Stenhouse**, General Manager of Screening at **Exact Sciences** (Madison, WI), said the company is in the process of hiring another 150 sales reps this month to market its Cologuard screening test. The company currently employs nearly 600 Cologuard sales reps, including 500 reps focused on primary care physicians, 60 reps targeting gastroenterologists and 35 reps selling to health systems. In addition, Exact has a marketing agreement with Pfizer Inc. under which Pfizer’s reps market the Cologuard test.

In a presentation at the recent J.P. Morgan Healthcare Conference, Stenhouse noted, “The number one relationship we see in our sales force and Pfizer’s sales force is that sales force visits to a practicing doctor, the frequency of touches, linearly drives test orders.”

Exact’s Cologuard test volume increased by 80% to reach 1.68 million tests in 2019.

Exact closed on its acquisition of Genomic Health in early November. Exact reported that Genomic Health’s Oncotype DX test volume increased by 14% to 156,000 tests in 2019.

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## NeoGenomics Expands Pharma Services Business With Acquisition

**N**eoGenomics (Fort Myers, FL) has acquired the Oncology Division assets of Human Longevity, Inc. (San Diego, CA) for \$37 million in cash. The acquired Oncology Division performs Next Generation Sequencing services for pharmaceutical customers. The division generated approximately \$10 million in revenue in 2019 and ended the year with a backlog of approximately \$15 million of signed contracts.

NeoGenomics will add 20 employees and sub-lease a lab facility in La Jolla as part of the deal. The acquisition will expand NeoGenomics' existing pharma services menu to include germline, whole exome and whole genome sequencing. NeoGenomics' existing pharma services business currently generates nearly \$50 million of annual revenue and is growing by roughly 25% per year.

The acquisition, which closed on January 10, is expected to be slightly dilutive to NeoGenomics' 2020 earnings before becoming accretive in 2021.

## DermTech's Pigmented Lesion Assay Gets Medicare Coverage

**D**ermTech (La Jolla, CA) received a Proprietary Laboratory Analyses CPT code (0089U) for its Pigmented Lesion Assay in late October, according to CEO John Dobak, MD. Medicare reimbursement has been set at \$760 per test effective January 1.

The Pigmented Lesion Assay (PLA) is a non-invasive gene expression test used for early melanoma detection. The test uses an adhesive patch, about the size of a quarter, that is applied across an entire skin lesion. The tape removes the very upper layer of the skin, called the stratum corneum. RNA is then extracted from the collected skin cells and RT-PCR is used to assess the expression level of two specific genes, PRAME and LINC00518, associated with melanoma. If one or both of the target genes is detected, the test is positive.

Dobak notes that gene expression changes are detectable before physical changes to a skin lesion occur. In two validation studies comparing the PLA test to traditional histopathology diagnosis (n=398), the PLA demonstrated a sensitivity of 91%, a specificity of 69%, and a negative predictive value of 99%. The PLA reduces the probability of missing melanoma to less than 1% (compared to 16% for early stage melanoma with visual assessment and histopathology), according to Dobak.

DermTech performs the test at its CAP-accredited lab in southern California. DermTech is marketing the test directly to dermatologists through 22 employed sales reps. Dobak plans to double the sales rep staff by year's end.

Challenges include educating the nation's 12,000 dermatologists on the benefits of the PLA test. There is also a small economic disincentive because the PLA test eliminates the need for a dermatologist to perform and bill for a biopsy procedure (-\$100). However, dermatologists that perform the PLA test can bill for a Level IV office visit versus a Level II visit, notes Dobak.

With financial backing from RTW Investments, HLM Venture Partners, and Irwin Jacobs, a co-founder of Qualcomm, DermTech came public by merging with a dormant publicly traded company (Constellation Alpha Capital) in early September.

DermTech reported billable test volume of 3,596 for the three months ended September 30, 2019, up 18% compared to 3,043 for the same period in 2018. Test revenue increased to \$385,000 from \$321,000.

### **Some Pathology Groups Dropping Contracts With Anthem** (*cont'd from p. 1*)

Anthem BC comprises an estimated 10% to 20% of the payer mix for most pathology groups in northern California.

Our anonymous pathology executive notes that Anthem BC denied a request to negotiate a separate contract with less severe rate cuts and also denied a request to delay the cuts. As a result, his pathology group has given Anthem BC notice of its plans to terminate its contract and become an out-of-network (OON) provider.

Other providers in northern California have also decided enough is enough, and are moving to OON with Anthem, according to the pathology executive. “We can’t just sit here and accept those kind of rate cuts. Other insurers are watching and might do the same thing. We have to make a stand now.”

The new pathology rates at Anthem BC, which took effect July 1, 2019, are equivalent to less than 50% of current Medicare rates in northern California. In contrast, Anthem BC pays OON providers at 125% of Medicare fees. “It may make some patients unhappy because they’ll be paying out-of-network fees, but we still think it’s worth it to go out of network,” the pathology executive told *LE*.

Anthem BCBS has encountered similar pushback from pathology groups in other states, including Missouri and Virginia, that resulted in some concessions from the insurer (see *LE*, October 2019).

### **Shareholder Vote To Decide Enzo’s Fate**

**T**he activist hedge fund manager Harbert Management Corp. (Birmingham, AL) is seeking to replace two board members at Enzo Biochem (New York City) with its own nominees. A shareholder vote at Enzo’s annual meeting on January 31 will decide the matter. Harbert has an 11.8% stake in Enzo making it the company’s largest shareholder. Harbert acquired its stake in Enzo from May to August 2019 at prices ranging from \$3.07 to \$3.65 per share.

Enzo’s board has five members and is led by Elazar Rabbini, PhD, age 76, an original founder who has served as the company’s Chairman and CEO since its inception in 1976. Harbert wants to replace board members Barry Weiner, 69, who is President of Enzo, and Bruce Hanna, PhD, 76, an independent director who is Clinical Professor of Pathology and Clinical Professor of Microbiology at the New York University School of Medicine. Rabbini owns a 4% stake in Enzo, while Weiner has a 2.8% stake.

Harbert’s two nominees are Fabian Blank, 45, who is former CEO of Meduna Klinik Group in Germany and a former McKinsey consultant, and Peter Clemens, 54, who has held CFO positions at Caremark Rx and Surgical Care Affiliates. If both are elected, Harbert would control 40% of Enzo’s board.

Harbert says that Enzo’s stock has underperformed for years as a result of a bloated cost structure and poor strategy. Harbert wants Enzo to: 1) sell its drug development business and non-core patents; 2) relocate its headquarters from Madison Avenue to its laboratory in Long Island; and 3) focus its clinical lab business on the greater New York City market. Harbert has created a website (CureEnzo.com) to convince Enzo shareholders to vote for its two board nominees.

Meanwhile, Enzo management has countered that Harbert’s board nominees: 1) have irrelevant experience; 2) declined an opportunity to participate in a standard interview process; and 3) are likely to promote Harbert’s short-term objective of driving a fire sale of Enzo’s assets at depressed valuations.

## Top 25 Fastest-Growing Independent Labs

Surprisingly, Vista Clinical Diagnostics (Clermont, FL), which specializes in testing for nursing home clients, was the fastest growing laboratory company for the five-year period (2012-2017) based on Medicare Part B payments, according to an analysis by Laboratory Economics. Vista grew its Medicare Part B revenue from \$105,338 in 2012 to \$12.9 million in 2017 for an average annual growth rate of 162%. Vista sold its physician office client business to LabCorp in late 2017, but kept its nursing home business (see *LE*, November 2017).

In general, genetic testing labs (7 labs) and toxicology labs (also 7 labs) dominated the list of fastest-growing independent labs. Two anatomic pathology labs (Theranostix and PathGroup Labs) and one hospital-owned outreach lab (Alverno Laboratories) made the list.

Overall, the nation's roughly 2,800 independent labs increased their Medicare Part B payments by an average of only 0.3% per year between 2012 and 2017.

### Top 25 Fastest Growing Independent Labs by Medicare Part B Payments (2012-2017)

Laboratory Name	Location	Lab Type	Total Medicare Payments 2017	Total Medicare Payments 2012	CAGR 2012-2017
Advanced Clinical Laboratories Inc. (dba Vista Clinical Diagnostics)	Clermont, FL	nursing home lab	\$12,898,312	\$105,338	161.6%
BioReference/GeneDx Inc.	Gaithersburg, MD	genetic testing	7,336,612	160,493	114.8
Exagen Diagnostics	Vista, CA	autoimmune testing	7,875,351	182,126	112.4
Oral Cancer Prevention International (dba CDx Diagnostics)	Suffern, NY	genetic testing	11,950,168	475,706	90.5
CardioDx	Palo Alto, CA	genetic testing	28,803,814	1,798,795	74.1
MD Spine Solutions LLC.	Reno, NV	toxicology	7,883,780	648,227	64.8
Ambry Genetics Corp.	Aliso Viejo, CA	genetic testing	30,559,445	2,681,901	62.7
Cap Diagnostics (dba Pathnostics)	Irvine, CA	women's health/UTI testing	13,177,173	1,428,334	56.0
Compass Laboratory Services	Memphis, TN	toxicology	7,104,762	1,042,957	46.8
Theranostix Inc.	Beltsville, MD	anatomic pathology	5,257,324	939,340	41.1
Veracyte Inc.	So. San Francisco, CA	genetic testing	18,959,071	3,836,008	37.7
Clearpoint Diagnostic Laboratories	Lewisville, TX	flow cytometry	\$7,628,437	1,863,909	32.6
NeoGenomics Laboratories	Aliso Viejo, CA	flow cytometry	15,427,104	4,302,239	29.1
Peachstate Health Management LLC.	Gainesville, GA	toxicology	5,248,081	1,549,624	27.6
Empire City Laboratories	Brooklyn, NY	allergy testing	9,461,205	2,823,078	27.4
American Forensic Toxicology Services	Huntington, NY	toxicology	5,909,256	1,810,514	26.7
Myriad Genetics/Assurex Health	Mason, OH	genetic testing	31,477,282	9,846,215	26.2
Accu Reference Medical Lab	Linden, NJ	nursing home lab	17,385,490	5,790,925	24.6
Cleveland Heartlab Inc.	Cleveland, OH	advanced lipid testing	12,740,897	4,328,501	24.1
LabCorp	Rsrch. Triangle Pk, NC	toxicology lab division	5,497,619	2,130,514	20.9
PathGroup Labs	Nashville, TN	anatomic pathology	18,756,056	7,332,935	20.7
Drugscan Inc.	Horsham, PA	toxicology	5,492,085	2,157,335	20.5
Logan Laboratories	Tampa, FL	toxicology	6,645,684	2,637,363	20.3
Professional Clinical Laboratories (dba Alverno Laboratories)	Hammond, IN	hospital outreach lab	6,635,106	2,768,833	19.1
Agendia Inc.	Irvine, CA	genetic testing	7,869,478	3,298,346	19.0
Total for Top 25 Labs			\$307,979,592	\$65,939,554	36.1
Total ~2,800 Independent Labs			\$4,915,139,544	\$4,837,552,234	0.3%

Source: *Laboratory Economics* and Medicare Part B Carrier Payment Data (2012-2017)

## Lab Stocks Up 37% In 2019

Twenty lab stocks rose by an unweighted average of 37% in 2019. In comparison, the S&P 500 Index was up 32%. The top-performing lab stock in 2019 was Natera, which soared 141%, followed by NeoGenomics, up 132%. Shares of LabCorp were up 34%, while Quest Diagnostics was up 28% (total return was 32% including dividends).

Company (ticker)	Stock Price 12/31/19	Stock Price 12/31/18	2019 Price Change	Market Value (\$ millions)	Annual Revenue (Est'd 2019)	Market Value/Annual Revenue
LabCorp (LH)	\$169.17	\$126.36	34%	\$16,629	\$11,540	1.4
Quest Diagnostics (DGX)	106.79	83.27	28%	14,630	7,730	1.9
Sonic Healthcare (SHL.AX)	28.75	22.11	30%	13,685	6,100	2.2
Exact Sciences (EXAS)*	92.48	63.10	47%	13,616	1,265	10.8
Guardant Health (GH)	78.14	37.59	108%	7,290	206	35.4
NeoGenomics (NEO)	29.25	12.61	132%	3,155	406	7.8
Natera (NTRA)	33.69	13.96	141%	2,611	302	8.6
Myriad Genetics (MYGN)	27.23	29.07	-6%	2,015	807	2.5
Invitae (NVTA)	16.13	11.06	46%	1,542	219	7.0
Veracyte (VCYT)	27.92	12.58	122%	1,357	120	11.3
Opko Health (OPK)	1.47	3.01	-51%	978	877	1.1
CareDx (CDNA)	21.57	25.14	-14%	914	127	7.2
Castle Biosciences (CSTL)	34.37	16.00	115%	587	46	12.8
Exagen (XGN)	25.40	14.00	81%	319	41	7.9
DermTech Inc. (DMTK)**	12.40	6.50	91%	148	3	52.1
Enzo Biochem (ENZ)	2.63	2.78	-5%	125	81	1.5
Psychedics (PMD)	9.15	15.87	-42%	51	38	1.3
Interpace Biosciences (IDXG)	0.50	0.80	-38%	19	31	0.6
Cancer Genetics Inc. (CGIX)	5.96	7.20	-17%	13	9	1.4
Biocept (BIOC)	0.29	0.86	-66%	12	5	2.2
Unweighted Averages			37%	\$79,697	\$29,954	2.7

\*Revenue estimate for Exact Sciences includes full-year proforma revenue estimate for acquisition of Genomic Health.

\*\*DermTech share price results are for August 29 through December 31, 2019.

Source: *Laboratory Economics* and Bloomberg

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