

# LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## **Anthem Makes Some Small Concessions In “Rate Alignment” Strategy**

**A**nthem BCBS in Missouri has increased its rates for a handful of key surgical pathology codes (CPT 88300-88309 and 88341 & 88342) following widespread criticism from Missouri pathologists, CAP and ASCP. For example, Anthem BCBS of Missouri had cut the professional component for CPT 88305 by nearly 80% from \$66 to \$14.43 effective November 1, 2018 (see *LE*, May 2019). However, effective August 12, 2019, Anthem raised its rate for 88305-26 in Missouri up to \$34.49. That’s equivalent to exactly 88% of what Medicare pays for 88305-26 in Missouri. Anthem has similarly revised its professional component rates for the other key surgical pathology codes in Missouri to 88% of Medicare.

*Continued on page 2.*

## **Primary Care Docs Likely To Get More At Expense Of Pathologists And Other Specialists In 2021**

**M**edicare’s Proposed Physician Fee Schedule Rule for 2020 would basically hold steady the reimbursement rates for professional pathology services, while slightly increasing technical fees (see *LE*, August 2019). However, the outlook for 2021 isn’t as sanguine. That’s because CMS has proposed to redistribute roughly \$7 billion of annual Medicare Part B payments to primary care physicians (e.g., family practice, internal medicine, rheumatology, et al.) and away from certain specialists (e.g., pathology, ophthalmology, radiology, et al.). CMS estimates that the proposed redistribution will result in an across-the-board 8% cut to pathologist professional rates and a 4% cut to pathology lab technical rates in 2021.

*Continued on page 3.*

## **Florida Cancer Specialists Opens Expanded Pathology Lab**

**F**lorida Cancer Specialists & Research Institute (FCS—Fort Myers, FL) has opened a new 50,000-square-foot pathology laboratory in Fort Myers that is more than double the size of its previous pathology lab. The for-profit and physician-owned FCS is the largest independent oncology/hematology practice in the United States. The new pathology lab will serve FCS’s 230 physicians located at 99 offices throughout Florida. It will also provide testing services to American Oncology Network LLC (AON—Fort Myers). AON was formed by FCS and a group of its physician owners in late 2017 with the goal of acquiring oncology/hematology practices outside of Florida. *Continued on page 4.*

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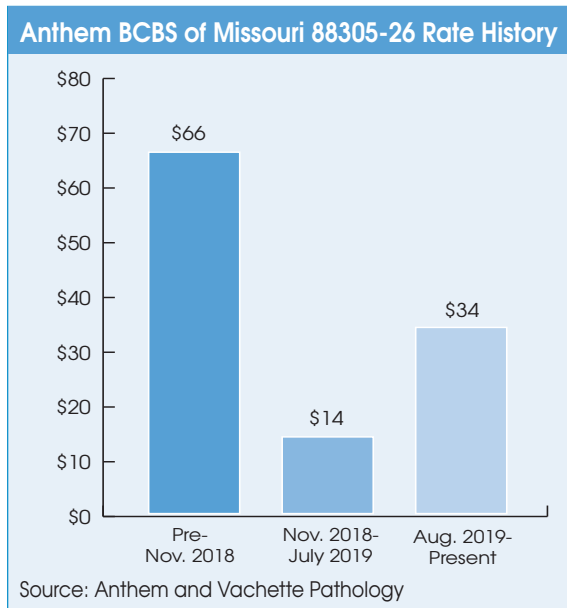
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### **Anthem Makes Some Small Concessions** *(cont'd from page 1)*

However, these codes (CPT 88300-88309 and 88341 & 88342) were the only services that Anthem revised in Missouri—with no reprocessing of claims paid under the previous lower rates implemented 11/1/18. In addition, all other pathology codes (e.g., flow cytometry, special stains, FISH, et al.) remain as originally cut—significantly below Medicare.



Anthem BCBS of Missouri had been ground zero for Anthem Inc.'s new national rate alignment strategy that equalizes reimbursement rates for clinical lab and pathology services regardless of whether the service is provided by a hospital-based provider or independent lab. Over the past year, Anthem has been rolling out new rate schedules across its BCBS plans in 14 states resulting in big cuts for hospital-based pathologists and labs.

Mick Raich, CEO of Vachette Pathology (Sylvania, OH), notes that the rate changes have af-

ected pathologists and labs covered by Anthem's standard rate schedule for in-network providers. Larger pathology groups and labs that have unique separately negotiated contracts with Anthem have not been affected by the change. "Smaller hospital-based pathology groups have been hit the hardest," observes Raich.

### **Pathologists Opting Out in Ohio**

So far, Missouri is the only state where Anthem has made reimbursement concessions. However, pathologists en masse in Ohio are terminating their contracts with Anthem in response to rate cuts. In fact, the pathologist drop-out rate in Ohio has been so widespread that Anthem has twice delayed the effective date of its new rates in that state.

Anthem BCBS in Ohio had initially planned for its new pathology and clinical lab fee schedules to take effect July 10, 2019. While Anthem's new rate for 88305-26 in Ohio was scheduled to increase by a few percent to \$53, most other key pathology codes were set to decline by 70% to 80%, according to Chris Condon, General Manager of Practice Management at APS Medical Billing (Toledo, OH).

Anthem notified pathology groups in Ohio of the planned changes in April. The great majority of pathologists responded by exercising "material change" clauses in their contracts and gave notice to Anthem of their plans to drop out of network. As a result, Anthem delayed its planned changes in Ohio to October 14, and has announced a second delay pushing back the effective date until December 1.

Condon says it's not clear what Anthem will do to remedy the situation in Ohio. The most likely option would be for Anthem to give rate concessions on at least some pathology codes, he notes.

### **Pushback in Virginia**

Anthem has also encountered strong pushback in Virginia, where several hospital-based pathology groups have dropped out of network in protest of rate cuts that became effective September

1, 2019. In a letter to Anthem, The Virginia Society of Pathology warned that the reductions were “the most aggressive in history, and are likely to result in closure or considerable reduction in hospital-based pathology services.”

In late July, for example, Dominion Pathology Associates (DPA-Roanoke, VA) publicly announced it was terminating its contract with Anthem BCBS of Virginia. The group noted that some of Anthem’s cuts represented reductions of as much as 65%, were equal to only one third of current Medicare rates and, in some cases, did not even cover the cost of services.

DPA is a hospital-based group with seven pathologists that is affiliated with Carilion Clinic. On September 4, Anthem announced that it had reached a new agreement with DPA that kept the group in-network. Pathologists at DPA were not available for comment. *Laboratory Economics* can only assume that Anthem provided DPA with improved rates to keep this key group under contract.

Meanwhile, Anthem has not budged for many smaller pathology groups in Virginia that have opted to go out-of-network. In these cases, Anthem is directing providers to send their pathology specimens to larger contracted pathology labs in Virginia, including Quest Diagnostics, Sonic/Aurora’s Greensboro Pathology and PathGroup.

### Primary Care Likely To Get More At Expense Of Pathologists (*cont’d from p. 1*)

Budget neutrality rules require that if Medicare significantly increases physician payments (>\$20 million per year) for some services, they must be offset by an equal amount of cuts from other services.

CMS has proposed increasing reimbursement rates for the evaluation and management (E&M) office/outpatient visit codes (CPT 99202-99215) billed by primary care doctors. The agency also plans to introduce a new add-on G-code that primary care doctors can tack on to most patient encounters. These spending increases will be offset by across-the-board cuts to specialties, such as pathology, that generally do not perform or bill for E&M services.

A similar shift in payments had been proposed by CMS in late 2018 for an effective date of January 1, 2019. However, strong pushback by the College of American Pathologists (CAP) and other specialist groups led CMS to delay the redistribution by two years.

#### Proposed Medicare Rate Changes for 2021

##### Specialists that Get Hurt

Pathology Lab Technical Rates .....	-4%
Anesthesiologists .....	-7%
Pathologists .....	-8%
Radiologists .....	-8%
Cardiac surgery .....	-8%
Ophthalmologists .....	-10%

##### Specialists that Benefit

Physician Assistants.....	+7%
Nurse Practitioners.....	+8%
General Practice .....	+8%
Family Practice .....	+12%
Rheumatologists .....	+15%
Endocrinologists.....	+16%

Source: CAP and CMS

In their comment letters to CMS on the proposed rule, CAP and the American Society for Clinical Pathology (ASCP) made a number of suggestions aimed at mitigating the proposed cuts to pathologists and pathology labs.

- Urge Congress to provide updates to the Medicare conversion factor to offset the proposed redistribution.
- Apply budget neutrality adjustments uniformly across all specialties and services.
- Withdraw the new add-on G-code for primary care doctors.
- Provide a five-year phase-in of the proposed rate changes.

The Medicare Physician Fee Schedule Final Rule is expected to be released in early November.

## Florida Cancer Specialists Opens Expanded Pathology Lab *(cont'd from page 1)*

FCS was founded by a sole oncologist, William Harwin, MD, in 1984. During its first 15 years, FCS grew slowly, but steadily, reaching 48 physicians by year-end 2008. Then in 2009, FCS hired Brad Prechtel as its Chief Executive. Prechtel's previous experience included executive positions at the practice management firms Phycor Inc. and U.S. Oncology. Over the past 10 years, Prechtel has accelerated FCS's growth, largely by practice acquisitions, to reach its current 230 doctors (plus 220 physician extenders, including physician assistants and nurse practitioners).

### Insourcing Pathology Lab Services

The growth strategy at FCS has also included bringing as many ancillary services as possible in-house, including pathology lab services. FCS opened its own flow cytometry testing lab in 2010 and then a full-service histology lab with immunohistochemistry and FISH testing in 2012-2013. The growth at FCS and the anticipated growth at AON led to the construction of the new lab facility. Currently, the FCS lab, which is located on the first floor of the new lab building, has a total of 80 employees, including six hematopathologists and one surgical pathologist. It processes approximately 12,000 flow cytometry cases, 5,000 bone marrow biopsies and 3,000 surgical pathology cases plus 13 million clinical lab tests per year. NeoGenomics (Fort Myers) provides courier/logistic support to the FCS lab and also acts as its primary reference lab for molecular testing.

### Growth Expected from American Oncology Network

The AON lab is located on the second floor and serves new practices outside of Florida that are being



Ryan Olson, MD

acquired by AON. Over the past year, AON has acquired nine oncology practices in eight states (AR, IA, IN, KY, LA, NV, OH and VA) with a combined 50 physicians and 10 nurse practitioners. Its largest acquired practice so far is Zangmeister Cancer Center (Columbus, OH), which has 15 physicians. AON anticipates adding five additional practices in four states by January 1.

FCS's pathologists and lab staff currently serve AON on a contracted basis, although eventually AON will have its own dedicated staff, according to Ryan Olson, MD, Medical Director for the pathology labs at both FCS and AON. Over the next few years, Olson anticipates that AON and its lab will grow to be bigger than FCS.

### Benefits of an In-House Pathology Lab

Olson says that being part of the FCS and AON practices allows pathologists to provide a faster and higher quality of service to referring physicians.

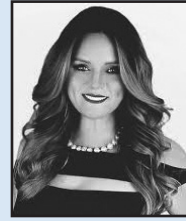
- **Highly personal communication.** "We know our referring oncologists personally, and we're on call 24/7 by text, cell and email for questions or stat requests."
- **A high volume of specialized work that builds expertise.** "Over the past five years, I've done as many bone marrow biopsies as my mentor in hematopathology did in 20 years."
- **Direct access to EMR and patient medical history.** "I always have a patient's EMR open on one computer screen while reviewing a flow cytometry case on an adjacent screen."
- **Faster turnaround time.** "Seventy-five percent of flow cytometry results are delivered the day after specimen pickup and 100% within 48 hours. IHC results are delivered within 2-3 days."

## West Cancer Center Opens In-House Pathology Lab

West Cancer Center & Research Institute (WCC—Germantown, TN) recently opened a full-service in-house pathology lab in Collierville, TN (a suburb of Memphis) in August. The new lab is headed by David Robbins, MD, who joined West Cancer Center in January 2019 to develop the lab and serve as its Medical Director. Robbins was formerly with Memphis Pathology Group. WCC employs more than 100 physicians and nurse practitioners. The new lab processes patient samples obtained from WCC Interventional Radiology, Margaret West Breast Center, and other WCC offices in Tennessee, Mississippi and Arkansas.

## Butterworth's Take On The Laboratory M&A Market

**M**elissa Butterworth started her lab career in 1993 as a sales representative for Consolidated Lab Services, an outreach lab owned by Ascension's St. Vincent Medical Center (Jacksonville, FL). Over the next 24 years, she worked her way up to Vice President of Managed Care and Southeastern Sales V.P. at Dynacare Laboratories, which was acquired by LabCorp in 2002. In 2007, she left LabCorp/Dynacare to co-found, along with Dan Lucky, the M&A consulting firm Advanced Strategic Partners (ASP-Miami, FL). Over the past 12 years, ASP has helped close more than 60 clinical, anatomic, molecular and hospital outreach lab transactions valued at more than \$1.3 billion. Butterworth is also author of the recently published book *The End Game: The Laboratory Owner's Exit Strategy*. Below we summarize Butterworth's thoughts on several key topics in today's laboratory M&A market.



*Melissa  
Butterworth*

### ***Laboratory M&A activity has not been as active as many experts had predicted given the pricing pressure related to PAMA. Why not?***

It's become a buyer's market. Pricing pressure has scared away most potential private equity buyers. Meanwhile, the strategic buyers, including Quest Diagnostics, LabCorp, Sonic Healthcare, NeoGenomics, PathGroup and Eurofins, are still making deals, but have become more selective.

### ***Many analysts thought PAMA would motivate health systems to sell their outreach labs, but not much has happened.***

Health systems move slowly. While it takes an average of about nine months to complete an independent lab transaction, hospital outreach lab deals typically take two years to close. There will probably be more hospital outreach M&A activity in the next three years, than there has been in the past three years.

### ***What's the ideal acquisition candidate look like in the eyes of a strategic buyer like Quest or LabCorp?***

An independent lab with no legal or compliance issues and \$10 million or more in annual revenue that can be consolidated into an existing lab. Buyers are also wary of labs that are overly dependent on one particular client (15% or more) or payer (40% or more).

In terms of hospital outreach lab transactions, a long-term contract to provide reference testing services to the selling hospital system is a very important component of the agreement.

### ***What can labs do to increase their value prior to a sale?***

Get your financial statements in order. Potential buyers will want access to at least three years of your lab company's income statements, cash flow statements and balance sheets that, preferably, have been certified or reviewed by an outside accounting firm.

In addition, potential buyers will want to review all documents related to your lab's articles of incorporation, lease documents, insurance contracts, employee contracts, CLIA certification, etc. In total, they'll want to review 450 to 500 different documents and this level of scrutiny often surprises and overwhelms sellers.

For example, sellers should be prepared to provide a random two-week period of requisitions. Potential buyers will analyze each requisition from initial order to payment.

The number one reason that can cause a potential lab sale to fall apart is the inability of the seller to meet the buyer's documentation requests. These documents should be gathered, orga-

nized and placed into a secure web-based document management system prior to taking the lab to the market.

***What are your thoughts on non-compete clauses?***

Sellers should expect a three- to five-year non-compete as part of the sale.

***What about contingent consideration (i.e., earnouts)?***

It's best to get the money upfront. About 20% of the deals we've helped negotiate have involved earnouts, and only a small minority (~5%) of those wound up getting the full earnout payment. The problem is that the seller has no control over the business after it's sold and there can be subjectivity in how the new owner calculates earnout benchmarks like revenue and EBITDA (earnings before interest, taxes, depreciation and amortization).

***In a straight cash deal, what kind of valuation can an independent clinical lab reasonably expect from a sale in today's market?***

There are a myriad of variables that affect valuation, but independent clinical labs are typically sold for a range of between 5-8 times their EBITDA or between 1-2 times annual revenue.

***What's your advice for buyers?***

There is so much time and attention spent on reaching a purchase agreement that the transition services agreement and planning is frequently neglected. Too often key employees, especially sales reps, at the acquired lab fear layoffs and will seek new jobs at competitors right after a deal is announced. The buyer needs to identify and communicate with the most productive employees they want to retain immediately after a deal is made public.

### Laboratory Acquisition Summary (latest 12 months through 10/15/19)

Date	Buyer	Target	Purchase Price	Acquired Revenue	Price/Revenue
Pending	Exact Sciences	Genomic Health	\$2,540	\$452	5.6
Oct-19	Quest Diagnostics	True Health	8.5	66	0.1
Sep-19	LabCorp	South Bend Medical Foundation	NA	80	NA
Sep-19	PathGroup	Southeastern Pathology Associates	NA	NA	NA
Jul-19	siParadigm	Cancer Genetics lab business	1	6	0.2
Jun-19	Precision IBD	Prometheus Laboratories	NA	NA	NA
Jun-19	Eurofins Scientific	Transplant Genomics	NA	NA	NA
May-19	PathGroup	Pathologists Bio-Medical Labs	NA	NA	NA
Apr-19	Unipath LLC	Cedar Diagnostics	NA	2.5	NA
Apr-19	LabCorp	Metropolitan Medical Laboratory	NA	NA	NA
Mar-19	LabCorp	MNG Laboratories	NA	NA	NA
Mar-19	Predictive Technology Group	Taueret Laboratories	10	NA	NA
Feb-19	Quest Diagnostics	Boyce & Bynum clinical lab division	61	NA	NA
Jan-19	ICON Plc.	MolecularMD	42	NA	NA
Jan-19	Sonic Healthcare	Aurora Diagnostics	540	310	1.7
Dec-18	Health Network Labs	Connective Tissue Gene Tests	NA	NA	NA
Dec-18	NeoGenomics	Genoptix	140	100	1.4
Dec-18	Gamma Healthcare	Boyce & Bynum nursing home division	NA	NA	NA
Dec-18	LabCorp	American Clinical Laboratories	NA	NA	NA
Dec-18	Pike Street Capital	US BioTek Laboratories	NA	NA	NA
Nov-18	Quest Diagnostics	Oxford Immunotec	170	66	2.6
Nov-18	Quest Diagnostics	Marin General Hospital outreach lab	NA	NA	NA

Source: Laboratory Economics

## Spotlight Interview With UniPath's General Manager Joe Zimmerman

UniPath (Denver, CO), which purchased Cedar Diagnostics (Durango, CO) in April, now offers comprehensive clinical laboratory testing to clients in Colorado and nearby states. UniPath is owned by American Pathology Partners (AP2 – Nashville), which in turn is primarily owned by New Enterprise Associates (NEA), a private equity investment firm. *Laboratory Economics* recently spoke with Joe Zimmerman, AP2's Chief Operating Officer and General Manager at UniPath.



### *Tell me about UniPath.*

UniPath has been around for 25+ years in one form or another. We are one of the five laboratories owned by AP2. Currently we have about 150 employees and eight pathologists. We have dense market share in Colorado, but we also serve the other mountain states—Wyoming, Montana and New Mexico. We also have a fair amount of business in Kansas, Oklahoma and Arizona. With our acquisition of Cedar Diagnostics, we also have some hospital directorships and some clinic-based work coming out of Utah.

UniPath historically had been a hospital-based group that also had a robust outreach market. We offered outreach pathology services in OB/GYN, family practice and dermatology. In 2019 that changed, and we moved our focus to an outreach full-service clinical and anatomic pathology lab. We have five hospitals we serve as medical directorships in eastern Colorado and in the four corners area (where Arizona, Colorado, New Mexico and Utah meet). Our main hospital relationship is with HCA—we provide technical laboratory services for two of the larger HCA hospitals in Denver.

### *Does UniPath operate its own technical lab?*

We have a 30,000-square-foot lab in Denver doing histology, IHC, non-gyn cytology, Pap smears and flow cytometry. We also have a massive molecular department. We perform many FDA-approved STD tests, but we also have a robust LDT (laboratory-developed test) laboratory. We perform those for our clients here in Denver, but also for the other laboratories that are part of the AP2 network. We also have several other women's health laboratories around the country that send us their molecular testing. And we do a lot of technical flow cytometry for Presbyterian St. Luke's Cancer Hospital here in Denver.

### *Who do you use as your reference laboratory?*

Locally, we use Colorado Genetics and Children's Hospital. For almost everything else we use NeoGenomics.

### *What has UniPath been seeing in terms of insourcing by specialty groups (derm, urology, gastro)?*

The pure insourcing we're not seeing as much because the health plans have figured it out. But it's not gone completely. The further you go west, the more you see dermatologists reading their own cases. We have several clients that we support with technical services or as a reference laboratory.

### *Do you use digital pathology? What do you use it for?*

We do. We have an APERIO scanner. We use it for quantification of breast panels. We are not using it for primary diagnostics. Its main function is to help us meet the turnaround time expectations of our pathology clients both internal and external. We review the scanned slides the same day and then send the glass slides for final review the next day. I do see digital pathology playing a much bigger role going forward, but I don't see it taking over completely for glass slides. The speed of the scanning is getting better, and costs are coming down. From a service level, there are definite advantages.

***What are your thoughts on future use of artificial intelligence to increase pathologist productivity?***

We're all anxious to see when it will become widely available so pathologists in the commercial setting can start to utilize it and form opinions. There certainly will be efficiencies, especially for routine, high-volume cases. We're all for anything that will help us deliver better quality and efficiency for our patients and clients. I think pathologists are interested in it, but most have not had any exposure to it yet.

***Why did you acquire Cedar Diagnostics, given the pricing pressure from PAMA?***

We're definitely feeling pricing pressures in pathology, too. The acquisition allowed us to expand our service offerings and to round out our menu to become more competitive and get more business from our current clients.

It made sense to bring on Cedar Diagnostics because we are leveraging our current infrastructure—we have more than 20 couriers, a strong client services staff, sales and marketing, so we did not have to invest in all of the overhead we needed to offer clinical laboratory services to our clients.

We also wanted to buy Cedar's expertise—they have a solid group of managers, technicians, and pathologists. When we acquired them, Cedar had about 20 employees and generated between \$2 and \$3 million per year in revenue. This first year we expect to grow that business by 25-30%.

***Are your volumes growing? What about revenues?***

We do about 70,000 surgical cases a year, 100,000 Pap smears and 375,000 molecular tests.

Because we changed our focus this year, we are able to focus on outreach and grow that business more. We're seeing nice growth in outpatient volume. We are expecting to end 2019 with double-digit growth in our outreach business

***What new molecular tests has UniPath added recently?***

We just added the BD MAX Enteric Solutions portfolio (bacterial, parasite and viral panels). We're always adding to our OB/GYN menu – we recently added an aerobic vaginitis panel.

***What do you see as the greatest challenges facing UniPath and pathology in general?***

Reimbursement and pressure by health plans to narrow networks. The other thing we struggle with is the misperception that pathology is a commodity because we don't see patients in our office. We see a pathologist as a specialist physician, just like a neurologist or an oncologist. Conveying that is one of our bigger challenges.

## **ACLA Needs Speedy Favorable Judgment As Next PAMA Reporting Period Nears**

**T**he window for the U.S. Dept. of Health and Human Services (HHS) to ask for a rehearing from the U.S. Court of Appeals has expired, and so ACLA's PAMA lawsuit has been sent back to Judge Amy Berman Jackson at D.C. District Court (see *LE*, August 2019). A schedule for ACLA's summary judgment motion has been set. The earliest that Judge Jackson can issue a decision is mid-January next year. Speed is important. Ideally, Judge Jackson would issue a summary judgment that halts PAMA's upcoming private-payer payment rate reporting period (January 1 through March 31, 2020).

**Key Upcoming Milestones in PAMA Lawsuit**

ACLA's summary judgment motion due.....	Oct. 14, 2019
HHS/CMS's opposition and cross-motion due.....	Nov. 22, 2019
ACLA's reply and cross-opposition due.....	Dec. 13, 2019
Medicare CLFS rates for 2020 take effect (most codes cut by 10%).....	Jan. 1, 2020
HHS/CMS's cross-reply is due.....	Jan. 10, 2020
Labs to report PAMA pricing data to CMS.....	Jan. 1, 2020 through Mar. 31, 2020
CMS to publish preliminary CLFS rates for 2021-2023.....	summer 2020

Source: *Laboratory Economics* and D.C. District Court



## Harbert Pushes For Change At Enzo

**F**unds managed by Harbert Management Corp. (HMC-Birmingham, AL) have purchased an 11.8% equity stake in Enzo Biochem Inc. (New York City) and nominated two new independent directors—Fabian Blank and Peter Clemens—to Enzo’s board. Enzo currently has a five-member board and the next annual shareholders meeting will take place in early January 2021.

In a September 17 letter to Enzo’s shareholders, Harbert said, “For decades, Enzo has operated as a ‘lifestyle business,’ where management has seemingly placed its own personal and financial interests ahead of its shareholders’ best interests.” Harbert noted that Elazar Rabbani, PhD, age 75, has served as Enzo’s Chairman and CEO since he founded the company in 1976, while his brother-in-law Barry Weiner, 68, is President, CFO and board member.

Over the past 10 years (ended August 31), Enzo’s total shareholder return has been -36% versus +199% for the Russell 2000 Index of small cap stocks and +337% for its peer group of lab and biotech companies, according to Harbert. In addition, Harbert notes that Enzo has reported operating losses every year since 2004, with cumulative negative operating income of \$180 million, excluding legal expenses and settlements.

Harbert wants Enzo to sell its drug development division as well as non-core patents in its diagnostic products division.

Harbert says Enzo should focus on its clinical lab division, which operates a 44,000 square-foot lab in Long Island and 30 PSCs in New York and New Jersey. Focusing on the densely populated New York City area and prudently cutting costs could return Enzo’s lab segment to profitability, according to Harbert.

In the nine months ended April 30, 2019, Enzo’s clinical lab division recorded an operating loss of \$13.3 million versus operating income of \$2.7 million for the same period a year earlier; revenue fell by 32% to \$38 million as a result of pricing pressure related to PAMA and lower genetic testing volume due to increased competition.

## Exagen Raises \$58 Million From IPO

**E**xagen Inc. (Vista, CA) completed an IPO on September 23, raising gross proceeds of \$58 million from the sale of 4.14 million shares at \$14 per share. Net proceeds were approximately \$54 million after deducting the underwriting discounts and commissions and other IPO expenses. Cowen, Cantor Fitzgerald and William Blair managed the IPO.

Exagen operates an 8,000-square-foot CAP-accredited lab in southern California. The company’s main product is a laboratory-developed test named AVISE CTD that was commercially launched in 2012. AVISE CTD is a blood test panel that can help doctors diagnose lupus, an autoimmune disease that occurs when your body’s immune system attacks its own tissues and organs. Exagen has a total of about 150 employees, including 55 sales reps who market AVISE CTD to 5,000 rheumatologists across the United States. Under an exclusive agreement, Exagen’s reps also market Janssen’s drug Simponi for the treatment of adult patients with moderate to severe rheumatic arthritis.

In the six months ended June 30, 2019, Exagen recorded a net loss of \$9.8 million, unchanged from the same period a year earlier; revenue was up 35% to \$19.7 million; and average reimbursement per AVISE CTD test increased by 5% to approximately \$325 per test. The company has accumulated total losses of \$158 million since being formed in 2002.

## Quest Diagnostics Buys Assets From Bankrupt True Health

**T**True Health and its parent company THG Holdings have finalized a bankruptcy court-approved sale of their assets to Cleveland HeartLab, a subsidiary of Quest Diagnostics, for \$8.5 million.

The deal did not include True Health's 100,000-square-foot lab in Richmond or its hundreds of employees. True Health acquired the Richmond lab when it purchased the assets of bankrupt Health Diagnostic Laboratory (HDL) for \$37 million in late 2015.

HDL went bankrupt in 2015 after agreeing to pay \$47 million to settle allegations that it defrauded Medicare and Medicaid by paying kickbacks to doctors in exchange for ordering its lipid test panels.

True Health filed for bankruptcy in July (see *LE*, August 2019) after CMS suspended all Medicare payments to the company based on "credible allegations of fraud." According to an ongoing investigation by the OIG, True Health had set up labs inside rural hospitals that receive higher rates of reimbursement from Medicare. From there, OIG investigators claim that True Health engaged in a kickback scheme by enlisting doctors into Management Service Organizations (MSOs) that incentivized them to send patient samples to the rural hospital labs. The OIG investigators say that these physicians never had privileges with or visited the rural hospitals, and never provided their patients with a choice as to where to send their lab tests.

A Quest spokesman says that Quest chose not to acquire True Health's facilities, staff, or accounts receivable "nor will we adopt its policies and business practices." Essentially, Quest has purchased True Health's client list and some instruments and supplies.

In the seven-month period January 1 through July 31, 2018, True Health recorded revenue of \$38.5 million, equal to an annual rate of \$66 million, according to its bankruptcy filings. If Quest's Cleveland HeartLab can retain a fraction of True Health's clients and revenue, then the \$8.5 million purchase price will be a huge bargain, observes *Laboratory Economics*.

True Health is majority-owned by the private-equity firm The Riverside Company (New York City), while Founder and CEO Chris Grottenthaler has a 6% stake. True Health has \$173 million in total liabilities. Its largest secured creditors are Monroe Capital Management (owed \$123 million) and Riverside Strategic Capital (owed \$34 million). True Health had initially filed for Chapter 11 bankruptcy reorganization in July, and is now likely headed for Chapter 7 liquidation.

## uBiome Headed For Chapter 7 Liquidation

**U**Biome Inc. (San Francisco), which filed for Chapter 11 bankruptcy reorganization in early September, has moved to a liquidation under Chapter 7, after unsuccessful attempts to secure new loans or find a buyer.

The company was founded in 2012 and had marketed its top-selling SmartGut test directly to consumers by email and online ads. Patient test orders were signed off by remote physicians via a telemedicine service. SmartGut is a stool test that costs \$2,970 and purportedly identifies microbes in the gut for patients with chronic gut conditions such as irritable bowel syndrome and Crohn's Disease.

In late April, the FBI raided uBiome's headquarters to investigate allegations that the company may have billed insurers using inaccurate codes to increase the likelihood of coverage and higher reimbursement. More recently, it's come to light that the patient database used to validate Smart-

Gut was populated by samples volunteered by employees and participants in an online fundraiser and were tainted by a number of specimens taken from infants and pets.

## Ratliff To Head LabCorp's Diagnostic Testing Division

LabCorp has announced that John Ratliff, age 59, will become head of its diagnostic testing business effective November 1, coinciding with LabCorp CEO David King's retirement from this position. Ratliff is currently the CEO of Covance, LabCorp's drug development business.

As previously announced, Adam Schechter, 54, a LabCorp board member and former Executive Vice President at Merck, is taking King's position as LabCorp's President and CEO (see *LE*, June 2019). King, 62, will stay on as Chairman of LabCorp through at least the end of 2020.

## DOJ Charges 35 People In Genetic Testing Scam

The U.S. Department of Justice (DOJ) has charged 35 people across the nation for allegedly billing Medicare for more than \$2 billion of unnecessary cancer genetic tests (CGx). Among those charged were three lab owners and nine telemedicine doctors.

Based on Medicare payments, the biggest alleged offender is Minal Patel, age 40. Patel founded a lab company named LabSolutions (Atlanta, GA) in 2013. LabSolutions initially focused on toxicology testing, then switched mostly to CGx testing in 2016.

According to the DOJ, Patel's lab company solicited medically unnecessary CGx tests from Medicare beneficiaries through telemarketing and health fairs. The tests were then approved by telemedicine doctors who allegedly did not engage in treatment of the beneficiaries, and often did not even speak with the patients for whom they ordered tests. In addition to the charges, the government seized approximately \$30 million in bank accounts from Patel, as well as luxury vehicles, including a Ferrari and a Range Rover.

The latest available data from CMS shows that LabSolutions received \$59.3 million of Part B payments in 2017. It tested 16,651 Part B beneficiaries and was paid an average of \$3,561 per beneficiary. Its highest volume codes were the ambiguous CPT 81405 (Molecular pathology procedure, Level 6) and CPT 81406 (Molecular pathology procedure, Level 7).

Other labs named by the DOJ in the alleged scam are Acadian Diagnostic Laboratories (Baton Rouge, LA), CLIO Laboratories (Lawrenceville, GA), Performance Labs (Oklahoma City, OK) and Lazarus Services (New Orleans, LA).

### Labs Named By DOJ In Alleged Genetic Testing Scam: Medicare Part B Data from 2017

Laboratory Name	Owner/Age	Location	Medicare Beneficiaries Tested	Total Medicare Payment Amount	Average Payment Per Beneficiary
LabSolutions LLC	Minal Patel, 40	Atlanta, GA	16,651	\$59,302,111	\$3,561
Acadian Diagnostic Laboratories	Kevin Hanley, 42	Baton Rouge, LA	13,331	\$7,159,046	\$537
CLIO Laboratories	Khalid Satary, 47	Lawrenceville, GA	996	\$4,684,399	\$4,703
Performance Laboratories	Khalid Satary, 47	Oklahoma City, OK	756	\$549,189	\$726
Lazarus Services	Khalid Satary, 47	New Orleans, LA	NA	NA	NA

Source: U.S. Department of Justice and CMS

## Lab Stocks Up 29% Year To Date

Nineteen lab stocks have risen by an unweighted average of 29% year to date through October 11. In comparison, the S&P 500 Index is up 19% so far this year. The top-performing lab stock thus far in 2019 is Natera, which has soared 165%, followed by Veracyte, up 101%, and Guardant Health, up 64%. Shares of LabCorp are up 31%, while Quest Diagnostics is up 24%.

Company (ticker)	Stock Price 10/11/19	Stock Price 12/31/18	2019 Price Change	Enterprise Value (\$ millions)	Enterp Value/ EBITDA	Enterp Value/ Annual Revenue
LabCorp (LH)	\$165.76	\$126.36	31%	\$23,430	12.4	2.1
Quest Diagnostics (DGX)	103.52	83.27	24%	18,370	12.4	2.4
Sonic Healthcare (SHL.AX)	28.63	22.11	29%	15,910	16.3	2.6
Exact Sciences (EXAS)	92.50	63.10	47%	11,560	NA	18.6
Guardant Health (GH)	61.56	37.59	64%	5,220	NA	36.0
Natera (NTRA)	37.06	13.96	165%	2,520	NA	9.2
Genomic Health (GHDX)	68.74	64.41	7%	2,380	41.8	5.5
Myriad Genetics (MYGN)	29.51	29.07	2%	2,280	22.2	2.7
NeoGenomics (NEO)	19.73	12.61	56%	2,000	42.3	5.8
Invitae (NVTA)	17.99	11.06	63%	1,590	NA	9.0
Opko Health (OPK)	2.05	3.01	-32%	1,480	NA	1.6
CareDx (CDNA)	28.15	25.14	12%	1,120	NA	10.9
Veracyte (VCYT)	25.30	12.58	101%	1,020	NA	9.4
Castle Biosciences (CSTL)	19.67	16.00	23%	391	154.4	11.3
Enzo Biochem (ENZ)	3.66	2.78	32%	115	NA	2.0
Psychemedics (PMD)	9.10	15.87	-43%	48	5.7	1.2
Interpace Diagnostics (IDXG)	0.82	0.80	2%	30	NA	1.2
Cancer Genetics Inc. (CGIX)	0.16	0.24	-31%	15	NA	0.5
Biocept (BIOC)	0.80	0.86	-7%	9	NA	2.3
Unweighted Averages			29%	\$89,488	38.4	7.1

Source: *Laboratory Economics* and Capital IQ

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