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Competitive Market Analysis For Laboratory Management Decision Makers

HHS Says Its New CLFS Rates Can't Be Challenged

The U.S. Department of Health and Human Services (HHS) says that ACLA's lawsuit challenging its definition of the term "applicable laboratory," is simply a "circuitous challenge" to Medicare's new Clinical Laboratory Fee Schedule (CLFS) rates established under The Protecting Access to Medicare Act of 2014 (PAMA), and is therefore barred.

In its response to ACLA's lawsuit, HHS cited PAMA statute (§ 1395m-1(h)(1)), which bars any "administrative or judicial review" to the "establishment of payment amounts" in the new private-payer-rate-based CLFS.

HHS has asked U.S. District Judge Emmet Sullivan to deny ACLA's request for a summary judgment that would force CMS to reinstate 2017 CLFS rates and recalculate new rates based on a broader segment of the lab industry that includes private-payer data from hospital outreach labs. *Continued on page 2.*

Medicaid Rate Reductions Compound Medicare CLFS Cuts In Ohio and Missouri

Effective January 1, the Ohio Medicaid program reduced its fee-for-service lab test rates to a maximum of 75% of Medicare CLFS rates; pathology services are limited to 75% of the Medicare Physician Fee Schedule. In addition, payment amounts for clinical laboratory, molecular pathology, and pathology procedures are reduced by 5%, also effective January 1. Previously, lab test rates for Ohio Medicaid had been set at approximately 91% of Medicare.

Similarly, the MO HealthNet Division (aka Missouri Medicaid) reduced fee-for-service lab test rates to 80% of the most current Medicare CLFS rates effective January 1. Previously, they had been set at 100% of the Medicare CLFS.

As previously reported, many managed Medicaid plans are also using cuts to the 2018 Medicare CLFS as an excuse to lower rates paid to contracted labs. *Continued on page 3.*

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HHS Says Its New CLFS Rates Can't Be Challenged (*cont'd from p. 1*)

Judge Emmet Sullivan

The HHS response said that the U.S. Court of Appeals for the District of Columbia Circuit recently rejected a virtually identical attempt to plead around a jurisdictional bar in the Medicare statute (see Florida Health Sciences vs. Secretary of HHS (D.C. Circuit 2016)). In that case, Florida Health Sciences (dba Tampa General Hospital) argued that it could challenge the agency's choice of data it used to calculate a hospital's Disproportionate Share Hospital (DSH) payments. HHS noted that the court rejected this attempt, holding that "the dispositive issue is whether the challenged [action is] inextricably intertwined with an action that all agree is shielded from review, regardless of where that action lies in the agency's decision tree."

Furthermore, HHS said that it logically defined "applicable laboratory," in part, as a laboratory that actually receives Medicare revenues by billing under its own National Provider Identifier (NPI) number. "Plaintiff offers no workable alternative definition, let alone one clearly superior to that in the agency's Final Rule," according to HHS.

HHS excluded virtually all hospital labs from reporting their private-payer data to CMS by defining an "applicable laboratory" as a laboratory that bills Medicare under its own National Provider Identifier. Most hospital labs do not have their own NPI.

HHS noted that during the rulemaking process, ACLA and others had recommended defining "applicable laboratory" based on CLIA certification. However, HHS said that CLIA certificates are not associated with Medicare billing and—unlike the NPI—cannot be used to identify revenues for specific services.

HHS said that ACLA's lawsuit, if successful, would "undo years of painstaking effort" by the agency in both the rulemaking process and the corresponding data-collection process. "Enjoining the new fee schedule would inject considerable confusion into the CLFS payment system, and would conceivably require the agency to reanimate the previous fee schedule, with its numerous separate rates for different localities and potentially outmoded payment amounts." The PAMA law included statutory language "expressly precluding judicial review to avoid such disruption," according to HHS.

Finally, HHS says that ACLA's repeated citation to a colloquy between Senators discussing the intent of PAMA to include all sectors of the laboratory market, including hospital labs, is irrelevant. This exchange (citing 160 Cong. Rec. S2860, May 8, 2014) occurred over one month after PAMA was enacted and is an unreliable guide to legislative intent that should not be taken seriously, according to HHS.

"If Congress truly wished to collect private-payer data from 'all sectors of the laboratory market,' as Plaintiff contends, then it could simply have mandated that any and all laboratories report private payer data," according to HHS.

In an April 6 filing responding to HHS's arguments, ACLA said the case of Florida Health Sciences vs. Secretary of HHS is not comparable because Congress did not require HHS to select the data it used through a separate public notice-and-comment rulemaking process. In contrast, Congress in PAMA required HHS to develop regulations for data-reporting requirements that were subject to the public notice-and-comment rulemaking process.

"The Secretary asserts that granting relief would 'undo years of painstaking effort' by the agency. But that disruption is only a consequence of the agency's refusal to comply with the statute and respond seriously to the hundreds of comments it received during the notice-and-comment process," according to ACLA.

ACLA said that just because it might be difficult to determine the revenue attributable to a hospital laboratory "does not mean that the Secretary was free to just throw up his hands and rewrite the statutory requirements."

The final rule saddled many ACLA's members with substantial data collection costs and the threat of civil penalties while unlawfully exempting their direct competitors [hospital outreach labs] from reporting requirements, according to ACLA. For example, satisfying the reporting requirements cost ACLA member Quest Diagnostics almost $2 million and took approximately 240 people eight weeks to complete.

ACLA reiterated its request for a summary judgment that would force HHS to rewrite the final rule so that hospital labs are required to report their private-payer rates. It may be a long shot, but if granted, the 2018 CLFS would revert back to the 2017 rates.

A final rebuttal from HHS is due to be filed on April 20. And a decision from Judge Sullivan is likely to come by the end of May.

Alternatively, ACLA and HHS could potentially reach a compromise settlement that keeps the current Medicare CLFS intact, but requires CMS to include hospital outreach lab data in the next data-collection period (scheduled for January 1, 2019 to June 30, 2019).

Medicaid Rate Reductions Compound Medicare CLFS Cuts (*cont'd from page 1*)
In a March 9 letter to CMS, Julie Khani, President of ACLA, warned that laboratories serving Medicaid recipients are already facing unprecedented reimbursement cuts in both the Medicare and Medicaid programs. Medicare rates for most high-volume lab tests were lowered by 10% in 2018, and face additional 10% cuts in both 2019 and 2020 under the PAMA repricing.

Khani noted that since most state Medicaid programs already base their rates on the Medicare CLFS, state Medicaid programs will realize significant savings in laboratory services without taking any action of their own. In addition, Medicaid programs by law are not allowed to pay more than the Medicare CLFS for any particular test.

"The recent reductions in Medicaid reimbursement for laboratory tests recently adopted by some states, layered on top of PAMA reductions, will reduce Medicaid reimbursement for laboratory services to a level that will threaten patient care," wrote Khani. She has urged CMS Administrator Seema Verma to educate state Medicaid agencies about the PAMA cuts by issuing a State Medicaid Director letter and Informational Bulletin. In addition, where a state plan amendment is required to implement rate reductions, Khani has urged CMS to reject such proposed amendments.

Top 25 Hospital-Based Outreach Laboratories For 2016

Everyone knows that hospital-based outreach labs represent a substantial segment of the lab market competing to provide lab testing services to physician offices.

There were some 3,000 hospital-based labs that received $25,000 or more of Medicare CLFS payments for outreach lab services in calendar-year 2016. However, this portion of the lab market was essentially unrepresented in the payment calculations used by CMS to determine the new market-based Medicare CLFS rates for 2018-2020.

The table below lists the top 25 hospital-based outreach labs as measured by Medicare CLFS payments in 2016. The list provides insight into some of the larger hospital-based outreach labs that were not represented when CMS made its market-based rate calculations.

Top 25 Hospital Outreach Labs by 2016 Medicare CLFS Payments

Hospital Name	*Location*	*Beds*	*Total CLFS Revenue 2016*
New York-Presbyterian Hospital/ Weill Cornell Medical Center	New York, NY	2,408	$12,130,530
Northwestern Medicine Central DuPage Hospital	Winfield, IL	395	11,383,878
Carolinas Medical Center	Charlotte, NC	1,185	9,918,964
Saint John Hospital and Medical Center	Detroit, MI	636	8,006,528
Beaumont Hospital	Royal Oak, MI	1,071	7,419,420
Memorial Hermann - Texas Medical Center	Houston, TX	960	7,380,296
Sentara Norfolk General Hospital	Norfolk, VA	525	7,205,650
The Mount Sinai Hospital	New York, NY	1,107	7,012,832
Northwestern Memorial Hospital	Chicago, IL	887	6,683,590
The Cleveland Clinic	Cleveland, OH	1,285	6,641,085
Evanston Hospital	Evanston, IL	789	6,185,502
Cedars-Sinai Medical Center	Los Angeles, CA	879	6,059,016
Sparrow Regional	Lansing, MI	623	5,744,277
Baystate Medical Center	Springfield, MA	713	5,445,768
Sarasota Memorial Hospital	Sarasota, FL	750	5,433,200
Huntsville Hospital	Huntsville, AL	897	5,415,648
Beaumont Hospital Dearborn	Dearborn, MI	632	5,316,930
Abbott Northwestern	Minneapolis, MN	661	5,114,040
Florida Hospital Orlando	Orlando, FL	2,635	5,037,228
Strong Memorial Hospital	Rochester, NY	818	4,941,760
Charlton Memorial Hospital	Fall River, MA	867	4,565,967
NYU Langone Medical Center Tisch Hospital	New York, NY	1,044	4,484,473
Duke University Hospital	Durham, NC	940	4,440,162
Indiana University Health Methodist Hospital	Indianapolis, IN	1,287	4,280,196
The University of Texas M.D. Anderson Cancer Center	Houston, TX	660	4,223,457
Total, top 25 hospital-based outreach labs			**160,470,397**
Total, all hospital outreach labs			**$1,768,000,000**

Note: The above list does not include hospital-owned independent labs that bill through their own NPI, such as ACL Laboratories, ACM Medical Labs, DMC University Labs, Health Network Labs, Northwell Health Labs, Regional Medical Laboratory, Scripps Health, Sutter Valley Medical Foundation, Tricore Reference Labs, et al.
Source: *Laboratory Economics from The U.S. Clinical Laboratory Industry Forecast & Trends 2018-2020*

CMS Releases Advanced Diagnostic Laboratory Test Application Process

On March 23, CMS released the long-awaited application and designation process for Advanced Diagnostic Laboratory Tests (ADLTs) as required by the market-based payment reforms enacted under PAMA. ADLTs get special treatment under PAMA, including unique billing codes and Medicare payments at their actual list price during the first nine months of their launch.

Unlike the rest of the laboratory industry, The Coalition for 21st Century Medicine (C21) strongly supported PAMA because of the preferential treatment given to ADLTs. C21 is comprised of a small group of genetic testing labs and their private equity investors.

"C21 commends CMS for finalizing the ADLT application and designation process," said Hannah Murphy, Executive Director of C21. "We believe the ADLT process can serve as a catalyst for innovative tests that benefit patients by personalizing critical medical treatment decisions."

To qualify as an ADLT an assay must be offered by a single laboratory and demonstrate that it provides new clinical diagnostic information.

As previously noted, new ADLTs will be paid at a rate equal to their actual list charge during an initial period of three calendar quarters. After the initial period, the payment amount for a new ADLT will be based on the weighted median of private-payer rates from data collected by the laboratory. Under this pricing system, lab companies introducing new ADLTs might game the system by setting high initial list prices and then marketing their test to the best, or most ignorant, private payers. Medicare will then set their rate based on this skewed information.

Meanwhile, the special treatment being given to ADLTs has allowed proprietary lab testing companies to raise hundreds of millions of dollars since the 2018 CLFS and ADLT designation were finalized last fall. Over the past six months, C21 members alone have raised more than $250 million from private equity investors and new loan agreements (see table).

Capital Raised By C21 Members, October 2017-March 2018

C21 Member	Location	Test Product	Recent Funding
Biocept	San Diego	Circulating tumor cell and DNA assays	Raised net proceeds of $13.3 million from public offering on January 30, 2018.
Bioarray Genetics	Farmington, CT	BA100 breast cancer test	Raised $4 million in Series B equity financing from Quark Ventures and GF Securities in October 2017.
Biodesix Inc.	Boulder, CO	VeriStrat for patients with non-small cell lung cancer (NSCLC)	Raised $1.5 million from a Series G preferred shares sale and entered into a debt refinancing agreement with Innovatus Capital Partners for a $23 million loan in early March 2018.
CareDx	Brisbane, CA	AlloMap and AlloSure tests for transplant patients	Converted $26.3 million of outstanding notes owned by JGB Collateral LLC. to 6.1 million shares of CareDx common stock in March 2018.
Counsyl	South San Francisco	Prelude Prenatal Screen	Raised $80 million in financing from life sciences investment firm Perceptive Advisors in November 2017.
Foundation Medicine	Cambridge, MA	Foundation One genomic profiling assays	Received $30 million in new borrowings in late 2017 under the company's Credit Facility Agreement with Roche Finance.
MDxHealth	Irvine, CA	ConfirmMDx test for prostate cancer	Raised $44 million from the sale of 10 million new shares of common stock.
VeraCyte	South San Francisco	Afirma thyroid FNA analysis	Completed a $35 million senior secured credit facility.
Grand Total			$257.1 million

Source: *Laboratory Economics* from companies

Spotlight Interview with Aculabs' President Peter Gudaitis

Aculabs (East Brunswick, NJ) and its 277 employees provide lab testing services to 370 long-term care (LTC) facilities (nursing homes and assisted living facilities) in New Jersey, Eastern Pennsylvania, Maryland and Delaware. *Laboratory Economics* recently spoke with Peter Gudaitis, President.

Peter Guidaitis

Would you describe the current state of the nursing home lab market?
Yes, we started as a one-man operation in 1972; however we have experienced continued growth, especially within the last couple of years. There have been major events which have aided in our growth, such as this past December when other providers closed their doors or left the market. Hospitals and other non-specialized labs don't want to service this market because it isn't cost-effective for them. There are only five or six laboratories in the country that solely focus on LTC – that's it. This group services roughly 40% to 50% of all the LTC facilities in the country.

What are your volume and revenue trends?
Revenues for 2015 and 2016 were relatively flat. Volume and revenues picked up in 2017. We are seeing a major uptick in 2018 because of increased market share although Medicare payment levels for lab tests are down. Due to the nature of the testing we perform, Aculabs was hit with a full 10% reduction. Unlike genetic testing, very few of our CPT codes saw an increase.

To what extent are the cuts under the new CLFS fee schedule impacting your bottom line?
Currently, it's a struggle, but when next year comes, it's going to be much more difficult. We are doing more but getting less, although Aculabs is in a better position than most because we only have two major revenue streams – Medicare Part B and Medicare Part A. We have offset some of the cuts by moving to a quality-of-service model where facilities pay a slightly higher rate for superior service.

What has Aculabs done to reduce costs since the Medicare cuts were announced?
We continue to examine service levels. We look at how many times we go to a facility to make sure we are able to cost-justify the phlebotomy service (our largest expense). By evaluating necessary service levels, it's allowed us to become more efficient. In addition, our partners have assisted us in becoming more operationally efficient. For example, our instrument manufacturers have been particularly helpful by reducing costs, extending terms, and providing more efficient equipment.

Have private payers started to make proportionate cuts to their lab fee schedules?
We receive a small percentage of our revenues from private payers. We haven't seen any cuts in their reimbursement yet, but I suspect that they will be coming soon.

How do you envision the nursing home lab market will evolve over the next three to five years?
I believe the market will become even more specialized. Those that specialize will continue to gain market share while those that dabble in the market will exit. We are seeing this within the area we serve. As hospital laboratories are managed by large commercial labs like LabCorp and Quest, I expect more hospitals will close their doors to nursing home outreach as well.

Why haven't LTC facilities built their own inhouse clinical labs?
Some have tried but it in this region it has not worked. It isn't a very effective use of space and maintaining a 24 hour laboratory operation is quite expensive. When you tack on the issues of billing and decreased reimbursement, it really is not a viable option for them.

What are your thoughts on potential mergers between nursing home lab companies?
I don't see that happening because there are geographical limitations. A lab can only go so far to draw blood and still maintain a reasonable turnaround. As acuity in sub-acute care increases, clinicians need faster turnaround times, not slower. Scaleability is difficult due to the logistical challenges we face.

What do you see as your biggest opportunity in the current lab market?
Diversification. There are opportunities for labs that are willing to diversify and look at other revenue streams related to the LTC market. For example, we started a mobile radiology division in late 2014. We provide services in New Jersey and Pennsylvania and it has helped offset some of the Medicare payment cuts.

We are now moving into point of care testing within the nursing home. We're partnering with Abbott and have created what we call a "Point of Care Program." We handle orders, results and EMR integration, as well as provide training and support. Real-time result verification ensures clinicians treat with accuracy. We have several facilities using this service and are rolling out 10 more in the second quarter of 2018. Point of care is the next evolution of lab services for LTC.

MolDx LCD Development Slowing Under New Law

Implementation of new local coverage determinations (LCD) have slowed significantly as a result of the 21st Century Cure Act, signed into law at the end of 2016, according to James Almas, MD, MolDx Medical Director for Palmetta GBA. Almas, a board-certified pathologist, replaced former Medical Director Elaine Jeter, MD, in spring of 2017.


James Almas, MD

Under the law, as of June 11, 2017, Medicare Administrative Contractors (MACs) are required to publish a summary of evidence that they considered when developing an LCD. If a national coverage determination (NCD) does not exist or address coverage for a product or service, MACs may develop their own coverage policies.

"Those changes have added a burden to us so that we have to weigh our evidence in a separate way," said Almas during the annual meeting of the American Clinical Laboratory Association in March. "We have to put LCDs in a format that is more similar to NCDs. We have to send an LCD to CMS (the Centers for Medicare and Medicaid Services) 21 days prior to it being posted, and then we hold an open meeting with carrier advisory committees. Then there is a 45-day comment period. We have to address each of those comments, and those are published in an article."

Almas says he holds monthly conference calls with medical directors from other MACs to discuss coverage policies, as well as regular calls with carrier (or contractor) advisory committees (CACs). There are about 42 CAC members who work with Palmetto, and the MAC is constantly recruiting new members, noted Almas.

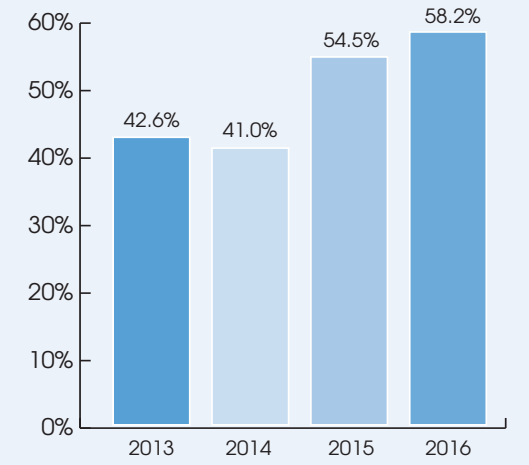
Almas advises those seeking coverage for their tests to focus on clinical utility first before they focus on analytical validity. "Clinical utility as defined by Medicare is really something you have to hone in on," he says. "Craft your studies so that they are rock solid."

The MolDx program, run by Palmetto GBA, currently covers JE, JF, JM, J15, JJ, J5 and J8. Altogether, more than 30 states and territories are subject to MolDx coverage decisions. More than 90 percent of Medicare payments for molecular testing are covered by the program, according to estimates. A list of MolDx LCDs is available on the MolDx website at www.palmettogba.com/MolDx.

High Denials Still Plague MDx Testing Market

The percentage of molecular diagnostic (MDx) test claims denied by Medicare Part B contractors in 2016 jumped to 58.2%, according to an exclusive analysis of the latest available Part B data by Laboratory Economics. That compares with an average 54.5% denied MDx test claims in 2015 and 41% in 2014, and it towers above the average 5% to 10% denial rate for routine lab tests.

Medicare Part B Claims Denial Rates on Molecular Tests ($ millions)



Source: Medicare Part B aggregate denied claims vs. submitted claims for CPT codes 81200-81407, 81479, 81519, 81599, 88381 and G0452

The introduction of more specific codes in 2013 has allowed both Medicare Administrative Contractors (MACs) as well as commercial payers to deny claims for tests that they say lack medical necessity.

MDx test codes with high denial rates (see table) include CPT 81479 (unlisted molecular pathology procedure) with a denial rate of 75% by Medicare contractors paying Part B claims.

Anecdotal evidence suggests that molecular labs are still experiencing difficulty in collecting on claims today.

For example, Cancer Genetics Inc. (Rutherford, NJ), which is focused on molecular oncology testing, including next-generation sequencing and gene expression panels, recently reported that its bad-debt expense jumped to $5.3 million, or 18% of its revenue, in calendar-year 2017 versus $723,000, or 3% of its revenue, in 2016.

Cancer Genetics said that its collection efforts have been challenged by the demands by payers for copies of patient medical records or diagnosis codes, which can be difficult to obtain. In addition, the company noted collection difficulties due to the lack of coverage for certain next-generation sequencing tests by Medicare and most third-party managed care plans.

Bad-debt writeoffs contributed to Cancer Genetics' overall net loss of $20.9 million on revenue of $29.1 million in 2017. The company has hired the investment firm Raymond James to assist in the evaluation of strategic alternatives, including an outright sale of the company.

Denied Medicare Claims for 10 High-Volume Molecular Tests in 2016

CPT	Short Description	Submitted Claims	Denied Claims	Percent Denied	Allowed Charges
81479	Unlisted molecular pathology procedure	291,954	218,381	74.8%	$108,452,107
81519	Oncology breast mRNA, gene expression	18,366	487	2.7%	61,127,540
81211	BRCA1,BRCA2 full sequence analysis	13,047	3,193	24.5%	21,258,609
81226	CYP2D6 genotype	75,315	48,225	64.0%	12,205,667
81401	Molecular pathology procedure, Level 2	189,084	130,607	69.1%	7,870,935
81225	CYP2C19 genotype	84,764	62,533	73.8%	6,454,706
81213	BART Testing	10,955	1,875	17.1%	5,280,867
81317	PMS2 gene analysis	7,226	1,640	22.7%	4,352,908
81235	EGFR mutation analysis	17,344	5,833	33.6%	4,169,586
81400	Molecular pathology procedure, Level 1	76,424	45,137	59.1%	3,569,103

Source: *Laboratory Economics* from CodeMap LLC. and CMS

Aurora Diagnostics Buys Cascade Pathology Services

Aurora Diagnostics (Palm Beach Gardens, FL) has acquired Cascade Pathology Services (Portland, OR), a pathologist-owned multispecialty pathology practice with 16 pathologists and five other employees.

The deal included the simultaneous acquisition of Cascade Cytology Reference Laboratories (Portland, OR), an affiliated lab providing cytology support services to physician groups. Financial terms of the deal were not disclosed.

The acquisition of Cascade Pathology adds to Aurora Diagnostics' presence in the Pacific Northwest, where the company also acquired Pacific Pathology Associates (Salem, OR) in 2016.

Theranos May Not Make It Through The Summer

In an April 11 letter to stockholders, Theranos CEO Elizabeth Holmes outlined the company's desperate situation. In a nutshell, Theranos' testing technology still isn't working and the company is running out of cash.

Elizabeth Holmes

Despite raising $65 million from a loan from Fortress Investment Group on December 11, 2017, Theranos plans to lay off most of its staff by June 11. Even with those cuts, the company anticipates it will run out of cash by the end of July, according to Holmes. Her letter noted that Theranos was behind schedule in filing for FDA approval for its Zika assay for use on its miniLab platform. "We continue to face issues with the reliability of the Zika assay chemistry itself," wrote Holmes.

"After June 11, our remaining staff [roughly 24 people] will consist primarily of financial, legal and administrative personnel alongside a core technical team, who will dedicate their efforts toward generating the maximum near-term return achievable for our stakeholders, likely through a sale of the company or its assets," according to Holmes.

Laboratory Economics thinks that the most likely scenario is that Theranos defaults on its loan and is forced to shut down operations. Fortress Investment Group would then get Theranos' assets, which consist primarily of approximately 1,175 granted or pending patents worldwide.

Holmes claims that these patents cover technologies underlying point-of-care devices currently on the market and generating sizable revenue. Fortress, or whoever the eventual owner of Theranos might be, could seek to monetize these assets by seeking out licensing deals (under threat of patent litigation) with existing point-of-care test system manufacturers. This may sound farfetched, but it's probably a more realistic business model than Theranos's original plan, observes *Laboratory Economics*.

Theranos's layoffs occur in the wake of last month's charge by the Securities & Exchange Commission (SEC) that the firm's CEO Elizabeth Holmes had committed a massive fraud (see *LE*, March 2018). The SEC contends that Holmes misled investors about nearly every aspect of her company's business model and its technology, in the course of raising $700 million from private investors. For this, Holmes agreed to a settlement in which she would pay a $500,000 penalty.

At its peak in 2013-2014, Theranos employed more than 700 people, was valued at $9 billion, and its board of directors included such luminaries as Henry Kissinger, George Schultz, Larry Ellison, and the country's current Secretary of Defense General Jim Mattis.

Publicly-Traded Labs Grew By 3.5% In 2017

On a combined basis, 17 publicly-traded labs grew their revenue by 3.5% to $18.8 billion in 2017 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 15 smaller publicly-traded labs grew by 4.4% last year (after adjusting for acquisitions).

Revenue growth was fastest at three genetic-testing lab companies: Exact Sciences (up 168%), Foundation Medicine (up 31%) and Invitae Corp. (up 29%).

Acquisition-adjusted revenue for LabCorp was up 5% last year, while Quest Diagnostics' revenue was up 1.8%. The third largest U.S. lab company, Opko/Bio-Reference Labs, reported a revenue decline of 12.2%.

Revenue Growth at 17 Publicly-Traded Lab Companies ($000)

Company	Revenue 2017	Revenue 2016	Reported Change	Pro Forma Change*
Quest Diagnostics	$7,709,000	$7,515,000	2.6%	1.8%
LabCorp Diagnostics[1]	7,170,500	6,593,900	8.7%	5.0%
Opko/Bio-Reference	889,100	1,012,129	-12.2%	-12.2%
Sonic Healthcare USA[2]	888,160	843,950	5.2%	3.0%
Myriad Genetics[3]	771,400	753,800	2.3%	2.3%
Genomic Health	340,750	327,868	3.9%	3.9%
Exact Sciences	265,989	99,376	167.7%	167.7%
NeoGenomics	258,611	244,083	6.0%	6.0%
Foundation Medicine	152,903	116,865	30.8%	30.8%
Enzo Clinical Labs[4]	77,407	70,915	9.2%	9.2%
Veracyte	71,953	65,085	10.6%	10.6%
Invitae Corp.	68,221	25,048	172.4%	28.7%
Psychemedics	39,701	38,980	1.8%	1.8%
CareDx	33,106	29,680	11.5%	11.5%
Cancer Genetics Inc.	29,121	27,049	7.7%	7.7%
Aeon Global Health[5]	18,912	33,953	-44.3%	-44.3%
Interpace Diagnostics	15,897	13,085	21.5%	21.5%
Total, 17 companies	$18,800,731	$17,810,766	5.6%	3.5%
Total, 15 companies (excluding Quest and LabCorp)	$3,921,231	$3,701,866	5.9%	4.4%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

[1]LabCorp's revenue is for its lab testing business only (excluding clinical trials); [2]Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2017 (using constant exchange rate of 1 AUD = 0.78 USD; [3]Myriad Genetics' revenue is for fiscal year ended June 30, 2017;; [4]Enzo's revenue is for lab services only for fiscal year ended July 30, 2017. [5]Aeon's revenue is for lab services only for fiscal year ended June 30, 2017.

Source: *Laboratory Economics* from company reports

LabCorp Signs Comprehensive Deal With Appalachian Regional Healthcare

LabCorp (Burlington, NC) has agreed to provide technical services for Appalachian Regional Healthcare's hospital-based clinical labs and reference testing services for its entire network of facilities and physician practices.

Appalachian Regional Healthcare (ARH) is a not-for-profit health system that includes 11 hospitals and 40 physician clinics in Eastern Kentucky and Southern West Virginia. Its largest hospital is Hazard ARH Regional Medical Center (Hazard, KY) which has 322 beds and an annual lab department budget of about $10 million.

The agreement went into effect on February 1, 2018. Prior to the LabCorp agreement, ARH used a variety of reference laboratories.

Most routine testing will be performed at LabCorp's regional laboratory in Dublin, Ohio. Most specialty testing is expected to be sent to LabCorp's Center for Molecular Biology and Pathology (CMBP) in Research Triangle Park, North Carolina.

ARH Hospital Laboratory Department Expenses for 2016

Hospital Name	Location	# Beds	Total Lab Dept. Expense	Total Hospital Operating Expense	% Lab Exp/ Hospital Exp
Hazard ARH Regional Medical Ctr.	Hazard, KY	322	$9,652,627	$198,563,844	4.9%
Beckley ARH Hospital	Beckley, WV	160	5,942,504	98,720,807	6.0%
Harlan ARH Hospital	Harlan, KY	100	4,889,138	59,310,288	8.2%
Tug Valley ARH Regional Medical Ctr.	So. Williamson, KY	123	3,908,122	42,072,181	9.3%
Whitesburg ARH Hospital	Whitesburg, KY	90	3,159,334	44,287,172	7.1%
Barbourville ARH Hospital	Barbourville, KY	25	2,289,356	17,867,490	12.8%
Middlesboro ARH Hospital	Middlesboro, KY	73	1,635,061	42,035,976	3.9%
Summers County ARH Hospital	Hinton, WV	25	1,406,930	16,379,577	8.6%
Morgan County ARH Hospital	West Liberty, KY	25	1,261,241	14,900,282	8.5%
McDowell ARH Hospital	McDowell, KY	25	1,159,300	15,253,420	7.6%
Mary Breckenridge Hospital	Hyden, KY	25	1,132,398	14,183,254	8.0%
Total, 11 hospitals		993	$36,436,011	$563,574,291	6.5%

Source: *Laboratory Economics* from American Hospital Directory/hospital cost reports

St. Charles Picks Mayo For Reference Testing

St. Charles Health System (Bend, OR) has selected Mayo Medical Laboratories (Rochester, MN) as its primary reference laboratory. Most laboratory testing will continue to be performed by St. Charles Laboratory with only the most specialized tests—including pain-management drug screens, allergy panels, therapeutic drug monitoring, hepatitis C quant testing, celiac panels and others—sent to Mayo. St. Charles Health System includes four hospitals—the largest is St. Charles Medical Center located in central Oregon and has 259 beds with a total annual lab department budget of $25 million.

Lab Stocks Down 9% Year To Date

Prices for 16 publicly-traded lab stocks were down 9% on an unweighted average basis through April 13. In comparison, the S&P 500 Index is down 1% year to date. The top-performing lab stocks so far this year are CareDx, up 23%, and Foundation Medicine Health, up 17%. At the two largest public labs, LabCorp is up 3% and Quest Diagnostics is up 1%.

Company (ticker)	Stock Price 4/13/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$0.97	$1.85	-48%	$27	NA	0.9	0.8
CareDx (CDNA)	9.01	7.34	23%	262	NA	5.4	NA
Enzo Biochem (ENZ)	6.06	8.15	-26%	285	NA	2.6	3.2
Exact Sciences (EXAS)	44.96	52.54	-14%	5,440	NA	20.4	10.4
Foundation Medicine (FMI)	80.00	68.20	17%	2,960	NA	19.4	92.5
Genomic Health (GHDX)	33.02	29.39	12%	1,170	NA	3.4	6.2
Interpace Diagnostics (IDXG)	0.92	1.02	-9%	28	NA	1.6	0.7
Invitae (NVTA)	5.67	9.08	-38%	367	NA	5.4	2.5
LabCorp (LH)	164.82	159.51	3%	16,810	13.5	1.7	2.5
Myriad Genetics (MYGN)	29.09	34.35	-15%	2,030	15.6	2.6	2.2
NeoGenomics (NEO)	8.49	8.57	-1%	684	NA	2.6	4.0
Opko Health (OPK)	2.99	4.90	-39%	1,670	NA	1.6	0.9
Psychemedics (PMD)	21.38	20.56	4%	117	19.4	3.0	6.3
Quest Diagnostics (DGX)	99.76	98.49	1%	13,550	18.1	1.8	2.7
Sonic Healthcare (SHL.AX)	23.05	21.40	8%	9,750	21.1	1.8	2.5
Veracyte (VCYT)	5.42	6.53	-17%	186	NA	2.6	5.0
Unweighted Averages			-9%	$55,336	17.5	4.8	9.5

Source: Capital IQ

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