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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

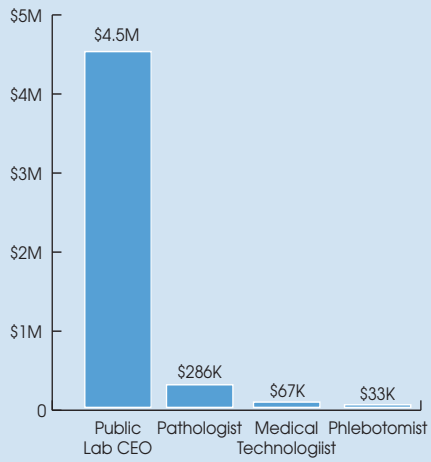
New Judge Assigned To ACLA Lawsuit

Unprompted by the parties, the U.S. District Court for the District of Columbia has reassigned ACLA's lawsuit versus the U.S. Department of Health and Human Services (HHS) from Judge Emmet Sullivan to Judge Amy Berman Jackson. ACLA President Julie Khani says both sides are now waiting for Judge Jackson to schedule oral arguments. *Continued on page 8.*

Public Lab CEOs Paid Average $4.5 Million

The chief executives at 15 publicly-traded lab companies were paid an average of $4.5 million each last year, according to an analysis of shareholder proxy statements by *Laboratory Economics*. Altogether, the 15 CEOs earned a total of $67.8 million, including $9.9 million from salary, $9 million from bonuses, $48.2 million from stock and option awards, and $830,927 from other compensation. In comparison, the average pathologist earned $286,000 in salary and bonus last year, according to the latest survey by Medscape. *Continued on page 6.*

Compensation Comparison



Source: *Laboratory Economics* from SEC filings, Medscape and Salary.com

CellMax Ready To Launch "Liquid Biopsy" for Colorectal Cancer

CellMax Life (Sunnyvale, CA) has already been marketing its blood test for the early detection of colon cancer in Asia for the past two years and plans to offer it in the U.S. market as a laboratory-developed test within the next few months, according to CEO Atul Sharan. He says the test, CellMax-CRC Colorectal Cancer Early Detection Test, has been validated and will be performed at the company's CLIA-certified laboratory in Sunnyvale, California, at a list price of approximately $150. In addition, Sharan says that CellMax will soon initiate a major clinical study of the test involving more than one thousand patients as a first step toward gaining FDA clearance. "There is a tremendous need for an easy and affordable colorectal cancer screening test," notes Sharan. *Continued on page 2.*

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CellMax Ready To Launch "Liquid Biopsy" (*cont'd from page 1*)

Using technology exclusively licensed from Academia Sinica in Taiwan, the CellMax CRC test detects even the smallest amounts of circulating tumor cells (CTCs), cells that are discarded from a tumor, from a blood sample.

Atul Sharan

Sharan notes that the test can detect 1 CTC in a billion blood cells, which makes it capable of diagnosing precancerous lesions. In most cases, early-stage cancer is equivalent to 10 CTCs per billion and late-stage cancer has more than 100 CTCs per billion blood cells.

The CellMax CRC test was 84% to 88% accurate at detecting precancerous and cancerous colorectal lesions, according to results from a prospective study released at the Gastrointestinal Cancers Symposium in San Francisco earlier this year.

The 620-patient study took place at Chang Gung Memorial Hospital, the largest hospital in Taiwan, and found the sensitivity for the test for detecting precancerous lesions was 77% and 87% for detection of stage I to IV colorectal cancer. The specificity of the test was 97.3% across all patient cohorts, indicating a probability of less than 3% of potential false positives.

Importantly, the study was the first to show high sensitivity for a CTC assay at detecting precancerous lesions, when it is easier to treat successfully, notes Sharan.

As mentioned earlier, CellMax is now preparing to begin a much larger clinical study with U.S. patients.

CellMax was founded by Sharan and Ying-Chih Chang, PhD, in 2012. Previously Sharan was President and CEO of AutoESL Design Technologies (acquired by Xilinx in 2011). Chang is a Research Fellow and Professor at the Genomics Research Center at Academia Sinica. She has a PhD in chemical engineering from Stanford University.

CellMax has raised approximately $22 million from private investors to date. Its investors include the Silicon Valley venture capital firm Artiman Ventures, as well as several Taiwanese venture investors including Stan Shih, founder and Chairman of the computer and electronics firm Acer Inc.

The Need for an Easy and Affordable Colorectal Cancer Screening Test

Colorectal cancer treated in localized, early stages has a five-year survival rate of 90%. But only about 40% of cases are diagnosed in early stages, due to low screening rates. Each year in the U.S. there are approximately 140,000 new cases and 51,000 deaths from colorectal cancer, according to the American Cancer Society.

Colonoscopy, the "gold standard" for colorectal cancer screening, has >95% sensitivity and 90% specificity. However, of the more than 85 million people in the U.S. age 50-75 for whom routine colorectal cancer screening is recommended, 38% have not been screened according to current guidelines. Patients resist or delay colonoscopy most often because of: unpleasant preparation, high cost for the uninsured, fear of pain, and embarrassment.

Stool DNA Testing

In August 2014, Exact Sciences' Cologuard became the first multi-target stool DNA test approved by the FDA for general CRC screening. The Cologuard test includes a combination of a traditional fecal immunochemical test (FIT) plus markers for abnormal DNA present in malignancies.

Exact's 10,000-patient pivotal clinical study published in *The New England Journal of Medicine* (April 2014) showed Cologuard has a 92% sensitivity for detecting CRC. Unfortunately, Cologuard detected fewer than half of all large advanced adenomas (42%), limiting its preventive role.

Nonetheless, Exact is aggressively marketing Cologuard as an option for the roughly 33 million U.S. patients that resist or delay colonoscopy. Last year, Exact spent $154 million on marketing, including its sales staff of 350 reps and a national television advertising campaign. This year Exact is in the process of expanding its sales force by hiring 200 more reps. Exact performed 571,000 Cologuard tests in 2017 and expects to perform about 900,000 tests this year.

Comparison of Colorectal Cancer Screening Options

Product	Company	Sample Type	Method/ Analyte	Commercially Available	All Stages	Pre-Cancer	Specificity	FDA Approved?	Approximate Cost
Fecal Immunochemical Test (FIT)	Various	Stool	Immunochemical	Yes	79%	24%	94%	Yes	~$20
Epi proColon	Epigenomics	Blood	Septin9 DNA	Yes	68%	18%	80%	Yes	~$150
CellMax CRC Test	CellMax Life	Blood	Circulating Tumor Cells (CTCs)	Soon	87%	77%	97%	No	~$150
Cologuard	Exact Sciences	Stool	DNA and Protein	Yes	92%	42%	87%	Yes	~$500
Traditional Colonoscopy	Various	NA	Endoscopic Screening	Yes	>95%	>95%	90%	Yes	~$1,000

Source: *Laboratory Economics*, *CellMax* and *World Journal of Gastrointestinal Oncology*, November 15, 2016

Liquid Biopsy for CRC Screening

In addition to CellMax, there are several other lab companies in the early stages of bringing a liquid biopsy for CRC screening to market in the United States.

Epigenomics (Berlin, Germany and Germantown, Maryland) received FDA clearance for the first blood-based colorectal cancer screening test, Epi proColon, in August 2016. Epi proColon is a PCR-based test that detects methylated Septin9 DNA. FDA approved the test for use in average-risk patients, who are age 50 years and older, that have not undergone screening by colonoscopy or stool-based fecal immunochemical tests (FITs). Epigenomics has licensed its Septin9 biomarker technology to ARUP Labs, LabCorp and Quest Diagnostics. However, despite having these lab heavyweights behind it, utilization of the test has failed to take off.

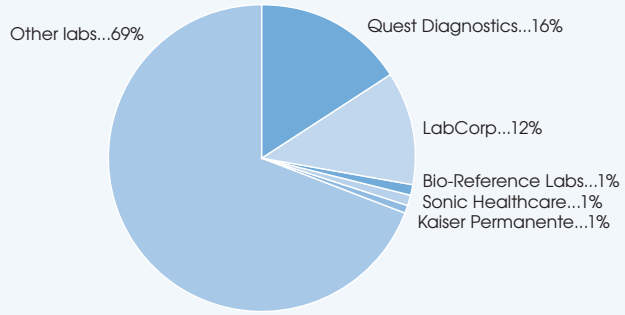
DiaCarta Inc. (Richmond, CA) received approval to market its colorectal cancer test, ColoScape, in Europe (CE-IVD) early last year. ColoScape is a real-time PCR assay that detects 20 DNA mutation markers from four oncogenes (APC, CTNNB1, KRAS and BRAF), obtained from either solid tumor, plasma or stool samples. DiaCarta operates an 18,000-square-foot CLIA lab in the San Francisco area and is currently offering ColoScape for research use only in the United States. In February, DiaCarta raised $45 million from a Series B funding round led by Fortune Fountain Capital (Beijing, China). DiaCarta says it will use the funds to set up clinical study programs and for commercial launch of ColoScape.

Clinical Genomics (Bridgewater, NJ) markets two forms of colorectal cancer tests. Its InSure ONE FIT is the only FIT that is performed from samples taken using long-handled brushes to collect a toilet bowl water sample from a single bowel movement. The water sample is placed on a test card and sent to a laboratory for testing. Lab reimbursement is approximately $20.

Mark Boyle, President of In Vitro Diagnostics at Clinical Genomics, notes that Exact Sciences' competing stool-based DNA test includes a FIT test that accounts for most of the sensitivity. "You're paying a lot more [~$500 versus ~$20] but not getting a lot in terms of improved sensitivity above the FIT alone," says Boyle.

Meanwhile, Clinical Genomics also markets a circulating tumor DNA blood test designed to monitor residual disease and recurrence in patients being treated for colorectal cancer. The test is sold as a laboratory-developed test under the brand name "Colvera" and is performed at the company's CLIA-certified lab in northern New Jersey. Eventually, Colvera will be developed into a CRC screening test, according to Boyle. Ultimately, Boyle says that the ease of use of a liquid biopsy has the potential to dramatically raise compliance rates for CRC screening in the United States.

Estimated U.S. Laboratory Market Share of FIT Testing



Source: *Laboratory Economics'* estimates based on Medicare Part B utilization data for CPT 82274 and G0328

The U.S. Multi-Society Task Force of Colorectal Cancer recommends that people age 50-75 get a colonoscopy every 10 years and an annual fecal immunochemical test (FIT). Despite recommendations for an annual FIT, there are only an estimated 10 million fecal immunochemical tests (FITs) completed each year in the United States. Market share by performing labs is highly fragmented. Together, the top five labs, Quest Diagnostics, LabCorp, Bio-Reference, Sonic Healthcare and Kaiser Permanente, account for only an estimated 31% share. The remaining 69% is held by more than 20,000 independent labs, hospitals and physician-office-based labs that perform FIT testing.

Medicare Decision on NGS Testing Could Lead to Increase in Cancer Panels

A recent decision by the Centers for Medicare and Medicaid Services (CMS) to finalize a national coverage decision on next-generation sequencing (NGS) cancer panels is likely to lead to a large increase in panel testing done on NGS platforms, say industry experts.

Under the final coverage policy, issued March 16, an NGS cancer panel that is approved or cleared by the FDA as an in vitro companion diagnostic will automatically receive full Medicare coverage, provided it is indicated for a patient's type of cancer. The National Coverage Determination (NCD) covers NGS tests for patients with advanced cancer (i.e., recurrent, metastatic, relapsed, refractory, or stages III or IV).

The decision was made following the parallel review with the FDA of FoundationOne's F1CDx companion diagnostic test, the first FDA-approved NGS-based companion diagnostic for 15 targeted therapies. The test can detect genetic mutations in 324 genes and two genomic signatures in any solid tumor.

While the NCD applies to NGS tests approved or cleared by the FDA as in vitro companion diagnostics, coverage determinations for other diagnostic laboratory tests using NGS for Medicare patients with advanced cancer will be made by local Medicare Administrative Contractors (MACs).

In a change from the draft coverage policy, the final decision expands coverage to patients with relapsed, refractory or stage III cancers and extends coverage to repeat testing when the patient has a new primary diagnosis of cancer. What's more, CMS removed coverage with evidence development (CED) from the NCD, noting that many commenters reported they are already developing

or have developed evidence to demonstrate improved health outcomes using NGS tests. Under CED, coverage would have been conditional. CMS is encouraging the continuation and publication of the results of the studies, especially regarding overall survival, progression-free survival, objective response and patient reported outcomes.

Bruce Quinn, MD, PhD, Principal at Bruce Quinn Associates and author of the blog Discoveries in Health Policy, tells *Laboratory Economics* that the NCD gives a huge advantage to FDA-approved tests on NGS platforms.

"Right now, the only high-volume test is the Foundation One test," he says. "However, clinical laboratories can have the same coverage benefits for Medicare patients if and when they are able to adopt FDA-approved NGS tests based on kits. Labs that perform LDTs and neither get direct FDA approval nor use FDA-approved kits seem to benefit the least."

Because there has been very little locally-based coverage of large gene panel tests in the Medicare system until now, this NCD is likely to lead to a large increase in panel testing, he adds, noting that some of these will migrate from single-gene tests.

It remains to be seen whether MACs will alter their local coverage determination criteria for coverage of NGS tests in response to the NCD, says Helen Trilling, a partner with Hogan Lovells (Washington, D.C.), in an advisory. "By reversing its proposal to require CED for most NGS tests and allowing Medicare contractors to continue covering these tests under LCDs, CMS has preserved access to currently covered tests and maintained a less onerous pathway to coverage for additional NGS tests," she explains.

The final NCD does raise a couple of concerns, says Quinn. For one, CMS is attempting to write a short, general coverage statement although there are many different types of cancers and different situations. Another concern is how Medicare contractors will handle the potential increase in requests for off-label drug use when a validated gene pops up in an unexpected cancer type.

"If we are going to use these gene panel tests in very large numbers of patients, there should be some basic way to track the correlation between tumor, gene and drug response," he says. "CMS has data on tumor type and on every drug given, but CMS won't have any data on the gene profiles that link the tumor type and the drugs provided."

OPKO Hires Former Quest Exec To Run BioReference Labs

OPKO Health has hired Geoff Monk as its new General Manager for Bio-Reference Laboratories. Monk was previously Managing Director of the New York and New Jersey unit of Quest Diagnostics. OPKO says that Monk's goals will include increasing efficiency and lowering costs at BioReference to offset consistent pricing pressure. In terms of growth, BioReference will seek more contracts with large IPAs and ACOs.

Geoff Monk

Separately, OPKO reported that BioReference had an operating loss of $8 million for the three months ended March 31, 2018, versus an operating loss of $3 million for first-quarter 2017; revenue fell 7.5% to $211.3 million reflecting a volume decrease of approximately 3% combined with reimbursement pressure as a result of PAMA.

And finally, OPKO says that BioReference remains under investigation for allegedly improperly billing Medicare and TRICARE for lab tests provided to hospital inpatient beneficiaries at certain hospitals. OPKO says that BioReference is still reviewing and assessing the allegations made by the U.S. Attorney's Office for the Southern District of New York.

PUBLIC LAB CEOs PAID AVERAGE $3.1 MILLION IN 2016 (*cont'd from page 1*)

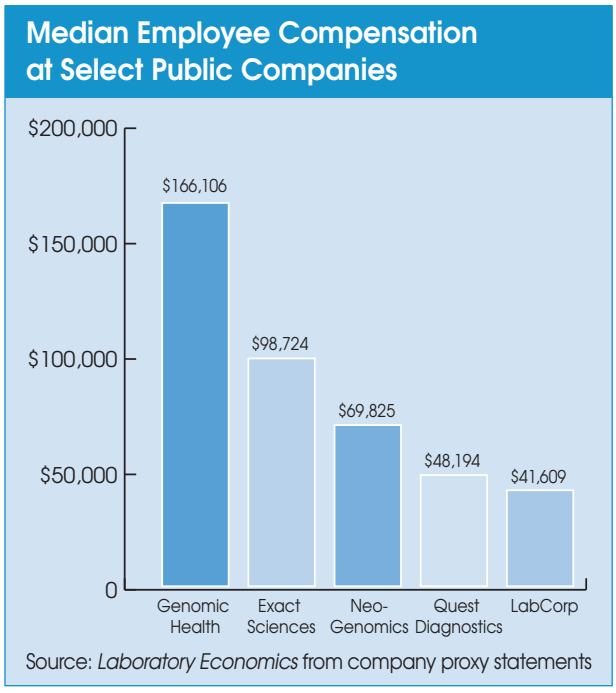
Exact Sciences' Kevin Conroy, 52, was the highest paid lab CEO in 2017. He received five different categories of compensation last year that totaled $13.3 million. In comparison, the median of the annual total compensation of all Exact's employees was $98,724 in 2017. Conroy's compensation included: 1) salary of $632,500; 2) cash bonus of $920,920; 3) stock awards valued at $5.2 million; 4) stock options valued at $6.5 million; and 5) other compensation of $16,200, which represented 401K matching contributions.

LabCorp's David King, age 61, was the second highest paid lab CEO in 2017. He received total compensation of $11.6 million. In comparison, the median of the annual total compensation of all LabCorp's employees was $41,609 in 2017. King's compensation included: 1) salary of $1.15 million; 2) stock awards of $6.7 million; 3) stock options of $1.6 million; 4) incentive plan cash bonus of $2 million; 5) increased pension value of $128,904; and 6) other compensation of $75,990, which included financial planning services, 401K matching contributions, long-term disability insurance, use of a company car and home security services.

Quest Diagnostics' Stephen Rusckowski, 60, got total compensation of $10.3 million last year versus median compensation of $48,194 for all other Quest employees. Rusckowski received: 1) a salary of $1.1 million; 2) cash incentives of $1.4 million; 3) stock option awards of $3 million; and 4) stock awards valued at $4.5 million. He also received $304,591 in perks, which included $79,004 for personal use of a company car and driver plus $99,001 for personal use of company aircraft.

Foundation Medicine's Troy Cox, 54, was paid total compensation of $6.2 million, including: 1) salary of $486,539; 2) bonus and cash incentives totaling $738,356; 3) stock awards of $4.9 million; and 4) "other" compensation totaling $61,571, which included travel and relocation reimbursement of $57,596 and matching 401K contributions of $3,975.

Myriad Genetics' Mark Capone, 55, got total compensation of $5.2 million, including: 1) salary of $852,000; 2) bonus and cash incentives totaling $741,547; 3) stock awards of $3.6 million; and 4) "other" compensation totaling $10,848, which included company-paid life insurance premiums and matching 401K contributions.



Genomic Health's Kim Popovits, 59, received total compensation of $4.1 million versus median compensation of $166,106 for the company's employees.

NeoGenomics' Douglas VanOort, 62, earned total compensation of $3.5 million versus median employee compensation of $69,825.

The lowest-paid laboratory CEO was **Psychemedics' Raymond Kubacki, Jr.**, 73, who earned total compensation of $764,200 in 2017.

2017 Laboratory CEO Compensation

Company/Executive	Salary	Bonus and Incentives	Value of Stock & Option Awards	Other Comp*	2017 Total Comp	2017 Revenue Growth	2017 Stock Price Total Return
Cancer Genetics Inc.							
Panna Sharma, 47, former President and CEO	$500,000	$250,000	$327,645	$709	$1,078,354	8%	37%
CareDx							
Peter Maag, PhD, 51, President & CEO	450,000	378,000	571,737	1,560	1,401,297	19%	172%
Enzo BioChem							
Elazar Rabbani, PhD, 74, Chairman & CEO	585,802	575,000	180,150	191,044	1,531,996	5%	17%
Exact Sciences							
Kevin Conroy, 52, Chairman & CEO	632,500	920,920	11,695,469	16,200	13,265,089	168%	293%
Foundation Medicine							
Troy Cox, 54, President & CEO	486,539	738,356	4,895,631	61,571	6,182,097	31%	285%
Genomic Health							
Kim Popovits, 59, Chairman & CEO	700,128	440,360	2,976,817	0	4,117,305	4%	16%
Interpace Diagnostics							
Jack Stover, 65, President & CEO	318,500	1,029,058	695,993	12,910	2,056,461	22%	-77%
Invitae							
Sean George, PhD, 44, President & CEO	479,077	0	3,084,767	0	3,563,844	172%	14%
LabCorp							
David King, 61, Chairman & CEO	1,150,000	1,960,367	8,330,993	204,894	11,646,254	8%	24%
Myriad Genetics							
Mark Capone, 55, President & CEO	852,000	741,547	3,613,500	10,848	5,217,895	2%	106%
NeoGenomics							
Douglas VanOort, 62, Chairman & CEO	616,346	200,000	2,664,162	3,000	3,483,508	6%	3%
Opko Health Inc.							
Phillip Frost, MD, 81, Chairman & CEO	960,000	0	0	10,800	970,800	-13%	-62%
Psychemedics							
Raymond Kubacki, Jr., 73, Chairman & CEO	487,500	87,500	178,400	10,800	764,200	2%	-14%
Quest Diagnostics							
Stephen Rusckowski, 60, Chairman & CEO	1,100,000	1,443,420	7,500,007	304,591	10,348,018	3%	9%
Veracyte Inc.							
Bonnie Anderson, 60, Chairman & CEO	550,000	220,000	1,441,128	2,000	2,213,128	11%	-16%
Totals, 15 companies	9,868,392	8,984,528	48,156,399	830,927	67,840,246		
Averages, 15 companies	$657,893	$598,969	$3,210,427	$55,395	$4,522,683	30%	54%

*Other compensation includes reimbursement for financial planning services, car allowance, personal liability insurance premiums, executive physical exams, home security systems, country club memberships, personal use of company jets and other perks. Source: *Laboratory Economics* from company proxy statements

New Judge Assigned To ACLA Lawsuit (*cont'd from page 1*)

Judge Jackson

Judge Sullivan had been expected to rule on the case by late May or early June. Reassignment to Judge Jackson is likely to delay a decision by at least a few more weeks, observes *Laboratory Economics*. Judge Jackson, age 63, is a Harvard Law School graduate who was appointed by President Barack Obama in 2010. Previously, Jackson was a Member of Trout Cacheris, PLLC (Washington, DC), where she specialized in complex criminal and civil trials and appeals.

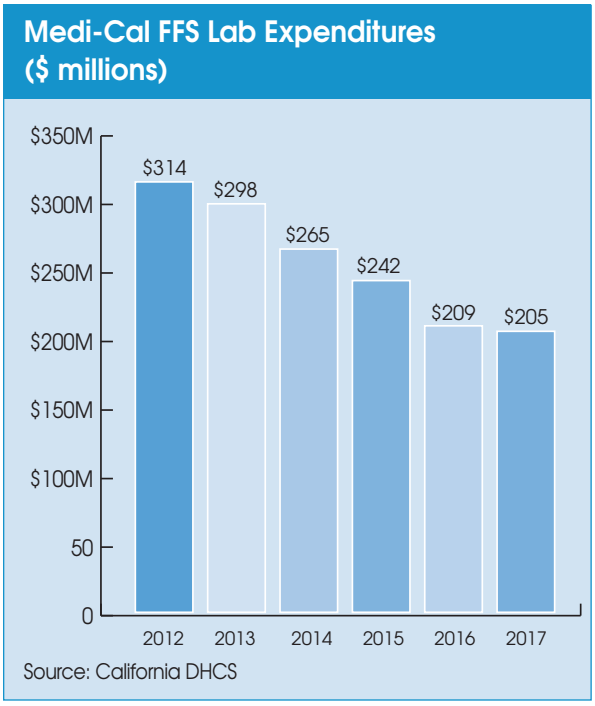
ACLA's lawsuit was filed on December 11, 2017, shortly after CMS issued the final Medicare Clinical Lab Fee Schedule (CLFS) for 2018 which included drastic cuts to nearly all routine clinical lab tests. ACLA charges that HHS wrongly excluded hospital lab payment data when it formulated new market-based rates for the CLFS.

HHS claims that its data reporting requirements were "integral to the establishment of payment amounts, which is shielded from judicial review." HHS says that ACLA's challenge of its data reporting requirements is simply an "end-run around a bar on judicial review" of the final rates.

California Says Medi-Cal Lab Tests Rates Are Near Equilibrium

The California Department of Health Care Services (CDHCS) says its fee-for-service rates for lab tests have now reached equilibrium with private-payer rates. As a result, a bill (AB 659) was passed into law last year that directs CDHCS to lengthen the interval that labs are required to submit their private-payer data. Instead of reporting annually, California labs will report every three years. The switch to a three-year interval was made in part to lower reporting costs for labs. The California Clinical Laboratory Association had lobbied for the change.

CDHCS received data from 124 labs, including 60 hospital labs, from its most recent data collection period covering calendar-year 2016. This information was used to set Medi-Cal fee-for-service rates effective July 1, 2017 that averaged roughly 60% to 65% of the Medicare CLFS for 2017.



The next Medi-Cal data collection will cover calendar-year 2018, with data due in 2019, and rate adjustments effective July 1, 2020, according to Anthony Cava, spokesman for CDHCS.

As of December 2017, Medi-Cal serves 13.3 million people, including 2.4 million in fee-for-service plans and 10.9 million in managed care. During the five-year period from 2012-2017, Medi-Cal spending on fee-for-service lab tests decreased by an average of 8% per year.

The largest commercial labs by Medi-Cal revenue for 2017 are Quest Diagnostics ($28.1 million), LabCorp ($5.4 million), Whitefield Medical Lab ($3.9 million), Foundation Laboratory ($3.8 million) and Alpha Clinical Lab ($3.3 million). The largest hospital labs are Dignity Health ($3.2 million) and Children's Hospital of Los Angeles ($2.4 million).

Spotlight Interview with CSI Laboratories' COO Fred Daugherty


Fred Daugherty

CSI Laboratories (Alpharetta, Ga.) specializes in cancer diagnostics and serves clients throughout the United States, as well as Puerto Rico and Kuwait. Started in 1997 as a flow cytometry laboratory, CSI now offers more than 350 flow, FISH, molecular diagnostic and immunohistochemistry tests. CSI primarily serves as a reference laboratory for pathology practices. The lab has 130 employees, including six pathologists and four PhDs. *Laboratory Economics* recently spoke with COO Fred Daugherty.

Where are the majority of the clients you serve?
The majority are in the southeast, although we do serve clients both nationally and internationally. We have about a 180- to 200-mile radius that we serve by courier. The rest we service through FedEx.

Is CSI growing in terms of volumes and revenues?
We are growing. Our annual growth is consistent at about 12% based on case volume. In 2017, our revenues were just over $29 million. Projected revenue for 2018 is just above $37 million. Volume in 2017 was just over 74,000 cases. We're projecting between 84,000 and 85,000 cases for 2018.

What is driving growth?
We're seeing a big increase in FISH and molecular due to new targeted therapies that are available. Specifically, we're seeing growth in PD-L1, eGFR, ALK, ROS1, and BRAF testing for lung cancer.

Who is your biggest competitor?
Overall, I would say its NeoGenomics. We compete with Quest and LabCorp as well, but CSI specializes in cancer diagnostics and does not offer routine clinical testing.

Did CSI participate in the data collection and reporting under PAMA?

We didn't. Only 30% to 40% of our testing is paid by third-parties, and only 15% of that is Medicare. The rest is paid directly by our pathology clients. We are not directly impacted by PAMA. The challenge will be how PAMA affects our hospital clients – we might see price compression across the board.

Have you found that private payers are starting to follow Medicare's lead in pricing changes for clinical laboratory tests?
Most definitely. They've become adopters of the Medicare fee schedule much more quickly in recent years than they have historically.

Tell me about CSI's new cancer diagnostics laboratory in Florida.
We're building a 2,400-square-foot facility in Jupiter. We've historically had a strong client base in Florida, and this will provide us the capability of offering a level of service to them and new clients that we haven't been able to previously. We will be able to offer them same-day flow services. Also, the addition of Dr. Mojdeh Naghashpour to our medical team strengthens our level of medical expertise. We expect the lab to open in summer 2018. We're expecting in the neighborhood of 20 to 40 cases per day. Flow will be done there; everything else will go to the main lab in Alpharetta.

How is CSI coping with prior authorization requirements by United Healthcare in Florida? What about prior authorization requirements by Avalon/BCBS of North and South Carolina?
That's a challenge for the reference lab industry overall, not just for CSI. We are one or two layers

removed from the clinician who has to get the authorization. Our third-party billing is managed by APS Medical Billing, and they identify early in the process which CPT codes require prior authorization. On the United Healthcare side, we are in the process of becoming a "Lab of Choice" through Beacon, which will help in this process. In terms of Avalon, we were one of the first labs they took on board, so that has helped us work through some of the growing pains with them. We're not willing to compromise patient care, and in cases where we don't get approval for a test, we will often absorb the cost. One of our credos is that we will not determine testing based on ability to pay.

What do you see as CSI's greatest challenges?
Reimbursement, overall compression in the revenue cycle. It requires us to become more efficient and control costs. We are working to improve automation.

What are your greatest opportunities?
The consolidation of the marketplace as far as oncology diagnostics goes provides us more opportunities for growth. We've built a strong reputation in the marketplace.

How do you think the laboratory industry will change over the next five years?
From a science standpoint, we'll see more targeted testing driven by molecular diagnostics. I also think there's a good possibility that digital pathology will become more utilized. It will never replace a microscope, but it has an opportunity to make pathology more efficient.

Aegis Sciences Hires Jeter As Senior Medical Policy Advisor

Aegis Sciences Corp. (Nashville, TN) has hired Elaine Jeter, MD, as its Senior Medical Policy Advisor. Jeter will assist with both regulatory and medical coverage policy compliance, managed care relationships, and development of evidence-based clinical utility evidence for Aegis's testing services.

Previously, Jeter was the Senior Medical Director at Palmetto GBA (Columbia, SC), which processes Medicare Part B claims in Jurisdiction M (North and South Carolina, Virginia, and West Virginia) and Jurisdiction J (Alabama, Georgia, and Tennessee). While at Palmetto, Jeter helped create and directed the MolDX program.

Aegis Sciences, which has more than 800 employees, specializes in forensic toxicology testing.

LabCorp Expands Relationship With Mount Sinai

LabCorp has won a contract to help Mount Sinai Health System (New York City) standardize its test menus, equipment, supplies, logistics, and processes across the laboratories at its seven acute-care hospitals. In addition, LabCorp is now the primary reference laboratory for Mount Sinai. The new contract follows LabCorp's purchase of Mount Sinai's clinical lab outreach testing business early last year (see *LE*, January 2017).

Genoptix Buys Rosetta Genomics

Genoptix Inc. (Carlsbad, CA), which specializes in blood cancer testing, has acquired Rosetta Genomics (Philadelphia) for $9 million. Rosetta Genomics operates CLIA labs in Philadelphia and Lake Forest, California that specialize in molecular cancer diagnostics. Rosetta was struggling and reported a net loss of $4.6 million on revenue of $1.6 million for the six months ended June 30, 2017. Genoptix, which had been owned by the drug giant Novartis, was acquired by the private investment firms Ampersand Capital Partners and 1315 Capital in March 2017.

Wake Forest Baptist Addressing Lab Mix-Ups That Led to Wrong Diagnoses

Wake Forest Baptist Medical Center (Winston Salem, NC) is taking steps to resolve problems in its pathology laboratory that led to three patients incorrectly receiving a diagnosis of cancer and another patient wrongly being told they did not have cancer when they did.

Internal complaints prompted an investigation by the Centers for Medicare and Medicaid Services (CMS) in early February. The period being reviewed was between June 2014 and August 2017. A report released March 21 by CMS identified at least four cases of erroneous test results on patient tissues. In March, CMS placed the hospital in "immediate jeopardy" status, which could have resulted in a loss of Medicare billing privileges. The hospital subsequently identified an additional 19 patients who received erroneous test results, but said their treatment was not affected due to additional testing.

Among the deficiencies cited were not following all testing procedure protocols; not properly monitoring water quality, temperature and humidity levels; not discarding expired supplies; and not performing and documenting certain quality-control procedures for hematoxylin and eosin stains.

Wake Forest Baptist submitted a corrective action plan on March 13, and CMS has since granted two extensions for the medical center to correct deficiencies. Paula Faria, a Wake Forest Baptist spokesperson, says the medical center is working to address the problems and that surveyors are expected to return to the laboratory in mid-June to assess progress in making corrective actions. Among the corrective steps Wake Forest Baptist is taking:

- Setting and meeting laboratory performance goals
- Addressing significant quality control incidents that involve calibration, maintenance function checks, temperature/humidity logs, etc.
- Addressing quality systems that include monthly checklists, audits, corrective action logs
- Implementing new procedures with manual reviews
- Obtaining new laboratory equipment
- Developing occurrence reporting issues/safety issues
- Increasing proficiency of testing incidents and associated corrective actions
- Addressing medical director/provider concerns, employee concerns and staffing issues

Medical center officials have said they became aware of the deficiencies in the fall of 2017 and that most, if not all, of the misdiagnoses centered on a single individual who is no longer with Wake Forest Baptist.

The medical center's billing privileges and Medicare payments are continuing during the extension period. Wake Forest Baptist's laboratory handles about 25,000 surgical cases each year, and Medicare and Medicaid beneficiaries represent about 44% of the medical center's revenues.

MAWD Pathology Buys Cytocheck Laboratory

MAWD Pathology (North Kansas City, MO) acquired Cytocheck Laboratory (Parsons, KS) effective April 16. Cytocheck employs 40 people at its main lab and office in Parsons and another five at a lab in Lawton, Oklahoma. Cytocheck performs roughly 125,000 Pap tests per year, as well as molecular tests for sexually transmitted diseases, and it also processes surgical specimen biopsies. Cytocheck was founded in 1991 by its President James Welch, MD, who retired effective upon MAWD's acquistion. Cytocheck now operates as a subsidiary of MAWD, providing technical pathology, cytology and laboratory services. MAWD, which employs 24 pathologists, provides professional pathology services for both entities.

Lab Stocks Up 4% Year To Date

Prices for 17 publicly-traded lab stocks were up 4% on an unweighted average basis through May 15. In comparison, the S&P 500 Index is down 0.4% year to date. The top-performing lab stocks so far this year are CareDx, up 49%, and NeoGenomics, up 31%. At the two largest public labs, LabCorp is up 10% and Quest Diagnostics is up 4%.

Company (ticker)	Stock Price 5/15/18	Stock Price 12/29/17	2018 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$0.91	$1.85	-51%	$25	NA	0.9	0.7
CareDx (CDNA)	10.91	7.34	49%	385	NA	7.6	11.5
Enzo Biochem (ENZ)	6.75	8.15	-17%	317	NA	2.9	3.6
Exact Sciences (EXAS)	50.77	52.54	-3%	6,189	NA	23.3	11.8
Foundation Medicine (FMI)	77.37	68.20	13%	2,860	NA	18.7	89.2
Genomic Health (GHDX)	38.00	29.39	29%	1,340	NA	3.9	7.1
Interpace Diagnostics (IDXG)	0.89	1.02	-13%	25	NA	1.6	0.6
Invitae (NVTA)	6.96	9.08	-23%	450	NA	6.6	3.1
LabCorp (LH)	175.83	159.51	10%	17,987	14.4	1.8	2.6
Myriad Genetics (MYGN)	33.81	34.35	-2%	2,360	18.1	3.0	2.6
Natera (NTRA)	11.59	8.99	29%	629	NA	3.0	NA
NeoGenomics (NEO)	11.24	8.57	31%	906	NA	3.4	5.2
Opko Health (OPK)	4.72	4.90	-4%	2,640	NA	2.5	1.4
Psychemedics (PMD)	20.20	20.56	-2%	111	19.4	2.8	6.0
Quest Diagnostics (DGX)	102.13	98.49	4%	13,871	18.2	1.8	2.8
Sonic Healthcare (SHL.AX)	24.01	21.40	12%	10,190	22.0	1.9	2.6
Veracyte (VCYT)	6.42	6.53	-2%	221	NA	3.1	5.9
Unweighted Averages			4%	$60,506	18.4	5.2	9.8

Source: Capital IQ

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