

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

LABS URGED TO COMMENT ON PAMA PROPOSAL

Medicare reimbursement for lab tests paid through the Clinical Laboratory Fee Schedule (CLFS) is likely to drop significantly—beginning as early as January 1, 2017—if the proposed PAMA rules are finalized without change. Under the proposed rule, CMS would use private-payer payment data primarily from the larger commercial labs to reset Medicare lab fees. Pricing information from hospital labs, which tend to have higher prices, would not be included.

“No matter who reports, we’re all going to be stuck with the same test prices. It’s in all of our interests to make sure the original intent of this law is implemented and that CMS not do it based on cherry-picking information,” ACLA President Alan Mertz told listeners on a special *Laboratory Economics* teleconference on October 22.

“It’s critically important that as many labs and people who work in labs as possible submit comments to CMS...If CMS is overwhelmed with comments to fix things, there’s a much better chance that they will get fixed,” said Mertz. *More details on page 6.*

FINAL PHYSICIAN FEE SCHEDULE LOOKS BENIGN

The final PFS for 2016 shows small increases in Medicare rates for the professional and technical components of CPT 88305. In addition, the key immunohistochemistry codes (88341 & 88342) are being raised by 20% to 30%, with most of the gain going to technical fees.

Details on pages 3-5.

NEOGENOMICS BUYING CLARIANT FOR \$300 MILLION

NeoGenomics (Fort Myers, FL) is buying Clariant Inc. (Aliso Viejo, CA) at about half the price that GE Healthcare paid for it just five years ago. Under the deal, NeoGenomics will acquire the cancer testing lab for \$80 million in cash, \$110 million in preferred stock, and 15 million shares of NeoGenomics common stock—currently valued at roughly \$110 million—for a total of \$300 million. *Continued on page 2.*

CONTENTS

HEADLINE NEWS

Labs Urged to Comment on PAMA Rule	1, 6
Final PFS for 2016 Looks Benign.....	1, 3-4
NeoGenomics Buying Clariant.....	1-2

MEDICARE

Final 2016 Rates for Key Pathology Codes.....	4-5
---	-----

INDEPENDENT LABS

Theranos Making Little Progress	7
---------------------------------------	---

MERGERS & ACQUISITIONS

Quest to Buy Clinical Lab Partners in Connecticut.....	8
Aurora Buys Big Toledo Pathology Group.....	8
LabCorp Acquires Food Testing Lab	10

PHLEBOTOMY

LabCorp Phlebotomists Unionize in California.....	9-10
---	------

MISCELLANEOUS

Pathology Blawg Ceases Publication: RIP (February 2012 – October 2015)	10
--	----

DRUG TESTING

Drug Tests Remain Fastest-Growing Medicare Lab Test Expense.....	11
--	----

FINANCIAL

Lab Stocks Down 12% YTD.....	12
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NEOGENOMICS BUYING CLARIANT FOR \$300 MILLION (cont'd from page 1)

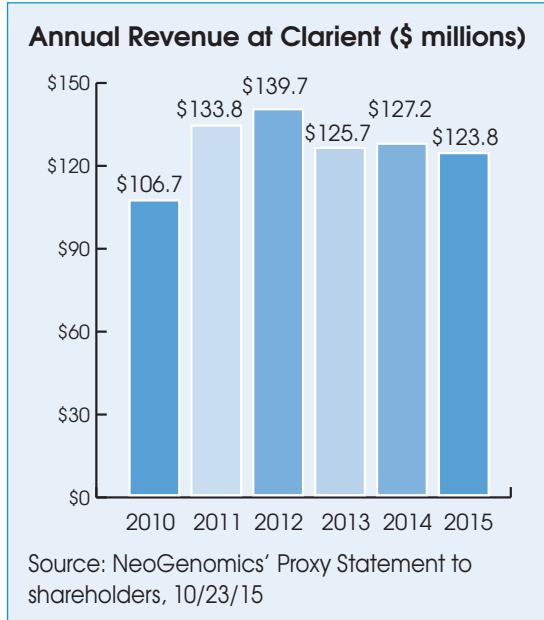
GE Healthcare had acquired Clariant in December 2010 for \$587 million in cash. That deal valued Clariant at 5.5 times its then annual revenue of \$107 million. GE Healthcare, which is focused on diagnostic imaging, had hoped to develop integrated pathology and imaging products. John Dineen, former president and CEO of GE Healthcare, had stated a goal of “building a \$1-billion-plus business by developing integrated diagnostic solutions for cancer and other diseases.” But this unrealistic goal was never realized and Clariant barely grew, resulting in a \$294 million asset write off in 2013. Dineen resigned from GE Healthcare in late 2014 to “pursue new opportunities.”

However, the combination of NeoGenomics and Clariant looks more promising.

NeoGenomics and Clariant have similar business models focused on providing tech-only test services to community pathologists who then perform and bill for the professional component. NeoGenomics is focused on molecular testing and blood-based cancers. Clariant’s focus is solid tumor cancers of the breast, colon and lung and it is the nation’s top digital pathology lab. NeoGenomics is hoping to cross-sell its molecular tests into Clariant’s client base.

For example, NeoGenomics performs 38 out of the top 40 tests that Clariant sends out. Likewise, Clariant’s digital pathology services can be marketed to NeoGenomics’ customers.

By consolidating billing, compliance, marketing, et al., NeoGenomics expects cost savings of \$4 million to \$6 million in 2016, with annual cost savings rising to \$20 million to \$30 million by the end of the third year following the deal. There is also the opportunity to consolidate two labs located 15 minutes apart in Orange County, California. NeoGenomics says it has outgrown its Irvine, California lab, while there is extra capacity in Clariant’s Aliso Viejo lab (80,000 sq. ft.).



NeoGenomics & Clariant in Brief			
	NeoGenomics	Clariant	Combined
Est'd Revenue 2015.....	\$100M	\$124M	\$224M
Average Revenue per Test*	\$410	\$361	~\$386
Employees.....	440	415	855
Sales Reps	27	27	54
Lab locations	Fort Myers & Tampa, FL	Aliso Viejo, CA	
	Nashville, TN	Houston, TX	
	Irvine, Fresno,		
	W. Sacramento, CA		

*Based on results for nine months ended Sept. 30, 2015
Source: Laboratory Economics from NeoGenomics, Clariant and CMS

The deal, which is expected to close by the end of this year, will give GE a 33% ownership stake in NeoGenomics (assuming full conversion of the preferred stock given to GE). As part of the transaction, NeoGenomics’ board of

directors will be expanded with the appointment of a new director from GE Healthcare (expected to be Kieran Murphy, chief executive of GE’s life sciences division). The two companies have also agreed to collaborate on a personalized oncology initiative aimed at developing new tests that combine genomic and diagnostic imaging data.

With the acquisition, NeoGenomics expects its revenue to more than double to about \$250 million next year. “Our vision is to become America’s premier cancer testing laboratory, and this acquisition is a major step forward in achieving that vision,” said NeoGenomics chairman and CEO Douglas VanOort.

FINAL PHYSICIAN FEE SCHEDULE LOOKS BENIGN (*cont'd from page 1*)**Small Increase for CPT 88305**

Global reimbursement for CPT 88305 will increase by 1.2% to \$74.16 next year, according to the Final PFS Rule for 2016. The professional component for 88305 is being increased by 1.5% to \$39.77; the technical component is raised by 0.8% to \$34.39.

Immunohistochemistry: CPT 88342 & 88341

After IHC rates got whacked down by approximately 30% in 2015, CMS has finalized an approximate hike in rates for IHC of roughly 20% to 30% in 2016 (depending on the number of stains per specimen), with most of the gain coming on the technical side.

Global reimbursement for the first IHC stain on a specimen (CPT 88342) is set to increase by 18% to \$107.48. The PC is being raised 1.7% to \$37.26, while the TC is set to jump 29% to \$70.22.

Global rates for each additional IHC stain on a specimen (CPT 88341) will increase by 33.5% to \$90.64. The PC is set to increase by 27.5% to \$27.95, while the TC will leap 36% to \$62.70.

FISH Testing

Final rates for multiplex FISH probe staining procedures (CPT 88374) were substantially raised (TC up 87%; PC up 2.1%).

Prostate Biopsy Rates Hammered Again

For the 2016 physician fee schedule, the CMS accepted recommendations from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) to reduce the direct practice expense inputs for G0416 (prostate biopsy pathology services, any method). As a result, the G0416-TC is being cut by 19% to \$375.83, while G0416-PC is being cut 14% to \$158. The global rate for 2016 is \$533.84, down 18%.

Medicare reimbursement for the pathology services associated with a typical 10-core prostate biopsy has now been slashed by 50% since 2012.

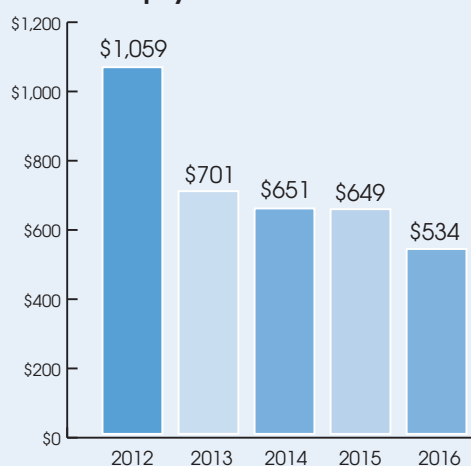
Further cuts to G0416 are likely in 2017. CMS says that it received comments suggesting that the typical number of blocks used in prostate biopsies is significantly lower than the assumption it used to determine the 2016 rates. As a result, CMS is “seeking evidence of the typical batch and block size used in furnishing this service.”

Flow Cytometry

CMS finalized cuts that will lower flow cytometry rates by approximately 19% in 2016, depending on the number of markers tested. For example, reimbursement for the highest-volume code—CPT 88185 (flow cytometry TC, each additional marker)—is set to decline by 19.6% to \$46.22.

Codes Under Review as Potentially Misvalued

CMS identified the following pathology services as “potentially misvalued” and subject to review in 2016 for potential payment reductions in 2017: CPT 88185 & 88189 (flow cytometry), CPT 88321 (microslide consultation) and CPT 88360 & 88361 (tumor immunohistochemistry).

Medicare Reimbursement for 10-Core Prostate Biopsy*

*National rate unadjusted for geography; assumes conversion factor for 2016=\$35.8279
Source: *Laboratory Economics* from MPFS, 2012-2016

Final Physician Fee Schedule Rates for 2016 for Key Pathology Codes

CPT CODE	DESCRIPTION	NON-FACILITY RATE 2016*	NON-FACILITY RATE 2015**	PAYMENT % CHANGE
88112-Global	Cytopath cell enhance tech	\$72.37	\$65.04	11.3%
88112-26	Cytopath cell enhance tech	29.02	28.75	0.9%
88112-TC	Cytopath cell enhance tech	43.35	36.29	19.5%
88120-Global	FISH-manual, 3-5 probes	639.89	626.32	2.2%
88120-26	FISH-manual, 3-5 probes	60.19	59.29	1.5%
88120-TC	FISH-manual, 3-5 probes	579.70	567.03	2.2%
88121-Global	FISH-computer assisted, 3-5 probes	558.20	556.97	0.2%
88121-26	FISH-computer assisted, 3-5 probes	51.95	51.74	0.4%
88121-TC	FISH-computer assisted, 3-5 probes	506.25	505.23	0.2%
88184	Flow cytometry/1st marker	76.31	94.51	-19.3%
88185	Flow cytometry/each additional marker	46.22	57.49	-19.6%
88189	Flow cytometry, read 16+	114.29	113.91	0.3%
88305-Global	Tissue exam by pathologist	74.16	73.30	1.2%
88305-26	Tissue exam by pathologist	39.77	39.17	1.5%
88305-TC	Tissue exam by pathologist	34.39	34.14	0.8%
88307-Global	Level V, tissue exam by pathologist	312.06	307.59	1.5%
88307-26	Level V, tissue exam by pathologist	87.42	86.24	1.4%
88307-TC	Level V, tissue exam by pathologist	224.64	221.35	1.5%
88312-Global	Special stains, group 1	98.89	98.10	0.8%
88312-26	Special stains, group 1	28.30	28.03	1.0%
88312-TC	Special stains, group 1	70.58	70.07	0.7%
88313-Global	Special stains; group 2	69.15	68.27	1.3%
88313-26	Special stains; group 2	12.54	12.58	-0.3%
88313-TC	Special stains; group 2	56.61	55.70	1.6%
88331-Global	Pathology consult during surgery; first block	97.09	103.85	-6.5%
88331-26	Pathology consult during surgery; first block	65.57	64.68	1.4%
88331-TC	Pathology consult during surgery; first block	31.53	39.17	-19.5%

CPT CODE	DESCRIPTION	NON-FACILITY RATE 2016*	NON-FACILITY RATE 2015**	PAYMENT % CHANGE
88341-Global	Immunohistochemistry (Add'l stain)	90.64	67.91	33.5%
88341-26	Immunohistochemistry (Add'l stain)	27.95	21.92	27.5%
88341-TC	Immunohistochemistry (Add'l stain)	62.7	45.99	36.3%
88342-Global	Immunohistochemistry (1st stain)	107.48	90.91	18.2%
88342-26	Immunohistochemistry (1st stain)	37.26	36.65	1.7%
88342-TC	Immunohistochemistry (1st stain)	70.22	54.26	29.4%
88360-Global	Tumor immunohistochem/manual	121.81	136.55	-10.8%
88360-26	Tumor immunohistochem/manual	56.61	55.7	1.6%
88360-TC	Tumor immunohistochem/manual	65.21	80.85	-19.3%
88361-Global	Tumor immunohistochem/computer	149.40	170.32	-12.3%
88361-26	Tumor immunohistochem/computer	60.91	60.37	0.9%
88361-TC	Tumor immunohistochem/computer	88.49	109.96	-19.5%
88367-Global	FISH Computer-assisted	107.48	107.80	-0.3%
88367-26	FISH Computer-assisted	35.83	35.57	0.7%
88367-TC	FISH Computer-assisted	71.66	72.23	-0.8%
88368-Global	FISH Manual	115.01	109.24	5.3%
88368-26	FISH Manual	41.20	41.32	-0.3%
88368-TC	FISH Manual	73.81	67.91	8.7%
88374-Global	FISH automated per probe (multiplex probe stain)	346.10	205.54	68.4%
88374-26	FISH automated per probe (multiplex probe stain)	46.22	45.28	2.1%
88374-TC	FISH automated per probe (multiplex probe stain)	299.88	160.26	87.1%
G0416-Global	Prostate biopsy, any method	533.84	649.32	-17.8%
G0416-26	Prostate biopsy, any method	158.00	182.9	-13.6%
G0416-TC	Prostate biopsy, any method	375.83	466.42	-19.4%

*Conversion factor for 2016 is \$35.8279; **Conversion factor for 2015 is \$35.9335

Note: The rates above do not reflect the 2% sequestration reduction in effect since April 1, 2013.

Source: Final Physician Fee Schedule Rule for 2016

LABS URGED TO COMMENT ON PAMA PROPOSAL (*cont'd from page 1*)

Mertz also said that the schedule for collecting information from labs was “ridiculously compressed.” Under the current schedule, labs would be required to begin submitting private-payer data to CMS starting January 1, 2016. “They’re asking us to start reporting data before they’ve even finalized what the rule is, what the rules are, what has to be reported and who has to report,” noted Mertz. He said that ACLA will ask CMS to push the schedule back so that the final rule comes out in June 2016 and the new prices become effective in November 2017 rather than January 2017.

In terms of what to write when submitting comments to CMS, Mertz said, “I hate to say this, but CMS doesn’t really care about job loss that much, but I think they do care about beneficiaries losing access to testing, either because the test isn’t available or your lab can’t provide service in an area anymore.”

Jane Pine Wood, attorney with McDonald Hopkins, advised teleconference listeners to be specific in their comments. “It doesn’t particularly help CMS to have a comment that says: “This regulation is stupid; it doesn’t make any sense.” But rather to say: “Here is our situation; this is the type of lab we are.” A big area of uncertainty is how do labs report rates when they’re out-of-network?

As of November 17, 270 comments had been submitted to CMS regarding the PAMA lab test repricing.

Is it the initial payment? Is it the payment after appeals have been exhausted? “It’s not as cut and dry as CMS may be presuming,” noted Wood.

Wood also noted that PAMA authorizes CMS to select between one to four Medicare administrative contractors (MACs) to either establish coverage policies or to both establish coverage policies and process claims. This means that CMS could potentially, for example, designate Palmetto GBA as the sole MAC responsible for making national coverage decisions and paying claims. A timetable for consolidating the MACs has not yet been announced, but Wood said that CMS is specifically requesting comments on the pros and cons of a potential consolidation.

As it stands right now, independent labs and physician-office labs that receive greater than \$50,000 per year in Medicare revenue from the Clinical Lab Fee Schedule will need to report their private-payer data from the period July 1, 2015 through December 31, 2015 to CMS starting January 1, 2016. Labs will be required to report private-payer allowed rates and volume for every lab test on the CLFS.

Lale White, CEO of XIFIN Inc., said that CMS is expected to specify the manner for reporting data through a sub-regulatory guidance issued prior to January 1, 2016. Among the many clarifications that need to be provided are:

- 1) Are payment rates for contracted amounts, or do they also include non-contracted amounts for non-network labs?
- 2) Is the rate after appeals or on the initial payment amount?
- 3) Are \$0 payments and allowables going to be factored in?
- 4) Which date should be used: date of service or date paid?
- 5) What will be the criteria for identifying an excludable service fee?

Meanwhile, *Laboratory Economics* notes that most hospital lab administrators are simply relieved that the proposed rule excuses them from the complicated task of compiling and reporting their private-payer payment data. However, although hospital labs will not be required to report, they will have to live with the resulting lower Medicare rates for their outreach lab tests.

The deadline for submitting comments is 5 pm. EST on November 24. Comments on the proposed rule can be submitted electronically at <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

THERANOS MAKING LITTLE PROGRESS WITH ITS BRAND NAME PARTNERS

Over the past two years, Theranos bolstered its claims of having developed a revolutionary low-cost lab testing system by announcing agreements with brand name partners. Theranos raised its status by associating itself with the likes of Walgreens, Intermountain Healthcare and Cleveland Clinic. However, *Laboratory Economics*' review of seven different deals shows that Theranos has made little progress with its "partners."

Walgreens

It's been two years since Theranos opened its first blood drawing site at a Walgreens store in Palo Alto, California, in September 2013. Another 40 sites at Walgreens stores in Arizona were quickly opened in the following months. "This marks the beginning of Theranos and Walgreens planned national rollout of Theranos Wellness Centers," said a November 2013 press release from Theranos. However, Walgreens now says that any plans to open more Theranos sites are on hold.

Cleveland Clinic

On March 9, 2015, Theranos announced a long-term strategic alliance that would "over time, implement Theranos' groundbreaking CLIA-certified laboratory services within Cleveland Clinic's patient populations." It's been eight months since the agreement was announced and Cleveland Clinic CEO Toby Cosgrove, MD, says that Cleveland Clinic has not yet seen or evaluated Theranos' technology. On an October 30 interview on CNBC, Cosgrove said, "We need to have verification of the technology. We don't have that. We have an agreement that we will begin to test that and publish the data."

Intermountain Healthcare

Theranos reached an agreement to provide testing services to Intermountain Healthcare, a 22-hospital system in Utah and Idaho, more than one year ago. However, Intermountain hasn't used their service yet. "It's likely that we'll soon begin to use it in a limited pilot at one clinic with their test and traditional testing done side by side for comparison," Daron Cowley, Senior Communications Director at Intermountain Healthcare, tells *Laboratory Economics*.

Dignity Health

In early 2014, Dignity Health, the largest hospital system in California, reportedly reached an agreement to begin deploying Theranos' testing system. However, a Dignity Health spokeswoman in San Francisco was unable to provide an update on the status of the health system's relationship with Theranos.

Pfizer and GlaxoSmithKline

For over a year, multiple magazines and newspapers—including *The New Yorker*, *Fortune* and *The Washington Post*—reported that Theranos earns revenue from large pharmaceutical companies, including Pfizer and GlaxoSmithKline, who have supposedly used Theranos' technology to conduct clinical trials. In addition, the Theranos' website says, "We have processed hundreds of thousands of tests in validating our work for 10 of the 15 largest pharmaceutical companies."

However, a spokesperson from Pfizer says, "We've done only very limited historical exploratory work with Theranos through a few pilot projects, and we do not have any current or active projects with them." Pfizer is the fourth-largest pharmaceutical company as measured by worldwide revenue for 2014.

And a spokesperson from GlaxoSmithKline says, "I cannot find any evidence that we have done business with them in recent years." GSK is the seventh-largest pharma company.

Safeway

And finally, the *Wall Street Journal* recently reported that Safeway has abandoned plans to offer Theranos' testing service at 800 of its supermarkets. *WSJ* reported that Safeway backed out after Theranos missed several deadlines and due to concern that its technology might still be "a work in progress."

QUEST TO BUY CLINICAL LAB PARTNERS IN CONNECTICUT

Quest Diagnostics is acquiring the laboratory outreach business Clinical Laboratory Partners (CLP-Newington, CT) from Hartford Healthcare in a deal expected to close in early 2016. Under the agreement, CLP will transition its clinical lab testing now provided by its lab in Newington (just south of Hartford) to Quest's rapid-response labs in Stratford, Torrington and Wallingford, Connecticut, and to Quest's new 200,000-square-foot mega-laboratory in Marlborough, Massachusetts.

Quest has been the reference lab for CLP and all five of HHC's affiliated hospitals since 1998. Elliot Joseph, President and CEO of Hartford HealthCare, said in a statement that the deal is being made in order to yield more cost-effective testing, both for patients as well as government and commercial health plans.

CLP is one of the largest health-system-owned lab outreach businesses in the country and is Quest's biggest competitor in Connecticut. CLP processed 11.4 million tests for 1.6 million patients and generated \$105 million of revenue in 2014, according to Hartford Healthcare's Annual Report for 2014. The planned combination of Quest and CLP in Connecticut might trigger antitrust scrutiny from the Federal Trade Commission, notes *Laboratory Economics*.

Hartford Healthcare's hospital-based labs, outpatient services and anatomic pathology services are not included in the deal, and will remain part of the Hartford Healthcare system, which owns five hospitals, including Hartford Hospital and the Hospital of Central Connecticut.

The sale to Quest could result in the loss of as many as 220 jobs: Clinical Laboratory Partners employs 570 people but Quest will only add 350 jobs as a result of the deal. CLP's President James Fantus is expected to retire after the deal is completed.

FAST FACTS CLINICAL LAB PARTNERS

President & CEO: James Fantus

Main Lab: Newington, CT

Patient Service Centers: 80

Employees: 500+

Physician Customers: 3,900

Annual Medicare Test Volume (2013): 1.7 million

Annual Medicare Collected Revenue (2013): \$11.5 million

Total Annual Tests (2014): 11.4 million

Total Annual Revenue (2014): \$105 million

Source: Hartford Healthcare, Clinical Lab Partners and CMS

AURORA DIAGNOSTICS BUYS CONSULTANTS IN LABORATORY MEDICINE

Aurora Diagnostics has acquired Consultants in Laboratory Medicine of Greater Toledo, Inc., a hospital-based practice providing anatomic laboratory medicine professional pathology services to 11 hospitals in Michigan and Ohio.

Consultants in Laboratory Medicine is the exclusive provider of pathology services to the ProMedica Health System, an 11-hospital system in Northwest Ohio and Southeast Michigan. Consultants in Laboratory Medicine, which does not own laboratory facilities, has a total of 25 employees, including 15 pathologists.

Consultants in Laboratory Medicine is led by its President Michael Walsh, MD, who is also Chairman of the Department of Pathology at ProMedica. Walsh will remain with CLM as part of Aurora Diagnostics.

LABCORP PHLEBOTOMISTS IN CALIFORNIA JOIN UNIONS

Seeking better wages and working conditions, approximately 150 LabCorp phlebotomists in California recently voted to join local unions. The workers, based at seven lab facilities across the southern part of the state, joined UFCW Locals 21, 135, 770, 1167 and 1428.

Leon Gutierrez, a LabCorp phlebotomist, told union officials that he joined to improve working conditions at LabCorp and to lift the standard of living for his coworkers.

“I have been in phlebotomy for more than 24 years and the conditions for non-union phlebotomists at companies like LabCorp have only gotten worse,” said Gutierrez, according to a union publication. “It’s time that LabCorp values us like the professionals we are and gives us the respect and dignity we deserve.”

Class-Action Lawsuits

The move to join unions comes on the heels of two class-action lawsuits filed last year accusing LabCorp and labs owned by the company of forcing employees to work long hours without meal breaks or overtime wages as required by state law. LabCorp employs about 1,000 phlebotomists in California.

Rachel Rabanes brought one lawsuit on behalf of herself and other current and former employees who work at stand-alone patient service centers and short-term assessment and treatment labs in Los Angeles County operated by LabCorp, California Laboratory Sciences and West Pacific Medical Laboratory.

“Defendants require these employees to clock out and keep working until production and testing goals are met while off the clock and to work through lawful meal and rest breaks without receiving statutory compensation,” according to the lawsuit.

Rabanes alleged she regularly worked in excess of 8 hours per day without receiving meal breaks or rest periods or being paid overtime. She alleged 10 causes of action under the California Labor Code and California Business and Professions Code.

A second class-action lawsuit alleging similar violations was filed in June 2014 by Rita Varsam in the Superior Court of California for the County of San Diego.

Beginning in April 2015, the UFCW filed a series of seven petitions with the National Labor Relations Board, according to LabCorp’s 10Q filing for the quarter ended June 30. UFCW filed a series of seven petitions with the National Labor Relations Board in Southern California for certification as the collective bargaining representative for phlebotomy employees located at discrete sites identified in each petition.

Regular Schedules, Pay Increases

Fredel Albritton, a LabCorp phlebotomist who works in Seattle, has helped unionize the phlebotomists in California. More than 600 LabCorp workers, including medical technologists, medical laboratory technicians and other lab workers, are members of the UFCW Local 21 in Seattle, he tells *Laboratory Economics*.

The Local 21 contract with LabCorp addresses a number of issues, including seniority, layoffs, work schedules, overtime, wages, shift differentials and annual leave (the contract is available online at <http://static1.squarespace.com/static/5418aa2ce4b097579b5c27e5/t/55244f56e4b00794e54c755d/1428442966278/Dynacare+14-17.pdf>).

“We’ve been able to really improve working conditions by working through the union,” says Albritton. The California LabCorp phlebotomists are seeking the same types of things—regular work schedules, regular cost-of-living and step increases, and better benefits, he says.

The UFCW locals in California are in the midst of negotiations with LabCorp, according to a union spokesperson. Currently, only phlebotomists have joined the California union. It’s unclear whether other lab workers have also been approached.

LabCorp Responds

Lisa Uthgenannt, the chief human resources officer for LabCorp, tells *Laboratory Economics* that while the company recognizes the rights of employees to unionize as they choose, LabCorp continues to believe that the best environment is one that allows employees to work out their concerns with their supervisors rather than seek third-party representation.

“At LabCorp, our employees are our most valuable resource,” she says. “Our wages and benefits are competitive. We are committed to treating employees with respect and fairness and maintaining a positive, open relationship that allows employees to raise and resolve issues directly with management.”

LABCORP EXPANDS INTO FOOD AND BEVERAGE TESTING

LabCorp (Burlington, NC) has acquired Safe Foods International Holdings, LLC, (SFIH) and its two operating companies, International Food Network (IFN) and The National Food Laboratory (The NFL). Terms of the acquisition were not disclosed.

With the acquisition, LabCorp builds upon services offered by the Nutritional Chemistry and Food Safety division of Covance, which LabCorp purchased earlier this year for \$6.2 billion.

“We identified nutritional chemistry and food safety as an exciting growth opportunity for our company immediately after the [Covance] acquisition,” said David King, Chairman and CEO of LabCorp, in announcing the deal. “With this acquisition, we extend our capabilities to offer a full range of product-development and product-integrity services to food and beverage manufacturers and retailers, industry organizations and academic institutions.”

International Food Network focuses solely on product development, with locations in Ithaca, NY; Naples, FL, and Reading in the United Kingdom. “With a team of over 50 food scientists and engineers based in facilities in the U.S. and the U.K., IFN has extensive knowledge that enables us to collaborate with our clients to develop successful new market products in a broad range of food categories,” the company says on its website. Revenue is estimated at about \$4 million annually.

The National Food Lab, a consulting and testing company, has two facilities located in Livermore, CA. According to the company website, it provides “creative, practical and science-based insights to solve food safety, quality, and product and process development challenges for food and beverage companies.” The NFL employs about 125 people and generates estimated annual revenue of approximately \$20 million.

PATHOLOGY BLAWG RIP

Over the past few years, PathologyBlawg.com had developed a large following for its critical reporting on key business and legal issues facing laboratories and pathologists. However, the website ceased publication in mid-October. “Due to a combination of personal, professional and legal issues related to operating the Blawg, I made the very difficult decision to stop operating the site,” its anonymous-pathologist owner tells *Laboratory Economics*.

DRUGS-OF-ABUSE TESTING LEADS IN GROWTH

The fastest-growing clinical lab tests continue to be drugs-of-abuse testing related to pain management medication, according to a *Laboratory Economics* analysis of CMS data for Medicare Part B carrier expenditures on clinical lab tests from 2011 to 2014.

The single-fastest-growing CPT code was 82542 (cannabinoids quantitation by GC/MS), a confirmation test for marijuana/THC. Part B carrier spending on CPT 82542 increased by an average of 50% per year between 2011 and 2014.

In addition, Part B carrier spending on four other test codes for drugs of abuse grew by 30% per year or more during the three-year period. Part B carrier spending on CPT 80154 (benzodiazepines) was up an average of 44% per year, while CPT 82145 (amphetamine or methamphetamine) increased 41%, CPT 83840 (methadone), up 34%, and CPT 83925 (opiates) was up 32%.

Overall, Medicare Part B carrier spending on the top 25 fastest-growing clinical lab tests increased by 10% per year between 2011 and 2014.

MEDICARE PART B CARRIER SPENDING ON FASTEST-GROWING LAB TESTS

CPT Code (description)	2014	2011	3-Year CAGR*
82542 (cannabinoids)	\$124,808,530	\$37,382,667	49.5%
80154 (benzodiazepines)	69,706,528	23,476,043	43.7%
82145 (amphetamine or methamphetamine)	46,127,088	16,425,213	41.1%
83840 (methadone)	53,039,267	22,157,222	33.8%
83925 (opiates)	178,879,003	77,922,525	31.9%
84999 (chemistry test)	88,652,569	56,738,467	16.0%
84481 (triiodothyronine T3; free)	24,547,005	19,061,789	8.8%
82570 (creatinine)	42,202,641	34,024,377	7.4%
81003 (urinalysis)	20,126,166	16,369,811	7.1%
83735 (magnesium)	25,818,030	21,329,516	6.6%
82043 (albumin)	23,303,046	19,780,335	5.6%
84403 (testosterone, total)	40,123,365	34,482,832	5.2%
83970 (parathormone)	74,075,751	68,014,528	2.9%
82607 (vitamin B12)	78,884,061	72,591,743	2.8%
84439 (thyroxine, free)	57,984,984	54,044,400	2.4%
84165 (protein; electrophoretic fractionation)	16,848,945	15,825,050	2.1%
82784 (immunoglobulin; IgA, IgD, IgG, IgM, each)	17,947,858	16,892,292	2.0%
82306 (vitamin D)	238,995,824	225,065,643	2.0%
87077 (culture, bacterial)	21,732,339	20,547,105	1.9%
86235 (nuclear antigen antibody)	25,827,098	24,731,938	1.5%
87186 (MIC)	33,282,300	32,146,272	1.2%
83036 (A1C)	180,705,434	175,994,402	0.9%
87086 (urine culture)	55,957,078	54,628,400	0.8%
82746 (folate)	42,737,501	42,373,305	0.3%
81001 (urinalysis)	31,242,978	31,136,974	0.1%
Total	\$1,613,555,389	\$1,213,142,848	10.0%

*CAGR=Compound annual growth rate

Source: *Laboratory Economics* from CMS Part B Carrier Spending Data, 2011-2014

LAB STOCKS DOWN 12% YTD

Fifteen lab stocks have declined by an unweighted average of 12% year to date through November 13. In comparison, the S&P 500 Index is down 2%. The top-performing lab stocks so far this year are NeoGenomics, up 79%, and Myriad Genetics, up 25%. Meanwhile, LabCorp is up 11% and Quest Diagnostics is unchanged.

Company (ticker)	Stock Price 11/13/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/Sales	Price/Book
Cancer Genetics Inc. (CGIX)	\$3.62	\$6.68	-46%	\$39	NA	2.4	1.4
CombiMatrix (CBMX)	0.79	1.29	-39%	10	NA	1.1	1.2
Enzo Biochem (ENZ)	4.50	4.44	1%	207	NA	2.1	4.7
Exact Sciences (EXAS)	9.39	27.44	-66%	905	NA	33.7	2.5
Foundation Medicine (FMI)	16.58	22.22	-25%	571	NA	6.4	2.0
Genomic Health (GHDX)	26.54	31.97	-17%	864	NA	3.0	6.4
Invitae (NVTA)	6.62	16.00	-59%	211	NA	35.6	1.4
LabCorp (LH)	119.69	107.90	11%	12,110	26.1	1.6	2.5
Myriad Genetics (MYGN)	42.63	34.06	25%	2,970	34.4	4.1	4.3
NeoGenomics (NEO)	7.45	4.17	79%	450	NA	4.6	7.4
Opko Health (OPK)	10.72	9.99	7%	5,840	NA	24.8	3.0
Psychedics (PMD)	11.09	15.15	-27%	60	29.9	2.2	4.9
Quest Diagnostics (DGX)	67.20	67.06	0%	9,630	13.8	1.3	2.1
Sonic Healthcare (SHL.AX)	19.17	18.50	4%	7,920	22.3	1.9	2.4
Veracyte (VCYT)	6.32	9.66	-35%	175	NA	3.6	2.9
Unweighted Averages			-12%		25.3	8.5	3.3

Source: Capital IQ

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