

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

QUEST TO PAY \$241M TO SETTLE MEDI-CAL SUIT

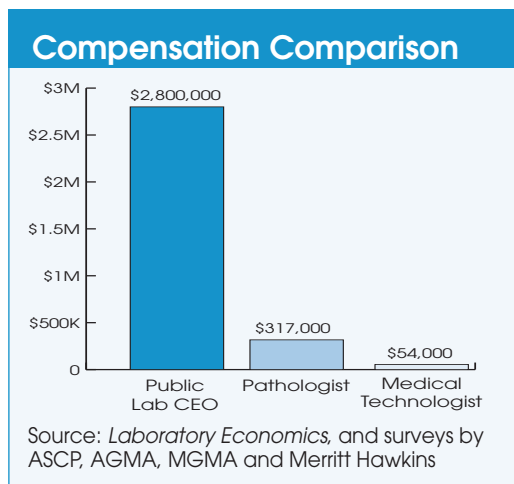
Quest Diagnostics has agreed to pay \$241 million to settle a lawsuit that accused the company of systematically overcharging California's Medi-Cal program over the past 15 years. The California Attorney General's office says the \$241 million settlement is the largest recovery in the history of California's False Claims Act.

The lawsuit was originally filed under seal by Hunter Labs and its owner Chris Riedel in November 2005. In March 2009, then-California Attorney General Jerry Brown announced that the state had joined the case (see *LE*, April 2009, page 1).

Final settlement of the case will bring a giant windfall to Riedel. The False Claims Act provides incentives to whistleblowers by granting them between 15% and 25% of any settlement amount plus reimbursement of legal fees. That means that Riedel will receive between \$36 million and \$60 million. *Continued on page 9.*

PUBLICLY-TRADED LAB CEOs PAID AVERAGE OF \$2.8M

The chief executives at 15 publicly-traded lab companies were paid an average of \$2.8 million each last year, according to an analysis of shareholder proxy statements by *Laboratory Economics*. This compares with a median salary of \$317,000 for pathologists and \$54,412 for medical technologists, according to the latest survey data from the American Society for Clinical Pathology (ASCP) and several other professional organizations. *Full details on pages 5-7.*



MYRIAD GENETICS TO BUY RBM FOR \$80 MILLION

Myriad Genetics (Salt Lake City, UT) has agreed to buy Rules-Based Medicine (RBM) for \$80 million in cash. RBM generated \$25 million of revenue in 2010, implying an acquisition price/revenue multiple of about 3.2. RBM has 160 employees and operates a CLIA-certified lab in Austin, Texas. In March 2010, the company began marketing a laboratory-developed molecular test panel, branded VeriPsych, for helping psychiatrists diagnose schizophrenia. VeriPsych, which has a list price of \$2,500, is the first blood-based test for schizophrenia. However, gaining market acceptance for this expensive test from psychiatrists and insurance companies has been a challenge. *Continued on page 2.*

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MYRIAD GENETICS TO BUY RBM FOR \$80M (cont'd from page 1)

RBM generates most of its revenue from clinical trial testing services provided to pharmaceutical companies, such as Johnson & Johnson, Merck and Eli Lilly, to help determine the efficacy and safety of new drug candidates. There is the potential for RBM to develop companion diagnostics for drugs developed through these relationships.

In 2002, RBM was spun off from Luminex Corp. (Austin, TX), which makes microsphere beads and fluorescent detection instruments. RBM has a long-term development and supply agreement with Luminex.

In December 2009, RBM filed plans to raise up to \$90 million from an initial public offering. However, the company withdrew its IPO plans late last year citing adverse market conditions.

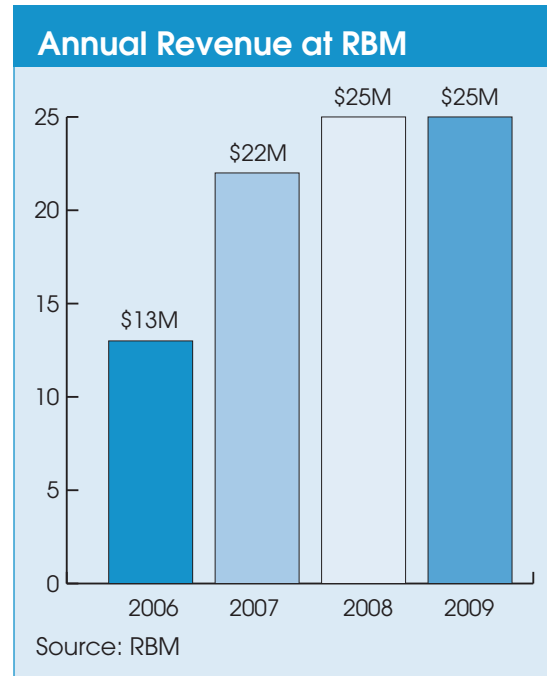
RBM posted a loss in 2010 versus net income of \$173,000 in 2009; revenue was flat at \$25 million.

The sale to Myriad is expected to be finalized by May 31. Myriad plans to maintain RBM's lab in Austin and operate the company as a wholly-owned subsidiary named Myriad RBM.

Owners of RBM include Mark Chandler, PhD, founder and chairman, and Craig Benson, president and chief executive. Equity Group Investments LLC, an investment fund founded by real estate tycoon Sam Zell, also has a large stake in RBM.

The acquisition of RBM will add another high-priced proprietary test to Myriad's menu. Myriad has deep pockets (\$450 million of cash and no debt as of March 31, 2011) and has a huge marketing infrastructure (315-person sales force) to support RBM's VeriPsych test.

Despite its growing test menu, Myriad still derives 90% of its total annual revenue of \$400 million from its BRACAnalysis genetic test for breast and ovarian cancer.

**Myriad Genetics' Test Menu**

Test Name	Market Launch	Test Purpose	List Price
BRACAnalysis	October 1996	Genetic risk for breast and ovarian cancer	\$3,340
Colaris	September 2000	Genetic risk for colon or uterine cancer	3,150
Melaris	November 2001	Genetic risk for malignant melanoma	900
Colaris AP	May 2002	Genetic risk for colon cancer	2,050
TheraGuide 5-FU	July 2007	Help determine best chemotherapy drugs	1,175
OnDose	April 2009	Help determine best chemotherapy drugs	300
Prezeon	January 2009	Help determine best chemotherapy drugs	500
Prolaris	March 2010	Determine risk of prostate cancer recurrence	3,400
Panexia	November 2010	Genetic risk for pancreatic cancer	3,025
VeriPsych	May 2011	Help diagnose schizophrenia	2,500

Source: Myriad Genetics

AMERIPATH REACHES SETTLEMENT WITH FORMER SALES REP

AmeriPath and Christian Stevens, a former regional sales manager, reached a settlement during a mediation hearing held April 21 in Miami. A Florida judge had ordered the case to mediation after ruling that Stevens breached a non-compete agreement by joining a rival pathology lab shortly after his resignation from AmeriPath in April 2010 (see *LE*, April 2011, page 1).

According to the final order issued on May 2 by the U.S. District Court for the Southern District of Florida, Stevens is not allowed to solicit any business from any doctor or dermatology practice located in Atlanta through January 22, 2012. Stevens is also required to pay \$100,000 to AmeriPath, which is owned by Quest Diagnostics, to help cover the company's legal expenses.

However, Stevens is allowed to continue working at SkinPath Solutions (Smyrna, GA). SkinPath is a dermatopathology lab started by former AmeriPath lab director Robert Wesley Wetherington, MD.

The settlement also allows SkinPath to continue providing dermatopathology services to six dermatology practices in the Atlanta area. These six practices employ 17 dermatologists and represent more than \$2 million in annual dermatopathology revenue. These practices were former clients of AmeriPath.

DALLAS PATHOLOGIST CHALLENGES AMERIPATH NON-COMPETE

Michael Robles, DO, has filed a lawsuit challenging the non-competition restrictions in his employment agreement with AmeriPath. Robles is currently director of gastrointestinal pathology at AmeriPath North Texas (Dallas). However, on April 1, 2011, he gave AmeriPath 120-day notice that he will resign at the end of July. Robles plans to go to work for a new pathology group that he is forming named Pathology Health Associates of Texas.

One of AmeriPath's largest clients in the Dallas area is Digestive Health Associates of Texas (DHAT). DHAT is a 75-doctor gastroenterology group with more than 30 offices in the Dallas area. The group opened its own histology lab in 2007 (see *LE*, July 2007, page 1) and contracted with AmeriPath for professional services. Over the past four years, Robles has been one of the primary pathologists at AmeriPath providing slide-interpretation services to DHAT.

According to the lawsuit, Robles has told DHAT that he is leaving AmeriPath, and DHAT, on its own without solicitation from Robles, has expressed a desire to continue to have its pathology work done by Robles.

Robles filed the lawsuit as a preemptive strategy. He wants to be allowed to continue to provide pathology services to DHAT at his new pathology group without concern that he will be in breach of the non-compete restrictions contained in his employment agreement with AmeriPath. Robles claims that AmeriPath's non-compete restrictions are not enforceable in Texas for physicians.

Robles filed the lawsuit (case no. 11-04109) in the District Court of Dallas County on Friday afternoon, April 1—the same day he gave notice to AmeriPath that he was resigning.

AmeriPath, which is owned by Quest Diagnostics, has not yet filed a response to the lawsuit.

AmeriPath is currently seeking to hire a GI pathologist, managing lab director and regional operations director in Dallas.

IN-OFFICE PATHOLOGY TRENDS

Most large urology and gastroenterology groups have insourced pathology services and others (e.g., Florida Digestive Health Specialists and Carolina Urology Partners) continue to do so.

NORTH CAROLINA UROLOGISTS MERGE AND OPEN HISTOLOGY LAB

Seven independent urology groups in North Carolina have merged, effective March 1, 2011, to form Carolina Urology Partners. The merged group has 31 urologists and more than 200 employees at 15 locations throughout the Charlotte region. Carolina Urology has opened a new 12,000-square-foot administrative office and about 20% of this space is for a pathology laboratory that will process the group's biopsies. The group has hired two uropathologists—Kemery Gilbert, MD, and B. Vittal Shnoy, MD—to provide professional services.

BIG FLORIDA GASTRO GROUP OPENS HISTOLOGY LAB

Florida Digestive Health Specialists (Bradenton, FL) has opened a freestanding histology lab for the group's 25 gastroenterologists. The new lab will perform technical services and has contracted with local pathologists for professional services. The group, which performs an estimated 50,000+ biopsies per year, will now bill and collect for global pathology services provided to its patients. Formerly the group had used Caris Life Sciences, GI Pathology and local hospitals for pathology services.

MORE INSOURCING AT DERM GROUPS

Insourcing at large urology and gastroenterology groups has been taking place for the past five years. More recently, dermatologists have joined the trend. Dermatologists have always read their own slides and now they are rapidly building in-office histology labs to capture slide-preparation fees (see *LE*, February 2011, pages 1-2).

Dermatology practices that have recently opened labs include **Dermatology Associates of Western Connecticut** (Danbury), with six dermatologists, and **Portland Dermatology Clinic** (Portland, OR), with seven dermatologists. In addition, **Marietta Dermatology and Skin Cancer Center** (Marietta, GA), with nine dermatologists, and **Moeller Dermatology** (Wichita, KS), with one doctor, are each in the process of building in-office labs.

10 Specialty Groups with New In-Office Histology Labs

Group Name	Location	# Physicians
Advanced Urology	North of Chicago	1
Carolina Urology Partners	Charlotte Region	31
Dermatology Associates	Portland, Maine	9
Dermatology Associates of Western Connecticut	Danbury, Connecticut	6
Florida Digestive Health Specialists	Southwest Florida	25
Gastroenterology Associates of Northern Virginia	Northern Virginia	10
Marietta Dermatology	Northwest Georgia	9
Moeller Dermatology	Wichita, Kansas	1
Pasco Hernando Oncology	Southwest Florida	4
Portland Dermatology Clinic	Portland, Oregon	7

Source: *Laboratory Economics*

COMMERCIAL LAB CEOs PAID AVERAGE OF \$2.8M (*cont'd from page 1*)

As mentioned in last month's *Laboratory Economics*, **Quest Diagnostics' Surya Mohapatra, PhD** (\$12.3 million) and **LabCorp's David King** (\$9.7 million) were the highest paid lab company CEOs in 2010.

The third highest paid was **Peter Meldrum**, 63, president and CEO of **Myriad Genetics**. Meldrum earned \$5.3 million, including a salary of \$832,550, bonus of \$649,710, stock options valued at \$3.8 million plus other compensation of \$10,475. In the fiscal year ended June 30, 2010, Myriad reported net income of \$152.3 million, up from \$136.3 million in 2009; revenue increased by 11% to \$362.6 million; its stock price fell 12% in 2010.

Next highest paid was **Tina Nova Bennett, PhD**, 57, president and CEO of **Genoptix**. Bennett earned a total of \$2.35 million, including a salary of \$569,423, incentive plan compensation of \$363,375, stock and options valued at \$1.4 million, and other compensation of \$24,289. In addition, Bennett received a \$9.6 million windfall as a result of the recent sale of Genoptix to Swiss drugmaker Novartis (see *LE*, March 2011, page 5).

Kathy Ordonez, 60, chief executive of **Celera Corp.**, which owns Berkeley Heart Lab, was paid a total of \$1.9 million. This included salary of \$650,000, incentive payments of \$237,900, stock and options valued at \$1 million, and other compensation of \$16,528. In addition, Ordonez is due to get a \$3.5 million windfall as a result of the pending sale of Celera to Quest Diagnostics (see *LE*, April 2011, page 10).

Kim Popovits, 52, president and CEO of **Genomic Health**, received a total compensation of \$1.6 million, including salary of \$465,000, incentive payments of \$38,585 plus stock options valued at \$1.1. Genomic Health posted net income of \$4.3 million in 2010 versus a loss of \$9.4 million in 2009; revenue was up 19% to \$178.1 million.

Other well-paid executives included **Robert Hagemann**, 54, senior vice president and chief financial officer at **Quest Diagnostics**, earned \$4.3 million in total compensation. **Jon Cohen, MD**, 56, senior vice president and chief medical officer, earned \$3 million. **Joan Miller, PhD**, 56, senior vice president, hospital and pathology services, earned \$2.9 million.

James Boyle, 54, executive vice president, chief operating officer at **LabCorp**, received total compensation of \$3.9 million last year. **William Hayes**, 45, executive vice president and chief financial officer, earned \$3.4 million.

Why do CEOs make so much money?

Because it's the chief executives, not shareholders, that appoint the board members who are supposed to be the watchdogs at publicly traded companies. And they choose their directors from the kennels of Chihuahuas, not Dobermans, as Warren Buffett has noted.

In addition, most CEOs are also chairman of the board. This allows CEOs to dictate their own compensation—aided by handpicked compensation consultants. Board members attend about a dozen meetings per year (often at fancy resorts or by teleconference) and are paid well, so they don't rock the boat.

For example, William Buehler, 71, who heads the board's compensation committee at Quest Diagnostics, received \$281,148 last year. And Keith Weikel, PhD, 73, compensation committee chair at LabCorp, received \$226,799.

2010 Laboratory Executive Total Compensation

<i>Company/Executive</i>	<i>Salary</i>	<i>Bonus and Incentives</i>	<i>Value of Stock & Option Awards</i>	<i>Other Comp*</i>	<i>2010 Total Compensation</i>	<i>2010 Revenue Growth</i>	<i>2010 Stock Price % Chg</i>
Aurora Diagnostics							
James New, 65, chairman and CEO	\$400,000	\$200,500	\$0	\$40,840	\$641,340	24%	NA
Bio-Reference Labs							
Marc Grodman, MD, 59, chairman and CEO	1,013,439	60,806	0	113,491	1,187,736	26%	13%
Celera							
Kathy Ordonez, 60, chief executive	650,000	237,900	1,018,527	16,528	1,922,955	-18%	-9%
CombiMatrix							
R. Judd Jessup, 63, president and CEO	153,461	0	641,400	0	794,861	38%	-66%
Enzo BioChem							
Elazar Rabbani, PhD, 67, chairman and CEO	546,192	465,000	189,750	108,262	1,309,204	8%	-2%
Genomic Health							
Kim Popovits, 52, president and CEO	465,000	38,585	1,111,530	0	1,615,115	19%	9%
Genoptix							
Tina Nova Bennett, PhD, 57, president and CEO	569,423	363,375	1,393,347	24,289	2,350,434	6%	9%
LabCorp							
David King, 54, chairman and CEO	885,333	1,902,675	6,693,729	191,009	9,672,746	7%	17%
Medtox Scientific							
Richard Braun, 66, chairman and CEO	390,000	1,036,616	0	105,550	1,532,166	17%	69%
Myriad Genetics							
Peter Meldrum, 63, president and CEO	832,550	649,710	3,805,820	10,475	5,298,555	11%	-12%
NeoGenomics							
Douglas VanOort, 55, chairman and CEO	325,000	9,750	134,467	0	469,217	17%	-13%
Orchid Cellmark							
Thomas Bologona, 62, president and CEO	581,950	293,800	184,926	131,168	1,191,844	8%	14%
Prometheus RxDx							
Joseph Limber, 58, president and CEO	677,500	614,250	0	115,057	1,406,807	52%	NA
Psychemedics							
Raymond Kubacki, Jr., 66, chairman and CEO	387,643	97,850	232,500	0	717,993	19%	18%
Quest Diagnostics							
Surya Mohapatra, PhD, 61, chairman and CEO	1,231,120	120,959	7,961,216	1,944,549	12,341,844	-1%	-10%
Totals, 15 executives	9,108,611	7,175,776	23,367,212	2,801,218	42,452,817		
Averages, 15 executives	\$607,241	\$478,385	\$1,557,814	\$186,748	\$2,830,188	15%	3%

*Other compensation includes changes in pension value plus 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 shareholder proxy statements

TOP IVD EXECES TAKE HOME AVERAGE OF \$7 MILLION

The CEOs at thirteen publicly traded lab instrument and reagent manufacturers earned an average of \$7 million each last year, according to an analysis of shareholder proxy statements by *Laboratory Economics*. **Johnson & Johnson's William Weldon**, 62, chairman and chief executive, was the highest paid IVD executive in 2010. Weldon earned total compensation of \$28.7 million. Next was **Abbott Labs' Miles White**, 56, chairman and chief executive, who received a total of \$25.6 million.

2010 IVD Executive Total Compensation

Company/Executive	Salary	Bonus and Incentives	Value of Stock & Option Awards	Other Comp	2010 Total Compensation	2010 Revenue Growth	2010 Stock Price % Chg
Abbott Laboratories							
Miles White, 56, chairman and CEO	\$1,893,371	\$3,700,000	\$13,622,800	\$6,348,112	\$25,564,283	14%	-4%
Beckman Coulter							
J. Robert Hurley, 61, president and CEO	483,873	0	648,162	95,697	1,227,732	12%	17%
Becton Dickinson							
Edward Ludwig, 59, chairman and CEO	1,070,000	850,000	5,891,687	2,193,335	10,005,022	6%	9%
Bio Rad Laboratories							
Norman Schwartz, 61, president and CEO	759,361	620,671	2,553,592	15,527	3,949,151	8%	8%
Gen-Probe Inc.							
Carl Hull, 54, president and CEO	680,000	504,900	1,766,061	48,205	2,999,166	9%	36%
Hologic							
Robert Cascella, 56, president and CEO	845,462	325,080	4,847,461	526,148	6,544,151	3%	30%
Immucor							
Gioacchino De Chirico, PhD, 57, president and CEO	571,304	50,624	860,664	66,194	1,548,786	9%	-2%
Johnson & Johnson							
William Weldon, 62, chairman and CEO	1,851,154	12,043,200	7,487,028	7,339,109	28,720,491	-1%	-1%
Luminex							
Patrick Balthrop, Sr., 54, president and CEO	506,138	440,340	3,188,067	11,000	4,145,545	17%	22%
Meridian Bioscience							
John Kraeutler, 62, CEO	540,346	0	414,328	54,017	1,008,691	-4%	12%
OraSure Technologies							
Douglas Michels, 54, president and CEO	499,152	317,600	544,222	4,000	1,364,974	0%	13%
Quidel							
Douglas Bryant, 53, president and CEO	482,538	0	803,984	8,516	1,295,038	-31%	5%
Thermo Fisher Scientific							
Marc Casper, 43, president and CEO	981,970	1,610,000	0	169,719	2,761,689	7%	16%
Totals, 13 executives	11,164,669	20,462,415	42,628,056	16,879,579	91,134,719		
Averages, 13 executives	\$858,821	\$1,574,032	\$3,279,081	\$1,298,429	\$7,010,363	4%	12%

Source: *Laboratory Economics* from shareholder proxy statements

M&A TRENDS: BIG EGOS DRIVING ACQUISITION PRICES HIGHER

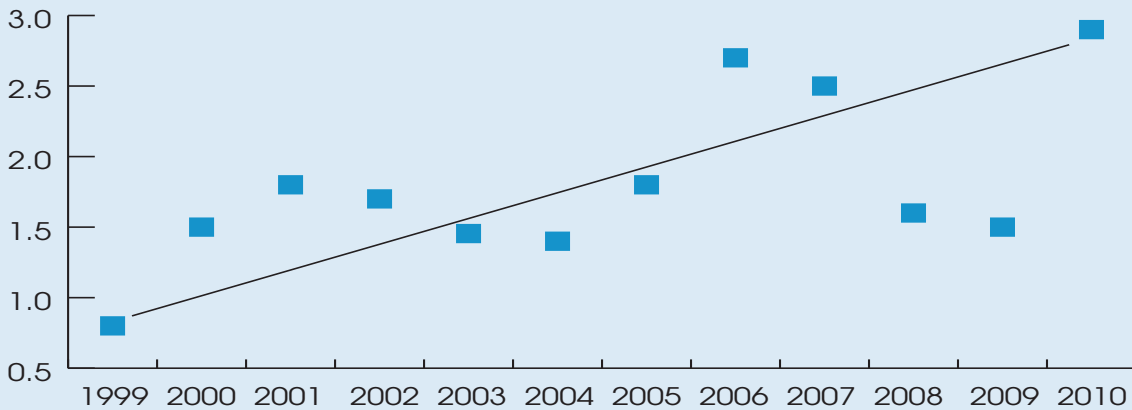
Quest Diagnostics paid less than 1x revenue to purchase SmithKline Beecham Clinical Labs in 1999. The deal made Quest far and away the biggest lab company in the United States. Quest has retained that position, but LabCorp has gained a lot of ground over the past five years through its contract with UnitedHealthcare and numerous acquisitions.

In fact, LabCorp has surpassed Quest by some measures. For example, LabCorp's stock market capitalization value of \$10 billion now exceeds Quest's value of \$9.1 billion.

Dave King wants LabCorp to be the biggest and Surya Mohapatra, PhD, does not want Quest to fall to second place on his watch. This is what is driving some of the silly multiples that are being paid by Quest and LabCorp for big acquisitions lately, in the opinion of *Laboratory Economics*. In addition, LE notes that both CEOs also have to boost weak growth rates at their companies through acquisitions.

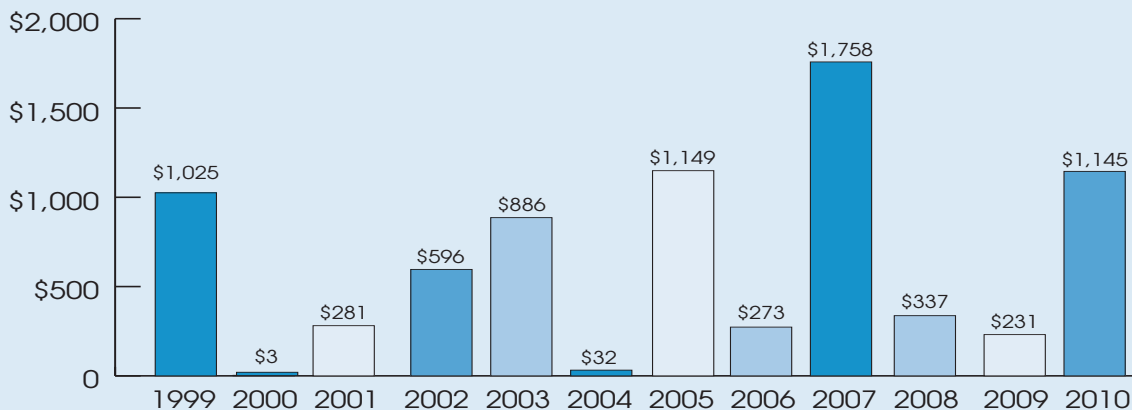
Quest currently trades at 1.2x its annual revenue (\$9.1 billion/\$7.3 billion) and LabCorp trades at 1.8x (\$10 billion/\$5.5 billion). So wouldn't the more rational strategy be—leaving CEO egos aside—to increase share repurchases?

Average Purchase Price to Revenue Multiples Paid for Clinical Labs



Source: Haverford Healthcare Advisors

Quest and LabCorp Cash Payments for Acquisitions (\$ millions)



Source: Annual reports from Quest Diagnostics and LabCorp

QUEST TO PAY \$241M TO SETTLE MEDI-CAL SUIT (*cont'd from page 1*)

LabCorp and several other labs were also named in the complaint (State of California ex rel v. Quest Diagnostics Inc. et al, #34-2009-00048046).

The state argued that these labs charged the Medi-Cal program up to six times more for lab tests than it charged other customers, such as IPAs, physician offices and hospitals. California law requires providers to bill Medi-Cal their lowest rates for the same services under comparable circumstances.

The higher prices charged to Medi-Cal effectively shifted the cost of doing business from the private sector to Medi-Cal, according to the complaint.

While denying liability, Quest said it is paying the \$241 million to avoid the uncertainty and risks of litigation. The case had been set to go to trial in October. The company has also agreed to certain reporting obligations regarding its pricing for a limited time period and, in lieu of such obligations for a transitional period, to provide Medi-Cal with a discount until the end of July 2012.

Prior to the lawsuit, most labs in California had simply charged Medi-Cal based on the program's clinical lab fee schedule. The Medi-Cal lab fee schedule is currently set at approximately 75% of Medicare rates. However, the fee schedule is meant to set the maximum allowable charge for lab tests, rather than a fixed reimbursement rate.

The Quest settlement is among the highest ever paid by a lab company (see table below). It may also set a precedent for similar settlements with other states. Other states that are currently investigating lab billing practices include Florida, Massachusetts, Michigan, New York and Virginia.

“This lawsuit will fundamentally change the way Laboratories do business. Now that ‘pull-through’ has been exposed as a violation of law, the old way of doing business will cease to exist. Moreover, independent labs will have a fair chance to compete for business based on servicing ability rather than deeply discounted pricing,” says Reidel’s lawyer Niall McCarthy at Cotchett, Pitre & McCarthy (Burlingame, CA).

Separately, LabCorp has reported that the State of California is seeking a refund of \$97.5 million for alleged overpayments (including interest) made to the company from November 7, 1995 through November 2009. LabCorp is in the process of trying to reach a settlement. The case is currently scheduled for trial on January 30, 2012.

Major Lab Industry Fraud and Abuse Settlements, 1992-2011

Settlement Year	Company (Predecessor)	Settlement Amount (\$ mill)
1992	LabCorp (National Health Labs)	\$111
1996	Quest Diagnostics (Damon)	119
1996	LabCorp (Roche Biomedical/Allied)	187
1997	Quest Diagnostics (SmithKline Beecham Labs)	325
2000	Fresenius Medical Care (LifeChem)	486
2005	Gambro Healthcare	326
2009	Quest Diagnostics (Nichols Institute Diagnostics)	302
2011	Quest Diagnostics	241

Source: *Laboratory Economics* and company reports

CARDIODX RAISES \$60 MILLION FOR HEART DISEASE TEST

CardioDx (Palo Alto, CA) has raised \$60 million from venture capital firms to fund clinical studies for its Corus CAD genetic test for coronary artery disease.

CardioDx's Corus CAD test analyzes 23 genes, then uses a software program to calculate a score of 0-40, which correlates with the likelihood that a patient has obstructive CAD. For example, a score 7 correlates to a 13% likelihood, a score of 27 is roughly 50% likelihood and a maximum score of 40 equates to about a 75% chance of obstructive CAD. CardioDx performs this laboratory-developed (aka homebrew) test at its CLIA-certified lab in Palo Alto.

Obstructive CAD is a chronic, progressive form of heart disease that results from atherosclerosis, or a buildup of damaging plaque in the arteries found on the surface of the heart. The arterial plaque that characterizes obstructive coronary artery disease obstructs the flow of blood to the heart. Heart attack or death may result.

CardioDx says its test can help primary care physicians and cardiologists evaluate patients with stable chest pain. For example, physicians could use Corus CAD early on to try to rule out the need for a patient to have an expensive, invasive angiograph or stress test.

The Corus CAD test has a list price of \$1,195, while a myocardial perfusion imaging (MPI) stress test costs about \$600 and angiography costs \$3,000 to \$5,000, according to CardioDx. The company began marketing the Corus CAD test in mid-2009 and has tested 13,000 patients to date.

Since being formed in 2004, CardioDx has raised more than \$150 million through five rounds of financing. New investors in the latest round included Longitude Capital, J.P. Morgan, Acadia Woods Partners, Artiman Ventures and Bright Capital. Existing investors include Kleiner Perkins, Mohr Davidow Ventures, TPG Biotech, Intel Capital, Pappas Ventures, DAG Ventures, Asset Management Group and GE Capital.

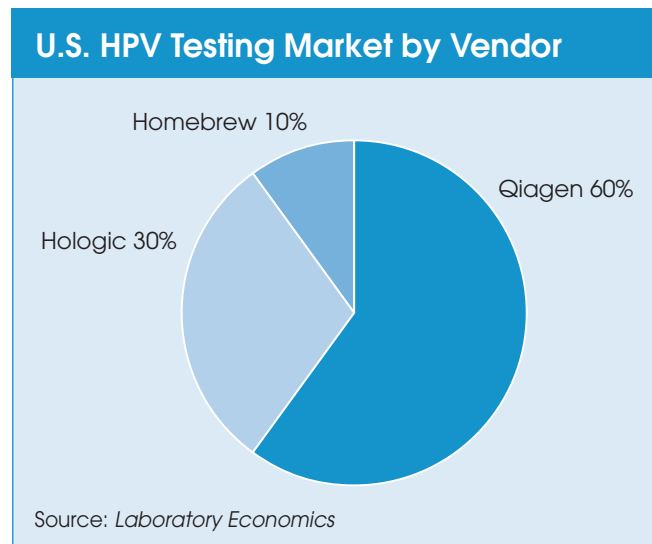
ROCHE GETS FDA CLEARANCE FOR HPV TEST

The FDA has approved Roche's cobas 4800 HPV test for identifying women at high risk of developing cervical cancer. The Roche test will compete against existing FDA-cleared tests made by Qiagen and Hologic.

Laboratory Economics estimates the U.S. market for HPV testing at \$350 million per year for manufacturer test kit sales and \$700 million for lab revenue.

Qiagen currently has an estimated 60% of the HPV test market, followed by Hologic at 30% and laboratory-developed tests (aka homebrew) at 10%.

Other companies developing HPV tests include Abbott Diagnostics, Gen-Probe, Arbor Vita Corp. and Sequenom/Sensi-Gen.



FTC REQUEST DELAYS LABCORP'S ACQUISITION OF ORCHID

LabCorp's plans to acquire Orchid Cellmark (Princeton, NJ) have been delayed because the Federal Trade Commission has requested additional information on the deal. LabCorp had hoped to finalize its \$85.4 million purchase of Orchid on May 17 (see *LE*, April 2011, pp. 1-2).

Evidently the FTC thinks the combination of LabCorp and Orchid might create a monopoly position in the DNA testing market for criminal investigations and/or paternity testing.

FTC Withdraws Complaint Against LabCorp's Westcliff Buy

After nine months of legal battling and expenses, the FTC has withdrawn its complaint against LabCorp's purchase of Westcliff Medical Labs (Santa Ana, CA).

LabCorp purchased bankrupt Westcliff Medical Labs for \$57.5 million in June 2010. Shortly thereafter, the FTC announced an investigation that delayed LabCorp's ability to integrate Westcliff. The FTC alleged that the LabCorp/Westcliff combination violated antitrust laws and would lead to higher prices for lab tests in Southern California.

"While we continue to have reason to believe that LabCorp's acquisition of Westcliff will result in anticompetitive effects, we are convinced that further adjudication of this case will not serve the public interest," the FTC said in an April 22 statement.

WASHINGTON GOV SIGNS DIRECT BILLING LEGISLATION INTO LAW

Direct billing legislation for anatomic pathology services was signed into law by Washington Governor Chris Gregorie (D) on April 20.

The new law is effective July 1, 2011, and prohibits markups on anatomic pathology services ordered by a physician who does not actually perform or supervise the service. It requires billing to be sent directly from the lab or physician performing or supervising anatomic pathology services to the patient or insurer. Direct billing prevents a treating physician from realizing a profit by charging a patient full price for anatomic pathology services the physician received at a discount.

Similar legislation is pending in Indiana, and if approved, Indiana would become the 18th state with a direct billing law.

States Requiring Direct Billing for Anatomic Pathology Services

Arizona	Louisiana	New York
California	Maryland	Ohio
Connecticut	Massachusetts	Rhode Island
Indiana*	Montana	South Carolina
Iowa	Nevada	Tennessee
Kansas	New Jersey	Washington

*Legislation pending in Indiana

Source: College of American Pathologists

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LAB STOCKS UP 14% YEAR TO DATE

Eleven lab stocks have risen by an unweighted average of 14% so far this year through May 16. The combined market capitalization for the group is currently \$23.7 billion. In comparison, the S&P 500 Index is up 6% and the Nasdaq is up 7%. The top-performing lab stock so far this year is the drugs-of-abuse testing company Psychomedics, up 31%. Meanwhile, the stock price of LabCorp is up 13% and Quest is up 7%.

Company (ticker)	Stock Price 12/31/10	Stock Price 5/16/11	2011 Price Gain	Market Capitalization (\$ millions)	Earnings Past 12 Months	Price-to-Earnings Ratio
Bio-Reference (BRLI)	\$22.18	\$24.57	11%	\$686	\$1.09	22.5
CombiMatrix (CBMX)	2.15	2.75	28%	29	-1.02	NA
Celera (CRA)	6.30	8.05	28%	662	-0.23	NA
Enzo Biochem (ENZ)	5.28	3.92	-26%	150	-0.42	NA
Genomic Health (GHDX)	21.39	26.00	22%	761	0.20	130.0
LabCorp (LH)	87.92	99.40	13%	9,958	5.66	17.6
Medtox Scientific (MTOX)	13.10	16.42	25%	146	0.42	39.1
Myriad Genetics (MYGN)	22.84	24.13	6%	2,069	1.20	20.1
Neogenomics (NGNM)	1.30	1.49	15%	64	-0.10	NA
Psychomedics (PMD)	8.20	10.71	31%	56	0.57	18.8
Quest Diagnostics (DGX)	53.97	57.65	7%	9,071	2.85	20.2
Averages			14%	23,652		38.3

Source: Bloomberg

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