

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

LABS JUMP TO OFFER BRCA1/2 TESTING FOLLOWING SUPREME COURT RULING

The Supreme Court has ruled that genes naturally found in the body cannot be patented, but that synthetically created genetic material, called complementary or cDNA, can be patented. The ruling in effect ends a nearly two-decade monopoly that Myriad Genetics (Salt Lake City) has had on BRCA1/2 testing for hereditary breast cancer. Immediately following the Supreme Court’s landmark decision, Quest Diagnostics said it intends to validate and offer a BRCA1 and BRCA2 test by year’s end. At least half a dozen other independent labs and medical centers have also announced plans to offer competing tests.

Myriad’s BRCAAnalysis test currently has a list price of \$3,340. However, DNATraits, part of Houston-based Gene By Gene, Ltd. — says it will offer BRCA gene testing for only \$995 — less than a third of Myriad’s current price.

“Anyone who says it will take a while for companies to offer the test, or that it is uncertain that this ruling will lower the cost, we now have proof that it won’t take a while because it is happening as we speak,” said Sue Friedman, executive director of Facing Our Risk of Cancer Empowered, a nonprofit group that filed a brief in the Myriad patent case. *Continued on page 9.*

CAP PRESSES AETNA FOR EXPLANATION ON NEW RATES

The College of American Pathologists (CAP) has requested a meeting with Richard Gentleman, Regional Network Operations Head at Aetna, to discuss Aetna’s forthcoming reimbursement changes for clinical lab and anatomic pathology services (see *LE*, page 1, April 2013). Effective July 1, Aetna is slashing its national fee schedule for lab and pathology services to between 45% and 50% of Medicare. *Continued on page 6.*

OIG SAYS MEDICARE PAYS TOO MUCH FOR LAB TESTS

The Medicare program could save an estimated \$910 million per year, or 38%, by paying labs at the lowest rates paid by Medicaid plans and federal employee health plans, according to a new report from the Department of Health and Human Services’ Office of Inspector General. The report recommends that CMS seek legislation that would allow it to lower payment rates for lab tests, and consider seeking legislation to institute copayments and deductibles for lab tests.

In response to the OIG report, CMS stated that it is exploring whether it has authority under current statute to revise payments for lab tests.

Laboratory Economics notes that Congress could use the OIG report as justification to cut Medicare’s Clinical Lab Fee Schedule (CLFS) as Congress scrambles to find the savings needed to avert a 25% cut to Medicare physician payment rates scheduled to take effect January 1, 2014. *Continued on page 2.*

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OIG SAYS MEDICARE PAYS TOO MUCH FOR LAB TESTS (*cont'd from p. 1*)

The OIG report looked at payment data for 20 high-volume lab tests from 50 State Medicaid programs and three Federal Employees Health Benefits (FEHB) plans. The report did not evaluate managed care rates.

Medicaid and FEHB payment rates in effect from January 1 through March 31, 2011, were compared against Medicare carrier rates paid to independent labs and physician offices during the same period. OIG calculated the potential savings to Medicare if it had paid labs at the lowest established rate for each of the 20 reviewed tests in each geographic area. Under this scenario, Medicare would have paid 38% less, saving \$910 million, according to the OIG report.

For example, Medicare paid approximately \$348 million for 14.8 million thyroid function tests (CPT 84443) during 2011. If Medicare had paid the lowest rate among the Medicaid and FEHP plans surveyed, it could have saved approximately \$140 million, or 40%.

Mark Birenbaum, Administrator at the National Independent Laboratory Assn. (Washington, DC), says that clinical labs have already taken significant cuts in reimbursement since 2011 (the year that data was analyzed for the OIG report). For example, the CLFS was cut by 3% effective January 1, 2013 and reduced another 2% on April 1 through sequestration. Furthermore Birenbaum says the report only looked at reimbursement rates for independent and physician-office-based labs, ignoring hospital labs, which make up a substantial proportion of the lab market.

The table below compares the Medicare Part B national limitation amounts for each of the 20 tests reviewed with the lowest available rate from the Medicaid and FEHP plans surveyed (regardless of geographic area).

Medicare NLA vs. Lowest Payer Amounts from OIG Report

CPT Code	Description	2011 Medicare NLA	Lowest Payer	Lowest Payer Rate	Percent of Medicare
80048	Metabolic panel, total calcium	\$11.91	FEHB 3	\$2.58	22%
80053	Comprehensive metabolic panel	\$14.87	FEHB 3	\$5.31	36%
80061	Lipid panel	\$18.85	FEHB 3	\$7.51	40%
81001	Urinalysis, auto with microscopy	\$4.45	FEHB 3	\$1.99	45%
81002	Urinalysis, non-automated	\$3.60	Medicaid MI	\$1.10	31%
81003	Urinalysis, auto w/o microscopy	\$3.16	Medicaid DC	\$1.00	32%
82306	Vitamin D	\$41.66	FEHB 3	\$14.00	34%
82570	Creatinine	\$7.28	FEHB 3	\$2.45	34%
82607	Vitamin B-12	\$21.21	FEHB 3	\$7.13	34%
82728	Ferritin	\$19.17	FEHB 3	\$6.44	34%
83036	Glycosylated hemoglobin test	\$13.66	FEHB 3	\$6.10	45%
83540	Iron	\$9.12	FEHB 2	\$2.10	23%
83550	Iron binding test	\$12.30	FEHB 3	\$4.13	34%
83880	Natriuretic peptide	\$47.77	Medicaid IL	\$14.86	31%
83970	Parathormone	\$58.08	FEHB 3	\$19.53	34%
84153	PSA Total	\$25.89	FEHB 3	\$8.70	34%
84443	TSH	\$23.64	FEHB 3	\$7.95	34%
85025	CBC	\$10.94	FEHB 3	\$3.68	34%
85610	Prothrombin time	\$5.53	FEHB 3	\$2.68	48%
87086	Urine culture colony count	\$11.36	FEHB 3	\$5.09	45%
Unweighted Average	NA	NA	NA	35%	

Source: CMS and OIG Report, June 2013, OEI-07-11-00010

The OIG report also illustrated the tremendous variance in pricing depending on payer and state. For example, Medicare paid a NLA of \$11.91 per CPT 80048 (metabolic panel, total calcium) in 2011. In comparison, one of the Federal Employees Health Benefits (FEHB) plans covering Louisiana paid a rate of only \$2.58 for each CPT 80048, while another FEHB plan paid \$165.75 in Wyoming.

Medicare paid a NLA rate of \$58.08 for CPT 83970 (parathormone), while one FEHB plan reimbursed \$19.53 for labs in Ohio and another FEHB plan paid a rate of \$365.90 in Connecticut for the same test.

A routine lipid panel (CPT 80061) was reimbursed at \$18.85 by Medicare, \$7.51 by a FEHB in Kentucky and \$99.45 by an FEHB plan in Wisconsin.

Laboratory Economics believes the variance in payment by payer is so wide that it calls into question the results of the study. In fact, by comparing the highest paying Medicaid and FEHB plans to the Medicare NLAs, it is possible to use the OIG report to make the argument that labs are grossly underpaid by Medicare. For example, Medicare's NLA for CPT 81001 (urinalysis) was \$4.45 in 2011, which is only a fraction of the \$32.20 paid by an FEHB plan in Wisconsin.

Does Medicare Underpay Labs?

CPT Code	Description	2011 Medicare NLA	Lowest Payer Rate	Highest Payer Rate
80048	Metabolic panel, total calcium	\$11.91	\$2.58	\$165.75
80053	Comprehensive metabolic panel	\$14.87	\$5.31	\$58.20
80061	Lipid panel	\$18.85	\$7.51	\$99.45
81001	Urinalysis, auto with microscopy	\$4.45	\$1.99	\$32.20
81002	Urinalysis, non-automated	\$3.60	\$1.10	\$17.10
81003	Urinalysis, auto w/o microscopy	\$3.16	\$1.00	\$23.80
82306	Vitamin D	\$41.66	\$14.00	\$107.45
82570	Creatinine	\$7.28	\$2.45	\$19.80
82607	Vitamin B-12	\$21.21	\$7.13	\$81.00
82728	Ferritin	\$19.17	\$6.44	\$55.80
83036	Glycosylated hemoglobin test	\$13.66	\$6.10	\$63.75
83540	Iron	\$9.12	\$2.10	\$37.96
83550	Iron binding test	\$12.30	\$4.13	\$57.00
83880	Natriuretic peptide	\$47.77	\$14.86	\$180.24
83970	Parathormone	\$58.08	\$19.53	\$365.90
84153	PSA Total	\$25.89	\$8.70	\$135.18
84443	TSH	\$23.64	\$7.95	\$105.40
85025	CBC	\$10.94	\$3.68	\$60.35
85610	Prothrombin time	\$5.53	\$2.68	\$57.00
87086	Urine culture colony count	\$11.36	\$5.09	\$86.45

Source: CMS and OIG Report, June 2013, OEI-07-11-00010

MEDICARE PART B LAB SPENDING UP 9% IN 2012

Medicare Part B spending on clinical laboratory services was up 9.1% at \$9.741 billion in calendar-year 2012, according to data from CMS's 2013 Medicare Trustees Report.

Intermediary labs (i.e., hospital lab outpatient/outreach) provided \$4.661 billion of Part B lab services in 2012—an increase of 7.1% compared with \$4.351 billion in 2011. Carrier labs (i.e., independent labs and POLs) accounted for \$5.08 billion, up 10.9% from \$4.579 billion.

Total Medicare spending in 2012 was \$574.2 billion, up 4.6% from \$549.1 billion in 2011. The number of Medicare beneficiaries increased by 3.7% to 50.7 million.

Part B lab services represented 1.7% of overall Medicare program expenditures in 2012.

Part B lab expenditures increased at an average rate of 5.1% per year between 2007 and 2012. This compares with an average rate of growth of 5.9% per year for total Medicare program expenditures over the same time frame.

The Medicare Trustees Report is compiled by actuaries from the Centers for Medicare and Medicaid Services (CMS). This annual report is required by law and constitutes the government's official report on the status of the Medicare program.

Medicare Part B Spending on Lab Services, 2007-2012 (\$ millions)*

	2012	2011	2010	2009	2008	2007	5-Year CAGR**
Intermediary Labs (hospitals)	\$4,661	\$4,351	\$4,110	\$3,982	\$3,615	\$3,471	4.2%
Carrier Labs (independents)	5,080	4,579	4,808	4,671	4,260	4,144	6.1%
Total Part B Lab Spending	9,741	8,930	8,918	8,653	7,875	7,615	5.1%
Total Medicare Expenditures	574,200	549,100	522,900	509,000	468,200	431,700	5.9%
Lab Spending as % of Medicare	1.7%	1.6%	1.7%	1.7%	1.7%	1.8%	NA

*Part B reimbursement amounts on a cash basis

**CAGR=compound annual growth rate

Source: 2013 Medicare Trustees Report

Unrealistic Medicare Spending Growth Estimates

Over the next 10 years, 2013-2022, The Medicare Trustees Report predicts that total Medicare program expenditures will rise by an average of 6.6% per year. However, this projected growth rate is unrealistically low because it is based on physician payment cuts that are unlikely to occur. For example, current law requires a reduction in Medicare payment rates for physician services (including pathologists) of 25% effective January 1, 2014—an implausible expectation. It is nearly certain that Congress will override this scheduled cut.

Part B physician fee schedule reductions have been scheduled for every year since 2002 under the sustainable growth rate (SGR) system. The SGR system was enacted as part of the Balanced Budget Act of 1997 with the intent of limiting growth in spending on physician services to a sustainable rate, roughly in line with overall economic growth.

An update of -4.8% was required and allowed to take effect in 2002—the only historical year in which a negative update was implemented under the SGR. For the past 11 years (2003-2013),

scheduled physician fee cuts of at least -5% have been overridden by new legislation, which provided updates ranging from zero to 2.2%.

The inability of Congress to make tough and politically unpopular decisions has allowed Medicare spending to consistently rise faster than estimates. For example, the Medicare Trustees Report for 2003 had predicted that total Medicare expenditures would rise by an average of 6.4% per year to reach \$495 billion in 2012. The actual growth rate turned out to be 8% per year with total spending of \$574 billion. In addition, CMS predicted that Medicare trust fund assets would total \$612 billion at year-end 2012. The actual figure has turned out to be less than half that amount, \$288 billion.

The \$27 Trillion Unfunded Obligation

The first of 77 million Baby Boomers turned 65 last year. Medicare enrollment will grow from 50.7 million in 2012 to 64.3 million in 2020. This swell of beneficiaries will rely on the taxed earnings of working Americans to pay for their Medicare benefits.

When Congress first enacted the Medicare program in 1965 there were approximately four working-age Americans for every beneficiary. However, a decline in U.S. birth rates combined with the retirement of the Baby Boomers means that there will be only 2.6 working Americans per Medicare beneficiary in 2020.

The shrinking worker-to-beneficiary ratio—combined with ever increasing medical costs per beneficiary—has created an unfunded obligation of \$27.3 trillion. In other words, the United States would need to deposit \$27.3 trillion into Medicare’s trust fund accounts today in order to pay for its benefit obligations in full over the next 75 years.

This amount of underfunding is staggering. Raising the \$27.3 trillion (or \$27,300,000,000) needed to shore up Medicare would require every U.S. household to pay a \$236,774 tax right now.

As troublesome as these numbers are, they are unrealistically optimistic because the \$27.3 trillion estimate by the Trustees counts on cost-cutting plans that are not likely to occur—such as the

Ratio of Working Population to Medicare Beneficiaries

Year	Labor Force	Medicare Population	Ratio
1970	82.8	20.4	4.1
1980	106.9	28.4	3.8
1990	125.8	34.3	3.7
2000	142.6	39.7	3.6
2010	153.9	47.7	3.2
2020	164.4	64.3	2.6

Source: CMS and U.S. Census Bureau

Medicare’s unfunded liability increases to \$36.2 trillion (or \$313,964 per U.S. household).

“Congress and the executive branch must work closely together with a sense of urgency to address the exhaustion” of the Medicare trust fund and growth in spending, according to the Trustees Report.

25% physician fee schedule cut due January 1, 2014.

The Trustees’ alternative projection assumes that the physician fee schedule would be held to a 1% annual increase instead of next year’s 25% cut, and that “productivity” cuts in other providers’ payments would be phased down starting in 2020. Under these more realistic assumptions,

CAP PRESSES AETNA FOR EXPLANATION ON NEW RATES (*cont'd from p. 1*)

For example, Aetna's new global rate for CPT 88305 is \$35.05, which is only 50% of the Medicare rate of \$70.09, which itself was reduced by 33% this year due to a big reduction in technical component reimbursement.

In a June 3 letter to Aetna, CAP Chairman Jonathan Myles, MD, said CAP was seeking the rationale behind the impending rate change and its impact on pathology services. Aetna has confirmed receipt of the letter but has not responded further.

In a written statement to *Laboratory Economics*, Aetna spokesman Ethan Slavin said that Aetna's national fee schedule rates apply to its nationally contracted labs. "The Aetna national fee schedule has been below the Medicare rate for many years....Aetna continuously monitors coding changes with Medicare/Medicaid fee schedule changes and we will adjust our national fee schedule as appropriate. Recently, CMS reduced rates on the Medicare fee schedule for surgical pathology fees so we made a corresponding adjustment to the base national fee schedule," according to Slavin.

Aetna's new lowered rates seem to be part of a broader strategy aimed at lowering its lab and pathology spending.

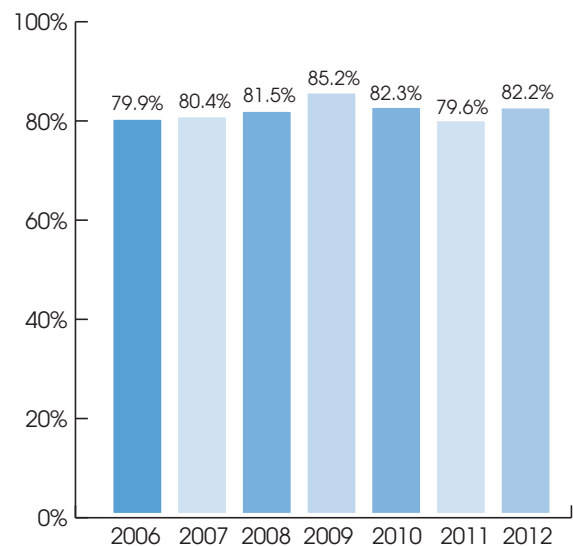
In an effort to discourage in-office pathology labs, Aetna is requiring these labs to have both CLIA certification and specialty society accreditation from either CAP, The Joint Commission or The Healthcare Facilities Accreditation Program, in order to receive payment from Aetna for the professional component of pathology services (CPT codes 88300-88314 and 88342). Dermatologists are exempt from this requirement. This policy went into effect April 1, 2013 (see pages 7-8).

In addition, over the past two years, Aetna has been shrinking its national lab network. Aetna has had a national contract with Quest Diagnostics since 2007. Aetna also has national contracts with about 50 smaller independent labs, including Bio Reference Labs, Bostwick Labs, CBLPath, Clariant, Myriad Genetics, ProPath Lab, Sonic Healthcare, et al.

LabCorp and its subsidiaries have been excluded by Aetna since 2007. Among the independent labs recently booted from the Aetna network are Ameritox, Shiel Medical Lab, Hunter Laboratories and Health Diagnostic Laboratory.

Aetna's push to drive lab reimbursement lower may have been prompted by an increase in its medical loss ratio (MLR). The MLR measures the proportion of each healthcare premium dollar spent on healthcare services versus administrative costs and profits, including executive salaries, overhead and marketing. In 2012, Aetna spent 82.2% of its collected premiums on healthcare expense, up from 79.6% in 2011.

Net income at Aetna decreased to \$1.658 billion in 2012 from \$1.986 billion in 2011. Nonetheless, Mark Bertolini, Chairman and CEO of Aetna, received total compensation of \$13.3 million in 2012, up 25% from \$10.6 million in 2011.

Aetna's Medical Loss Ratio

Source: Aetna

RECORD NUMBER OF IN-OFFICE LABS GETTING CAP ACCREDITATION

A record number of in-office pathology labs are getting CAP accreditation in response to Aetna's new pathology testing payment policy.

Aetna's policy became effective April 1, 2013 after several delays. It requires in-office labs to have both CLIA certification and specialty society accreditation from either CAP, The Joint Commission or The Healthcare Facilities Accreditation Program, in order to receive payment from Aetna for the professional component of pathology services (CPT codes 88300-88314 and 88342). The policy is aimed at urology and gastroenterology practices with in-office pathology labs (dermatology practices are exempt).

Year to date through May 31, a total of 33 specialty groups have received CAP accreditation for their pathology labs. This compares with 18 specialty group labs in 2012 and 17 groups in 2011.

Aetna says that in-office labs that have not received accreditation should refer their Aetna patients to in-network labs for pathology services. Aetna's preferred in-network lab is Quest Diagnostics/AmeriPath, although it has contracts with dozens of other independent pathology labs such as Bako Pathology, Bio-Reference Labs, Bostwick Labs, CBLPath, Clariant, NeoGenomics, Plus Diagnostics, ProPath Laboratory, etc.

In-Office Pathology Labs with CAP-Accreditation

<i>Group Name</i>	<i>Location</i>	<i># Physicians</i>	<i>CAP Accreditation</i>
Accredited Dermatology Medical Clinic	Fullerton, CA	2	May 2013
Gastroenterology Associates	Allentown, PA	5	May 2013
Gastroenterology Health Partners	New Albany, IN	8	May 2013
Kessel Dermatology	Hamilton Square, NJ	4	May 2013
Specialists in Gastroenterology	Creve Coeur, MO	5	May 2013
Urology Associates of Danbury	Danbury, CT	7	May 2013
Urology of Central PA	Camp Hill, PA	13	May 2013
Woodholme Gastroenterology	Baltimore, MD	11	May 2013
Associated Urological Specialists	Orland Park, IL	19	April 2013
Gastroenterology Associates	Reston, VA	11	April 2013
Middlesex/Monmouth Gastroenterology	Freehold, NJ	5	April 2013
Shore Gastroenterology	Oakhurst, NJ	6	April 2013
Atlantic Gastroenterology	Egg Harbor Township, NJ	4	March 2013
Bergen Gastroenterology	Emerson, NJ	12	March 2013
Bielinski Dermatology Group/SkinMD	Orland Park, IL	4	March 2013
Essex Gastroenterology Associates	Belleville, NJ	2	March 2013
Garden State Urology	Whippany, NJ	21	March 2013
Gastro Assoc. of Central Georgia	Macon, GA	6	March 2013
Greater Boston Urology LLC	Framingham, MA	2	March 2013
Premier Urology Assoc./Urology Care Alliance	Lawrenceville, NJ	25	March 2013
Digestive Health Associates	Dallas, TX	75	February 2013
Great Lakes Gastroenterology	Mentor, OH	2	February 2013
Houston Digestive Disease Consultants	Houston, TX	5	February 2013
Memphis Gastroenterology	Germantown, TN	13	February 2013
New York Urological Associates	New York, NY	9	February 2013
Texas Oncology Urology	Houston, TX	10	February 2013
Urology Associates of Cape Cod	Hyannis, MA	4	February 2013
Anne Arundel Gastroenterology	Annapolis, MD	12	January 2013

Gastroenterology Center of CT.....	Hamden, CT.....	14	January 2013
GI Specialists.....	Memphis, TN.....	6	January 2013
North Jersey Gastroenterology.....	Wayne, NJ.....	5	January 2013
Southeast Texas Gastroenterology.....	Beaumont, TX.....	5	January 2013
Troy Gastroenterology.....	Troy, MI.....	7	January 2013
Capital Digestive Care.....	Bowie, MD.....	55	December 2012
Dermatology Associates of Tyler.....	Tyler, TX.....	10	December 2012
Dermatology Surgery Center.....	Tyler, TX.....	1	December 2012
Gastroenterology Associates of North Texas.....	Fort Worth, TX.....	16	December 2012
Metropolitan Gastroenterology.....	Astoria, NY.....	3	December 2012
West Central Gastroenterology.....	St. Petersburg, FL.....	1	December 2012
Asheboro Dermatology & Skin Surgery.....	Asheboro, NC.....	2	November 2012
Dermatology and Skin Surgery.....	Shreveport, LA.....	7	November 2012
Digestive Health Associates.....	Reno, NV.....	9	November 2012
Gastroenterology Consultants.....	Edison, NJ.....	3	November 2012
Virginia Urology.....	Richmond, VA.....	30	November 2012
Integrated Medical Professionals.....	Garden City, NY.....	100	October 2012
Renewal Dermatology.....	Gainesville, VA.....	3	October 2012
Gulf Coast Dermatology.....	Panama City, FL.....	9	September 2012
Illinois Dermatology Institute.....	Park Ridge, IL.....	14	September 2012
Gastroenterology Limited.....	Levittown, PA.....	2	August 2012
Hillmont GI.....	Flourtown, PA.....	7	August 2012
Orange County Urology Associates.....	Laguna Hills, CA.....	11	August 2012
High Desert Gastroenterology.....	Lancaster, CA.....	6	December 2011
Advanced Urology Associates.....	New Lenox, IL.....	10	September 2011
Northeast Indiana Urology.....	Fort Wayne, IN.....	9	September 2011
Academic Urology of Pennsylvania.....	Rosemont, PA.....	31	August 2011
Arizona Digestive Health.....	Phoenix, AZ.....	59	August 2011
South Jersey Gastroenterology.....	Marlton, NJ.....	10	August 2011
Dermatologists of Greater Columbus.....	Dublin, OH.....	4	July 2011
Urological Services PC.....	Flint, MI.....	1	July 2011
Urology of Indiana.....	Greenwood, IN.....	34	July 2011
Capital Urology Associates.....	Okemos, MI.....	2	May 2011
Great Lakes Gastroenterology.....	St. Joseph, MI.....	4	May 2011
Illinois Gastroenterology Group.....	Libertyville, IL.....	32	May 2011
MacInnis Dermatology.....	Leesburg, FL.....	1	May 2011
Michigan Gastroenterology Institute.....	East Lansing, MI.....	10	May 2011
The Gastroenterology Group.....	Reston, VA.....	7	April 2011
Urologic Physicians.....	Edina, MN.....	7	March 2011
Altman Dermatology Associates.....	Arlington Heights, IL.....	2	January 2011
Associates in Dermatology.....	Louisville, KY.....	16	November 2010
Gastroenterology Consultants.....	Houston, TX.....	9	March 2009
Northwest Gastroenterology Assoc.....	Bellevue, WA.....	5	January 2008
Genito Urinary Surgeons.....	Toledo, OH.....	9	November 2007
Gastroenterology Associates.....	Pensacola, FL.....	1	April 2007
Michigan Institute of Urology.....	Saint Clair Shores, MI.....	53	February 2007
UroPartners.....	Westchester, IL.....	54	November 2006
The Urology Group.....	Cincinnati, OH.....	34	May 2004
Saginaw Valley Dermatology.....	Saginaw, MI.....	1	June 2001
University Dermatologists.....	South Euclid, OH.....	13	June 1999

Source: *Laboratory Economics* from CMS and CAP

LABS JUMP TO OFFER BRCA1/2 TESTING (*cont'd from page 1*)

Myriad launched its BRACAnalysis test in late 1996 at a list price of \$2,400. Since then, Myriad has regularly raised the price every two or three years. The current list price is \$3,340.

Managed care companies like Aetna and UnitedHealth have typically paid about 90% of the list price, or approximately \$3,000. Earlier this year, Myriad's Medicare carrier Noridian set pricing for BRACAnalysis at \$2,795. It will be interesting to see how these payers respond given that competing tests will soon be on the market at substantially lower prices.

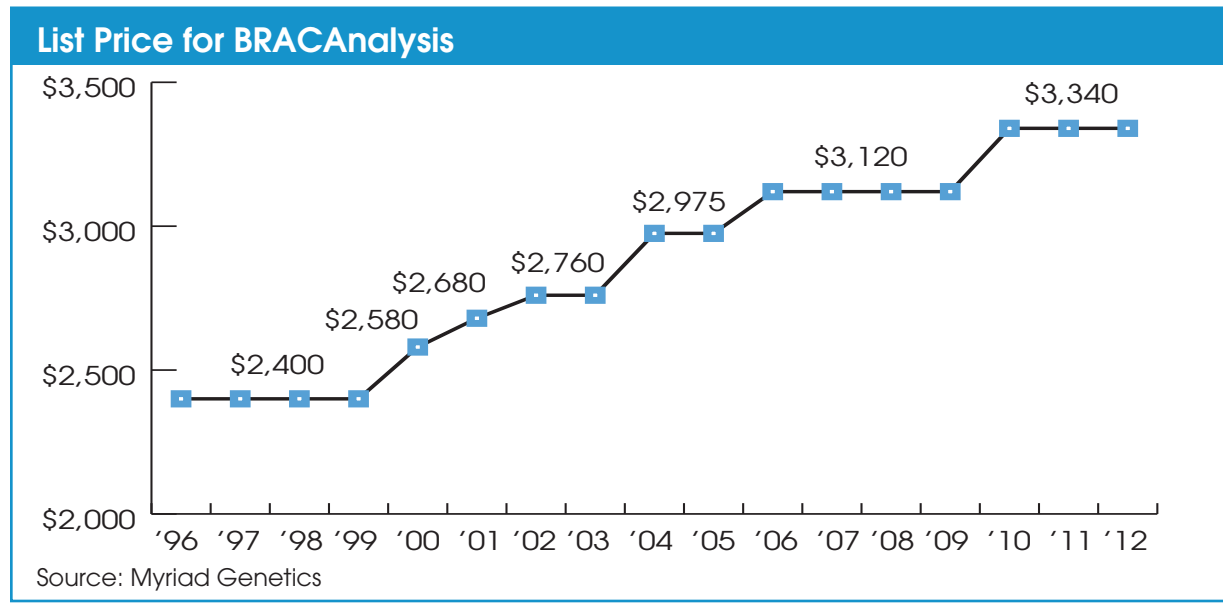
Among the labs that quickly announced plans to begin marketing BRCA1/2 testing were the aforementioned Quest Diagnostics and DNA Traits, as well as GeneDx (Gaithersburg, MD), Pathway Genomics (San Diego), Montefiore Medical Center and University of Washington.

In a statement, Sherri J. Bale, PhD, FACMG, Managing Director, GeneDx and Senior Vice President, BioReference Labs, said "We've waited a long time for this day, and now the playing field is leveled. We will deliver this test, as well as others, which until now we've been restricted from offering. We will now be able to compete on price as well as quality, customer service, and patient-friendly billing policies. Our alternative, called BRACfast, will be available August 1."

Although Myriad has tried to diversify its business through acquisitions and new test introductions, the company still derives the vast majority of its revenue (82%) from BRACAnalysis testing.

Ambry Genetics (Aliso Viejo, CA) posted a headline on its website soon after the decision saying, "Your Genes Have Been Freed." The company has already begun marketing a competing BRCA1/2 sequencing test for \$2,200. In addition, Ambry has launched a new high-risk hereditary breast cancer panel (under the brand BRCA Plus) that simultaneously analyzes six genes, BRCA1, BRCA2, CDH1, PTEN, STK11 and TP53, at a list price of \$3,300.

Myriad says that it has 24 patents and more than 500 patent claims on BRACAnalysis and the vast majority of these are still valid and enforceable. However, new competition and lower pricing are inevitable, notes *Laboratory Economics*. Myriad seems to have already acknowledged this with its recent plans to offer BRACAnalysis as part of hereditary cancer-risk panel named MyRisk Hereditary Cancer (see *LE*, May 2013, p. 5). But the company's initial targeted list price of between \$4,000 and \$4,500 may need to be cut in half given the new competition.



FIRST-QUARTER EARNINGS HIGHLIGHTS

First-quarter results for 11 publicly-traded lab companies show continued pricing pressure. However, many publicly-traded labs have been able to report higher revenue per requisition by increasing genetic and esoteric testing volumes.

AURORA DIAGNOSTICS (Palm Beach Gardens, FL) reported a first-quarter net loss of \$7.7 million versus a net loss of \$2.1 million in the same period a year earlier; revenue decreased by 13.5% to approximately \$61 million.

Total accessions at Aurora decreased by 3.7% to 521,000 for the quarter ended March 31, 2013. Average revenue per accession was approximately \$117, down 10% from \$130.

Aurora says that it continues to lose specialty group clients (GU, GI and dermatology) because of pathology lab insourcing, despite the steep Medicare cuts to CPT 88305-TC. Aurora expects to save \$3.5 million per year from personnel reductions (approximately 50 employees) that took effect May 1.

Aurora currently has total debt outstanding of \$323.5 million, including \$200 million in senior notes bearing interest at 10.75% annually. These senior notes (CUSIP: 051620AB8, 10.75%, 1/15/18) currently trade for about 70 cents on the dollar with a yield to maturity of 21%. As of March 31, 2013, Aurora held \$1.3 million in cash and had a working capital deficit of \$5.4 million.

Separately, Aurora announced that its Chief Financial Officer Greg Marsh resigned effective June 5, 2013. Aurora has named Michael Grattendick, age 47, as its new CFO. Grattendick has served as Aurora's Director of Finance and Assistant Treasurer since 2006 and Director of Finance and Treasury since 2011.

BIO-REFERENCE LABORATORIES (Elmwood Park, NJ) reported net income of \$11.3 million for the three months ended April 30, 2013, up 22% from \$9.3 million a year earlier; revenue was \$176.5 million (growth of 16%). Growth was led by the company's GeneDx, Women's Health and GenPath Oncology laboratories. Two small Florida lab acquisitions completed in December 2012, Florida Clinical Lab and Meridian Clinical Lab, also added to growth. Revenue per requisition for the three-month period ended April 30, 2013 was \$84.93, up 11% compared with the same period a year earlier.

CANCER GENETICS INC. (Rutherford, NJ) recorded a first-quarter profit of \$2.4 million versus a loss of \$1.1 million a year earlier; revenue increased 46%, to \$1.2 million. Test volume increased by 19% to 1,911 tests; average revenue per test increased by 23% to \$615 per test.

COMBIMATRIX (Irvine, CA) reported a first-quarter net loss of \$711,000 versus a net loss of \$2.4 million a year earlier; revenue increased 27% to \$1.611 million. Average revenue per test was up 2.1% to \$923 due to an increase in volume of higher-priced array-based prenatal tests.

GENOMIC HEALTH (Redwood City, CA) recorded a net loss of \$883,000 in the first quarter versus net income of \$777,000 a year earlier; revenue increased 8% to \$63.1 million. The company derives nearly all of its revenue from the sale of its Oncotype DX breast cancer test (list price=\$4,290). Genomic Health delivered 20,350 Oncotype DX test reports for use in treatment planning in the first quarter, compared to 18,630 reports in the same quarter a year ago. The com-

pany recently began marketing a new test, Oncotype Dx Prostate Cancer Test (list price=\$3,820), for differentiating aggressive forms of prostate cancer from less threatening ones.

LABCORP (Burlington, NC) recorded first-quarter net income of \$147.2 million, down 9% from \$161.5 million a year earlier; revenue was up 1.2% to \$1.441 billion. LabCorp's volume increased by 1.1% to 32 million, while its revenue per requisition increased by 0.2% to \$45.06. LabCorp's first-quarter revenue was flat after adjusting for the benefit of the acquisition of Medtox in July 2012.

LIPOSCIENCE (Raleigh, NC) reported a first-quarter net loss of \$2.8 million versus a net profit of \$248,000 a year earlier; revenue was down 1.2% to \$13.6 million. During the first quarter of 2013, physicians ordered approximately 518,000 of the company's NMR LipoProfile tests, representing an increase of 8.7% over the first quarter of 2012. However, the average selling price of NMR LipoProfile tests decreased by 6.4% to \$25.25 for the first quarter of 2013, compared to \$26.99 for the prior year period. LipoScience raised net proceeds of \$44 million from an initial public offering (IPO) on January 25, 2013.

MYRIAD GENETICS (Salt Lake City, UT) reported net income of \$37.7 million for the three months ended March 31, 2013, up 26.5% from \$29.8 million a year earlier; revenue increased 21% to \$156.5 million. Myriad's BRACAnalysis test for hereditary breast and ovarian cancer accounts for 74% of the company's overall revenue (for more on Myriad, see page 1).

NEOGENOMICS (Fort Myers, FL) earned a net profit of \$3,000 in the first quarter of 2013, down from \$603,000 in the same period a year ago; revenue grew by 3.3% to \$15.7 million. Requisition volume grew by 22% to 20,604 reqs. However, revenue per requisition fell by 15% to \$760 per req, primarily as a result of the expiration of the TC Grandfather Clause effective July 1, 2012.

QUEST DIAGNOSTICS (Madison, NJ) reported first-quarter net income of \$135.8 million, down 15% from \$159.1 million; revenue fell 6.4% to \$1.787 billion. Quest's revenue per requisition for the three months ended March 31, 2013 decreased 3.4% to an estimated \$44.62.

SEQUENOM (San Diego, CA), which operates molecular diagnostic labs in San Diego and North Carolina, recorded a first-quarter net loss of \$29.4 million versus a net loss of \$24.4 million a year earlier; revenue increased to \$38.5 million from \$14.9 million. The company processed 44,500 accessions during the quarter. The majority of volume (35,000 accessions) was for Sequenom's prenatal genetic test MaterniT21 Plus. Sequenom's estimated average revenue per accession for the first quarter was \$798.

First-Quarter Average Revenue Per Requisition

Company	Avg. Revenue Per Requisition	Year-Over-Year % Change
Aurora Diagnostics	\$117.00	-10%
Bio-Reference Labs	\$84.93	11%
Cancer Genetics Inc.*	\$615.00	23%
CombiMatrix*	\$923.00	2.1%
LabCorp	\$45.06	0.2%
LipoScience	\$25.25	-6.4%
NeoGenomics	\$760.00	-15%
Quest Diagnostics	\$44.62	-3.4%
Sequenom	\$798	88.2%

*Cancer Genetics Inc. and CombiMatrix figures are for average revenue per test (rather than requisition).

Source: *Laboratory Economics* from company reports

LAB STOCKS UP 1% YTD

Twelve lab stocks are, on average, up 1% in price year to date through June 17. In comparison, the S&P 500 Index is up 16% and the Nasdaq is up 14%. The top-performing lab stocks so far this year are NeoGenomics, up 66%, followed by Genomic Health, up 21%. CombiMatrix is down 52%. Quest Diagnostics is up 7% and LabCorp is up 16%.

Company (ticker)	Stock Price 6/17/13	Stock Price 12/31/12	2013 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/Sales	Price/Book
Bio-Reference (BRLI)	\$28.93	\$28.63	1%	\$802	17.7	1.2	3.3
Cancer Genetics Inc. (CGIX)	9.75	10.00	-3%	42	NA	9.0	NA
CombiMatrix (CBMX)	2.54	5.28	-52%	9	NA	0.6	3.8
Enzo Biochem (ENZ)	2.20	2.70	-19%	88	NA	0.9	2.5
Genomic Health (GHDX)	32.97	27.24	21%	996	164.9	4.2	7.6
LabCorp (LH)	100.44	86.62	16%	9,331	15.9	1.7	3.4
LipoScience (LPDX)	6.66	9.00	-26%	98	NA	1.8	1.7
Myriad Genetics (MYGN)	26.62	27.25	-2%	2,120	16.9	3.7	3.2
NeoGenomics (NEO)	4.11	2.48	66%	200	NA	3.3	10.5
Psychedics (PMD)	11.28	10.75	5%	60	19.8	2.4	5.2
Quest Diagnostics (DGX)	62.59	58.27	7%	9,890	14.7	1.4	2.3
Sonic Healthcare (SKHCY)	13.22	13.69	-3%	5,240	NA	NA	NA
Unweighted Averages			1%		41.6	2.7	4.3

Source: Bloomberg

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