

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FINAL MEDICARE NLAs FOR MOST MDx TESTS LOOK REASONABLE

On September 30, CMS released the long-awaited “final” 2014 National Limitation Amounts for 65 molecular tests described by Tier 1 codes. The NLA amounts for 25 higher-volume codes are, on a weighted-average basis, 14% below the payment levels labs had received under the old code-stack method of billing. The median price change is -16%. However, this is actually an improvement from the initial gap-fill rates proposed by Medicare contractors earlier this year, which were priced an average of 25% to 30% below the old code-stack rates used in 2012.

Continued on pp. 3-4.

QUEST OFFERS NEW BRCA TEST AT 25% DISCOUNT

Quest Diagnostics has begun marketing a genetic screening test for breast cancer under the brand name BRCAVantage. The test puts Quest in direct competition with Myriad Genetics’ BRCAAnalysis test. Quest is offering its test at a list price of \$2,500, which is 25% below Myriad’s list price of \$3,340. In addition, LabCorp has announced plans to launch its own BRCA test by year’s end.

Full details on page 10.

FOUNDATION MEDICINE RAISES \$110 MILLION FROM IPO

Cancer diagnostic company Foundation Medicine (Cambridge, MA) has completed an initial public offering (IPO) of 6.772 million shares of common stock at \$18 per share. Foundation will receive net proceeds of approximately \$110 million after deducting investment bank commissions and other expenses. Goldman Sachs and J.P. Morgan Securities were the IPO’s lead underwriters. On its first day of trading on the Nasdaq, Foundation shares jumped 96% to \$35.35 per share for a market valuation of nearly \$1 billion. This valuation is equal to roughly 45 times the company’s current annualized revenue of \$22 million per year. In comparison, Quest Diagnostics and LabCorp each currently trade at approximately 1.5 times their annual revenue.

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FOUNDATION MEDICINE RAISES \$110 MILLION (*cont'd from page 1*)

Foundation markets a comprehensive genomic test for solid cancer tumors under the brand name FoundationOne. The test analyzes the entire coding sequence of 236 cancer-related genes, including ALK, BRAF, BRCA1, BRCA2, EGFR, JAK2, KRAS, et al. The test is performed at Foundation's CLIA-certified and CAP-accredited laboratory in Cambridge, MA.

The FoundationOne test has not been cleared by the FDA and has not received a coverage decision from Medicare or any private-insurance payer.

Foundation expects to begin marketing its second commercial product, FoundationOne for hematologic malignancies, by early 2014.

Foundation plans to use proceeds from the IPO to fund expansion, new and ongoing clinical trials, working capital, and general corporate purposes. The company plans to spend about \$18 million to expand its sales force in the U.S. and internationally, another \$12 million to fund clinical trials, and \$10 million on both expanding its laboratory operations and infrastructure.

Foundation currently has 142 full-time employees, including 15 sales reps.

Foundation recorded a net loss of \$17.4 million on total revenue of \$11.1 million in the six months ended June 30, 2013. The company has accumulated losses totaling \$64.2 million since being formed in November 2009.

During the six months ended June 30, 2013, Foundation performed 1,218 tests for biopharmaceutical customers who paid an average of approximately \$3,800 per test. During this

period, Foundation also performed 2,766 tests for ordering clinical physicians, including 611 tests for Medicare patients for which the company does not currently submit claims. Average revenue for FoundationOne clinical tests that meet the company's revenue recognition criteria was \$3,700 per test.

The current list price for the FoundationOne test is \$5,800.

The biotech investment firm Third Rock Ventures has a 24% stake in Foundation; Kleiner Perkins Caufield & Byers owns 13% and Google Ventures owns 9%. In addition, Bill Gates and LabCorp each hold a 4% stake. Foundation's President, Michael J. Pellini, M.D., owns a 2.5% stake.

Foundation Medicine at a Glance (\$000)

	<i>Six months to June 30</i>		
	2013	2012	% Chg
Revenue	\$11,120	\$2,429	358%
Biopharma test revenue	6,000	2,429	147%
Clinical test revenue	5,100	0	NA
Loss from operations	-17,147	-11,070	NA
Net income	-17,390	-11,344	NA

Source: Foundation Medicine

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FINAL MEDICARE NLAs FOR MOST MDx TESTS (cont'd from page 1)

Stakeholders have until October 30 to request reconsideration of NLA for the 65 MDx tests. As a result, there could be additional rate adjustments for some codes when CMS publishes the 2014 Clinical Laboratory Fee Schedule (CLFS) in early November. The NLA amounts in the CLFS represent the upper limit that Medicare Administrative Contractors (MACs) can pay for a specific code beginning January 1, 2014. However, each MAC can establish a price that is lower than the NLA and can continue to pay that price in 2014.

As the single largest payer in the country, the rates set by Medicare often heavily influence Medicaid and private payer reimbursements as well. These payers often link their own payment rates to the Medicare NLAs (e.g., X% of Medicare rates).

Most of the MACs (10 out of 13) have fixed their reimbursement levels for the 65 MDx test codes to the same level as CMS's final pricing. However, three MACs have set prices significantly below the NLAs. These include WellPoint's National Government Services (New York, Connecticut, Massachusetts, et al.), BCBS of Alabama's Cahaba (Alabama, Georgia and Tennessee) and First Coast Service Options (Florida and Puerto Rico). Labs in these states will be at a disadvantage unless their MACs raise MDx reimbursement levels to the NLAs.

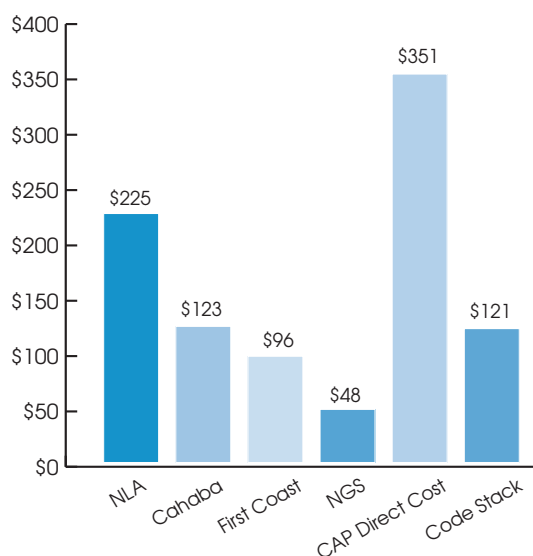
For example, CMS has set the NLA for the highest volume MDx test code, CPT 81206 (BCR/ABL 1 Gene Major BP), at \$225. In comparison, Cahaba has priced CPT 81206 at \$123, First Coast at \$96 and National Government Services at \$48. The College of American Pathologists (CAP) has estimated that the total direct cost (including equipment, supply and labor) to perform CPT 81206 is \$351. And *Laboratory Economics* has calculated that labs had previously billed a stack of codes totaling \$121 for CPT 81206.

So there is still confusion over what the proper pricing should be for some MDx tests. And none of the MACs has ever provided any details into exactly how they calculated their pricing for any of the MDx test codes.

No rates have been published for Tier 2 MDx test codes (representing over 500 gene-specific procedures). CMS says that it did not list pricing for Tier 2 codes because MACs are not currently paying for these tests. However, according to the College of American Pathologists, some MACs have indicated that CMS misinterpreted their submissions and that they are paying for some of the unlisted codes, but this discrepancy may not be corrected until the government shutdown ends.

Meanwhile, CMS continues its policy of not recognizing multianalyte assays with algorithmic analysis (MAAAs). MAAAs use mathematical formulas to analyze a combination of tests to produce a numeric score or probability of a patient's risk of disease. CMS says an algorithm is not a clinical diagnostic test and therefore MAAA codes are not payable under the CLFS. However, CMS will continue to consider each individual test that comprises a MAAA for payment on its own merits.

Sample Rates for CPT 81206 (BCR/ABL 1 Gene Major BP)



Source: *Laboratory Economics* and CMS

MDx Test Pricing Comparison: Code Stacks vs. Medicare NLAs

MDX Pricing Code	Short Descriptor	RUC Estimated Medicare Utilization	Code- Stack Median	Medicare National Limit	Percent Change
81206	BCR/ABL 1 Gene Major Breakpoint	45,729	\$121	\$225	86%
81241	Factor V Mutation Analysis	43,000	\$65	\$84	29%
81240	F2 gene analysis	31,000	\$136	\$68	-50%
81256	Hereditary Hemochromatosis	25,000	\$82	\$90	10%
81270	JAK2 Mutation Analysis	19,000	\$83	\$126	52%
81370	HLA Class I and II typing	14,000	\$783	\$553	-29%
81275	KRAS Mutation Analysis	14,000	\$284	\$199	-30%
81265	IGK short tandem repeat	14,000	\$777	\$296	-62%
81291	MTHFR gene Analysis	9,000	\$82	\$60	-27%
81235	EGFR Mutation Analysis	9,000	\$523	\$333	-36%
81210	BRAF Gene Mutation	7,000	\$84	\$181	115%
81245	FLT3 gene	6,000	\$344	\$167	-51%
81342	T-Cell Gene Rearrangement	5,000	\$169	\$277	64%
81310	NPM1 Gene	4,500	\$59	\$249	322%
81261	IGH gene rearrangement	4,500	\$154	\$272	77%
81213	BART testing	4,000	\$700	\$587	-16%
81211	BRCA1, BRCA2 gene analysis	4,000	\$3,340	\$2,795	-16%
81227	CYP2C9 Genotype	4,000	\$344	\$176	-49%
81207	BCR/ABL 1 Gene Minor	3,500	\$90	\$199	121%
81267	Chimerism Analysis	2,000	\$273	\$285	4%
81226	CYP2D6 Genotype	2,000	\$563	\$455	-19%
81225	CYP2C19 Genotype	2,000	\$386	\$294	-24%
81315	PML/RARalpha com Breakpoints	1,000	\$160	\$285	78%
81301	Microsatellite Instability	1,000	\$311	\$398	28%
81321	PTEN Gene Analysis	950	\$837	\$605	-28%
Unweighted Average % Change					22%
Weighted Average % Change					-14%
Median % Change					-16%

Note: Code-stack medians calculated by *Laboratory Economics* based on Clinical Lab Fee Schedule for 2012.

Source: *Laboratory Economics*

HOW WOULD THE PROPOSED OPPTS FOR 2014 CHANGE HOSPITAL OUTPATIENT LAB TEST REIMBURSEMENT?

The August and September issues of *Laboratory Economics* included analyses of CMS's proposal to eliminate separate fee schedule payments to hospital outpatient departments for most clinical lab tests and anatomic pathology technical services, effective January 1, 2014.

Laboratory Economics calculates that the proposed rule, if finalized, will reduce reimbursement to hospital outpatient departments by between 11% and 42% for the most common outpatient clinic and emergency department (ED) visits and associated lab tests.

Below we provide specific examples of how this proposal would change reimbursement for the most common hospital outpatient visits and associated lab tests.

Background

CMS has proposed creating one new CPT code to describe all levels of hospital outpatient clinic visits that would not distinguish between new and established patients. This new single code (GXXXC/APC 0634) would replace the 10 existing codes currently used to reimburse hospital outpatient clinic visits, including CPT 99201-99205 for new patients and CPT 99211-99215 for established patients. Reimbursement for the new code is a proposed \$88.31 (unadjusted for geography), which would be used to reimburse each outpatient clinic visit plus all associated lab tests. Under this proposal, Medicare would no longer pay separately for lab tests related to an outpatient clinic visit provided on the same date of service.

Separate payment by the Clinical Lab Fee Schedule would apply only when lab tests were provided alone with no other services on the same day.

Under the proposed rule, professional component fees paid to physicians would continue to be paid separately under the physician fee schedule.

Purpose

CMS believes that this proposal will remove incentives hospitals may have to provide medically unnecessary services and eliminate incentives to "up-code" to higher-paying outpatient visit codes.

Hypothetical Example #1:

Below we look at how the proposed rule would affect reimbursement for the most common Medicare hospital outpatient visit (CPT 99214/APC 0606) with two typical clinical lab tests provided: Complete Blood Count and Metabolic Panel.

Current Reimbursement 2013

The hospital bills Medicare CPT 99214/APC 0606 at a national unadjusted rate of \$96.96. In addition, the hospital bills the Part B Clinical Lab Fee Schedule for CPT 85025 (CBC) at \$10.69 and for CPT 80053 (Metabolic Panel) at \$14.53. Total reimbursement is \$122.18.

Proposed Reimbursement 2014

The hospital bills Medicare for new code GXXXC/APC 0634 at a national unadjusted rate of \$88.31. Lab tests are bundled into this new code and cannot be billed separately. This level of proposed reimbursement is 28% below the current reimbursement level for the same services at \$122.18.

Hypothetical Example #2:

Below we look at how the proposed rule would affect reimbursement for the most common Medicare emergency department outpatient visit (CPT 99285/APC 0616) with two typical clinical lab tests provided: Complete Blood Count and Metabolic Panel.

Current Reimbursement 2013

The hospital bills Medicare CPT 99285/APC 0616 at a national unadjusted rate of \$344.71. In addition, the hospital bills the Part B Clinical Lab Fee Schedule for CPT 85025 (CBC) at \$10.69 and for CPT 80053 (Metabolic Panel) at \$14.53. Total reimbursement is \$369.93.

Proposed Reimbursement 2014

The hospital bills Medicare for new code GXXXA/APC 0635 at a national unadjusted rate of \$212.90. Lab tests are bundled into this new code and cannot be billed separately. This level of proposed reimbursement is 42% below the current reimbursement level for the same services at \$369.93.

Most Frequent Hospital Outpatient Clinic and ED Visits

Visit Type	2013 HCPCS Code	2013 APC	2013 Rate	2013 Rate Plus Lab Tests*	Proposed 2014 Code	Proposed 2014 APC	Proposed 2014 Rate	Percent Change
Clinic Visit	99212	0605	\$73.68	\$98.90	GXXXC	0634	\$88.31	-11%
Clinic Visit	99213	0605	\$73.68	\$98.90	GXXXC	0634	\$88.31	-11%
Clinic Visit	99214	0606	\$96.96	\$122.18	GXXXC	0634	\$88.31	-28%
Clinic Visit	99215	0607	\$128.48	\$153.70	GXXXC	0634	\$88.31	-43%
ED Visit	99284	0615	\$229.37	\$254.59	GXXXA	0635	\$212.90	-16%
ED Visit	99285	0616	\$344.71	\$369.93	GXXXA	0635	\$212.90	-42%

*Total includes the Medicare outpatient facility rate plus Part B Clinical Lab Fee Schedule reimbursement for CPT 85025 (CBC) at \$10.69 and for CPT 80053 (Metabolic Panel) at \$14.53.

Source: *Laboratory Economics* from CMS Proposed OPPI/ASC Rule for 2014.

Conclusion

The bundling proposal, in effect, eliminates Medicare reimbursement for outpatient lab tests, notes *Laboratory Economics*.

Furthermore, *LE* notes that the examples given above probably understate the potential reduction in payment levels because CMS is seeking to bundle several other components of care into hospital outpatient clinic and ED visit codes, including certain drugs, biologics and imaging procedures.

Response from the American Hospital Association

Not surprisingly, the AHA is lobbying against CMS's bundling proposal. The AHA says the proposal could have significant negative consequences on hospitals whose patient case mix tends towards the higher-level services, such as trauma centers and cancer hospitals. In addition, the AHA says that implementing this proposal on January 1, 2014, would not allow hospitals enough time to fully understand how the new rules would affect their outpatient finances, making hospital budgeting for the upcoming year nearly impossible.

The final rule is scheduled to be released on November 1.

THE FASTEST-GROWING LAB TESTS: MD_x, DRUGS and VITAMIN D

The fastest-growing clinical lab tests over the five-year period, 2007-2012, were concentrated in three categories: 1) molecular diagnostics; 2) drugs-of-abuse testing; and 3) Vitamin D testing, according to a *Laboratory Economics* analysis of Medicare Part B carrier expenditures for the top 50 CPT codes.

The single-fastest-growing CPT code was 83909, a stacking code used for molecular diagnostics. Part B carrier spending on CPT 83909 increased by an average of 118.8% per year between 2007 and 2012. Effective January 1, 2013, this code and other generic molecular diagnostics were replaced with new more specific codes.

Part B carrier spending on five test codes for drugs of abuse grew by 50% per year or more between 2007 and 2012. Part B carrier spending on CPT 83925 (opiates) was up an average of 81.5% per year, while CPT 83840 (methadone) increased by 73.4%, CPT 82145 (amphetamine or methamphetamine), up 70.6%, CPT 80154 (benzodiazepines), up 67.1%, and CPT 82542 (cannabinoids), up 64.5%.

In addition, Part B carrier expenditures on vitamin D tests (CPT 82306) increased by 41.7% per year during the five-year period.

Overall, Medicare Part B carrier spending on the top 50 clinical lab tests increased by 5.2% per year between 2007 and 2012.

Medicare Part B Carrier Spending On Top 50 Clinical Lab Tests

CPT Code	2012	2007	5-Year CAGR*
84443 (TSH)	\$360,610,236	\$310,645,098	3.0%
85025 (CBC)	\$339,954,042	332,689,647	0.4%
80053 (metabolic panel)	\$327,937,097	285,424,913	2.8%
80061 (lipid panel)	\$303,497,598	291,262,445	0.8%
82306 (vitamin D)	\$232,005,257	40,581,633	41.7%
83036 (A1C)	\$177,983,408	152,869,189	3.1%
83925 (opiates)	\$130,004,035	6,599,159	81.5%
85610 (prothrombin time)	\$109,586,202	118,799,886	-1.6%
84153 (PSA)	\$90,982,640	94,109,547	-0.7%
80048 (metabolic panel)	\$88,291,744	96,470,549	-1.8%
82607 (vitamin B12)	\$77,410,073	48,620,247	9.7%
83970 (parathormone)	\$70,301,688	165,954,286	-15.8%
84999 (chemistry test)	\$65,124,809	16,533,132	31.5%
82542 (cannabinoids)	\$63,357,558	5,264,176	64.5%
87086 (urine culture)	\$57,271,548	45,542,568	4.7%
84439 (thyroxine, free)	\$56,563,650	39,861,338	7.2%
83880 (BNP)	\$48,232,439	42,847,452	2.4%
82728 (ferritin)	\$47,195,670	66,932,499	-6.7%
82746 (folate)	\$44,059,941	30,233,659	7.8%
84403 (testosterone, total)	\$42,584,471	17,865,079	19.0%

Continued on next page

Medicare Part B Carrier Spending On Top 50 Clinical Lab Tests *(continued)*

<i>CPT Code</i>	<i>2012</i>	<i>2007</i>	<i>5-Year CAGR*</i>
83904 (molecular diagnostics)	\$42,565,775	9,217,525	35.8%
82570 (creatinine)	\$37,926,882	20,940,096	12.6%
80154 (benzodiazepines)	\$37,858,813	2,901,880	67.1%
83898 (molecule nucleic ampli, each)	\$34,990,236	10,830,851	26.4%
87186 (MIC)	\$33,823,408	21,250,899	9.7%
85027 (CBC)	\$32,153,408	25,636,176	4.6%
83840 (methadone)	\$32,090,728	2,049,946	73.4%
81001 (urinalysis)	\$32,057,345	25,702,593	4.5%
87088 (urine culture)	\$27,346,200	23,481,621	3.1%
82145 (amphetamine or methamphetamine)	\$26,168,445	1,809,643	70.6%
86235 (nuclear antigen antibody)	\$26,137,746	21,226,108	4.3%
83550 (TIBC)	\$25,230,197	42,833,121	-10.0%
83540 (iron)	\$23,979,644	40,671,020	-10.0%
83909 (molecular diagnostics)	\$23,894,949	476,831	118.8%
83735 (magnesium)	\$23,085,282	17,796,532	5.3%
87077 (culture, bacterial)	\$21,895,926	16,946,805	5.3%
84481 (triiodothyronine T3; free)	\$21,687,140	10,504,121	15.6%
83704 (quantitation of lipoprotein)	\$21,631,342	7,610,338	23.2%
82043 (albumin)	\$21,284,128	13,631,257	9.3%
80076 (hepatic function panel)	\$21,058,550	29,231,120	-6.3%
86003 (allergen specific IgE)	\$19,042,689	10,479,009	12.7%
84480 (triiodothyronine T3; total)	\$18,854,139	8,448,005	17.4%
84436 (thyroxine; total)	\$18,520,115	21,100,986	-2.6%
82378 (CEA)	\$18,321,472	19,354,383	-1.1%
81003 (urinalysis)	\$18,288,010	11,728,450	9.3%
82784 (immunoglobulin; IgA, IgD, IgG, IgM, each)	\$17,368,586	13,169,481	5.7%
83721 (lipoprotein, direct measurement)	\$17,217,645	21,891,631	-4.7%
84165 (protein; electrophoretic fractionation)	\$16,367,496	12,017,098	6.4%
87536 (HIV-1 detection by nucleic acid)	\$15,987,020	14,544,617	1.9%
81002 (urinalysis)	\$15,907,916	15,120,981	1.0%
Total, 50 Tests	\$3,475,695,338	\$2,701,709,627	5.2%

*CAGR=compound annual growth rate

Source: *Laboratory Economics* from CMS's Part B Extract and Summary System (BESS), 2007-2012

QUEST BUYS CONVERGE DIAGNOSTIC SERVICES

Quest Diagnostics has acquired ConVerge Diagnostic Services LLC (Peabody, MA) for an undisclosed amount from the private investment firm Water Street Healthcare Partners (Chicago, IL). Water Street originally purchased ConVerge in 2009.

ConVerge is a full-service clinical and anatomic pathology lab with an emphasis on women's health. The company has a CLIA-certified lab in Peabody, Massachusetts (just north of Boston) and 14 patient service centers in Massachusetts, Connecticut and New Hampshire. ConVerge has approximately 110 employees and estimated annual revenue of \$15+ million. ConVerge's CEO, Bob Gorman, is a former Quest executive.

The acquisition is the fourth so far this year for Quest. Its other acquisitions have included UMass Memorial Medical Center's clinical and anatomic pathology outreach lab businesses, Concentra's toxicology lab and the clinical lab outreach business at Dignity Health in California.

HEART TEST MAKER CARDIODX SEEKS UP TO \$86M FROM IPO

CardioDx Inc. (Palo Alto, CA), which sells a proprietary blood test for heart disease under the brand name Corus CAD, has filed for an IPO seeking to raise up to \$86.25 million. The exact number of shares to be offered and pricing terms have yet to be decided. BofA Merrill Lynch and Jefferies LLC will serve as lead underwriters.

CardioDx plans to use proceeds from the planned IPO to expand its sales and marketing personnel, which currently stands at 33 sales reps. Proceeds will also be used to fund continuing operating losses as the company seeks additional payer reimbursement coverage determinations and to conduct additional clinical and marketing activities to enhance support for Corus CAD.

CardioDx's Corus CAD test is a laboratory-developed test (LDT) that has not received FDA clearance. The test is performed at the company's CLIA-certified, CAP-accredited lab in Palo Alto, California.

The Corus CAD test analyzes 23 genes from a patient's blood sample to help determine whether a patient is at low risk of coronary artery disease. The test is designed to help doctors determine whether a patient's chest pain symptoms are due to obstructive coronary artery disease. The test yields a score along a 1 to 40 scale, with a lower score representing a lower likelihood of a heart blockage.

Corus CAD is considered a multi-analyte test with an algorithm but does not have a MAAA CPT code. CardioDx's is covered by the regional MAC in California, Noridian, under CPT code 84999 (unlisted chemistry procedure). Noridian's reimbursement rate has not been disclosed; the list price for the test is \$1,245.

CardioDx recorded a net loss of \$24.2 million on total revenue of \$2.9 million in the six months ended June 30, 2013. The company has accumulated losses totaling \$165.9 million since being formed in 2003. Test volume for the six months ended June 30, 2013 was 7,644 compared with 5,752 for the same period in 2012. The average revenue per test increased to \$376 from \$81.

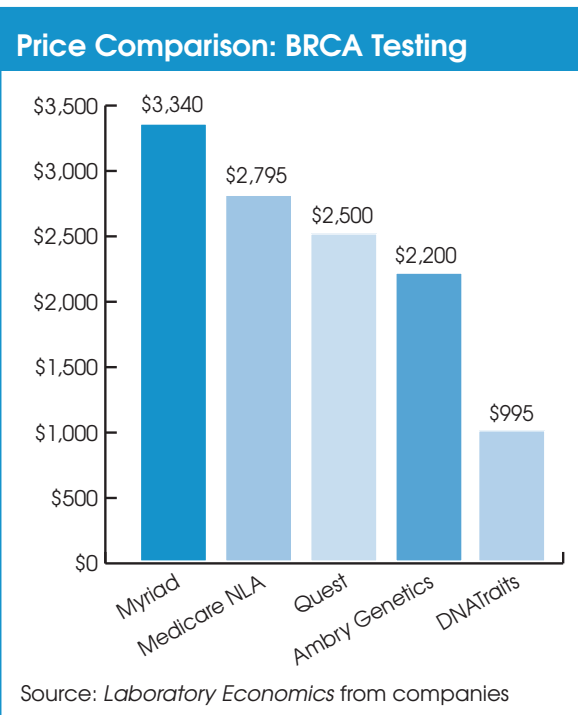
The company's biggest shareholder is V-Sciences Investments, a wholly owned subsidiary of Temasek Life Sciences Private Ltd., which holds a 19.9% stake. Other owners include Longitude Venture Partners, 17.9% stake, and Artiman Ventures, 13.9% stake.

QUEST OFFERS NEW BRCA TEST AT 25% DISCOUNT (*cont'd from page 1*)

The Supreme Court struck down some of Myriad's BRCA patents in June (see *LE*, June 2013, pp. 1 & 9). Some smaller labs, including Ambry Genetics and Gene By Gene, each immediately began marketing their own BRCA tests after the ruling. Myriad claims that its remaining patents bar competing BRCA tests from entering the market. In July, Myriad filed lawsuits against both of these companies for patent infringement, seeking an injunction barring them from selling their BRCA tests.

Anticipating a similar legal challenge, Quest filed a pre-emptive suit in federal court (case #13-cv-1587) on October 10, seeking a declaratory judgment that its BRCAvantage test does not violate Myriad's patents.

Myriad has not yet filed a response to Quest's lawsuit.

**QUEST DIAGNOSTICS 3Q REVENUE DOWN 2%**

Quest Diagnostics (Madison, NJ) reported third-quarter revenue of \$1.787 billion, down 1.9% from the same period a year earlier. Requisition volume was up 2% in the third quarter with recent acquisitions adding 3% to volume. Revenue per requisition was 4.3% below the prior year.

Challenges for Quest included increased denials for molecular tests due to the transition from code-stack billing to new more specific CPT codes and reimbursement rates. Quest executives said the company was seeing increased denials for MDx tests from Medicare, Medicaid and commercial payers. In addition, Quest said that increased denials were causing its hospital clients to order less MDx tests. Quest also cited weakness in its Pap testing business due to lengthening intervals of testing.

On an October 17 conference call with analysts, Quest CEO Steve Rusckowski said that Medicare reimbursement cuts are disproportionately affecting smaller labs that receive a higher portion of their overall revenue from Medicare.

This should result in continued opportunities for Quest to consolidate the lab industry and gain market share, according to Rusckowski.

Quest Diagnostics Financial Summary (\$ millions)

	3Q2013	3Q2012	% Chg
Total revenue	\$1,787	\$1,822	-1.9%
Pretax income	657	271	142.5%
Net income	405	163	148.4%
Diluted EPS	2.68	1.01	165.3%
Bad debt %	3.6%	3.4%	5.9%
Days sales outstanding	48	46	4.3%
Est'd number of reqs.	149.5	146.5	2.0%
Est'd revenue per req.	44	46	-4.3%

Source: Quest Diagnostics and requisition estimates from *Laboratory Economics*

LABCORP 3Q REVENUE UP 3%; NET INCOME FLAT

LabCorp (Burlington, NC) reported third-quarter revenue of \$1.462 billion, up 3% from the same period a year earlier; net income was unchanged at \$148 million.

Requisition volume was up 5.1% in the third quarter with recent acquisitions (Genesis outreach lab, Bendiner & Schlessinger and others) accounting for more than half of the volume growth.

Revenue per requisition decreased 1.9% to an estimated \$44.16. Pricing was affected by this year's 5% reduction to Medicare's CLFS, including a 2% sequestration cut, as well as lower reimbursement, delayed payment and increased denials for molecular diagnostic tests. Strong growth in LabCorp's lower-priced drug testing business (growing 10% to 15% per year) also contributed to a lower average revenue per requisition.

LabCorp Financial Summary (\$ millions)

	3Q2013	3Q2012	% Chg
Total revenue	\$1,462	\$1,419	3.0%
Pretax income	230	227	1.4%
Net income	148	148	0.2%
Diluted EPS	1.63	1.53	6.5%
Bad debt %	4.3%	4.3%	0.0%
Days sales outstanding	50	48	4.2%
Est'd number of reqs.	130.3	124	5.1%
Est'd revenue per req.	\$44.16	\$45.00	-1.9%

Source: LabCorp with requisition estimates from *Laboratory Economics*

PROPOSED CLFS REPRICING WOULD OCCUR QUICKER THAN YOU THINK

CMS has proposed repricing all 1,250 test codes paid under the clinical laboratory fee schedule (CLFS) with the intent of lowering payments to better align pricing with the cost of new and more efficient testing technologies (see *LE*, July 2013, pp. 1-2).

CMS has proposed that, each year, it would review certain codes on the CLFS to decide whether payment for these codes should be adjusted due to technological change. Proposed payment rates for the first batch of test codes under review would be announced in the 2015 PFS proposed rule and the new rates would take effect January 1, 2016. Inflation and productivity adjustments would continue to be applied to the CLFS each year.

CMS estimates that it would take at least five years to review all of 1,250 existing codes on the CLFS. The agency would start its review by examining the codes that have been on the CLFS the longest and have the highest annual test volume. The proposal indicates that CMS would review an average of about 250 test codes per year.

Reviewing all lab test codes over a five-year period sounds like a long-term project. But nearly 100% of the impact would likely be achieved in the first year of implementation. This is because the top 100 CPT codes account for more than 90% of all Medicare volume and expenditures on lab tests. Therefore, nearly the entire impact of this proposal would hit labs in the CLFS for 2016. The repricing of lower volume codes in subsequent years would have a minimal impact on most labs. More details on this proposal are expected in the Final Physician Fee Schedule for 2014 due to be released on November 1.

LAB STOCKS UP 16%; LABCORP MARKET CAP SURPASSES QUEST

Fourteen lab stocks are, on average, up 16% in price year to date through October 16. In comparison, the S&P 500 Index is up 17.6%. The top-performing lab stock so far this year is Foundation Medicine, which has jumped 89% from its IPO price of \$18 on September 30 (see pages 1-2). Meanwhile, LabCorp's current market capitalization of \$9.112 billion has surpassed Quest Diagnostics' \$8.923 billion; this makes LabCorp the largest lab testing company in the world as measured by market value.

Company (ticker)	Stock Price 10/16/13	Stock Price 12/31/12	2013 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	\$31.70	\$28.63	11%	\$866	18.3	1.2	3.3
Cancer Genetics Inc. (CGIX)	17.98	10.00	80%	102	NA	19.0	NA
CombiMatrix (CBMX)	2.85	5.28	-46%	13	NA	2.3	1.8
Enzo Biochem (ENZ)	2.40	2.70	-11%	97	NA	1.0	2.7
Foundation Medicine (FMI)	34.00	18.00	89%	945	NA	48.9	NA
Genomic Health (GHDX)	28.99	27.24	6%	897	732.0	3.7	6.4
LabCorp (LH)	101.13	86.62	17%	9,112	14.5	1.6	3.5
LipoScience (LPDX)	5.04	9.00	-44%	71	NA	1.3	1.3
Myriad Genetics (MYGN)	28.30	27.25	4%	1,870	13.1	3.1	2.5
NeoGenomics (NEO)	2.91	2.48	17%	139	NA	2.3	7.3
Psychemedics (PMD)	13.16	10.75	22%	70	22.6	2.7	6.0
Quest Diagnostics (DGX)	58.75	58.27	1%	8,923	14.0	1.2	2.3
Response Genetics (RGDX)	2.24	1.39	61%	76	NA	3.5	7.9
Sonic Healthcare (SHL.AU)*	15.43	13.33	16%	6,178	18.1	1.8	2.1
Unweighted Averages			16%		135.8	7.4	3.7

*Sonic Healthcare's stock price and market cap are in Australian dollars.

Source: Zacks

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