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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

MARKET PRESSURES LED UMASS TO SELL OUTREACH LAB TO QUEST DIAGNOSTICS

"Reimbursement for lab tests has been falling dramatically for quite some time and insurers are directing their patients and physicians to use labs that are lower cost than our service," said John O'Brien, president and CEO of UMass Memorial Health Care, in a letter to employees back in February. Fast forward six months and UMass has announced it is selling its clinical lab outreach business to Quest Diagnostics. The transaction is expected to close within 90 days. Quest expects the acquisition to add one percent (or approximately $75 million per year) to its annual revenue, be neutral to earnings in 2013, and add to earnings in 2014. Quest says it paid less than $100 million for the UMass outreach lab, which indicates a purchase price multiple of roughly 1x revenue. *Continued on page 11.*

PALMETTO DENYING COVERAGE FOR MOST MolDX TESTS

Since July, Medicare carrier Palmetto GBA has published coding guidelines and coverage updates for 13 tests under its new MolDX program. Ten tests have been denied coverage and only three have received positive coverage decisions, according to an analysis by *Laboratory Economics*.

Molecular tests that Palmetto will reimburse include Gen-Probe's FDA-cleared Progensa PCA3 Assay, Roche's FDA-cleared cobas BRAF V600 Test and CardioDx's Corus CAD Test.

Among the 10 tests denied coverage are five proprietary lab tests marketed by Celera's Berkeley HeartLab (Alameda, CA), which was acquired by Quest Diagnostics in March 2011. Other tests denied coverage include Agendia's BluePrint Test and Biocept's OncoCee Circulating Tumor Cell Assay.

"Up until now, there has been no process whatsoever to determine if an assay was appropriate," Elaine Jeter, MD, medical director at Palmetto GBA, told the audience at the recent G2 Lab Institute in Washington, DC. Furthermore, Jeter said that CMS has expressed an interest in expanding Palmetto's MolDx program to a national level. *Continued on pages 5-6.*

HOW MUCH DOES IT REALLY COST TO MAKE A SLIDE?

CMS was prompted to review its reimbursement rate for CPT 88305-TC, in part, because an anonymous stakeholder argued that it costs labs only $18 to produce a routine H&E slide versus Medicare's national payment rate of $70. But where did this $18 figure come from? *Laboratory Economics* thinks it may have come from a study published in the *Archives of Pathology & Laboratory Medicine* (APLM) in August 2010. *Continued on page 2.*

Contents

HOW MUCH DOES IT REALLY COST TO MAKE A SLIDE? (*cont'd from page 1*)
APLM is a peer-reviewed medical journal published by the College of American Pathologists. In August 2010, APLM published a study titled *Pathology Economic Model Tool: A Novel Approach to Workflow and Budget Cost Analysis in an Anatomic Pathology Laboratory*. The study used a proprietary software program developed by Dako Denmark to analyze the workflow processes at The Nebraska Medical Center's anatomic pathology laboratory to estimate the total cost per slide for routine, special and immunohistochemical (IHC) stains. Actual costs for 12 months of labor, consumables, instrument use and service, and overhead were used for the analysis. Time and costs relating to pathologist review and interpretation of slides were not included.

Cost of Preparation of a Single Hematoxylin-Eosin (H&E)-Stained, Immunohistochemistry-Stained, or Special-Stained Slide with the Costs also Divided Into Labor, Materials, Equipment and Other Categories

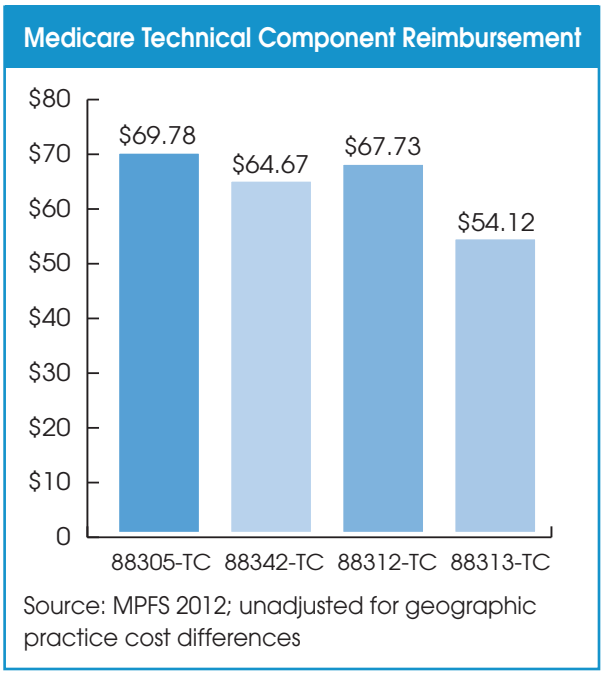
	Cost Per Slide		
	H&E	*IHC*	*Special Stains*
Labor	$8.77	$12.38	$11.11
Materials	3.39	31.22	18.33
Equipment	0.41	1.76	0.95
Other expenses*	5.49	5.49	5.49
Total	$18.06	$50.85	$35.88

*Other expenses includes overhead, facility costs, information technology and service contracts

Source: Arch Pathol Med—Vol 134, August 2010

The study found that it costs TNMC a total of $18.06 to prepare an H&E slide, including $8.77 for labor, $3.39 for materials, $0.41 for equipment and $5.49 for other expenses. The total cost to prepare an IHC slide was $50.85 and special stains cost $35.88.

In comparison, the Medicare Physician Fee Schedule (MPFS) pays a technical fee of $69.78 for a routine H&E slide under CPT 88305-TC. Medicare reimbursement for preparing an IHC slide is $64.67 under CPT 88342-TC. The technical component for special stains is reimbursed with two codes: 1) CPT 88312-TC (Special stains, group I) at $67.73; and 2) CPT 88313-TC (Special stains, group II) at $54.12.



Believe it or not, some pathologists are in favor of drastic cuts to technical fees by CMS. Many hospital-based pathologists make their living strictly from professional interpretations and have no financial interest in technical labs. These pathologists believe that technical reimbursement cuts will discourage urologists, gastroenterologists and dermatologists from building in-office pathology labs and result in more professional service work flowing back to hospital-based pathology groups.

SOME THOUGHTS ON LOOMING CUTS TO 88305-TC

On November 1, CMS is scheduled to release its Final Physician Fee Schedule Rule for 2013, which will reveal pricing changes to the technical component of CPT 88305.

Last year, CMS asked the AMA's Relative Value Upscale Committee (RUC) to review reimbursement for 88305-TC because of several factors: 1) CMS is looking to identify potentially overvalued codes so that it can redistribute resources toward primary care; 2) CPT 88305 is a high volume code whose technical component had not been reviewed since 1999; and 3) an anonymous stakeholder argued that the typical cost for 88305-TC is only $18 versus Medicare's national payment rate of $70 (*see page 2*).

It's now widely anticipated that Part B reimbursement for 88305-TC will be reduced for 2013. Keep in mind that the professional component of 88305 is not under review. Here are some other points to remember:

- The national Part B payment for 88305-TC unadjusted for geography is currently $70. However, reimbursement ranges from as much as $95 in northern California to as little as $58 in West Virginia.
- The RUC has likely determined that advances in automation have lowered the cost to prepare slides over the past 10 years, and thus recommend a reimbursement reduction to the technical component of 88305, as well as other codes in surgical pathology (88300-88309).
- CPT 88305 is by far the highest volume code in this series. However, other notable codes that are subject to technical component fee cuts include 88304, 88307 and 88309.
- CMS typically accepts RUC recommendations.
- CMS is not obligated to provide specific details behind its pricing decision.
- Medicare reimbursement to hospitals for 88305-TC under the DRG will not be affected, nor will the APC outpatient rate.
- Changes in Medicare reimbursement are likely to ripple through to private payer contracts tied to Medicare rates.

The magnitude of the expected fee reduction won't be made public until November 1. A reduction of 10% or less could be absorbed (with difficulty) by pathology labs. However, *Laboratory Economics* is aware that some consultants have warned their pathology lab clients to prepare for a cut of 30% or more. This level of reduction to technical fees would lead to a severe national restructuring of pathology services, forcing many smaller pathology labs out of business, notes *LE*.

IHC and Enhanced Cytology Are Next

In addition to the surgical pathology codes, CMS is targeting the technical and professional components of immunohistochemistry (CPT 88342) and enhanced cytology services (CPT 88112) for review as potentially overvalued. These codes will be reviewed by the RUC process in 2013 with any potential reimbursement changes effective in 2014. Both codes are in the top ten in terms of Part B expenditures for pathology services (*see page 7*).

PALMETTO STANDS BY PROSTATE BIOPSY CAP

"All I did was write an interpretation of what the NCCI said in January," explained Elaine Jeter, MD, medical director at Palmetto GBA. Speaking at the G2 Lab Institute, Jeter confirmed that the total number of specimens submitted for pathology evaluation is the determining factor when selecting the code for billing—NOT the surgical procedure used to obtain the specimens. Palmetto's policy update, issued on August 7, caps global pathology reimbursement for prostate biopsies at $671 by requiring code G0416 anytime five or more separate specimens are billed. The cap effectively cuts pathology reimbursement for a typical 12-core prostate biopsy by 50%.

Jeter said urologists had traditionally placed two prostate biopsy cores in a vial so that a 12-core biopsy would be billed using six units of CPT 88305. However, Jeter said more recently there has been a tendency to place each prostate biopsy core in its own vial and bill for 12 units of CPT 88305. "We saw a trend toward individual containers due to self referral. I'm assuming that had a lot to do with CMS' decision to basically reduce reimbursement," she told the Lab Institute audience.

Meanwhile, ACLA, CAP, the California Clinical Laboratory Association and the Large Urology Group Practice Association are urging CMS to instruct Palmetto to withdraw its August 7 directive. These groups are arguing that Palmetto endorsed NCCI policy for reporting prostate biopsies despite existing Medicare policy which supersedes the NCCI action.

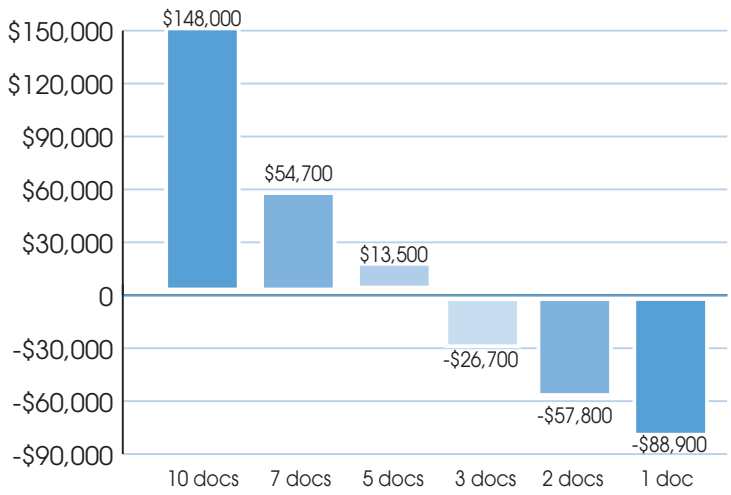
"This is a huge issue in terms of reimbursement. It's remarkable that CMS has been silent," says John Outlaw, vice president, regulatory affairs & compliance, at PSA, LLC (Florence, SC). "If you're in Palmetto's jurisdiction [CA, NV, HI, NC, SC, VA and WV] you have to follow their rules, but no other carriers have issued clarification." Outlaw says many pathology groups are holding on to prostate biopsy claims and waiting for guidance from CMS.

In-Office Pathology Labs No Longer Viable

The good news for pathologists is that in-office pathology labs are now unprofitable for small and mid-size urology groups (1-5 urologists) in Palmetto's jurisdictions. *Laboratory Economics* estimates that a urology group with four or five doctors will barely breakeven while groups with three urologists or less will lose money with an in-office pathology lab.

In addition, the profitability of on-site pathology labs at larger groups has shrunk significantly. *LE* had estimated that a 10-urologist group could earn a pretax profit of $730,000 per year (or $73,000 per doctor) with an in-office pathology lab (see *LE*, April 2012, p. 8). However, under Palmetto's new billing guidance a 10-urologist group will now only earn $148,000 per year (or $14,800 per doctor).

Estimated Urology Lab Profitability by Size of Group



Source: *Laboratory Economics*

As a result, the development of new in-office pathology labs at urology groups will cease and smaller groups with existing labs may close them and send their pathology work back to independent pathology groups and labs.

PALMETTO DENYING COVERAGE FOR MOST MolDX TESTS (*cont'd from p. 1*)

Palmetto GBA launched its ambitious Molecular Diagnostics Services Program (MolDx) earlier this year to "identify tests, determine coverage and determine reimbursement" for up to 1,500 molecular diagnostic tests (MDTs) in Jurisdiction 1, which covers more than five million Medicare beneficiaries in California, Nevada and Hawaii. The goal of the program is to assign new codes and make coverage decisions on all molecular tests that report a single test result, but are billed using code stacks.

Up until now, the utilization of molecular diagnostics has been driven by marketing rather than published clinical studies or medical society recommendations, according to Jeter. "The methodology-based codes are junk codes. You don't know what you're paying for," said Jeter. For example, Jeter noted that there are 27 labs billing Palmetto for KRAS testing using 25 different code stacks with reimbursement ranging from $172 to $860 per test. She noted that 29 labs perform BRAF testing using 21 different code stacks with reimbursement ranging between $85 and $513. Jeter said only three labs use the FDA-approved BRAF test, while 26 use laboratory-developed tests with most of these labs unnecessarily billing for manual microdissection (CPT 88381).

Palmetto MolDX Coverage Decisions (through Sept. 14, 2012)

Coverage Decision	*Test Name*	*Manufacturer/Marketer*	*Test Purpose*
Denied	ApoE genotype	various labs	Assess risk of cardiovascular disease
Accepted	Progensa PCA3 Assay	Gen-Probe	Identify patients with increased risk of prostate cancer
Accepted	BRAF V600 mutation test	Roche	Determines patient eligibility for Zelboraf for melanoma treatment
Denied	LPA-Aspirin genotype	Celera's Berkeley HeartLab	Predicts increased CVD risk and event reduction during aspirin therapy
Denied	9p21 Genotype Test	Celera's Berkeley HeartLab	Predict risk of early onset myocardial infarction
Denied	BluePrint	Agendia	Guide therapy selection for breast cancer patients
Accepted	Corus CAD Test	CardioDx	Diagnose coronary artery disease
Denied	OncoCee CTC Assay	Biocept	Detect metastatic disease for breast, prostate, lung and colon cancer
Denied	4q25-AF Risk genotype	Celera's Berkeley HeartLab	Predict risk of atrial fibrillation and CE stroke
Denied	PTEN testing	various labs	For therapy selection in range of cancers
Denied	KIF6 genotype test	Celera's Berkeley HeartLab	Predict risk of coronary heart disease
Denied	LPA-Intron 25 genotype	Celera's Berkeley HeartLab	Predict increased risk for coronary heart disease
Denied	SLCO1B1 genotype	various labs	Assess effectiveness of statin therapy

Source: *Laboratory Economics* from Palmetto GBA

Jeter also noted that some reference labs are charging between $3,500 and $5,500 to sequence a single gene. In comparison, Jeter said that academic medical centers are offering to sequence 50 genes for $500. She also pointed to data from the National Human Genome Research Institute that shows that the cost per raw megabase of DNA sequence has fallen from $500 per Mb in 2007 to only $0.09 per Mb in 2012. "So why is Medicare paying so much?" she asked.

Jeter said Palmetto will be using a value-based pricing system that factors in direct and indirect costs plus a profit margin. But tests will first need to receive a technical assessment and positive coverage determination from Palmetto before being reviewed for a pricing determination.

Lale White, president of the billing management firm Xifin (San Diego, CA), told the Lab Institute audience that Palmetto has set the bar high for coverage decisions. "Some tests that have been used for years and years would not pass Palmetto's technical assessment," she noted. This uncertainty is causing investors to pull back from investing in molecular diagnostics. A lot of molecular labs are finding it difficult to raise capital to continue their work, said White.

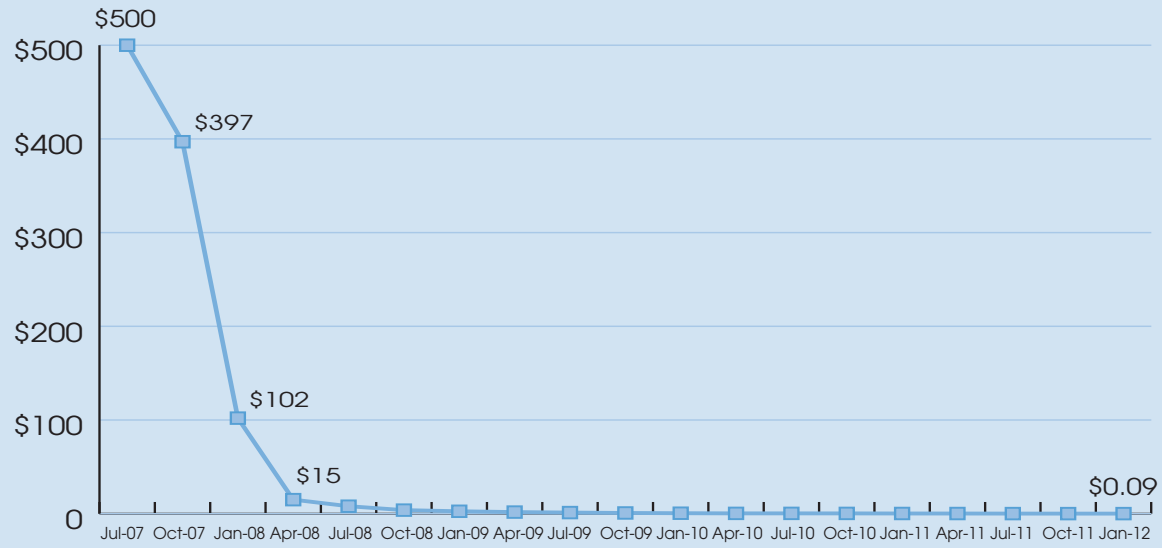
As for those tests that do pass Palmetto's stringent coverage requirements, White said pricing was likely to be reduced from current levels. "I'm anticipating a 20% reduction for molecular tests based on discussions so far."

Bruce Quinn, MD, PhD, senior health policy specialist at Foley Hoag LLP, said non-coverage decisions were likely to put some labs out of business. Agile labs will survive and benefit from picking up business from weaker labs that go bust, noted Quinn.

Will Noridian Replace Palmetto?

CMS announced on Sept. 20 that Noridian Administrative Services has won the J1 carrier contract away from Palmetto GBA. Palmetto will continue to administer provider claims for up to six months as CMS oversees the transfer of these Medicare contract responsibilities to Noridian. It is unclear yet whether Noridian will continue the MolDX program after it gains full control of the J1 contract. However, Jeter said, "Palmetto hasn't given up J1 yet. The contract protest may drag on for years."

Cost per Raw Megabase of DNA Sequence



Source: National Human Genome Research Institute

MEDICARE EXPENDITURES ON PATHOLOGY GREW 5.7% IN 2011

National Medicare Part B carrier payments for 12 high-volume pathology codes increased by 5.7% to $2.454 billion in 2011, according to data collected by the lab reimbursement consulting firm CodeMap LLC (Barrington, IL). Part B carrier spending on these 12 key pathology codes increased by an average of 7.2% per year between 2006 and 2011.

Part B carrier spending on CPT 88305—the most frequently billed anatomic pathology procedure—increased by 7.9% to $1.378 billion in 2011. Part B carrier spending on CPT 88342 (immunohistochemistry), which is used to diagnose the type of cancer and origin, increased by 15.5% to $278.5 million in 2011.

CPT 88185 (flow cytometry-technical component only) increased by 10.1% to $142.5 million in 2011. Flow cytometry is a method of counting cells that is routinely used to determine the type of leukemia, lymphoma or myeloma cells that are present.

CPT 88312 (special stains) increased by 12.1% to $96.8 million in 2011. Special stains are ordered by pathologists to assist in diagnosing particularly difficult cases.

Spending on CPT 88367 (FISH using computer assisted technology) fell dramatically. CPT 88367 had been the primary code used to bill for Abbott's UroVysion bladder cancer test. However, effective January 1, 2011, CMS created a new CPT code (88121) that cut reimbursement for UroVysion bladder cancer testing by 60%. Part B carrier spending on CPT codes 88367/88121 fell by 55.6% to $59.7 million in 2011.

Medicare Part B Carrier Spending on 12 Key Pathology Codes ($ millions)

Code (Description)	*2011*	*2010*	*1-Year Change*	*5-Year CAGR**
88305 (Level IV, tissue exam by pathologist)	$1,377.9	$1,277.5	7.9%	4.3%
88342 (Immunohistochemistry)	278.5	241.2	15.5%	15.1%
88185 (Flow cytometry, add-on)	142.5	129.4	10.1%	24.8%
88312 (Special stains)	96.8	86.4	12.1%	10.0%
84153 (Total PSA)	95.2	95.9	-0.7%	1.8%
88368/88120 (FISH-manual)	94.6	69.7	35.9%	28.5%
88112 (Cytopath cell enhance tech)	87.0	78.7	10.5%	8.1%
88307 (Level V, tissue exam by pathologist)	84.9	81.1	4.6%	0.4%
88313 (Special stains)	68.5	59.7	14.6%	16.4%
88367/88121(FISH-computer assisted)	59.7	134.4	-55.6%	35.6%
88331 (Pathology consult during surgery)	37.9	37.6	0.8%	-1.2%
88304 (Level III, tissue exam by pathologist)	30.3	29.5	2.8%	0.9%
TOTALS	**$2,453.9**	**$2,321.2**	**5.7%**	**7.2%**

*CAGR=compound annual growth rate

Note: Data is derived from analysis of the Physician Supplier Procedure Summary Master File (PSPSMF) which includes data from all Medicare Part B carriers. This data represents procedure-specific billing data for all physician/supplier services rendered to all Medicare beneficiaries during the calendar year named and processed by the carriers through the six months of the following year. Part B claims processed by fiscal intermediaries are not included.

Source: *Laboratory Economics* from CMS and CodeMap

MEDICARE SPENDING ON MDx TESTS GROWING BY +30% PER YEAR

National Medicare Part B carrier spending for the key pathology codes used to bill for molecular diagnostic increased by 32.4% to $187 million in 2011. Part B carrier spending on MDx tests increased by an average of 31.5% per year between 2006 and 2011.

The 27 codes analyzed include the stacking codes 83890-83914, microarray codes 88384-88386 and HER2 scoring codes 88360-88361. These are the codes predominantly used to bill for pharmacogenomics tests that help guide cancer treatments. Examples include ALK, EGFR, HER2, ER/PR and KRAS tests. CMS is in the process of eliminating the stacking codes (83890-83914) and substituting 100 more specific new codes in their place.

Medicare Part B Carrier Spending on Molecular Dx Codes*

Code (Description)	2011	2010	1-Year Change	5-Year CAGR**
83890 (Molecule isolate)	$232,428	$179,227	29.7%	23.6%
83891 (Molecule isolate nucleic)	2,165,841	1,886,593	14.8%	34.5%
83892 (Molecular diagnostics)	3,752,109	3,292,322	14.0%	32.2%
83893 (Molecule dot/slot/blot)	370,340	290,180	27.6%	15.1%
83894 (Molecule gel electrophor)	332,389	242,281	37.2%	4.2%
83896 (Molecular diagnostics)	10,646,217	7,434,157	43.2%	29.9%
83897 (Molecule nucleic transfer)	3,840	2,691	42.7%	-1.8%
83898 (Molecule nucleic ampli, each)	27,103,987	23,364,647	16.0%	27.1%
83900 (Molecular diagnostics)	4,612,551	3,034,557	52.0%	54.0%
83901 (Molecular diagnostics)	13,127,994	8,076,566	62.5%	85.6%
83902 (Molecular diagnostics)	1,135,829	1,051,884	8.0%	31.0%
83903 (Molecule mutation scan)	10,473,608	8,682,542	20.6%	41.2%
83904 (Molecule mutation identify)	20,566,436	14,818,634	38.8%	24.9%
83905 (Molecule mutation identify)	7,873	15,213	-48.2%	-8.9%
83906 (Molecule mutation identify)	779	1,267	-38.5%	-19.6%
83907 (Lyse cells for nucleic ext)	989,565	645,174	53.4%	122.8%
83908 (Nucleic acid, signal ampli)	5,691,823	3,380,126	68.4%	88.7%
83909 (Nucleic acid, high resolute)	17,864,664	14,931,323	19.6%	129.3%
83912 (Genetic examination)	3,591,652	3,081,188	16.6%	26.6%
83913 (Molecular, rna stabilization)	261,914	244,093	7.3%	NA
83914 (Mutation ident ola/sbce/aspe)	12,647,125	4,344,196	191.1%	112.3%
88360 (Tumor immunohistochem, manual)	24,122,087	18,705,000	29.0%	17.9%
88361 (Tumor immunohistochem, computer)	19,773,908	18,944,742	4.4%	10.5%
88381 (Microdissection manual)	4,587,407	3,367,994	36.2%	NA
88384 (Array-based eval, 11-50 probes)	167	274	-39.1%	NA
88385 (Array-based eval, 51-250 probes)	1,517,788	651,383	133.0%	NA
88386 (Array-based eval, 251-500 probes)	1,466,403	586,490	150.0%	NA
Medicare Part B Totals	$187,046,724	$141,254,745	32.4%	31.5%

*Includes stacking codes 83890-83914, microarray codes 88384-88386 and HER2 scoring codes 88360-88361; **CAGR=compound annual growth rate

Note: Data is derived from analysis of the Physician Supplier Procedure Summary Master File (PSPSMF) which includes data from all Medicare Part B carriers. Part B claims processed by fiscal intermediaries are not included. Source: *Laboratory Economics* from CMS and CodeMap

ACCELPATH BUYS DIGIPATH: WILL FOCUS ON IN-OFFICE LABS

AccelPath Inc (Gaithersburg, MD) has acquired privately-held DigiPath Solutions (Spring, TX) from its founder and chief executive Rishi Reddy. AccelPath paid an aggregate purchase price of $2.4 million, which consisted of $100,000 in cash, 1,250 shares of AccelPath convertible preferred stock, and a promissory note issued to Reddy in the amount of $1.05 million. In addition, Reddy entered into a one-year consulting agreement with AccelPath and agreed to serve on the company's medical advisory board for a monthly retainer of $8,333.

Founded in 2010, DigiPath markets a combination of in-office pathology lab development services to physician practices with digital pathology interpretations by contracted pathologists. The company currently services six pathology laboratories in Houston, Texas. DigiPath had audited fiscal year June 30, 2012 revenues of $1.1 million and EBITDA (earnings before interest, taxes, depreciation and amortization) of $561,000.

The $2.4 million purchase price is equal to 2.2 times revenue and 4.3 times EBITDA at DigiPath.

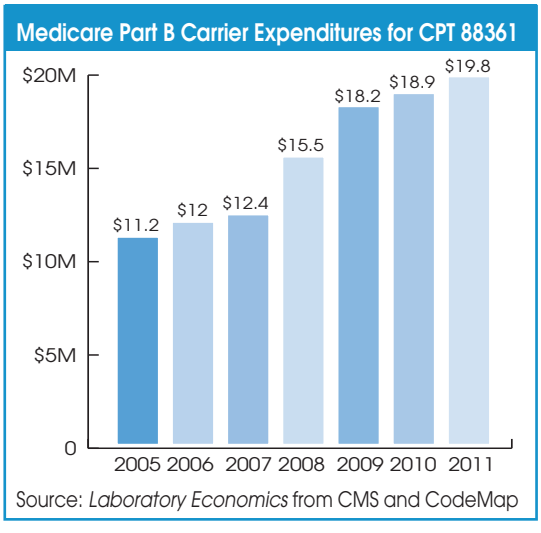
AccelPath is a small publicly-traded company focused on providing digital pathology services to in-office labs at physician practices. Accelpath partnered with the in-office lab consulting firm Triangle Biomedical Sciences (TBS-Durham, NC) and began marketing digital pathology services to urology, gastroenterology and dermatology groups in early 2011 (see *LE*, March 2011). Under the partnership, TBS helps specialty groups build in-office labs and AccelPath then installs digital slide scanners. Digitized slide images are sent electronically to AccelPath, which has contracted with the pathology department at Lahey Clinic (Burlington, MA) for professional interpretations.

AccelPath reported a net loss of $2.1 million in the 12 months ended June 30, 2012 versus a net loss of $3 million for the same period a year earlier; revenue increased to $594,328 from $449,937. AccelPath stock trades on the over-the-counter market at a current price of $0.01 per share with a market capitalization of $1.2 million as of October 5, 2012.

Laboratory Economics notes that the idea of setting up in-office pathology labs at physician practices and then sending digital slides to distant pathologists for interpretation should be alarming to traditional local pathologists. This business model has the potential to put pathologist professional services up for bid to the lowest price nationwide. However, AccelPath has yet to prove this is a sustainable business model.

PART B SPENDING ON DIGITAL IHC RISES JUST 4%

Medicare Part B carrier spending on CPT 88361 (digital pathology for quantitative IHC) increased by only 4.4% to $19.8 million in 2011. CPT 88361 is used to bill Medicare for the reading of digital HER2, ER and PR slides from a computer monitor. This is the second year in a row that Part B spending on 88361 grew by less than 5%, following several years of 10-15% annual growth (see *LE*, October 2011). Proponents of digital pathology point out that digital IHC represents only a portion of the market. They say the market is being driven more by non-reimbursed services, cost savings and competitive advantages provided by digital pathology.



SINGULEX SEEKS $86 MILLION FROM IPO

Singulex (Alameda, CA), which specializes in cardiovascular disease (CVD) testing, has filed for an initial public offering (IPO). The company is seeking to raise up to $86.3 million. The IPO will be managed by UBS Investment Bank, Piper Jaffray, William Blair and Leerink Swann.

Singulex operates a CLIA-certified lab in Alameda, California. The company's test menu includes proprietary laboratory-developed tests to detect and monitor heart attacks, heart failure, stroke and other heart diseases. Singulex is also developing a digital immunoassay monitoring system for advanced management of CVD.

Singulex reported a net loss of $9.9 million for the six months ended June 30, 2012, versus a net loss of $9.1 million for the same period a year earlier; revenue increased to $20.5 million from $7.8 million. For the six months ended June 30, 2012, the company received 78,180 patient samples compared to 36,552 in the corresponding period in 2011. The average number of tests performed on each patient sample increased to 7.9 tests from 6.1 tests over this time period.

Singulex has accumulated losses of $80.9 million since being formed in 1997. As of June 30, 2012, the company had cash and cash equivalents of $7.9 million. Singulex has 177 employees.

Singulex is owned by a group of private equity investors led by Fisk Ventures (48% stake) and OrbiMed Advisors (26% stake).

Among the risks facing Singulex is potential regulation of its LDTs by the FDA. In addition, *Laboratory Economics* notes that Singulex operates in the jurisdiction of Medicare carrier Palmetto GBA. Palmetto has become very stringent in its coverage decisions for non-FDA-cleared tests.

Finally, *LE* notes that LipoScience (Raleigh, NC), which also specializes in cholesterol testing, filed plans for an IPO in June 2011. However, the company has yet to complete its planned IPO.

AMPERSAND TO BUY CALLOWAY LABS

Calloway Laboratories (Woburn, MA) is being sold to the private equity firm Ampersand Capital Partners (Boston, MA) for an undisclosed sum. The transaction is expected to close during the fourth quarter.

Calloway, which provides urine testing services to addiction treatment centers, is being acquired under distressed circumstances. Earlier this year, Calloway agreed to pay $20 million to settle criminal charges that it defrauded Massachusetts Medicaid. At its height, Calloway had about 500 employees and annual revenue estimated at more than $50 million.

Ampersand has hired Gail Marcus to help turn around Calloway. Marcus has become president and chief executive of Calloway effective immediately. Marcus was formerly chief executive of Caris Diagnostics (now Miraca Life Sciences).

LABCORP ACQUIRES GENETICA

LabCorp has acquired Genetica DNA Laboratories (Cincinnati, OH) for an undisclosed sum. Genetica specializes in DNA identity and paternity testing. Genetica was formed in 1988 by Elizabeth Panke, PhD, MD. This acquisition follows LabCorp's purchase of DNA testing firm Orchid Cellmark in December 2011.

MARKET PRESSURES LED UMASS TO SELL OUTREACH LAB (*cont'd from p. 1*)

The UMass lab outreach business has about 500 employees and is based at 38,000 square feet of space at the Biotech Research Park in Worcester, Mass. (just outside of Boston). The lab outreach business operates approximately 65 patient service centers and serves approximately 5,000 physician clients in Massachusetts, New Hampshire, Rhode Island and Connecticut. UMass's biggest lab competitors had been Quest Diagnostics and Bay State Reference Labs (Springfield, MA).

Quest has a full-service lab in Cambridge, Mass., and its Athena Diagnostics specialty neurology testing lab in Worcester. Quest is planning to consolidate these two labs plus the acquired UMass lab into a new facility that will be centrally located in the area. Quest expects the full transition of services will take place over the next 18 to 24 months.

The UMass deal follows Quest's purchase of S.E.D. Medical Labs (Albuquerque, NM) for $50 million earlier this year (see *LE*, January 2012, p. 1).

Quest To Layoff 400+ Managers

In separate news, Quest announced plans to eliminate 400 to 600 management positions by the end of next year—saving the company about $65 million annually—as it moves to restructure itself into two new business groups. Quest said the restructuring will reduce three layers of management and speed decision making. Quest currently has as many as 10 layers of management between its CEO and its front-line employees (sales reps, couriers, phlebotomists, etc.). Quest has a total of approximately 42,000 employees.

The company will operate under two business groups called diagnostics information services and diagnostic solutions. The changes are expected to take effect on January 1.

Diagnostic information will include the vast majority of the company's revenue and replace the current physician-services, hospital-services and cancer-diagnostics businesses. It will develop and deliver diagnostic testing, information and services, sales and marketing, and other core pieces of the company's business.

In addition, Quest Diagnostics said several senior leaders will be leaving the company. Richard Mahoney, vice president of health-care information services, Joan Miller, PhD, senior vice president of oncology and neurology services, and David Norgard, vice president of human resources, plan to leave the company by year-end. Joseph Benage, vice president of insurer and employer services, will leave next year.

Quest Now Exclusive Lab for BCBS Tennessee Medicaid Plans

After several delays, BlueCross BlueShield of Tennessee has completed its transition to make Quest Diagnostics the exclusive outpatient lab provider for its two Medicaid plans (BlueCare and TennCare Select) effective October 1. The two plans cover a total of 455,000 members representing nearly one half of the state's total 1.2 million Medicaid population. BCBS says it had experienced double-digit annual growth in lab expenses and Quest offered "significantly lower rates." Services excluded from the contract include certain rapid tests performed at physician office, outpatient dialysis clinics and most anatomic pathology tests.

LAB STOCKS UP 32% YEAR TO DATE

Ten lab stocks have risen by an unweighted average of 32% so far this year. The combined market capitalization for the group is up 7% to $23.7 billion. In comparison, the S&P 500 Index is up 16% year to date through October 15. Shares of NeoGenomics have performed best (up 105%). In terms of valuation, Quest Diagnostics is currently trading at 1.3x its annual revenue and 8.8x its trailing EBITDA (earnings before interest, taxes, depreciation and amortization). LabCorp trades at 1.6x annual revenue and 8.4x trailing EBITDA.

Company (ticker)	Stock Price 10/15/12	Stock Price 12/30/11	2012 Price Change	Market Capitalization ($ millions)	Enterprise Value/ EBITDA	Price/ Sales
Bio-Reference (BRLI)	$32.11	$16.27	97%	$889	10.1	1.4
CombiMatrix (CBMX)	0.54	2.00	-73%	6	NA	1.2
Enzo Biochem (ENZ)	1.98	2.24	-12%	78	NA	0.7
Genomic Health (GHDX)	33.10	25.39	30%	1,007	58.8	4.5
LabCorp (LH)	93.59	85.97	9%	8,975	8.4	1.6
Medtox Scientific (MTOX)*	27.00	14.05	92%	242	16.6	2.1
Myriad Genetics (MYGN)	26.86	20.94	28%	2,188	9.2	4.6
NeoGenomics (NGNM)	2.87	1.40	105%	130	28.3	2.3
Psychemedics (PMD)	11.95	9.10	31%	63	9.6	2.5
Quest Diagnostics (DGX)	63.95	58.06	10%	10,152	8.8	1.3
Unweighted Averages			32%	$23,730	18.7	2.2

Source: Bloomberg

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