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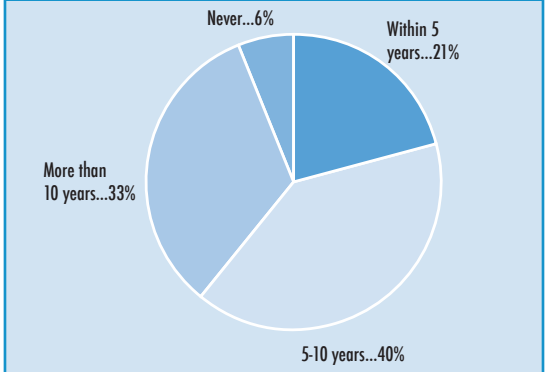
Laboratory Economics

Competitive Market Analysis For Laboratory Management Decision Makers

HOW LONG BEFORE DIGITAL PATH GOES MAINSTREAM?

Nearly everyone agrees that digital pathology will play a big role in pathology in the future. The question is "How long before it becomes common practice for primary diagnosis of cancer?" The answer is within 5-10 years, according to 40% of respondents to *LE's Anatomic Pathology Market Trends Survey* conducted in mid-July. Only 6% of survey respondents said digital pathology will "Never" become widespread for primary diagnosis. For more results from our exclusive survey, *see pages 3-4*.

How long before the majority of pathologists adopt digital pathology for primary diagnosis?

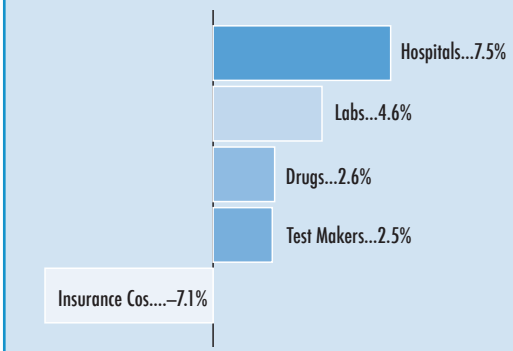


Source: *LE's Anatomic Pathology Market Trends Survey*, July 2012; n=174

WHO WILL BENEFIT FROM OBAMACARE?

The Supreme Court has upheld most of the Patient Protection and Affordable Care Act (aka ObamaCare). Most healthcare providers, including hospitals, labs, drug companies, etc., should benefit from the dramatic expansion of Medicaid, according to first reaction in the stock market. Between June 27 (the day prior to the Supreme Court ruling) and July 2 (three trading days later), hospital management stocks (Lifepoint, HCA, Tenet) rose an average of 7.5%, while lab stocks (Bio-Reference, LabCorp and Quest Diagnostics) climbed by 4.6%. Health insurance companies (Aetna, UnitedHealth and Wellpoint) fared worst, dropping by an average of 7.1%. *Continued on page 10.*

Wall Street's Reaction to ObamaCare Ruling



Source: *Laboratory Economics* (based on closing prices June 27-July 2)

NO NEW REGS FOR IN-OFFICE LABS PROPOSED FOR 2013

The Centers for Medicare and Medicaid Services' Part B physician fee schedule proposal for next year includes no new rules for in-office pathology labs. In fact, in-office pathology labs were not mentioned at all in the agency's 765-page document released on July 6. This means that urology, gastroenterology and dermatology groups will continue to build in-office labs to capture pathology technical and professional fees. *Continued on page 2.*

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NO NEW REGS FOR IN-OFFICE LABS (*cont'd from page 1*)

The proposed rule is the first step in an annual process intended to update Medicare Part B payment policies and rates. The comment period on the proposed rule is open for 60 days. CMS is scheduled to issue a final rule by November 1 that will apply to calendar-year 2013.

Specialty groups that have recently opened in-office pathology labs include **Pacific Urology** (Walnut Creek, CA), with 6 physicians; **Gastroenterology Associates of Fairfield County** (Fairfield, CT), 8 physicians; **Nashville Gastrointestinal Specialists** (Nashville, TN), 5 physicians; **Michiana Gastroenterology** (South Bend, IN), 6 physicians; and **Southwest Skin Specialists** (Phoenix, AZ), 6 physicians.

12-CORE BIOPSY + CYTOLOGY CONTROVERSY CONTINUES…

The June issue of *Laboratory Economics* described how some urology groups with in-office histology labs were routinely performing cytology testing on the preservative fluid from each prostate biopsy jar they process. This questionable practice adds $840 in extra charges to each 12-prostate-biopsy case.

The article named several urology groups with in-office labs that were performing this seemingly redundant combination of testing on their prostate biopsy specimens.

However, we failed to mention the name of the pathology lab involved with these arrangements. It's OncoDiagnostic Laboratory based in Cleveland, Ohio. OncoDiagnostic is owned by Predictive Biosciences, which in turn is owned by a group of private-equity investors, including Flybridge Capital Partners, Highland Capital Partners, Kaiser Permanente Ventures, New Enterprise Associates and ProQuest Investments.

Predictive Biosciences markets an in-office lab arrangement called iPath TC. Under iPath TC, Predictive will install a small CLIA-certified technical lab onsite at a urology group and recruit and train a histotech for the lab. Predictive installs and maintains all lab equipment and manages the in-office lab.

Under the iPath TC arrangement, the urology group bills and collects for the technical component. Slides are sent to Predictive's OncoDiagnostic Lab for professional interpretation. OncoDiagnostic's pathologists report results back to the urology group by fax or e-mail within 48 hours. OncoDiagnostic bills and collects the professional component.

Predictive says it has installed in-office labs in as little as 150 square feet. The company says its iPath TC arrangement offers urology groups the "lowest liability/ highest return" of all in-office lab business models.

A urology group with an iPath TC arrangement will bill Medicare a total of $1,428 in technical charges for a 12-core prostate biopsy. This includes 12 x CPT 88305-TC ($70 each) = $840 for tissue slide preparation plus 12 x 88108-TC ($49 each) = $588 for cytology testing.

In addition, OncoDiagnostic will bill Medicare a total of $672 in professional fees. This includes 12 x CPT 88305-26 ($35 each) = $420 for tissue analysis plus 12 x 88108-26 ($21 each) = $252 for pathologist cytology review.

The total combined charge for technical and professional services is $2,100, including $1,260 for preparation and examination of the tissue plus $840 for the added cytology testing.

DIGITAL PATHOLOGY SURVEY (*cont'd from page 1*)

Thirty-one percent of pathology groups and labs currently have a digital imaging system in place, according to *LE's Digital Pathology Trends Survey.* Thirteen-percent plan to add a system within 12 months and another 7% within the next 12-to-24 months.

In terms of market share, 44% of digital pathology users have an Aperio system, while Ventana/BioImagene has 29% share. Other vendors have a combined 27% share, including Leica Microsystems, BioView, CapSure, DigiPath, Nikon, Olympus, Philips and Carl Zeiss Inc.

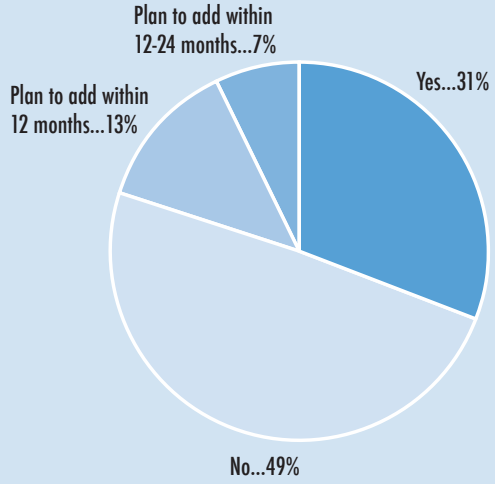
Among surveyed pathologists and labs using digital pathology, 56% are using it for quantitative immunohistochemistry for HER2 scoring. Fifty-four percent use it for education and/or training, while 50% use it for second opinions and/or consultations. Other uses include ER/PR scoring (35%), primary clinical diagnosis (20%), archiving specimens (19%), contract research for clinical trials (13%) and photography for autopsies (8%).

Forty percent of surveyed pathologists and labs without digital pathology cited "too expensive" as a barrier to adoption. Another 39% said "traditional pathology/microscope works fine" and 26% were concerned about the data storage requirements.

Meanwhile, *Laboratory Economics* notes that only a handful of quantitative IHC tests have been FDA cleared for use on digital pathology systems. The FDA has made it clear that digital pathology systems for primary diagnosis of cancer will be classified as a class III medical device, requiring manufacturers seeking approval to follow a lengthy and expensive Pre-Market Approval (PMA) process.

SURVEY DEMOGRAPHICS: The survey was e-mailed to approximately 5,000 hospital labs, independent labs and pathology groups in July 2012. A total of 174 surveys were judged usable, yielding a response rate of 3.5%. Survey participants included 58 hospital labs, 18 academic medical centers, 52 independent labs, 14 esoteric reference labs, and 32 pathology groups.

Does your lab use digital pathology?



What do you use digital pathology for?*

HER2 scoring	56%
Education and/or training	54%
Second opinions and/or consultations	50%
ER/PR scoring	35%
Primary clinical diagnosis	20%
Archiving specimens	19%
Contract research for clinical trials	13%
Photography of autopsies	8%

*Survey respondents were able to select multiple answers

If you do not use digital pathology: Why not?*

Too expensive	40%
Traditional pathology/microscope works fine	39%
Large data/image storage concerns	26%
Too slow	19%
Integration concerns with LIS	14%
Reimbursement issues	11%
Limited clinical test menu	5%
No time/patience to learn	5%

*Survey respondents were able to select multiple answers

Source: LE's Digital Pathology Trends Survey, July 2012; n=174

SURVEY PARTICIPANT COMMENTS

Surveyed pathologists and lab executives were asked to comment on digital pathology. Right now, digital pathology is being used mostly for niche applications. A lot needs to happen (e.g., cost reductions, workflow integration, FDA clearance, etc.) before digital pathology goes mainstream.

PROS FOR DIGITAL PATHOLOGY

"We are located in Canada and have been using digital pathology for primary diagnosis since 2005. It has been very successful in supporting our remote sites for both primary and subspecialty consultation."
—Pathologist from Canada

"As technology advances, the resolution-scan time-cost triad will be overcome allowing digital pathology to be the preferred modality. This will be a powerful factor in the centralization of histology labs and pathology practices. Digital will drive larger pathologist networks where sub-specialty readings become community standard."
—Anonymous

"Most likely will happen when the current batch of pathologists starts to retire and the younger ones bring new technology with them."
—Lab Administrator from Maryland

"Utilization for quality assurance is the primary way our practice employs digital pathology. It saves time and travel and has revolutionized the way we do consensus conferences."
—Pathologist from Georgia

CONS FOR DIGITAL PATHOLOGY

"Not practical for routine use. Why add extra steps in interpretation that increase turnaround time and require additional expensive technology and storage space?"
—Pathologist from National Lab

"Currently it is hard to justify the time and expense for uploading slides for primary diagnosis in comparison to the microscope. As the technology improves and becomes cheaper this may happen. Also the requirement to 'validate' the digital process for diagnosis is not rational—we do not 'validate' microscopes."
—Pathologist from California

"The use of digital pathology for primary diagnosis is mediated by the regulatory structure. It is also still dependent upon tissue processing and slide production so the ROI requirements are much more challenging than the equivalent migration from film to digital imaging/PACS in radiology."
—Lab Administrator from Oregon

"It is fine for sharing slides on difficult cases, for remote access, for receptor analysis, and interesting cases. However, in the systems that I have seen, data storage is too expensive for routine work (still have to keep slides), increased labor expenses, and the refresh is too slow for routine use."
—Pathologist from California

"Tangible ROI for digital pathology within a few years of implementation has been difficult to prove for community based/independent groups and this has slowed adoption."
—Pathologist from North Carolina

"FDA approval for diagnostic use of primary slide digital pathology must occur prior to widespread use of this technology."
Lab Administrator from California

"The image capture time must be dramatically reduced in order to cost effectively justify using the imaging device instead of sending slides to nearby locations for extended pathology practices such as ours."
—Pathologist from California

OIG REPORT FINDS BIG PRICING DIFFERENCES FOR GENETIC TESTS

A recent report issued by the Office of the Inspector General (OIG) has found wide variance in reimbursement rates paid by state Medicaid and federal employee health benefit (FEHB) programs for genetic tests. Labs and industry trade groups are worried that the report's data could be used to justify cuts in Medicare reimbursement for molecular and genetic tests.

The OIG report—*Coverage and Payment for Genetic Laboratory Tests*, OEI-07-11-00011—was conducted at the request of the Centers for Medicare & Medicaid Services. The report tracked reimbursement for 16 genetic tests and identified a wide range in reimbursement rates.

For example, the report showed that Pennsylvania Medicaid reimburses $1,000 for BRCA1 gene analysis, while Iowa Medicaid pays $4,498. In addition, Illinois Medicaid pays $2,050 for Genomic Health's OncoTypeDX breast cancer test compared with $3,416 for Minnesota.

OIG identified similar variations in FEHB plans. For example, reimbursement rates for XDx's AlloMap test ranged from $2 to $3,658; Precision Therapeutics' ChemoFx test ranged between $53 and $187; Pathwork Diagnostics' Tissue of Origin Test ranged between $5 and $38; and Biodesix's VeriStrat ranged between $2 and $3,658. (see table below).

Both Medicare and private health insurance companies suspect that the high variance in reimbursement rates may be an indication of over-pricing.

Federal Employee Health Benefits Plan Median Payment Rates For Selected Genetic Tests

State	XDx AlloMap	Precision Thera ChemoFx	Pathwork Tissue of Origin	Biodesix VeriStrat
Alabama	$13	$95	$10	$8
Alaska	NA	187	38	NA
Arizona	20	75	10	20
Arkansas	NA	150	8	NA
California	50	105	18	50
Colorado	11	93	10	11
Connecticut	NA	114	14	NA
Delaware	13	92	17	13
Dist. of Columbia	6	73	5	6
Florida	117	98	19	48
Georgia	177	95	10	NA
Hawaii	NA	109	14	NA
Idaho	NA	130	18	NA
Illinois	80	99	17	29
Indiana	455	72	15	455
Iowa	227	150	14	227
Kansas	270	124	18	422
Kentucky	18	57	12	18

State	XDx AlloMap	Precision Thera ChemoFx	Pathwork Tissue of Origin	Biodesix VeriStrat
Louisiana	171	126	16	171
Maine	42	65	6	NA
Maryland	8	73	10	8
Massachusetts	NA	98	16	NA
Michigan	102	60	27	102
Minnesota	16	125	15	16
Mississippi	NA	131	20	NA
Missouri	130	105	18	422
Montana	NA	88	19	NA
Nebraska	NA	132	10	NA
Nevada	2	116	10	2
New Hampshire	NA	125	27	NA
New Jersey	90	101	17	90
New Mexico	207	88	11	NA
New York	10	86	15	10
North Carolina	10	95	10	10
North Dakota	115	168	27	115
Ohio	35	83	17	35
Oklahoma	8	131	17	8
Oregon	40	121	21	40
Pennsylvania	90	54	18	90
Rhode Island	3,658	106	14	3,658
South Carolina	9	123	11	9
South Dakota	788	187	10	NA
Tennessee	NA	131	10	NA
Texas	9	115	10	9
Utah	NA	53	10	NA
Vermont	NA	182	28	NA
Virginia	428	88	8	1,869
Washington	NA	124	15	NA
West Virginia	8	93	29	8
Wisconsin	758	143	11	758
Wyoming	NA	130	15	NA
Range	$2 -$3,658	$53 - $187	$5 - $38	$2 - $3,658

Source: OIG analysis of Federal Employee Health Benefits plan payment rates, 2011

CMS to Price Molecular and Genetic Tests

The OIG findings were released as CMS is in the process of devising reimbursement rates for 101 new CPT codes for molecular and genetic tests. The new codes and rates will become effective on January 1, 2013, and will replace the current "code stacking" method of billing.

The 101 new CPT codes (81200-81408) are meant to provide a single specific CPT code to each molecular and genetic test. Reimbursement rates for these new codes could wind up substantially lower than current rates. The new codes and rates will affect all high-volume molecular and genetic tests, including cancer tests such as BCR/ABL, C-KIT, EGFR, KRAS, TPMT and UGT1A1.

CMS is in the process of deciding whether to place the new codes on the Part B clinical lab fee schedule (CLFS) or the physician fee schedule (PFS).

The College of American Pathologists (CAP) has argued for placing the new codes under the PFS. CAP says that physician interpretation is required for the majority of these tests and the PFS allows for more frequent updating, which is necessary for this rapidly changing test area. The American Clinical Laboratory Association (ACLA) has recommended that each new code be assessed individually to determine if it requires pathologist interpretation (put on PFS) or interpretation by a non-physician or computer (put on CLFS).

If CMS choses to place the new codes on the CLFS, then the national payment rates will be determined by crosswalking each new code to a similar existing code, or by gap-filling when no comparable code exists.

If the new codes are placed on the PFS, then CMS says it could not determine national payment rates at this time, and would ask local Medicare carriers to set reimbursement.

After reviewing submitted comments, as well as discussion from its CLFS annual public meeting held July 16-17, CMS says, "We will determine the appropriate basis for establishing payment amounts for these codes and publish the final decision in the PFS final rule [due out on November 1]. At the same time, we will post final payment determinations, if any, for those codes that will be paid under the CLFS."

A CLOSER LOOK AT CODE STACKING

Payers don't know what they are paying for under the current "code stacking" method of billing for molecular and genetic tests. Different labs use different methodologies to perform the same test, resulting in different stacks of CPT codes on their claim forms.

For example, *Laboratory Economics'* analysis of test menus at five major reference labs shows that each lab uses its own unique group of CPT codes to bill for cystic fibrosis mutation analysis—one of the most common genetic screening tests. The Oregon Health Sciences University Laboratory bills for a stack of codes with a total Medicare charge of $771 versus $1,757 for Molecular Pathology Laboratory Network (*see table next page*).

Next year, all labs will bill for cystic fibrosis mutation analysis under a single code (CPT 81223) and reimbursement will be uniform. Private payers are expected to follow Medicare's lead after it announces its reimbursement decision for cystic fibrosis (as well as 100 other molecular and genetic tests) in early November.

Cystic Fibrosis 32 Mutation Analysis: New CPT Code 81223

LABORATORY:	ARUP	LabCorp	MPLN	OHSU Laboratory	Quest Diagnostics
Code stack:	83891 83898(x32) 83904(x32) 88909 83912	83891 83900 83901(x14) 83909 83912 83914(x32)	88235 83900 83901(x30) 83909 83914(x32) 83912	83890 83900 83901(x23) 83896(x25) 83912 83914	83891 83892 83896(x23) 83900 83901(x17) 83908(x23) 83912
Charge*:	$1,554	$1,175	$1,757	$771	$1,145

Code stacks and pricing also vary from lab to lab for CYP2C19 genotyping. Code stacks vary from $335 at Matrix Genomics to $581 at ACL Laboratories.

CYP2C19 Genotype: New CPT Code 81225

LABORATORY:	ACL Laboratories	LabCorp	Matrix Genomics	Mayo Medical Laboratories	Quest Diagnostics
Code stack:	83891 83900 83901(x4) 83912 83914(x18)	83891 83892 83900 83901(x4) 83912 83914(x8)	83891 83892(x2) 83900 83901(x3) 83909 83912(x2) 83914(x7)	83890 83892 83894 83900 83901(x3) 83909(x10) 83912	83891 83892(x2) 83900 83901(x4) 83909 83912 83914(x10)
Charge*:	$581	$349	$335	$379	$426

Code stack billing for Factor V Leiden varies from $70 at Cleveland Clinic and Warde Medical Lab to $117 at Mayo Medical Laboratories.

Factor V Leiden: New CPT Code 81241

LABORATORY:	Cleveland Clinic Laboratories	Diagnostic Lab of Oklahoma	Mayo Medical Laboratories	ChildLab	Warde Medical Laboratory
Code stack:	83891 83896(x2) 83898 83903 83912	83891 83898 83909 83912 83914	83891 83892 83896(x5) 83903 83908(x2) 83912	83891 83896 83898 83903 83912	83891 83892 83896(x2)
Charge*:	$70	$83	$117	$65	$70

Code stack billing for Fragile X DNA Analysis varies from $46 at Boston University School of Medicine Human Genetics to $135 at Quest Diagnostics.

Fragile X DNA Analysis: New CPT Code 81270

LABORATORY:	Athena Diagnostics	Boston Univer. School of Med.	LabCorp	MPLN	Quest Diagnostics
Code stack:	83891 83892(x2) 83894 83896 83897 83898 83909 83912	83890 83891 83894 83898 83912	83891 83900 83909 83912	83890 83898 83909(x3) 83912	83891 83892(x2) 83894 83896 83897 83898 83900 83909 83912
Charge*:	$87	$46	$83	$106	$135

*Charges are calculated by 2012 Medicare Part B national limit amount for each code unadjusted for geographic practice cost differences
Source: Laboratory Economics from company test menus

FDA EXPANDS USE FOR ERBITUX WITH COMPANION KRAS TEST

The FDA has approved Erbitux (generic name: cetuximab) in combination with the irinotecan, 5-fluorouracil, leucovorin (FOLFIRI) regimen as a first-line treatment for patients with metastatic colorectal cancer (mCRC) who express EGFR and also test negative for the KRAS gene mutation. About 40% of patients with colorectal cancer have the *KRAS* mutation.

Erbitux was first approved to treat mCRC in 2004, but the previous approval was only for patients who were intolerant to irinotecan-based therapy.

Concurrent with the expanded indication, the FDA cleared a pharmacogenomic test made by Qiagen designed to help identify patients who will benefit from the combined therapies. The new drug label for Erbitux will instruct doctors to use an FDA-approved KRAS test to determine the status of the KRAS gene in patients. Until now, doctors have been using laboratory-developed tests to determine KRAS status. Qiagen estimates the U.S. market for KRAS testing in colon cancer is about $20 million per year.

Labs that plan to offer the Qiagen KRAS test include Applied Diagnostics, Boyce & Bynum Pathology Labs, Cellnetix, University of Kansas Medical Center, Dahl-Chase Diagnostic Services and Mayo Medical Labs. These labs are expected to charge about $300-$600 per test.

The clinical trial studies that led to the expanded indication for Erbitux showed that study participants treated with Erbitux plus FOLFIRI who tested negative for the KRAS mutation experienced median survival of 23.5 months compared with 19.5 months for those who just received FOLFIRI. Patients with KRAS mutations did not derive a survival advantage with the addition of Erbitux to FOLFIRI.

Erbitux, which is marketed by Bristol-Myers and Eli Lilly, costs about $7,500 per month per patient—a typical six-month course of treatment costs roughly $45,000. U.S. sales of Erbitux totaled $703 million last year, according to the pharmaceutical research firm IMS Health.

The U.S. market size for KRAS testing (~$20 million/year) is a fraction (3%) of the size of Erbitux market (~$703 million/year), notes *Laboratory Economics*.

FDA APPROVES PERJETA—NEW TARGETED DRUG FOR BREAST CANCER

The FDA has approved a new drug for HER2-positive breast cancer patients. The drug was developed by Roche's Genentech and will be used in combination with Genentech's HER2 inhibitor Herceptin and docetaxel chemotherapy. The FDA has also cleared two companion diagnostic tests for Perjeta: Dako's HercepTest and HER2 Fish pharmaDx kit.

A Phase III clinical trial showed that patients given Herceptin, chemotherapy and a placebo lived progression-free for an average of 12.4 months. In contrast, patients given Herceptin, chemotherapy and Perjeta lived an additional 6.1 months to an average of 18.5 months progression-free survival.

Perjeta costs $5,900 per month, while Herceptin costs $4,500. Genentech says most patients will take a combination of the two drugs for about 18 months. The estimated cost for an 18-month course of treatment with the two drugs will be approximately $188,000.

Labs performing the HercepTest typically charge between $200 and $400 per test.

WHO WILL BENEFIT FROM OBAMACARE? (*cont'd from page 1*)

The stock market views the expansion of healthcare coverage to more than 30 million uninsured—mainly through bigger state Medicaid programs—as a positive for lab companies. Shares of Quest Diagnostics climbed 5.1% in the three trading days following the Supreme Court's ruling, while LabCorp was up 3.2% and Bio-Reference Labs was up 5.5%.

However, ObamaCare includes new reimbursement systems aimed at lowering costs to help pay for the expansion of Medicaid.

Accountable care organizations created by major hospitals and health systems will be at the hub. Under ObamaCare, an ACO agrees to manage all the healthcare needs of a minimum of 5,000 Medicare beneficiaries for at least three years. ACOs that meet quality-of-care targets and reduce the cost of their patients relative to a spending benchmark will be rewarded with a share of the savings they achieve for the Medicare program. One hundred and fifty four ACOs covering 2.4 million Medicare members have been created so far.

In addition, ObamaCare directs the Secretary of HHS to develop a national pilot program for bundled payments (i.e., capitation) effective January 1, 2013. Under payment bundling, hospitals, doctors and labs will be paid a flat rate for an episode of care. The law gives the Secretary of HHS the authority to expand the payment bundling pilot if it is found to improve quality and reduce cost.

ObamaCare will also establish a new entity called the Independent Payment Advisory Board (IPAB). To be launched in 2015, IPAB will have authority, if healthcare costs exceed certain targets, to recommend changes to Medicare to lower costs. Those changes would take effect automatically unless Congress came up with equivalent savings elsewhere.

The unanswered question is "How will pathologists and labs be compensated under shared savings and bundled payment programs?" And "Where will the IPAB look when Medicare goes over budget?"

Stock Market Reaction to ObamaCare Ruling

	July 2	June 27	% Chg
Lab Companies			4.6%
BioReference	$27.36	$25.93	5.5%
LabCorp	92.23	89.37	3.2%
Quest Diagnostics	60.4	57.48	5.1%
Test Manufacturers		2.5%	
Becton Dickinson	75.37	73.48	2.6%
Hologic	18.44	17.76	3.8%
Thermo Fisher	51.38	50.89	1.0%
Drug Makers			2.6%
Bristol-Myers	35.71	34.76	2.7%
Merck	41.85	40.53	3.3%
GlaxoSmithkline	46.36	45.54	1.8%
Hospital Managers		7.5%	
Lifepoint	40.82	38.47	6.1%
HCA Inc.	29.99	26.61	12.7%
Tenet Healthcare	5.17	4.98	3.8%
Health Insurers			-7.1%
Aetna	38.39	40.77	-5.8%
UnitedHealthGroup	56.26	59.29	-5.1%
Wellpoint	62.26	69.49	-10.4%

Source: Laboratory Economics

GENOVA DIAGNOSTICS BUYS METAMETRIX

Genova Diagnostics (Asheville, NC) has acquired Metametrix (Duluth, GA) for an undisclosed sum. Both labs will continue to operate under their respective names at their current locations for the time being.

Metametrix was founded in 1984 by its chief executive, J. Alexander Bralley, PhD. Bralley will step down as CEO and serve as a consultant. Genova's chairman and CEO, Ted Hull, will maintain his positions at the combined company.

Metametrix operates a CLIA-certified lab that specializes in test panels for nutrition and metabolism. Its ION (Individual Optimal Nutrition) Profile, for example, tests for over 100 markers relating to a wide range of conditions, including heart disease, cancer, mental/emotional disorders, chronic fatigue, et al. The ION Profile has a list price that ranges from $700 to $1,000. Physicians use Metametrix's test services to customize nutritional therapies and lifestyle changes to prevent and treat various chronic diseases.

Genova, established in 1986 as Great Smokies Diagnostic Laboratory, markets more than 100 test panels aimed at helping physicians diagnose and treat a range of chronic conditions, including pre-diabetes, cardiovascular disease, nutritional deficiencies, hormone imbalances, depression, auto-immune disease, allergies, and irritable bowel syndrome.

Together, Genova and Metametrix will have 400 employees and estimated revenue of more than $60 million per year.

FDA CLEARS HIV TEST FOR OTC SALE

OraSure Technologies (Bethlehem, PA) has received FDA approval for its OraQuick In-Home HIV test--the first over-the-counter, self-administered HIV test. The test uses saliva swab samples and provides results within 20 to 40 minutes. OraSure will offer test buyers access to a 1-800 phone line (24/7) to provide information on performing the test, and guidance on what to do after test results have been obtained.

The test is expected to be on shelves at more than 30,000 retail outlets, including Walgreens, CVS and Walmart, in early October at a retail price of between $30 and $40. OraSure plans to launch a television, print, radio and social media marketing campaign to promote the test.

About 1.2 million people have HIV in the United States and about 20% of them are not aware of it, according to estimates by the Centers for Disease Control and Prevention. Those unaware they have HIV contribute to 50,000 new infections annually, according to the agency.

Clarification: The June issue of *Laboratory Economics* reported that Sonic's Sunrise Medical Lab received a termination letter from Aetna earlier this year. This was accurate. However, the termination date is June 1, 2013. After that date, Sunrise Medical Lab will be on the Sonic National contract with Aetna which has not been terminated. The contract changeover will not disrupt Sunrise's lab test services to Aetna members.

LAB STOCKS UP 20% YEAR TO DATE

Ten lab stocks have risen by an unweighted average of 20% so far this year. The combined market capitalization for the group is up 12% at $25.6 billion. Shares of Medtox Scientific, which is being acquired by LabCorp, have performed best (up 92%). In comparison, the S&P 500 Index is up 8% and the Nasdaq is up 12% year to date through July 16. In terms of valuation, Quest Diagnostics is currently trading at 1.3x its annual revenue and 8.9x its trailing EBITDA (earnings before interest, taxes, depreciation and amortization). LabCorp trades at 1.7x annual revenue and 8.7x trailing EBITDA.

Company (ticker)	Stock Price 7/16/12	Stock Price 12/30/11	2012 Price Change	Market Capitalization ($ millions)	Enterprise Value/ EBITDA	Price/ Sales
Bio-Reference (BRLI)	$27.20	$16.27	67%	$753	9.2	1.2
CombiMatrix (CBMX)	0.94	2.00	-53%	10	NA	2.0
Enzo Biochem (ENZ)	1.58	2.24	-29%	62	NA	0.6
Genomic Health (GHDX)	34.21	25.39	35%	1,028	56.8	4.7
LabCorp (LH)	94.62	85.97	10%	11,171	8.7	1.7
Medtox Scientific (MTOX)	26.95	14.05	92%	242	16.6	2.1
Myriad Genetics (MYGN)	25.30	20.94	21%	2,147	9.2	4.6
NeoGenomics (NGNM)	1.70	1.40	21%	76	24.3	1.5
Psychemedics (PMD)	11.19	9.10	23%	59	8.9	2.4
Quest Diagnostics (DGX)	63.46	58.06	9%	10,068	8.9	1.3
Unweighted Averages			20%	$25,616	17.8	2.2

Source: Bloomberg

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