

# LABORATORY



# ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## EUROFINS TO BUY VIRACOR-IBT FOR 3.2X REVENUE

**E**urofins Scientific (Brussels, Belgium) has agreed to acquire Viracor-IBT Laboratories (VIBT—Lee’s Summit, MO) for \$255 million. The purchase price is equal to 3.2x Viracor-IBT’s expected revenue of \$80 million this year and 10x its expected EBITDA (earnings before interest, taxes, depreciation and amortization) of \$25 million. The transaction shows that some buyers are still willing to pay top dollar for specialty labs despite the difficult reimbursement environment in the United States.

*Full details on page 4.*

## AETNA SLAMS OUT-OF-NETWORK LABS WITH NEW RATES SET AT 75% OF MEDICARE

**A**etna is setting its Market Fee Schedule (AMFS) for clinical lab and pathology testing to exactly 75% of local Medicare rates in Ohio, effective September 1, 2014. The new reimbursement applies to out-of-network claims for all Aetna plans in Ohio. The rate change was announced through an Aetna letter to providers dated May 30, 2014, and was first reported by *The Pathology Blawg* (June 16, 2014). Previously, Aetna had reimbursed out-of-network claims based on a percentage of billed charges with some pathology groups in Ohio getting 100% of their billed charge, according to Michelle Miller, Vice President at Vachette Pathology (Blissfield, MI).

*Continued on page 2.*

## QIAGEN AND AMGEN GET FDA APPROVAL FOR VECTIBIX/KRAS TEST

**T**he FDA has approved Qiagen’s therascreen KRAS Test to identify those colorectal cancer patients most likely to benefit from Amgen’s drug, Vectibix. In conjunction, the FDA expanded the approval of Vectibix to allow its use as a first-line treatment for colon cancer in combination with chemotherapy. The expanded Vectibix approval is for patients who have a non-mutated, or wild-type, KRAS gene. Close to 40% of colorectal cancer patients have tumors with mutated forms of the KRAS gene, which make them poor candidates for Vectibix. The rest have the non-mutated, or wild, forms and stand a better chance of benefiting from the drug.

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**AETNA SLAMS OUT-OF-NETWORK LABS** (*cont'd from page 1*)

In its letter to providers, Aetna said it based its rates on factors such as industry standards, the resource-based relative value scale (RBRVS), external vendor pricing and Medicare fee schedules. However, the new AMFS rates are equal to exactly 75% of 2014 Medicare rates in Ohio for both clinical lab and pathology services. And while Aetna will soon be paying out-of-network lab claims at 75% of Medicare, its new rates for x-ray services are set at 95% Medicare, while MRI services are set at 100%.

Vachette's Miller expects Aetna to make similar changes to its AMFS rates in other states as well. She says the rate reduction is substantial but difficult to quantify because billed charges vary from lab to lab.

Aetna's rate change will have its greatest effect on LabCorp and its many subsidiaries, including Dianon, Dynacare, Esoterix and Genzyme Genetics. LabCorp has been out of Aetna's network since July 1, 2007. Since then Quest Diagnostics has been Aetna's preferred laboratory, although Aetna has continued to contract with dozens of other independent and hospital-based labs across the nation.

**Aetna Market Fee Schedule for Ohio**

<b>Code</b>	<b>Short Descriptor</b>	<b>Medicare Nat'l Limit</b>	<b>Medicare Ohio</b>	<b>Aetna Rate</b>	<b>Aetna/OH Medicare</b>
80048	Metabolic panel total ca	11.54	10.01	7.51	75%
80053	Comprehen metabolic panel	14.41	14.41	10.81	75%
80061	Lipid panel	0.00	17.35	13.01	75%
80076	Hepatic function panel	11.14	8.62	6.47	75%
81001	Urinalysis auto w/scope	4.32	4.32	3.24	75%
84443	Assay thyroid stim hormone	22.93	22.93	17.20	75%
85025	Complete cbc w/auto diff wbc	10.61	10.61	7.96	75%
85610	Prothrombin time	5.37	5.37	4.03	75%
88142	Cytopath c/v thin layer	27.64	26.99	20.24	75%
88305-26	Tissue exam by pathologist	38.33	37.52	28.14	75%
88305-TC	Tissue exam by pathologist	32.08	29.83	22.37	75%
88305-Global	Tissue exam by pathologist	70.22	67.34	50.51	75%
88342-26	Immunohistochemistry	30.81	30.23	22.67	75%
88342-TC	Immunohistochemistry	57.67	53.30	39.98	75%
88342-Global	Immunohistochemistry	88.48	83.53	62.65	75%
71010-26	Chest x-ray 1 view frontal	9.31	9.16	8.70	95%
73510-26	X-ray exam of hip	11.82	11.70	11.11	95%
76942-26	Echo guide for biopsy	34.03	33.54	31.86	95%
72141-26	MRI neck spine	75.94	74.8	74.8	100%
72158-26	MRI lumbar spine	117.5	115.81	115.81	100%
73721-26	MRI joint of lower extremity	70.21	69.23	69.23	100%

Source: Laboratory Economics

### Double Whammy for Immunohistochemistry

Meanwhile, Aetna's new AMFS fee schedule continues to use the old CPT code 88342 for immunohistochemistry. However, *Laboratory Economics* notes that Aetna has set its new AMFS rate for CPT 88342 at 75% of the Medicare rate for G0461 in Ohio. CMS eliminated CPT 88342 effective January 1, 2014, and replaced it with G0461 & G0462 with an approximate 30% fee reduction.

The combination of Medicare's cut plus Aetna's cut means that Aetna will now be paying out-of-network claims for CPT 88342-Global in Ohio at \$62.65. That's 43% below the Ohio Medicare carrier rate of \$109.46 paid last year.

### Still Better than what Aetna Pays the National Labs

Aetna's move to fix out-of-network lab reimbursement at 75% of local Medicare rates follows a more drastic reimbursement cut made to in-network national labs last year (*LE*, April 2013, pp. 1-2). Effective July 1, 2013, Aetna lowered its standard lab fee schedule—the Aetna National Contact Default (ANCD)—for all its health plans to rates equal to only 45% or 50% of Medicare's national clinical lab and pathology rates.

The ANCD applies to Aetna's nationally-contracted labs. These include Quest Diagnostics and all its subsidiaries, including AmeriPath, Athena Diagnostics, CompuNet Clinical Labs, Sonora Quest, et al. The ANCD also applies to other national participating labs such as Bio-Reference Labs, Bostwick Labs, Enzo Clinical Lab, Miraca Life Sciences, NeoGenomics, Sonic Healthcare, et al.

### What Will Aetna Pay Local In-Network Labs?

The big question now is "If, when and how much will Aetna adjust its rates paid to local in-network labs and pathology groups?" *Laboratory Economics* thinks that Aetna may soon fix its payments to local in-network labs and pathology groups at somewhere between 50% and 75% of Medicare fees.

### Steering Patients to Quest Diagnostics and Other In-Network Labs

Finally, Aetna is urging physicians to steer their patients to Quest Diagnostics and other in-network labs by emphasizing the higher out-of-pocket costs for patients that use an out-of-network lab. In a brochure sent to physicians, Aetna illustrates the cost difference with the following table:

	<i>In-network lab</i>	<i>In-network hospital lab</i>	<i>Out-of-network lab</i>
Cost of lab test	\$30	\$60	\$300
Member copay percent	20%	20%	40%
Member pays	\$6	\$12	\$120

Note: Based on patient whose deductible has already been met. Data is not representative of hospitals that have a separately negotiated laboratory agreement.

Source: Aetna 4/2014

Aetna provides health insurance to 22.7 million people in the United States, making it the third largest private health insurance company after UnitedHealth Group, which covers 40 million members, and Wellpoint, 36.9 million members.

**EUROFINS TO BUY VIRACOR-IBT FOR 3.2X REVENUE** (*cont'd from page 1*)

VIBT is an esoteric reference lab specializing in immunology, infectious disease and allergy testing. VIBT, which has 270 employees, is based in the Kansas City area with a satellite lab in Los Angeles.

VIBT is majority-owned by the private investment firm Ampersand Ventures, which made an initial investment of \$5 million into IBT Reference Laboratory in 2004. IBT merged with Viracor Laboratories to form VIBT in 2009. Ampersand made an additional investment in the combined company in connection with the merger. At the time of the merger, VIBT had annual revenue of approximately \$36 million (see *LE*, July 2009, p. 3). Since then, VIBT has grown by approximately 17% per year to reach expected revenue of \$80 million this year.

Eurofins, which is publicly traded on the Paris Stock Exchange, specializes in food and pharmaceutical products testing. The acquisition of VIBT represents Eurofins' first foray into the U.S. clinical lab testing market. Eurofins plans to continue operating both VIBT sites with no site consolidation or major restructuring.

The purchase price for VIBT looks reasonable based on the average multiple of 12.1x EBITDA that labs have been purchased for in the past. However, it's not clear whether or not Belgium-based Eurofins has a full understanding of the reimbursement pressure that U.S. labs are currently facing, including Medicare's plans to reprice the Clinical Lab Fee Schedule beginning in 2017.

**Lab Valuations Based on EBITDA**

<i>Date</i>	<i>Buyer</i>	<i>Target</i>	<i>Purchase Price (\$MM)</i>	<i>Acquired EBITDA</i>	<i>Price/EBITDA</i>
Pending	Eurofins	Viracor-IBT Laboratories	\$255	\$25	10.2
Jun-12	LabCorp	Medtox Scientific	\$242	\$15	16.1
Feb-11	Novartis	Genoptix	\$330	\$45	7.3
Nov-10	GE Healthcare	Clariant Inc.	587	-3	NM
Sep-08	Sonic Healthcare	Clinical Laboratories of Hawaii	121	18	6.7
May-07	Quest Diagnostics	AmeriPath	2,000	119	16.8
Jan-07	Sonic Healthcare	American Esoteric Laboratories	180	19	9.5
Jan-06	AmeriPath	Specialty Laboratories	330	-5	NM
Oct-05	Quest Diagnostics	LabOne	947	68	13.9
Mar-03	Welsh Carson	AmeriPath	839	111	7.6
Jan-03	LabCorp	Dianon	600	41	14.6
Apr-02	Quest Diagnostics	American Medical Labs	500	30	16.7
Nov-01	Dianon	UroCor	202	11	18.4
Aug-99	Quest Diagnostics	SmithKline Beecham Clinical Labs	1,187	158	7.5
<b>Average</b>					12.1

NM=not meaningful

Source: *Laboratory Economics*

**MEDLAB SELLS NURSING HOME BIZ TO AMERICAN HEALTH ASSOC.**

A bankruptcy judge has approved the sale of MedLab's long-term care division, the last remaining branch of its business, to a joint venture between American Health Associates (Ft. Lauderdale, FL) and MedLab's secured lender for \$5.5 million. The sale includes MedLab's Kilbourne Medical Labs and Suburban Medical Laboratory units in Ohio. The sale of the nursing home business follows the sale of MedLab's Indiana assets to LabCorp in February for \$10.5 million. MedLab (aka Laboratory Partners) filed for Chapter 11 bankruptcy in late 2013.

## AURORA DIAGNOSTICS TO BUY MID-ATLANTIC PATHOLOGY SERVICES

**A**urora Diagnostics (Palm Beach Gardens, FL) has reached an agreement to acquire Mid-Atlantic Pathology Services (MAPS—Sterling, VA). MAPS is a dermatopathology lab with four pathologists that serves the Northern Virginia and greater Washington DC areas. MAPS was founded by its President Eva Mikhail, MD, and Vice President Sonia Kheir, MD, in 1995. Aurora says it will finance the acquisition through its cash flow and by borrowing from its credit line. The purchase price has not yet been disclosed.

Meanwhile, Aurora reported a net loss of \$6.6 million in the three months ended March 31, 2014 versus a net loss of \$7.7 million for the same period a year earlier; revenue decreased by 6.4% to \$57 million. Accession volume decreased by approximately 24,000, or 4.7%, to 497,000 for the quarter ended March 31, 2014. Aurora's average revenue per accession was down 2% to approximately \$115.

As of March 31, 2014, Aurora's balance sheet showed \$338 million in debt and cash holdings of \$2.7 million. The company had \$25.1 million available to borrow through a revolving credit line as of March 31, 2014.

As of mid-June, Aurora's senior debt (CUSIP: 051620AB8, 10.75%, maturity 1/15/2018) was selling at 84-88 cents on the dollar with a yield to maturity of approximately 16%. Although the market is currently valuing Aurora's debt at the extreme junk bond level, this is a big improvement from early this year when the company's debt was trading at 70-75 cents on the dollar with a yield of 20%. The market may be betting that there is a chance for Aurora to restructure its debt and lower its interest expense, which currently exceeds \$33 million per year.

## INCYTE BUYS MCL IN YAKIMA

**I**ncyte Diagnostics (Spokane, WA) has acquired Medical Center Laboratory (MCL), a pathology group in Yakima, Washington. Terms of the deal were not disclosed.

Incyte will assume the Medical Laboratory Directorships for Yakima Valley Memorial Hospital, Yakima Regional Medical and Cardiac Center, and Toppenish Community Hospital. Incyte is also negotiating with a fourth hospital, Sunnyside Community Hospital, previously overseen by MCL. Incyte will also continue to operate the MCL's core lab at its current location in Yakima.

The sale of MCL comes in conjunction with the retirement of MCL's John Onstad, MD. MCL's three other pathologists will join Incyte.

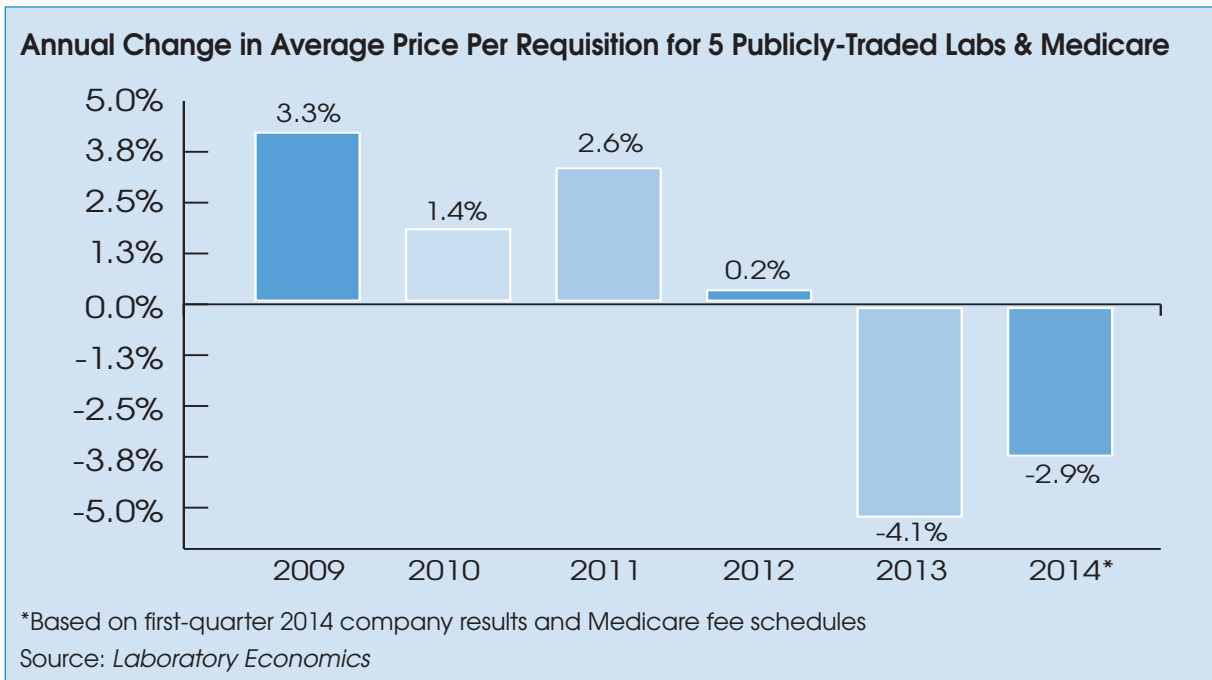
Incyte Diagnostics (formerly Incyte Pathology) now has 40 pathologists and provides anatomic pathology services to 30 hospitals in Washington and northern Idaho, including medical directorships at 13 hospitals.

## CELLNETIX ACQUIRES HIGHLINE PATHOLOGY ASSOCIATES

**C**ellNetix (Seattle, WA) has acquired Highline Pathology Associates, a three-pathologist group located at Highline Medical Center in Burien, Washington (south of Seattle). Highline Medical Center is a 154-bed acute care hospital and a 115-bed specialty center. CellNetix now has 53 pathologists serving 19 hospitals and large clinics in Washington and Alaska. CellNetix is owned in part by PAML (Spokane, WA).

## PRICE PER REQ. DOWN AN AVERAGE OF 2.9% THIS YEAR

The average full-service independent lab performing both clinical and anatomic pathology testing will see its average collected price per requisition fall by 2.9% this year, according to *Laboratory Economics*' analysis of pricing information from five publicly-traded lab companies and final Medicare rates for 2014.



*LE*'s Price per Requisition estimates are based on reported changes in revenue per requisition from Quest Diagnostics (weighted 32%), LabCorp (28%), Bio-Reference Labs (5%), Aurora Diagnostics (2%) and NeoGenomics (1%). Annual changes to Medicare's Clinical Lab Fee Schedule are weighted 21%, while rate changes to anatomic pathology codes are weighted 11%.

Meanwhile, *Laboratory Economics* estimates that Medicare's CLFS will be cut by 0.65% in 2015. This estimate is based on the latest 12-month inflation change of +2.1% (CPI for 12 months ended May 2014) minus a productivity adjustment of 1% and an additional fixed cut of 1.75% as mandated by the Affordable Care Act (aka Obamacare).

### Annual Change in Average Price Per Requisition by Lab Company

Laboratory	2009	2010	2011	2012	2013	2014*
Aurora Diagnostics	NA	-5.0%	3.7%	-5.0%	-9.3%	-1.7%
Bio-Reference Labs	6.0%	4.7%	1.5%	1.7%	6.2%	-0.4%
LabCorp	2.6%	6.4%	7.0%	0.6%	-1.6%	-3.3%
NeoGenomics	5.0%	-4.0%	-1.2%	-8.1%	-7.4%	-3.1%
Quest Diagnostics	3.9%	-0.2%	2.0%	0.0%	-3.6%	-2.8%
Medicare CLFS	4.5%	-1.9%	-1.8%	0.7%	-5.0%	-0.8%
Medicare PFS	0.0%	0.0%	2.3%	-0.1%	-14.0%	-7.5%
Weighted Average	3.3%	1.4%	2.6%	0.2%	-4.1%	-2.9%

\*Based on first-quarter 2014 company results and Medicare CLFS & PFS for 2014

Source: *Laboratory Economics*

## COMPARING PRODUCTIVITY AT QUEST, LABCORP AND BRLI

On a weighted basis, three publicly-traded lab companies collected average revenue of \$45.72 per requisition in 2013, according to a *Laboratory Economics*' analysis of year-end results. Average collected revenue per test is an estimated \$15.76.

The three companies—Quest Diagnostics, LabCorp and BioReference Labs Inc. (BRLI)—generated an average of \$172,126 in revenue per employee this year. The average number of requisitions processed is 3,611 per employee per year, while employees processed an average of 10,472 tests per year. These figures are based on the total number of employees at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

In terms of billing and collection, the average bad-debt expense for the big three commercial labs is 4.3% with an average days in accounts receivables of 52 days.

The combined revenue mix at the three publicly-traded labs is approximately 50% from commercial insurance, 28% client bill, 15% Medicare, 4% patient bill and 3% from Medicaid.

### Productivity Stats at Quest, LabCorp and BioReference Labs

	<i>Quest</i>	<i>LabCorp</i>	<i>BioReference</i>	<i>Totals*</i>
Annual Revenue 2013	\$7,146,000,000	\$5,808,300,000	\$709,592,000	\$13,663,892,000
Annual Pretax Income 2013	\$1,348,000,000	\$915,600,000	\$81,097,000	\$2,344,697,000
# Employees	41,000	34,500	3,883	79,383
Avg. Revenue per Employee	\$174,293	\$168,357	\$182,743	\$172,126
Avg. Pretax Income per Employee	\$32,878	\$26,539	\$20,885	\$29,537
Annual Requisitions 2013	147,100,000	131,000,000	8,549,000	286,649,000
Avg. Revenue per Requisition	\$44.78	\$44.33	\$83.00	\$45.72
Avg. Reqs processed per Employee	3,588	3,797	2,202	3,611
Annual Tests (assumes 2.9 tests per req.)	426,590,000	379,900,000	24,792,100	831,282,100
Avg. Revenue per Test	\$15.44	\$15.29	\$28.62	\$15.76
Avg. Tests processed per Employee	10,405	11,012	6,385	10,472
Bad-Debt Expense	\$270,000,000	\$255,565,200	\$58,917,000	\$584,482,200
Bad-Debt %	3.8%	4.4%	8.2%	4.3%
Days in AR	47	49	100	52

\*Averages are weighted based on size

Source: *Laboratory Economics* from company reports

## TOP 50 MDx LABS BASED ON STACKING CODE VOLUME

**H**ealth Diagnostic Laboratory, Inc. (Richmond, VA) billed Medicare for the greatest number of molecular diagnostic test stacking codes in 2012, according to a Laboratory Economics' analysis of Medicare Part B data recently released by CMS.

*Laboratory Economics* calculated the MDx test volume for each lab by adding the total number of test codes that each lab performed for the Medicare Part B program in 2012 for the stacking codes CPT 83890-83914 plus CPT 88381 (microdissection) and the array codes CPT 88384-88386.

Health Diagnostic Laboratory, Inc. billed the Part B program for 6.544 million MDx test codes in 2012. HDL, Inc. markets test panels that help determine risk of cardiovascular disease and diabetes. HDL, Inc. also markets genetic tests that help determine susceptibility of an individual to statin-induced myopathy (muscle weakness).

Myriad Genetics (Salt Lake City, UT) was the second largest MDx testing lab in terms of volume of MDx stacking codes billed to Medicare Part B in 2012. Myriad performed 3.890 million MDx tests for 16,500 Medicare beneficiaries in 2012.

Natural Molecular Testing Corp. (NMTC—Renton, WA) performed 2.992 million MDx tests for Part B beneficiaries in 2012. NMTC specializes in molecular testing for cancer, prenatal screening and infectious disease. On April 24, 2013, CMS suspended all Medicare payments to NMTC stating that the suspension of payment “involves credible allegations of fraud.” NMTC filed for Chapter 11 bankruptcy reorganization on October 21, 2013.

Quest Diagnostics billed Part B for 1.329 million MDx stacking codes in 2012, while LabCorp billed for 628,651 codes.

## TOP 50 MOLECULAR DIAGNOSTIC TESTING LABS BY TEST VOLUME

LABORATORY NAME	LOCATION	PART B MDx TEST VOLUME*
HEALTH DIAGNOSTIC LABORATORY, INC.	RICHMOND, VA	6,543,990
MYRIAD GENETIC LABORATORIES	SALT LAKE CITY, UT	3,889,582
NATURAL MOLECULAR TESTING CORPORATION	RENTON, WA	2,991,516
QUEST DIAGNOSTICS (including Ameripath, LabOne, Unilab, et al.)	MADISON, NJ	1,328,503
AMERICAN INTERNATIONAL BIOTECH (AIBIOTECH)	RICHMOND, VA	655,572
LABCORP (including Dianon, Esoterix, Monogram, et al.)	BURLINGTON, NC	628,651
BOSTON HEART DIAGNOSTICS CORP.	FRAMINGHAM, MA	523,609
CLARIANT DIAGNOSTIC SERVICES, INC.	ALISO VIEJO, CA	502,987
ASSURERX HEALTH, INC.	MASON, OH	452,858
PHARMACOGENETICS DIAGNOSTICS LABORATORY, LLC.	LOUISVILLE, KY	308,361
IVERSON GENETIC DIAGNOSTICS, INC.	SEATTLE, WA	302,154
GENELEX CORPORATION	SEATTLE, WA	260,349
BIO-REFERENCE LABORATORIES (including GeneDx and Hunter Labs)	ELMWOOD PARK, NJ	237,585



COMPANION DX REFERENCE LAB, LLC	HOUSTON, TX	230,905
RESPONSE GENETICS	LOS ANGELES, CA	204,706
STRAND DIAGNOSTICS LLC.	INDIANAPOLIS, IN	182,311
ONCO DIAGNOSTIC LABORATORY	CLEVELAND, OH	134,321
GENOPTIX, INC.	CARLSBAD, CA	127,380
AMBRY GENETICS CORPORATION	ALISO VIEJO, CA	125,921
SEQUENOM CENTER FOR MOLECULAR MEDICINE LLC	GRAND RAPIDS, MI	96,966
TRANSGENOMIC, INC.	NEW HAVEN, CT	79,652
PRECISION THERAPEUTICS, INC.	PITTSBURGH, PA	78,342
ATHEROTECH	BIRMINGHAM, AL	73,633
PROMETHEUS LABORATORIES INC.	SAN DIEGO, CA	69,673
CARIS MPI, INC.	PHOENIX, AZ	69,587
BOSTWICK LABORATORIES, INC.	RICHMOND, VA	69,405
NEOGENOMICS LABORATORIES INC.	FORT MYERS, FL	66,207
MIRACA LIFE SCIENCES (Including Plus Diagnostics)	IRVING, TX	56,163
MITOMICS (USA) INC.	AURORA, CO	48,803
PATHGROUP/ACCUPATH DIAGNOSTICS LABORATORIES	BRENTWOOD, TN	48,756
TZAM DIAGNOSTICS LLC.	WILMETTE, IL	45,645
SORENSEN GENOMICS, LLC	SALT LAKE CITY, UT	38,543
CLINICAL PATHOLOGY LABS (including CBLPath, MPL, Sunrise, et al.)	AUSTIN, TX	32,572
ACCESS GENETICS, LLC	EDEN PRAIRIE, MN	31,831
ENZO CLINICAL LABS, INC.	FARMINGDALE, NY	31,824
MAYO MEDICAL LABORATORIES	ROCHESTER, MN	29,578
DNA DIAGNOSTICS CENTER	FAIRFIELD, OH	27,790
HEMATOLOGICS INC.	SEATTLE, WA	21,950
CLINICAL LABORATORY PARTNERS	NEWINGTON, CT	18,889
ASURAGEN INC.	AUSTIN, TX	18,441
PROST DATA, INC.	NASHVILLE, TN	17,359
MILLENIUM LABORATORIES OF CALIFORNIA, INC.	SAN DIEGO, CA	16,804
THE TRUSTEES OF COLUMBIA UNIVERSITY	NEW YORK, NY	16,451
MOLECULAR PATHOLOGY LABORATORY NETWORK INC.	MARYVILLE, TN	10,610
PHYSICIANS CHOICE LABORATORY SERVICES, LLC	CHARLOTTE, NC	10,602
HEMATOGENIX LABORATORY SERVICES, LLC	TINLEY PARK, IL	9,590
SPECTRACELL LABORATORIES, INC.	HOUSTON, TX	8,641
STEVE GROSHONG, MD (NATIONAL JEWISH HEALTH)	DENVER, CO	8,146
BOYCE AND BYNUM PATHOLOGY LABORATORIES, INC.	COLUMBIA, MO	6,724
VITRO MOLECULAR LABORATORIES	MIAMI, FL	6,671
ACL LABORATORIES	WEST ALLIS, WI	6,280

\*Includes total volume of CPT codes 83890-83914, 88381, and 88384-88386 provided to the Medicare Part B program in 2012.  
Source: 2012 Medicare Fee-for-Service Provider Utilization & Payment Data

## CALIFORNIA BILL TO ELIMINATE IN-OFFICE LABS IS DEFEATED

**T**he California Medical Association (CMA) and California Urological Association (CUA) have quashed a bill (SB 1215) that would have eliminated the in-office exception to the self-referral law for anatomic pathology, thereby outlawing in-office pathology labs. The bill died in the Senate Business and Professions Committee after receiving just one vote (from the bill's author, Democratic Sen. Ed Hernandez). Three Senators on the committee voted "no" and five abstained.

The CMA and CUA had lobbied against the bill arguing that it would have been a major blow to the integrated care model and would have resulted in increased costs. If the bill were to pass, anatomic pathology, imaging, radiation and physical therapy services would be driven toward more expensive hospital settings and inhibit the development of coordinated care, according to CMA.

The bill had been supported by the California Radiological Society, California Physical Therapy Assn., American Clinical Lab Assn. and CAP, which argued that the bill would reduce unnecessary utilization and lower healthcare costs.

Hernandez, Chair of the California Senate's Committee on Health, modeled the bill after federal legislation, HR 2914, authored by U.S. Representative Jackie Speier (D-CA). HR 2914, Promoting Integrity in Medicare Act of 2013, has been sitting in a congressional committee for nearly 1 year. The committee must consider it before possibly sending it on to the House or Senate as a whole.

## BIO-REFERENCE REPORTS DOUBLE-DIGIT GROWTH

**B**io-Reference Laboratories Inc. (Elmwood Park, NJ) continues to outpace its national lab competitors, reporting a 14% increase in revenue to reach \$201.4 million for the three months ended April 30, 2014. Requisition volume increased 14.4% to 2.4 million reqs, while revenue per requisition decreased 0.9% to \$84.18 per req. BRLI's net income was \$10.3 million for the latest quarter, down from \$11.3 million in the same quarter a year ago.

## DIGIPATH HIRES TURNAROUND EXPERT

**D**igiPath Inc. (Agoura Hills, CA) has hired "turnaround expert" Joe Tanner, age 67, to serve as Executive Chairman. Tanner has received 500,000 shares of DigiPath valued at approximately \$140,000 (based on recent price of \$0.28 per share). Tanner will also be paid \$5,500 per month.

DigiPath, a publicly-traded company that markets digital pathology systems, has been struggling. In the six months ended March 31, 2014, DigiPath reported a net loss of \$297,812 on revenue of only \$105,544.

Over the past three months, DigiPath has raised \$8.2 million from individual investors. The company is in the process of exploring "new lines of business associated with the research, development, licensing and operation of botanical and nutri-pharmaceutical products and services."

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**QIAGEN AND AMGEN GET FDA APPROVAL** (*cont'd from page 1*)

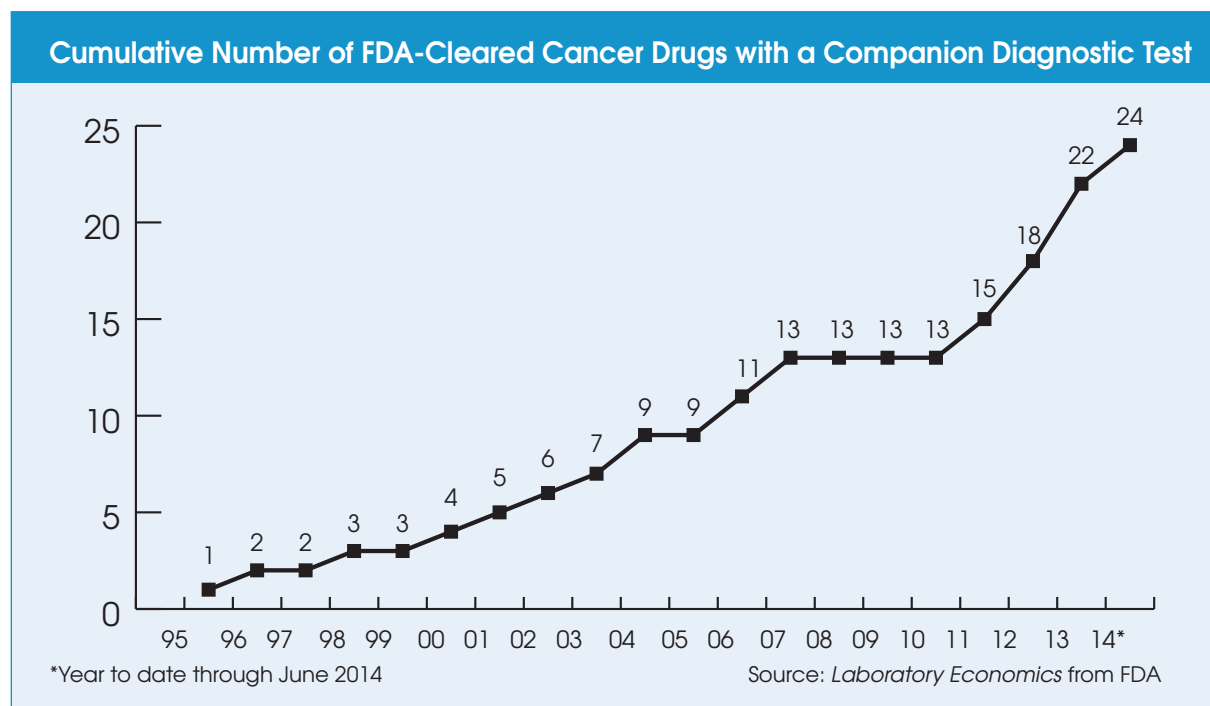
Vectibix costs approximately \$7,500 per month, or \$45,000 for a six-month treatment. Qiagen charges its lab customers about \$130 for the thescreen KRAS test kit. In turn, most labs bill three CPT codes per KRAS test, CPT 81275, 88381 and G0452, for a total charge of approximately \$350. So the KRAS test clearly provides a big benefit and low cost when linked with treatment decisions for Vectibix.

The companion test (CDx) for Vectibix is the latest FDA approval of thescreen KRAS and marks the third FDA approval of a CDx from Qiagen that has been paired with a cancer drug. Prior approvals include the thescreen KRAS test paired with the 2012 approval of Erbitux, and Qiagen's thescreen EGFR test, which was approved by the FDA in 2013 to guide the use of Gilotrif for treatment of metastatic non-small cell lung cancer.

Overall, the FDA has now approved more than 110 new cancer drugs since 1995. Twenty four of these drugs, or approximately 20%, have a CDx test associated with them.

Recently approved cancer drugs with a CDx test:

- Zykadia (ceritinib); Novartis: For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib. Approved April 2014.
- Tafinlar (dabrafenib); GlaxoSmithKline: For the treatment of unresectable or metastatic melanoma with BRAF V600E mutation. Approved May 2013.
- Gilotrif (afatinib); Boehringer Ingelheim: For the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Approved July 2013.



## LAB STOCKS UP 9% YTD

**F**ourteen lab stocks increased an average of 9% year to date through June 18. In comparison, the S&P 500 Index is up 5%. The top-performing lab stock so far this year is Enzo Biochem, up 82%, followed by Myriad Genetics, up 76%. LabCorp is up 10% and Quest Diagnostics is up by 9%.

Company (ticker)	Stock Price 6/18/14	Stock Price 12/31/13	2014 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	\$29.28	\$25.54	15%	\$811	20.8	1.1	2.9
Cancer Genetics Inc. (CGIX)	11.23	13.78	-19%	104	NA	15.3	2.4
CombiMatrix (CBMX)	2.38	2.30	3%	26	NA	3.9	1.9
Enzo Biochem (ENZ)	5.32	2.92	82%	233	NA	2.5	6.2
Foundation Medicine (FMI)	24.21	23.82	2%	683	NA	18.7	5.4
Genomic Health (GHDX)	27.99	29.27	-4%	874	NA	3.3	6.2
LabCorp (LH)	100.33	91.37	10%	8,510	16.7	1.5	3.4
LipoScience (LPDX)	3.45	4.25	-19%	53	NA	1.1	1.1
Myriad Genetics (MYGN)	37.00	20.98	76%	2,770	15.9	3.6	3.8
NeoGenomics (NEO)	3.17	3.62	-12%	158	77.3	2.3	6.9
Psychomedics (PMD)	14.35	14.69	-2%	76	20.5	2.8	6.2
Quest Diagnostics (DGX)	58.54	53.54	9%	8,460	10.7	1.2	2.1
Response Genetics (RGDX)	0.99	1.16	-15%	38	NA	2.1	15.7
Sonic Healthcare (SHL.AX)	17.15	16.58	3%	6,874	18.8	1.9	2.3
Unweighted Averages			9%		25.8	4.4	4.7

Source: Bloomberg and Zacks

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