

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

WOMEN'S HEALTH CONNECTICUT OPENS LAB

On December 15, 2013, Women's Health Connecticut (Avon, CT) opened its own 11,000-square-foot laboratory in Rocky Hill, Connecticut (about 5 miles south of Hartford). Previously, Women's Health had used both national labs as well as a variety of local hospital-based labs and pathology groups.

The transition of testing to the new lab has resulted in the loss of more than 20% of Pap test volume at many hospital-based labs and pathology groups throughout the state. That's because Women's Health Connecticut employs approximately one-third of the 665 Ob/Gyn physicians practicing in the state. In fact, Women's Health Connecticut is the largest Ob/Gyn group practice in United States, employing 215 Ob/Gyns at 100 office locations throughout Connecticut. *Full details on page 2.*

CMS TO USE PRIVATE INSURANCE RATES TO DETERMINE PART B LAB TEST REIMBURSEMENT

The new "doc fix" law (SGR, H.R. 4302), which delays a 20+% cut to the physician fee schedule for one year, contains short-term good news and long-term bad news for clinical labs. The good news is that potential major cuts to the Part B Clinical Lab Fee Schedule (CLFS) have been pushed back two years (January 1, 2015 → January 1, 2017). The bad news is that CMS has now been directed explicitly to use private insurance data to establish the rates that Medicare will pay labs under the CLFS.

If put into effect as currently written, the Congressional Budget Office (CBO) estimates that the lower lab test prices paid by Medicare would result in total savings of \$2.5 billion between 2017 and 2024. The CBO estimate suggests that the Part B CLFS would suffer cuts that ranged from 1% to 10% per year starting in 2017 and ending in 2024. *Laboratory Economics* estimates that the cumulative effect of eight straight years of continuous cuts would easily add up to more than a 25% cut in Part B lab test prices by 2024. *Continued on page 10.*

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WOMEN’S HEALTH CONNECTICUT OPENS LAB *(continued from page 1)*



Matthew Saidel, MD, a founding member and co-medical director of Women’s Health, says the group chose to insource lab and pathology services for a variety of reasons. The group is self-insured for malpractice insurance and the new lab was part of a broader quality and safety initiative, according to Saidel. For example, Saidel says that Women’s Health is now better able to monitor its 100 office locations to ensure that Pap and HPV testing guidelines are uniformly applied and followed. The new lab has also allowed for standardized Ob/Gyn test profiles and prenatal genetic test panels.

In addition, Saidel says that test result turnaround time has been cut roughly in half. The majority of Pap test results are now provided within 24 hours versus previous turnaround time of anywhere between 48 hours and two weeks. Biopsy results are now provided within three days compared with between four days to two weeks.

Finally, Saidel says that the physicians at Women’s Health now have a more direct and personal relationship with the pathologists reading the slides. Women’s Health bills globally for all testing done at its new lab and contracts with Hartford Pathology Associates (HPA) for professional services. HPA’s Donna Rose, MD, serves as lab director for the new lab, which is named Women’s Health Connecticut Laboratory (WHCL). HPA has 27 pathologists and is based at Hartford Hospital.

Over a year ago, Women’s Health put out a competitive bid and Clinical Lab Partners (Newington, CT) won the job of helping to design

Inside Women’s Health CT Laboratory



Women’s Health Connecticut Laboratory (WHCL) at a Glance	
Location	Rocky Hill (central Connecticut)
Opened.....	December 15, 2013
Professional Pathology Services	Hartford Pathology Assoc.
Lab Director	Donna Rose, MD
Lab Mgmt. and Courier Services.....	Clinical Lab Partners
Lab Operations Director	Nancy Albert
Staff	25 FTEs (approx. 35 employees)
Size	11,000 sq. ft. (lab and office)
Client base.....	215 Ob/Gyns at 100 offices
Annual Pap test volume	92,000
Source: <i>Laboratory Economics</i> from Women’s Health Connecticut and Clinical Lab Partners	

and manage the new lab. Saidel says the new lab was opened on schedule and on budget, and is in the process of obtaining CAP accreditation.

CLP is an independent lab company owned by Hartford Health Care. CLP has 875 employees and performs more than 11 million tests per year, making it one of the largest independent labs in the Northeast.

Twenty-five FTEs from CLP staff and manage the new lab, according to Jim Fantus, President of CLP. In addition, CLP provides phlebotomy and courier services to Women's Health offices throughout Connecticut. CLP sorts the requisitions. The majority of samples are sent to WHCL for testing, although some samples are directed to CLP's central lab in Newington because of insurance restrictions or test complexity. CLP also manages day-to-day operations at the new lab, including staffing, equipment selection, IT connectivity, et al. In return, CLP gets a management fee from Women's Health.

WHCL has a histology lab for cervical biopsies and performs Pap tests and related STD tests (e.g., HPV, Chlamydia/GC, Gardnerella, Trichomonas, Yeast and Vaginosis Profile). It also performs OB Profiles (ABO, Rh, antibody screen, CBC, Syphilis MIA, HBsAg, +/- HIV, Rubella), as well as TSH, Glucose, CBC, urine culture, et al., according to Nancy Albert, Director of Laboratory Operations at CLP.

Inside Women's Health CT Laboratory



But Robert Babkowski, MD, Chair of Pathology and Laboratory Medical Director at Stamford Hospital and President of Stamford Pathology Group PC, says the opening of WHCL has resulted in a significant loss of not just anatomic pathology and cytology volume for his hospital, but clinical laboratory tests as well. This has been the effect on nearly every hospital in Connecticut (e.g., Yale-New Haven Hospital, Middlesex Hospital, St. Francis Hospital, Norwalk Hospital, et al.).

Babkowski believes that physician groups are insourcing pathology and lab services for one primary reason: money. In Babkowski's opinion, "Pathologists are delusional if they think they are somehow partners with the physician groups that open in-office labs. In reality, the pathologists are viewed by these practices as nothing more than high paid techs providing a commodity service."

Is Women's Health New York Next?

In related news, *Laboratory Economics* has learned that Women's Health New York may also be in the process of opening its own full-service laboratory. Women's Health New York was formed in 2005 when more than a dozen New York practices merged into one large group practice.

WHNY and WHCT are related in that both are physician-owned groups that receive practice management services from Women's Health USA (Avon, CT).

Women's Health USA was founded in 1997 by healthcare entrepreneur Robert E. Patricelli, who is Chairman and CEO. The company's initial outside investor was The Sprout Group, an affiliate of Credit Suisse First Boston. In 2011, the company and Patricelli acquired Sprout's interests, so that management now owns 100% of the company's equity.

Prior to forming Women's Health USA and Evolution Benefits, Patricelli was Founder, Chairman and CEO of Value Health, a NYSE company that specialized in prescription drug and mental health benefit management. In 1997, Value Health was sold to Columbia/HCA Healthcare Corporation for \$1 billion.

Women's Care Florida Opens Full-Service Lab

In separate news, Women's Care Florida (WCF) recently received CAP accreditation for its new custom-built laboratory in the West Shore area in Tampa. Previously, WCF had operated a "read only" lab, but it is being expanded to include molecular microbiology and histology including immunohistochemistry and cytology. WCF has a full-time Laboratory Director, Jamie Shutter, MD, with fellowship training in gynecological pathology, and is in the process of hiring a second pathologist and additional lab staff. WCF employs 135 Ob/Gyns and 50 nurse practitioners/midwives at over 50 offices in West Central Florida.

Is this the Beginning of a Major Trend for Ob/Gyn Practices?

"It's not going to happen. I have spent countless hours exploring that market and I come to it with many years of GYN testing experience," says Joe Plandowski, Co-Founder of In-Office Pathology LLC.

In order for an in-office lab to make sense, the group has to be large, at least 25 Ob/Gyn's using today's annual testing guidelines. There are relatively few such large groups across the U.S., according to Plandowski.

Another reason is that Ob/Gyn groups have got to recognize that their Pap test volume will shrink as new guidelines are adopted that limit testing for women classified as "normal" to once every 3-5 years versus today's annual testing practice. That will also dramatically cut back on associated STD testing.

Furthermore, Plandowski says the base costs are very high for a Pap testing lab which undoubtedly will use thin-layer technology with an imager and automated equipment for STD testing. Other significant costs associated with operating a Pap testing lab include hiring cytotechnologists (average annual salary ~\$65,000), as well as complying with regulations for record keeping and slide retention.

In addition, Plandowski notes that the liability risk associated with Pap testing is great. He points to a recent \$15.8 million jury verdict against LabCorp. On April 16, a jury in West Palm Beach Florida determined that LabCorp was 75% responsible for misreading a Pap test on a 37-year-old woman who died as a result.

What all this means is that the group size has to be huge to economically justify an in-office lab, according to Plandowski. "Anyone who thinks this is the next big market for in-office labs doesn't know what they are talking about," he concludes.

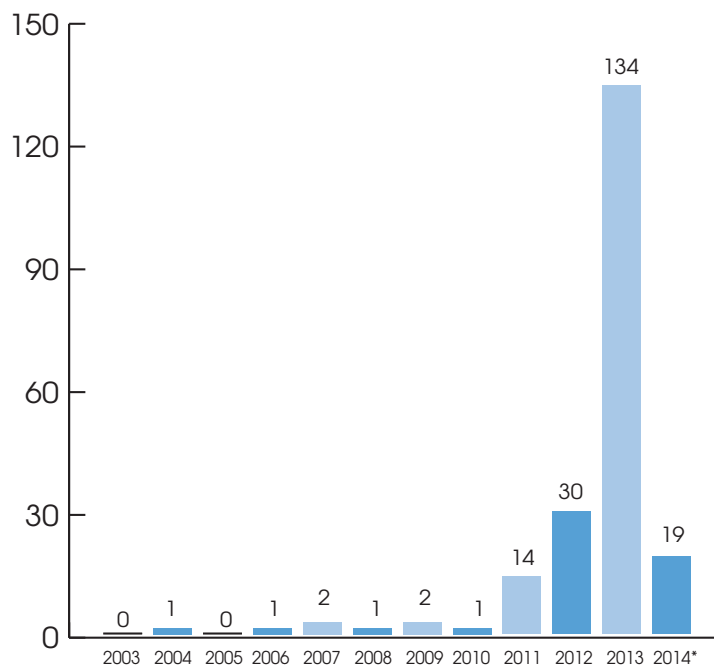
RECORD NUMBER OF IN-OFFICE LABS GETTING ACCREDITATION

A record number of in-office pathology labs obtained either CAP or Joint Commission accreditation last year in response to Aetna's new pathology testing payment policy.

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

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

In-Office Pathology Labs Receiving CAP Accreditation

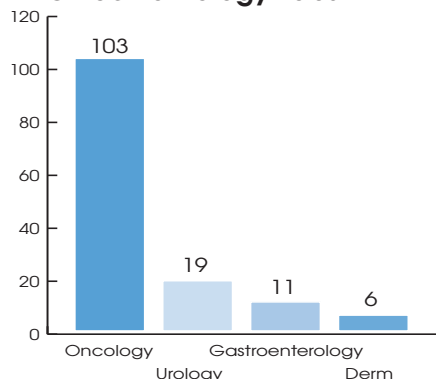


*Year to date through March 31, 2014

Source: *Laboratory Economics* from CMS, CAP and The Joint Commission

A total of 134 specialty groups had their labs accredited by either CAP or The Joint Commission in 2013 and another 19 in-office labs have received accreditation year to date through March 31, 2014.

Average Size of Accredited In-Office Pathology Labs



Source: *Laboratory Economics* from CMS, CAP and The Joint Commission

A grand total of 206 specialty groups with nearly 3,000 physicians now operate accredited pathology labs. Gastroenterology groups have the greatest number of accredited labs (122), followed by urology (54), dermatology (24), oncology (4) and Ob/Gyn (2). Gastroenterology groups with accredited labs have an average of 11 gastroenterologists, while urology groups have an average of 19 urologists. The four oncology groups with accredited labs average 103 doctors per group.

Looking strictly at the 40 specialty groups that most recently received accreditation (*see table on page 6*), gastroenterology groups obtained the greatest number of accredited labs (25), followed by urology (8), dermatology (4), oncology (2) and Ob/Gyn (1).

In-Office Pathology Labs Recently Accredited by CAP or Joint Commission

Group Name	Specialty	City	State	Number Physicians	Accrediting Organization	Accreditation Date
Tennessee River Dermatology	Dermatology	Florence	AL	3	CAP	Mar-14
Gastrointestinal Specialists of Georgia	Gastroenterology	Marietta	GA	20	JC	Mar-14
Southwest Dermatology	Dermatology	Chicago	IL	5	CAP	Mar-14
Gastroenterology Associates of Fredericksburg	Gastroenterology	Manassas	VA	7	CAP	Mar-14
Gastro and Hepatology Assoc. PC	Gastroenterology	Alexandria	VA	2	CAP	Mar-14
UW Health Digestive Health Center	Gastroenterology	Madison	WI	36	CAP	Mar-14
Women's Care Florida	Ob/Gyn	Tampa	FL	135	CAP	Feb-14
Gastrointestinal Specialists PC	Gastroenterology	Troy	MI	8	CAP	Feb-14
Arizona Urology Specialists	Urology	Phoenix	AZ	22	CAP	Jan-14
Fall Hill Gastroenterology Associates	Gastroenterology	Fredericksburg	VA	3	JC	Jan-14
Arizona Center for Cancer Care/ AZCCC Labs	Oncology/Urology	Litchfield Park	AZ	50	CAP	Jan-14
Centers for Gastroenterology	Gastroenterology	Fort Collins	CO	14	CAP	Jan-14
Pinski Dermatology	Dermatology	Bourbonnais	IL	2	CAP	Jan-14
The Gastroenterology Group	Gastroenterology	Glen Ridge	NJ	4	CAP	Jan-14
Urology Professional Association	Urology	Collegeville	PA	6	CAP	Jan-14
Urology Clinics of North Texas	Urology	Collegeville	PA	30	CAP	Jan-14
Pasadena GI PA	Gastroenterology	Pasadena	TX	1	CAP	Jan-14
Liver Associates of Texas	Gastroenterology	Pearland	TX	4	CAP	Jan-14
Coastal Gastroenterology Assoc. PA	Gastroenterology	Webster	TX	2	CAP	Jan-14
Yuma Gastroenterology	Gastroenterology	Yuma	AZ	8	CAP	Dec-13
Digestive Disease Consultants	Gastroenterology	Brunswick	OH	5	CAP	Dec-13
Florida Digestive Health Specialists	Gastroenterology	Bradenton	FL	31	CAP	Nov-13
Digestive Care Physicians	Gastroenterology	Johns Creek	GA	2	JC	Nov-13
Hamilton Gastroenterology	Gastroenterology	Hamilton	NJ	7	CAP	Nov-13
Las Vegas Urology	Urology	Las Vegas	NV	14	CAP	Nov-13
Digestive & Liver Disease Consultants	Gastroenterology	Houston	TX	5	CAP	Nov-13
GI Associates of Maryland	Gastroenterology	Ft. Washington	MD	8	CAP	Oct-13
Alliance Urology	Urology	Greensboro	NC	11	CAP	Oct-13
Premier Urology Group	Urology	Cranford	NJ	13	CAP	Oct-13
Twin Rivers Endoscopy Center	Gastroenterology	Easton	PA	3	JC	Oct-13
Urology Team Austin	Urology	Austin	TX	8	CAP	Oct-13
Gastroenterology Associates Inc.	Gastroenterology	Providence	RI	8	CAP	Oct-13
Oncology/Hematology Care	Oncology	Cincinnati	OH	9	JC	Sep-13
Gastroenterology Associates of Fairfield County	Gastroenterology	Fairfield	CT	8	CAP	Sep-13
Advanced Urology Specialists	Urology	Oxford	FL	16	CAP	Sep-13
Metropolitan Dermatology (aka MetroDerm)	Dermatology	Atlanta	GA	7	CAP	Sep-13
Digestive Disease Associates	Gastroenterology	Baltimore	MD	15	CAP	Sep-13
Digestive Health Care Center	Gastroenterology	Hillsborough	NJ	7	CAP	Sep-13
Digestive Disease Specialists	Gastroenterology	Las Vegas	NV	4	CAP	Sep-13
North Shore Gastroenterology Assoc.	Gastroenterology	Great Neck	NY	7	CAP	Sep-13

Source: *Laboratory Economics* from CMS, CAP and The Joint Commission

TOP 30 CLINICAL LABS RANKED BY AVERAGE MEDICARE PART B PAYMENT

The Medicare Part B program spent an average of \$184 per beneficiary on clinical lab tests provided by all 2,743 clinical labs with a national provider ID in 2012, according to Medicare Part B data recently released by CMS.

Laboratory Economics identified the top 30 clinical labs with the most expensive testing services. We did this by analyzing the total Part B payments received by each of the 2,743 clinical labs and dividing by the number of unique beneficiaries served by each lab in 2012. This calculation provided the average Part B payment received by each lab for each beneficiary they served in 2012. As measured by this yardstick, *LE's* Top 30 Most Expensive Clinical Lab List is dominated by two types of labs: 1) those with a proprietary molecular diagnostic test; and 2) drugs-of-abuse/pain management testing labs.

The most expensive clinical lab in 2012 was **Precision Testing Laboratories** (Southbridge, MA), which received an average Part B payment of \$8,322 per beneficiary served in 2012. PTL specializes in drugs-of-abuse and pain management testing. PTL billed the Part B program for 143,736 units of service provided to 382 Medicare beneficiaries in 2012, according to CMS data. That equates to an average of 31 test codes billed per beneficiary per month. Last year, the Massachusetts Office of the State Auditor issued a report accusing PTL and two other labs of using deceptive billing practices, including unbundling, to circumvent price limits and overcharge the state's Medicaid program.

In addition to PTL, other pain management testing labs on the Top 30 list include **Nexus Lab 2.0 LLC** (Danville, KY), **PremierTox Laboratory** (Russell Springs, KY), **AmeriDrug Laboratories** (Loveland, CO) and **AvuTox Laboratories** (Rocky Mount, NC).

The second most expensive clinical lab was **XDx Inc.** (Brisbane, CA). XDx markets a proprietary gene expression test (AlloMap) to aid in heart transplant management. XDx received an average of \$5,335 in Part B payments per beneficiary served in 2012.

Two competing breast cancer testing labs were third and fourth. **Agendia Inc.** (Irvine, CA), which markets the MammaPrint test, received an average of \$3,815 in Part B payments per beneficiary in 2012. **Genomic Health** (Redwood City, CA), which markets the OncoType DX test, was paid an average of \$3,442 per Part B patient served in 2012.

Pathwork Diagnostics (Sunnyvale, CA), which developed the Pathwork Tissue of Origin Test to aid in diagnosis of patients with uncertain primary cancers, received an average Part B payment of \$3,299 per beneficiary. Pathwork was acquired by Response Genetics (Los Angeles, CA) in August 2013. Response Genetics received an average Part B payment of \$1,541 per beneficiary in 2012, according to CMS data.

Myriad Genetics (Salt Lake City, UT), which markets the BRACAnalysis test for assessing risk of breast and ovarian cancer, was paid an average of \$3,267 per Part B beneficiary in 2012.

Natural Molecular Testing Corp. (Renton, WA), which specializes in molecular testing for cancer, prenatal screening and infectious disease, received an average Part B payment of \$3,087 per beneficiary.

TOP 30 CLINICAL LABS RANKED BY AVERAGE MEDICARE PAYMENT PER BENEFICIARY

PROVIDER NAME	LOCATION	TOTAL UNIQUE BENEFICIARIES	TOTAL SERVICES	TOTAL MEDICARE PAYMENT	AVERAGE PAYMENT PER BENEFICIARY
PRECISION TESTING LABORATORIES	SOUTHBRIDGE, MA	382	143,736	\$3,179,179	\$8,322
XDX, INC.	BRISBANE, CA	1,880	3,595	10,029,593	5,335
AGENDIA INC.	IRVINE, CA	864	1,370	3,296,180	3,815
GENOMIC HEALTH	REDWOOD CITY, CA	14,335	15,325	49,334,918	3,442
PATHWORK DIAGNOSTICS INC.	SUNNYVALE, CA	707	3,569	2,332,679	3,299
MYRIAD GENETICS	SALT LAKE CITY, UT	16,554	3,889,582	54,083,068	3,267
NATURAL MOLECULAR TESTING CORP.	RENTON, WA	22,760	2,991,516	70,266,696	3,087
PRECISION THERAPEUTICS, INC.	PITTSBURGH, PA	2,812	106,569	8,591,522	3,055
BIOETHERANOSTICS, INC.	SAN DIEGO, CA	693	5,251	2,019,021	2,913
GENOPTIX, INC.	CARLSBAD, CA	18,289	759,546	50,162,159	2,743
AMBRY GENETICS CORPORATION	ALISO VIEJO, CA	994	126,049	2,676,896	2,693
UNIVERSITY OF MIAMI	MIAMI, FL	1,644	239,664	4,014,964	2,442
REDPATH INTEGRATED PATHOLOGY	PITTSBURGH, PA	1,275	2,098	3,068,232	2,406
AMERICAN INTL. BIOTECH (AIBIOTECH)	RICHMOND, VA	6,429	655,572	15,358,775	2,389
ASSURERX HEALTH, INC.	MASON, OH	4,176	452,858	9,846,215	2,358
HEMATOGENIX LABORATORY SERVICES	TINLEY PARK, IL	1,795	66,009	4,194,292	2,337
COMPANION DX REFERENCE LAB, LLC	HOUSTON, TX	1,165	230,905	2,485,031	2,133
INTERSCIENCE DIAGNOSTIC LABS, INC.	BROOKLYN, NY	863	19,688	1,705,088	1,976
MONOGRAM BIOSCIENCES (LABCORP)	SAN FRANCISCO, CA	2,249	12,210	4,338,151	1,929
TRANSGENOMIC, INC.	NEW HAVEN, CT	899	79,652	1,663,430	1,850
NEXUS LAB 2.0 LLC	DANVILLE, KY	3,730	259,706	6,564,482	1,760
CARIS MPI, INC.	PHOENIX, AZ	4,017	128,408	7,052,829	1,756
PATHOLOGY SERVICES.ORG LLC	LANSING, MI	1,125	88,172	1,833,271	1,630
RESPONSE GENETICS, INC.	LOS ANGELES, CA	2,874	212,974	4,430,222	1,541
PHARMACOGENETICS DIAGNOSTICS LAB	LOUISVILLE, KY	2,691	308,361	4,040,670	1,502
STRAND DIAGNOSTICS LLC	INDIANAPOLIS, IN	2,809	175,649	4,126,744	1,469
PREMIERTOX LABORATORY	RUSSELL SPRINGS, KY	5,195	282,850	7,115,081	1,370
AMERIDRUG LABORATORIES INC.	LOVELAND, CO	2,113	149,612	2,815,225	1,332
SIPARADIGM LLC	ORADELL, NJ	1,821	33,161	2,367,148	1,300
AVUTOX, LLC	ROCKY MOUNT, NC	5,738	281,464	7,258,415	1,265
TOTAL, TOP 30 CLINICAL LABS		132,878	11,725,121	350,250,180	2,636
TOTAL, ALL 2,743 CLINICAL LABS		26,223,745	364,776,133	\$4,824,116,149	\$184

Source: *Laboratory Economics* from CMS Part B data released in April 2014

DRUG TESTING NOW BIG BUSINESS

Drugs-of-abuse testing, which not long ago was thought of as dull, slow-growing and low margin, is now a \$2 billion-per-year business in the United States that is now characterized by fast growth, high profits, private equity backing, lawsuits and government investigations. Drugs-of-abuse testing has been transformed by the growth in pain medication prescriptions and associated monitoring tests.

The Medicare Part B program paid an estimated \$525 million to labs specializing in drugs-of-abuse testing in 2012. Including all payers, *LE* estimates that the U.S. drugs-of-abuse testing business is now over \$2 billion per year.

Millenium Laboratories (San Diego, CA), which was founded in 2007, generated \$190 million in Part B payments in 2012. Ameritox, which has labs in North Carolina and Texas, generated a total of \$100 million in Part B revenue. Aegis Sciences Corp. (Nashville, TN) generated \$36 million in Part B payments.

TOP DRUG TESTING LABS RANKED BY MEDICARE PART B REVENUE FOR 2012

PROVIDER NAME	LOCATION	TOTAL UNIQUE BENEFICIARIES	TOTAL PART B MEDICARE REVENUE	AVERAGE PAYMENT PER BENEFICIARY
MILLENNIUM LABORATORIES	SAN DIEGO, CA	188,893	\$190,031,769	\$1,006
AMERITOX, LTD.	GREENSBORO, NC	114,375	86,771,308	759
AEGIS SCIENCES CORP.	NASHVILLE, TN	66,583	36,150,368	543
ALERE TOXICOLOGY SERVICES	AUSTIN, TX	39,903	16,937,116	424
AIT LABORATORIES	INDIANAPOLIS, IN	37,411	13,845,881	370
AMERITOX, LTD.	MIDLAND, TX	25,938	12,781,951	493
DOMINION DIAGNOSTICS	N. KINGSTOWN, RI	20,736	12,551,313	605
ROCKY MOUNTAIN TOX LLC	DENVER, CO	16,701	8,667,932	519
AVUTOX, LLC	ROCKY MOUNT, SC	5,738	7,258,415	1,265
PREMIERTOX 2.0 INC.	RUSSELL SPRINGS, KY	5,195	7,115,081	1,370
CALLOWAY LABORATORIES	WOBURN, MA	19,433	6,918,973	356
NEXUS LAB 2.0 LLC	DANVILLE, KY	3,730	6,564,482	1,760
MEDTOX (LABCORP)	SAINT PAUL, MN	13,945	3,670,935	263
PRECISION TESTING LABS	SOUTHBRIDGE, MA	382	3,179,179	8,322
AMERIDRUG LABS INC.	LOVELAND, CO	2,113	2,815,225	1,332
LAB USA, INC.	HAVERHILL, MA	2,317	2,237,935	966
DRUGSCAN, INC.	HORSHAM, PA	7,377	2,157,335	292
ETHOS HOLDING CORP.	FAIRFIELD, OH	3,651	2,039,023	558
PHYSICIANS TOXICOLOGY LAB	KALAMAZOO, MI	2,663	2,038,531	766
AMER. FORENSIC TOXICOLOGY	HUNTINGTON, NY	4,085	1,810,514	443
QUEST, LABCORP & OTHERS*		400,000	100,000,000	250
MEDICARE PART B TOTALS		981,169	\$525,543,267	\$536

*Estimated by *Laboratory Economics*

Source: *Laboratory Economics* from CMS Part B data released in April 2014

CMS TO USE PRIVATE INSURANCE RATES (*cont'd from page 1*)

Under the new law, nearly all labs that receive Part B revenue will be required to report all private payer payment rates (after all discounts and other price concessions) and volumes for their tests to CMS beginning on January 1, 2016. CMS will then take this data and develop “weighted median” prices for each lab test on the CLFS. These prices will become the new payment rates for most tests effective January 1, 2017. No administrative or judicial review of payment rates is permitted under the law.

To avoid sudden significant fee cuts for existing tests, HR 4302 limits the rate cut for any given test to 10% per year during 2017-2019, and for the years 2020-2022 reductions may not exceed 15% per year.

The new law requires an officer of each reporting laboratory to certify the accuracy and completeness of the information given to CMS. Civil Money Penalties of up to \$10,000 per day may apply for each failure to report or each such misrepresentation or omission in reporting.

Laboratory Economics observes that the new method of setting lab test prices on the Part B CLFS could be dominated by the price data supplied by Quest Diagnostics and LabCorp. A key unanswered question is whether or not hospital labs will be required to submit their lab test pricing data. The inclusion of hospital data would tend to raise the weighted median price for each lab test. “It’s very important that the entire market, including hospital labs, be counted,” says Alan Mertz, President of the American Clinical Laboratory Assn.

Meanwhile, the new law makes a number of other important changes for labs. It eliminates the annual CPI adjustment to the CLFS starting in 2017. It also raises the specimen collection fee for services provided to nursing home or home health patients by \$2; effective January 1, 2017, the collection fee will be \$5. And finally, the implementation of ICD-10 coding has been delayed by one year to October 1, 2015.

MORE ON LABCORP’S CONTRACT WITH IBC

As previously reported last month, LabCorp has won a contract to become the exclusive national lab provider for Independence Blue Cross (IBC), which covers 2.2 million people in the Philadelphia region. Currently both Quest Diagnostics and LabCorp have contracts with IBC. Effective July 1, 2014, Quest Diagnostics is losing its contract with IBC. Thereafter only LabCorp and about a dozen other smaller labs and hospitals will be in-network lab providers to IBC.

The threat of significant cuts to the Medicare Part B CLFS seems to be leading LabCorp and other labs to seek longer-term contracts with private payers to lock in rates. For example, LabCorp’s contract with IBC has an 8-year term.

The LabCorp/IBC deal also illustrates the intensifying efforts to keep lab tests in-network. IBC is directing its providers to refer patients to an in-network lab to save on out-of-pocket costs. In addition, IBC is telling its providers that out-of-network labs should not be waiving member cost sharing (e.g., copays, coinsurance and deductibles) because it is a violation of federal anti-kickback laws when used in connection with Medicare and Medicaid. IBC is also instructing providers that routine waiver of cost-sharing may be a violation of the Federal False Claims Act, subject to investigation by the Office of Inspector General.

Private insurance plans like IBC have always encouraged the use of in-network labs. However, IBC may be the first plan to explicitly warn providers of the legal risks associated with using an out-of-network lab that waives member cost-sharing, notes *Laboratory Economics*.

PUBLICLY-TRADED LABS SHRINK BY 1% IN 2013

On a combined basis, 16 publicly-traded labs saw their revenue shrink by 0.8% to \$15.8 billion in 2013 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 14 publicly-traded labs grew by 7% last year (after adjusting for acquisitions).

Revenue growth was fastest at three cancer-testing lab companies—Foundation Medicine (up 172%), Cancer Genetics (up 54%) and Myriad Genetics (up 24%). The two companies reporting the largest revenue declines were Transgenomic (down 12.5%) and Aurora Diagnostics (down 10.7%).

Acquisition-adjusted revenue for Quest Diagnostics was down 4.3% last year, while LabCorp's revenue was flat. The third largest U.S. lab company, Bio-Reference Labs, had estimated revenue growth of 11% (after adjustments for the acquisitions of Meridian Clinical Lab, Florida Clinical Lab and Hunter Laboratories).

Revenue Growth at 16 Publicly-Traded Lab Companies (\$000)

Company	Revenue 2013	Revenue 2012	Reported Change	Pro Forma Change*
Quest Diagnostics	\$7,146,000	\$7,382,562	-3.2%	-4.3%
LabCorp	5,808,300	5,671,400	2.4%	0.0%
Bio-Reference ⁽¹⁾	715,354	614,255	16.5%	11.0%
Sonic Healthcare USA ⁽²⁾	702,490	717,490	-2.1%	-2.1%
Myriad Genetics ⁽³⁾	613,165	496,005	23.6%	23.6%
Genomic Health	261,595	235,173	11.2%	11.2%
Aurora Diagnostics	248,169	277,886	-10.7%	-10.7%
NeoGenomics	66,467	59,867	11.0%	11.0%
Enzo Clinical Labs ⁽⁴⁾	55,889	59,403	-5.9%	-5.9%
LipoScience	52,383	54,798	-4.4%	-4.4%
Foundation Medicine	28,990	10,645	172.3%	172.3%
Transgenomic Inc.	27,544	31,480	-12.5%	-12.5%
Psychemedics	26,870	25,224	6.5%	6.5%
Response Genetics	19,801	18,737	5.7%	5.0%
Cancer Genetics	6,610	4,302	53.6%	53.6%
Combimatrix	6,367	5,350	19.0%	19.0%
Total, 16 companies	\$15,785,994	\$15,664,576	0.8%	-1.0%
Total, 14 companies (excluding Quest and LabCorp)	\$2,831,694	\$2,610,614	8.5%	7.0%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

¹Bio-Reference's revenue is for fiscal year ended October 31, 2013; ²Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2013; ³Myriad Genetics' revenue is for fiscal year ended June 30, 2013; ⁴Enzo's revenue is for lab services only for fiscal year ended July 30, 2013.

Source: *Laboratory Economics* from company reports

LAB STOCKS UP 12% YTD

Fourteen lab stocks increased an average of 12% year to date through April 17. In comparison, the S&P 500 Index is up 1% and the Nasdaq is up 4%. The top-performing lab stock so far this year is Myriad Genetics, up 81%, followed by Enzo Biochem, up 47%. LabCorp is up 9% and Quest Diagnostics is up by 11%.

Company (ticker)	Stock Price 4/17/14	Stock Price 12/31/13	2013 Price Change	Market Capitalization (\$ millions)	P/E Ratio	Price/Sales	Price/Book
Bio-Reference (BRLI)	\$27.20	\$25.54	6%	\$754	18.8	1.0	2.8
Cancer Genetics Inc. (CGIX)	15.34	13.78	11%	142	NA	21.5	3.1
CombiMatrix (CBMX)	2.61	2.30	13%	29	NA	4.5	1.8
Enzo Biochem (ENZ)	4.29	2.92	47%	183	NA	1.9	5.4
Foundation Medicine (FMI)	26.54	23.82	11%	734	NA	7.4	5.6
Genomic Health (GHDX)	26.81	29.27	-8%	836	NA	3.2	5.7
LabCorp (LH)	99.45	91.37	9%	8,613	15.8	1.6	3.5
LipoScience (LPDX)	3.21	4.25	-24%	49	NA	0.9	1.0
Myriad Genetics (MYGN)	37.97	20.98	81%	2,771	16.3	4.0	4.2
NeoGenomics (NEO)	3.15	3.62	-13%	155	63.0	2.3	7.1
Psychemedics (PMD)	16.85	14.69	15%	90	23.4	3.3	7.3
Quest Diagnostics (DGX)	59.48	53.54	11%	8,581	10.7	1.2	2.2
Response Genetics (RGDX)	1.16	1.16	0%	45	NA	2.3	8.0
Sonic Healthcare (SHL.AX)	17.61	16.58	6%	7,058	19.3	1.9	2.3
Unweighted Averages			12%		23.9	4.1	4.3

Source: Zacks and Bloomberg

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