

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PALMETTO TAKES AIM AT CODE STACKING

Medicare carrier Palmetto GBA is rolling out its ambitious Molecular Diagnostics Services Program (MolDx) 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.

“California has a high concentration of MDTs and the need to bring some transparency to that group of tests is a priority,” Mike Barlow, J1 program manager at Palmetto GBA, tells *Laboratory Economics*. The goal is to assign new McKesson Z-Codes, perform technical assessments and make coverage decisions on all MDTs that report a single test result, but are billed using code stacks.

National Medicare Part B carrier spending on code-stacked MDTs grew by 43% per year between 2005 and 2010, and reached an estimated \$150 million in 2011. *Continued on pages 5-8.*

FINAL 3 MEDI-CAL LAWSUITS SETTLED, BUT QUESTIONS ON LAB TEST PRICING REMAIN

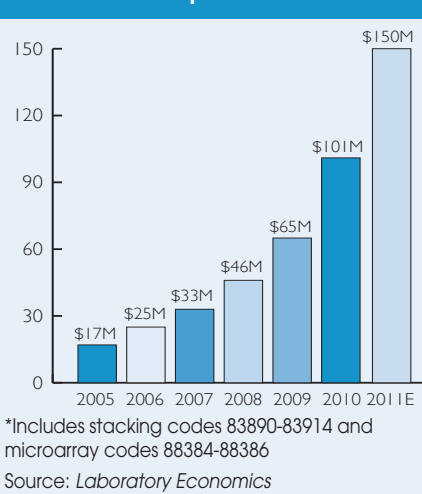
On November 18, three independent labs announced settlement agreements to resolve their respective Medi-Cal lab test pricing cases with the California Attorney General. Physicians Immunodiagnostic Laboratory (PIL) will pay the State \$600,000, Primex Clinical Laboratories (PCL) will pay \$750,000 and Whitefield Medical Laboratory (WML) will pay \$400,000.

All the Medi-Cal pricing lawsuits have now been settled, including Quest Diagnostics’ record-setting \$241 million settlement and LabCorp’s \$49.5 million settlement.

“While the cases have concluded, all labs need further guidance from Medi-Cal on how to charge the program,” says Dawn Brewer, attorney for PIL, PCL and WML. “I know of no laboratory owner, other than Chris Riedel, who believes his suit benefited any independent labs,” she adds.

Continued on page 2.

Part B Carrier Expenditures on MDTs*



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FINAL 3 MEDI-CAL LAWSUITS SETTLED *(continued from page 1)*

In total, eight lab companies paid more than \$300 million to settle allegations that they over-charged California's Medi-Cal program for lab tests. The lawsuit was originally filed under seal in 2005 by whistleblower Chris Riedel and his company Hunter Labs. Three years later the California Attorney General intervened. Later the lawsuits were separated into individual cases.

Riedel received more than \$75 million of the settlement proceeds and was named this year's "Whistleblower of the Year" by the Tax Payers Against Fraud Education Fund.

But Brewer says Riedel's lawsuit was unfair to her clients and other independent labs in California:

Medi-Cal Lawsuit Settlements

Quest Diagnostics	\$241M
LabCorp	49.5M
Westcliff Medical Labs	5.2M
Stanford Medical Labs	~\$2.5M
Primex Clinical Labs	750K
Physicians Immunodiagnostic Lab	600K
Whitefield Medical Lab	400K
Seacliff Diagnostics Medical Group	275K
Total	>\$300M

Source: *Laboratory Economics*

Riedel's filing of the false claims action under seal gave both Quest and LabCorp years of advance notice of the inquiry before the public or the small labs named in the suit. During these years, most independent labs lost some market share to one or both of these labs as those labs continued pricing their services below Medi-Cal rates. Since the Quest and LabCorp settlements, our clients are finding that these labs continue to price their services below Medi-Cal rates and our clients perceive their settlement agreements as creating the opportunity for this to continue during 2012. Riedel's suit and the settlements failed to secure any clarification of the ambiguous Medi-Cal regulation. In sum, our lab clients believe the suit made it more difficult, if not impossible, for the smaller labs to compete and the suit is directly responsible for lower revenues.

In response, Riedel says:

Ms. Brewer is right that Quest and LabCorp have not yet changed their practices. To allow time for Quest and LabCorp to restructure hundreds of contracts, the settlement provided that the Medi-Cal program will receive a 15% discount until August 2012. Thereafter, all discounts, including capitation, must be passed on to the Medi-Cal program. It is apparent from Ms. Brewer's quote that she has limited knowledge of the lab industry. The settlement has the support of the California Society for Pathologists and I have received many calls from other labs thanking me for taking on these industry giants in an attempt to level the playing field and stop taxpayers from being ripped off. Among them is the General Manager of the 47 hospital outreach programs for Catholic Healthcare West and the Medical Director of the University of California San Diego Clinical Laboratories.

One thing for sure, though, is that the lawsuits placed a tremendous burden on the small independent labs that were charged.

"This resolution to the costly and disruptive detour from running our business demonstrates that despite the competitive disadvantages of being named a defendant in the case, we defended our

practices as fair and in compliance with the dozens if not hundreds of billing instructions that govern our industry,” according to Erik Avannis-Aghajani, PhD, vice president at Primex Clinical Labs (Van Nuys, CA).

“The 130 employees of PIL feel vindicated by the agreement, and we are recommitting ourselves to maintaining the highest standard of conduct for our industry. We hope the conclusion of the case will now lead to a dialogue with regulators about what is needed to ensure a level playing field and open competition among labs of all sizes,” says Alfred Ramzi, chief executive of Physicians Immunodiagnostic Laboratory (Burbank, CA).

“Our clients—and our competitors for that matter—understood that we vehemently denied that we had improperly charged Medi-Cal for testing. We are anxious to return our focus to service to our loyal and valued clients,” stated Jatin Laxpati, president of Whitefield Medical Laboratory (Pomona, CA).

However, not all of the independent labs sued by Riedel and the California AG survived. Seaclyff Diagnostics Medical Group (Monterey Park, CA) is out of business and its owner and president, John Hiserodt, MD, has filed for Chapter 7 bankruptcy. Hiserodt listed assets of \$1.6 million versus liabilities of \$5.7 million, according to the filing made at the U.S. Bankruptcy Court for the Central District of California on October 21, 2011. Liabilities included \$237,489 in lawsuit settlement expenses owed to the California Department of Health Care Services, Medi-Cal Division. A second lab owned by Hiserodt, Central Medical Laboratory (Cypress, CA), is in the process of shutting down.

LABCORP MANAGER CHARGED WITH FRAUD

A federal grand jury has indicted Eric Engle, age 36, with wire fraud for allegedly stealing \$342,430 from LabCorp.

According to the indictment, Engle was employed as a patient service territory manager for LabCorp in St. Louis between 2007 and September 2011. Engle’s duties included the collection of money for services rendered as well as payment of expenses necessary to manage the centers.

The indictment alleges that during his employment with LabCorp, Engle created a fictitious cleaning service company called OptiClean. He allegedly created false invoices from OptiClean for work that was never done. Engle faxed the fake bills to LabCorp in North Carolina. LabCorp would then pay the bills and mail checks to a St. Louis post office box, according to the charges.

OptiClean was created Jan. 25, 2008, and Engle was the registered agent, according to records with the Missouri Secretary of State’s office. LabCorp paid \$342,430 to OptiClean during the four years that the alleged scheme lasted.

If convicted, Engle faces up to 20 years in prison and fines up to \$1 million.

In a similar case settled a few years ago, David Smith, former facilities manager for Quest Diagnostics in Tampa, Florida, was sentenced to five years in prison and agreed to forfeit his house, after pleading guilty to charges of expense report fraud (see *LE*, June 2008, page 11). Between January 2001 and September 2007, Smith stole \$1.3 million by billing Quest for expenses from fictitious companies.

LABCORP COMPLETES ACQUISITION OF ORCHID

LabCorp has finally completed its acquisition of Orchid Cellmark (Princeton, NJ) for \$2.80 per share in cash for a total purchase price of \$85 million. The price tag is equal to about \$71 million after accounting for the \$14 million in cash and short-term securities held by Orchid.

The acquisition was originally announced in April (see *LE*, April 2011, pp. 1-2), but the Federal Trade Commission blocked the deal alleging that it would give LabCorp a near monopoly on U.S. government paternity testing services.

Government agencies contract with labs to provide DNA testing services to resolve paternity issues. The FTC had argued that LabCorp and Orchid are the two biggest providers of these paternity testing services, and have an overwhelming majority of this \$27 million per year market. They consistently have been head-to-head competitors for these contracts, the FTC complaint alleged.

Under the terms of the consent decree with the FTC, LabCorp is required to sell Orchid's U.S. government paternity business to another company, DNA Diagnostics Center (Fairfield, OH), which is the largest provider of private DNA paternity testing services.

Orchid's U.S. government paternity testing business represented roughly \$15 million in revenues and the deal will add roughly \$50 million in annual revenues to LabCorp after the divestiture.

In connection with the sale, Thomas Bologna, former president and chief executive of Orchid, received a payout totaling \$3 million. This included \$871,938 for his stock and options plus a lump-sum cash severance package worth \$2.1 million. In addition, Bologna will get 36 months of family healthcare coverage worth \$77,337.

PATHOLOGY INC. BUYS WEST COAST CLINICAL LABS

Pathology Inc. (Torrance, CA) has purchased West Coast Clinical Laboratories (WCCL-Van Nuys, CA). In connection with the transaction, Pathology Inc. issued \$20.7 million of equity securities in early December.

WCCL, which has 120 employees, is a full-service lab focused on women's health and reproductive donor testing for in-vitro fertilization clinics and OB/Gyns. WCCL has estimated annual revenue of more than \$10 million. WCCL was founded in 1990 by Yair Kempler and Shuli Suman. Yair will now serve as a consultant to Pathology Inc. Suman will be the general manager of WCCL and executive vice president of Women's Health Services.

Earlier this year, Pathology Inc. purchased Central Coast Clinical Laboratories (Templeton, CA). In connection with this deal, Pathology Inc. issued \$8.9 million of equity securities in January.

Pathology Inc. is owned by the private equity investment firm ABS Capital Partners (Baltimore, MD). With its two acquisitions, Pathology Inc. now has more than 300 employees and estimated annual revenue of nearly \$50 million.

ABS Capital has backed other lab companies, such as Inform DX (sold to AmeriPath for \$55 million), US Pathology Labs Inc. (sold to LabCorp for \$155 million) and American Esoteric Laboratories (sold to Sonic Healthcare for \$180 million).

PALMETTO TAKES AIM AT CODE STACKING (*cont'd from page 1*)

Labs will be required to obtain new McKesson Z-Codes (5-character alphanumeric code, starting with the letter Z) for tests that use more than one CPT code to identify the service, including the methodology-based stacking CPT codes (83890-83914) and micro-array codes (88384-88386).

Under a contract with Palmetto GBA, McKesson will offer its Web-based platform for labs to apply for Z-Codes. Over the next few months, McKesson is expected to assign more than 1,000 new codes. A unique Z-Code will be assigned to each unique test offered by every lab. Eaton Dunkelberger, assistant vice president at McKesson Health Solutions, expects the granting of Z-Codes to move swiftly.

Effective March 1, 2012, all molecular diagnostic claims submitted to Palmetto J1 will be required to post their Z-Code in the narrative/comment field on claims.

Dunkelberger says that the addition of Z-Codes to the Medicare claims process for molecular diagnostics will not replace American Medical Association-issued CPT codes. Palmetto's stated intent is to reimburse in the same manner they are reimbursing today, since the same CPT codes currently used can still be used on a claim that also has a Z-Code. The Z-Codes are meant to offer Palmetto a way to track test utilization with greater clarity than the current coding system allows, according to Dunkelberger.

"We're not going to interrupt payment as long as each MDT has received a Z-Code by March 1," says Barlow. But over time, he expects labs to voluntarily submit analytical and clinical validity evidence so that Palmetto can make technical assessments and coverage decisions for each MDT. Barlow says that Palmetto made approximately 20 lab test coverage decisions in California in 2011. This year he anticipates that Palmetto will make between 150 and 500 coverage decisions.

Lale White, chief executive at the billing management firm Xifin (San Diego, CA), says, "While the Z-Codes in and of themselves do not require a re-pricing, the MolDx program along with the two Local Coverage Decisions that support its implementation provide a path for re-pricing tests and Palmetto has already indicated that they believe the stacking code reimbursement levels are too high."

National Medicare Part B carrier spending on code-stacked molecular diagnostics reached an estimated \$150 million in 2011. Total spending on these codes by all payers was an estimated \$750 million.

Market Size and Growth for Molecular Dx Stacking Codes*

Year	Part B Carrier Allowed Charges	Annual Growth Rate	Medicare Multiplier	Estimated U.S. Market Size
2005	\$16,559,331		5.0	\$82,796,655
2006	\$25,017,835	51.1%	5.0	\$125,089,175
2007	\$33,079,517	32.2%	5.0	\$165,397,585
2008	\$46,494,675	40.6%	5.0	\$232,473,375
2009	\$65,169,717	40.2%	5.0	\$325,848,585
2010	\$100,551,262	54.3%	5.0	\$502,756,310
2011E	\$150,000,000	49.2%	5.0	\$750,000,000

*Includes stacking codes 83890-83914 and microarray codes 88384-88386

Source: *Laboratory Economics*

THE PROBLEM WITH CODE STACKING

Medicare carriers and private payers have been complaining for years about not being able to manage the utilization of molecular tests or track what they pay for them. That's because the molecular diagnostic codes are generic and describe methodologies rather than specific tests.

Different labs use different methodologies to perform the same test, resulting in different stacks of CPT codes on their claim forms. Even labs using the same methodology to perform the same test may not necessarily submit an identical stack of CPT codes.

Because the molecular diagnostic codes are generic and stacked differently from lab to lab, it's impossible for payers to identify these claims as a specific test. In other words, payers don't know what they are paying for.

"The selection of code stacks is wholly subject to each lab's testing methodology and interpretation of coding. There is no 100% correct way of doing things. But just like any other business, some labs are taking full advantage of the ambiguity to maximize their revenue," says Mike Barlow, J1 program manager at Palmetto GBA.

A good example is KRAS mutation analysis, which is used to help determine which colorectal cancer patients will benefit from the cancer drugs Erbitux or Vectibix. Approximately 30% to 50% of colorectal cancer patients have KRAS mutations and are not responsive to either drug.

An analysis of test menus at six major reference labs shows that each lab uses its own unique group of CPT codes to bill for KRAS testing. ARUP Labs bills for a stack of seven codes with a total Medicare charge of \$302.91, while Clariant stacks 28 codes for a total of \$636.63. GenPath, Genzyme Genetics, Mayo Medical Labs and Quest Diagnostics each have different code stacks with different claims totals as well.

KRAS Mutation Analysis Comparison

Laboratory:	ARUP	Clariant	GenPath	Genzyme Genetics	Mayo	Quest Diagnostics
Code stack:	83898(x2)	83891	83891	83890	83890	83891
	83904(x2)	83896(x8)	83892	83898	83896(x7)	83892(x2)
	83907	83898(x8)	83900	83907	83898(x7)	83898(x2)
	83912	83907	83901(x4)	83909(x2)	83912	83904(x4)
	88381	83912	83904(x5)	83912	88387	83909(x4)
		83914(x8)	83912	83914(x4)		83912
		88381		88381		
Charge:	\$302.91	\$636.63	\$276.32	\$379.29	\$256.25	\$258.36

Source: *Laboratory Economics* from company test menus and Medicare Part B fee schedule

Another case in point is EGFR mutation analysis, which is used to help guide treatment of some cancers (e.g., colon and non-small-cell lung cancer) and to determine whether a patient can benefit from the drugs Tarceva or Iressa. There is no single CPT code used to bill for EGFR testing and coding varies from lab to lab.

For example, Clariant bills a stack of codes (83907, 83900 x2, 83901 x18, 83891, 83896 x29, 83898 x6, 88381, 83914 x29 and 83912) for EGRF mutation analysis for a total charge of \$1,721.89 under the Medicare Part B national limit amount. In contrast, Quest Diagnostics bills (83891, 83892, 83898 x4, 83904 x4, 83909 x4 and 83912) for a total charge of \$299.88.

EGFR Mutation Analysis

Laboratory:	ARUP	Clariant	GenPath	Genzyme Genetics	Mayo	Quest Diagnostics
Code stack:	83892 83896(x2) 83898(x2) 83907 83909 83912 88381	83891 83896(x29) 83898(x6) 83900(x2) 83901(x18) 83907 83912 83914(x29) 88381	83891 83892 83898(x7) 83904(x7) 83909(x7) 83912	83890 83898(x12) 83900 83901(x2) 83907 83909(x8) 83912 88381	83890, 83892(x4) 83898(x4) 83900 83901(x2) 839049(x8) 83907 83912 88381	83891 83892 83898(x4) 83904(x4) 83909(x4) 83912
Charge:	\$296.25	\$1,721.89	\$512.10	\$780.17	\$802.73	\$299.88

Source: *Laboratory Economics* from company test menus and Medicare Part B fee schedule

UGT1A1 genotyping, which is used to help determine which colorectal cancer patients will benefit from the cancer drug Camptosar, is another common molecular test that is code stacked. In this case, four labs (ARUP, LabCorp, PAML and University of Chicago Genetics Center) bill similarly for the test. The two outliers are Molecular Pathology Lab Network (MPLN), which charges \$312.72 and Quest Diagnostics, which charges \$150.72.

UGT1A1 Genotyping

Laboratory:	ARUP	LabCorp	MPLN	PAML	Quest Diagnostics	University of Chicago
Code stack:	83891 83898 83909 83912	83891 83898 83909 83912	83891 83892(x8) 83896(x12) 83903(x4) 83908(x4) 83912	83891 83898 83909 83912	83891 83892(x4) 83896(x4) 83908(x4) 83912	83891 83898(x2) 83912
Charge:	\$58.44	\$58.44	\$312.72	\$58.44	\$150.72	\$58.44

Source: *Laboratory Economics* from company test menus and Medicare Part B fee schedule

Another common molecular diagnostic test that is code stacked is BCR/ABL quantitative, which is used to diagnosis chronic myeloid leukemia and monitor treatment with Gleevec. Among six labs, the charges ranged from \$102.43 at ARUP to \$349.36 at NeoGenomics.

BCR/ABL Quantitative

Laboratory:	ARUP	Clariant	Cleveland Clinic	Genzyme Genetics	Neo Genomics	Quest Diagnostics
Code stack:	83891 83898(x2) 83902 83904 83912	83891 83892(x2) 83896(x2) 83902(x2) 83912	83891 83896(x4) 83898(x4) 83902 83912	83891 83896(x4) 83898(x4) 83902 83912	83891 83892 83896(x8) 83898(x8) 83902(x4) 83907 83912	83891 83896(x3) 83898(x3) 83901 83902(x2) 83912
Charge:	\$102.43	\$120.94	\$148.13	\$148.13	\$349.36	\$162.46

Source: *Laboratory Economics* from company test menus and Medicare Part B fee schedule

Code stacking becomes even more confusing to payers when labs bill for panels of tests that use code stacking.

For example, Quest Diagnostics offers its Lung Cancer Mutation Panel (includes EGFR, KRAS, ALK) to predict patient eligibility for non-small-cell lung cancer targeted therapies such as Iressa, Tarceva and Xalkori.

This panel of tests is billed using nine different CPT codes, according to the test menu at Quest's Nichols Institute. Some codes are billed multiple times so the total number of codes used is 32. Based on the Medicare Part B fee schedule for 2011, the total charge for this test would be \$698.61.

Quest's Lung Cancer Mutation Panel might be a bargain given that the cancer drugs involved cost thousands of dollars per month. Nonetheless, Palmetto and other payers want more specific information on billing claims for these tests.

Quest's Lung Cancer Mutation Panel

CPT Code	Medicare Fee 2011	Quantity Billed	Charge
83891	\$5.64	x1	\$5.64
83892	\$5.64	x3	\$16.92
83898	\$23.58	x6	\$141.48
83904	\$23.58	x8	\$188.64
83909	\$23.58	x8	\$188.64
83912	\$5.64	x2	\$11.28
88271	\$30.14	x2	\$60.28
88275	\$56.51	x1	\$56.51
88291	\$29.22	x1	\$29.22
Totals		32	\$698.61

Source: *Laboratory Economics* from company test menu and Medicare Part B fee schedule

101 NEW CPT CODES FOR MOLECULAR PATHOLOGY

Palmetto is moving forward with the assignment of McKesson Z-Codes to MDTs in California, Nevada and Hawaii. At the same time, the national Medicare program is rolling out 101 additional molecular pathology procedure test codes established by the American Medical Association (AMA).

"As of January 1, 2012, Medicare requests that Medicare claims for molecular pathology procedures reflect both the existing CPT 'stacked' test codes that are required for payment and the new single CPT test code that would be used for payment purposes if the new CPT test codes were active," according to CMS's recently released Calendar Year 2012 Annual Update for Clinical Laboratory Fee Schedule.

Medicare claims for MDTs will continue to be reimbursed by the stacked CPT code fees. However, Medicare is requesting that claims also report a charge for the new non-payable 101 molecular codes.

The Medicare program is likely to use these reported (but non-payable) charges to help set reimbursement prices for the 101 new molecular codes in 2013.

IN-OFFICE PATHOLOGY TREND STRONGEST AT DERM PRACTICES

A total of 233 in-office pathology labs received CLIA certification in 2011, according to an analysis of Clinical Laboratory Improvement Amendments (CLIA) application forms data by *Laboratory Economics*. That's a record.

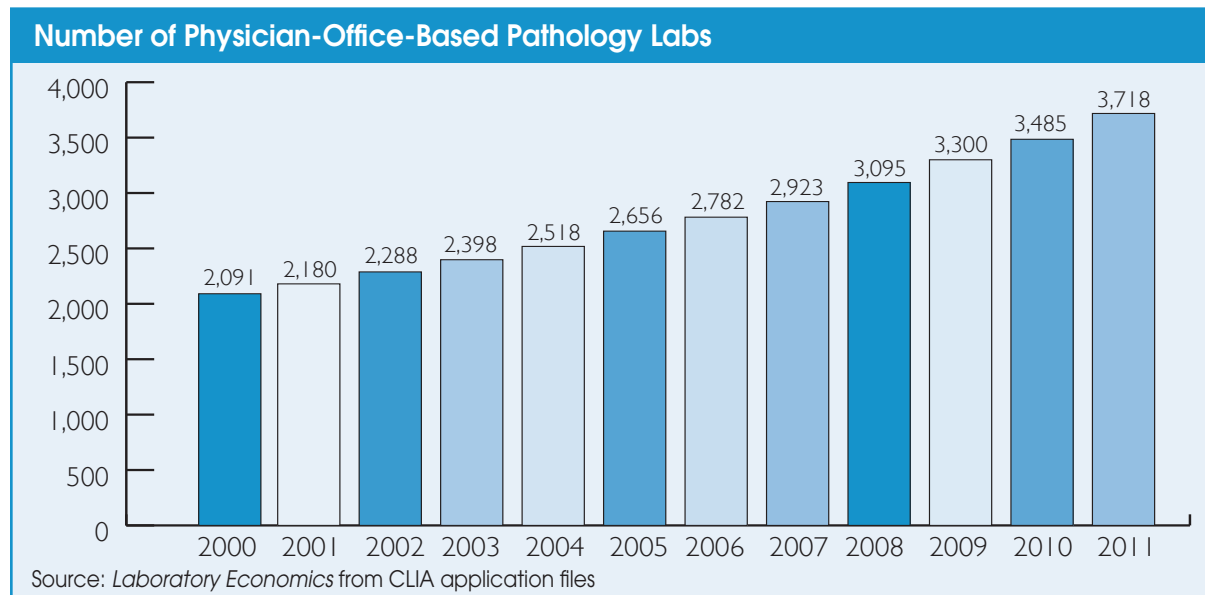
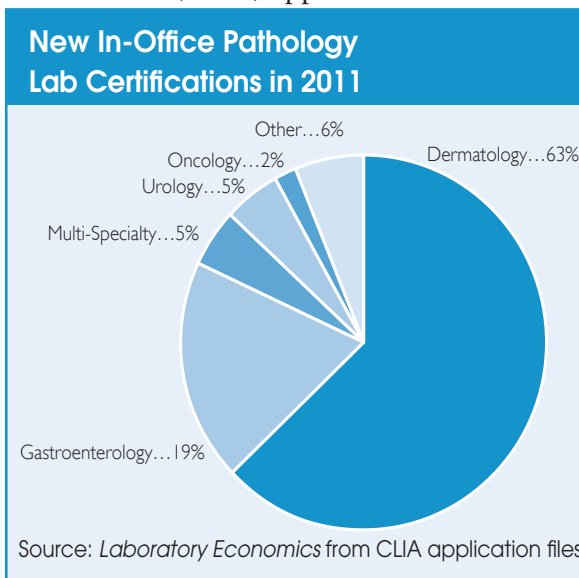
The previous record was in 2009 when 205 in-office pathology labs were CLIA certified. There are now a grand total of 3,718 physician offices certified to perform pathology testing.

Dermatology groups were most active in 2011. They opened 146 pathology labs representing 63% of all new in-office labs. Among the larger dermatology groups opening pathology labs was Mid Florida Dermatology Associates (Orlando, FL), with 10 doctors, including two dermatopathologists.

Gastroenterology groups opened 45 new in-office labs in 2011. Gastroenterology groups opening pathology labs included Gastro Health (Miami, FL), with 31 doctors; The Oregon Clinic - Portland GI, 31 doctors; Virginia Endoscopy Group (Richmond, VA), 30 doctors; Gastroenterology Associates (Kingsport, TN), 13 doctors; and Illinois Gastroenterology Institute (Peoria, IL), 11 doctors.

Most big urology groups have already opened in-office pathology labs and 11 more groups opened labs in the past year. These included Carolina Urology Partners (Huntersville, NC), with 37 doctors; Urological Associates of Dothan (Dothan, AL), eight doctors; and San Fernando Valley Urological Associates (Tarzana, CA), with six urologists and a staff pathologist.

Big oncology groups have also begun opening up their own pathology labs. For example, Florida Cancer Specialists (Fort Myers, FL), which employs more than 100 oncologists, opened a pathology lab and hired two hematopathologists in early 2011. And so did Comprehensive Blood and Cancer Center (Bakersfield, CA), which has 12 oncologists and a staff pathologist.



300 UROLOGY GROUPS NOW HAVE IN-OFFICE LABS

An estimated 300 urology groups representing about 2,000 urologists have now opened in-office pathology labs, according to an analysis of CLIA lab certifications by *Laboratory Economics*.

Urology group activity in constructing in-office pathology labs was greatest between 2008 and 2010. During these three years an average of more than 20 urology groups opened in-office labs per year. Activity has now slowed because most big urology groups (10+ doctors) already have their own labs.

The consulting firm In-Office Pathology (Lake Forest, IL) estimates that the average office-based urologist generates 1,000 billable 88305s per year. Add in special stains, cytology and UroVysion bladder cancer testing and each urologist is the source of about \$150,000 in pathology revenue per year, including \$50,000 from professional services and \$100,000 from technical work.

Overall, *LE* estimates that \$300 million per year of pathology work (professional and technical) is now being performed at in-office labs at urology groups.

Top 25 Urology Groups with In-Office Pathology Labs

Name of Group	Location	#Docs	Estimated # 88305s	Pathology Revenue
Michigan Institute of Urology	St. Clair Shores, MI	54	54,000	\$8,100,000
UroPartners LLC	Chicago, IL	52	52,000	\$7,800,000
Chesapeake Urology Associates	Baltimore, MD	50	50,000	\$7,500,000
Urology Associates of North Texas	Dallas, TX	50	50,000	\$6,750,000
Carolina Urology Partners	Huntersville, NC	37	37,000	\$5,550,000
Georgia Urology	Atlanta, GA	37	37,000	\$5,550,000
Academic Urology of Pennsylvania	Rosemont, PA	36	36,000	\$5,550,000
Comprehensive Urology	Royal Oak, MI	35	35,000	\$5,400,000
The Urology Group	Cincinnati, OH	34	34,000	\$5,100,000
Urology of Indiana	Greenwood, IN	34	34,000	\$5,100,000
Delaware Valley Urology	Marlton, NJ	33	33,000	\$4,950,000
Urology Associates	Nashville, TN	30	30,000	\$4,500,000
Urology San Antonio	San Antonio, TX	30	30,000	\$4,500,000
Urology Specialty Group	Miami, FL	30	30,000	\$4,500,000
Virginia Urology	Richmond, VA	29	29,000	\$4,050,000
Urology Group of New Jersey	West Orange, NJ	27	27,000	\$3,750,000
Central Ohio Urology Group	Columbus, OH	25	25,000	\$3,750,000
Metro Urology	St. Paul, MN	25	25,000	\$3,750,000
Urology Health Specialists LLC	Philadelphia, PA	25	25,000	\$3,750,000
Arizona Urology Specialists	Phoenix, AZ	24	24,000	\$3,600,000
Garden State Urology	Whippany, NJ	24	24,000	\$3,600,000
Western NY Urology Associates	Buffalo, NY	23	23,000	\$3,450,000
Urology Specialists of West Florida	Clearwater, FL	22	22,000	\$3,300,000
Boston Urology Institute	Norwood, MA	21	21,000	\$3,150,000
Houston Metro Urology	Houston, TX	19	19,000	\$2,850,000
Total 25 Big Groups		806	806,000	\$120,600,000
Total All Urology Groups		2,000	1,750,000	\$300,000,000

Source: *Laboratory Economics*

250 GASTRO GROUPS NOW HAVE IN-OFFICE LABS

An estimated 250 gastroenterology groups representing about 1,500 gastroenterologists, now operate in-office pathology labs, according to an analysis of CLIA lab certifications by *Laboratory Economics*. GI groups opened an average of 10 to 20 in-office pathology labs per year between 2006 and 2010. A record 45 labs were opened in 2011.

On an annual basis, the average office-based gastroenterologist performs about 500 biopsy procedures with an average 2.2 tissue samples per patient. This equals roughly 1,000 billable 88305s per year per gastroenterologist, plus special stains. So the average GI doctor is the source of roughly \$125,000 in pathology revenue (technical and professional) per year.

The nation's biggest GI group, Digestive Health Associates of Texas (Dallas, TX), employs 77 gastroenterologists at 31 clinics in the Dallas/Fort Worth area. DHAT performs and bills for histology services and contracts with Quest/AmeriPath for professional services. The group is the source of an estimated \$9.6 million in annual pathology service revenue (professional and technical).

Overall, *LE* estimates that \$187.5 million per year of pathology work is now being performed by in-office labs at gastroenterology groups.

Top 25 Gastroenterology Groups with In-Office Pathology Labs

<i>Name of Group</i>	<i>Location</i>	<i>#Docs</i>	<i>Estimated # 88305s</i>	<i>Pathology Revenue</i>
Digestive Health Associates of Texas	Dallas, TX	77	77,000	\$9,625,000
Minnesota Gastroenterology	Minneapolis, MN	63	63,000	\$7,875,000
Atlanta Gastroenterology Associates	Atlanta, GA	58	58,000	\$7,250,000
Capital Digestive Care	Silver Spring, MD	55	55,000	\$6,875,000
Arizona Digestive Health	Phoenix, AZ	53	53,000	\$6,625,000
Digestive Care	Coral Springs, FL	50	50,000	\$6,250,000
Texas Digestive Disease Consultants	Dallas, TX	46	46,000	\$5,750,000
Gastro Health	Miami, FL	31	31,000	\$3,875,000
The Oregon Clinic-Portland GI	Portland, OR	31	31,000	\$3,875,000
Illinois Gastroenterology Group	Libertyville, IL	30	30,000	\$3,750,000
Virginia Endoscopy Group	Richmond, VA	30	30,000	\$3,750,000
Florida Digestive Health Specialists	Bradenton, FL	25	25,000	\$3,125,000
Ohio Gastroenterology Group	Columbus, OH	25	25,000	\$3,125,000
Austin Gastroenterology	Austin, TX	23	23,000	\$2,875,000
Rocky Mountain Gastroenterology	Denver, CO	22	22,000	\$2,750,000
Dayton Gastroenterology	Beavercreek, OH	22	22,000	\$2,750,000
Ohio Gastro and Liver Institute	Cincinnati, OH	21	21,000	\$2,625,000
Digestive Health Specialists	Tacoma, WA	21	21,000	\$2,625,000
Gastro One	Germantown, TN	20	20,000	\$2,500,000
Northern California Gastroenterology	Berkeley, CA	20	20,000	\$2,500,000
Asheville Gastroenterology	Asheville, NC	18	18,000	\$2,250,000
Gastroenterology Consultants	Reno, NV	18	18,000	\$2,250,000
GI Associates and Endoscopy Center	Jackson, MS	18	18,000	\$2,250,000
Midwest Gastrointestinal Associates	Omaha, NE	18	18,000	\$2,250,000
Gastro Associates of North Texas	Fort Worth, TX	16	16,000	\$2,000,000
Total 25 Big Groups		811	811,000	\$101,375,000
Total All Gastro Groups		1,500	1,500,000	\$187,500,000

Source: *Laboratory Economics*

LAB STOCKS DOWN 8% YEAR TO DATE

Ten lab stocks have fallen by an unweighted average of 8% so far this year through December 16. The combined market capitalization for the group is currently \$20.2 billion. In comparison, the S&P 500 Index is down 3% and the Nasdaq is down 4%. The top-performing lab stock so far this year is Genomic Health, up 23%. Meanwhile, the stock price of LabCorp is down 7% and Quest is up 4%.

Company (ticker)	Stock Price 12/31/10	Stock Price 12/16/11	2011 Price Gain	Market Capitalization (\$ millions)	Earnings Past 12 Months	Price-to-Earnings Ratio
Bio-Reference (BRLI)	\$22.18	\$15.51	-30%	\$434	\$1.29	12.0
CombiMatrix (CBMX)	2.15	1.59	-26%	17	-0.81	NA
Enzo Biochem (ENZ)	5.28	2.13	-60%	82	-0.43	NA
Genomic Health (GHDX)	21.39	26.30	23%	777	0.23	114.3
LabCorp (LH)	87.92	81.63	-7%	8,090	5.73	14.2
Medtox Scientific (MTOX)	13.10	14.10	8%	126	0.49	28.8
Myriad Genetics (MYGN)	22.84	19.96	-13%	1,691	1.16	17.2
Neogenomics (NGNM)	1.30	1.47	13%	64	-0.06	NA
Psychemedics (PMD)	8.20	8.60	5%	45	0.66	13.0
Quest Diagnostics (DGX)	53.97	56.24	4%	8,872	2.96	19.0
Averages			-8%	20,198		31.2

Source: Bloomberg

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