

LABORATORY



ECONOMICS

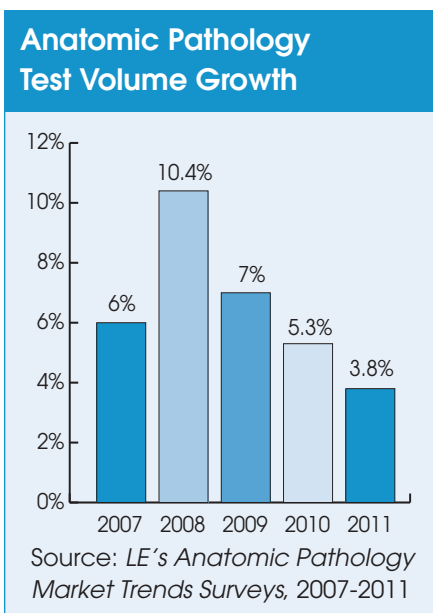
Competitive Market Analysis For Laboratory Management Decision Makers

MORE IN-OFFICE LABS GETTING CAP ACCREDITATION

The College of American Pathologists is vigorously lobbying CMS to exclude anatomic pathology services from the in-office ancillary services exception to the Stark rules that prohibit self-referral. “When physicians order on the basis of financial interest, there is enormous potential for tests to be over-utilized, lower quality of results and reduced efficiencies in laboratory testing,” according to CAP. However, in an ironic twist, more and more in-office pathology labs are getting CAP accreditation. Among the latest is Academic Urology of Pennsylvania (Rosemont, PA), the largest urology group in Pennsylvania. *Continued on page 8.*

GROWTH SLOWS IN ANATOMIC PATHOLOGY

After several years of growth ranging from 5% to 10% per year, test volume growth at anatomic pathology groups and labs has slowed. Anatomic pathology volumes grew by only 3.8% this year, according to an exclusive survey of 236 pathology groups and labs conducted by *Laboratory Economics* in September. The shift in pathology testing to in-office labs at specialty groups is clearly hurting local pathologists. It’s hurting the national labs too—Quest Diagnostics and LabCorp continue to report flat to declining volumes for their pathology businesses. For a full summary of *LE’s Anatomic Pathology Market Trends Survey*, see pages 5-7.



LABCORP EXTENDS UHC AGREEMENT

LabCorp has extended its contract with UnitedHealthcare for two more years. The agreement, which was effective January 1, 2007, will now continue through the end of 2018. LabCorp will continue to be the primary national lab for UnitedHealthcare and the exclusive lab for certain HMO plans in Colorado, Arizona, Florida, Maryland and Virginia. *Continued on page 2.*

LABCORP FORMS LAB BENEFIT MANAGEMENT FIRM

LabCorp has created a new subsidiary named Beacon Lab Benefit Solutions (BeaconLBS) aimed at lowering lab costs for health plans and employers. The new company is based in Burlington, North Carolina, and headed by Paul Conlin, a former UHC executive. *Continued on page 3.*

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LABCORP EXTENDS AGREEMENT WITH UNITEDHEALTHCARE (*cont'd from p. 1*)

UnitedHealthcare covers 34 million health plan members nationwide and spends an estimated \$2+ billion on lab testing per year.

LabCorp announced its original 10-year contract with UnitedHealthcare back in October 2006. The deal kicked Quest Diagnostics out of United’s lab network and set off a new wave of pricing competition for managed care contracts.

“We’re going to take strategic action to defend the contracts we have and at the same time we’ll get some new contracts. It is a situation where for the next six to twelve months we will see pricing pressure in the industry,” Surya Mohapatra, PhD, chief executive at Quest, told investors on a January 25, 2007 conference call (see *LE*, February 2007, p. 1). Quest then went on to negotiate a contract with Aetna that put LabCorp out of Aetna’s network (see *LE*, May 2007, p. 4).

However, while LabCorp and Quest have fought to exclude each other from managed care contracts, many regional and local labs have remained in-network providers.

For example, UnitedHealthcare still contracts with dozens of independent labs in the New York City area, including Bio-Reference Labs, Enzo Clinical Labs, Shiel Medical Labs and Sunrise Medical Labs (owned by Sonic Healthcare). Numerous hospital labs are also in-network including Mount Sinai Hospital and North Shore-LIJ Laboratories. In addition, AmeriPath (acquired by Quest in 2007) has remained an in-network lab in New York and on a national basis.

In fact, UnitedHealthcare’s lab network includes more than 1,500 independent and hospital-based labs nationwide. In addition to LabCorp, UnitedHealthcare also has national contracts with 14 specialty labs (*see table*).

Despite this vast network, leakage to out-of-network labs remains a problem. *Laboratory Economics* estimates that leakage to non-contracted labs accounts for less than 15% of UnitedHealthcare’s total lab testing volume. But these tests are paid in the range of 200% and 300% of Medicare Part B fees, so they represent an estimated 20% to 30% of UnitedHealthcare’s \$2+ billion in annual lab spending.

UnitedHealthcare’s National Lab Contracts

Lab Company	Specialty
AmeriPath (owned by Quest).....	anatomic pathology
Myriad Genetics.....	genetic testing
Nationwide Lab Services.....	dialysis testing
Satellite Laboratory Services.....	dialysis testing
Dominion Diagnostics.....	drug testing
LabCorp.....	full scope lab testing
GI Pathology.....	gastrointestinal pathology
Medical Diagnostic Labs.....	infectious disease testing
Berkeley HeartLab (owned by Quest).....	lipid testing
Medical Neurogenetics.....	genetic testing
Genomic Health.....	breast cancer testing
NTD Labs.....	prenatal testing
Genzyme Genetics (owned by LabCorp).....	anatomic pathology and genetic testing
OURLab.....	urologic pathology
Bostwick Laboratories.....	anatomic pathology

Source: UnitedHealthcare

For years, UnitedHealthcare has threatened to decrease fees or terminate contracts with physicians that routinely use out-of-network labs, but this strategy has not been effective. And concern over leakage is growing, especially with respect to high-cost molecular diagnostics and pathology services.

LABCORP FORMS LAB BENEFIT MANAGEMENT FIRM (*cont'd from page 1*)

LabCorp's formation of a lab benefit management company, BeaconLBS, probably played a part in UnitedHealthcare's decision to extend its contract with LabCorp for another two years.

BeaconLBS was incorporated in December 2010 and is headquartered in Burlington, North Carolina, according to records filed with the North Carolina Secretary of State, Corporations Division.

The top executives at BeaconLBS are all associated with UnitedHealthcare and LabCorp. Paul Conlin is president. Conlin is a former executive vice president of healthcare services at UHC/Oxford and played a key role in crafting the original UHC-LabCorp deal. Other former UHC executives now at BeaconLBS include Lynn McGrew, senior vice president, networks, and Robert Verrengia, senior vice president, sales.

LabCorp's chief financial officer, William (Brad) Hayes, is executive vice president and treasurer at BeaconLBS. And LabCorp's senior vice president and general counsel, Sandra D. van der Vaart, is secretary of the new company.

LabCorp has not formally announced BeaconLBS—although a web site (www.beaconlbs.com) is under construction—and the company did not respond to *LE's* request for an interview.

However, *LE* believes that BeaconLBS will operate like other radiology benefit management (RBM) firms such as CareCore (*see below*). *LE* envisions that BeaconLBS will target high-cost molecular and genetic tests. It also may attempt to try and reduce potential over-utilization of anatomic pathology testing at in-office labs at urology and gastroenterology groups.

The basic workflow requires that doctors will need to have certain procedures pre-authorized. The doctor's office will call BeaconLBS for preauthorization. Once the test is authorized, then BeaconLBS will direct the office to the 'best' lab provider. But as one laboratory executive told *LE*, "This is where this really becomes a 'fox in the hen house' scenario. Where do you think a LabCorp-owned entity is going to direct testing?"

CareCore (Bluffton, SC) was founded in 1994 with a focus on radiology utilization management. In July 2010, the company launched its LabPrint Lab Management Program. LabPrint was developed in partnership with the University of Washington Department of Laboratory Medicine and is focused on utilization and payment policy for molecular and genetic testing and anatomic pathology.

In addition, pharmacy benefit management (PBM) companies have begun to expand into genetic testing management. For example, Medco Health Solutions (Franklin Lakes, NJ) bought DNA Direct last year, CVS Caremark (Woonsocket, RI) has invested in Generation Health (Waltham, MA), and McKesson (San Francisco) launched its Advanced Diagnostics Management program in 2009.

LABCORP FINALIZES \$49.5 MILLION SETTLEMENT WITH CALIFORNIA

LabCorp has agreed to pay \$49.5 million to settle a lawsuit that accused the company of overcharging California's Medi-Cal program for lab tests.

The settlement also requires LabCorp to provide quarterly pricing reports from November 1, 2011 through Feb. 1, 2014, to assist the California Department of Health Care Services (DHCS) in determining the company's compliance with Medi-Cal pricing rules. In lieu of submitting these reports, LabCorp has the option of submitting its Medi-Cal claims at no more than 85% of the Medi-Cal clinical lab fee schedule for the first year.

California law, section 51501, requires that "no provider shall charge [Medi-Cal] for any service or any article more than would have been charged for the same service or article to other purchasers of comparable services or articles under comparable circumstances." The lawsuit, originally filed by Hunter Labs and its owner Chris Riedel in November 2005, alleged that LabCorp and other labs routinely billed Medi-Cal prices far above what was charged to other payers (e.g., IPAs, physician offices and hospital clients).

The False Claims Act provides incentives to whistleblowers by granting them a share of any settlement amount plus reimbursement of legal fees. In the LabCorp case, whistleblower Chris Riedel will get \$14.4 million and the State of California will receive \$35.1 million. LabCorp must also pay Riedel's legal fees incurred in the lawsuit.

Quest Diagnostics settled a similar lawsuit in May (see *LE*, May 2011, p. 1) by paying \$241 million. Riedel got \$69.9 million and California got \$171.1 million.

Smaller California labs that have reached settlements include Health Line Clinical Labs, Westcliff Medical Labs, Stanford Medical Labs and Seaclyff Diagnostics. Overall, the amount of settlements so far totals \$301 million, including more than \$85 million for Riedel. Similar cases are still pending against three other labs: Physicians Immunodiagnostic Lab, Primex Clinical Labs and Whitefield Medical Lab.

Riedel's attorney, Niall McCarthy of Cotchett, Pitre & McCarthy LLP, stated, "There is no shortage of bilking the state and federal governments, especially in the healthcare industry. This case demonstrates that with one courageous whistleblower, like Chris Riedel, and a team of dedicated private and government attorneys, massive amounts of money can be returned to taxpayers. Corporations cannot be allowed to treat the government like a broken ATM machine that gives free money."

LabCorp denies any wrongdoing and says it settled the case to avoid the uncertainty and costs associated with prolonged litigation. The case had been scheduled to go to trial on January 30, 2012. LabCorp contends that its billing practices were in compliance with all applicable laws as well as industry practice. Furthermore, LabCorp says that California has been aware of the company's billing practices with respect to Medi-Cal and other payers since before November 2002 and that DHCS has offered inconsistent interpretations of its Medi-Cal pricing rules.

However, *Laboratory Economics* notes that legal disputes on lab test pricing for Medicaid programs are far from over. Riedel and his lawyers are believed to have filed similar lawsuits in other states with whistleblower rewards and "lowest charge" rules for Medicaid. Florida fits both of these qualifications and has issued subpoenas to certain labs requesting documents related to their Medicaid billing (see *LE*, July 2011, p. 1).

GROWTH SLOWS IN ANATOMIC PATHOLOGY (cont'd from page 1)

Pathology groups and labs continue to lose business to specialty groups (e.g., urologists, gastroenterologists, dermatologists, etc.) that have built in-office histology labs. Eleven percent of survey respondents said they had lost “significant business” in 2011, down from 17% a year earlier. However, the percentage that reported losing “some business” increased to 36% from 29%.

“Pathology laboratory insourcing is having a significant negative impact. There exists a total lack of loyalty to local pathology groups,” according to a pathology lab executive from Texas.

“The loophole in the Stark amendment needs to be closed. I expect whistleblowers will attempt to gain the attention of the DOJ by alleging increased biopsy rates driven by financial gain incentives,” says a hospital lab executive from New Jersey.

“The quality of slides produced in those small environments is usually very poor and this makes diagnosis difficult (I will not read them). In addition, office-based histology leads to over-utilization and unnecessary biopsies and excisions,” asserted a pathologist from Alabama.

Has your pathology group/lab lost business in the past year because a physician group client created its own histology lab?

	2011	2010	2009	2008	2007
Yes, we’ve lost significant business	11%	17%	15%	8%	5%
Yes, we’ve lost some business	36%	29%	37%	28%	28%
No, we have not been affected	53%	54%	48%	64%	67%

Source: LE’s Anatomic Pathology Market Trends Surveys, 2007-2011

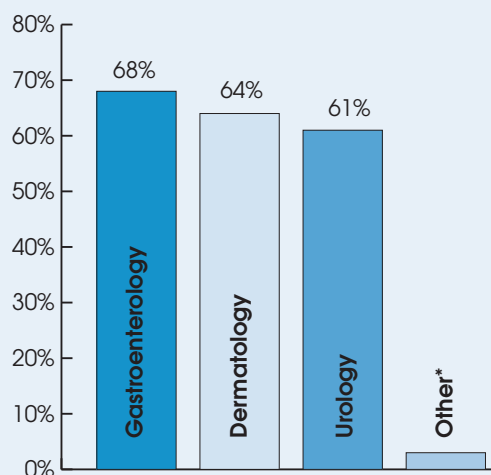
The survey showed that insourcing is most prevalent at GI, urology and dermatology practices. So far, the insourcing trend has not spread to other specialties in a meaningful way.

But while most pathologists have chosen to fight the insourcing trend, others have accepted it and are trying to adapt to the changing tide rather than fight it. The national labs, including Quest/Ameripath, LabCorp/Dianon, Bostwick Labs, OURLab, etc., as well as some local pathology groups, are establishing partnerships with specialty groups in an effort to maintain control of professional services.

“Insourcing of pathologists by GI, urology, derm is prevalent, but we have chosen to work with them and be their pathologists. This has proven to be high productivity work for us and has substantially increased revenue by about 40% (with only a 10-15% increase in hours worked),” according to a pathologist from Pennsylvania.

“Clinical in-sourcing of pathology is not necessarily a bad thing, if the pathologist does not allow himself to be abused in such a relationship. This survey is clearly biased against insourcing because the author [Jon David Klipp] has drunk the CAP Kool-Aid,” says a pathologist from Georgia.

What types of groups have in-sourced histology in your area?



*Includes multi-specialty, podiatry and hematology/oncology groups

Source: LE’s Anatomic Pathology Market Trends Surveys, September 2011; n=236

DECLINING REIMBURSEMENT REMAINS TOP CONCERN

The shift to in-office pathology testing is a growing concern. However, “declining reimbursement” remains the biggest challenge that pathology groups and labs will face over the next five years, according to the survey. Twenty-six percent of survey respondents cited reimbursements as their biggest concern in *LE’s* latest poll. In fact, “declining reimbursement” has been the top concern every year since *LE* conducted its first *Anatomic Pathology Market Trends Survey* in 2007.

Concern regarding “specialty physician groups insourcing” has grown to 19% from 15% in 2007.

Meanwhile, “competition from large commercial labs” was at a high of 20% for *LE’s* first survey in 2007. This was the year that Quest bought AmeriPath. This concern has slipped to 16% in our latest survey.

What is the biggest challenge pathology groups will face over the next 5 years?

	2011	2010	2009	2008	2007
Declining reimbursement	26%	29%	25%	27%	23%
Specialty physician groups insourcing pathology	19%	17%	18%	14%	15%
Competition from large commercial labs	16%	15%	15%	19%	20%
Staffing shortages	7%	8%	13%	19%	15%
Technical staff shortages	5%	7%	12%	13%	NA
Pathologist shortages	2%	1%	1%	6%	NA
Exclusion from managed care contracts	9%	8%	10%	NA	NA
Increased expenses for information technology	8%	9%	10%	6%	NA
Difficulty/expense of adding new molecular diagnostics	5%	5%	7%	9%	NA
Weak economy	8%	8%	NA	NA	NA
Other	2%	1%	1%	2%	16%

Source: *LE’s Anatomic Pathology Market Trends Surveys, 2007-2011*

Thirty percent of survey respondents said the cancer-testing services offered by Quest Diagnostics and LabCorp were becoming more competitive. This figure has been trending down since 2007.

The top three competitive advantages that Quest and LabCorp have are: 1) exclusive managed care contracts; 2) ability to provide Web-connectivity and EMR packages; and 3) competitive pricing, according to survey participants. At the bottom of the list of perceived competitive advantages were: 1) high service level; 2) knowledgeable sales reps; and 3) fast turnaround time.

In terms of their ability to compete for cancer-testing business, Quest Diagnostics and LabCorp are:

	2011	2010	2009	2008	2007
Getting more competitive	30%	29%	31%	39%	46%
Getting less competitive	14%	14%	11%	10%	11%
Unchanged	56%	57%	58%	51%	43%

Source: *LE’s Anatomic Pathology Market Trends Surveys, 2007-2011*

MOLECULAR DIAGNOSTICS LEADS GROWTH

Twenty-six percent of surveyed pathology groups and labs reported molecular diagnostics as their fastest-growing sub-specialty. Next was traditional surgical pathology, cited by 18%, followed by dermatopathology, 15%. Only 5% cited urological pathology as fastest growing and just 12% cited gastroenterology.

“With all the pressures on the pathology business it is important to diversify into more molecular testing to maintain a healthy organization financially. This will be extremely difficult for small pathology groups due to high investment and volume needs,” according to a pathology lab executive from Kentucky.

EMERGING TRENDS

Survey participants pointed out several newly developing trends:

How Will Advances in Radiology Affect Anatomic Pathology?

“Imaging will change the way we perform surgical pathology,” predicted a pathologist from Michigan.

“There is the potential for some type of molecular radiology to supersede biopsy as a diagnostic modality and eliminate the need for histology labs and pathologists in the process,” said a pathologist from Ohio.

Will Digital Pathology Finally Gain Traction?

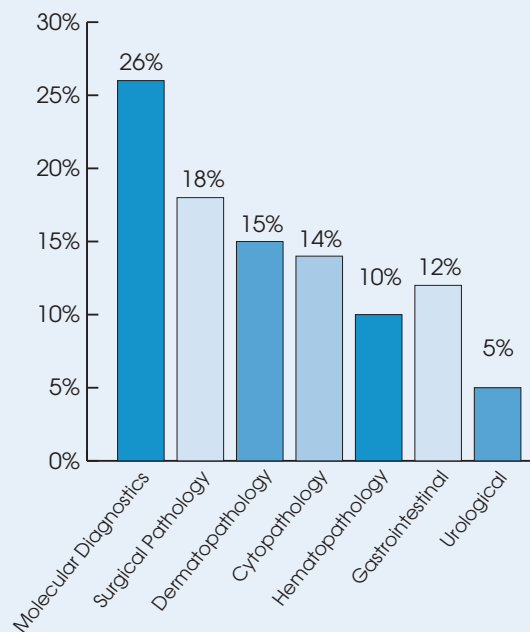
“Technological and reporting advances, like digital pathology as well as patient-friendly reporting and enhanced physician reporting, are keys to long-term competitive advantages for independent reference labs and hospital reference labs,” said a lab executive from New York.

Will More Hospital Systems Put Pathology Contracts Up for Bid?

“Hospitals appear increasingly willing to put their pathology contracts out for bids for lower Part A payments and access to sub-specialized large-pathology-group expertise,” observed a pathologist from Massachusetts.

“Hospitals and IDNs are putting pathology contracts out to bid (RFPs). I have become aware of five of these in our region in the last year,” noted a pathology lab executive from Washington.

In which sub-specialty is your pathology group seeing its fastest growth?



Source: LE's Anatomic Pathology Market Trends Surveys, September 2011; n=236

SURVEY DEMOGRAPHICS: The survey was e-mailed to approximately 5,000 pathology groups, independent labs and hospitals in early September 2011. A total of 236 surveys were judged usable, yielding a response rate of 5%. Among the respondents, 89 were from hospital-based pathology groups, 104 from local or regional independent pathology groups and labs, 22 from academic medical center-based pathology groups, 10 from national pathology companies and 11 from in-office pathology labs. Overall, the average surveyed pathology group employed 11 pathologists and collected \$14 million of revenue per year.

MORE IN-OFFICE LABS GETTING CAP ACCREDITATION (*cont'd from p. 1*)

CMS regulates all medical labs in the United States under the Clinical Laboratory Improvement Act (CLIA). In-office pathology labs at most specialty groups are CLIA-certified, which requires filling out an application and passing an onsite inspection conducted by CMS personnel or state health departments.

Alternatively, medical labs can choose to be inspected by one of five CLIA-approved accrediting agencies. They are: CAP, Joint Commission, American Osteopathic Association, American Association of Blood Banks and The American Society for Histocompatibility and Immunogenetics. Inspection standards from these agencies must meet or exceed those of CLIA.

CAP accreditation is widely considered to be the most prestigious. “CAP accreditation reinforces that the Academic Urology Laboratory exceeds the most stringent requirements for outstanding laboratory services,” according to lab director Maysoun Ghabra, MD.

A total of 12 specialty groups have received first-time CAP accreditation so far this year through August. This is more than the total number for all prior years combined.

Part of the reason for the big increase is COLA’s voluntary withdrawal as an accrediting agency for pathology labs effective June 30, 2010. COLA (formerly known as The Commission of Office Laboratory Accreditation) has remained an accrediting agency for other lab specialties (e.g., chemistry, microbiology, hematology, etc.).

In-Office Pathology Labs with CAP-Accreditation

Group Name	Location	# Physicians	CAP Accreditation
Academic Urology of Pennsylvania	Rosemont, PA	36	August 2011
Arizona Digestive Health	Phoenix, AZ	39	August 2011
South Jersey Gastroenterology	Marlton, NJ	10	August 2011
Dermatologists of Greater Columbus	Dublin, OH	5	July 2011
Urological Services PC	Flint, MI	1	July 2011
Urology of Indiana	Greenwood, IN	30	July 2011
Capital Urology Associates	Okemos, MI	1	May 2011
Illinois Gastroenterology Group	Libertyville, IL	30	May 2011
MacInnis Dermatology	Leesburg, FL	1	May 2011
Michigan Gastroenterology Institute	East Lansing, MI	10	May 2011
The Gastroenterology Group	Reston, VA	6	April 2011
Urologic Physicians	Edina, MN	6	March 2011
Associates in Dermatology	Louisville, KY	15	November 2010
Gastroenterology Consultants	Houston, TX	9	March 2009
Northwest Gastroenterology Assoc	Bellevue, WA	6	January 2008
Genito Urinary Surgeons	Toledo, OH	11	November 2007
Gastroenterology Associates	Pensacola, FL	10	April 2007
Michigan Institute of Urology	Saint Clair Shores, MI	54	February 2007
The Urology Group	Cincinnati, OH	34	May 2004
Saginaw Valley Dermatology	Saginaw, MI	1	June 2001
University Dermatologists	South Euclid, OH	12	June 1999

Source: *Laboratory Economics*

PRIVATE EQUITY CONTINUES TO FLOW INTO LABS

The slumping stock market has prevented or delayed any privately-held lab companies (e.g., Agendia, Aurora Diagnostics, Bostwick Labs, etc.) from going public for the last four years. In fact, the last successful lab IPO was Genoptix (now owned by Novartis) in October 2007. But private equity investors and venture capital funds continue to invest in startup lab companies marketing proprietary high-cost specialized tests.

Here's a sample of activity for the last few months:

Atossa Genetics Raises \$6.6 Million for Breast Cancer Test

Atossa Genetics (Seattle, WA) plans to use the funds to bring its MASCT breast cancer test system to market. MASCT, which stands for Mammary Aspirate Specimen Cytology Test, uses fluid from the nipple in a painless 5-minute procedure to determine if cancer cells are present. Atossa opened a CLIA-certified lab in Seattle earlier this year and is in the process of hiring sales reps. The company plans to launch its test in the Pacific Northwest this year with a national roll-out slated for 2012.

The MASCT system was cleared by the FDA in May 2003. But the test has not gained wide acceptance among doctors, payers or patients.

Atossa, which was founded by its chairman and chief executive, Steven Quay, MD, PhD, in 2009, has acquired all ownership and commercialization rights to the MASCT system.

Atossa had filed plans with the Securities & Exchange Commission to raise approximately \$17 million from an IPO in October 2010. However, the company withdrew those plans in February 2011.

Cleveland HeartLab Gets \$18.4 Million

The series B investment was led by Excel Venture Management and HealthCare Ventures, both of Boston. Cleveland HeartLab plans to find a new headquarters that is three times bigger than the 7,000-square-foot space it now occupies. The company, which employs nearly 80 today, also aims to double the size of its staff over the next two years, according to chief executive Jake Orville.

Cleveland HeartLab operates a CLIA-certified lab that specializes in lipid testing. The Cleveland Clinic spun off the company in late 2009 with a cardiac inflammation biomarker developed by Stanley Hazen, MD, PhD, and his colleagues there. The Hazen test, CardioMPO, has been cleared by the FDA and is used to evaluate patient risk of heart attack. It is reimbursed under CPT 83876 at a Medicare Part B national limit price of \$47.77.

Cleveland HeartLab raised \$4.5 million in March 2010 from a series A round from Glengary LLC, Second Generation Ltd. and Zapis Capital Group LLC, as well as individual investors.

Foundation Medicine Raises \$10 Million

Foundation Medicine (Cambridge, MA) raised \$10 million and plans to raise another \$10.5 million. Foundation was launched in April 2010 with a \$25 million investment from Third Rock Ventures.

Foundation has developed a comprehensive genomic test that analyzes 200 cancer-related genes from routine formalin-fixed, paraffin embedded clinical specimens. The test is designed to help physicians make treatment decisions for cancer patients.

Foundation named former Enzo Clinical Labs president Kevin Krenitsky, MD, as chief operating officer in June. That appointment followed the hiring of Michael Pellini, MD, as president and chief executive in May. Pellini was formerly president at Clariant Inc., which was acquired by GE Healthcare in October 2010.

Prenatal DX Firm Verinata Raises \$48.5 Million

Verinata Health (San Carlos, CA) is developing non-invasive tests for early identification of fetal chromosomal abnormalities such as Down Syndrome. The company recently raised \$48.5 million in a third round of financing led by existing investors Mohr Davidow Ventures, Sutter Hill Ventures and Alloy Ventures. Verinata opened a CLIA-certified lab in 2011 and plans to begin marketing a proprietary laboratory-developed test in early 2012. The prenatal test will require only a single blood draw and uses technology licensed from Stanford University. Verinata, formerly known as Artemis Health, was founded in 2001 and has raised a total of more than \$75 million to date.

PathCentral Gets \$3 Million

PathCentral Inc. (Irvine, CA) has raised \$3 million from undisclosed investors, according to a regulatory filing with the Securities & Exchange Commission. PathCentral markets a web-based practice management system to pathology groups. It also operates an esoteric cancer-testing lab that offers technical services. The company has now raised a total of \$14.5 million, including \$10 million raised in November 2010 from Okapi Venture Capital, Arboretum Capital and Baird Venture Partners (see *LE*, November 2010, p. 8).

MYRIAD LENDS \$25 MILLION TO CRESCENDO BIOSCIENCES

Myrriad Genetics (Salt Lake City, UT) has made a six-year loan of \$25 million to Crescendo Biosciences (San Francisco, CA) at an annual interest rate of 6%. In addition, Myriad has an exclusive option to acquire the company in three years if Crescendo meets certain revenue milestones, with the acquisition multiple based on revenue growth. If Crescendo does not meet the predetermined goal, Myriad can still acquire the company at a fixed purchase price by the end of the three-year period.

The deal came in tandem with a \$31 million series C equity financing round led by Aeris Capital AG and was joined by existing investors Mohr Davidow Ventures and Kleiner Perkins. Crescendo, formerly named Riley Genomics, has now raised more than \$100 million since being founded in 2002.

Crescendo's chief executive is William Hagstrom, who was formerly president of UroCor Inc., which was acquired by Dianon in 2001. Dianon was then acquired by LabCorp in 2003.

Crescendo operates a CLIA-certified lab in South San Francisco that specializes in rheumatology testing. The company launched its first product, Vectra DA, in November 2010. Vectra DA is a laboratory-developed test (priced at roughly \$400-\$500) that evaluates 12 proteins and provides a score of between 1 and 100 to help guide treatment for rheumatoid arthritis patients. Crescendo says the \$56 million (\$25 million debt + \$31 million equity) investment will be used to commercialize Vectra DA and develop other tests for rheumatoid arthritis.

Myriad currently derives more than 85% of its revenue from its BRACAnalysis (list price of \$3,340) genetic test for breast cancer. The company, which has about \$400 million in cash and securities, is trying to diversify. Earlier this year, Myriad acquired Rules-Based Medicine (Austin, TX), which markets a test to diagnose schizophrenia (see *LE*, May 2011, page 1).

MEDPAC PROPOSES MAJOR CUTS TO LABS

The Medicare Payment Advisory Commission (MedPac) has proposed \$235 billion in cuts, including \$9 billion from Part B lab fees, to avert a 29.5% reduction in the physician fee that is scheduled to take effect January 1, 2012.

The proposed fix, which will ultimately require Congressional approval, was presented by commission members on September 15, with the aim of eliminating the sustainable growth rate (SGR) system used to calculate rates for the Medicare Part B physician fee schedule.

The SGR system was enacted as part of the Balanced Budget Act of 1997 with the intent of limiting growth in spending on physician services to a sustainable rate, roughly in line with overall economic growth. But Congress has always stepped in to block cuts mandated by the SGR.

Under MedPac's plan, the looming 29.5% cut would be prevented at a cost to the government of roughly \$300 billion. However, physicians would still lose about \$100 billion in Medicare payments. Reimbursement for primary care physicians would be frozen for 10 years, and specialists (including pathologists) would see a reduction in payments for three years, followed by a seven-year freeze. These changes would save the government about \$100 billion.

Another \$200+ billion in offsets would come from Medicare Part D drug plans (32%), post-acute care facilities (21%), hospitals (11%), laboratories (9% or \$21 billion), suppliers of durable medical equipment (6%), Medicare Advantage plans (5%) and other providers (2%), with an additional 14% in benefit cuts to seniors. Details of the proposed cuts have not been released.

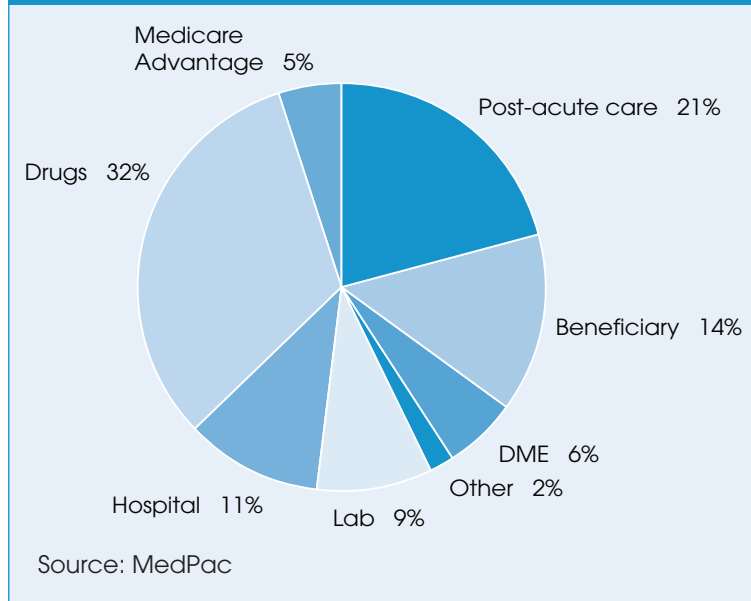
START-UP DIGIPATH OFFERING LOW-COST DIGITAL PATHOLOGY

DigiPath Inc. (Henderson, NV) has begun marketing its desktop PathScope Slide Scanner for a capital purchase price of between \$24,999 and \$64,999. The system is also available for rent for as little as \$2,999 per month (three-year term). Image storage services cost an additional 25 cents to \$1 per slide per year. Scan speed for the PathScope system is 2.5 minutes per slide (20x for 15mm x 15mm).

"In the past, prices were not advertised. We are putting our prices out in the open," says Eric Stoppenhagen, founder and chief executive of DigiPath. "Affordability has been an obstacle to widespread adoption of digital pathology," he adds.

Stoppenhagen is a former distributor for BioImagene (now owned by Roche-Ventana). He was also vice president of finance and operations at Trestle (now owned by Carl Zeiss Inc.).

Offsetting the Cost of Repealing the SGR System: ~\$235 Billion Over 10 Year



LAB STOCKS DOWN 5% YEAR TO DATE

Ten lab stocks have fallen by an unweighted average of 5% so far this year through September 16. The combined market capitalization for the group is currently \$19.5 billion. In comparison, the S&P 500 Index is down 3% and the Nasdaq is down 1%. The top-performing lab stocks so far this year are CombiMatrix, up 34%, followed by Medtox Scientific, up 8%. Meanwhile, the stock price of LabCorp is down 5% and Quest is down 9%.

Company (ticker)	Stock Price 12/31/10	Stock Price 9/16/11	2011 Price Gain	Market Capitalization (\$ millions)	Earnings Past 12 Months	Price-to-Earnings Ratio
Bio-Reference (BRLI)	\$22.18	\$19.23	-13%	537	1.23	15.6
CombiMatrix (CBMX)	2.15	2.89	34%	31	-0.87	NA
Enzo Biochem (ENZ)	5.28	2.88	-45%	111	-0.35	NA
Genomic Health (GHDX)	21.39	21.07	-1%	621	0.25	84.3
LabCorp (LH)	87.92	83.42	-5%	8,459	5.72	14.6
Medtox Scientific (MTOX)	13.10	14.19	8%	127	0.47	30.2
Myriad Genetics (MYGN)	22.84	20.22	-11%	1,720	1.11	18.2
Neogenomics (NGNM)	1.30	1.15	-12%	50	-0.09	NA
Psychemedics (PMD)	8.20	8.27	1%	43	0.61	13.6
Quest Diagnostics (DGX)	53.97	49.09	-9%	7,770	2.88	17.0
Averages			-5%	19,469		27.6

Source: Bloomberg

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