

LABORATORY

INDUSTRY REPORT®



Stephanie Murg, Managing Editor, smurg@ioma.com

Vol. XI, No. 7/July 2007

HIGHLIGHTS

TOP OF THE NEWS

- LabCorp buys DSI Labs..... 1
- CIGNA doesn't play favorites..... 1

MERGERS & ACQUISITIONS

- Sonic acquires Swiss and U.S. labs 2
- Midwest Clinical Labs on the block..... 3
- AEL headquarters moves to Austin 9
- DNA testing labs merge..... 10

PATHOLOGY

- Caris Diagnostics plans for growth 3

INSIDE THE LAB INDUSTRY

- State demographics and the lab market 5

REGULATORY

- 'Substantially in excess' proposal withdrawn 9

NEW ON THE SCENE

- New lab for Florida Hospital 10

FINANCIAL

- Lab stocks up 1%..... 11

INDUSTRY BUZZ

- AMA wary of retail clinics 12



LabCorp To Acquire Florida Hospital Lab

LabCorp (Burlington, NC) has agreed to acquire DSI Laboratories (Fort Myers, FL) from NCH Healthcare System (Naples, FL). DSI, a reference and toxicology laboratory, operates a core lab in Fort Myers, hospital laboratories in Naples and North Collier, and the Bonita Community Center Laboratory.

Financial terms of the deal were not disclosed, but according to one industry insider, LabCorp paid between \$60 million and \$70 million for DSI, which has annual revenues of about \$24 million. Quest Diagnostics and Spectrum Laboratories were reportedly also interested in DSI but, unlike LabCorp, were not willing to pay the premium purchase price of nearly three times earnings.

Founded in 1984 to provide laboratory services for NCH Healthcare System hospitals and local physicians, DSI serves clients throughout southwestern Florida, marketing clinical laboratory services in Collier, Lee, Charlotte, and Sarasota counties and toxicology services throughout Florida. It is one of only two laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) for drug screening in Florida. DSI has 20 regional patient service centers and approximately 400 employees. LabCorp plans to retain internal, patient laboratory testing at DSI's two hospital locations, with LabCorp assuming the remainder of the operation. 🏛️

CIGNA Extends Quest And LabCorp Contracts

Unlike UnitedHealthcare and Aetna, CIGNA will not play favorites and shut out one of the top two national laboratory providers with an exclusive national provider contract arrangement. The health insurer has announced that it has signed multi-year contract extensions with both Quest Diagnostics (Lyndhurst, NJ), its largest laboratory services provider, and LabCorp (Burlington, NC), allowing both companies to remain providers to all CIGNA markets. Financial terms of the deals were not disclosed.

There's a little something extra in the deal for LabCorp. The company's contract extension includes a provision that will ease existing restrictions on how LabCorp may market its relationship with CIGNA. Beginning Jan. 1, 2008, LabCorp will no longer be contractually restricted from advertising that it is a fully participating, in-network provider to CIGNA for all services in all major markets. ➡ p. 2



CIGNA Extends Quest And LabCorp Contracts, *from page 1.*

With 2006 revenues of \$16.5 billion, CIGNA enrolls approximately 21 million people in its medical, dental, behavioral health, pharmacy, and/or vision plans in the United States. Approximately 9 million people are enrolled in CIGNA's health plan, compared to UnitedHealth's 28 million and Aetna's 15 million. 🏛️

Sonic Healthcare Acquires Labs In Switzerland And U.S.

Sonic Healthcare (Sydney, Australia) continues to snap up laboratories worldwide. The Australian lab giant, which recently acquired American Esoteric Laboratories (recently relocated to Austin, TX) for \$180 million, has announced two new acquisitions in the Swiss and American laboratory markets: the Medica Laboratory Group (Zurich, Switzerland) and Mullins Pathology & Cytology (Augusta, GA).

Sonic's Recent Acquisitions

2005

Enters U.S. market with acquisition of 82% interest in Clinical Pathology Laboratories (Austin, TX)

2006

American Esoteric Laboratories (Nashville, TN)
Muskogee Clinical Laboratory (Muskogee, OK)
Cognoscenti Health Institute (East Orlando, FL)
Lookadoo Skyline Laboratories (Port St Lucie, FL)

2007

Remaining 18% of Clinical Pathology Laboratories
Central Queensland Pathology Laboratory (Queensland, Australia)
Mullins Pathology & Cytology Laboratory (Augusta, GA)
Medica Laboratory Group (Zurich, Switzerland)

Sonic purchased Medica in a debt-funded transaction valued at CHF98 million (\$79.7 million). According to Sonic, Medica's unique strengths include a tradition of providing personalized laboratory services throughout Switzerland. In keeping with Sonic's "federation model," which calls for retention of the acquired company's management, name, and "local flavor," Medica's CEO Franz Kaeppli, M.D., will continue to lead the business.

With instability in the Australian and New Zealand laboratory industries, Sonic is moving to

expand its presence in Western Europe. In the case of Medica, Sonic is expected to exploit economies of scale in some testing segments through its presence in Augsburg, Germany, where the company owns a majority stake in the Schotttdorf Group, one of the largest providers of pathology services in the German market.

Meanwhile, Switzerland is home to one of the most consolidated pathology markets in Europe, and the country recently endured a 10% cut in government reimbursement rates for pathology services. With annual revenues of CHF55 million (\$44.7 million), Medica is the country's number-two lab behind Unilabs, which has CHF170 million (\$138.1 million) in annual revenues.

Sonic executed its other recent acquisition—of Georgia-based Mullins Laboratory—much more quietly than the Medica buy. With six locations, including two in South Carolina, Mullins is the largest pathology provider in the Augusta region and has been in operation for 53 years. According to Sonic, the management of Mullins will remain the same. The current director is Steven C. Mullins, M.D. Washington G-2 Reports estimates the annual revenue of Mullins at approximately \$15 million. 🏛️

Want the full scoop on Sonic Healthcare and its view on the U.S. laboratory market? Don't miss Washington G-2 Reports's 25th Annual Lab Institute, which will feature "Where is the U.S. Lab Market Going?: The World View," a keynote address by Dr. Colin Goldschmidt, CEO and managing director of Sonic Healthcare. The conference will take place October 10-13, 2007 at the Crystal Gateway Marriott in Arlington, Virginia. To register or for more information, visit www.g2reports.com/lab institute25



Sale Looks Imminent For Midwest Clinical Laboratories

Wheaton Franciscan Healthcare (WFH; Glendale, WI) is negotiating the sale of Midwest Clinical Laboratories (MCL; Wauwatosa, WI), a full-service reference laboratory and the hospital system's outreach arm. "We are in a period of exclusive negotiations with a potential buyer," WFH's Vice President for Communication Anne Ballentine tells *LIR*.

The decision to sell MCL was based on a number of factors, including declining reimbursement in the managed care environment. "As a nonprofit organization, we have decided to focus on our core business of patient care and sell the for-profit portion of our lab," says Ballentine.

Founded in 1992, MCL performs more than two million tests each year in 10 Wisconsin counties. The laboratory is staffed by more than 600 employees, including pathologists, Ph.D.-level technical directors, clinical laboratory scientists, and clinical laboratory technicians. MCL is a regional provider for UnitedHealthcare and more than 60 other managed care providers.

According to Ballentine, WFH is seeking to sell MCL to "a company that would continue to provide excellent service to our customers." If MCL does change hands, WFH would still provide laboratory services to its own physician offices and hospitals, but the healthcare organization would no longer provide services for the independent physicians and nursing homes currently served by MCL.

WFH is a not-for-profit organization and one of the largest integrated regional healthcare delivery systems in Wisconsin. Its member organizations—including five major acute care hospitals—provide nearly one-fourth of the total healthcare delivered in Milwaukee, Waukesha, Washington, Racine, and Ozaukee counties. It is affiliated with more than 1,300 physicians in southeast Wisconsin. 🏛️

Caris Diagnostics Chases Strong Growth



Gail B. Marcus

Pathology laboratory Caris Diagnostics (Irving, TX) is moving into high gear, opening a new facility in Phoenix, Arizona, and merging with Cohen Dermatopathology (Newton, MA). It's all part of a strategy for strong growth based on what President and Chief Executive Officer Gail B. Marcus says is a three-pronged strategy: quality, technology, and service.

Caris Diagnostics, which changed its name from Pathology Partners last August, has historically focused on GI pathology. "We are a subspecialty-focused leader in anatomic pathology," says Marcus. "In the GI market most other pathology organizations will use general pathologists. Ours are either subspecialty-trained in a fellowship program or are trained by us here in the equivalent of a fellowship program." The merger with Cohen Dermatopathology will broaden Caris's market reach, as well as deepen their geographic penetration on the east coast.

Caris Diagnostics employs 350 people and in 2006 reported \$64.9 million in revenue. According to CLIA records, Caris performed 210,000 tests in 2005 and Cohen



Dermatopathology performed 124,900 in 2006. Although unwilling to commit to current test volumes, Caris Diagnostics suggests that the 2005 numbers are out-of-date. In light of the merger and the opening of the 24,000-square-foot laboratory in Phoenix, it's not unreasonable to predict that Caris's test volumes will exceed 500,000 in the near future.

Despite competition from the major players such as the recently merged Quest Diagnostics and AmeriPath, as well as LabCorp and other regional pathology groups and laboratories, Marcus is confident. "We feel like the package we have is unmatched in the industry," she says. "The first area of focus is quality. Our pathologists have very high quality-assurance processes. On the GI side, for example, our pathologists will see cases that are unique or unusual with a much greater frequency. But because they see them at much greater frequency, they won't seem that unique or unusual." They also have daily internal consultations, leveraging the broad expertise of the group.

The second area Marcus cites is technology. "We believe in partnering with the physicians that work with us to help make them more effective and efficient. We work with them to install technology that helps in interfacing with us, but also helps their work flow and office operations."

And finally, the third way Marcus feels that Caris distinguishes itself is service, including fast turnaround times. "We feel very strongly about having a local service presence and having the people who help them visit them. Part of that is the technology we've installed with them and the partnership that creates."

Marcus emphasizes that Caris goes out of its way to employ the best and the brightest. In that vein, they have begun their own GI pathology fellowship affiliated with the University of Texas Southwestern Medical School in Dallas, which begins this year and is already filling up for 2008. "Caris Diagnostics is creating academic quality pathology combined with all the very best of the commercial

environment," says Marcus. "You have that top-quality pathology, but then you can invest in the commercial environment and systems and people, so it's really bringing those things together. What our pathologists find is that it's a fairly unique environment."

In the midst of its rapid growth and expansion, Marcus insists that Caris Diagnostics focus on their primary goal. "Our commitment is to health improvement. Basically it starts from a foundation of

health improvement, which is the best quality of care at a low cost. We don't see that as an either/or proposition. When you think about diagnostics, a lot of the power of diagnostics is getting it right the first time. And by being a really high-quality diagnostic provider, you're able to help deliver improved care at the most effective cost." 🏛️

Caris Diagnostics At A Glance

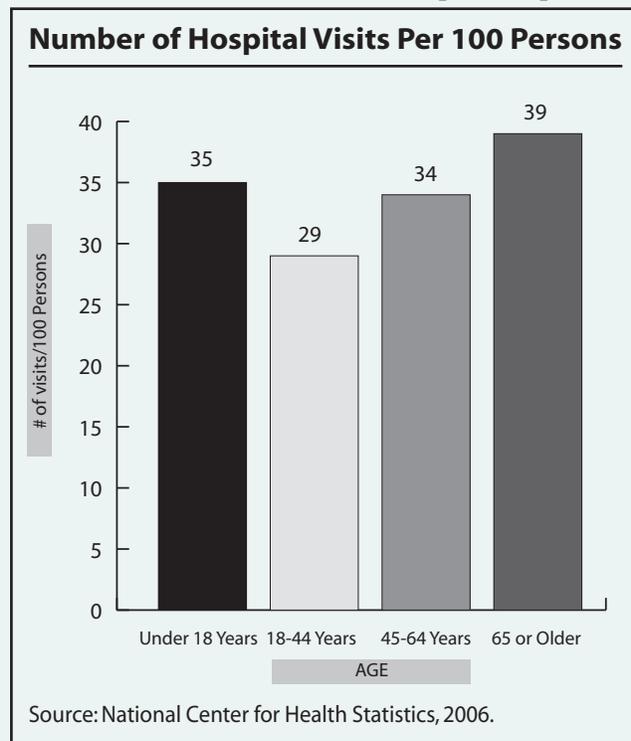
- ❑ Irving, Texas-based GI anatomic pathology laboratory, which has recently expanded into dermatopathology.
- ❑ Completing a new 24,000 square-foot facility in Phoenix, Arizona, and have merged with Cohen Dermatopathology in Newton, Massachusetts.
- ❑ Reported \$64.9 million in revenue in 2006.
- ❑ Employs 350 people.
- ❑ Recently began a pathology fellow program affiliated with the University of Texas Southwestern Medical School.

State Demographics And Laboratory Market Growth

There is a correlation between laboratory test volume growth and population growth. Simply put, the longer people live, the more laboratory tests required. The older the population, the more people require hospital care. By looking at national demographic data—what states have the highest growth—we are able to get a picture of where demand for medical services is likely to increase. We'll also take a look at who the dominant players are in the highest-growth areas.

A Population Both Growing and Growing Older

As patients age, they have more hospital visits. Patients 65 years or older make 39 visits per 100 persons compared to only 29 visits per 100 persons



made by those between the ages of 18 and 44. In 2006 the first baby boomers turned 60. In five years, this largest chunk of the general population will be hitting the period when hospital visits start to go up. This will increase the demand for laboratory tests.

Inpatient days in U.S. hospitals correlate to inpatient laboratory testing volumes. According to the American Hospital Association, there has been a slight increase in inpatient days from 1997 to 2006. The annual increase is small, about 0.3%, although there was a drop of nearly half a million days (total) between 2004 and 2005. However, Washington G-2 Reports estimates those numbers have readjusted in 2006 to slightly higher than the 2004 levels. The American Hospital Association also indicates that from 1997 to 2005, the number of outpatient visits has increased by 3.7% a year, from 440.8 million in

1997 to 587.3 million in 2005. Again, with an aging population, we can expect more patients to stay longer in hospitals, which will have a direct effect on clinical laboratory testing.

Laboratory test volumes in the United States' independent (commercial) laboratories, hospital labs, and physician office laboratories are estimated to grow at approximately 2.4%. However, that is overall. Hospital laboratory test volumes have grown 4% annually from 2000 to 2006, and the independent (commercial) lab industry test volumes have grown by 2.7% annually. Washington G-2 Reports estimates that approximately half of this growth is due to population growth.

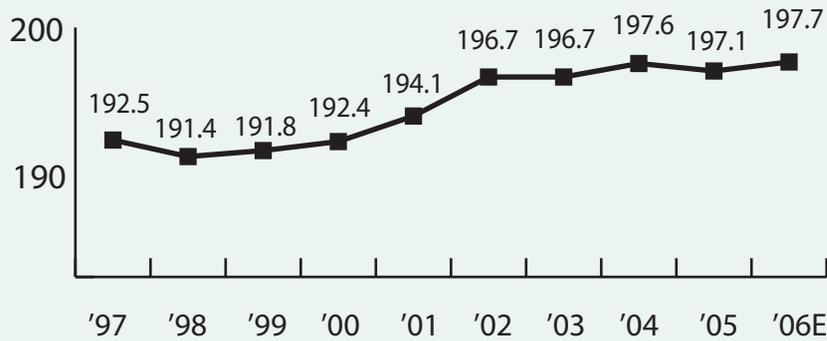
Some states, and areas within states, are growing faster than others. Nevada, for instance, registered a 57.8% growth rate over the 10-year period from 1995 to 2005, followed by Utah with 26.6% over the same period. But just looking

at overall growth rate isn't necessarily a good indicator of a growing market. In some cases the reason a state like Nevada or Idaho may have such a high growth rate is simply because they have a relatively low population

density overall. Washington G-2 Reports has evaluated potential growth markets as having fairly high population density, high growth rate, and an overall growth over a six-year period of at least 100,000 persons.

Population trends can be indicators of which areas of

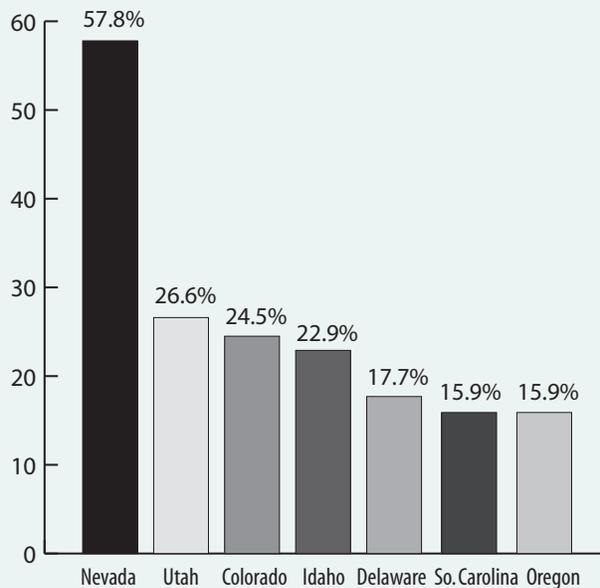
Inpatient Days at U.S. Hospitals (in millions)



Source: American Hospital Association

the country show the most promise for hospitals and commercial laboratory testing facilities. Not surprisingly, there is strong growth in southern states—Florida, Georgia, Texas, and North Carolina, with states that might be more accurately described as southwestern—California, Nevada, Utah, and Arizona also showing strong growth.

States with Highest Population Growth, 1995-2005



Source: U.S. Census Bureau

Most Populous States

California is the most populous state with 36.1 million people as of 2005. It picked up 4.5 million people in the 10-year period from 1995 to 2005, giving it an average growth rate of 1.4%. Texas has a higher annual growth rate of 2%, and has the second-highest population, 22.9 million, up 4.1 million from 1995. New York is third with 19.2 million, its growth rate a relatively low 0.6%, especially compared to Florida's and Georgia's 2.3% annual growth rate. Of the 20 most populous states, Arizona has the fastest annual growth rate of 3.5%. From 1995 to 2005 Arizona grew by 1.7 million people to hit 5.9 million. Florida and Georgia tie for second.

Fastest-Growing Markets in the U.S.

Below are the top 20 fastest-growing markets in the United States. They are ranked by percentage of population

Census Data for the 20 Most Populous States

	<i>Population</i> 2005	1995	Net Change	10-Year CAGR*
California.....	36,132,147	31,589,000	4,543,147	1.4%
Texas.....	22,859,968	18,724,000	4,135,968	2.0
New York.....	19,254,630	18,136,000	1,118,630	0.6
Florida.....	17,789,864	14,166,000	3,623,864	2.3
Illinois.....	12,763,371	11,830,000	933,371	0.8
Pennsylvania.....	12,429,616	12,072,000	357,616	0.3
Ohio.....	11,464,042	11,151,000	313,042	0.3
Michigan.....	10,120,860	9,549,000	571,860	0.6
Georgia.....	9,072,576	7,201,000	1,871,576	2.3
New Jersey.....	8,717,925	7,945,000	772,925	0.9
North Carolina.....	8,683,242	7,195,000	1,488,242	1.9
Virginia.....	7,567,465	6,618,000	949,465	1.4
Massachusetts.....	6,398,743	6,074,000	324,743	0.5
Washington.....	6,287,759	5,431,000	856,759	1.5
Indiana.....	6,271,973	5,803,000	468,973	0.8
Tennessee.....	5,962,959	5,256,000	706,959	1.3
Arizona.....	5,939,292	4,218,000	1,721,292	3.5
Missouri.....	5,800,310	5,324,000	476,310	0.9
Maryland.....	5,600,000	5,042,000	558,388	1.1
Wisconsin.....	5,536,201	5,123,000	413,201	0.8

Source: U.S. Census Bureau

growth according to updated U.S. Census Bureau records. (The last official national census was in 2005). To be included on this list, each market must have gained at least 100,000 persons between July 1, 2000, and July 1, 2006. The markets themselves are made up of Metropolitan Statistical Areas (MSA). MSAs are methods used by the United States Office of Management and Budget and the U.S. Census Bureau to define and describe a metropolitan area. Although those definitions are redefined every 10 years, they are loosely created on the basis of a central urbanized area, which is to say, a contiguous area of relatively high population density. So although a specific city may be at the core of an MSA, the MSA itself may spread throughout surrounding counties if they have strong

Top 20 Fastest-Growing Markets in the U.S. Population

Markets	July 1, 2006	July 1, 2000	Net Change	Percent
Las Vegas-Paradise, NV.....	1,777,539	1,375,738	401,801	29.2%
Raleigh-Cary, NC.....	994,551	797,025	197,526	24.8
Phoenix-Mesa-Scottsdale, AZ.....	4,039,182	3,251,876	787,306	24.2
Riverside-San Bernardino-Ontario, CA.....	4,026,135	3,254,821	771,314	23.7
Austin-Round Rock, TX.....	1,513,565	1,249,763	263,802	21.1
Atlanta-Sandy Springs-Marietta, GA.....	5,138,223	4,248,012	890,211	21.0
Orlando-Kissimmee, FL.....	1,984,855	1,644,563	340,292	20.7
Charlotte-Gastonia-Concord, NC-SC.....	1,583,016	1,330,403	252,613	19.0
Houston-Sugar Land-Baytown, TX.....	5,539,949	4,715,402	824,547	17.5
Dallas-Fort Worth-Arlington, TX.....	6,003,967	5,161,518	842,449	16.3
Sacramento-Arden-Arcade-Roseville, CA.....	2,067,117	1,796,857	270,260	15.0
Jacksonville, FL.....	1,227,997	1,222,750	155,247	13.8
San Antonio, TX.....	1,942,217	1,711,716	230,501	13.5
Tampa-St. Petersburg-Clearwater, FL.....	2,697,731	2,396,013	301,718	12.6
Portland-Vancouver-Beaverton, OR-WA.....	2,137,565	1,927,881	209,684	10.9
Nashville-Davidson-Murfreesboro, TN.....	1,455,097	1,311,789	143,308	10.9
Denver-Aurora, CO.....	2,408,750	2,179,320	229,430	10.5
Washington-Arlington-Alexandria, DC-VA-MD-WV.....	5,290,400	4,796,180	494,220	10.3
Indianapolis-Carmel, IN.....	1,666,032	1,525,104	140,928	9.2
Miami-Fort Lauderdale-Miami Beach, FL.....	5,463,857	5,007,988	455,869	9.1

Source: U.S. Census Bureau

social and economic ties to the central counties, particularly in relationship to commuting and employment. In some cases, they may even cross state borders. Because much of Medicare and Medicaid policy is also based on MSAs, Washington G-2 Reports has chosen to define the markets along the same lines as MSAs.

Top Labs in the Fastest-Growing Markets

Quest Diagnostics operates the largest commercial laboratory facility in 10 of the country's fastest-growing markets:

- Las Vegas-Paradise, Nevada
- Riverside-San Bernardino-Ontario, California
- Atlanta-Sandy Springs-Marietta, Georgia
- Orlando-Kissimmee, Florida
- Dallas-Fort Worth-Arlington, Texas
- Sacramento-Arden-Arcade-Roseville, California
- Tampa-St. Petersburg-Clearwater, Florida
- Denver-Aurora, Colorado
- Washington-Arlington-Alexandria, D.C., Virginia, Maryland, West Virginia
- Miami-Fort Lauderdale-Miami Beach, Florida

The fastest-growing market is the Las Vegas-Paradise, Nevada, area, which had a 29.2% growth rate from 2000 to 2006. The second-fastest was Raleigh-Cary, North Carolina, with a 24.8% growth rate in the same period.

LabCorp has also dominated, with five laboratory facilities in the top 20 fastest-growing markets: Raleigh-Cary, North Carolina; Phoenix-Mesa-Scottsdale, Arizona; Charlotte-Gastonia-Concord, North Carolina and South Carolina;

Houston-Sugar Land-Baytown, Texas; and San Antonio, Texas. Jacksonville, Florida does not have any large commercial laboratories operating in the area, but LabCorp has several small laboratories and/or patient service centers in the area. However, from a geographical point of view, Florida is not that large a state—it is 172 miles from Jacksonville to Tampa, where both Quest Diagnostics and LabCorp operate major laboratory facilities. 🏛️

Highest Test Volume Performing Laboratories in Fastest-Growing U.S. Markets

Market	Commercial Labs	Hospital Labs
Las Vegas-Paradise, NV	Quest Diagnostics	Sunrise Hospital and Medical Center
Raleigh-Cary, NC	LabCorp	University of North Carolina Hospitals
Phoenix-Mesa-Scottsdale, AZ	LabCorp	Banner Good Samaritan Medical Center
Riverside-San Bernardino-Ontario, CA	Quest Diagnostics-Nichols Inst.	Cedars-Sinai Medical Center
Austin-Round Rock, TX	Clinical Pathology Laboratories	St. David's Hospital
Atlanta-Sandy Springs-Marietta, GA	Quest Diagnostics	Grady Memorial Hospital
Orlando-Kissimmee, FL	Quest Diagnostics	Florida Hospital
Charlotte-Gastonia-Concord, NC-SC	LabCorp	Carolinas Medical Center
Houston-Sugar Land-Baytown, TX	LabCorp	St. Luke's Episcopal Hospital
Dallas-Fort Worth-Arlington, TX	Quest Diagnostics	Baylor University Medical Center
Sacramento-Arden-Arcade-Roseville, CA	Quest Diagnostics	Stanford Hospital and Clinics
Jacksonville, FL	LabCorp *	St. Vincent's Medical Center
San Antonio, TX	LabCorp	Methodist Hospital
Tampa-St. Petersburg-Clearwater, FL	Quest Diagnostics	St. Joseph's Hospital
Portland-Vancouver-Beaverton, OR-WA	Oregon Medical Laboratories	Southwest Washington Medical Center
Nashville-Davidson-Murfreesboro, TN	DCI Laboratory	Centennial Medical Center
Denver-Aurora, CO	Quest Diagnostics	University of Colorado Hospital
Washington-Arlington-Alexandria, DC-VA-MD-WV	Quest Diagnostics	Johns Hopkins Hospital
Indianapolis-Carmel, IN	Clarian Health Partners	Covance Central Laboratory Service
Miami-Fort Lauderdale-Miami Beach, FL	Quest Diagnostics	Baptist Hospital of Miami

*Jacksonville, Florida, does not have a large commercial laboratory presence. However, LabCorp has numerous small laboratories and patient service centers in Jacksonville.

Source: U.S. Census Bureau, CLIA Provider Applications Files, and the U.S. Office of Management and Budget



AEL Headquarters Moves To Austin As Sonic Consolidates Acquisitions

American Esoteric Laboratories (AEL), which was acquired by Sonic Healthcare (Sydney, Australia) in December of 2006 for \$180 million, has moved its headquarters from Nashville, Tennessee, to Austin, Texas. The transition is part of Sonic's efforts to consolidate AEL's administrative functions with those of Austin-based Clinical Pathology Laboratories (CPL), which Sonic purchased in 2005 as an entry into the U.S. laboratory market.

Despite the move, AEL's operations will remain the same, according to Robert Connor, M.D., chairman and CEO of Sonic's U.S. business. Sonic has been phasing out operations at AEL's Nashville headquarters since closing on the acquisition in January. Four-year-old AEL was previously owned by two private equity firms, ABS Capital Partners and Oak Investment.

In September of last year, AEL acquired DRL Labs (Tyler, TX), an affiliate of East Texas Medical Center Regional Healthcare System and then the largest remaining Texas-based independent reference laboratory. That acquisition came just six months after the company's purchase of Physicians Medical Laboratory (Morristown, TN), a full-service lab serving 20 counties in East Tennessee.

With 2006 revenues of approximately \$100 million, AEL currently consists of two laboratories in Tennessee (Memphis and Morrystown) and two in Texas (Dallas and Tyler). The company also serves parts of Arkansas, Louisiana, and Missouri. AEL and CPL, now both based in Austin, have combined revenue of more than \$300 million, which represents 19% of Sonic's 2006 revenue of \$1.6 billion. 

Industry Relieved As OIG Withdraws 'Substantially In Excess' Proposal

If finalized, the proposal could have limited the ability of labs to negotiate discounted contracts with physicians or managed care plans for Medicare and Medicaid Services.

The Health and Human Services Office of Inspector General (OIG) announced on June 18 that it is withdrawing the 2003 proposed rule in which it attempts to define what constitutes excessive charges to Medicare and Medicaid. This is welcome news to many in the laboratory industry, who worried that Medicare would move forward with the almost four-year-old proposal in the wake of the price concessions granted by laboratories to managed care providers to secure contracts. If finalized, the proposal could have limited the ability of laboratories to negotiate discounted contracts with physicians or managed care plans for Medicare and Medicaid Services.

The proposed rule, issued on Sept. 15, 2003, attempted to define the terms "substantially in excess" and "usual charges" for purposes of determining when providers had overcharged Medicare and Medicaid. Under the proposal, the OIG would have defined "substantially in excess" as any charge that is more than 120% of the usual charge for an item or service.

"Usual charges" would have been based on either a provider's average charge or median charge and would have included amounts billed to cash-paying patients and patients covered by indemnity insurers with which the provider has no contractual arrangement. Significantly, "usual charges" would also have included any fee-for-service rates that a provider agrees to accept from any payor, including any discounted fee-for-service rates negotiated with managed care plans. The OIG had stated that since negotiated rates make up a large part of provider revenues, those discounts effectively are their charges.



In a notice published in the June 18 *Federal Register*, the OIG says it has concluded that it does not have sufficient information at this time to establish a single, fixed numerical benchmark for “substantially in excess” that could be applied equitably across health-care sectors and across items and services as originally proposed. “Our intent in proposing the 120% benchmark was to create a bright line standard by which all providers could evaluate their usual charges,” the OIG wrote. “Upon reviewing the comments, we believe that a single benchmark for ‘substantially in excess’ is inadvisable at this time.”

The OIG, however, noted that it remains concerned about disparities in the amounts charged to Medicare and Medicaid when compared to private payors and retains its right to evaluate and address instances where it believes the federal programs are being overcharged. “We will continue to evaluate billing patterns of individuals and entities on a case-by-case basis and to use all tools available to OIG to address instances where Medicare or Medicaid are charged substantially more than other payors, without good cause,” the OIG wrote in the June 18 notice. 🏛️

Work Begins On New Florida Hospital Lab

Construction has begun on the 24,000-square-foot laboratory that will be known as the Florida Hospital Center for Diagnostic Pathology (Orlando, FL), part of the Florida Hospital Healthcare System (FHHS). The standalone facility will employ about 80 people and process more than 80,000 samples each year. The laboratory is expected to be completed in the spring of 2008.

The new building will augment the anatomic pathology services of the Florida Pathology Laboratory (FPL), which is located on the second floor of Florida Hospital Orlando, and free up space for FPL. The Florida Hospital Center for Diagnostic Pathology will support all seven FHHS hospitals in Central Florida, more than 1,000 doctors’ offices, and 37 nursing homes. It will also act as a reference lab for Adventist Health System hospitals in Florida and throughout the southeastern United States. 🏛️

DNA Testing Lab Sorenson Genomics Buys Identigene

DNA-testing laboratory Sorenson Genomics (Salt Lake City) has acquired Identigene (Houston), which specializes in forensic and paternity DNA testing. Financial terms of the deal were not disclosed.

Founded in 1993 by Caroline Caskey, Identigene pioneered short tandem repeat analysis, a technology for human identification used in forensics and relatedness DNA testing. In addition to direct-to-consumer paternity, forensic, and ancestry testing, the company offers mouse genotyping services to researchers. The laboratory will keep its name and remain at its Houston facilities.

Sorenson Genomics, founded by James LeVoy Sorenson, also serves the forensics and relatedness testing markets. The company’s 10-year-old GeneTree division offers direct-to-consumer DNA testing. List price for a home paternity test is \$199, and the company’s PCR-based Pink or Blue Early Gender Test detects Y chromosomal DNA in maternal blood for a cost of \$249. In 2001, Sorenson opened a high-throughput DNA purification, genotyping, and sequencing facility and launched Relative Genetics, a division that serves the genetic genealogy and ancestry markets. The company has a network of over 3,000 DNA collection sites worldwide. 🏛️



Lab Stocks Gain 1% Led By Genomic Health And Medtox

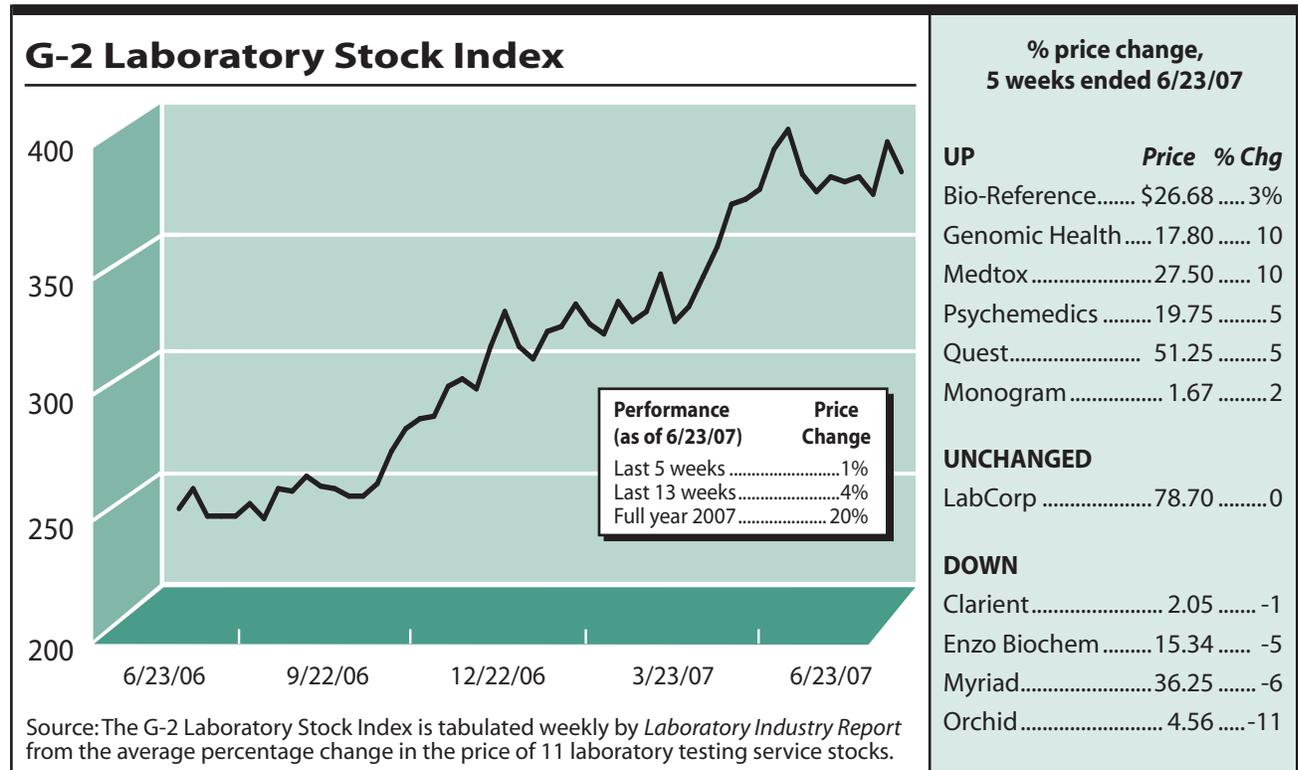
The G-2 Laboratory Stock Index rose 1% in the five weeks ended June 22, with six stocks up in price, four down, and one unchanged. Year to date, the G-2 Index is up an impressive 20%, while the Nasdaq is up 7% and the S&P 500 is up 6%.

Genomic Health (Redwood City, CA), best known for its Oncotype DX breast cancer prognostic test, was up 10% to \$17.80 per share for a market cap of \$468 million. At the recent meeting of the American Society of Clinical Oncology, the company presented the results of a multi-center study of 89 patients demonstrating that the Oncotype DX test result both alters treatment decisions and increases confidence for a high proportion of patients with early-stage node-negative, estrogen receptor-positive breast cancer.

Notably, the test was shown to influence treatment practice at both the academic and community hospital level. Genomic Health has performed approximately 27,000 Oncotype DX tests to date.

Things were also looking up at **Medtox** (St. Paul, MN). Shares in the clinical laboratory, which also manufactures diagnostic tests, were up 10% to \$27.50 per share for a market capitalization of \$247 million.

Shares in **LabCorp** (Burlington, NC) are holding steady at \$78.70. The company recently announced that Exact Sciences (Marlborough, MA) will extend the commercial lab's exclusive rights to distribute PreGen-Plus, Exact's DNA-based test for colon cancer. Under the agreement, LabCorp will be the sole distributor of the test through 2010. 🏛️





AMA calls for greater oversight of retail health clinics. . . . Among the hottest topics at this year's annual meeting of the policy-making House of Delegates of the American Medical Association (AMA; Chicago), held from June 23 through June 27, was the in-store clinics operated by retail giants such as Wal-Mart and CVS. AMA physicians questioned the quality and safety of the care provided by retail clinics and launched

an official investigation into the potential conflicts posed by joint ventures between retail clinics and pharmacy chains. The AMA will ask state and federal agencies to launch similar investigations into this rapidly growing patient-care model.

On June 24, one group of AMA members called for nothing short of a ban on retail clinics, testifying before the House of Delegates that the clinics endanger patient care, are staffed mostly by nonphysicians (advanced degree nurses and physicians' assistants), and are largely unregulated.

Pointing to retailers' reports that retail clinics help to drive additional store traffic, particularly sales of prescription drugs, the AMA is particularly concerned about the potential conflict of interest involved. "There are clear incentives for retailers to participate in the implementation and operation of store-based health clinics," said AMA board member Peter Carmel, M.D. "The nation's physicians want the AMA to ensure these incentives do not compromise the basic obligation of store-based health clinics to provide patients with quality care." 🏛️

References in this issue

- Caris Diagnostics 800-979-8292
- CIGNA 800-882-4462
- Florida Hospital Orlando 407-303-6611
- Genomic Health 650-556-9300
- LabCorp 336-584-5171
- Medtox 651-636-7466
- Midwest Clinical Labs 414-476-3400
- NCH Healthcare System 239-436-6000
- Quest Diagnostics 800-222-0446
- Sonic Healthcare 61-2-9855-5222
- Sorenson Genomics 801-462-1446
- Wheaton Franciscan Healthcare
414-465-3000

*Fully updated
for 2007!*

Lab Industry Strategic Outlook

Order online:
www.ioma.com/LabOutlook07

LIR Subscription Order or Renewal Form

YES, enter my one-year subscription to the *Laboratory Industry Report (LIR)* at the rate of \$399/yr. Subscription includes the *LIR* newsletter and electronic access to the current and all back issues at www.ioma.com/g2reports/issues/LIR. Subscribers outside the U.S. add \$50 postal.*

AAB & NILA members qualify for special discount of 25% off — or \$344.25 (Offer code LIR11)

I would like to save \$180 with a 2-year subscription to *LIR* for \$718*

YES, I would also like to order the *Lab Industry Strategic Outlook 2007: Market Trends & Analysis* for \$1195 (\$1095 for Washington G-2 Reports subscribers). (Report #1866C)

Check enclosed (payable to Washington G-2 Reports)

American Express VISA Mastercard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Name/Title _____

Company/Institution _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

e-mail address _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

MAIL TO: Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Or call 212-629-3679 and order via above credit cards or fax order to 212-564-0465. LIR 7/07

© 2007 Washington G-2 Reports, a division of the Institute of Management and Administration, New York City. All rights reserved. Copyright and licensing information: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact IOMA's corporate licensing department at 212-576-8741, or e-mail jping@ioma.com. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *Laboratory Industry Report* (ISSN 1060-5118) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Web site: www.g2reports.com.