

# LABORATORY INDUSTRY REPORT®

Stephanie Murg, Managing Editor, smurg@ioma.com

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## HIGHLIGHTS

### TOP OF THE NEWS

LabCorp awarded United contract ..... 1-4  
Will CMS crack down on pod labs? ..... 1-2

### INSIDE THE LAB INDUSTRY

Lab Institute highlights ..... 6-7

### HOSPITAL LABS

Steady growth for hospital lab testing ..... 8-9

### MERGERS AND ACQUISITIONS

MDS sold for \$1.2 billion ..... 10

### MEDICARE

Medicare Part B premiums to rise 6% ..... 5

### FINANCIAL

Quest revenues up 17% ..... 5  
United CEO resigns over options ..... 10  
Lab stocks soar 11% ..... 11

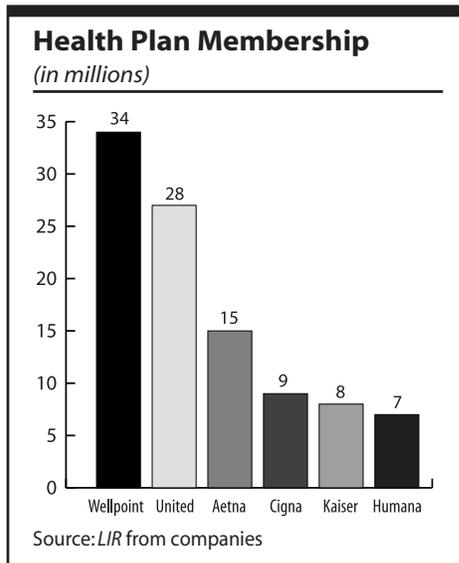
### INDUSTRY BUZZ

Keys to outreach competition ..... 12



## United Healthcare Awards Exclusive 10-Year Contract To LabCorp

About a year after issuing its industry-shaking request for proposals (RFP) for laboratory management services to its approximately 28 million health plan members, United Healthcare (Minnetonka, MN), announced that it has awarded a 10-year exclusive service contract to LabCorp (Burlington, NC), effective Jan. 1, 2007. Contract negotiation and implementation, including network communication, system preparation, and related transition activities, are now underway. United's annual lab spending is \$2.1 billion, which is currently split among Quest (20%), LabCorp (6%), physician office labs (34%), and other labs (40%).



"I am not familiar with any relationship in the lab industry with such a significant geographic scope, such comprehensive lines of services, and such a significant time frame," said LabCorp CEO Thomas P. Mac Mahon in a conference call with investors and analysts. ➔ p. 2

## Self-Referral Crackdown: Pod Labs In CMS's Crosshairs

The Centers for Medicare and Medicaid Services (CMS) is proposing changes that will close the Medicare benefit loophole that enables the existence of so-called "pod" or "condo" laboratories, in which labs for several group practices are located in small offices within the same building, and a pathologist moves among them. CMS recently announced a proposal to change the Stark definition of a "centralized building" to exclude both spaces under 350 feet and those that do not permanently house the equipment necessary to perform 90% of its designated health services. Medicare has reportedly received over 2,000 comments on the proposed rules. ➔ p. 2

## ■ SELF-REFERRAL CRACKDOWN, *from page 1*

CMS is anxious to halt the financial abuse that stems from its decision last year to relax Medicare's reassignment of benefit rules to allow physicians to reassign billing rights to an entity for those services that they performed off-site. "When the group practice bills Medicare for the supposedly in-office ancillary service, it invariably marks up the cost it paid the pod provider and profits from the 'spread' between the provider's charge and Medicare reimbursement," explains Elizabeth Neuwirth, counsel at the Stamford, Connecticut, office of Murtha Cullina LLP. "In CMS's view, once the sham of the centralized building is stripped away, what the physician group is really doing is purchasing a test and/or a test interpretation from a vendor." 🏠

## ■ UNITED HEALTHCARE CONTRACT, *from page 1*

Under the terms of the agreement, LabCorp will become United Healthcare's exclusive national laboratory and will also work with regional and local laboratory providers to develop and manage for United Healthcare a series of laboratory networks in selected regions of the country. United provides health plan coverage (including HMO, POS, PPO, and indemnity plans) to a total of about 28 million members, which equates to roughly one out of every 12 people in the United States.

LabCorp expects to gain more than \$3 billion from United over the decade-long deal. Additionally, LabCorp has committed to reimburse United up to \$200 million for the first three years of the contract for transition costs related to developing an expanded network in certain local markets.

Quest Diagnostics (Lyndhurst, NJ) will no longer be a national contracted provider of lab services for United, which accounts for about 7% of Quest's annual revenues. Less than an hour after the announcement, shares in Quest Diagnostics (Lyndhurst, NJ) had plummeted by 13% to \$53.25.

"We offered to substantially reduce [United]'s laboratory costs," said Quest Chairman and CEO Surya N. Mohapatra, Ph.D. "Unfortunately, the terms and

### What United Healthcare Wanted

- 1) **Electronic Data Interchange (EDI):** 100% adoption of EDI for claims submission and electronic funds transfer for accepting fee-for-service claims payment
- 2) **Long Term:** three years or more
- 3) **Pricing:** 15% to 20% savings over current lab budget
- 4) **Network Management:** assistance in designing laboratory services network
- 5) **Patient Access:** at least one service center within 10 miles of all members in urban areas, within 30 miles for rural areas
- 6) **Utilization Management:** assistance in developing protocols and reimbursement policies for lab services and physician compliance



conditions that were offered by United Healthcare would have been irresponsible for us to accept." Quest says that it will now compete for United's lab business as a noncontracted provider, thereby positioning the nation's largest lab as a direct competitor with many local labs and pathologists. The goal is "to keep as much of the United business as possible, now and after January 1," said Mohapatra during the company's third quarter earnings call. "We will fight for every doctor and every patient," he added.

In addition to becoming United's exclusive national laboratory, LabCorp will assume responsibility for managing the Oxford Health Plan network in New York and Connecticut, as well as become the sole national capitated laboratory for HMO benefit plans offered by Neighborhood Health Partnership in Florida, Mid Atlantic Medical Services (MAMSI) in Maryland and Virginia, and PacifiCare of Colorado. LabCorp Chief Operating Officer David P. King, who will succeed Mac Mahon as CEO on January 1 of next year, singled out Oxford as the company's "long-desired managed care anchor in the New York market."

## **Q&A with Brad Smith, LabCorp's executive vice president of corporate affairs:**

***You have talked about the number of patient service centers you will be adding, but will you be adding additional capacity in your laboratories to handle this increased volume?***

We do not believe that it will be necessary for us to build additional laboratories; however, additional testing equipment in certain facilities will be needed as the United Healthcare volume ramps up.

***How does the price per accession (PPA) for the new United Healthcare contract compare to your existing managed care PPA and your PPA with United Healthcare under the old contract?***

For competitive reasons, we do not provide details about pricing of specific contracts. While price is always an important element in negotiations with managed care organizations, we feel that the terms of the agreement are favorable to both LabCorp and United Healthcare and will produce margins that are at least equal to our current industry-leading margins.

***How does this agreement differ from the one that you have with Wellpoint?***

While the Wellpoint agreement designated LabCorp as Wellpoint's sole strategic laboratory partner, it essentially requires us to win additional business one local plan at a time. This new agreement with United Healthcare establishes LabCorp as United's exclusive national laboratory services provider for all United Healthcare markets. In addition, LabCorp will manage selected networks and will participate in the networks as a provider of laboratory services to United Healthcare's members.

***Will the contract change your payer mix?***

I would expect the payer mix to look similar to the payer mix that we have today....There's associated revenue that comes with the contract with United. The capitated could go up slightly, but I don't think in the short term that would be a big movement



LabCorp is preparing for the additional volume by spending the rest of 2006 adding several hundred patient service centers and hiring additional personnel, especially in the areas of phlebotomy, logistics, and sales. Since the contract announcement, LabCorp has been opening patient service centers at the rate of 20 per week. According to King, the company expects this pace to accelerate through the end of the year.

Expanding access in New York City, a region blanketed by Quest patient service centers, is a tall order, so on October 23, LabCorp announced a new agreement

with New York City drugstore chain Duane Reade, which has over 250 locations throughout the Metro area and is the market share leader in Manhattan. "Beginning immediately, LabCorp and Duane Reade will work together to open patient service centers in at least 20 key Duane Reade stores," said King. At these locations, patients can have blood drawn as well as have prescriptions filled and shop for various products. In the months

ahead, LabCorp plans to expand the relationship with Duane Reade beyond the 20 initial sites.

The goal of United's RFP, which sought proposals for both regional and national solutions, was to cut a minimum of 15% to 20% off its over \$2 billion per year lab testing expenses (including outpatient and outreach, clinical lab, and anatomic pathology). In recent years, United has been on an acquisition spree, acquiring MAMSI, Oxford, Neighborhood, and PacificCare for a total of \$16.0 billion and 6 million new members. By soliciting bids with an RFP, United sought to roll up the various lab contracts at the acquired companies into one huge contract. By awarding the contract to a single provider, United will simplify its lab services needs and substantially lower its healthcare expenses. 🏠

## United's Acquisition Spree (2002-2006)

<i>Health Insurer Acquired</i>	<i>Announced</i>	<i>Deal value (millions)</i>
John Deere Health Group .....	December 2005 .....	500
PacifiCare Health Systems .....	July 2005 .....	8100
Definity Health .....	November 2004 .....	300
Oxford Health Plans .....	April 2004 .....	4900
Mid Atlantic Medical Services .....	October 2003 .....	2960
AmeriChoice .....	January 2002 .....	560

Source: *LIR* and *The Deal*

**T**o get an inside look at how LabCorp's new exclusive arrangement with United will impact the lab industry, and specifically local laboratories and pathology groups, tune in to ***LabCorp's Exclusive Provider Deal With United HealthCare: Market Strategies for Labs & Pathology Groups to Apply in 2007***, Washington G-2 Reports' 90-minute national audio conference on November 2, featuring Michael Snyder, principal of Clinical Laboratory Solutions, and Mick Raich, president and CEO of Vachette Pathology.

During this program, you'll:

- Discuss major provisions relating to United HealthCare's agreement with LabCorp;
- Gain insight on how local markets will be affected by United's decision to axe Quest as a contracted provider;
- Assess how the new arrangement with LabCorp will impact existing United lab networks;
- Identify key changes in store for labs and pathologists in competing for United's business;
- Discover opportunities in competing for United's work under the LabCorp agreement; and
- Describe business strategies to implement in responding to the United initiative.

For more information, please call 800-401-5937, ext. 2.

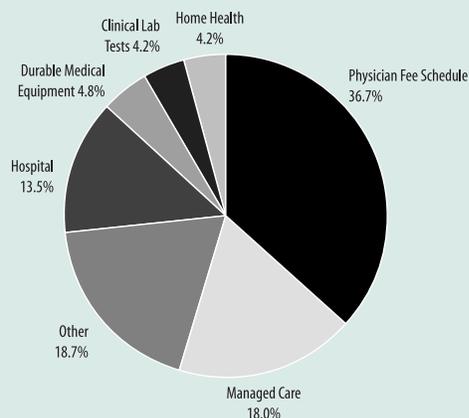


## Medicare Part B Premiums To Go Up 6% Next Year

The Centers for Medicare and Medicaid Services (CMS) has announced that Medicare premiums for Part B services will rise by 5.6% in 2007 to \$93.50 per month per beneficiary—the smallest percent increase since 2001 and less than half of the dollar increase in the premium for 2006. The annual deductible is also increasing by 5.6% to \$131.

### Breakdown of Part B Spending

#### 2006 Estimates\*



Total Part B Spending = \$169.8 billion

\*Does not add up to 100% due to rounding.

Source: LIR from 2006 Medicare Trustees Report

The 5.6% increase is comprised of an estimated jump in Part B medical expenditures plus another hike to help restore Medicare's assets. Medical costs are increasing mostly because of rapid growth in the use of physician services, lab tests, and other outpatient services, according to CMS.

Because Part B spending was lower than indicated by preliminary data and historical trends, the \$93.50 Part B premium is lower than the projections released earlier this year. CMS suggests that this lower spending might be attributable to "more timely submission of electronic claims and steps to promote quality performance through competition among the Part B carriers."

In calendar year 2006, total Part B spending will be \$169.8 billion, according to CMS's 2006 Medicare Trustees Report. Hospital outpatient procedures, which comprise 13.5% of the overall Part B budget, will rise an estimated 11.5% to \$22.9 billion, and physician payments (36.7% of budget) will increase by an estimated 7.9% to \$62.3 billion. Part B spending on clinical lab testing (only 4.2% of budget) is pegged to rise 7.6% to \$7.1 billion in 2006. 🏠

## Quest '06 Revenues Up 17%, Driven By Esoteric Testing And LabOne

It was a busy third quarter for Quest Diagnostics (Lyndhurst, NJ). The company spent \$230 million to acquire Focus Diagnostics and Enterix while working to wind down operations of Nichols Institute Diagnostics (NID; San Clemente, CA), its troubled test kit manufacturing subsidiary. Quest posted third-quarter revenue of \$1.6 billion, up 16.3% from last year. The company attributed 9.4% of the revenue increase to LabOne, which it completed the purchase of on Nov. 1, 2005, while newly acquired Focus added 1% to revenues. So far this year, Quest's revenues are up 17.1% to \$4.7 billion, about 10% of which is due to the LabOne acquisition.

During the third quarter, Quest's clinical testing volume (number of requisitions), increased 4.9% and revenue per requisition increased 5.4%. "The increase in revenue per requisition continues to be primarily driven by a shift to a more esoteric test mix and an increase in the number of tests ordered per requisition," said CFO Bob Hagemann. The company continues to see double-digit growth for gene-based tests for women's health, including HPV, Chlamydia, and gonorrhea testing. Additionally, allergy testing using ImmunoCAP, a quantitative blood test that measures allergen-specific IgE, grew by more than 20%. 🏠

# INSIDE THE LAB INDUSTRY

## Lab Institute Highlights Medicare Reimbursement Squeeze, Need For Collaboration

**W**ashington G-2 Reports's 24th Annual Lab Institute program featured presentations from more than 70 lab executives, consultants, and political figures. Below we've highlighted some key news and advice given by a few of the speakers:

**THOMAS P. MAC MAHON**, outgoing chairman and CEO of LabCorp, provided perspective on his 25 years in the clinical laboratory industry and reflected on

the industry's future. "In the last five years, I have observed an increased awareness by regulators, by legislators, and the public capital markets that the lab industry is essential to the delivery of quality care for patients," he said. "Investors are lining up at the doors of this industry to invest large amounts of capital, because they know that medical testing will continue to prosper as our population continues to age, as innovations continue to occur, and as new tests continue to be introduced." However, Mac Mahon cautioned that laboratory testing is now at "a historic inflection point," necessitating collaboration to address common challenges.

One industry trend he highlighted was consolidation on a variety of levels. "There are thousands of smaller laboratories who would like to combine with other laboratories in the not too distant future," adding that LabCorp is contacted every day by the owners or brokers of labs seeking to be acquired.

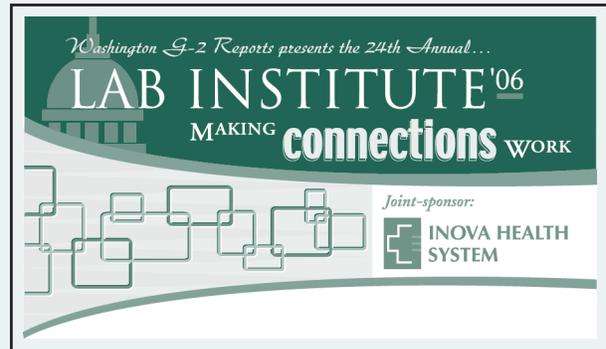


Rep. Fortney "Pete"  
Stark (D-CA)

**REP. FORTNEY "PETE" STARK** (D-CA), ranking member of the House Ways & Means Health Subcommittee observed, "What's changed since 1994 and the *Contract With America* and Newt Gingrich and his gang is that they *really* want to disband, dismantle, take apart the Medicare system," which has spurred the development of such initiatives as competitive bidding for lab services.

Stark also predicted a move toward standardization of electronic medical records and of information technology in healthcare. "One person, one entity with the ability to enforce it, and the way Medicare can enforce it is they won't pay you unless you have it in the right format," said Stark. "And that might trickle down to the others. The Blues [Blue Cross and Blue Shield] can do it. Somebody's got to say, 'Gang, this is the system! And you've got five years to convert into it, and you know what? You're not going to like it.'"

American Clinical Laboratory Association (ACLA) President **ALAN MERTZ** evaluated the political landscape, noting: "Whether the Democrats take the



## Lab Professionals Weigh In on Top Issues

### What is the lab industry's most potent reimbursement threat in the future?

Stagnating and/or declining Medicare payment rates: .....	25.9%
Implementing Medicare's lab competitive bidding demonstration: .....	48.2%
Push by large health insurers such as  United Health to negotiate lower rates: .....	20%
Inequitable coverage and payment policies for molecular/esoteric testing: .....	5.9%

### What is your own lab's biggest reimbursement challenge in the year ahead?

Trend by private insurers of doing business only with preferred labs: .....	31%
Unfair and/or arbitrary payment and coverage decisions by Medicare: .....	41.7%
In-sourcing of anatomic pathology services by physician specialty groups: .....	6%
"Low-ball" pricing imposed by competitors in your market area: .....	21.4%

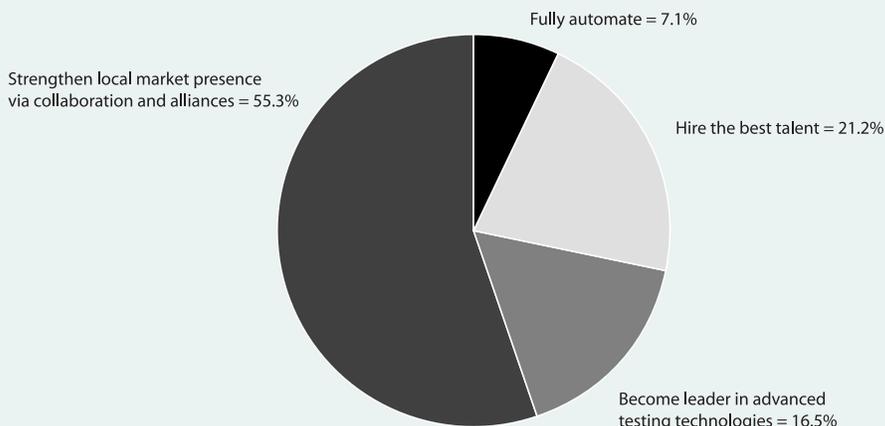
Source: Washington G-2 Reports 2006 Lab Institute Attendee Survey

House and the Senate or if they just pick up a few seats, no matter what happens, it will be much harder to pass any legislation. I think there will be a lot of oversight in the House if they do take over, and that can be good or bad for labs."

On the approximately 4% cut in the physician fee schedule slated for January, Mertz said, "I think there's a pretty good chance a bill will pass in the lame duck session that would eliminate that cut." He also speculated that there would be up to a two-year freeze on payments so that they would not be reduced. "There is even some possibility for a small increase for the physician fee schedule for the sustained growth rate (SGR), perhaps .5% or 1% tied to some sort of performance measure."

As for Medicare cuts, "it's only to get worse," according to Mertz, as providers and the soaring number of beneficiaries battle for their share. "We must continue to work together on the reimbursement for labs, something we all agree on, from the very smallest labs to the largest."

### What is the single most important step that labs should undertake to assure that they remain competitive into the next decade?



Source: Washington G-2 Reports 2006 Lab Institute Attendee Survey

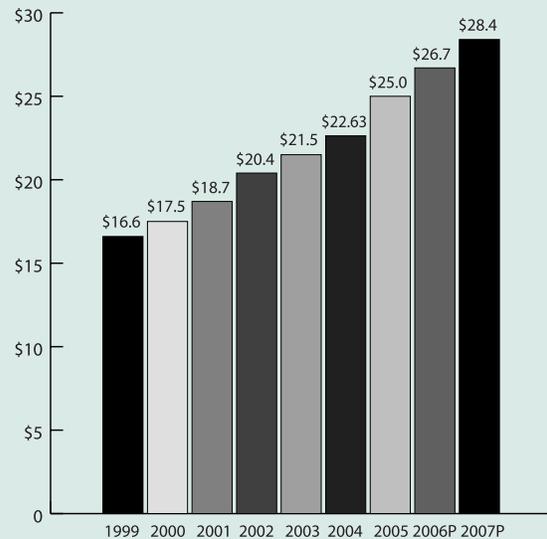
For more on Lab Institute 2006, including an in-depth look at how telepathology is affecting patient care and an update on the competitive bidding demonstration, see the December 2006 issue of *Laboratory Industry Report*. 🏛️

## Steady Growth Projected For Hospital Lab Sector

Washington G-2 Reports estimates that the hospital laboratory clinical testing market continues to grow at about 6.5% in 2006 and will continue at that pace in 2007 to reach approximately \$28.4 billion. Although the hospital laboratory's biggest competitors are clearly Quest Diagnostics and LabCorp, many face stiff competition from each other. Still, hospitals are indicating that the laboratory market, especially for hospital outreach facilities, can be a profitable business activity.

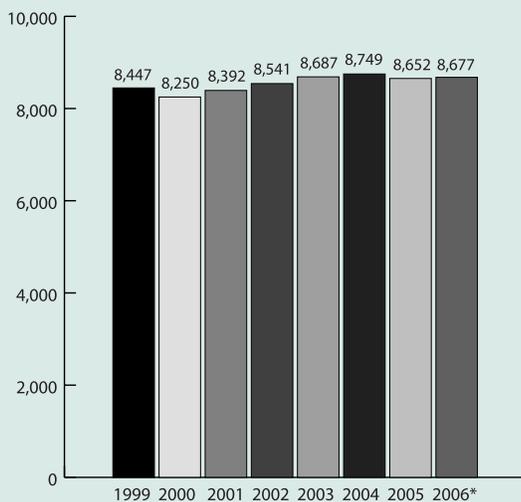
Hospital laboratories make up 55% of the clinical laboratory testing market. Quest Diagnostics (Lyndhurst, NJ) represents 13% of the total clinical laboratory testing market, with Laboratory Corporation of America (LabCorp; Burlington, NC) accountable for 8%. Their combined market share is 21%, an enormous majority of the 32% total independent clinical laboratory market share. Physician office labs (POLs) make up 8%, and "other" independent clinical labs make up the remaining 5%.

**Hospital Laboratory Revenues (\$BB)**



Source: Washington G-2 Reports; LabCorp and Quest Diagnostics documents

**Hospital Laboratory Facilities**



\*From June 2006 CLIA Laboratory Update  
Source: CMS-CLIA

According to CMS, total national expenditures on hospital care have averaged a 5.99% growth in the period from 2003 to 2006. They expect spending to reach \$662.5 billion in 2006.

### Growth Trends in Hospital Test Volume

In 2005, hospital test volume (inpatient, outpatient, and outreach combined) grew by a median of 5% and an average of 6.45%, according to the Washington G-2 Reports' *Third Annual Outreach Survey* conducted in May 2006. The 5% median growth rate is consistent with numbers from 2003 and in line with our estimate of hospital laboratory revenue growth of an average growth of 6.4% and a median revenue growth of 5.25%. Smaller hospital laboratories with annual volumes of less than 250,000 showed the highest annual median and average growth rate of 6.4% and 7.5%, respectively.



## Number of Hospital Laboratory Facilities

The number of CLIA-certified hospital laboratory facilities, according to CMS data, has shown a drop from 2004 to 2005 after a gradual increase from 2000 through 2004. At the end of 2005, this figure was 8,652. June 2006 numbers were 8,677, indicating a modest increase from 2005, but still down from 2004 and 2003.

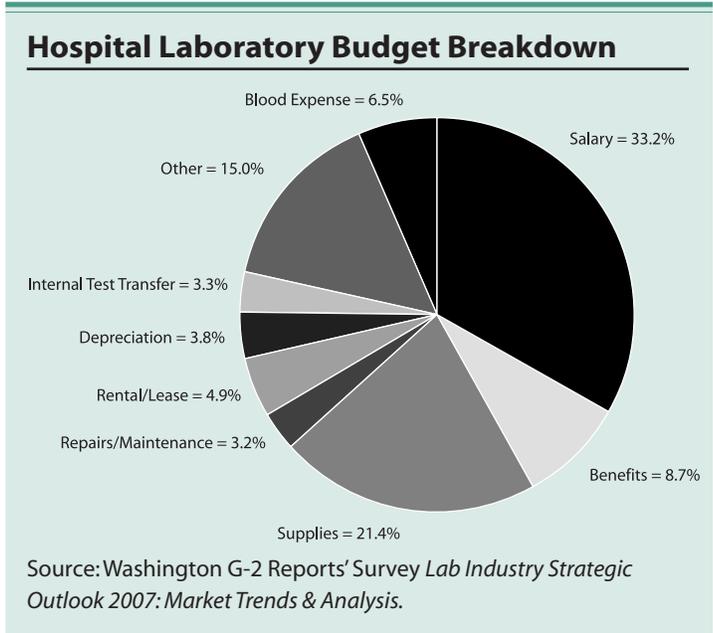
The American Hospital Association lists 5,759 registered hospitals in the United States as of 2005. Many hospitals operate more than one CLIA-certified laboratory, accounting for the higher number of laboratories than hospitals.

## Hospital Laboratory Budgets

In the 2005 Washington G-2 Reports: *Third Annual Outreach Survey*, 25% of hospital laboratories' budgets were between \$1 million and \$5 million; 17.3% said their budgets were between \$10 million and \$20 million; and 19% said their budgets were between \$20 and \$50 million.

Of laboratories recently surveyed by Washington G-2 Reports, over a third of their reported budgets are taken up by salaries and benefits: 33.2% of laboratory budget is taken up by salaries and 8.7% with employee benefits. The second largest laboratory budget item is supplies, which takes up 21.4% of budgets.

Nearly half of laboratories surveyed indicate that their fastest-growing budgetary expense is employee salaries, at 48%. The second fastest-growing expense is a tie with both blood products and reagent costs registering at 17.1% each. 🏠



## Total Hospital Laboratory Budgets for 2006

Less than \$1 million .....	10.7%
\$1 million to \$5 million .....	25%
\$5 million to \$10 million .....	17.3%
\$10 million to \$20 million .....	20.2%
\$20 million to \$50 million .....	19%
More than \$50 million .....	7.7%

Source: Washington G-2 Reports: *Third Annual Outreach Survey*

## UnitedHealth CEO Resigns Over Stock Options Scandal

Just as UnitedHealth was getting its laboratory services squared away, the company's stock options scandal (see *LIR*, June 2006, p. 10) has led to the resignation of its longtime chairman and CEO. William McGuire agreed to leave the company after the release of a report that found he likely received backdated stock options. At the end of 2005, McGuire's stock options were valued at approximately \$1.5 billion.

McGuire is expected to leave United by December 1 and will be succeeded by Stephen Hemsley, the company's president and chief operating officer. In the wake of McGuire's resignation, the Senate Finance Committee has requested a number of documents related to his \$1.1 billion severance package. 🏠

## Canada's Largest Lab Services Provider Sold For \$1.2 Billion



Stephen P. DeFalco,  
President and  
CEO of MDS

Global life sciences company MDS (Toronto, Canada) has agreed to sell MDS Diagnostics Services, its Canadian laboratory services business, to Borealis Infrastructure Management in a transaction valued at CAD\$1.325 billion (US\$1.163 billion). The deal with Borealis, a subsidiary of one of Canada's largest pension plans, is part of MDS's strategy to divest its lab services business and focus on the life sciences market. The transaction is expected to close by the end of January 2007.

MDS Diagnostic Services is Canada's largest provider of laboratory services, with annualized revenues of CAD\$335 million (about US\$294 million) and over 2,900 employees. The business provides more than 50 million diagnostic tests for approximately 20,000 healthcare providers and 10 million patients each year.

What's left at MDS without the diagnostic services business? The company will focus on its franchises in drug discovery instruments, molecular imaging, radiopharmaceuticals, and contract research services for pharmaceutical and biotech clients.

"I think our focus going forward is getting the pharma services division to be the profit producer," said MDS President and CEO Stephen DeFalco in a conference call with analysts and investors. The division is the third-largest supplier of central lab clinical trial testing services and has central labs in Canada, Germany, France, Singapore, and China as well as affiliate labs in Argentina, Brazil, and Mexico.

On October 17, MDS Pharma Services opened its first central lab in the United States, a CAP-accredited, 15,000-square-foot facility in North Brunswick, New Jersey, that provides services for clinical trials. The facility provides esoteric testing as well as standard drug safety testing. 🏠

### MDS Diagnostic Services

- ❑ Community Medical Laboratory Testing
- ❑ Specialized Clinical Laboratory Testing
- ❑ Hospital Laboratory Services
- ❑ Occupational Health and Safety Testing
- ❑ Drugs of Abuse Collection and Testing



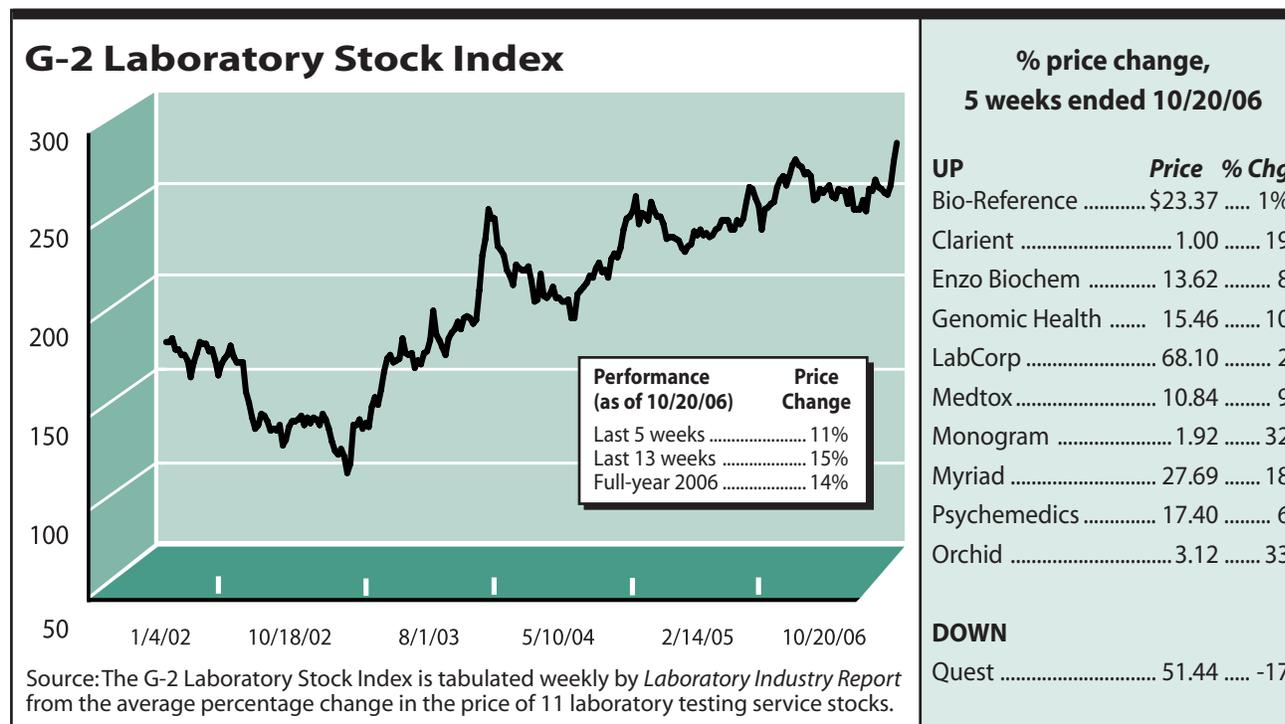
## Lab Stocks Up 11%; Quest Is Only Loser

The G-2 Laboratory Stock Index soared 11% in the five weeks ended October 20, with a whopping 10 stocks up in price and only one down. Year to date, the G-2 Index is up 14%, while the S&P 500 is up 10% and the Nasdaq is up 6%.

**Monogram Biosciences** (South San Francisco, CA), which performs specialized HIV and cancer testing, was up 32% to \$1.92 per share for a market cap of \$251 million. The company recently announced that it has received a \$10 million revolving line of credit from Merrill Lynch. According to CFO Alfred G. Merriweather, the company will use the credit to finance working capital, particularly accounts receivable, and fund continuing development of its HIV and oncology businesses.

**Myriad Genetics** (Salt Lake City, UT) was up 18% to \$27.69 per share for a market cap of \$1.08 billion. The developer of therapeutic and molecular diagnostic products just reported positive clinical results for Azixa, a compound licensed to Myriad as part of an exclusive, worldwide development and commercialization agreement with EpiCept (San Francisco, CA). Myriad is now preparing to begin Phase II clinical trials for the drug, which is a small-molecule tubulin inhibitor for the treatment of solid cancer tumors and brain metastases.

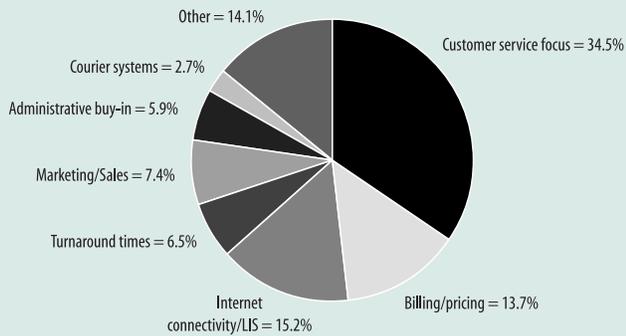
Meanwhile, shares of **Quest Diagnostics** (Lyndhurst, NJ) took a beating in the wake of United Healthcare's announcement that LabCorp will be its exclusive lab services provider beginning Jan. 1, 2007 (see pp. 1-2). Quest plummeted 17% to \$51.44 per share for a market cap of \$10.05 billion, while **LabCorp** (Burlington, NC) was up 2% to \$68.10 per share for a market cap of \$8.57 billion. 🏠



# INDUSTRY Buzz

**Competing To Win . . .** Hospital outreach programs surveyed for the Washington G-2 Reports' *Third Annual Outreach Survey* cite customer service and quality as the most important part of their "best practices" (34.5%). Surprisingly, only 6.5% of respondents include turnaround time among their key competitive strategies. A far greater concern is proper billing and pricing (13.7%).

## Key Competitive Success Strategies



Source: Washington G-2 Reports' *Third Annual Outreach Survey*

Although good customer service will (and should) probably always remain high on the list of a hospital laboratory outreach program's business assets, there is now a greater focus on Web connectivity and information systems: 15.2% versus 9% from a similar survey conducted in 2004. This is due to a leveling of the playing field among the larger national labs (LabCorp and Quest Diagnostics) and hospital labs in terms of turnaround times as the industry moves toward automation and online reporting. It also indicates a greater emphasis on laboratory efficiency. 🏰

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## References in this issue

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LabCorp 336-584-5171  
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