

LABORATORY INDUSTRY REPORT®

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San Diego Labs Prepare for Competitive Bidding Demo

The first question on many minds of San Diego County laboratorians is why the Centers for Medicare & Medicaid Services (CMS) chose this region as the first of two sites for the competitive bidding demonstration project. In selecting a site or Metropolitan Statistical Area (MSA), CMS wanted to have enough labs for effective bidding and multiple winners, as well as a patient population that reflected the national laboratory market. But this is not the case in San Diego, explained Donna Serpico-Thompson, the vice president of business development for Sharp HealthCare, an area healthcare system that includes four hospital outreach laboratories, as well as eight independent labs.

Bidder's Conference Rescheduled for December 5

"CMS initially wanted an area that didn't have a large number of Medicare managed care patients, but in San Diego, about 42% of the Medicare population is covered by Medicare managed care, so it's probably one of the highest percentages in the country," she said. This site, which includes San Diego, Carlsbad, and San Marcos, is the 16th-largest MSA in the country with a population of over 3 million. This population includes over 330,000 people under Medicare's Part B coverage, according to the most recent data from CMS released in 2003.

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Quest Confirms Launch of India Operations

Citing the potential to serve an area of rapid population growth, Quest Diagnostics is currently building a lab in India's New Delhi region and expects to have the business up and running in 2008. The laboratory company also appointed Janak Singh Bajwa as managing director of Quest Diagnostics Pvt. Ltd.

"This is a growth opportunity to serve the Indian healthcare community—patients and doctors—as opposed to outsourcing laboratory work from the United States," said company spokeswoman Barb X. Short. "Second, we see a growing demand for some of the higher value esoteric or highly specialized testing we perform, such as cancer diagnostics and infectious disease. For example, we have seen significant growth in our Leumeta family of tests that measure markers for leukemia and lymphoma in blood plasma instead of relying on painful bone marrow biopsies using a large bore needle through the hipbone."

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Competitive Bidding Demo, from page 1

Another issue involves the pending legislation before the House and Senate to repeal the project (see *LIR*, September, p. 1). “We feel that it’s confusing to have laws introduced to repeal it, but at the same time CMS is going forward,” said Rick Nicholson, president and CEO of Westcliff Medical Laboratories (Santa Ana, CA), whose lab network includes facilities located in San Diego County.

Nationwide, California currently has the largest outreach testing market, with over 119 million billable tests per year, according to Washington G-2’s *Laboratory Market Leaders Report 2008*. But the two national labs—Quest Diagnostics and LabCorp—comprise about 80% of the region’s outreach market, estimates Serpico-Thompson.

The dominance by Quest and LabCorp is another reason why the San Diego area is not representative of the national market, added Nicholson.

Shortly after announcing that San Diego County would be the first competitive bidding demonstration site, CMS scheduled a Bidder’s Conference for October 31. However, the conference was postponed to December 5 due to the fires

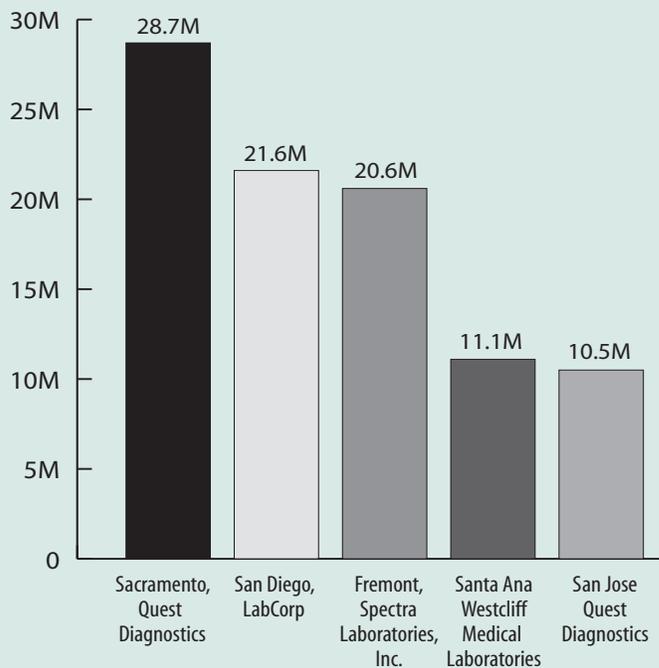
burning across the county. In the meantime, laboratories in the San Diego metropolitan region that will be required to bid are reacting to the selection news, as well as assessing how the demonstration is likely to impact their bottom line.

Serpico-Thompson also has a lot of questions about some of the details of the bidder’s package, which CMS released before announcing the MSA selection, including what annual volume information needs to be provided as part of the bid proposal. The bidder’s package is asking for annual volume data, but it’s unclear if this means annual outreach volume, inpatient volume, or outpatient volume. CMS would use this information to evaluate local capacity and ensure there are enough winning bidders to provide testing services. “One of my other questions is that the pricing has to

be below 99% of the composite bid price for fiscal 2007,” said Serpico-Thompson. “We haven’t been given that information, and we are not sure if CMS is going to provide it or if we will need to obtain it from another source.”

CA’s Top 5 Commercial Labs

Test volume/yr



Source: Washington G-2 Reports’ *Laboratory Market Leaders Report (2008)*



In terms of how the demonstration project will impact Sharp's laboratories, Serpico-Thompson said that if Sharp wins the bid, it will likely be business as usual, but losing the bid would have an impact. "If we don't win the bid, we would expect to see a significant decrease in our volumes," she said. "Depending on which hospital—each of our four hospitals provides outreach laboratory services—probably about 30% to 40% of our volumes are Medicare fee-for-service. So it would have an impact." If they did lose, Sharp would have to reconsider their role in the outreach business, given the high overhead costs like courier service, software maintenance, and patient service centers. "We need that volume to make it work effectively," she added.

While Westcliff's Nicholson is confident that his lab will be able to compete fairly, he is concerned about how Quest and LabCorp will bid. "If the bidding comes out at a level that is profitable to labs, then we can compete . . . but we don't know what the big labs are going to do," he said. "There's the concern that they are going to bid so low that no one makes any money. We would bid responsibly, but the big labs have shown that they won't always do that." 🏠

Counterpoint: Time Is Right for Competitive Bidding Demo



Joseph Plandowski

While most of the clinical lab industry have denounced CMS's competitive bidding demonstration project as a misguided attempt to lower reimbursement prices for testing services, some are supporting the initiative, stating that it's an appropriate approach to reign in healthcare spending and put Medicare prices in line with those of private payors.

"The Medicare program is headed for a world of hurt with a lot of older people coming in to the program over the next 10 to 20 years," explained Joseph Plandowski, a former laboratory executive and current president of Lakewood Consulting Group (Lake Forest, Ill.). "Medicare is the largest purchaser of clinical laboratory services, and they don't get the right prices. Medicare is paying twice what United HealthCare is paying [under their national contract with LabCorp], and that is not right."

This pricing problem reaches back to the 1980s when CMS released the first laboratory fee schedule, said Plandowski, who was directing a SmithKline Beecham laboratory in Florida at the time. The fee schedule was initially based on how much labs billed CMS for tests. "For example, there was an automated chemistry profile . . . the fee Medicare was going to pay us was \$16 or \$17, even though the list price for that test in our catalog was \$7.50," he explained. "How did that happen? We would sell tests to a physician for \$5 a test, and then the physician would mark it up from \$40 to \$60, and that price went into the calculations for the fee schedule."

Realigning Prices

One of the most repeated concerns by critics is that even if CMS doesn't move competitive bidding out of the demonstration phase, the agency might use the bid prices to lower the reimbursement levels in the future.



But according to an Institute of Medicine study released in 2000, the current Medicare fee schedule for labs has no substantial relationship to actual costs, explained Stephen T. Mennemeyer, Ph.D., a professor with the University of Alabama at Birmingham's School of Public Health. Mennemeyer is one of the initial architects of the competitive bidding demonstration project for laboratory services. From 1979 to 1989, he worked at Abt Associates, Inc., where he served

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— Joseph Plandowski

as the project director on a contract funded by the Health Care Financing Administration—now CMS—to design a demonstration project that he said is similar to the program about to move forward.

The Medicare price list needs to be more realistic about identifying which tests are relatively expensive to produce and which are relatively inexpensive, according to Mennemeyer. "Al-

though the information from competitive bidding may help to realign some of the prices of particular tests, I doubt that Medicare competitive bidding will make HMOs and insurance companies any more aggressive than they already are about seeking low prices," he added. "Medicare may save some money due to competitive bidding but, if it does, it will only be catching up with what has already happened in the rest of the healthcare industry." 🏛️

2008 Fee Schedule Ends Pod Labs

CMS is cracking down on pod labs through a new anti-markup provision in the *2008 Final Physician Fee Schedule*. The rule takes away any financial incentive for physician groups to set up pod labs to profit from anatomic pathology work, explained Donna Meyer, assistant director of professional affairs for the College of American Pathologists (CAP).

While the anti-markup provision is based on recommendations from CAP, the organization would like the provision applied to all contract joint ventures (CJVs). "We're happy that it is focusing on the issue of the potential abuse from the financial incentive of the referring physician, but we really feel that CMS needs to take that important second step to not just apply it based on the site of service, but to recognize the fundamental problem with self-referring physicians profiting from anatomic pathology," she said. Under CMS's definition, a pod lab is an off-site laboratory remotely located from where the billing physician provides patient care. The new provision applies to reassigned diagnostic testing services if the service is done off site.

Meyer added that she is hoping the provision will be broadened to include all CJVs when CMS implements stricter regulations against physician self-referral under the Stark Law. "As much as this a great start, we expect to see a greater impact on the industry in the next year or two when CMS starts looking at the Stark law, and that's when we will be able to effectuate a bigger impact on these practices," said Meyer. 🏛️

Spokane's Sacred Heart Molecular Lab Growing in Unexpected Ways

For 2007, Washington G-2 Reports values molecular diagnostic testing at \$4.1 billion and estimates growth of approximately 19% each year through 2010. Last year, estimates for the U.S. market for molecular diagnostic testing totaled \$3.5 billion, with infectious disease testing accounting for about half of that amount and the remainder comprising blood screening and genetic testing.

The molecular diagnostic lab at Sacred Heart Medical Center & Children's Hospital in Spokane, Washington, is an example of one lab realizing the potential of this growing testing market. In 2006, the molecular diagnostics lab billed out over \$7 million in testing, reporting out close to 24,000 test results. This year, results reporting is expected to surpass 28,000 test results. And researchers at the lab have also uncovered another unexpected revenue stream—the sale of synthetic molecular controls for confirmation of cystic fibrosis (CF) testing.

Since the laboratory began producing and marketing these controls in 2005, annual revenues have grown from \$75,000 the initial year to \$150,000 in 2006. This year, lab personnel expects to take in close to \$200,000 in revenue from the controls, with a net margin of 15% to 20% for the hospital.

Bringing Quality Controls to Market

The Sacred Heart molecular diagnostic lab was forced to design and produce these control materials because they were unsatisfied with what was avail-

able to them to ensure their CF testing was efficient and of high quality. "We saw the need for a control that would be comprehensive in terms of our CF testing," explained Marcy L. Hoffmann, Ph.D., technical director of Sacred Heart's Molecular Diagnostic Laboratory. "But as we put together our own CF test and quality control program, we saw that what was available in terms of quality control was not meeting the mark. So we set about designing synthetic controls with the sole intent and purpose of putting together control materials for our internal purpose."

While the initial intent of producing these controls was for the Sacred Heart lab, other labs wanted to buy the controls. The research and development of these materials also led to peer-reviewed articles, as well as some national and international presentations at scientific meetings.

The investment in the research and development was on the front end and primarily came from money saved from purchasing reagents, explained Todd Christensen, a medical technologist and one of the lead researchers and developers of the control material. "For instance, over a period of a year, this would save us around \$60,000 to \$70,000 in purchasing reagents," he explained. "We put these dollars that were going toward reagents into research and development, and once the controls started to sell, any revenue went

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of key practical business,
financial and technical trends
driving molecular diagnostics
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Cambridge, MA

back, returning that investment.” Given that the revenues were \$75,000 in 2005, the initial investment was recouped rather quickly.

From the standpoint of the hospital, these controls are an important product line because they have improved the quality of the CF testing internally, as well as introduced a comprehensive product into the marketplace that is not available anywhere else, said Gerard Fischer, a Sacred Heart vice president.

“It’s kicked up the quality of our testing done in that department on those specific tests,” he explained. “This is money we’re not spending some place else, and we have created a very good customer list. People have tried the product and liked it in their operations, and it does generate profitable income.”

Growth and More Growth

The success of the CF testing controls product reflects the growth of the Sacred Heart molecular diagnostic lab, which was established in 1999. Sacred Heart’s clinical laboratories are affiliated with Pathology Associates Medical Laboratories (PAML). Both Sacred Heart and PAML are owned

by the Spokane-based Providence Health Care, a network of hospitals and agencies in eastern Washington state.

Over 50% of the testing performed in the clinical laboratories at Sacred Heart is esoteric testing for PAML, explained Fischer. “That’s really how departments like our molecular diagnostics and cytogenetics have grown,” he added. “Over 90% of the molecular volume is from outside of Sacred Heart medical center—very little has do with our inpatient testing.”

By subcontracting with PAML, Sacred Heart provides a more comprehensive menu of tests and gives PAML a lot more control over the way testing is done than if it was sent out to another reference lab. “For us, we simply bill PAML on a monthly basis for the testing that is done,” said Fischer. “It’s a very easy transaction. We send them a monthly statement, and they pay us. Overall for Providence Health Care, it’s an important component of being a comprehensive laboratory.”

The Sacred Heart molecular diagnostics lab first began with an operating budget of \$212,763, although the expenses came in under budget at \$143,168. These expenses included salaries for two full-time equivalent (FTE) personnel, reagents, lab supplies, office supplies, and instrument maintenance. Over seven years, the lab has seen significant growth. “In 1999 we billed out \$118,175, whereas in 2006, our billables were greater than \$7.7 million,” said Hoffman. The lab now employs 14 FTEs.

There are three primary drivers of growth in this market, according to G-2 Reports’ *Business Strategies for Molecular Diagnostics in the Lab* (2007).

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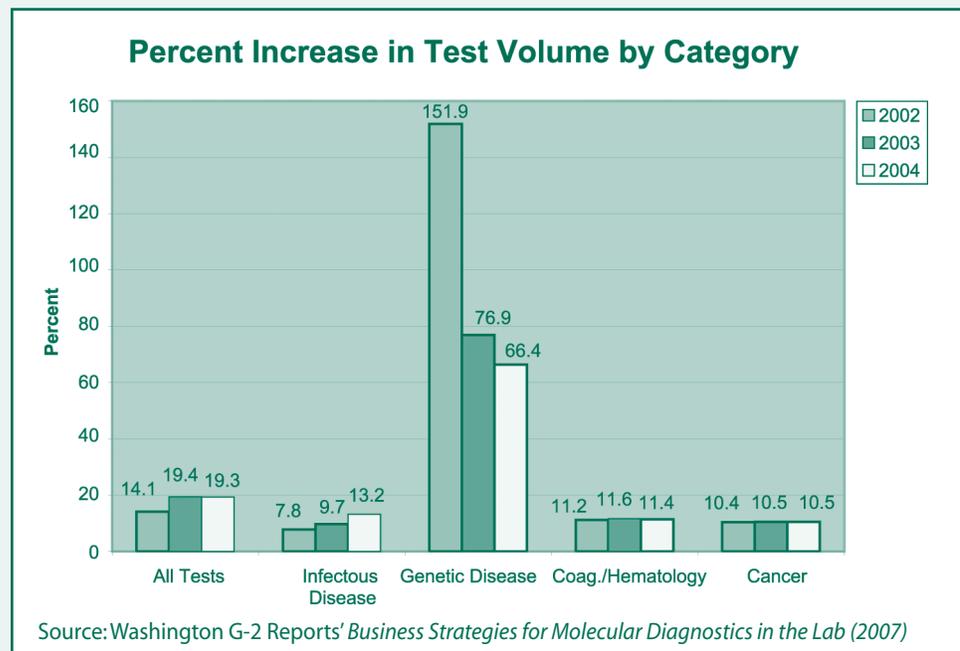
The first driver is the growth of molecular tests for infectious diseases like HPV and CT/NG for chlamydia. Secondly, these tests have improved in sensitivity and specificity, and finally, the growth of an aging population in the United States will continue to increase demand for tests.

At Sacred Heart’s lab, marketing efforts also helped boost growth. “Our marketing team has had a couple of successful marketing initiatives with regard to molecular testing,” said Hoffman. “Cystic fibrosis is one of those. The PAML marketing team decided to make it a formal marketing initiative, and we then saw dramatic growth with more involvement by making our clients aware that we were offering this test.”

But it can be a challenge to convince the marketing staff about the value of building initiatives around tests. In the case of cystic fibrosis, the value was apparent because this test became the national standard of care. However, the molecular diagnostics lab now wants to push their menu of genetic tests through marketing initiatives, and they are also currently launching a molecular oncology test menu. It’s been a bit of a struggle to convince the marketing staff of the value of some of these testing menus, but Hoffman thinks it’s simply a matter of education. “We have to get the marketing agenda in alignment with the technical agenda,” she added. “We need to make them [the marketing staff] aware that we have an important service to offer and that we’ve barely even scratched the surface in terms of possibilities.”

Launching a Molecular Diagnostic Lab

Despite this market growth, however, many hospital labs are hesitant to bring molecular testing in-house, according to Gregory J. Tsongalis, PhD, director of molecular pathology and co-director of the pharmacogenomics



program at Dartmouth Medical School and Dartmouth Hitchcock Medical Center (Lebanon, N.H.). “Most hospital-based labs in the U.S. are not offering any molecular testing—they are sending it out,” he explained. “But if you look at the cost of sending [this testing] out, and the cost of bringing it back in-house with some of the newer technologies, it’s really a no-brainer.”

In recent years, there have been several changes in the molecular diagnostics industry making it now easier for hospital labs to bring this testing in-house. “The technologies have become much more user-friendly,” said Tsongalis. “Some of them have become turnkey, which means that laboratories that are not focused specifically on molecular diagnostics can start offering this type of testing. The smaller community hospitals and mid-size hospitals that don’t have a dedicated molecular lab can start doing some of these things.”

Once a hospital lab decides to offer molecular testing, it’s wise to initially offer high volume tests, which will most often be infectious disease testing for hepatitis C, gonorrhea, and HPV, said Sacred Heart’s Hoffman. “Look for the really high-volume tests that will give you the biggest bang for the buck,” she explained. While there are constantly new tests coming

into the lab for application, there are well-established tests with FDA approved instruments and reagents that are ideal for use in labs with no molecular experience. These tests require little background knowledge and are easy to trouble shoot when things go wrong.

Some labs might be tempted to jump right into genetic testing—according to Washington G-2 data, test volumes have increased from by 66.4% in 2004, compared to infectious disease and cancer test volumes, whose volume increased by 13.2% and 10.5% respectively. But Hoffman doesn’t advise labs to offer genetic testing when launching a molecular diagnostics lab. “Genetic testing is a little tricky in that you need more expertise in terms of personnel,” she explained, adding that even though there are FDA approved assays for CF testing, the results

require highly skilled interpretation. “That test is tricky in that the genetics are not straightforward and in many instances you really need to have access to somebody who is trained in clinical genetics, molecular genetics, or even clinical cytogenetics to be able to offer some insight and valuable interpretation of test results.” For these reasons, she doesn’t believe genetic testing is viable for every lab wanting to get into molecular testing. Infectious disease testing is a more practical place for labs to begin cutting into this burgeoning market of molecular diagnostic testing. 🏛️

PAML Expands Outreach Services With MountainStar

PAML will join forces with MountainStar to expand outreach lab services into Idaho and Utah under a new joint venture called MountainStar Clinical Laboratories. MountainStar’s healthcare system operates eight hospitals in the two states.

This joint venture will combine the testing capabilities at two MountainStar Hospitals in Utah, St. Mark’s Hospital in Salt Lake City and Lakeview Hospital in Bountiful. Both hospitals will be connected using PAML’s Outreach Advantage laboratory IT services. Approximately 85% of the testing by MountainStar Clinical Laboratories will be performed in Utah, according to a company release.



United, Georgia Diagnostic Clinic End Contract Disputes

Months of tense negotiations with United HealthCare has finally resulted in a new contract between one of the nation's largest health insurance providers and the Northeast Georgia Diagnostic Clinic, located northeast of Atlanta.

In the summer of 2006, United HealthCare notified the clinic that it would be on a new fee schedule. This new fee schedule impacted lab test reimbursement levels, as well as fees for radiology and other services provided by the clinic to almost 5,000 United HealthCare patients. The clinic has approximately 40,000 to 50,000 total patients. "When we agreed to a fee schedule for the three-year contract back in 2004, we were looking at a fee schedule that was above Medicare," said Emmett Forrester, the clinic's chief financial officer. "Then the new fee schedule they came out with was significantly below Medicare." Forrester declined to provide details on the reduction in fees for lab testing services, except to say it was substantial.

The situation is indicative of what many diagnostic clinics and laboratories are facing since United Healthcare signed a national contract with LabCorp last fall, according to Dave Griffin, Ph.D., president of TechnoClin Consulting (Deerfield, IL). He estimates that this national contract is between 50% to 60% of Medicare reimbursement.

"These national exclusive contracts are the 2000 version of the capitation pricing we saw in the 1990s," said Griffin. "The managed care companies are exercising their national clout. And with these national contracts, local labs don't have a lot of options; their only options are through their local community. If they have a strong local presence and LabCorp doesn't, then insurance companies will sometimes carve out an exclusion agreement with a local lab and not require everybody to use the national lab, but they will have to meet those same rates."

While United HealthCare declined to comment, Forrester said that when it came to negotiating lab fees, officials said the reimbursement levels in its revamped fee schedule were in line with their current "national initiative," which means nationwide reimbursement levels for lab tests, as well as radiology and ancillary services.

Standing Firm

After months of unsuccessful attempts to contact the insurance provider to negotiate a new fee schedule, Forrester and his colleagues notified United HealthCare officials in Georgia that the contract would be terminated at the end of 2006. In addition, they also notified 4,500 clinic patients who were currently covered by the insurance provider. These patients complained to United, prompting the provider to get in touch and begin discussions with Forrester and other clinic officials.

But by this past August, negotiations were at a standstill. The clinic's contacts at United had changed numerous times, and now their phone calls were going unanswered. Again, they reached out to their patients. "The reason we did that



was because about 55% of the 4,500 patients who we sent the letter to were state employees, and the open enrollment period for state employees was beginning the first of October until the first of November,” said Forrester. “We wanted to give those patients plenty of notice so that they could make an informed decision about their healthcare. The state employees have options other than United HealthCare in terms of their insurance benefits.” Again, this move caught United’s attention, and negotiations began soon after-

ward with a new representative. A new contract was agreed upon within weeks, which will be effective Jan. 1, 2008.

“The managed care companies are exercising their national clout. And with these national contracts, local labs don’t have a lot of options; their only options are through their local community.

—Dave Griffin, Ph.D.

The clinic’s financial bottom line will likely take a hit, since they have been at the reduced fee schedule since November 2006. Nevertheless, Forrester advises other healthcare service providers to stay firm throughout the negotiation

process. “We can’t survive off of rates below Medicare,” he said. “We stood our ground on that and made it clear that we weren’t going to accept rates that were below Medicare. Our feeling was that if we bow down to one managed care company, the other companies and carriers would follow suit, and that would put us in a very precarious position.” 🏛️

Quest Confirms Launch of India Operations, *from page 1*

Mr. Bajwa is coming to Quest from Fortis Healthcare Ltd., an Indian healthcare network. He will be based in Quest’s recently opened office in Gurgaon.

In the United States, Quest continues to dominate the clinical test market—claiming a 13% market share, while LabCorp has about 8%, according to Washington G-2 estimates in the recently released *Laboratory Market Leaders Report 2008*. Hospital labs account for 55% of the market. While Quest will gain even more market share after its May 2007 acquisition of AmeriPath, a dominant anatomic pathology lab, LabCorp’s national contract with United HealthCare will also increase its share of the market. Because of these changes, Washington G-2 estimates that 2007 will prove to be a transition year for both Quest and LabCorp, as businesses adjust to these changes.

Short declined to provide any details on the lab operations, except to say that Quest has partnered with HCL Technologies, a global IT company based in India. HCL will establish and manage Quest’s IT infrastructure, as well as host the company’s data center and network support services in Noida, India.

In addition to its presence in India, Quest is also looking to expand to other developing countries, according to Short. “We are looking at a number of opportunities in developing countries, where a growing middle class has an interest in managing their health and the means to pay for diagnostic tests that help them to do so,” she added. “India’s explosive growth is one example, and we are also looking at additional markets.” Overseas, the company currently has labs in the United Kingdom and Mexico and manufactures test kits in Sweden and Australia. 🏛️



Janak Singh Bajwa



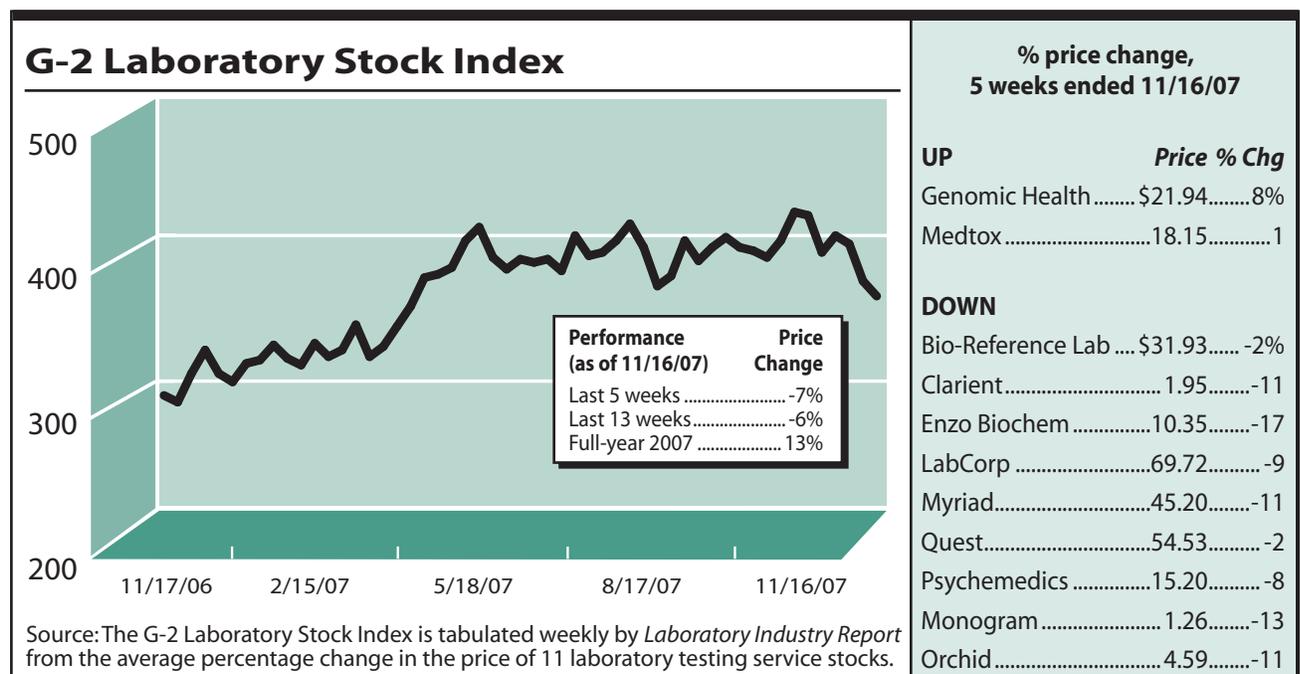
Lab Stocks Take a 7% Dip in November

The G-2 Laboratory Stock Index is reflecting the current turbulence on Wall Street, with lab stocks down 7% over the five weeks ended November 16. So far this year, the index is up 13%, while the Nasdaq and S&P 500 continue to make small gains; the Nasdaq is up over 9% and the S&P is up almost 3% over the end of 2006.

Those leading the recent downward trend include **Enzo Biochem** (Farmingdale, NY), whose stock fell 17% to \$10.35 per share for a market cap of \$380 million over the last five weeks. Other labs experiencing falling prices included **Mono-gram Biosciences** (South San Francisco, CA)—down 13% to \$1.26 per share for a market cap of \$166 million, as well as **Clariant** (Aliso Viejo, CA) and **Orchid Cellmark** (Princeton, NJ)—both down 11% over this period. Clariant was down to \$1.95 per share for a market cap of \$140 million, while Orchid’s price was \$4.59 per share with a market cap of \$134 million.

While Enzo Biochem had the biggest slide, the company’s subsidiary Enzo Clinical Labs is growing. In early October, the laboratory was awarded a new contract with United HealthCare (Minnetonka, MN) to perform expanded regional lab services for the health insurance provider in the New York and New Jersey area. The clinical laboratory company was also awarded a similar contract with Aetna (Hartford, CT) earlier in 2006. In response to these contracts, the company is expanding to increase the number and complexity of tests performed in-house.

Both **Quest Diagnostics** (Madison, NJ) and **LabCorp** (Burlington, NC) had losses. While Quest was down 2% to \$54.53 per share for a market cap of \$10.6 billion, LabCorp posted a 9% drop over this time period. Nevertheless, LabCorp officials have indicated that the current stock price—which closed at \$69.72 per share for a market cap of \$8.1 billion on November 16—does not fully reflect the value of the company. 🏠





Canada's MDS Is Now LifeLabs

As a result of a recent corporate sale, MDS Diagnostics has been renamed LifeLabs. In February 2007, MDS was sold to Borealis Infrastructure, an investment entity of OMERS (Ontario Municipal Employees Retirement System), for CAD\$1.33 billion. The laboratory company was formerly owned by MDS Inc., a Toronto-based international life sciences company.

This name change is part of the condition of the sale and will mean that the LifeLabs name and brand will be integrated over the next several months, replacing the MDS Diagnostics logo on building signage, courier vehicles, e-mail addresses, and Web sites. LifeLabs has locations in Ontario, Quebec, and British Columbia, and its partners also include Toronto Medical Laboratories. This Canadian reference laboratory has an annual volume of over 50 million laboratory tests for over 10 million patients, according to a company release. 🏛️

References in this issue

Bio-Reference 201-791-2600

CAP 800-323-4040

Clariant 949-425-5700

CMS 877-267-2323

Enzo Biochem 631-755-5500

LabCorp 800-334-5161

Medtox 651-636-7466

Monogram Biosciences
650-635-1100

Myriad Genetics 801-584-3600

Northeast Georgia Diagnostic
Clinic 770-536-9864

Orchid Cellmark 609-750-2200

PAML 509-755-8600

Quest Diagnostics 800-222-0446

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