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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

WASHINGTON G-2 REPORTS

Labs Boost Efficiency With Lean and Six Sigma Techniques

Process management philosophy might work wonders in an automotive plant, but can it result in a meaningful improvement in the performance, quality, and efficiency of clinical laboratories and other healthcare settings? Increasingly, yes. Laboratories and hospitals of all sizes are adapting the principles of Lean manufacturing and Six Sigma to streamline their workflow, fine tune their information systems, eliminate errors, and minimize turnaround time.

One recent example from the hospital sector is Meadows Regional Medical Center (Vidalia, GA). The hospital's emergency room began implementing Lean principles in June of 2005, when it was plagued with bottlenecking, long turnaround times, decreased satisfaction, and overworked staff. Since then, they have achieved a 44% reduction in average length of stay per patient, a 10% boost in patients served, and a 92% patient satisfaction rate. The hospital is now preparing to integrate Lean methods into a new, state-of-the-art facility that is now in the planning stages. For an in-depth look at how laboratories are learning from Lean and Six Sigma experts, see *Inside the Laboratory Industry*, pp. 5-7.

Myriad Premieres TV Ad for Breast Cancer Test

Myriad Genetic Laboratories (Salt Lake City, UT) is following the lead of Digene with direct-to-consumer marketing. The difference? Digene's test is designed to detect a virus (human papilloma virus) that affects approximately 20 million people in the United States and can cause cervical cancer. Myriad's BRACAnalysis test, which costs $3,125, has a much smaller candidate pool, and many are concerned that the advertising may lead to unnecessary testing.

The television ad, which premiered in selected Northeast markets (Boston, Hartford, Providence, and New York City) in early September and will run through next spring, is part of Myriad's newly launched "BRACAnalysis Awareness campaign." The company says the ad is designed to reach women with a family history of breast and/or ovarian cancer and the healthcare providers that treat them. Now being conducted across the Northeast, the campaign also includes physician education and outreach, consumer education, and public relations.

Continued on page 2

Breast Cancer Test, *from page 1*

According to Myriad, the BRACAnalysis advertisements are intended to "encourage women to think about their family history of breast and ovarian cancers." The ads direct women to talk to their doctors and visit www.bracnow.com or call Myriad's toll-free number for more information. Four years ago, the company piloted the ad in the Atlanta and Denver markets and found that BRCA testing increased by 30%.

The BRACAnalysis test is performed only by Myriad. The test detects alterations in the BRCA1 and BRCA2 genes to help determine a woman's risk of developing breast or ovarian cancer and has become the standard of care in identification of individuals with hereditary breast and ovarian cancer (HBOC) syndrome.

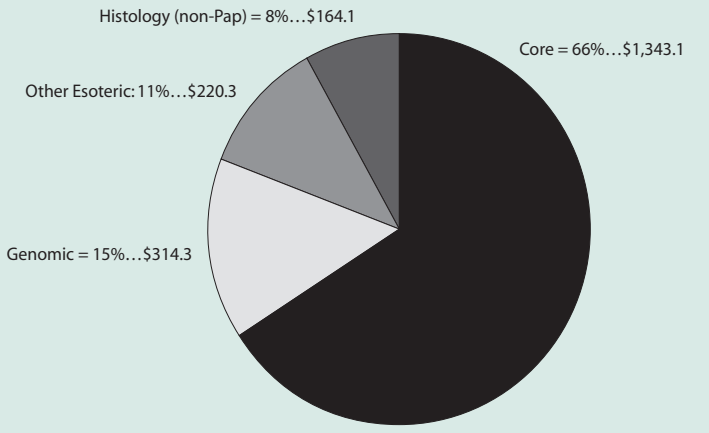
Critics say the commercial suggests that any woman with a relative with cancer should be tested for BRCA mutations, but only 2% of women in the general population may be good candidates for testing. In addition, experts question whether there are enough genetic counselors to meet an increase in demand that can result from the ad campaign. Myriad estimates that there are more than a million people in the United States with inherited genetic mutations predisposing them to an increased risk of cancer and that fewer than 3% of them know it.

LabCorp Nears Close on Indiana Laboratory

In mid-September, LabCorp (Burlington, NC) quietly reached an agreement to acquire Pathology Associates Labs (PA Labs; Muncie, IN), which was originally formed from a merger of Pathologists Associated and Follas Labs. The laboratory is a joint venture between Cardinal Health Systems and East Central Indiana Pathology. Financial terms of the deal were not disclosed.

With approximately 550 employees in 52 locations throughout Indiana, PA Labs offers testing in the areas of anatomic pathology, hematology, thrombosis, employment drug testing, cytopathology, toxicology, immunology, endocrinology, microbiology, and flow cytometry. More than 98% of its tests are performed locally, with results provided within 24 hours.

LabCorp's Revenue by Business Area* *(in millions)*



*Revenues from second quarter of 2007. Source: LabCorp

The acquisition of PA Labs would give LabCorp a stronghold in Quest-dominated Indiana. The state's largest laboratory, Mid America Clinical Laboratories (Indianapolis, IN), is a joint venture owned by and in partnership with Quest, Community Hospital, St. Vincent Hospital, and CoLab. In 2006, Mid America Clinical Labs performed approximately 4.5 million tests.

Also notable is PA Labs's specialty in anatomic pathology. In discussing near-term opportunities for revenue growth in the lab industry at the UBS Global Life Sciences conference on September 25, LabCorp CEO Dave King noted,

"There will be opportunities for growth as a result of the integration of Ameripath into our competitor," referring to Quest's recent acquisition of the pathology powerhouse in a transaction valued at $2 billion.

The pending deal for PA Labs comes in the wake of LabCorp's recent acquisition of DSI Laboratories (Fort Myers, FL), which it purchased from NCH Healthcare System (Naples, FL) for approximately $75 million. DSI is a reference and toxicology lab that operates a core lab in Fort Meyers, hospital laboratories in Naples and North Collier, and the Bonita Community Center Laboratory.

A Closer Look at a Provider of Direct Access Testing

Business is booming for the sometimes controversial direct access testing market, especially with a reported 47 million uninsured in the United States. Todd Myers, managing member of direct access testing (DAT) company, Personalized Lab Services (Dunedin, FL), says that in the two years the company has been in existence, they have had "steady, good growth."

At its most basic, DAT is a way of providing healthcare consumers a way to acquire laboratory testing without visiting a physician. It has numerous other names, including "consumer-initiated testing," "patient-directed testing," "direct access to lab services," and "self-ordering." Some states do not allow DAT. Where permitted, DAT is commonly ordered by an individual without a prior consultation with a physician or a physician's request for testing.

Is Personalized Lab Services simply acting as a middleman between the patient and the lab? "To a degree," says Meyers. "What we're doing is facilitating a test for an individual by providing them the proper script, the proper instructions, as well as a doctor's authorization if they don't have a doctor. In a sense what we're doing is third-party billing for lab testing."

Myers goes on to describe it this way: "Personalized Lab Services is a company that focuses on selling testing—either in the form of individual kits or through lab testing in clinical laboratories—that is accessible to the public. Our concept primarily is that we're able to give those without insurance and those that are interested in alternative health practitioners or an alternative healthcare system an opportunity to get the same tests that would be ordered by their doctor and paid for by their insurance." Myers adds that fundamentally, they are a cash business.

Personalized Lab Services offers tests in 22 different categories, including allergy testing, cancer detection, sexually transmitted diseases, and nutrition/fitness. Patients visiting their Web site (www.MyLabServices.com) can choose a test and, using the location finder, will be directed to a patient service center near them. Personalized Lab Services' testing menus are handled by Private MD Lab Services. All laboratory work that isn't at-home kit testing is handled by LabCorp.

Myers says, "As the order for the test is processed, the individual gets an e-mail confirmation. In that secure e-mail are requisition papers. It's really a script that

says this individual is taking this test at this location and here are the requirements, like fasting or no water, for example. They take the script to the patient service center, have the specimens collected, and within 24 hours they receive another e-mail that directs them to a secure Web site where they can get their results."

Myers notes that their in-home testing business and their laboratory business are two separate businesses. Personalized Lab Services employs one physician who is licensed in 33 states, as well as five additional staff members who look at laboratory results. There are another five involved in administrative matters.

One of the controversies surrounding DAT is the issue of appropriate responses to abnormal results and counseling for complex test results. In the case of Personalized Lab Services, abnormal results are flagged. A Personalized Lab Services' physician reviews these tests and arranges for contact with the patient, suggesting that he or she seeks medical advice when needed.

Myers notes that the at-home HIV test is their most-acquired test, followed by an at-home drug testing kit for marijuana. According to a recent survey of a handful of DAT companies, the most frequently requested tests include those for HIV, chlamydia, and prostate specific antigen, as well as lipid panels and ABO/Rh blood typing.

Most Requested Direct Access Tests

- ❑ HIV-1 antibody test
- ❑ STD Panel
- ❑ Complete blood count with differential
- ❑ Chlamydia and gonorrhea test
- ❑ Herpes simplex virus (HSV) type II IgG
- ❑ Herpes simplex virus (HSV) type I and II IgG
- ❑ Syphilis test
- ❑ Thyroid profile with TSH (Thyroid Stimulating Hormone)
- ❑ Liver function profile

Source: Private MD Lab Services

Part of the draw of DAT is cost savings. Myers says that testing provided by Personalized Lab Services is less expensive than tests performed via a physician's office or hospital. "The main labs that offer testing have to maintain a pricing structure so that, after the billing and discounts, the doctor is still making money, the lab is making money, and the insurance company is making money," he says. "Through our volume we're able to negotiate lower prices for these tests, usually about 30% of what the retail price is, and pass it along as a savings to the client because the client pays cash."

A number of other factors are driving the market for DAT, including the direct marketing of laboratory testing to consumers, consumer privacy concerns, convenience, and the trend of consumer-directed healthcare.

In a statement on how CLIA affects the availability of this testing, the Centers for Medicare and Medicaid Services (CMS) notes that CLIA authorizes regulation of laboratories that conduct testing, not the individuals who order the tests or receive test results. Therefore, CLIA regulations and standards do not differentiate between facilities performing DAT and facilities performing provider-ordered testing. All facilities that meet the definition of "laboratory" under CLIA must obtain an appropriate CLIA certificate prior to conducting patient testing, including DAT.

Lab Industry Looks to Lean Manufacturing Experts to Boost Efficiency

As the healthcare and laboratory industries look for ways to implement Lean and Six Sigma, it increasingly is turning to experts in the manufacturing field and bringing them in-house to apply their expertise to the world of healthcare. Part of the reason behind this is simply that Lean and Six Sigma originated in manufacturing. Lean, which broadly applies to efficiency, came out of Toyota; Six Sigma, which broadly applies to quality, came out of Motorola. Both Lean and Six Sigma, however, overlap significantly, and both apply to quality and efficiency. Now, approximately 30 years after its inception, the most experienced practitioners generally have a manufacturing background.

But is there more to it? And what are the pitfalls in bringing a manufacturing mindset to healthcare and more specifically, the laboratory industry?

Is It Really a Trend?

Ted Stiles, vice president of marketing and a search consultant for Stiles Associates (New London, NH), an executive search company focused on Lean practitioners, does think that it's a trend, although he admits his perspective is anecdotal. "We've checked with the American Hospital Association to see if they've got any statistics on the migration of manufacturing leaders, but it's too new and we haven't found statistical data to back it up," he says. "But I can say that two years ago we made zero assignments for hospitals. In 2006 we did two, and in 2007 so far we've done closer to eight or 10."

Herb DeBarba

Others say that the trend is clear. "Not only is there a trend to hiring out of the manufacturing industry into healthcare, but there are a number of hospital systems that have reached out to local manufacturing companies and manufacturing associations and solicited their support in instituting Lean/Six Sigma programs in their hospitals," says Herb DeBarba, executive director of Lean/Six Sigma for Cancer Treatment Centers of America (Schaumburg, IL). DeBarba himself came out of 19 years of working in the manufacturing end of Johnson & Johnson, followed by 12 years of running his own consulting firm.

The general consensus among experts interviewed for this article is that, yes, it is a trend. Heather Dahmen, quality project manager of Medtox Scientific (St. Paul, MN), doesn't dissent exactly, but says, "I don't feel it is a trend as much as it is an increasing awareness of the effectiveness of Lean/Six Sigma in the healthcare setting regardless of where the expert came from. Lean/Six Sigma/DMAIC can be applied to any process."

Cultural Awareness

One of the oft-cited problems with bringing in someone from manufacturing is a cultural one—the belief, at least by those involved in healthcare, that their industry is different and manufacturing experts don't understand it. Many

people would argue that, in fact, there are real differences. The most common statement heard is: "We don't want assembly-line healthcare."

Mark Graban

"I think coming into healthcare as an outsider, you have to be sensitive to the fact that healthcare is a different industry; a sensitivity is needed to balance out the caring nature of people's work," says consultant Mark Graban, founder of www.leanblog.com and author of the forthcoming book, *Lean Hospitals: Improving Quality, Patient Safety, and Employee Satisfaction* (Healthcare Performance Press, tentative publication date, June 2008). "One particular dynamic that's just different is interactions with physicians. It's a complex dynamic, in that most doctors aren't employees of the hospital and have an independent contractor-type relationship with the hospital."

Dino Kasdagly

Dino Kasdagly, chief operating officer for Mayo Collaborative Services, which includes Mayo Medical Labs and Mayo Clinical Trials (Rochester, MN), comes from a manufacturing background with a work history that includes DuPont and IBM. He says that manufacturing-experienced people "can't be free to roam. To me it's important that people who come in from the outside of healthcare work tightly with those that understand the basic sciences that are involved. There are those things that you perhaps could do that could violate certain regulations and increase the risk for patients. Again, it's a marriage, so the pitfall would be the 'free to roam.' You wouldn't let an engineer be free to roam in a clean environment at Intel. There are guidelines that have to be followed."

The root of the cultural differences may be one that is a central tenet of Lean: Who's the customer? "For us, it's the patient," says DeBarba. "And unfortunately that's not always the case in healthcare. Doctors become the customer, insurance companies become the customer, and so forth. But everything we do is based on satisfying the wants and needs of the patients."

"If an organization really wants to make the move and put some effort behind this, the smart thing to do is to bring someone in from the outside who has been through multiple cycles of transformation."

Kasdagly essentially agrees. But he notes that although the ultimate clients are patients, from a departmental point of view they have many different clients, from physicians in Mayo's intramural practice to other laboratories, hospitals, or physician offices for their extramural activities. "When you get right down to it, whether a reference lab or

an intramural practice, the ultimate clients are those patients needing our service, but there are different mechanisms to get to them."

Internal Advocacy

One of the typical ways companies have attempted to implement Lean methods is to send department heads to seminars and then return to the company—whether it be a hospital, a lab, or any other business—and attempt to put what they have learned into action.

"You want to have someone who can go in and be an internal champion for Lean transformation," says Stiles. "You can't do it really well or quickly by converting someone who's already there, sending them to seminars or reading books. It happens, but it's rare. So if an organization really wants to make the move and put some effort behind this, the smart thing to do is to bring someone in from the outside who most importantly has been through multiple cycles of transformation."

DeBarba is inclined to agree. "I think what healthcare is beginning to realize is that although one can go to a seminar and learn these tools, it really takes years of study and years of application before you truly understand how to do it."

Denis Gallagher

Denis Gallagher, vice president of Six Sigma for Quest Diagnostics (Lyndhurst, NJ), notes that at Quest, as their program matures, they've come to the point where they have about a 50/50 split between external resources and internal resources for Lean/Six Sigma. "They bring in fresh ideas. They bring in their expertise and the techniques they're very good at," he says. "Then they learn the lab business, and in parallel we have internal resources that know the lab business that get to learn the Lean/Six Sigma techniques and bring these two types of resources together."

More Than Manufacturing?

It's possible, of course, that hiring people out of manufacturing is just the tip of the iceberg. Gallagher notes that not only has Quest been bringing in Lean manufacturing experts into the company since 1998, but also bringing in people from other industries. "We have people with expertise in customer relations, billing operations, from manufacturing, or sometimes financial aspects," he says. "People from other industries often have Six Sigma/Lean expertise, but they bring other areas of expertise as well. They do have knowledge and expertise in Six Sigma/Lean, so they bring with them techniques and approaches in how they look at problems and improving operations."

Kasdagly believes that it's the marriage of the two areas that makes for a stronger union, not just the fresh eyes of someone from outside healthcare. "There's an enormous amount of talent that comes from outside

the healthcare industry that can walk in coupled with a lab person," he says. "If you can couple the talent of a manufacturing operations-type person from a technology industry, specifically a manufacturing operations environment, with the knowledge people in laboratories have, and marry them, then you have the laboratorians telling you a little bit about the medical parameters you can deal with. You have the engineers talking about the process, the flow, the touch points, the value-add points, and they look at it from a system perspective versus, perhaps, a silo laboratory perspective. You marry that and then you get a 1 + 1 symbiosis of 3. I think it's getting recognized."

All Things Take Time

Stiles says that one of the things he and his company worry about the most is the speed at which healthcare companies are implementing Lean and Six Sigma. "There are a lot of expectations around how big this trend will be, which only time will tell. Is this going to be a passing phase or will it have lasting and stable power? Right now the outlook is very good. The thing we get concerned about is that it's happening so fast. We worry about hospitals that say they're going to try Lean and take three people from their organization and send them to a weekend seminar. If that's how the majority of folks in the industry look to implement Lean, I think Lean could quickly get a reputation for being largely ineffective."

"Is this going to be a passing phase or will it have lasting and stable power? Right now the outlook is very good."

DeBarba agrees, saying that he doesn't think the conversation now is whether Lean or Six Sigma works. "They clearly work. They've worked for years at Toyota; they've worked for years in industry. A number of us have proven that it works in healthcare, so the conversation should be around: Why do they fail in some places?"

DeBarba goes on to say that in the case of Cancer Treatment Centers of America, every single Lean project is aimed at the patient satisfaction issue. "It's not aimed at cutting costs. It's not aimed at profit motivation. It's not aimed at internal efficiencies. We always start every single project with: How can we improve our care to the patients? Then we look for the projects that do that."

Gallagher believes laboratories need to look at Lean and Six Sigma as strategies with long-term benefits. "When we bring in people from other industries, they're not going to be effective the very next month. They need to learn the lab business. Then they can figure out how to best apply their Lean/Six Sigma expertise to the lab industry and make it more effective," he says. "I would say that any industry, not just the lab industry, has to acknowledge that it does take a certain amount of time for those resources to come up to speed in their knowledge of the lab business to be effective. Once they do, we're pretty much assured there will be a degree of improvement they will be bringing."

As Lab Vendors Consolidate, Keep Your Eye on Siemens

In 2006, the six largest in vitro diagnostics vendors generated a total of $8.23 billion in revenue in the U.S. market. Excluding diagnostic revenue created by self-monitoring glucose testing, the six companies reported combined revenue of $5.55 billion.

By comparing the "best value" (i.e., service plus price) citations of 178 laboratory respondents to a recent survey to the U.S. market share of each reagent vendor, Washington G-2 Reports was able to get some indication of which vendors may gain share in the next 12 months.

Roche Diagnostics has the greatest U.S. market share of the six vendors (20.8%) but received only 16.5% of the respondents' "best value" citations. This leaves a result of –4.3 (16.5% – 20.8% = –4.3), which suggests that Roche Diagnostics may lose market share in the United States. Beckman Coulter, however, which was rated as having the best value by 30% of survey respondents, also has a 24% market share, which suggests, with a result of 6 (30% – 24% = 6) that they may be gaining market share. The remaining companies, Dade Behring, Abbott Diagnostics, Ortho-Clinical Diagnostics (OCD), and Bayer Diagnostics have spreads ranging from -4.8 (OCD) and 3.7 (Dade).

U.S. Market Share for 2006 ($ millions)

Company	*Total Diagnostics Revenue*	*Market Share*	*Diagnostics Revenue**	*Market Share*
OCD	$1,911	23.3%	$756	13.6%
Roche Diagnostics	1,777	21.6	1,155	20.8
Abbott Diagnostics	1,346	16.4	799	14.4
Beckman Coulter	1,330	16.2	1,330	24.0
Bayer Diagnostics	1,048	12.7	704	12.7
Dade Behring	805.9	9.8	805.9	14.5
Top 6 totals	8,217.9	100.0	5,549.9	100.0

*Revenue for professional diagnostics excludes revenue from self-monitoring glucose testing businesses at Roche, OCD, Bayer, and Abbott.

Source: Washington G-2 Reports, *Quality Counts: Second National Reagent Vendor Quality Survey Report*

Washington G-2 Reports believes that the "lowest prices" category, in addition to the "best value" category, may provide an indication about future market share changes. Beckman Coulter ranked highest overall by survey respondents for "lowest prices" with 30.2% of laboratory responses. Beckman Coulter posts a 24% U.S. market share, which provides a 6.2 spread (30.2% – 24.0% = 6.2), suggesting that Beckman Coulter will gain market share in the United States. Roche, which has the largest U.S. market share (20.8%), however, received only 16.6% of overall responses to "lowest prices," which gives it a spread of –4.2, suggesting its market share may go down.

Beckman Coulter ranked highest of the two categories that Washington G-2 Reports believes are the best predictors for future market share gains: best value and lowest prices. In 2006, Beckman Coulter posted overall worldwide diagnostics revenue growth of 3.5%. Although some areas showed losses, namely chemistry (–1.7%) and its cellular division (–0.2%), its immunodiagnostics division showed a whopping increase of 16.7% between 2005 and 2006.

OCD ranked sixth out of six in overall responses to the five categories of questions and has the second-to-smallest U.S. market share before Bayer Diagnostics. In addition, under the categories of "best value versus market share" and "lowest prices versus market share," OCD received the most negative values, –4.8 and –5.3, respectively. As a result, Washington G-2 Reports predicts that OCD's market share will show continued decline.

One thing is for sure: the market is going to change significantly in the upcoming year in light of the recent and pending acquisitions of Siemens AG. The conglomerate recently closed on its purchase of Bayer Diagnostics and is now wrapping up its $7 billion deal to acquire Dade Behring. Siemens was not part of this survey. However, with Bayer Diagnostics and Dade alone, Siemens will have 26.3% of the U.S. clinical diagnostics market, not counting its numerous other clinical diagnostics assets.

United Healthcare to Pay Up to $20 Million to Resolve Claims Concerns

United Healthcare Insurance Co., a division of UnitedHealth Group (Minnetonka, MN), has struck a deal with 36 states and the District of Columbia, agreeing to pay up to $20 million to resolve regulatory concerns over the company's insurance claims payment system.

As part of the multi-state deal, the Connecticut-based insurance company also must establish a detailed process improvement plan to evaluate and regulate the performance of its claims-processing system over the next three years, through Dec. 31, 2010, according to the terms of the agreement. The settlement also establishes performance benchmarks for claims accuracy, timeliness, appeals review, and handling consumer complaints.

If United fails to meet the yearly improvement benchmarks laid out in the agreement, the company could be forced to pay an additional $20 million in penalties, according to a September 6 release from the Iowa Insurance Division.

Iowa joined with Arkansas, Connecticut, Florida, and New York to lead negotiations for the settlement deal. Those five states will continue to monitor United's compliance with the process improvement plan. Iowa will take the lead role for purposes of examination and statutory requirements.

The agreement follows a state-led investigation into United's mishandling of insurance claims, according to a September 6 release from the New York State Insurance Department. The investigation found that the company frequently violated prompt payment rules and committed several errors in claims processing. In addition, due to poor controls and oversight, United generally was "unable to correct problems when they were brought to its attention by state regulators," the release said. Thirty-six states and the District of Columbia have signed onto the agreement thus far, Voss said. Other states are free to join the settlement as well.

Under the terms of the agreement, United will distribute $13 million to the 37 currently participating states. If additional states join the agreement, the company's maximum commitment could increase to $20 million over three years, United said in a separate release.

Lab Stocks Fall 2%; Bio-Reference Climbs

The G-2 Laboratory Stock Index fell 2% in the four weeks ended September 21, with six stocks up in price, four down, and one unchanged. Year to date, the G-2 Index is up 20%, while the Nasdaq is up 11% and the S&P 500 is up 8%.

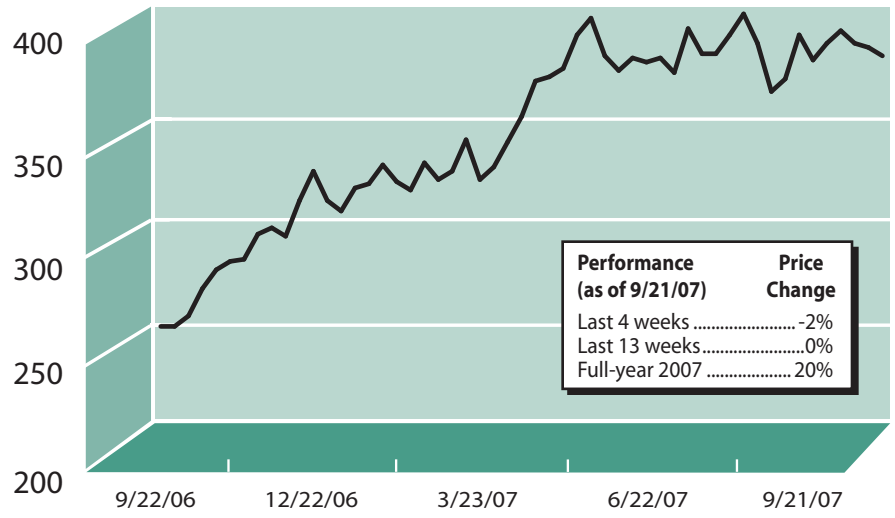
Bio-Reference (Elmwood Park, NJ) climbed 17% to $33.01 per share for a market cap of $456 million. The company recently announced its best ever quarterly results. In the third quarter of 2007, Bio-Reference recorded revenues of $66 million, an increase of 35% over the $49 million recorded in the third quarter of fiscal year 2006. Revenue per patient for the third quarter was $68.08, an increase of 11% over 2006. Esoteric testing accounted for 44% of the company's quarterly revenues.

Shares in **Enzo Biochem** (Farmingdale, NY) plummeted 30% to $11.96 per share for a market capitalization of $442 million. In early September, the U.S. District Court for the District of Connecticut dismissed all remaining claims in the patent infringement case Enzo brought against Applied Biosystems (AB). The suit claimed that some AB products for detecting nucleic acid sequences infringed upon six patents held by Enzo and Yale University.

Meanwhile, molecular diagnostics and testing company **Monogram Biosciences** (South San Francisco, CA) dropped 15% to $1.47 per share for a market cap of $196 million. On September 25, the company announced its new licensing agreement with the National Surgical Adjuvant Breast and Bowel Project (NSABP). The research contract focuses on Genentech's breast cancer drug Herceptin and gives Monogram access to tissue samples from up to 1,600 breast cancer patients treated with Herceptin in a NSABP study.

Monogram could use the research to develop pharmacogenomic tests to predict breast cancer patients' response to Herceptin.

G-2 Laboratory Stock Index



Source: The G-2 Laboratory Stock Index is tabulated weekly by *Laboratory Industry Report* from the average percentage change in the price of 11 laboratory testing service stocks.

% price change 4 weeks ended 9/21/07

UP	Price	% Chg
Bio-Reference	$33.0	17%
Clarient	2.00	6
Genomic Health	19.50	3
LabCorp	77.61	2
Myriad	46.37	9
Quest	56.66	2
UNCHANGED		
Medtox	19.04	0
DOWN		
Enzo Biochem	11.96	-30
Monogram	1.47	-15
Orchid	5.49	-8
Psychemedics	16.90	-5

INDUSTRY buzz

Is CYP450 AmpliChip testing taking off? It is at the Center for Molecular Medicine (CMM; Grand Rapid, MI). The laboratory added Roche's AmpliChip CYP450 test to its menu in the spring, becoming the first laboratory in the Midwest to offer the test. According to CMM Executive Director Daniel Farkas, Ph.D., the test is exceeding expectations.

Roche's FDA-approved and CE-marked CYP450 AmpliChip test analyzes variations in CYP2D6 and CYP2C19, enzymes that play a major role in drug metabolism. Approximately 25% of all prescription drugs are metabolized by these enzymes, including many of the most-prescribed drugs for treating depression.

"I have been out and about in the community, educating physicians about the clinical value, and the test is really gaining traction," says Farkas. "We didn't do our first test for a month or two [after adding it to our test menu], but we've got a batch of 15 that we're running right now, so the volume is really on the upswing." The laboratory performs the test once per week at a cost of $900, which is not covered by insurance. Turnaround time is seven to 10 days.

In talking with physicians, Farkas emphasizes that the ability to respond to and metabolize certain drugs is genetically controlled. "I give them a list of drugs that are metabolized by the enzymes that are coded for by the genes on the chip, and they put it together rather quickly," says Farkas. "In large part, it's a matter of exposure as much as education."

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Mid America Clinical Labs 877-803-1010

Monogram Biosciences 650-635-1100

Myriad Genetics 801-584-3600

Pathology Associates Labs 765-747-3328

Personalized Lab Services 727-738-0439

Quest Diagnostics 800-222-0446

Stiles Associates 603-526-6566

United Healthcare 800-328-5979

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