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LABORATORY INDUSTRY REPORT®

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Issue 11-10/November 2010

HIGHLIGHTS

LabCompete Sales and Marketing Conference 2010
Dec. 8-10, 2010
The Venetian, Las Vegas
www.g2reports.com/LabCompete

WASHINGTON G-2 REPORTS

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GE Strengthens Integrated Diagnostics Play With Purchase of Clarient for $587 Million

GE Healthcare's decision to acquire Clarient Inc. (Aliso Viejo, Calif.) should help GE in its bid to become the leading player in the integrated diagnostics market.

GE Healthcare announced Oct. 22 that it would buy Clarient in a deal valued at approximately $587 million. GE will acquire all outstanding common and preferred shares of Clarient at $5 per common share and $20 per preferred share. That's a premium of about 34 percent for common shares, compared with Clarient's Oct. 22 closing price of $3.74. The deal is expected to close in late 2010 or early 2011.

In announcing the deal, GE Healthcare emphasized Clarient's leading position in molecular diagnostics, which is widely viewed at the optimal point to integrate diagnostic testing with diagnostic imaging, in which GE is a leading player. The combined company would initially focus on developing novel integrated tools for the diagnosis and characterization of cancer.

Continued on page 2

N.Y. Prohibits Labs From Donating EHRs To Referring Physicians

The New York Department of Health is prohibiting laboratories operating in the state from providing electronic health record (EHR) systems and software packages to referring physicians even though federal law allows labs to donate or cost-share up to 85 percent of the cost of EHR software.

In a Sept. 27 letter sent to clinical laboratories operating in New York state, the Department of Health said that state rules "do not allow cost sharing; therefore, provision of EHR, software, and training that otherwise may be permitted under federal law is prohibited in connection with a laboratory's operating in [New York state]." The letter noted that the preamble to the federal EHR regulations, published in the *Federal Register* Aug. 8, 2006, makes it clear that the EHR-related federal payment allowance does not preempt state laws and regulations. The policy stated in the letter presumably would apply to pathologists

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GE ACQUIRES CLARIENT, *from page 1*

Clarient provides pathologists and oncologists with access to key diagnostic tests that shed light on the complex nature of various cancers. The company is focused on developing novel, proprietary diagnostic markets and tests for the profiling of breast, prostate, lung, colon, and blood-based cancers. Clarient reported $91.6 million in net revenue for 2009. Since 2005, revenues have grown at a 68 percent compounded annual growth rate. The rapid increase in the incidence of cancer worldwide, together with advances in specific cancer-focused therapies, is driving significant demand for molecular diagnostics.

> ***"Adding Clarient's leading technology to our portfolio will accelerate our expansion into cancer diagnostics and therapy selection tools while strongly enhancing our current diagnostic and life sciences offerings."***
> ***– John Dineen***

"Adding Clarient's leading technology to our portfolio will accelerate our expansion into cancer diagnostics and therapy selection tools while strongly enhancing our current diagnostic and life sciences offerings," said John Dineen, president and CEO of GE Healthcare, in a statement announcing the deal. "We believe we can build a $1-billion plus business by developing integrated diagnostic solutions for cancer and other diseases."

The purchase may boost profit within two years as GE adds products, research, and marketing resources, Dineen said. GE Healthcare posted its third straight profit increase in the three months ended in September, and that performance is expected to continue into 2011, he said. The division provided $16 billion of the parent company's $157 billion in sales last year.

More Acquisitions on the Horizon?

Acquisitions such as Clarient could continue to fuel merger and acquisition speculation, according to equity research firm William Blair & Co. (Chicago). Both Myriad and Genoptix, whose share prices have increased in recent trading, appear to be prime targets, says analyst Amanda Murphy.

"We believe the Clarient announcement, as well as comments made by Quest Diagnostics on its third-quarter earnings call . . . suggest the company is very focused on M&A opportunities in esoteric testing [and] could continue to fuel take-out speculation in the space."

Murphy believes acquisition of both Genoptix and Myriad Genetics would make a lot of sense from a strategic perspective for Quest, providing exposure to esoteric testing as well as a more specialized salesforce. In both cases, she thinks multiples could fall closer to the high end of the eight to 10 times EBITDA (earnings before interest, taxes, depreciation, and amortization) range, which puts a value in the low-$20s per share for both companies.

Given depressed stock prices, large potential market opportunities for Myriad, and strong underlying markets for Genoptix, Murphy believes an acquisition of one or both of the companies is becoming increasingly likely.

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Quest, LabCorp Report Higher Profits in Third Quarter But Wall Street Unimpressed

Both Quest Diagnostics (Madison, N.J.) and Laboratory Corporation of America (Burlington, N.C.) reported an increase in profits for the third quarter of fiscal 2010, but share prices dropped after analysts indicated they were not impressed with the numbers.

Quest's profits grew by 3 percent during the quarter as a tax benefit canceled out continued declines in revenue and clinical testing. Net income for the quarter rose from $192.2 million last year to $198 million this year. Earnings per share increased from $1.02 in the third quarter of 2009 to $1.13 per share in the third quarter of 2010. However, Quest said revenue actually fell 2 percent, from $1.9 billion to $1.86 billion. The increase in net income was due primarily to an 8 cent per share tax-related benefit. In addition, the company recently aggressively repurchased stock, with the lower share count boosting earning per share.

Company officials said testing volume slipped 0.3 percent, while clinical testing revenue fell 1.7 percent and revenue per test was down 1.3 percent.

Quest adjusted its profits forecast, saying it now expects to earn $3.95 to $4 per share in 2010. Previously, it expected $3.90 to $4 per share. But company officials also lowered its 2010 revenue growth expectations, anticipating that revenue will fall by 1.5 percent.

The fact that Quest lowered revenue guidance, primarily based on lower volume expectations for the fourth quarter, raises some concerns among analysts, who note that initiatives the company has put in place to accelerate revenue growth, such as adding sales reps in esoteric testing and adding phlebotomists, have been slower to gain traction than expected.

Quest and LabCorp at a Glance ($MM)

	Third Quarter	
	2009	2010
LabCorp		
Revenue	$1,185.1	$1,276.5
Net earnings	131.4	140.0
Quest		
Revenue	1,897.2	1,864.7
Net earnings	192.2	198.02

Source: Company reports

LabCorp

LabCorp reported a higher-than-expected third-quarter profit, but shares slipped as analysts said the results were boosted by tax benefits. Quest's announcement that its revenue would fall more than anticipated also likely dragged down LabCorp's shares.

Net earnings were $140 million for the quarter compared to $131.4 million in the third quarter of 2009. Earning per diluted share, excluding restructuring and other special charges, were $1.47 for the quarter compared to $1.22 for the same period last year.

Revenues for the quarter were $1,276.5 million, an increase of 7.7 percent. Testing volume, measured by requisitions, increased 1.9 percent, and revenue per requisition increased 5.7 percent.

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The company raised and narrowed its 2010 guidance. It now expects revenue growth of 5 percent versus the prior 4.5 percent to 5.5 percent. LabCorp also raised its projected earnings per share of $5.52 to $5.57 compared to the previous guidance of $5.40 to $5.55. The updated guidance does not include any impact from the Genzyme Genetics acquisition.

While physician office visits remain flat and are unlikely to pick up in the fourth quarter, analysts suggest that the company is benefiting from recent acquisitions and may be gaining share. Amanda Murphy, an analyst with William Blair & Co. (Chicago), says she is encouraged by 3.2 percent accession growth in histology, which supports the notion that the insourcing trend is beginning to slow.

Genoptix Revised Expectations Suggest Challenges

Genoptix (Carlsbad, Calif.) recently lowered its revenue projections for the third quarter, saying revenue will be down 5 percent to 10 percent from second-quarter levels. Actual third-quarter results will be announced Nov. 4.

Management cited continued macro challenges, including physician insourcing of lab tests, the high number of uninsured patients, and acquisition of physician practices by hospitals, as well as increased pressure from managed care given the labs' out-of-network status with most managed care providers. Management also references a maturing market, with a stable hematology/oncology ordering base, driven by an intensifying competitive environment, which suggests that the company is losing market share.

Genoptix at a Glance ($MM)

	2009				2010		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3E*
Net sales	$39.2	$45.3	$50.8	$49.1	$47.4	$50.9	$46.4
% change	+76%	+63%	+58%	+45%	+21%	+12%	-8%
Gross profit	23.8	28.5	32.4	30.5	28.6	30.5	26.9
Gross profit margin	60.6%	63.0%	63.8%	62.1%	60.4%	59.8%	57.7%

** Estimate*
Source: Avondale Partners

Equity research firm Avondale Partners (Nashville, Tenn.) recently downgraded Genoptix from Market Outperform to Market Perform, noting that the company faces a number of challenges including increased competition from copycat firms, a slowing rate of customer acquisition, unfavorable trends in patient profiles and physician practice management, declining patient volumes, and health plans' efforts to reduce "leakage."

Avondale has lowered its revenue estimate for Genoptix from $210 million to $191 million for 2010 and from $234 million to $182 million for 2011. The shares currently trade at depressed levels at three times EBITDA (earnings before interest, taxes, depreciation, and amortization).

"The company would be a good fit with a larger lab, but a buyer likely will need volumes to stabilize and a higher mix of in-network revenue to make a move," says Kemp Dolliver, managing director of Avondale.

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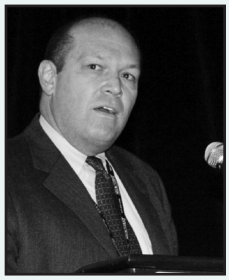
The New World of Laboratory Medicine: It's Not Just Your Father's Microscope Anymore



Richard Friedberg

The world of diagnostics is changing, and clinical laboratories and pathologists need to embrace the ongoing evolution if they want to stay competitive in today's marketplace. That was the message of one of the keynote speakers and thought leaders at Washington G-2 Reports' 28th annual Lab Institute conference, held in Arlington, Va., Oct. 13-15.

Richard Friedberg, M.D., Ph.D., chairman of the Department of Pathology at Baystate Health in Springfield, Mass., and deputy chairman of the Department of Pathology at Tufts University School of Medicine, noted that the evolution of today's diagnostic environment is marked by six primary trends:

1 **Discrete to Multiplex.** This is most evident in clinical pathology (CP), where the field has moved from conducting single tests to conducting multiple tests on a single platform.

2 **Structural to Functional.** This is best evident in anatomic pathology (AP), where the field has moved from simply identifying parts of cells to determining the function of different parts of cells.

3 **Qualitative to Quantitative.** In immunohistochemistry, stains are becoming assays as pathologists use computer alogorithms to quantify them.

4 **Analog to Digital.** Similar to what happened in radiology years ago, pathology is now moving from analog (glass slides) to digital pictures of slides and ultimately to actual digital images.

5 **AP Evolution Mimicking CP.** Anatomic pathologists are now more concerned with analytical precision, reproducibility, accuracy, specificity, and reliability. As one well-known pathologist in California said, "The demand for quantification has become paramount; it is no longer enough that the 'stain' is there, rather it is a question of 'How much is there?'" Why? Because results are directly tied to treatment.

6 **AP Evolution Mimicking Radiology.** Analog images established the field, market and technology forces drive digital imaging, and digitization allows new applications. This all has significant workload and throughput implications.

"Diagnostics is clearly evolving with data integration," says Friedberg. "There is increasing dependence on integrated structural, functional, molecular, genetic, proteomic, and genomic information, regardless of the 'historical' source."

The traditional pattern recognition fields of anatomic pathology and radiology are changing, he explains. Both are now becoming more quantitative with an increased focus on precision, accuracy, reliability, and measurability. "Once information becomes digital, integration shifts into high gear and

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things really take off. That's where we are getting to be in the world of traditional anatomic pathology."

Because diagnosis now involves so many different types of information, the info provided by anatomic pathology is now a smaller piece of the overall diagnostic equation than it was in the past, says Friedberg. Now that information is combined with genetic tests, gene expression profiles, pharmacogenomics, and imaging data to arrive at a diagnosis. As health care payers look to bundle payment for diagnosis, it's possible that pathologists could get a smaller piece of the reimbursement pie. "If your field is only looking at one of these areas, don't be surprised if you get smaller and smaller in the whole picture," he says.

Drivers in Diagnostic Medicine

In diagnostic medicine, as in many other areas, there are a few major forces driving change: resources, including health care payment, research and development funding, and money to hire adequately trained personnel; demand, which comes both from demographics (people getting older and more people getting health insurance coverage) and expectations; and technology.

Patients expect all possible helpful information, available as soon as technically possible, so that they can make the best-informed decision possible to reduce the risk of any possible bad outcome, notes Friedberg.

Historically the health care system has taken a reactive approach to patient management—a patient visits the doctor, who makes a broad symptom-based diagnosis and tries different medications to see what works. In the "new world" of diagnostics, patient management will be more targeted and proactive, believes Friedberg. Focusing screening will aid clinicians in prevention and monitoring while targeted diagnostics will lead to personalized treatment when a diagnosis is made. Integrated diagnostics, which he defines as earlier diagnosis and earlier cure by advancing the optimal point of medical intervention earlier in the natural course of a disease, will be key in bringing this kind of targeted and proactive medicine about, he says.

"Once information becomes digital, integration shifts into high gear and things really take off. That's where we are getting to be in the world of traditional anatomic pathology."
– Richard Friedberg

So what is changing today? "The identification and measurement of markers of interest has progressed exponentially over the past decades," notes Friedberg. "Clinical expectations, technology, and novel biomarkers are pushing all of diagnostics into a quantitative and digital era. What's different now is the ability to combine data at hand with massive historical databases to create information, to simultaneously assess multiple markers as data elements, and to integrate infor-

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mation across technological domains into useful knowledge."

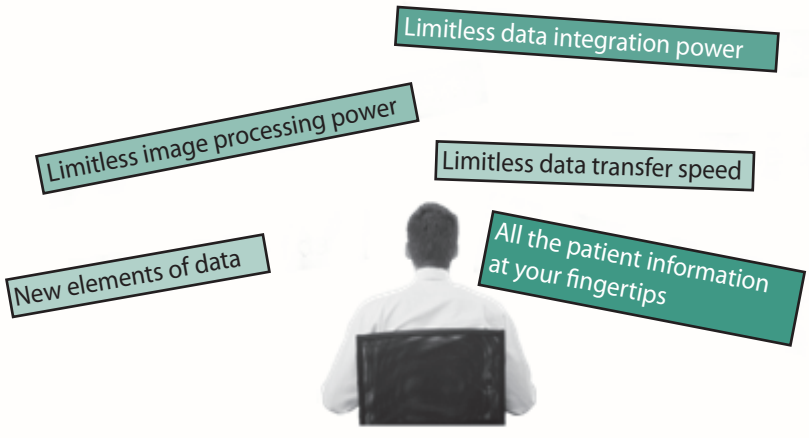
Diagnosis tomorrow will be dependent upon the ability to integrate disparate bits of information, use mathematical algorithms that have been optimized to meta-interpret data, and produce a diagnostic report that will be more than just a label. "If all you're doing is putting a label on things, you are going to be squeezed out," says Friedberg.

In the not-too-distant future, diagnostic information will be subject to validation, accuracy, reproducibility, precision, and quality control. It will be aggregated and analyzed using disparate tools, such as image-based computer-assisted analytic tools to "assay" specimens. Intelligently designed picture archiving and communications systems (PACS), now common in diagnostic imaging, will revolutionize pathology workflow. The net result will be improved efficiency, novel opportunities, and increased reliance upon pathology (meaning the study of disease as opposed to the field of pathology).

Friedberg envisions a future where all the patient information and data are available at a clinician's fingertips, combined with limitless image processing power and limitless data transfer speed. A diagnostic workstation would look far different than it does today. The clinician would have access to integrated lab, imaging, and test data; could have real-time consultations with the pathologist; and would be able to access external resources such as patient history, knowledge databases, and medical literature.

"We're going to end up with something that looks like this," says Friedberg. "You will be more valuable if you are able to synthesize all this in-

Imagining the Future of Pathology



Source: Richard Friedberg, M.D., Ph.D.

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formation rather than just one part. If you can only do one part, you will be a commodity. This is an opportunity for us."

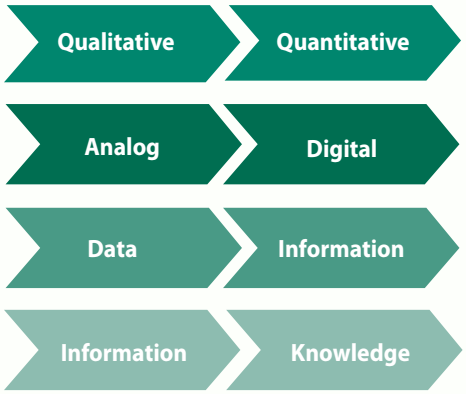
Who is going to make the diagnoses? asks Friedberg. "It will be those who have all the tools will make the diagnoses. If you have a tool, you are a tool. If you have a set of tools that you can integrate, it's a different picture."

Differentiators—Tools and Skills

To succeed in this brave new world, you will need to differentiate yourself both in terms of tools and skills, advises Friedberg. Figure out where you want to go—do you want to stay in the traditional fields of laboratory and pathology medicine, or do you want to be on the cutting edge, moving into areas where there is a need but not enough supply? Pathologists also must get out of the volume game, says Friedberg. Innovation is what you'll get paid for.

Patterns of History Are Clear

- Qualitative evolves to quantitive
- Analog evolves to digital
- Distant evolves to integrated
- Data becomes aggregated into information
- Information with context becomes knowledge



Source: Richard Friedberg, M.D., Ph.D.

Perhaps most important is that pathologists must be trained as diagnosticians, not as microscopists. "I tell all my residents that the microscope is a tool, it is not a field. If you are defined by your tool, then when that tool becomes unnecessary, you become archaic," he says.

Those in pathology have choices, explains Friedberg. For example, there are opportunities to become involved in new practice models, such as virtual large groups, accountable care organizations (ACOs), alternative quality contracts (AQCs), and medical homes. Ultimately, however, pathologists need to decide if they want continue operating as they always have or whether they want to embrace the coming changes in the diagnostic arena.

"There will always be a need for diagnostics," says Friedberg. "You have choices. Staying put is not one of the good ones."

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■ **N.Y. PROHIBITS LABS FROM DONATING EHRS** , *from page 1*

as well, says Jane Pine Wood, an attorney with McDonald Hopkins (Boston), who advises pathology groups.

Between 2011 and 2015, it is predicted that nationally 350,000 or more physicians will implement EHR systems for use in their daily practices, according to the letter. The rapid and widespread adoption of EHRs by both hospitals and physician practices is unprecedented and creates several challenges for labs, including being asked by health care providers to pay for or contribute to the cost of the interface to client EHRs or being asked to donate or cost-share up to 85 percent of the cost of new EHR software.

While the federal and state governments are involved in a variety of efforts to encourage the use of health information technology, the Department of Health has become aware of abusive business practices, says the letter—"specifically, that clinical laboratories are offering new EHRs and software packages as an inducement for practitioners to refer patient specimens for testing, resulting in a financial benefit conferred to the practitioner."

While labs operating in New York state may not donate EHRs to physicians, they may provide limited types of software and hardware that facilitate test ordering and transfer and storage of laboratory-generated data, says the Department of Health. For example, labs may:

1 Interface their laboratory information system to the client's existing EHR to enable seamless laboratory test ordering and laboratory test reporting and facilitate other laboratory-related functions (see item 2 below) and may assume, as a cost of doing business, the cost of a such a limited interface;

2 Provide to a practitioner computer hardware, software, and information technology training and supplies that are restricted to laboratory-related functions that enable the practitioner to (a) order tests from the laboratory, including access to a directory of services (i.e., specimen type, collection container, and test information); (b) receive, access, print, and store test results received from the laboratory, including storing cumulative results for individual patients; (c) transmit data necessary for the laboratory to prepare requisitions and generate bills, invoices, or claims for reimbursement; and (d) transfer laboratory data received from the lab to any computer system maintained by the practitioner;

3 Provide computer hardware and software as noted above that also contain functionality that permits a practitioner to make referrals to other laboratories and/or provides access to other laboratories' Internet portals; and

4 Provide to a Regional Health Information Organization (RHIO) or health information exchange (HIE) computer equipment and supplies, information technology, and software in accordance with the requirement in item 2 above. Laboratories may not contribute to the RHIO's or HIE's acquisition costs for EHR components, including software interfaces, or a practitioner's

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costs of participation unless in accordance with the requirements in item 2 above. Nothing in this bullet requires a laboratory to provide such EHR components to an RHIO or HIE for its participants.

The Department of Health also says the labs operating in New York state must retrieve all computer equipment placed with the health services provider and related unused supplies and discontinue paying for an interface upon termination of a laboratory services agreement or arrange for a one-time purchase at fair-market value that transfers ownership of hardware and software to the practitioner.

Potential Problems for Labs, Pathologists

Several health care attorneys contacted by G-2 Reports say the letter could create significant problems for labs and pathologists who thought they were covered by the federal exception that allows labs to pay up to 85 percent of the cost of EHR technology, software, and training. Enforcement of this policy could require labs and pathologists to undo current contracts with referral sources and possibly even seek reimbursement for the share of the cost they have paid for.

Rob Mazer, an attorney with Ober Kaler (Baltimore), notes that physicians may try to enforce any contracts they have with labs covering EHR software, technology, and training, particularly since the physicians likely have signed a contract with the EHR vendor. Mazer says he hopes the New York Department of Health will provide a reasonable amount of time for labs to unwind existing contracts.

While this is not necessarily a new policy, Wood, from McDonald Hopkins, notes that the policy has never been widely publicized or enforced, and many labs and pathologists may have been unaware of the state prohibition.

For now, Wood advises that labs wait for further clarification from the department before starting the process of undoing agreements. "I would advise my clients to take a wait-and-see approach for right now until we have more answers," she says.

Cypress Biosciences Sells Diagnostic Business to Exagen

Cypress Biosciences, a San Diego-based pharmaceutical company that develops innovative drugs to treat central nervous system disorders, has entered into an asset purchase agreement under which Exagen Diagnostics Inc. (Albuquerque, N.M.) will acquire Cypress's diagnostics business for up to $8 million in up-front and milestone payments, with additional future payments in the form of royalties on product sales.

Under terms of the agreement, Exagen Diagnostics will purchase the diagnostic business in its entirety, including all testing services, intellectual property rights, and equipment. Exagen will assume the lease for Cypress's laboratory operations at the current San Diego location.

Exagen will pay Cypress a $4 million up-front cash payment, split into two payments, 24 months apart. In addition, there are potential milestone payments of up to $4 million. Cypress is also eligible to receive a 10 percent royalty on defined product sales.

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Lab Index Regains Some Ground, Up 9% in October

The G-2 Reports' Laboratory Stock Index reversed its downward trend in October, climbing 9 percent in the four weeks ended Oct. 29, 2010. For the year, the index is down an unweighted average of 2 percent. In comparison, the Nasdaq composite is up almost 11 percent, and the S&P 500 is up about 6 percent.

Ten of the 13 publicly traded lab companies tracked by the index posted gains during the period, while three experienced declines in their share prices.

Share of **Clarient** (Aliso Viejo, Calif.) soared 45 percent to $4.97 on reports that the company was being purchased by GE Healthcare (*see related article on p. 1*) in a deal valued at about $587 million. GE will acquire all outstanding common and preferred shares of Clarient at $5 per common share and $20 per preferred share.

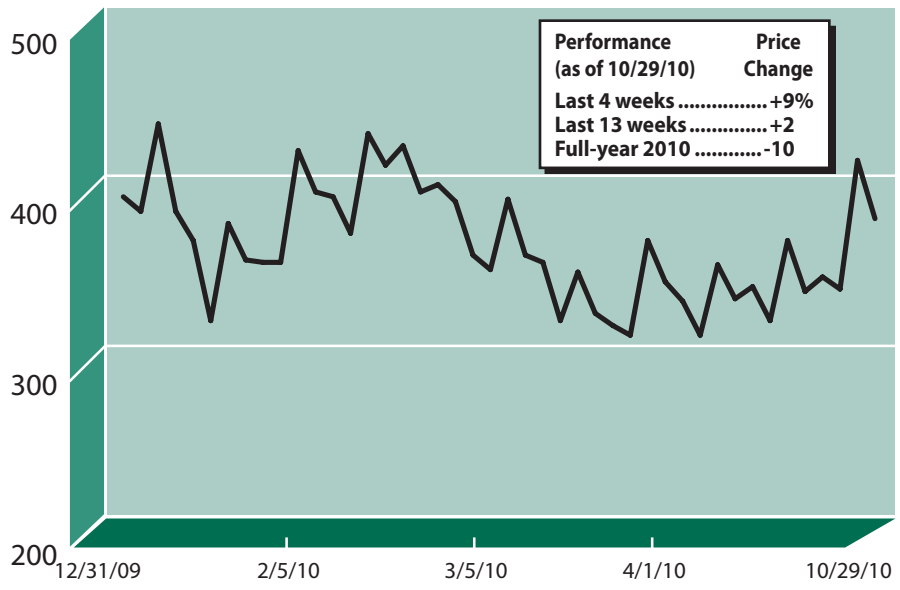
Myriad (Salt Lake City) shares jumped 20 percent to $19.86, driven midmonth by a research note published by RBC Capital Markets suggesting the firm may be an acquisition target. The note named a handful of potential buyers including Roche, AstraZeneca, and Sanofi-Aventis.

Shares of **Enzo-Biochem** (New York) rose 11 percent to $4.31 after the company reported a fourth-quarter loss of $5.5 million, or 15 cents per share. Revenue rose 2 percent from $24.5 million in the same quarter last year to $24.9 million. Earnings per share actually beat analysts' projections slightly while revenue matched what analysts had expected.

For up-to-the-minute laboratory and diagnostic firm data and financial news—go to **www.g2reports.com**

Shares of **Neogenomics** (Fort Myers, Fla.) climbed 9 percent to $1.20 after the company reported a healthy increase in revenue and test volume for the three months ended Sept. 30, 2010. Revenue increased 19 percent to $8.7 million over the same period last year while test volume increased by about 29 percent.

G-2 Laboratory Stock Index



Source: The G-2 Laboratory Stock Index is tabulated weekly by Laboratory Industry Report *from the average percentage change of 13 laboratory testing service stocks.*

Percent Price Change, Four weeks ended 10/29/10

	Price	Percent Change
UP		
Bio-Reference	$21.56	+6%
Clarient	4.97	+45
Enzo Biochem	4.31	+11
Genomic Health	14.16	+5
LabCorp	81.32	+4
Medtox	11.73	+3
Myriad Genetics	19.86	+20
Genzyme	72.25	+2
Neogenomics	1.20	+9
Genoptix	17.02	+17
DOWN		
Quest	49.14	-2
Psychemedics	8.75	-7
Orchid Cellmark	1.50	-1

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INDUSTRY buzz

GE, UPMC Unveil New Digital Pathology Technology Platform

GE Healthcare and UPMC (Pittsburgh) in late October announced that their imaging joint venture, Omnyx, is initiating clinical research testing of a digital pathology platform that is expected to help transform the 125-year-old practice of pathologists using glass slides.

By digitizing the slides and corresponding workflow, the Omnyx technology is intended to do what a traditional microscope cannot—unite an entire pathology department and improve collaboration, communication, and efficiency.

The new technology is a combination of patented scanners that can boost scan speed by using one camera to scan the slide and a second to simultaneously focus new imaging software for highest-quality images, along with an information technology backbone that digitizes a pathology department's workflow.

UPMC, Montefiore Medical Center, Stanford University Medical Center, and University Health Network are currently installing, testing, and providing feedback on the Omnyx platform and will collect data for a Food and Drug Administration submission. GE Healthcare and UPMC have invested $40 million in the venture to date.

References

Avondale Partners 615-467-3500

Baystate Health Pathology Services 413-773-2219

Clarient 888-443-3310

Cypress Biosciences 858-452-2323

Enzo Biochem 212-583-0100

Exagen 505-272-7966

GE Healthcare 800-778-3375

Genoptix 760-268-6200

LabCorp 800-334-5161

Myriad Genetics 801-584-3600

Neogenomics 239-768-0600

Quest Diagnostics 800-222-0446

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Laboratory Industry Report (ISSN 1060-5118) is published by Washington G-2 Reports, 1Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Tel: 973-718-4700. Fax: 973-622-0595. Web site: www.g2reports.com.

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