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G2 INTELLIGENCE

LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

The Time Is Right for Developing an MDx Lab

Is your organization considering developing a molecular diagnostics (MDx) lab? If so, your timing couldn't be better. G2 Intelligence estimates that the market for molecular diagnostics laboratory testing will reach $7 billion in 2011 and that it is growing at about 15 percent per year. This growth rate compares to 5 percent for most other areas of laboratory testing.

G2 Intelligence's 2011 Molecular Diagnostic Laboratory Survey found that 76 percent of responding laboratories that are performing MDx believe that their molecular testing operations are profitable, and 89 percent are planning to expand their MDx testing menu in the near future.

For more on how your organization can take advantage of this emerging market, see *Inside the Lab Industry* beginning on p. 5.

Lab Tests to Be Included in Bundled Reimbursement Initiative

Federal officials have talked about it for years, but bundling of payment for lab services may be one step closer to reality. The Centers for Medicare and Medicaid Services (CMS) in late August announced a new bundled payment initiative that specifically references lab testing in two of the models that it plans to test.

CMS said the initiative, mandated by the Patient Protection and Affordable Care Act (PPACA) will align payments for services delivered across an episode of care, such as heart bypass or hip replacement, rather than paying for services separately. Bundled payments will give doctors and hospitals new incentives to coordinate care, improve the quality of care, and save money for Medicare, the agency said.

The initiative, published in the Aug. 25 *Federal Register*, will allow providers to apply to help test and develop four different models of bundling payments, CMS said. Providers will have flexibility to determine which episodes of care and which services will be bundled together.

Organizations interested in applying to the Bundled Payments for Care Improvement initiative must submit a letter of intent no later than Sept. 22 for Model 1 and Nov. 4 for Models 2, 3, and 4, CMS said.

Continued on page 2

■ **Lab Tests to Be Included**, *from page 1*

The initiative is being launched by the Center for Medicare and Medicaid Innovation, which was created under PPACA to carry out the task of finding new and better ways to provide and pay for health care to a growing population of Medicare and Medicaid beneficiaries. "Payments [currently] are based on the quantity of care, and not on the quality of that care," Health and Human Services Secretary Kathleen Sebelius said during an Aug. 23 call with reporters. "There is little financial incentive for the kind of care coordination that can help patients from returning to the hospital."

Currently, Medicare makes separate payments to providers for the services they furnish to beneficiaries for a single illness or course of treatment, leading to fragmented care with minimal coordination across providers and health care settings, CMS said. Payment is based on how much a provider does, not how well the provider treats the patient. Under the new initiative, CMS said it would link payments for multiple services patients receive during an episode of care and eliminate incentives for multiple readmissions.

Four Models

CMS said the initiative is seeking applications for four broadly defined models of care, three of which would involve a retrospective bundled payment arrangement, with a target price (target payment amount) for a defined episode of care.

In Model 1, the episode of care would be defined as the inpatient stay in the general acute-care hospital. Medicare would pay the hospital a discounted amount based on the payment rates established under the inpatient prospective payment system (IPPS). Medicare would pay physicians separately for their services under the Medicare Physician Fee Schedule. Hospitals and physicians would be permitted to share gains arising from better coordination of care, CMS said.

In Model 2, the episode of care would include the inpatient stay and post-acute care and would end, at the applicant's option, either a minimum of 30 or 90 days after discharge, while in Model 3, the episode of care would begin at discharge from the inpatient stay and would end no sooner than 30 days after discharge, CMS said.

In both Models 2 and 3, the bundle would include physicians' services, care by a post-acute provider, related readmissions, and other services proposed in the episode definition such as clinical laboratory services; durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); and Part B drugs. The target price would be discounted from an amount based on the applicant's historical fee-for-service payments for the episode. Payments would be made at the usual fee-for-service payment rates, and any reduction in expenditures would be paid to the participating providers to share.

Under Model 4, CMS would make a single, prospectively determined bundled payment to the hospital that would encompass all services furnished during the inpatient stay by the hospital, physicians, and other practitioners. Physicians and other practitioners would submit "no-pay" claims to Medicare and would be paid by the hospital out of the bundled payment.

Sonic Healthcare Posts 6% Profit Growth for 2011

Sonic Healthcare, the Australian-based diagnostic company that owns more than half a dozen labs in the United States, reported fiscal 2011 revenues of $3.096 billion ($3.287 billion on a constant currency basis), an increase of 10 percent over the previous year's level. Net profits increased 6 percent to $295 million ($311 million on a constant currency basis).

Net profit was in line with guidance given in February 2011, said officials, who pointed to strong second-half performance. The company paid dividends of 35 cents per share.

Sonic CEO Colin Goldschmidt said the company could weather spending cuts across the United States and Europe as leaders struggle to rein in spiraling government debt. However, the company expects to see a sharp rise in interest rates on its $1.7 billion debt as lower rates expire.

Sonic expects to grow earnings before interest, taxes, depreciation, and amortization by 10 percent to 15 percent over the 2011 level of $570 million. Net interest expense is expected to increase by approximately 30 percent over the 2011 level of $65 million on a constant currency basis. About half of this increase relates to funding for acquisitions completed from July 2010 to date and the balance to higher margins following refinancing of debt facilities in 2011.

"Our laboratory operations in the USA and Europe have expanded further, with pleasing revenue and earnings growth, as well as margin expansion due to synergy capture," said Goldschmidt. "The performance of our Australian pathology division in the second half of the year was very pleasing, with revenue growth of 6 percent and significant margin improvement after a first half impacted by low market-volume growth rates, fee cuts, and other regulatory interventions. The new five-year funding agreement between the industry and the government will provide much-needed stability and predictability going forward."

Bio-Reference Labs Reports Record Quarter

Bio-Reference Laboratories (Elmwood Park, N.J.) posted third-quarter revenues of $148 million, the best-ever quarter in terms of revenues and an increase of 22 percent over the $122 million recorded the same period in 2010.

Net income after taxes in the quarter was $10.1 million, an increase of 26 percent over the prior year's third quarter, resulting in fully diluted earnings per share (EPS) of 36 cents. Gross profits for the quarter were $73.4 million, resulting in a 50 percent profit margin.

Revenue per patient for the quarter was $84.20, an increase of 2 percent over the third quarter of 2010. The number of patients served increased 20 percent to 1,745 in the current quarter from the same period the previous year. Esoteric business for the company was 60 percent of the revenues for the quarter.

For the first nine months of the fiscal year, revenues increased to $407.3 million, an increase of 23 percent over the same period in 2010. Net income after taxes for the nine months was $22.1 million, an increase of 24 percent, resulting in EPS of 79 cents. The company reported gross profit on revenues for the current nine months of $195.9 million, resulting in profit margin of 48 percent. The number of patients served increased 21 percent to 4,917 in the first nine months of the year, up from 4,072.

According to CEO Marc Grodman, M.D., the company has invested heavily in its prenatal program and its plans to introduce a solid tumor genotyping program in conjunction with Massachusetts General Hospital. Bio-Reference will begin offering these clinical programs by the end of the current year and expects them to be valuable contributors to the company's continued growth.

"We do not grow through acquisition like so many others in our industry," said Grodman. "We grow by leveraging our existing assets; we make acquisitions to enhance our core assets. Our new clinical programs are designed to build on our existing presence in women's health and oncology."

Medicare Part B Lab Spending Up 4.7% in 2010

Medicare Part B spending on clinical laboratory services continued to increase in 2010 though at a slower pace than in previous years, according to the latest data from the Centers for Medicare and Medicaid Services (CMS).

Part B lab spending totaled $8.424 billion in 2010, a 4.7 percent increase over 2009. The rate of growth has slowed considerably since 2009, when it was 11 percent over the 2008 total.

The Medicare program covered a total of 47.5 million people in 2010. Total Medicare expenditures in 2010 was $522.8 billion, an increase of 2.7 percent over 2009 levels. Part B lab services represented 1.6 percent of overall program expenditures in 2010, the same percentage as in 2009.

Medicare Part B Spending on Lab Services *($ millions)*

	2010	2009	2008	2007	2006	2005	5-Year CAGR*
Intermediary labs (hospitals)	$3,424	$3,331	$2,967	$2,932	$2,941	$2,784	4.2%
Carrier labs (independents)	5,000	4,723	4,261	4,144	3,694	3,548	7.1%
Total Part B labs	8,424	8,054	7,228	7,076	6,635	6,332	5.9%

** CAGR = compounded annual growth rate*
Source: 2011 Medicare Trustees Report

Of the $8.424 billion total Part B lab spending, $3.424 billion (40.6 percent) was for intermediary lab-related services, which include hospital outpatient and outreach testing. The remaining $5 billion (59.4 percent) was for lab-related carrier services, which includes independent and physician office labs.

Between 2005 and 2010, Part B lab expenditures increased at an average rate of 5.9 percent per year compared to an average growth rate of 9.2 percent per year for total Medicare spending.

According to the trustees' report, the financial outlook for the Medicare program is substantially improved as a result of the changes in the Patient Protection and Affordable Care Act (PPACA). In the long range, however, much of this improvement depends on the feasibility of the law's downward adjustments to future increases in Medicare prices for most categories of health care providers.

Inside The Lab Industry

The article is excerpted from G2 Intelligence's new report, How to Build a Molecular Testing Laboratory: Key Strategic & Operational Considerations, *written by L. Eleanor J. Herriman, M.D., MBA, director of research and analysis. The full report is available for $995 from* www.G2Intelligence.com.

Strategic Planning for the MDx Lab: A Primer

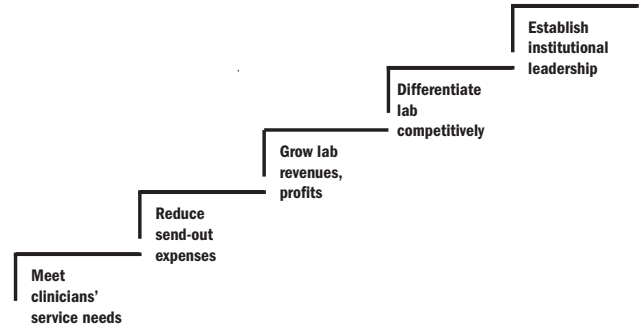
Developing your laboratory's MDx strategy is a five-stage process—(1) Define strategic objectives; (2) Evaluate requirements vs. lab's capabilities and resources, and iterate; (3) Analyze market context and iterate; (4) Develop financial plan for staged growth; and (5) Create a business case.

1. Define strategic objectives:

There are a number of potential objectives your institution might have for starting an MDx lab. The rationale will also depend on, for example, whether your lab is a reference or hospital lab, a community hospital or academic medical center.

The figure below defines example MDx lab objectives, starting on the left with the more basic and operational goals, and becoming more strategic as one moves to the right.

Laboratory Objectives for Launching MDx



Source: G2 Intelligence

- *Meeting clinicians' service needs*—For instance, a lab may decide to start an MDx lab because clinicians need faster turnaround time on particular MDx tests. G2 Intelligence's winter 2011 survey of 90 labs found the most important factor academic medical centers reported for starting in-house MDx was clinicians' demand for in-house expertise.[1]
- *Reduce send-out expenses*—A common reason for starting an MDx lab for hospital labs is to reduce send-out costs. In the 2011 G2 lab survey it was the most important reason for starting internal MDx testing reported by community hospital labs.[2] Meeting this objective then becomes a financial exercise in calculating internal vs. send-out costs for various tests and instrument platforms, and making decisions accordingly.
- *Grow lab revenues, profits*—A more ambitious plan for an MDx lab might be to turn a lab cost center into a revenue and profit center, which is certainly achievable with this high-growth area. This may entail everything from obtaining more samples from current clients to starting an outreach program. Ilke Panzer, vice president, diagnostic laboratories, BloodCenter of Wisconsin, explained, "By adding molecular assays, a lab can conduct more testing with current clients, add new clients in its current areas of service, and offer new areas of service. Molecular diagnostics can increase volume and revenues, protect current business, and improve profitability."[3]

[1] *G2 Intelligence MDx survey, winter 2011.*
[2] *G2 Intelligence MDx survey, winter 2011.*
[3] *"Optimize the lab's test menu: how molecular dx can impact the bottom line,"* Medical Laboratory Observer, *August 2010*

- *Differentiate lab competitively*—In regions with little MDx penetration, a laboratory has an opportunity to be "first to market" in establishing a local MDx lab. Besides building a reputation as an early adopter of advanced technologies, such a move would enable the lab to serve as a regional reference lab. There is likely only a limited window of opportunity for being the first MDx lab, however there are a multitude of ways a lab can differentiate its MDx services—breadth of menu, value-added services, and professional expertise, for example.
- *Establish institutional leadership*—Given MDx's central role in personalized medicine, many labs affiliated with academic medical centers have launched MDx centers as part of an institutional personalized medicine initiative. For example, Preveen Ramamoorthy, Ph.D., director, molecular diagnostics, National Jewish Health, communicated that the greatest driver for the launch of their hospital's MDx lab in 2008 was the CEO's vision of creating a personalized medicine center at National Jewish. The lab's business plan and interactions with the institution and research ecosystem have all been in fulfillment of that strategy.[4] Another objective might be to support a hospital's new flagship department. This might take the form of developing cutting-edge testing as part of a translational medicine center.

2. Evaluate requirements vs. lab's capabilities and resources, and iterate:
This step involves first determining what requirements are needed to meet the strategic objectives defined in step one. The requirements for building the MDx lab depend on the strategic objectives. Some of the requirement categories that need to be considered include the type of lab, client network (the clinicians or other labs being served), personnel (techs and other lab staff), and technology (assays and instrumentation).

One simplified way of classifying MDx labs creates two groups—basic and full service, according to the level of expertise and testing complexity. A basic lab would be one performing only Food and Drug Administration-cleared MDx tests, i.e., in vitro diagnostics (IVDs), and mostly on automated systems requiring little specialized expertise. A full-service MDx lab would be one able to perform a wide range of assay types, conduct extensive validation, and routinely create laboratory-developed tests (LDTs).

Next, the laboratory should assess its internal facility, capital, personnel, client base, and technology baseline states to determine what gaps versus the requirements exist. Filling these gaps will be addressed after considering the local market context and conducting financial analyses.

If the requirements needed to build the desired MDx lab are beyond what the lab had planned, one can return to step one and revise the objectives.

3. Analyze market context and iterate:
The laboratory's local health care community plays an important role in any strategic planning. Simply put, an analysis of MDx supply and demand is needed.

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[4] *Preveen Ramamoorthy, Ph.D., Director, Molecular Diagnostics, National Jewish Health, interview with G2 Intelligence, April 7, 2011*

❑ MDx "supply" questions:

- What other laboratories are performing MDx testing?
- Which reference labs are being used for send-outs by most local labs?
- What range of testing is being performed by local MDx labs? For example, is only infectious MDx being performed?
- Are any local MDx labs creating LDT MDx tests?

❑ MDx "demand" questions:

- Are there clinicians expressing interest in having local MDx expertise?
- Are there MDx tests being requested by clinicians but not provided because of unacceptable service issues?
- What do the patient demographics and disease prevalence statistics indicate about the potential market for various MDx testing categories?

❑ Competitive positioning:

- How does your lab compare to others in terms of client services (turnaround times, reporting, customer service)?
- How does your MDx send-out menu compare to other local labs'?
- How do your payer mix and reimbursement rates compare to other local labs'?
- What is your lab's market positioning—e.g., early adopter or low-cost provider?

The results of these market analyses will inform how feasible your strategic objectives are and what opportunities for filling requirement gaps might exist. Does sufficient demand vs. supply exist to allow for growth? Are there opportunities to establish competitive or leadership positions? In this way, your strategic objectives and requirements can be iterated.

For instance, if demand exceeds supply locally, then a growth strategy can easily be pursued. If there are particular types of MDx testing where demand is not being met, then the lab can target those tests.

MDx labs have suggested guidelines for minimum MDx test volumes in order to break even or reach profitability, based on basic infectious MDx tests that reimburse for around $60-$80. For example, Robin Felder, Ph.D, professor of pathology, associate director of clinical chemistry laboratory, University of Virginia School of Medicine, estimated that a minimum of about 200-300 samples per day are needed to start.[5]

If local MDx supply seems to be satisfying demand, then the MDx lab could focus on transferring send-outs to internal tests. Alternatively, the lab could pursue a full-service LDT strategy if it is affiliated with an academic center. In this way it can develop one-of-a-kind tests that can be launched nationally, a strategy that has been financially quite successful for other MDx labs.

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[5] *Robin Felder, Ph.D., Professor of Pathology, Associate Director of Clinical Chemistry Laboratory, University of Virginia School of Medicine, interview with G2 Intelligence, March 30, 2011*

4. Develop financial plan for staged growth:
Integrating the fundamentals of the plan and the requirements as determined in the steps above, the lab can develop a pro forma financial plan. Most experienced MDx labs recommend pursuing a staged build-out plan, with a more limited operation in the first several months that aims to establish a positive return on investment, then a further rollout expansion based on the particulars of the lab's operations and setting.

Further details are needed before a complete financial plan can be developed, and these are addressed in Chapters 4 and 5 of this report. These include which tests will be included in the menu, which instruments, what type of personnel and facility space, etc.

Revenues are projected from a combination of test volumes and payer reimbursement rates.

Again, iteration is suggested until the plan can show a positive return on investment if this is important to the lab's institution. In other settings in which the institution is investing in a major initiative, the primary objective may not be financial but strategic, and growth may outweigh finances.

5. Create a business case:
Finally, in many cases, depending on form where the impetus for the lab originated, the lab needs to "sell" the proposal for the MDx lab to the institution's administration.

Creating a business case involves developing a business plan, including describing the strategy, objectives, execution plan, and financial pro forma. Importantly, the business case should convince the executives of the benefits that will accrue to the hospital or corporation. These may go beyond the MDx objectives, to include:

- ❏ Cost avoidance for hospitals from decreased lengths of stay, decreased rates of infections, avoidance of complications, etc.;
- ❏ Better performance on quality metrics/clinical outcomes from more accurate diagnoses and better therapeutic guidance; and
- ❏ Attraction of clinicians and patients due to enhanced reputation from using advanced technology.

A final point is the trend toward increasingly expensive MDx send-out testing, and the competitive advantage a hospital can achieve by building internal testing. Thomas Pribyl, Ph.D., group manager, technical marketing for molecular diagnostics at Beckman Coulter Inc., explains, "Hospitals that perform molecular testing in house operate at an economic advantage. On average, labs lose about 15 percent in cost savings by sending out samples. The ongoing shift in payer policy toward pay for performance will further impact the cost of outsourcing complex tests. Hospitals will face diminishing returns unless they can find a cost-efficient and reliable way to perform MDx testing in-house."[6]

[6] *Kelly J. Graham, "Building, Sustaining an MDx Lab,"* Advance, *January 8, 2009*

M&A, Equity Investment in Labs Continues at Healthy Pace

Following a strong 2010 and first half of 2011, mergers and acquisitions and equity investment in the clinical laboratory and pathology space continued at a healthy pace during the summer, with a number of companies announcing purchases or investments. Among recent deals:

US Clinical Laboratories Acquires Two Georgia Labs

US Clinical Laboratories in June acquired Vidalia Lab Services (VLS), headquartered in Vidalia, Ga. This marks the company's first market entry outside the greater Houston area. VLS services south Georgia and specializes in nursing home and skilled nursing clientele. VLS also provides walk-in testing to the Vidalia community.

Riley McDonald, founder and president of VLS, will remain as president and will spearhead the integration of VLS with US Clinical Laboratories and focus his efforts on the expansion of business throughout Georgia and neighboring states. Terms of the deal were not disclosed.

In August, US Clinical acquired Augusta Laboratory Inc., headquartered in Augusta, Ga. Augusta Lab services northeastern Georgia and specializes in nursing homes and skilled nursing clientele. Terms of the deal were not disclosed.

US Clinical Laboratories is a privately held company based in Houston. The company was formed in 2010 to pursue opportunities and growth strategies in the laboratory testing industry. With the Vidalia and Augusta Lab acquisitions, the company now has five laboratories and 14 draw stations.

Signal Genetics, DiagnoCure Ink $13.3 Million Collaboration

Signal Genetics, a privately held predictive genetics testing company based in New York, and DiagnoCure, based in Quebec, in June announced a collaboration agreement valued at $13.3 million over the first five years.

Under terms of the agreement, Signal paid $5.7 million to acquire DiagnoCure's West Chester, Pa.-based CLIA lab and will pay a minimum of $5.1 million in annual installments and royalty payments over the first five years of the license agreement. In addition, Signal will pay DiagnoCure $2.5 million under a research and development agreement to advance certain genomic tests being developed in the company's Quebec-based laboratories. All payments will be made in cash.

The collaboration aims to maximize the commercialization of Previstage GCC Colorectal Cancer Staging Test, which Signal CEO Joe Hernandez says has an estimated global market potential of more than $400 million.

Founded in 2010, Signal Genetics is the parent company for three subsidiaries: Myeloma Health, which offers myeloma-related diagnostics; Respira Health, which focuses on lung cancer tests; and the newly founded CC Health, which will market tests for colorectal cancer.

Signal operates a CLIA-certified lab in Little Rock, Ark., that performs a pro-

prietary molecular test for multiple myeloma patients. MyPRS is based on the Affymetrix GeneChip microarray platform and uses a gene-expression signature to predict a patient's prognosis and enable personalized treatment decisions, according to the company.

Linden Purchases Majority Stake in Strata Pathology

Linden, a Chicago-based private equity firm, has entered the anatomic pathology sector through a major investment in Strata Pathology Services Inc., a leading independent anatomic pathology lab in New England.

Based in Lexington, Mass., Strata offers anatomic pathology services in the dermatology, urology, podiatry, oral pathology, gastroenterology, and gynecology segments. Strata currently serves clients in more than 40 states and has recently added a number of international customers. The company has more than 100 employees.

Linden operating partner Richard Novak, a 30-year veteran of the laboratory industry and former CEO of LabCorp, will serve as chairman of Strata. Terms of the deal were not disclosed.

Please Take Our Diagnostic Testing Survey

G2 Intelligence is conducting a survey to explore clinical laboratories' outlook on diagnostic testing and how current changes within the industry will affect your ability to compete in the coming years. We would appreciate if you would take a few minutes to fill out the brief questionnaire online:

www.G2Intelligence.com/DTTRSurvey

For your participation, we will provide a summary of the survey results (if you provide your contact info). Portions of the survey results may appear in future G2 Intelligence newsletters. As is G2 Intelligence's policy, responses will remain completely confidential and will not be connected to individual respondents.

Aurora Diagnostics Buys Pathology Labs

Aurora Diagnostics (Palm Beach Gardens, Fla.) has acquired two more pathology labs, bringing total acquisitions since being formed in 2006 to 22.

In June, Aurora acquired DermPath New England (Boston), a dermatopathology lab founded in 2006 by Hongmei Li, M.D. In August, Aurora purchased Global Pathology Laboratory Services (Hialeah, Fla.), which also specializes in dermatopathology. Terms were not disclosed for either deal.

On Aug. 15 Aurora announced that company founder James New would be retiring effective Sept. 1. Jon Hart will serve as CEO and a member of the board of directors. New will remain chairman of the board and will serve as a consultant to the company. New founded Aurora in 2006 and served as its CEO and chairman since its inception. He was also instrumental in the development of AmeriPath Inc., where he was the chairman and CEO from 1996 to 2003.

Hart has 26 years' experience in the laboratory industry. Since 2006 he has served as the senior vice president and head of Genzyme Genetics, which was sold in 2010 by Genzyme Corp. to LabCorp. From 1998 to 2006, he was a senior vice president of Quest Diagnostics. Prior to that, he was an executive with Smith-Kline Beecham.

Lab Index Falls 12% in Last Four Weeks

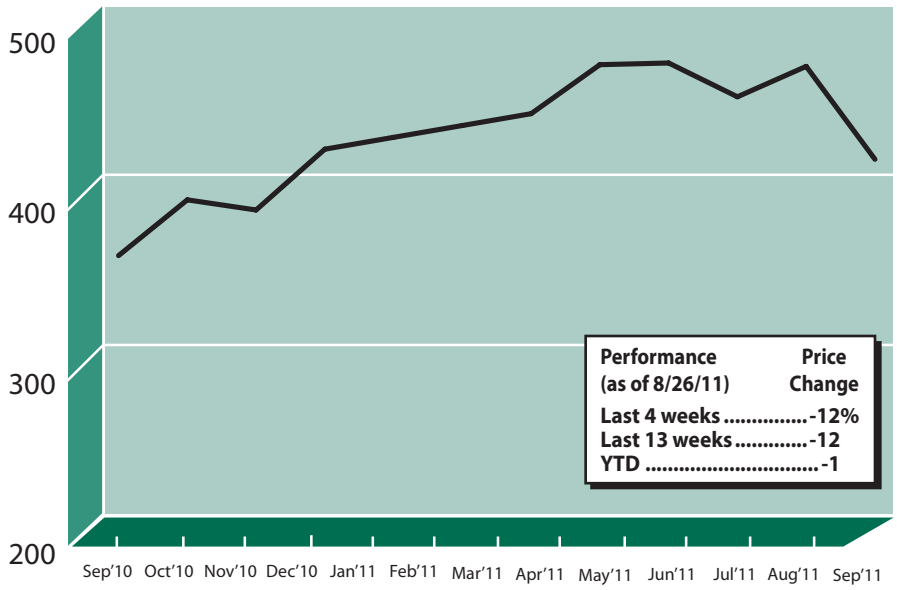
The G2 Intelligence Laboratory Stock Index fell an unweighted average of 12 percent in the four weeks ended Aug. 26, 2011, with all 10 stocks in the index losing value, brought down by a jittery stock market. Since the beginning of the year, the index is down 1 percent. In comparison, both the Nasdaq and S&P 500 are down more than 6 percent.

Shares of **Medtox** (St. Paul, Minn.) fell 15 percent to $13.23 despite the company posting a 17 percent increase in gross profit for the second quarter, ended June 30. Company revenues increased 11 percent to $27.9 million when compared with the same quarter in 2010 as demand for drug testing increased. The company reported gross profit of $12.1 million and net income of $1.4 million, or 16 cents per share.

Genomic Health (Redwood City, Calif.) shares fell 10 percent to $24.08. For the second quarter, ended June 30, total revenue increased 17 percent to $50.8 million when compared with the same period the previous year. Product revenue increased 19 percent. Net income was $2.3 million in the second quarter of 2011, compared with net income of $900,000 in the second quarter of 2010. Basic and diluted net income per share was 8 cents.

Shares of **LabCorp** (Burlington, N.C.) fell 11 percent to $80.64. The company is still dealing with Federal Trade Commission scrutiny of its plans to buy DNA testing firm Orchid Cellmark and has once again extended its tender offer, this time until Sept. 9. The deadline has already been extended three times. In other news, LabCorp on Aug. 25 announced the availability of a nucleic acid sequencing assay that reports NS3 and NS4A mutations and NS3-associated resistance to the recently approved hepatitis C virus (HCV) protease inhibitors, adding to LabCorp's suite of HCV testing. G2

G2 Laboratory Stock Index



Source: The G2 Laboratory Stock Index is tabulated weekly by Laboratory Industry Report *from the average percentage change of 10 laboratory testing service stocks.*

Percent Price Change, Six weeks ended 8/26/2011

	Price	*Percent Change*
DOWN		
Bio-Reference	$19.02	-5%
Enzo Biochem	2.89	-25
Genomic Health	24.08	-10
LabCorp	80.64	-11
Medtox	13.23	-15
Myriad Genetics	19.28	-9
Quest Diagnostics	48.31	-11
Psychemedics	7.94	-7
Orchid Cellmark	2.69	-2
Neogenomics	1.15	-21

INDUSTRY BUZZ

FDA Draft Guidance on IUO, RUO Products Could Compromise Patient Care: AMP

The Food and Drug Administration's (FDA) draft guidance on in vitro diagnostic products labeled for research use only (RUO) or investigational use only (IUO) could compromise the quality of patient care by severely reducing the availability of certain reagents and laboratory-developed testing services that have become the standard of care for many diseases or conditions, according to the Association for Molecular Pathology (AMP).

In comments submitted to the FDA, AMP says the draft guidance, if finalized as written, could limit patient access to new or improved molecular tests.

"Some products used for laboratory tests are available only as research- or investigational-use-only products," explained AMP Professional Relations Chair Elaine Lyon, M.D. "If this guidance were to be finalized, we're concerned that patients won't be able to access tests such as those for hepatitis C genotyping, newborn screening, and HLA testing."

AMP supports FDA clearance and approval of RUO and IUO products, especially test kits and test systems. However, to prevent disruption of patient care, accommodations should be made to ensure continued patient access to critical tests as manufacturers come into compliance and in instances where low test volume would deter a manufacturer from submitting an application to the FDA for that product, says AMP.

References

Augusta Laboratory 540-332-4500

Aurora Diagnostics 866-420-5512

Beckman Coulter 800-526-3821

Bio-Reference Labs 201-791-3600

DermPath 617-254-7284

DiagnoCure 888-900-6626

Genomic Health 650-556-9300

Global Pathology Laboratory Services 866-825-4422

LabCorp 336-436-5274

Linden 312-506-5600

Medtox 800-832-3244

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Vidalia Lab Services 912-537-0622

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