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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

G-2's 2009 AP Market Survey Indicates Reimbursement, New Client Development as Key Growth Challenges

A recent G-2 survey of the anatomic pathology market found that most hospital and independent labs, as well as many pathology groups, are struggling with reimbursement and new business development issues as they struggle to grow their businesses during this economic recession. Specifically, when asked to identify their top three challenges to growth, almost half of the over 140 respondents cited reimbursement, followed by expanding and developing new clients and business at 44 percent and competition from commercial labs, at over 30 percent.

Another challenge indicated was the cost of acquiring and adopting new technology, although most respondents appear to be embracing new and emerging technology, including digital pathology and automated image analysis. For more on the findings and analysis from the *2009 Washington G-2 Reports Anatomic Pathology Market Strategic Outlook Survey*, read the special insert featured in the center of this issue.

Quest's First Quarter Revenue Increases 1.3% to $1.8 Billion; Announces Settlement of Nichols Institute Case for $302 Million

While Quest Diagnostics (Madison, N.J.) posted a 1.3 percent revenue increase to $1.8 billion for the first quarter of 2009, a slight decline in clinical testing volume, primarily due to a 25 percent drop in drugs-of-abuse testing volumes, indicates that the slowing economy continues to impact the nation's leading lab testing provider. But aggressive cost cutting initiatives and a strong EBITDA (earnings before interest, taxes, depreciation, and amortization) margin of 21.4 percent indicates that the company is performing relatively well during this recession.

Quest's clinical testing revenues increased 2.2 percent compared to the prior year and revenue per requisition increased 4.1 percent. However, clinical testing volumes decreased by almost 2 percent. Of this total decrease, 1.7 percent is attributable to the drop in drugs-of-abuse testing volumes,

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■ **QUEST'S FIRST QUARTER REVENUE INCREASES**, *from page 1*
which are closely linked with rising unemployment rates and declining hiring rates. Underlying volume growth was 1.5 percent, which is below the industry standard of between 2 percent and 3 percent.

Volume was also reduced 1 percent on the termination of certain lab management agreements. "In assessing these agreements, they were not meeting the profitability thresholds that we've set, and as a result, we have not renewed them," said Robert A. Hagemann, senior vice president and chief financial officer, on the earnings conference call. "This had a significant impact on volume, it had a relatively insignificant impact on revenue, which tells you that they were pretty low priced."

Two other benchmarks linked to the economy—bad debt and days sales outstanding (DSO)—improved for the company. Bad debt expense improved to 4.5 percent, compared to 4.8 percent in the prior year. DSO was down to 43 days, compared to 48 days a year ago and 44 days at year end. Cash flow from operations improved to $273 million, up from $158 million in the first quarter of 2008. These improvements were a result of heightened cost control diligence during this first quarter, explained Hagemann. The lab provider is in the final phase of a three-year $500 million cost cutting initiative.

Nevertheless, the economy remains a challenge for Quest. "In terms of expectations for the economy, we are not anticipating any significant change in the economy, which is going to impact our volumes over the course of the year," said Hagemann. "But our underlying growth in our physician and hospital reference testing business is in excess of 3 percent for this quarter, and we feel good about that being able to continue . . . we feel good about our 3 percent revenue growth estimate for this year."

Settlement Reached in NID Case

These results were released only days after Quest announced that it had finalized its settlement of criminal and civil claims concerning diagnostic tests marketed and sold through Nichols Institute Diagnostics (NID), the test kit developer that it shuttered in 2006. The company will pay a total of $302 million to resolve the allegations, the United States Department of Justice Department announced on April 15.

In Brooklyn Federal Court, Quest's NID subsidiary pleaded guilty to a felony misbranding charge relating to the Nichols Advantage Chemiluminescence Intact Parathyroid Hormone (PTH) Immunoassay. As part of the plea, NID will pay a criminal fine of $40 million. The $262 million civil settlement resolves False Claims Act allegations relating to five NID assays, including the PTH test that allegedly provided inaccurate and unreliable results. Quest has also agreed to pay various state Medicaid programs approximately $6.2 million to resolve similar civil claims.

The government's civil and criminal investigation was sparked by a whistleblower suit brought by Thomas Cantor, president and founder of Scantibodies Laboratory (Santee, Calif.), which developed its own PTH assay and opened a clinical lab in 2000. Cantor will receive approximately $45 million from the False Claims Act settlement.

St. Pierre Named Acting Director of FDA's OIVD

FDA'a Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) has another new acting director—Don St. Pierre, who once served as the deputy director of the office under OIVD's former director Steve Gutman, Ph.D., until his retirement last year.

Gutman's immediate successor to the acting director position, Alberto Gutierrez, Ph.D., has been named the deputy office director of the new device evaluation. An FDA spokesperson told *LIR* that the office is doing a series of details for director candidates, which is typical for directorship positions. The OIVD is part of the FDA's Center for Devices and Radiological Health (CDRH).

St. Pierre joined CDRH in 1990 and has served various senior-level positions, including deputy division director of the division of clinical laboratory devices and the deputy division director of the division of clinical laboratory devices, and most recently as the associate director for policy and operations for the OIVD.

In related news, the CDRH and OIVD have reportedly received additional funding to increase staffing. OIVD has reportedly been approved to increase staffing by an additional 30 FTEs. In addition, the office has reportedly been approved to create an initiative called the Personalized Medicine Program.

Prometheus Partners With Rosetta Genomics to Enter Oncology Mol Dx Market

San Diego-based pharmaceutical and diagnostic manufacturer Prometheus Laboratories has entered in to a license and collaboration agreement with Rosetta Genomics (Philadelphia; Rehovot, Israel) for selling tests, as well as research and development funding. Prometheus has develops and markets molecular diagnostic testing services and treatments related to gastrointestinal disease, and this partnership signals Prometheus's move into the oncology molecular diagnostic testing market.

Under the licensing agreement, Prometheus will have rights in the United States to sell three of Rosetta's recently announced microRNA-based cancer diagnostic tests. The three tests are the miRview mets, which identifies the tissue-of-origin of metastatic tumors; the miRview squamous, which differentiates squamous from non-squamous non-small cell lung cancer; and miRview meso, which differentiates malignant pleural mesothelioma from other carcinomas in the lung and pleura. The tests will be performed at Rosetta's CLIA-certified laboratory in Philadelphia.

This agreement also includes plans for the two companies to develop two new microRNA-based gastroenterology tests, which will be funded by Prometheus. Additional financial terms of the collaboration include payments to Rosetta, including royalty payments on net sales in the United States. Under a separate stock purchase agreement, Prometheus will make an equity investment in Rosetta of $8 million at $4 per share, which represents an approximate 41 percent premium over the closing price of Rosetta stock over three business days.

Enzo Clinical Labs New President Details Mol Dx Expansion Plans

In the last two years, New York City-based Enzo Biochem's Life Sciences subsidiary has employed an aggressive growth strategy by making four acquisitions to rapidly expand product lines and infrastructure. Now, the company plans on executing a similar growth strategy in its clinical laboratory subsidiary, which in recent years has struggled to post significant gains. Since 2006, the laboratory's division's annual revenue grew by around 30 percent. From 2006 to 2007, revenue growth was around 26 percent due largely to the implementation of a UnitedHealthcare contract. The following year, this growth was around 4.2 percent, as the division experienced a settling out of the new business from the previous year, according to David Goldberg, a senior executive with Enzo Biochem Inc.

The lab division targets physicians in both New York and New Jersey and performs testing at a 45,000-foot facility in Farmingdale, N.Y., and Paramus, N.J. Now the company is focused on bringing more high-value and esoteric testing to its physician clients by expanding its presence in the molecular diagnostic testing market, which Washington G-2 Reports estimates will grow by approximately 12 percent this year to $5.6 billion amidst a relatively favorable pricing environment. "We're in the perfect storm in the molecular diagnostic testing industry right now," said Goldberg. "We are located in one of the largest esoteric testing markets in the world, and we've got an IP (intellectual property) portfolio that has yielded us more than $250 million in revenue so far. These factors, coupled with the growing molecular diagnostic market, the interest from the pharmaceutical industry in developing companion diagnostics, and our strong financial position of having no debt make for an ideal time for our clinical labs subsidiary to take a larger role in the molecular diagnostic testing industry."

The architect behind this growth plan is the clinical lab subsidiary's newly tapped president, Kevin Krenitsky, who was previously the C.E.O. of the molecular diagnostic developer Bioserve Biotechnologies (Beltsville, Md.). He is also the former C.E.O of Parkway Clinical Laboratories (Bensalem, Pa.), a lab specializing in both routine and esoteric testing that was sold to Rosetta Genomics in 2007. A trained physician who joined Enzo in March, Krenitsky is replacing one of the company's founders, Shahram Rabbani, who will remain on the board of directors until later in 2009.

LIR recently talked to Krenitsky about his vision for the future of Enzo's clinical laboratory division, and what operational changes he is making in the near term to execute his growth strategy.

LIR: What can you tell us about your current vision for Enzo's growth in the molecular diagnostic market?

KRENITSKY: The growth of the clinical lab business has to be different than growth in the life sciences division because this is a services business. My strategy is two-pronged. First of all, we need to focus on organic growth by continuing to improve the quality of the service we provide. But then we also must embrace

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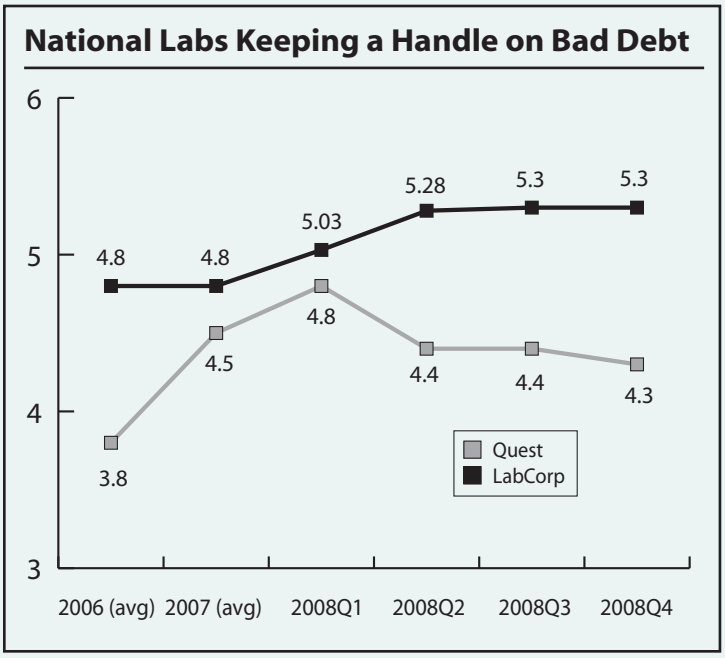
Tough Economic Times Forcing Labs to Focus on Billing Weak Spots

Keeping control of creeping bad debt has been a primary topic of discussion during the publicly traded laboratories' earnings calls in recent months, with Wall Street analysts using these financial benchmarks to assess how these companies are weathering the current economic crisis. However, the national laboratory leaders—Quest and LabCorp—appear to be staying strong during this recession. Both labs have continued to post revenue gains over the past two years while managing to keep bad debt from escalating by making billing and collections a priority.



If the national labs are focusing more on billing and collections, it stands to reason that so must the rest of the lab industry. In this current economic environment when unemployment is rising (prompting uninsured rates to go up), people are forgoing routine medical procedures—such as testing—and finding it harder to pay their deductibles and copays due to financial constraints. More than ever, there is increased pressure on labs to optimize billing and collection processes to boost the bottom line in the face of sluggish volume and revenue growth. But few independent and hospital outreach labs, as well as pathology practices have the resources to implement and maintain a robust billing and collection operation.

One primary issue is that traditional billing systems have not enabled good analysis on outstanding accounts related to patients with co-pays and deductibles versus those related to indigent care, according to Thomas Hirsch, co-founder and president of Laboratory Billing Solutions (Portsmouth, N.H.), a company that performs billing services for hospital outreach and smaller independent laboratories. In fact, as much as 31 percent of hospital patient revenue that is written off as bad debt and sent to a collection agency should be classified as charity care, according to a recent research study by Connance Inc. (Waltham, Mass.) and PARO Decision Support, LLC (Ft. Lauderdale, Fla.). Many hospitals are eligible for tax exemptions based on their charity care cases.

"There are definitely more co-pays and higher deductibles as employers pass along more of the costs associated with health insurance increases to employ-

ees," he explained. "Labs are going to get more people who are underinsured than uninsured, and it's hard to know how to effectively go after that patient population when it's historically been an afterthought, but these patients are really the lion's share of your self-pay."

More Billing to Secondary, Tertiary Payors

Because bad debt is ticking upward, many labs are looking beyond just billing a patient's primary insurer if they have secondary or even tertiary coverage, noted Lâle White, executive chairman and founder of Xifin (San Diego), a company that develops billing and financial management software for laboratories and other health care providers.

"The bad debt rate is increasing incrementally, and we are seeing this across the board," she explained. "We're also, however, seeing a decline in the amount of billing that's actually ending up in the patient's hand due to the increase of automatic secondary and tertiary billing being done. But of what's left, we are seeing a bit of an increase of bad debt. Right now, it's not huge, but we are paying attention to it."

Traditionally, labs have only billed the primary insurer and then billed the patient for the balance. But if you maximize the electronic billing with all of the insurances that a patient carries, you minimize how much you end up having to bill the patient, according to White.

While the bad debt may be increasing, White said her clients are not seeing a decrease in patient payments. "But of course, the DSO [days sales outstanding] does go up because less is being paid, but we are not necessarily seeing a slow down in payments," she explained. Because most patients are paying at least something, many of White's lab clients are offering their patients more flexible payment plans. In particular, labs that do esoteric and molecular testing are offering longer payment plans due to the economic situation.

Collecting Payments

Of course, working with a collections agency is another integral part of this process, and officials from one agency contacted by *LIR* indicate that the economy is driving some of their growth. "We're certainly not seeing decreased levels of charge offs coming our way from our clients," said Harold Gartner, executive vice president of American Medical Collection Agency a division within Retrieval Masters Creditors Bureau (AMCA; Elmsford, N.Y.), where most of the company's business comes from the laboratory industry. "I can't speak about specific clients, but I can say that the pure volume that our clients have to place with us is certainly growing."

However, the current recession underscores the importance of working with a collection agency that ideally specializes in clinical laboratories and pathology practices so that the collectors can explain the bill when they contact patients. At the very least, the agency *Continued on page 7*

SPECIAL REPORT:
Highlights of G-2's 2009 Anatomic Pathology Survey

Washington G-2 Reports' 2009 AP Market Survey Finds Reimbursement, Expanding Client Base Are Top Challenges to Growth

As clinical laboratories and pathology practices struggle to increase revenue and market share in this unprecedented economic environment, many identify reimbursement, developing new business, and competition as their top growth challenges, according to findings from the *2009 Washington G-2 Reports Anatomic Pathology Market Strategic Outlook Survey*. There were 143 total respondents to the survey, most of whom identified themselves as working for hospital or independent labs or a pathology group.

When asked to cite the top three challenges to growth in 2009, those chosen most often were reimbursement (50.3 percent), expanding and developing new clients and business (44.1 percent), and competition from commercial labs (31.5 percent), as detailed in Table 1.

Table 1

Top Three Challenges to Growth in 2009, by Facility Type					
	Hospital	***Independent Lab***	***Pathology Group***	***Other***	***Overall***
Reimbursement	52.7%	51.1%	42.9%	48.3%	50.3%
Expanding/developing new client business	41.8	62.2	42.9	20.7	44.1
Competition from large commercial labs	41.8	28.9	35.7	13.8	31.5
Specialty physician groups insourcing pathology	27.3	35.6	35.7	3.4	25.9
Cost of acquiring or using new technology	34.5	8.9	21.4	27.6	23.8
Competitive pricing	16.4	17.8	14.3	20.7	17.5
Staffing shortages	21.8	4.4	28.6	17.2	16.1
Quality/test turnaround time	21.8	11.1	7.1	13.8	15.4
Expense of adding new molecular diagnostics	9.1	13.3	14.3	10.3	11.2
POD labs	7.3	15.6	7.1	3.4	9.1
Competing for managed care contracts	1.8	15.6	14.3	6.9	8.4
Education of users on selection and use of new tests	1.8	17.8	7.1	6.9	8.4
Educating pathologists on application of new tests	5.5	8.9	0.0	6.9	6.3
Others	5.5	0.0	7.1	10.3	4.9

"The concern over reimbursements represents the greatest challenge in anatomic pathology for 2009," said survey author Stanley J. Geyer, M.D., a pathologist and founder of the consulting company Geyer Pathology Services (Pittsburgh). "Since the survey found that most respondents expect to achieve growth in 2009, I think we can conclude that the reason for concern over reimbursement arises from diminished payments for individual tests. In addition, the growing number of uninsured people may also cause an increase in nonreimbursed care."

Challenge to Expand Technology

Another key growth issue is technology. Almost 24 percent of respondents identified expanding or developing new technology as a major challenge. The automation of histology and Pap smear interpretations, the growth of molecular diagnostics, and the use of PCR techniques have expanded the diagnostic repertoire of the pathologist, but the acquisition of these technologies may be costly and unapproachable during an economic downturn when the availability of capital dollars is limited, said Geyer.

While a significant challenge, most survey respondents appear to be embracing various forms of emerging and evolving technology, as detailed in Table 2, which illustrates the current use or planned use of various forms of emerging or evolving technologies by practice type. Overall, 32.6 percent of practices currently use telepathology, 41.8 percent use automated image analysis, 64.5 percent use molecular diagnostics, and 71.3 percent use informatics.

Table 2

Use/Plan to Use the Followings Technologies, By Facility Type				
	Telepathology	***Automated Image Analysis***	***Molecular Diagnostics***	***Informatics***
Hospital				
Currently use	19.4%	39.4%	57.5%	71.8%
Plan to use in next two years	80.6	60.6	42.5	28.2
Independent Lab				
Currently use	37.9	48.6	69.2	74.2
Plan to use in next two years	62.1	51.4	30.8	25.8
Pathology Group				
Currently use	55.6	50.0	63.6	50.0
Plan to use in next two years	44.4	50.0	36.4	50.0
Other				
Currently use	40.0	26.7	70.6	75.0
Plan to use in next two years	60.0	73.3	29.4	25.0
Overall				
Currently use	32.6	41.8	64.5	71.3
Plan to use in next two years	67.4	58.2	35.5	28.7

Another type of emerging technology—digital pathology—also appears to be gaining traction among survey respondents, as indicated in Table 3. When asked about their use of this technology, 25 percent of the overall respondents said they currently use digital pathology technology and another 54.5 percent indicated that they were exploring its use in the future.

Table 3

Does Your Lab Do Digital Pathology Work? By Facility Type			
	Yes	***No***	***No, but exploring how we can use in future***
Hospital	21.8%	16.4%	61.8%
Independent Lab	30.2	14.0	55.8
Pathology Group	21.4	35.7	42.9
Other	25.0	35.0	40.0
Overall	25.0	20.5	54.5

Another important component of expanding technology capabilities is bringing pathology data into electronic health records (EHRs). In this survey, 63.6 percent of respondents from pathology practices reported integrating their reports into an EHR. This is important, as pathology practices can lose clients to commercial laboratories if they fail to keep pace with the information integration developments in the commercial laboratory marketplace, noted Geyer. "The integration also enhances the informatics functions of pathology by allowing correlation with other clinical data and by improving the availability and use of clinically important pathology information," he added.

Drop in ThinPrep, Liquid-based Pap Smears Predicted for '09

In terms of test-volume growth between 2008 and 2009, respondents from all practice types expected growth in all areas with two exceptions (see Table 4). The pathology groups expected a 0.4 percent decrease in liquid-based Pap smears and a 0.2 percent loss of work in ThinPrep automated imaging of Pap smears. For overall expectations comparing last year and this year, the groups expected an 8.5 percent growth in surgical accessions, a 9.5 percent growth in biopsies (code 88305), a 6.1 percent growth in all other categories, a 13.3 percent growth in immunohistochemical tests, a 14.5 percent growth in FISH, a 6.3 percent growth in cytopathology, a 2.9 percent growth in liquid-based Pap smear evaluations, a 4.3 percent increase in ThinPrep automated imaging of Pap smears, a 16.3 percent expansion of other molecular tests, an 18 percent growth of PCR-based testing, and a 15.1 percent increase in other tests.

Independent laboratories predicted the greatest growth, with anticipated increases of 17.5 percent and 20.3 percent for surgical pathology accessions and biopsies, respectively. The independent laboratories also reported an anticipated growth of 36 percent and a 32.6 percent growth for molecular diagnostic testing and PCR-based testing.

Table 4

Anticipated Percent Change in Test Volume From '08 to '09

	Hospital	*Independent Lab*	*Pathology Group*	*Other*	*Overall*
Surgical pathology accessions	3.4%	17.5%	5.6%	5.5%	8.5%
Biopsies (88305)	3.3	20.3	7.5	5.5	9.5
All others	2.5	11.8	6.0	4.4	6.1
Immunohistochemistry	10.7	20.0	7.7	7.3	13.3
FISH (fluorescent in situ hybridization)	6.6	22.9	1.8	19.7	14.5
Cytopathology	3.1	12.0	5.1	2.3	6.3
Liquid-based Pap	1.8	6.0	-0.4	2.7	2.9
Thin-Prep automated imaging of Pap smears	0.7	10.0	-0.2	2.5	4.3
Other Molecular diagnostic tests (i.e., Urovysion)	2.6	36.0	5.0	11.0	16.3
PCR-based tests	6.9	32.6	17.8	12.8	18.0
Others	6.4	31.7	1.3	7.6	15.1

Planning for Growth, Decline

The survey asked respondents to indicate how they were planning to achieve anticipated growth or managing the expected loss of work this year. Of the 116 respondents, most said that they were planning to expand outreach through improved sales and marketing efforts. Some groups acknowledged the need to expand their IT capabilities to compete against commercial laboratories and to improve the desirability for clinicians to send work to those labs hoping to expand outreach activities. Competing against national reference laboratories can be a daunting task because of the amount of resources available to national labs. Some other responses are featured in Box 1.

But successful expansion in outreach requires the diversion of work from competitor laboratories, said Geyer, who noted that some respondents expect a downturn in overall health care volumes and procedures because of the current economic situation. "For outreach to be successful in a flat or declining market as a whole, work must be diverted from one or more competitors for the expectant outreach lab to achieve significant growth," he explained. "Local pathologists hold an advantage over national reference labs because the local pathologists know the referring clinicians can respond quickly and personally to the problems encountered by the clinicians and can integrate results from various parts of the laboratory into a consolidated explanation of findings for the referring clinician." Because of advances in tissue processing, same-day turnaround time has become more commonplace, providing advantages to clinicians, pathologists, and technologists.

For those labs expecting less work this year, respondents indicated that pathologists and technologists will work more hours, take less vacation time, and either decrease or cross-train technical staff. Additional efforts to plan

Box 1
How will you achieve growth during 2009?

- ❑ Add product lines, expand menu of tests
- ❑ Expand sales and service force
- ❑ Expand geographic reach
- ❑ Hire additional professional and technical staff
- ❑ Increase fluorescent in situ hybridization (FISH) and immunohistochemistry (IHC) testing due to new test development and increasing clinical requests for these tests
- ❑ Improve customer service in outreach programs
- ❑ Expand marketing activities to surgeons
- ❑ Improve marketing and expand client base by increasing the PCR menu with new test development

for a downturn in business are detailed in Box 2. However, the continuing evolution of new technologies and new tests may create new work for pathologists, according to Geyer. To that end, the expanding menu of immunohistochemical tests improves diagnostic capabilities and was cited by many respondents as an expected source of growth for 2009.

Surveying the Competitive Environment

When asked to identify their top three competitors, almost 80 percent of survey respondents from all facility types identified national commercial laboratories as their main competitor as shown in Table 5. However, local and regional pathology groups and independent laboratories also received more than 50 percent of the responses, revealing that most pathologists are concerned about local competition. Because many respondents identified outreach as a principal means of achieving growth in 2009, competition for both existing and new work is likely to be intense, said Geyer. "However, not all labs will grow if the acquisition of new technology and new information systems is limited by reimbursements and other financial constraints," he added.

Box 2
How will you handle expected work loss in 2009?

- ❑ Improve cost management processes to strictly control costs
- ❑ Implement LEAN processes, Six Sigma efficiencies
- ❑ Lower end-of-year bonuses for all employees
- ❑ Delay technology upgrades
- ❑ Change work schedules and decrease or increase the hours of specific personnel to manage the changes in testing volumes

There's no doubt that the national reference labs are stiff competition to local laboratories looking to improve their outreach business. The country's leading lab provider—Quest Diagnostics (Madison, N.J.), with a current market share of 14 percent to 15 percent—not only has widespread operations and thousands of patient service centers throughout the United States, but it also had international operations in Mexico, Puerto Rico, India, and the United Kingdom. The second largest testing provider in the United States, LabCorp (Burlington, N.C.) is estimated to have a 9 percent market share. It's almost an understatement to say that it's hard for the local and independent labs and pathology practices to compete against a company with such resources and large capitalization, said Geyer. "What ends up happening is that local laboratories frequently compete against themselves, which means they are ultimately gaining business at the expense of another local or regional laboratory," he added.

Table 5

Top Three Competitors, by Facility Type

	Hospital	*Independent Lab*	*Pathology Group*	*Other*	*Overall*
National commercial labs	83.6%	82.2%	92.9%	62.1%	79.7%
Local/regional pathology groups	60.0	75.6	78.6	37.9	62.2
Independent labs	54.5	66.7	64.3	51.7	58.7
Hospital outreach laboratories	41.8	33.3	14.3	27.6	33.6
POD labs	25.5	20.0	28.6	13.8	21.7
Others	7.3	6.7	0.0	10.3	7.0

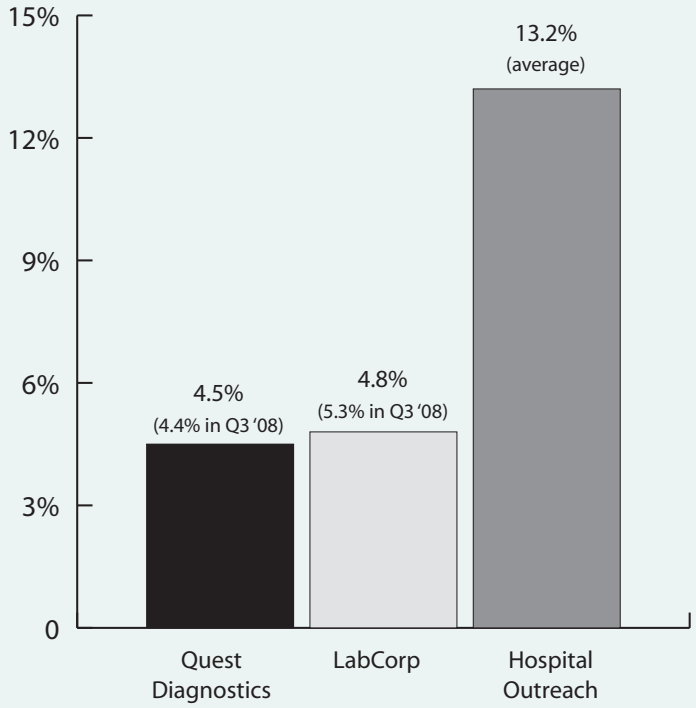
David Ulrich, Sales Director, AMCA

■ **LABS FORCED TO FOCUS ON BILLING WEAK SPOTS**, *from page 6*
should specialize in collecting lower balance medical bills, said David Ulrich, AMCA's sales director.

This is where outreach labs often run into trouble with high bad debt rates because they are often forced to use their hospital's collection agency, which doesn't segment balances by department. Indeed, the average bad debt expense for hospital outreach labs was 13.2 percent in 2007, compared to Quest's average of 4.5 percent and LabCorp's average of 4.8 percent for that same year, according to Washington G-2 Reports' recently published *Lab Industry Strategic Outlook: Market Trends & Analysis 2009*. "Based on our experience, you can't treat a $100 lab bill the same as you'll treat a $10,000 or $15,000 inpatient bill and the same as you'll treat a $50,000 emergency room bill," said Ulrich. "If hospital outreach labs were able to segment their work more specifically by sector or balance range and pass those accounts onto low-balance collectors, I'm confident they would collect a lot more money. Agencies who service hospitals are set up to collect those high-balance bills, and there's more of a financial incentive for them to settle those high balances."

During these economic times, it's also key for all laboratories—independent and outreach—to hire a collection agency that has technological capabilities, including the ability to send detailed custom and automated reports to clients on a regular basis that analyze account aging, as well as gross and net collections. Other technology-related services include account scrubbing, which includes bad address and telephone look up, and the ability

Bad-Debt Expense as a Percentage of Revenue, 2007



Source: *Lab Industry Strategic Outlook: Market Trends & Analysis 2009*

to send the new address to the lab if they have to bill them again in the future. Advanced dialer systems are also important because they allow for efficient calling campaigns at specific times of the day when it is best to find debtors available to pay their bills.

In addition, the agencies who are dealing with hospitals and other industries, such as the automobile and credit card industry are currently deluged, trying to collect on outstanding accounts ranging from credit balances to car notes. But Ulrich said that while their collection demands are growing, the industry as a whole is growing and lab-focused agencies continue to collect relatively well.

Furthermore, lab bills tend to be in the hundreds, not thousands—or tens of thousands—in debt that many consumers are grappling with from other creditors, including health care providers like hospitals. "It's much easier right now to take care of a low-balance debt and clear that up, said AMCA's executive vice president Gartner. "Right now, a consumer might be willing and able to take care of a $20 to $100 lab bill, which is easier to collect on compared to an overdue $5,000 credit card debt."

Confronting Bad Debt Through Billing Analysis

For labs or pathology practices that are noticing a climb—however slight—in their bad debt rate, Thomas Hirsch, co-founder and president of Laboratory Billing Solutions (Portsmouth, N.H.), recommends a thorough analysis of a facility's billing and collection process using some of these methods:

- **Work on your bad mail.** "I know this sounds so mundane, but a lot of labs don't do this systematically," said Hirsch. Many labs will send out a statement that gets returned due to a bad address, but they keep sending subsequent statements to that same address. Labs need to track bad mail, know how much of a percentage of statements have to be reworked, and work with clients to identify ways to get better addresses.
- **Analyze where, on average, payment is coming in the statement cycle.** Labs need to track how many statements they are sending on average before they are getting paid and how long they are giving patients to pay. A different cycle, or slight changes to this cycle, might improve collection rates.
- **Analyze bad debt by client.** Identify clients with a higher percentage of bad debt. Determine if this is happening because the client is providing inaccurate patient information, because they have a higher percentage of indigent patients, or another reason.
- **Differentiate between bad debt associated with co-pay/deductibles and purely self-pay or indigent.** "You really can't do a lot about indigent bad debt," said Hirsch. "You've provided the service, and if people don't have the means to pay, you might be able to put them on an installment plan, but you probably won't see anything." The people with insurance are your best chance of receiving payment.
- **Set your write-off balance at the right amount.** "We have labs who write off $10 and $20, which is way too high," said Hirsch. "Labs shouldn't go any lower than $3, but you need to go after the money."
- **Scrutinize statement language.** Look at how clear your statements are and if they explain exactly what tests were ordered, as well as identifying the ordering physician. When your patients call with questions, are their calls returned quickly and are customer service reps able to address common questions?

Kevin Krenitsky, President, Enzo Clinical Labs

■ **ENZO CLINICAL LABS**, *from page 4*

new tests and new technology because to grow aggressively, you must differentiate yourselves in this way. However, your test menu must also be marketable and make sense financially from a physician adoption perspective so as a whole it's not an easy task. Nonetheless, it is our goal to be a first-in-class provider of esoteric laboratory services.

LIR: Can you tell us what areas of molecular diagnostics that you plan on focusing on?

KRENITSKY: We're defining the direction of our expansion now, but I will say that we're in discussions with numerous companies in the molecular and esoteric space. Women's health testing, such as HPV and cytology, continues to be of interest to us, and our most recent menu expansion includes adding tests such as infectious disease viral loads, cellular immunology assays, and immunohistochemistry testing capabilities.

We're also taking a hard look at what barriers exist in this market, including regulatory issues such as the IVDMIA [in vitro diagnostic multivariate index assays] draft guidance. Because the leadership at the FDA's Office of In Vitro Diagnostic Device (OIVD) Evaluation and Safety is still in question, it's unclear right now where the oversight of that technology is headed. But we are in a good position in terms of IVDMIAs. If there is increased oversight and these tests have to go through some clinical trials process, we can do that because we have the infrastructure already in place through Enzo's Life Sciences and Therapeutics divisions.

LIR: Is the current economy having any impact on your growth?

KRENITSKY: We are in excellent financial condition right now—we have in excess of $60M in cash and no debt. Our life sciences and clinical laboratory divisions are moving toward achieving greater synergies. In addition, because of the tight capital market, molecular diagnostic testing companies are now more interested than ever in working with a strong lab in either licensing, distribution, or other types of partnerships, rather than attempting to open up a CLIA lab on their own. We are also the right size to serve as a molecular diagnostics partner—not too big like one of the national labs, and we are nimble enough to react quickly to bring in new technology and implement precise marketing and sales strategies.

LIR: Speaking of operational improvements, what changes are you making in the sales and service operations of your divisions?

KRENITSKY: I'm currently evaluating operations from top to bottom. I'm analyzing the patient experience at our patient service centers, including the performance of our phlebotomists, as well as our current courier network of 50 to 60 drivers and their routes.

Our sales organization is now comprised of more than 30 FTEs. These are divided into sales representatives, sales support, and client service representatives. The sales representatives are no longer responsible for doing any sort of inside sales or client support. They are now focused on sales. Each client has a dedicated salesperson and a dedicated support person to handle service issues and

technical questions. As I said before, our goal is to provide service that is the best in our region, and this is a key part of our growth strategy.

I'm also analyzing our billing operations. We recently upgraded our laboratory billing system, and I've brought in additional Medicare billing specialists, as well as an outside consulting company to continue to help us enhance our systems.

LIR: What are your priorities right now?
KRENITSKY: My first priority is to drive sales by both internal growth, as well as the expansion of our test menu both via partnership as well as from within Enzo. We need to make changes where needed, whether by additional resources or by reorganizing what we currently have to meet the new future needs of the lab. While growing the business is a priority for us, I'm not interested in sacrificing short-term goals in performance for long-term goals in growth. As a business grows and as you acquire new clients, you have to make sure you provide top-quality service to both new, as well as existing clients or they won't be clients for long.

Enzo Clinical Labs at a Glance

Annual Revenue:	$42.1 million in 2008; $40.4 million in 2007
Locations:	45,000 square foot primary laboratory in Farmingdale, N.Y.; laboratory in Paramus; 28 patient service centers in New York and New Jersey
FTEs: Total:	675; Clinical Lab subsidiary: 371
Client Base:	Physicians in New York metro region
Sales Force:	14 FTEs

Gov. Schwarzenegger Commits $32 Million to Combat California's Allied Health Worker Shortage

California's Governor Arnold Schwarzenegger (R) plans to add thousands of allied health professionals, including lab and radiology technicians and technologists, to the state's hospitals and health care facilities over the next three years through a $32 million public-private partnership called the "Allied Health Initiative."

Under this program, regional industry and education leaders will work together to develop effective allied health partnerships. The three-year program will be funded through $16 million from the state, $8 million from the federal Workforce Investment Act, and $8 million from the economic stimulus act, or the American Recovery and Reinvestment Act of 2009. In addition, private partners, such as schools and hospitals, will provide $16 million in matching funds or in-kind contributions.

The Allied Health Initiative will be structured along the same lines as Gov. Schwarzenegger's $90 million California Nurse Education Initiative. Created in 2005, this five-year public-private partnership helped drive an increase of more than 54 percent in the number of registered nurse graduates by 2008.

According to recent statistics from the California Labor Market Information Division and Federal Bureau of Labor Statistics, California only has 65 percent of the medical lab technologists and 62 percent of the radiation technologists and technicians of the national average per 100,000 people.

Lab Stocks Make Gains in April; Up 9% Over Five Weeks, 7% For 2009

After struggling in March, lab stocks rebounded slightly in April, posting gains of 9 percent over the past five weeks for the week ended April 17, 2009. The 14 publicly traded labs tracked by the G-2 Reports Laboratory Stock are up 6 percent over the past 13 weeks and 7 percent so far in 2009. The Nasdaq also showed strength, even though the S&P 500 continues to post losses. For 2009, the Nasdaq is up 2.5 percent, but the S&P 500 remains down over 6 percent so far in the year.

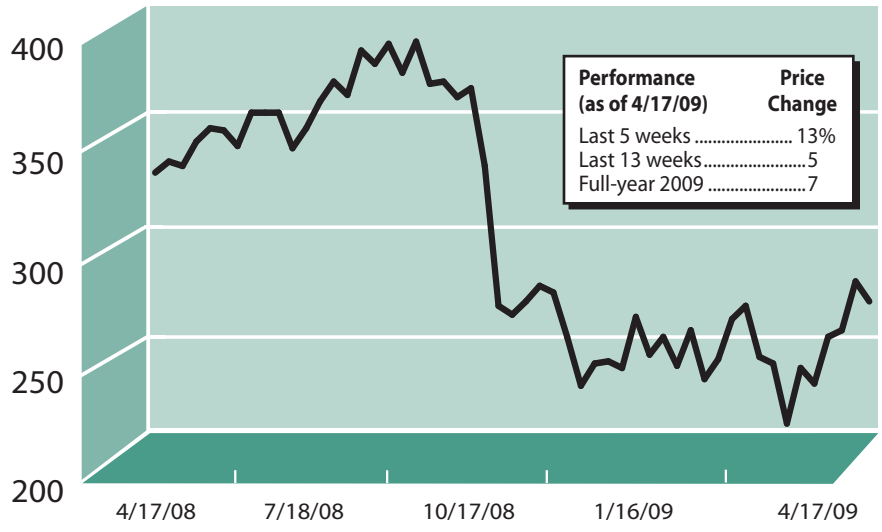
All the labs tracked in G-2's stock index posted gains this month, led by **Orchid Cellmark** (Princeton, N.J.), which is up 62 percent to $.94 per share for a market cap of $28.77 million over the past four weeks for the week ended April 17. Following Orchid is **Clarient** (Aliso Viejo, Calif.), which is up 41 percent to $2.44 per share for a market cap of $193.39 million. Rounding out these top gaining labs is **Psychemedics** (Acton, Mass.), which is up 37 percent to $6.02 per share for a market cap of $31.33 million. This sign of strength is good news for this drugs-of-abuse testing business, which has been negatively impacted by the economic downturn and declining hiring rates in recent months.

Two labs tracked by the index each only posted one percent gains: biotech powerhouse Genzyme (Cambridge, Mass.), which was up to $54.99 per share for a market cap of $14.74 billion and Neogenomics (Ft. Lauderdale, Fla.), which was up to $1 per share for a market cap of $37.93 million.

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

In related news, **Myriad Genetics**, a molecular diagnostic technology developer and testing company based in Salt Lake City, implemented a two-for-one stock split on March 25, 2009. This testing provider was up 12 percent to $45.29 per share for a market cap of $4.05 billion over the past four weeks for the week ended April 17.

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 14 laboratory testing service stocks.

Top Gains and Losses Over Past Four Weeks

Percent price change, week ended 4/17/09

	Percent Change	Price
UP		
Orchid Cellmark	62%	$.94
Clarient	41	2.44
Psychemedics	37	6.02
Other Strong Performers		
Bio-Reference	15	24.72
Enzo Biochem	14	4.48
Quest	12	50.27
LabCorp	10	62.43

INDUSTRY buzz

Signature Genomic Labs Appoints New Lab Director

Spokane, Washington-based Signature Genomic Laboratories has appointed Trilochan Sahoo, M.D., as a laboratory director. Prior to joining Signature, Sahoo spent six years as an assistant professor in the Department of Molecular and Human Genetics at Baylor College of Medicine in Houston, Texas. Sahoo received his M.D. in Clinical Microbiology from Christian Medical College and Hospital in Vellore, India, and completed his post-doctoral training at the Government of India Department of Biotechnology and the Duke University Medical Center Departments of Microbiology and Genetics (Durham, N.C.). He is certified by the American Board of Medical Genetics in Clinical Cytogenetics and completed his training under Signature President and CEO Lisa G. Shaffer, Ph.D., during her tenure at Baylor.

Sahoo joins Signature's other lab directors: Beth Torchia, Ph.D., Roger Schultz, Ph.D., Allen Lamb, Ph.D., and Gail Wenger, Ph.D.

The laboratory also recently received its New York clinical laboratory permit allowing it to perform microarray-based comparative genomic hybridization used for the evaluation of individuals with unexplained mental retardation and birth defects in the state.

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LabCorp 800-334-5161

Laboratory Billing Solutions 603-766-8200

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Rosetta Genomics 888-522-7971

Signature Genomics 877-744-2447

Quest Diagnostics 800-222-0446

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