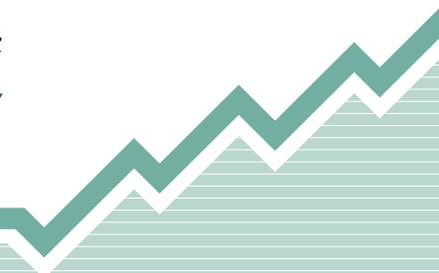


LABORATORY

INDUSTRY REPORT®



Julie McDowell, Managing Editor, jmcdowell@ioma.com

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Lab Stocks Level Out After October Plunge; Six Execs Offer Views on Latest Economic Developments

It was a rough October for the lab industry and the G-2 Laboratory Stock Index, which was down 29 percent over the past five weeks and 30 percent so far this year. But in the last two weeks the Index has leveled out, according to up-to-the-minute tracking of the Index available on www.g2reports.com.

To get a sense of how the industry is weathering this turbulence, *LIR* talked to a number of industry executives over the past month and found that many are taking a steady approach and continue to feel confident about the overall health of their companies and the industry. "Our stock price has moved up and down due to recent market volatility, but overall we have held up well," said specialty test provider Genoptix's CEO, Tina Nova. "We are seeing some of our venture capital investors moving out of the stock, so there was some associated downward pressure this summer. However, the investment community seems to understand that our exposure to broader economics is somewhat limited right now."

For more reaction on the economy from industry executives, read "Inside the Lab Industry" on pp. 5-7. For more analysis on recent stock activity, turn to p. 11. 🏠

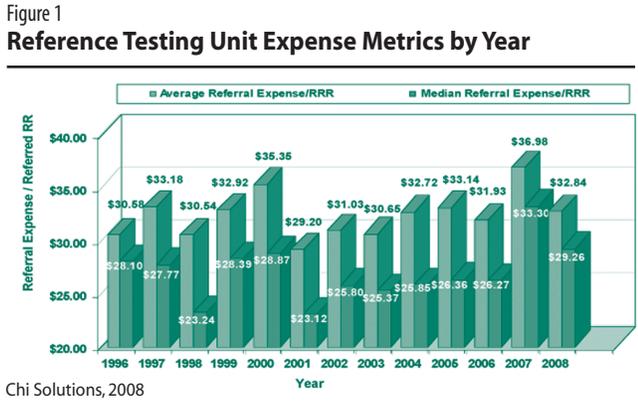
Hospital Referral Expense per Reportable Result Expected to Drop 11% by Year End

By the end of this year, the average referral expense per reportable result of sending a test to an outside reference laboratory is expected to fall to \$32.84, down 11 percent from 2007's figure of \$36.98, according to analysis of hospital labs by the laboratory consulting firm Chi Solutions Inc. (Ann Arbor, Mich.). The median is expected to drop 12 percent from \$33.30 in 2007 to \$29.26 in 2008 (see Figure 1, p. 2). Hospital labs currently dominate the \$50 billion clinical lab market with 54 percent market share.

Both demand and the falling cost of various diagnostic technologies are driving these pricing trends, which are cyclical in nature, explained Earl Buck, vice president of Chi Solutions. According to referral utilization statistics, the percent of overall referral testing to total testing dropped from 2.3 percent in 2007 to *Continued on page 2*

■ AVERAGE HOSPITAL REFERRAL EXPENSE, from page 1

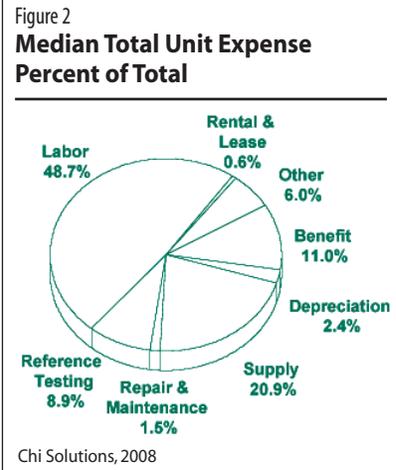
1.8 percent in 2008. Both independent and other hospital outreach labs need to compare their own costs based on expenses to these figures to ensure that they are competitive with these benchmarks.



implemented. Don't think that you don't have to do anything because the prices are coming down, it's still important to do a solid negotiating job in contracting."

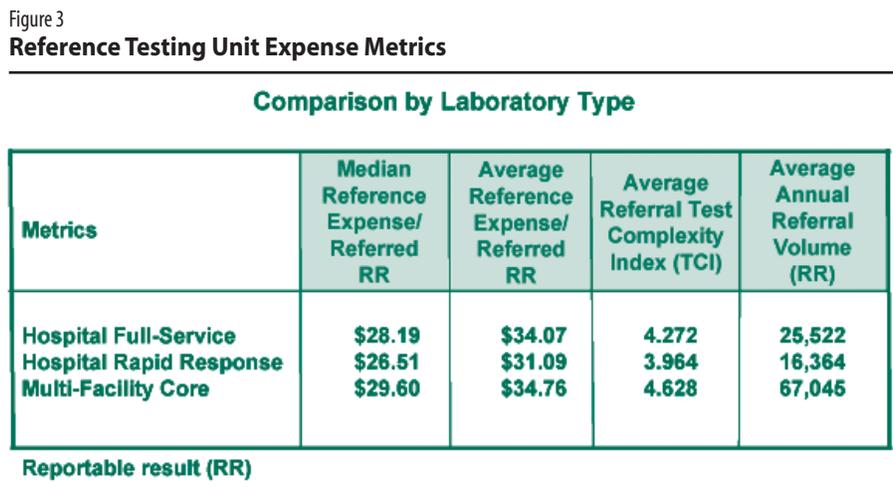
Breaking Down Expenses

The expenses used to calculate expense per referral figures are detailed in Figure 2. Labor comprises a majority of expenses at 48 percent, followed by supplies at 20.9 percent, and benefits at 11 percent. Reference testing comprises 8.9 percent of expenses. According to Chi Solutions's analysis—which is based on data submitted by over 100 hospital labs nationwide on a quarterly basis—the current median total expense per total reportable result is \$4.87.



For hospital labs, it's important to compare among different laboratory types. For example, Figure 3 shows that multi-core facilities tend to have the highest average and median reference

expenses per performed and transferred reportable result at \$34.76 and \$29.60 respectively, but they also have the highest test complexity. "The cost is going to be somewhat proportional to test complexity," said Buck, adding that for example, a cytogenetic test is going to cost more than a biochemical or serologic test in terms of sending it out to a reference lab. 🏠



Survey Finds Many Starting Salaries for Pathologists Are Between \$100k and \$250k

Over 66 percent of starting salaries for pathologists are ranging between \$100,000 to \$250,000, according to the American Society for Clinical Pathology's (ASCP) 2008 Resident Council Fellowship and Job Market Survey. Of the 121 respondents in 2008, 20 percent said they would be starting at under \$100,000, 33 percent indicated they were receiving a starting salary in the range of \$100,000 to \$150,000, and another 33 percent said their starting salaries were between \$150,000 and \$250,000. Fourteen percent of the pathologists indicated they would be starting at a salary greater than \$250,000 (see Figure 1). These salaries do not include benefits.

When compared to findings from the same survey conducted in 2007, the percentage of respondents receiving salaries on the lower and higher ranges ap-

pears to have increased in 2008, while the middle salary ranges have experienced a bit of a decline. Last year, 12 percent of respondents indicated starting salaries of under \$100,000—compared to 20 percent this year—and 9 percent received starting salaries of over \$250,000, compared to 14 percent this year. Between the past two years, those receiving starting salaries of between \$100,000 and \$150,000 declined 3 percent from 36 percent in 2007 to 33 percent this year, while there was a 10 percent drop in the \$150,000 to \$250,000 range, from 43 percent in 2007 to 33 percent in 2008.

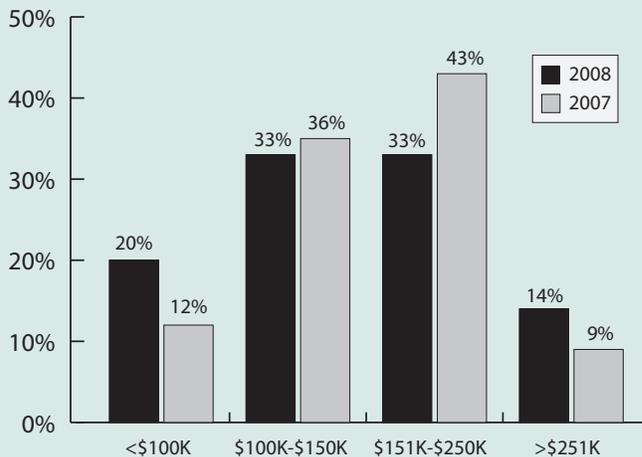
The ASCP study also looked at the type of practice that a pathologist desired, with 36 percent indicating an academic position,

33 percent indicating a community group practice, and only 2 percent indicating a reference laboratory. Why might a reference lab or publicly traded lab seem unattractive compared to academia? It likely reflects a lifestyle choice, according to one of the survey's analysts, Thomas J. Bollinger, M.D., who is currently in residency training at the Orlando Regional Medical Center in Florida. "While the money might be better at a public[ly traded] lab or community practice, working in academia is perceived as much less grueling and the pace is slower, while there might be more pressure at the community or reference lab," he explained.

Subspecialty Salaries on the Climb

The boost in the highest salary range is in line with the trend toward paying pathologists with a subspecialty significantly more, explained Tara Kochis, executive vice president and partner with the recruitment and consulting firm Slone Partners (Centreville, Va.). For example, pathologists with a dermatology subspecialty have been commanding salaries around \$275,000—often \$100,000 more than a general surgical pathologist.

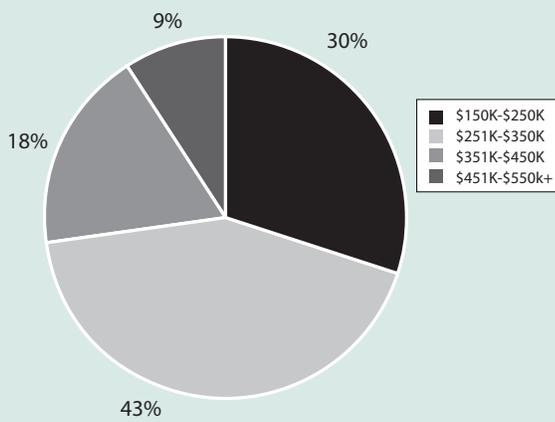
Figure 1
Survey of Current Starting Pathology Salaries, 2007 v. 2008



Source: 2007 and 2008 ASCP Resident Council Fellowship and Job Market Survey



Figure 2
Snapshot of Current Pathology Salaries



Source: Slone Partners, Sept. 2008

This trend toward the \$250,000-plus salaries is also evident in Slone's recent pathology compensation figures. Although Slone's statistics reflect those with three years-plus experience, the firm's September data show that most of the starting base salaries for pathologists with subspecialties were in the \$275,000 range with total compensation in the \$300,000-plus range (see Figure 2). Other data suggest that pathologists can also look forward to healthy annual pay raises. From 2006 to 2007, pathologists received the second largest average increase of 12.7 percent in total annual compensation along physician specialties, right behind oncology at 13.9 percent, according to *Modern Healthcare's Physician Compensation Survey*. 🏛️

Nebraska's Pathology Services Saves \$3k a Year by Paying Customer Service Reps More

Since Pathology Services, P.C.'s CEO David Glenn increased the hourly rate paid to customer service representatives in 2006 from \$9 per hour to \$12 per hour, he estimates he's saved \$3,000 a year. This has been realized primarily by decreasing turnover—at a monthly savings of approximately \$1,000—as well as by improving efficiency, eliminating one-half of a full-time employee (FTE) at a savings of over \$8,000.

Based in North Platte, Neb., Pathology Services is a small to midsize regional reference lab whose test volumes total over 500,000 per year. Because it's a smaller operation, the customer service reps (CSRs) perform a variety of functions—including phlebotomy, phone duty, and requisition entry.

From 1999 to 2006, Glenn was hiring phlebotomists at \$9 per hour and training them to perform customer service duties, including answer client questions and requisition entry. "This was a job with a lot of responsibility and some of our CSRs were prone to make mistakes, some were prone not to show up when scheduled, and others were just not up to our quality standards," he explained. "You get what you pay for, and at \$9 per hour, we were not getting what we needed."

At that time, Pathology Services had about 10 FTEs who were considered CSRs, although some entry-level employees do not perform all of the functions. Glenn said that three of these 10 FTE positions kept turning over, approximately every nine months.

Increasing Pay, Cutting Overall Costs

When he increased the pay to \$12 per hour, the quality of his applicants—and hires—improved and the turnover went down, but he needed to find ways to offset the additional salary costs. "Paying them \$9 per hour when working a 35-hour week was costing us approximately \$16,400 a year for each of those employees," said Glenn. "Now, I'm paying them \$12 per hour for that 35-hour work week, and it's costing me \$21,800 per person, which means an additional \$16,200 a year." *Continued on page 8*

Lab Execs See Economy Driving More Consolidation, Will Push New Administration for Higher Reimbursement

While Wall Street continues to find its footing following the recent infusion of \$700 billion from the federal government, the current economic downturn is likely to further fuel consolidation in the lab industry, according to several CEOs and executives from both reference and esoteric labs who were recently interviewed by *LIR*. However, the tight credit market is likely to complicate the merger and acquisition (M&A) process.

"The access to credit for new acquisition deals may be a bit tougher in this market until things sort out, which I think is a major issue," said Thomas Hirsch, co-founder and president of Laboratory Billing Solutions (Portsmouth, N.H.) and the former CEO of PathLab prior to its sale to LabCorp in 2001 for over \$100 million.

In this current credit environment, it's also more important than ever to have a strong balance sheet, according to Quest Diagnostics's (Madison, N.J.) vice president of communications and investor relations, Laure Park. "A company's ability to access the necessary cash to fund operating needs will be more challenging for those companies, in any industry, that do not have strong cash flows and solid credit metrics," she explained. "This may impact some companies' abilities to fund acquisitions or other growth. Additionally, we believe in the current market that valuation for acquisitions will decline." Some industry insiders have estimated current valuations at between 11.2x and 11.9x EBITDA.

But the chaotic financial environment is not the only issue that lab executives discussed with *LIR*. With a new president set to be elected this month and a new administration in the White House for the first time in eight years, reform and lobbying priorities are the focus of much discussion among industry leaders. Below are their thoughts in their own words.

LIR: In recent earnings calls by publicly traded labs, the economy has been blamed for declined physician utilization and a climb in bad debt, as related to an increase in self payors and deductibles. Has your lab been impacted and what other ways is the economy affecting your business?



Ronald L. Weiss, M.D.,
COO, ARUP

Ronald L. Weiss, M.D., president and COO of ARUP Laboratories (Salt Lake City): "ARUP Laboratories continues to see growth in referrals from its client base of hospitals and independent laboratories around the country. We do know, however, that current economic conditions are beginning to have an impact on decisions that patients, with and without their physicians, make on their health care needs. In addition, the entire supply chain in our industry is being affected, from the impact of high fuel costs on transportation and supply costs to the availability of capital to fund infrastructure improvements."

Laure Park, vice president, communications and investor relations, Quest Diagnostics: "As we told investors on our call in July, no company is immune to the economy, but with the exception of our drugs-of-abuse testing

and risk-assessment businesses, we were not able to specifically attribute any changes in our business to the economy. We are watching our daily volume closely and believe that we will be able to adjust our cost structure as necessary.”

Petros Tsipouras, CEO and chairman, Ikonysis and Ikonysis Clinical Laboratory (New Have, Connecticut), cell-based in vitro diagnostic company that opened CLIA lab earlier this year to run on its proprietary Ikoniscope fastFISH imaging system: “Our clinical lab business began operations well into the economic slowdown, and we therefore have no real basis for comparison. With Ikonisys and the Ikoniscope business, however, we can say with fair certainty that sales will slow down. But we also believe that the reduced efficiency of the FDA, due in part to their manpower shortage, has affected the clearance process of new applications, in some instances doubling the statutory time.”

Tina Nova, CEO, Genoptix (San Diego), specialty lab providing testing related to hematolymphomas: “If there are impacts making their way to our top line, they have been camouflaged by our expansion into new sales territories and the resulting new business driving our growth. As always, we are closely monitoring the payment practices of our payers and patients, but have not seen any appreciable changes in receivables so far.”



*Doug Berg, CEO,
Plus Diagnostics*

Doug Berg: CEO, PLUS Diagnostics (Lakewood, N.J.); specializes in genitourinary (GU) and gastrointestinal (GI) pathology markets: “What our clients—and even our AP [anatomic pathology] clients—have said is that many patients have met the deductibles for 2008, so if anything, this quarter will feel less of an impact because patients are trying to get visits done before the end of the year. But in January, I think it’s fair to say that patients may delay routine physician visits because they can’t pay the deductible. That being said, we think that the economic conditions will most likely impact the clinical labs versus the specialized anatomic pathology lab like PLUS Diagnostics. But we are aware of the physician encounter challenge, and we are keeping an eye on it.”

LIR: What about the current credit crunch? How is it impacting your operations, and how do you think it will affect the overall lab industry?

Weiss: “ARUP’s financial condition is sound, and the current credit crunch will not have a material affect on our operations. Industrywide, however, we are seeing, and will likely continue to see, organizations falter because of the combination of high debt, marginal profitability, and tight credit. Consolidations have been commonplace in our industry, and there is no reason to believe that this trend won’t continue.”

Tsipouras: “Private funding and solid financial standing are ensuring that Ikonisys is not directly affected by the credit crunch. However we believe that our clients, who rely on financing for purchasing our machines, are affected. As such we are concerned about the health of our market and are hopeful in seeing immediate action by the new administration.”

Berg: “PLUS is fortunate to be owned by Water Street Healthcare Partners (Chicago), which has over \$1 billion in capital invested in their private equity fund and has relationships with key lenders in the marketplace, so we are uniquely positioned in that we have access to people who lend the money in the first place. In terms of the lab industry, health care is 14 percent of the gross domestic product, and unlike some of the other large segments of our economy, like the auto and housing industries, purchase decisions can be made on criteria that are not as variable in nature. If you are a lender right now, health care would be a good place to make capital available because it’s a lower-risk investment.”

LIR: This month, a new president will be elected, and there are likely to be significant changes in Congress. With the new Congress and administration, what should be the lab industry’s lobbying priorities?

Weiss: “We need to continue to work with Congress to preserve future consumer price index updates and not allow cuts to the Medicare Lab Fee Schedule. Other important priorities are to lobby for a permanent extension of the TC [technical component] grandfather clause, to change the “date of service” rule for hospital specimens to permit independent laboratories to bill for laboratory testing referred out of hospitals and performed after the patient has left the hospital, and to update the Medicare specimen collection fee (unchanged since 1984).”

Tsipouras: “We believe that lobbyists should push federal and state government regulatory and reimbursement agencies to keep up with the pace of introducing new technologies in the diagnostics space.” 🏛️

Cigna, Wellpoint, and Humana Lose Millions in Lehman and AIG Exposure

Three of the largest managed care organizations in the United States—Cigna, Wellpoint, and Humana—have each lost millions from exposure to the recent financial meltdowns of Lehman Brothers and AIG, wrote analyst Charles Boorady with Citibank Global Markets in a recent report on global pathology markets. Pathology providers receive an estimated 40 percent of their income from managed care organizations, and these organizations have large investment portfolios that they rely on to generate a significant percentage of their earnings. “Investment income as a percent of earnings per share can range from a low of 15 percent at UnitedHealthcare to a high of 60 percent at Cigna,” wrote another analyst, Helen Cameron, in the report. “A risk to a payor is a potential risk to a creditor such as a clinical lab service provider, especially given the relative size of managed care organizations’ contributions to clinical lab revenues.”

Here’s a brief look at the estimated combined losses as a result of exposure to Lehman and AIG, according to Citibank’s Boorady:

- ❑ Humana: \$67 million, \$.26/share, approximately 6 percent of 2008 estimated earnings per share (EPS);
- ❑ Wellpoint: \$190 million, \$.23/share, approximately 4 percent of 2008 estimated EPS;
- ❑ Cigna: \$77 million, \$.17/share, approximately 4 percent of 2008 estimated EPS; and
- ❑ UnitedHealthcare: exposure said to be “immaterial,” no estimates cited.



■ NEBRASKA'S PATHOLOGY SERVICES, *from page 4*

One of the keys to cutting costs was reducing turnover. "Using the industry estimate that turnover costs amount to a half-year's salary, I used this to estimate cost savings for three FTEs, which I calculated to be an average monthly savings of \$1,000 per month," said Glenn. "This means \$11,000 a year."

The remaining savings came from eliminating half of a FTE. An employee wanted to work part-time, rather than full-time, and Glenn said this was possible because the reduced turnover also meant reduced training time. This saved \$8,200 a year.

Glenn also believes that he's saved money in billing FTEs. Because there are fewer mistakes by CSRs on the front end in collecting the patient and other information, he has not had to replace two billing FTE positions that became vacant through attrition. "I don't have the data to back that up," he explained. "My current annual net gain is \$3,000 in savings without the billing savings, but I think this is a conservative figure." 🏠

Response Genetics Teams With NeoGenomics to Expand Cancer Testing Sales Effort

Los Angeles-based Response Genetics wants to sell its lung and colorectal cancer tests beyond the West Coast market and is partnering with NeoGenomics Laboratories (Ft. Myers, Fla.) to develop a national sales strategy. NeoGenomics is a CLIA-certified lab that specializes in cancer genetic testing and offers testing services that include cytogenetics, flow cytometry, molecular diagnostics, and fluorescence in-situ hybridization—also known as FISH.

Under terms of the agreement, NeoGenomics's 20-person national salesforce will sell the PCR-based tests in a panel format, which perform genetic analysis to help physicians with treatment decisions for patients with nonsmall cell lung and colorectal cancer. Response Genetics recently formed a small specialized salesforce based in Los Angeles, and NeoGenomics currently has two salespeople and a regional manager who are based in California. All testing will be performed through Response Genetics's CLIA-certified laboratory.

The national sales strategy will include selling to pathologists, oncologists, and other clinician groups, which can be challenging, explained Robert Feeney, Ph.D., vice president of sales, marketing, and business development. "This testing relies on the need to procure formalin-fixed, paraffin-embedded specimens, and although the clinicians order the test and are considered the end-users of the test results, they may encounter resistance within the hospital environment by pathologists and/or laboratory administrators due to pricing concerns and other considerations," he explained. "You have to couch the needs of pathologists and clinicians alike, and as a salesforce, we've triangulated in this manner very effectively. There really aren't that many national boutique players left that can faithfully sell to both pathology and the clinician office market because the trend has been to bypass the pathologists and market directly to clinicians, as the latter is perceived to be the more lucrative market segment."



This agreement will also give NeoGenomics more access to the clinician market, as opposed to their current focus on pathologists. “Clearly, we might be able to set up new accounts on the basis of offering these tests in the pathology setting, but also in the oncology office setting, where we could use a little help in expanding our feet-on-the-street coverage,” said Feeney. “We are not doing their testing and they are not doing our testing, so it’s very clean and is viewed as a win-win for both parties.” 🏠

Industry Veterans Plunge Into Dental Mol Dx Market With Launch of OralDNA Labs

Some former executives with American Esoteric Labs (AEL) and Lab One have joined forces to enter the dental molecular diagnostics market with the recent launch of Nashville-based OralDNA Labs. The initial menu will feature two saliva-based diagnostic panels—MyPerioPathsm and MyPerioIDsm—based on technology previously only available in Europe to target periodontal disease. The company plans on eventually expanding this menu to offer a broad offering of molecular, genetic, and other clinical tests.

OralDNA’s management team has a rich background in the esoteric testing business. The president and CEO is Brian Carr, who was the founder and CEO of AEL before the company was sold to Sonic Healthcare (Sydney, Australia) in 2007 for \$180 million. The new lab’s chief information officer (CIO) is J. Mark Farrington, who was CIO and senior vice president at AEL. OralDNA’s senior vice president and chief operating office is Ken Clarke, who was the former vice president of operations for LabOne in Ohio before the company was sold to Quest Diagnostics in 2005 for \$934 million. The chairman and chief dental officer

is Tom Nabors, M.D., who was a practicing dentist and former founder and CEO of ADDX, an independent distributor of perio-testing products for a German manufacturer. The company is funded through Oak Investment Partners, a former investor in AEL.

No details will be made public about the size of Oak’s investment nor will the company provide details on the size of the lab or the current number of OralDNA’s full-time employees, explained senior vice president of sales and marketing Rob Walker, who was AEL’s former vice president of administration.

Targeting Dentists and Hygienists

OralDNA Labs’s target customers are the more than 200,000 dentists and dental hygienists in the United States. The

OralDNA’s Initial Test Menu

- ❑ **MyPerioPathsm:** DNA test to identify and quantify bacterial load of disease-causing pathogens associated with periodontal disease.
- ❑ **MyPerioIDsm:** Genetic test to determine susceptibility to periodontal disease by analyzing the interleukin 1 genes, performed in-house by OralDNA under a license from Interleukin Genetics (Waltham, Mass.) as part of a multi-year agreement.

In the current health care environment, dentists are in a unique position because patients often see their dentists more often than their physicians, and they are also seeing them for preventative care, explained OralDNA’s senior vice president of sales and marketing Rob Walker. “We see saliva being the next wave in the clinical lab market, especially within the dentist arena,” he added. “If we can catch periodontal disease earlier by using the dentists who are already doing personalized medicine, we will be better off.”



market for oral diagnostics in the United States is difficult to estimate because it is an emerging market, but Walker said that in 2007 dental service expenditures totaled \$96.9 billion. “It’s hard to break out what is diagnostic and cosmetic, but we estimate that general dentists are in perio-services, which includes routine cleanings, and these dentists are spending anywhere from \$10 billion to \$12 billion a year on these perio-services in the United States,” he explained.

The market potential of over 200,000 dentists and hygienists offers a significant market opportunity, emphasized Walker. If you compare this with the market size of those where molecular diagnostics have been introduced—such as the estimated 50,000 oncologists in the United States—the potential is significant. “If you look at the market size of 150,000 dentists and then add to it the more than 125,000 dental hygienists, who are doing a lot more screening and helping in the decision tree for applying the tests, then the market opportunity is phenomenal,” he explained. 🏠

High Rates of Test Ordering, Reporting Errors in Physician Offices Highlight Role for Labs

In a recent study analyzing 590 event reports in physician offices (POLs), there were almost 1,000 testing errors, with almost 25 percent of these errors relating to reporting results to clinicians. Almost 13 percent of the 966 testing processing errors involved test ordering, while almost 18 percent were related to implementing the testing, including not performing the test at all, which was noted 6.7 percent in the study published in a recent issue of *Quality and Safety in Health Care* (2008;17;194-200).

One of the primary messages from these findings is the need for a physician office to have a system in place to track the specimens from the time the test is ordered until the result is returned and reported back to the patient, explained one of the study’s lead investigators, John D. Hickner, M.D., from the University of Chicago Pritzker School of Medicine’s Department of Family Medicine. “As we talk to physicians in family practices, it’s clear that their systems are not as fully developed as they want them to be,” he said.

An important service that a lab can provide its physician clients would be providing them a system to track errors known to be common in these offices, said Hickner. “For example, a lab may notice that a particular office may consistently have trouble with drawing the right tube or with completely filling the tub or getting complete information,” he added.

Hickner acknowledged that this type of system is one that most independent and local outreach labs have mastered and one that could be offered as a valuable service to these physician offices. “Labs can really help physician offices by tracking problems systematically, providing feedback and meeting periodically with their customers to find out if they can improve their services, especially when it comes to quality and safety,” explained Hickner. 🏠



Lab Stocks Dip Sharply; Down 29% Over 5 Weeks, 30% for Year

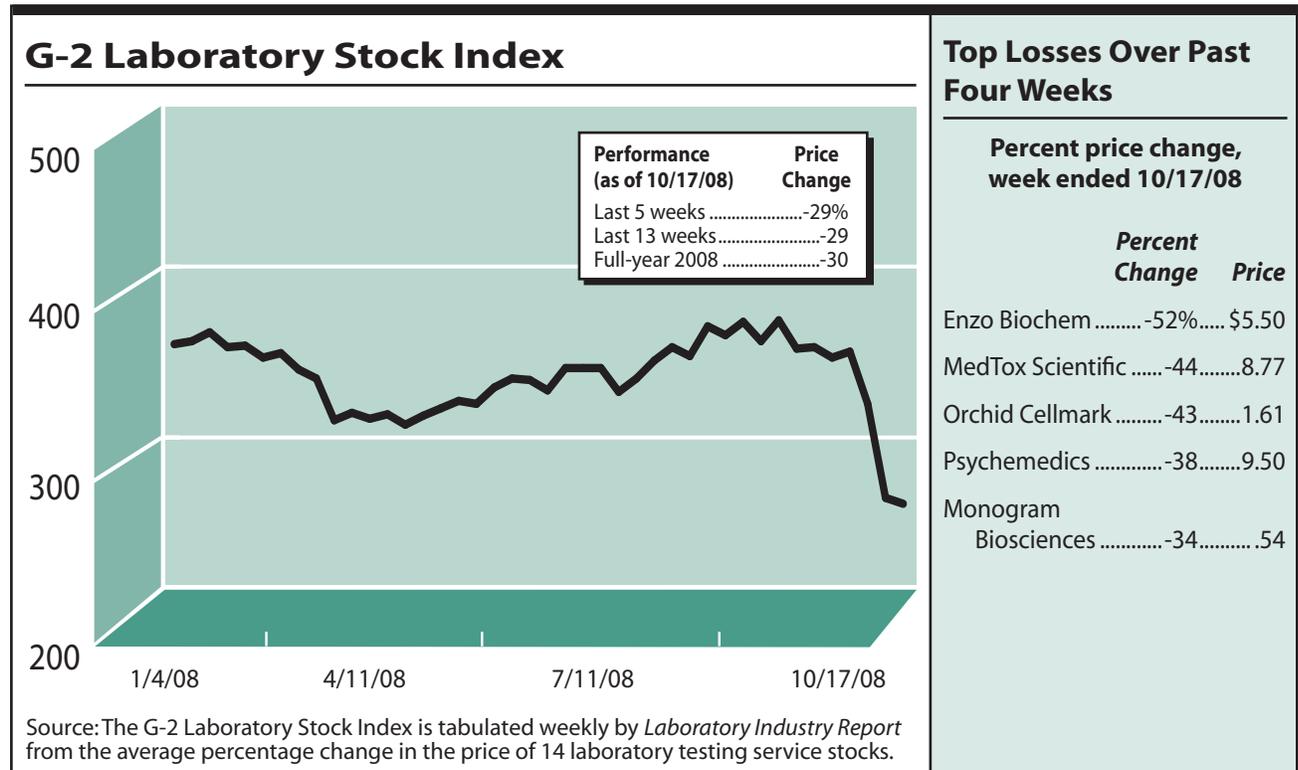
The historic falls on Wall Street continued to impact the lab industry through late September and early October. For the week ended Oct. 17, 2008, the G-2 Laboratory Index was down 29 percent over the past five weeks and 30 percent so far in 2008. None of the 14 publicly traded labs tracked by the Index showed any growth over the past four weeks. In fact, all except one are down in the double digits compared to the previous four weeks. In addition, Nasdaq and S&P have yet to lift. The Nasdaq is down 36 percent, while the S&P 500 is down 36.38 percent so far in 2008.

Because there were no gainers this month, *LIR* is looking at the top five labs posting the largest drops over four weeks for the week ended October 17. Posting the biggest drop was **Enzo Biochem** (New York City), which was down 52 percent to \$5.50 a share for a market cap of \$207.10 million. Second was **MedTox Scientific** (St. Paul, Minn.), which was down 44 percent to \$8.77 a share for a market cap of \$73.43 million.

Following MedTox was **Orchid Cellmark** (Princeton, N.J.), which was down 43 percent to \$1.61 a share for a market cap of \$58.73 million. Acton, Mass., based **Psychemedics** was down 38 percent to \$9.50 a share for a market cap of \$51.4 million. Closing out the top five was **Monogram Biosciences** (South San Francisco, Calif.), down 34 percent to \$.54 a share for a market cap of \$79.68 million.

The only lab posting a single digit drop was Genoptix (San Diego), which was down 4 percent to \$31.84 a share for a market cap of \$514.94 million. 🏠

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FDA Threatens LabCorp With Regulatory Action Over OvaSure Claims

The FDA's concern over LabCorp's marketing of its OvaSure ovarian cancer test appears to be intensifying (*LIR*, October 2008, p. 10). In a letter dated September 29, Steven Gutman, the FDA's director of the Office of In Vitro Diagnostic Device Evaluation and Safety, warned CEO David P. King that the agency had conducted a review of the marketing and technical information available for the tests and concluded that there are "serious regulatory problems involving this device," and that regulatory action would be initiated if the premarket approval was not initiated to correct violations.

When asked if the test is still currently available, Eric Lindblom, LabCorp's senior vice president of investor and media relations, stated that the company is in discussions with the FDA over the most appropriate next steps and will provide an update as soon as possible. LabCorp officials again expressed a willingness to work with the FDA to address these regulatory issues. "While we are disappointed in the letter, we will continue our discussions with the FDA on this matter," added Lindblom. 🏠

References in this issue

- ARUP Laboratories 800-242-2787
- American Society for Clinical Pathology 312-541-4999
- Bio-Reference Labs 800-229-5227
- Chi Solutions 800-860-5454
- Enzo Biochem 631-755-5500
- Genoptix 800-755-1605
- Ikonyosis .203-776-0791
- LabCorp 800-334-5161
- Laboratory Billing Solutions 603-766-8200
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- Myriad Genetics 801-584-3600
- Neogenomics 239-768-0600
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- Orchid Cellmark 609-750-2200
- PLUS Diagnostics 800-440-7284
- Pathology Services, P.C. 800-762-6811
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