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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

WASHINGTON G-2 REPORTS

GAO Study Criticizes CMS Oversight Of Labs

Has lab quality improved over recent years? Probably not, says a new report by the United States Government Accountability Office (GAO). Titled *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened*, the report highlights the lack of knowledge about the quality of lab testing and the inadequacy of CMS oversight of CLIA and makes recommendations for executive action to address these problems.

One critical problem, according to the report, is the impossibility of a standardized assessment of lab quality given the varying standards of survey organizations such as the College of American Pathologists (CAP), state agencies, and COLA. For example, the proportion of survey organization requirements classified as serious (and equivalent to CLIA condition-level deficiencies) ranges widely, from 20% for COLA to 100% for the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). For more on the GAO report, see *Inside the Laboratory Industry*, pp. 5-7.

Supreme Court Dismisses LabCorp Patent Case

On June 22, the Supreme Court announced its decision to dismiss *Laboratory Corporation of America Holdings v. Metabolite Laboratories*, the controversial patent case heard by the Court on March 21 of this year. The justices voted 5-3 to dismiss the case and issued a single-sentence opinion stating that its writ of certiorari had been "improvidently granted." Chief Justice John Roberts recused himself from the case, presumably because his former law firm represented LabCorp.

Many viewed *LabCorp v. Metabolite* as a potential benchmark patent case that could have narrowed the range of inventions eligible for patents. At stake was whether a patent held by the defendant, University of Colorado-affiliated Metabolite, covers a natural phenomenon or scientific principle and is therefore not patentable under U.S. law. The case stemmed from a 1990 patent on a widely used method for detecting vitamin B12 and folate deficiencies: the "total homocysteine-only" test, which directly assays the amino acid homocysteine.

Justices Stephen Breyer, John Paul Stevens, and David Souter dissented. "In my view, we should not dismiss the writ.

➥ *p. 2*

LABCORP PATENT CASE, *from page 1*

The question presented is not unusually difficult. We have the authority to decide it," Breyer wrote in his dissenting opinion. "And those who engage in medical research, who practice medicine, and who as patients depend upon proper healthcare, might well benefit from the Court's authoritative answer."

Breyer's opinion went on to suggest that he places the testing method in the category of a "phenomenon of nature" that is excluded from patent protection. "The reason for the exclusion is that sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection," wrote Breyer.

Patents are becoming an increasingly contentious issue in science and medicine, and another case—one on which all nine justices may rule—could soon appear on the Court's docket. In a statement made after the decision to the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) on behalf of the College of American Pathologists (CAP), Carol Ann Rauch, medical director of microbiology and chief of clinical pathology at Baystate Medical Center, commented on the issue of gene patents. "We are facing an unprecedented situation in which a single patent owner can prevent physicians throughout the country from performing diagnostic procedures that use certain gene-based tests," said Rauch.

Is Clarient The Next Anatomic Pathology Powerhouse?

Clarient (Aliso Viejo, CA) has paid approximately $3 million to acquire the assets of Trestle Holdings (Irvine, CA), a supplier of digital imaging products for pathology and telemedicine applications. Trestle posted 2005 revenues of $4.01 million and a gross profit of $1.38 million, down from the previous year's revenues of $4.81 million and gross profit of $2.56 million.

Seventeen-year-old Trestle's digital imaging products, MedMicro and MedScan, allow users to share, store, and analyze tissue images. The company's telemedicine product, MedReach, is a platform for remote examination, diagnosis, and treatment of patients.

Founded in 1996 to develop and market a system for slide-based testing, Clarient expanded its business model in 2004 to include a range of diagnostic technologies, including flow cytometry and molecular testing, which it performs in-house. The acquisition of Trestle, which includes high-speed scanning technology, will round out Clarient's cellular imaging capabilities, enabling the company to cover virtually all pathology samples needing anatomical laboratory analysis.

Clarient also recently announced results for the first quarter, in which it posted net revenue of $6.7 million, up 68% from the first quarter of 2005 and the highest quarterly revenue of the company's history. Additionally, the company has named James V. Agnello to the position of CFO. Agnello previously served as CFO at Teleflex, Impath, and the clinical laboratory division of SmithKline Beecham. He replaces Jay Roberts, who became interim CFO in February of this year, following the resignation of Stephen Dixon.

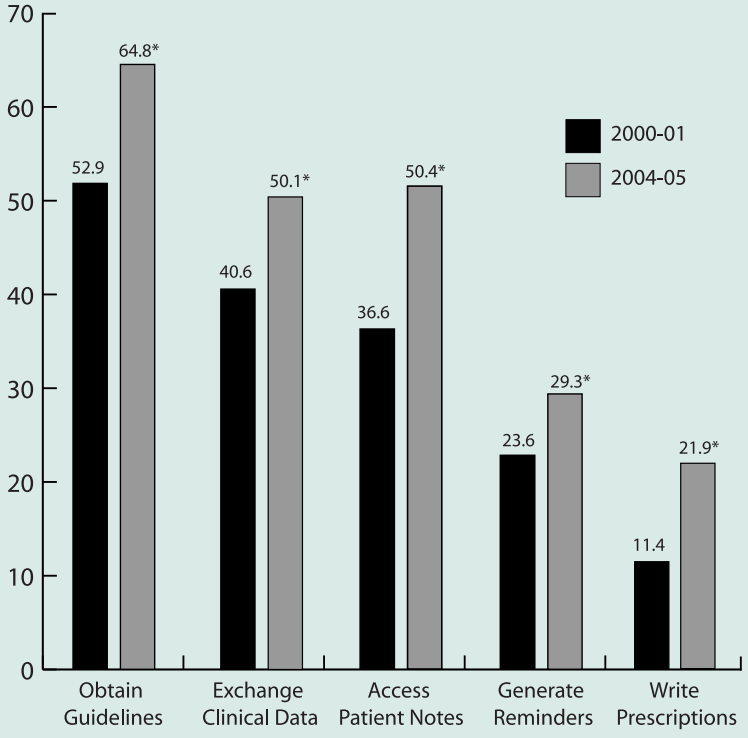
Clinical IT More Widely Available In Physician Practices

Physician access to practice-based clinical information technology (IT) has grown significantly since 2000, according to a new survey from the Center for Studying Health System Change (HSC; Washington, DC). The telephone survey, conducted in 2000-01 and again in 2004-05, contains information on a total of about 18,000 physicians involved in direct patient care in the United States.

The survey asked physicians about the availability of IT in their practices for five clinical activities: obtaining information about treatment alternatives and recommended guidelines; exchanging clinical data and images with other physicians; assessing patient notes, medication lists, or problem lists; generating preventative treatment reminders for the physician's use; and writing prescriptions.

Between 2000-01 and 2004-05, the percentage of physicians in practices with IT increased in each of the five areas, with the largest increase in the number of physician practices that can access patient notes, from 36.6% in 2000-01 to 50.4% in 2004-05. This access encompasses a variety of mechanisms, including electronic medical records (EMRs), practice management systems, or Web-based portals. A given application, such as an EMR, can support some or all of the clinical activities.

Percent of Physicians in Practices with IT for Specific Clinical Activities



*Change from 2000-01 is statistically significant at p<.0001.
Source: *HSC Community Tracking Study Physician Survey*

In addition to the finding of increased physician access to IT in each of the five areas, the survey found that physicians in 2004-05 were also more likely to be in practices that have access to IT for multiple clinical areas than in 2000-01. About one-fifth of physicians (20.9%), almost double the proportion from 2000-01 (11.1%), reported that their practice has IT access for four or five of the clinical activities. Meanwhile, the percentage of physicians reporting that they had IT access available for none of the five activities decreased significantly, from 25.8% in 2000-01 to 16.8% in 2004-05.

Despite the increased access to IT in physician practices, barriers to adoption of the technology remain. Among the major barriers to adoption are start-up and maintenance costs, as well as the significant effort and costs of changing workflow to effectively use IT.

Beaumont Hospital Succeeds With Centralized Molecular Pathology Laboratory

In 2005, the William Beaumont Hospital Molecular Pathology Laboratory had yearly operating revenue of $2.8 million. The lab grew by 18% from 2003 to 2004 and showed 9% growth from 2004 to 2005.

"One-stop shopping" for lab tests, while appealing in theory, is often difficult to realize in practice, particularly within a large hospital system, but Michigan's William Beaumont Hospital has made it work for molecular testing. At Beaumont, all of the molecular tests are offered in a centralized laboratory.

"I think it's unusual for a large hospital to have the whole molecular diagnostic testing centralized in one place," says Domnita Crisan, M.D., Ph.D., director of Beaumont's Molecular Pathology Laboratory. "In the academic centers I know, there is a separate laboratory for molecular diagnosis of infectious diseases and molecular genetics, but here it's just one laboratory."

Because many molecular tests are replacements for specific laboratory tests, individual laboratories often offer some form of molecular tests, for example, a microbiology laboratory offering molecular-based infectious disease tests. This has led some observers to predict that hospitals and laboratories will eventually organize their labs around various technical platforms rather than in the traditional manner of separating them by type of specimen or overarching type, such as microbiology or hematology.

The William Beaumont Hospital Molecular Pathology Laboratory supports two hospitals located in the Detroit, Michigan, metropolitan area and also offers an outreach program with their reference laboratory. The Beaumont facility in Royal Oak is a level-one trauma center with 1,061 beds. The hospital has a clinical pathology department that is separate from the surgical pathology department; the Molecular Pathology Laboratory is a part of the clinical pathology department.

The Molecular Pathology Laboratory opened in 1991 with two medical technologists. They currently employ six full-time technologists, two part-time technologists, and a supervisor. The laboratory's growth rate from 2003 to 2004 was 18%. From 2004 to 2005 it was 9%. Crisan notes that it appears to be slowing on a percentage basis, but, "if you look at the number of tests, it's a hefty increase each year, a few thousand each year."

The laboratory offers over 25 tests in five general areas: inherited disorders, genetic risk factors for cardiovascular disease and stroke, infectious diseases, molecular pharmacology, and pharmacogenomics. The laboratory's highest volume area is infectious disease testing (including tests for chlamydia and gonorrhea, human papilloma virus (HPV), and HIV), the majority through their reference laboratory, which primarily serves the southeast Michigan region. Molecular hematology is an area in which they are adding tests this year. Crisan notes that they make a "pretty fast transition from research to clinical testing in some areas, but most of the growth is for infectious disease tests that were previously offered."

Quality Control:
GAO Report Calls For Strengthened Lab Oversight

Real and potential lab quality problems are masked by survey, complaint, and enforcement weaknesses, says GAO in its newly published report, *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened*.

The report also cited widespread problems with Centers for Medicaid and Medicaid Services (CMS) oversight of laboratories, namely that CMS does not require labs to participate in a key quality assurance test as frequently as CLIA does. Moreover, the report criticized CMS's principal oversight tool as lacking independence because many of the oversight reviews are conducted simultaneously with survey organizations. Finally, GAO faulted CMS for its failure to track serious deficiencies identified by each survey organization, noting that getting a handle on this information would enable CMS to assess whether lab quality is improving or declining.

As of December 2005, there were approximately 193,000 laboratories in the United States.

The GAO study was requested last year by Mark Souder (Republican - Indiana), chairman of the House Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources, and panel member Elijah Cummings (Democrat - Maryland) in the wake of highly publicized lab quality problems at Maryland General Hospital in early 2004.

GAO Study Objectives

GAO was asked to examine:

1) Quality of lab testing

2) Effectiveness of surveys, complaint investigations, and enforcement actions in detecting and addressing lab problems

3) Adequacy of CMS's CLIA oversight

Insufficient Data

Among the critical problems identified was the sheer lack of standardized data available with which to analyze or assess lab quality. One aspect of this is the 2004 implementation of revised CLIA survey requirements, which modified stored state survey agency findings so that they no longer reflect key survey requirements in effect at the time of the surveys. Another aspect of this issue is the inability to link similar requirements across survey organizations, making it impossible to aggregate and compare findings.

Survey, Complaint, and Enforcement Weaknesses

GAO also faults the systems for surveying labs, soliciting complaints, and enforcing sanctions. On the topic of surveys, they found a number of reasons why lab survey findings may not accurately reflect the

Key GAO Recommendations for Executive Action

GAO made several key recommendations to the CMS Administrator to improve CLIA oversight, including:

- ❑ Standardize reporting of survey deficiencies to permit meaningful comparisons across survey organizations
- ❑ Work with survey organizations to ensure that educating lab workers does not preclude appropriate regulation, such as identifying and reporting deficiencies that affect lab testing quality
- ❑ Impose appropriate sanctions on labs with consecutive condition-level deficiencies in the same requirements
- ❑ Require all survey organizations to develop, and require all labs to prominently display posters instructing lab workers on how to file anonymous complaints
- ❑ Allow CLIA program to fully use revenues generated by the program to hire sufficient staff to fulfill its statutory reponsibilities
- ❑ Establish an enforcement database to monitor actions taken by state survey agencies and regional offices on labs that lose their accreditation

Source: GAO

quality assurance process that is in place in a lab on a daily basis. One such reason is the tendency of most survey organizations to announce all surveys, sometimes months in advance, enabling labs to prepare for inspections. GAO also cited the inadequacy of the inspections themselves. The report goes on to question the effectiveness of CMS's enforcement of sanctions and cites the large number of labs with proposed sanctions that were never imposed.

CMS Oversight Inadequate

The report focused on determining the adequacy of CMS oversight to ensure that labs are meeting CLIA requirements. GAO was highly critical of CMS's proficiency testing requirements (three times a year instead of quarterly, like CLIA), its monitoring of the equivalency of accrediting organization and exempt-state inspection requirements and processes, and its use of data to monitor survey organization activities and processes.

Recommendations

GAO directed 13 recommendations to the CMS Administrator (see box for highlights). According to GAO, CMS "endorsed [the report's] overall conclusion that quality assurance for the nation's clinical labs should be strengthened and said that it would take actions in response to 11 of our 13 recommendations." The two recommendations with which CMS disagreed concern the frequency of proficiency testing and the extent of simultaneous accrediting organization validation reviews.

In response to the report, COLA CEO Thomas Beigel testified before the House Subcommittee on Criminal Justice, Drug Policy, and Human Resources that clinical laboratory quality has indeed improved since 1992. Similarly, CMS Administrator Mark McClellan wrote in response to the findings that he believes that "the overall performance of all labs has improved, especially when viewed over a longer period of time."

While Beigel agreed with the majority of the recommendations, he took issue with the report's assertion that advance notice of inspections (which in the case of COLA is 12 weeks, the longest of all the survey organizations studied) allows labs to forge documents in order to pass. "While much of a laboratory's evidence of compliance is documentary, there is little of this evidence that can be fabricated in a short period of time," said Beigel. "More importantly, however, I believe the vast majority of laboratory professionals are dedicated to providing the highest quality patient care possible and therefore would not falsify records."

Private Equity Dollars Flow Into Lab And Life Sciences Markets

Private equity's appetite for the lab and life sciences markets is bigger than ever. Essex Woodlands Health Ventures (Palo Alto, CA; New York, NY; and The Woodlands, TX) has just completed $600 million in fundraising for its seventh and largest private equity fund focused exclusively on the healthcare industry. The fund is expected to invest in companies at various stages of development within the company's six areas of focus, with about 75% of the capital earmarked for companies in biotechnology, medical devices, and pharmaceuticals. The remaining quarter will be divided evenly among health services, managed care, and health information.

Founded in 1985, Essex Woodlands has $1.6 billion under management. The management team has been involved in the founding, investing, and management of over 100 healthcare companies. Among Essex's portfolio companies is UroCor Labs, a reference lab specializing in testing for prostate cancer, bladder cancer, kidney stones, and other urologic disorders. The firm also owns Accumetrics, which is focused on developing point-of-care testing products in the areas of cardiovascular and neurovascular disease.

Meanwhile, Pelican Life Sciences, the recently launched $100 million private equity fund powered by Grotech Capital Group and Ferrer Freeman & Company (see *LIR*, June 2006, p. 10), has recently purchased three companies: Continental Laboratory Products (San Diego, CA), PGC Scientific Corporation (Frederick, MD), and Kemp Biotechnologies (Frederick, MD).

Continental Laboratory Products distributes molecular biology-related instruments, reagents, plastics, and safety equipment. The company also manufactures disposable laboratory plastic products for fluid handling in molecular biology and diagnostic test kits. PGC is also a manufacturer of molecular biology and scientific product consumables. Kemp Biotechnologies provides cell culture, protein expression, and protein purification services on a contract basis. The companies join Pelican's initial acquisition, PML Microbiologicals (Wilsonville, OR), a provider of culture media and microbiological products.

LabCorp Builds On Strength In Molecular Testing With Duke Collaboration

Geoffrey S. Ginsburg, M.D., Ph.D.

In its latest move to expand its molecular diagnostic test offerings, Laboratory Corporation of America (LabCorp; Burlington, NC) has announced its collaboration with Duke University. Through the newly created Duke-LabCorp Scholars in Genomic Medicine Program, LabCorp will expand its opportunities to offer novel genomic tests.

The Duke-LabCorp program will be led by Geoffrey S. Ginsburg, M.D., Ph.D., director of Duke's Institute for Genome Sciences and Policy (IGSP) and a veteran of Millennium Pharmaceuticals, and support advanced research studies in clinical testing applications in genomic medicine. The specific applications were being identified at press time. According to LabCorp, the goal of the collabora-

In 2005, LabCorp earned $505.2 million in molecular-based test revenue, accounting for 15.2% of total annual revenue.

tion is to develop a commercial partnership that enables the translation of important genomic into clinical practice as rapidly as possible.

The Duke collaboration promises not only to enrich LabCorp's testing pipeline but also to give it an edge in the rapidly growing area of molecular diagnostics. LabCorp, one of the world's largest clinical laboratories, tests more than 360,000 samples daily—about 1.1 million tests daily—for over 220,000 clients across the United States. In 2005 their revenues were $3.3 billion. They employ approximately 24,000 people.

LabCorp began molecular-based testing in 1990. At that time they had a dedicated facility in Research Triangle Park, North Carolina, that employed 20 to 30 people. Because of the way molecular-based tests have infiltrated so many different areas of LabCorp and its decentralization, there is no way to indicate how many employees are involved in molecular testing. Their initial work was in infectious disease testing, as well as early work in genetics, oncology, and identity testing.

The company sees continued high growth in four main areas:
• *Infectious Disease*. This has always been the strongest area of growth for molecular testing for LabCorp and for molecular testing in general, but in the mid-1990s it rapidly expanded due to the almost simultaneous FDA approval of HIV viral load testing and the introduction of early HIV drugs. "Infectious disease remains a very important area," says Myla Lai-Goldman, M.D., LabCorp's executive vice president, chief scientific officer, and medical director. "Our test menus are very long and very broad and are very likely to continue to grow as molecular methods supplant some of the more traditional microbiology techniques."
• *Genetics*. This area grew strongly in 2001 when the American College of Obstetricians and Gynecologists (ACOG) changed their guidelines and recommended that Caucasian couples contemplating pregnancy should be tested for cystic fibrosis.
• *Cancer*. LabCorp continues to see growth of molecular testing in this area. "We now see significant growth and emphasis on broadening the menu for molecular oncology, both in sold tumors and liquid tumors," says Lai-Goldman.
• *Human Identity*. LabCorp has a strong interest in human identity testing, including forensic testing and paternity testing. Their laboratory has been involved in identity testing of soldiers' remains since Operation Desert Storm, the first Iraq War (1991). Marcia Eisenberg, Ph.D., vice president and senior director of Research & Development, is also the founder of the LabCorp forensic identity testing laboratory. She says, "As part of our molecular testing we also have an identity paternity laboratory, which we believe is probably the largest paternity laboratory in the world."

Molecular Diagnostics at LabCorp

- ❑ Infectious disease
- ❑ Genetics
- ❑ Cancer
- ❑ Human identity testing

LabCorp also is actively utilizing microarray technology, specifically CGH comparative genomic hybridization for developmental delay. They are also evaluating several new microarrays for leukemia testing. The company has experienced a significant increase in both test volumes and revenue in their molecular testing areas.

LabCorp Molecular Test Volumes Versus Total Test Volumes

Year	Molecular Volumes (000s)	Total Volume (000s)
2001	4,150.8	71,680.0
2002	4,988.2	79,078.5
2003	5,857.3	87,915.1
2004	6,351.9	91,117.6
2005	6,700	92,000.0
Q1 2006	1,700	23,700.0

Source: LabCorp

Although much of LabCorp's molecular tests are kit-based, Lai-Goldman notes that they still perform a significant number of homebrew or in-house developed assays. "The reality is there are very few kits in the molecular world. The majority of genetic tests are done using in-house developed tests. I do see that there's a continuation of production of kits, but with the hundreds of tests that clinicians use every day, I don't see that completely changing. In the world of genetics we have to keep in mind that many of the assays we have are not for common disorders or very high-volume disorders. We see diagnostic vendors particularly focused on the high-volume tests, and clinicians' needs are much broader than that. I envision that there will always be a need for in-house developed assays."

LabCorp has expanded their molecular capabilities since 2001 through several major acquisitions. They include ViroMed Inc. (Minneapolis, MN), Dianon Systems (Stratford, CT), Esoterix (Austin, TX), and US LABS (Irvine, CA).

As with its new relationship with Duke, LabCorp expands their molecular testing capabilities via partnerships with companies like EXACT Sciences (Marlborough, MA). Their partnership with EXACT led to the launch of PreGen-Plus, a screening test for colon cancer. LabCorp is also introducing molecular testing for flu, including avian flu, and an advanced HIV screening program for acute HIV, which can detect recently infected HIV patients.

LabCorp Molecular Testing Revenues and Percentage of Total Revenues

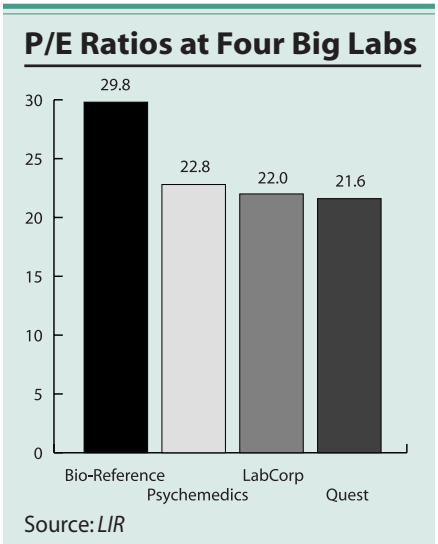
Year	Molecular Testing Revenues	Percentage of Total Revenues
2001	$281.0 million	12.8%
2002	$337.9 million	13.5
2003	$435.2 million	14.8
2004	$465.5 million	15.1
2005	$505.2 million	15.2
Q1 2006	$134.4 million	15.3

Source: LabCorp

Lab Stocks Slip 2% In Latest Five Weeks

Stock prices for the 11 companies in the G-2 Laboratory Index were down an unweighted average of 2% in the five weeks ended June 23, 2006, with five stocks up in price and six down.

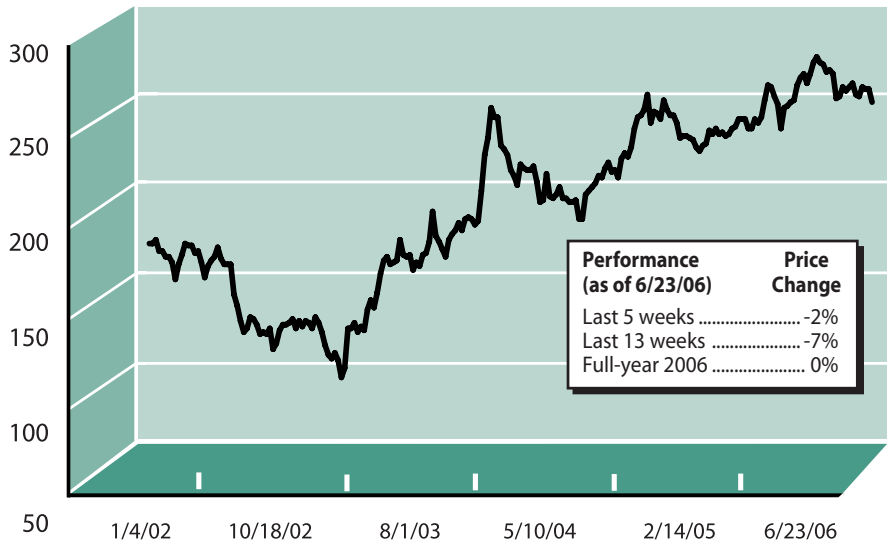
DNA testing lab **Orchid Cellmark** (Princeton, NJ) was down 33% to $2.47 per share for a market value of $36 million. The company recently announced a first quarter loss of $6.6 million, wider than last year's $1.7 million. Revenue for the quarter was down 14% to $12.6 million compared to $14.7 million in 2005. CEO Thomas Bologna attributed the results to "operational weaknesses" that the company is now aggressively addressing through restructuring and management changes.



Monogram Biosciences (South San Francisco, CA) fell 16% to $1.74 for a market value of $161 million. However, the company recently announced that it has settled its outstanding Contingent Value Rights (CVRs) with a cash payout of about $57 million. The liability was a key concern for investors.

Meanwhile, **Enzo Biochem** (Farmingdale, NY) was up 35% to $13.00 per share for a market value of $376 million. **Bio-Reference** (Elmwood Park, NJ) was up 17% to $21.49 per share for a market value of $279 million.

A quick review of the price-to-earnings ratios at four large, publicly traded labs shows that Bio-Reference (P/E=29.8) is the most expensive and Quest Diagnostics is cheapest (P/E=21.6).



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

% price change, 5 weeks ended 6/23/06

UP	Price	% Chg
Bio-Reference	$21.49	17%
Enzo Biochem	13.00	35
LabCorp	61.29	3
Quest	57.95	1
Psychemedics	17.20	3
DOWN		
Clarient	0.92	-13
Genomic Health	10.35	-2
Medtox	9.69	-5
Monogram	1.74	-16
Myriad	23.51	-5
Orchid	2.47	-33

INDUSTRY buzz

Consolidation among drug testing labs . . . Substance abuse testing giant Kroll Laboratory Specialists (New Orleans, LA) has acquired Express Analytical Laboratory (EAL; Marion, Iowa), a privately owned lab that is certified by the Substance Abuse and Mental Health Services Administration (SAMHSA). This acquisition comes less than a year after Kroll's November 2005 acquisition of Scientific Testing Laboratory, a SAMHSA-certified laboratory in Richmond, Virginia.

Kroll Laboratory Specialists, a subsidiary of global risk consulting company Kroll Inc., has grown steadily through acquisitions, having purchased a total of 14 labs since 1994. According to John Patterson, company president, the strategy is "to acquire and consolidate key laboratories and point-of-collection testing distributors" with an eye to expanding market share in the Midwest. Kroll employs 180 employees in its Gretna, Louisiana, and Richmond, Virginia, facilities.

Founded in 2001 by Carolyn Cooper, EAL was headquartered in Austin, Minnesota, before moving to expanded facilities in Iowa's Cedar Rapids area. EAL has sought to differentiate itself through customer service and rapid, advanced results reporting technology. The lab's clients include occupational health and drug treatment centers, third-party administrators, and construction firms.

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Center for Studying Health Change 202-484-5261

Essex Woodlands Health Ventures 281-364-1555

Enzo Biochem 631-755-5500

Kroll 888-209-9526

LabCorp 336-584-5171

Monogram Biosciences 650-635-1100

Orchid Cellmark 609-750-2200

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