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LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

WASHINGTON G-2 REPORTS

CMS Moving Forward With Medicare Competitive Bidding Project For Lab Testing

"For the first time in two decades, CMS is serious about going forward with competitive bidding. We think it will actually happen in terms of a demonstration," Dennis Weissman, president of Weissman & Associates and founder of Washington G-2, told the audience at the Lab Institute conference in Washington, DC, October 19-22. The two demonstration sites for competitive bidding for Part B lab services will be announced this February, according to Linda Lebovic, project officer for Medicare's Clinical Laboratory Competitive Bidding Demonstration Project.

The two demonstrations are supposed to last three years each and then the Centers for Medicare & Medicaid Services (CMS) will decide whether to move forward on a national scale. However, the timetables for competitive bidding could be accelerated because of the new federal budgetary pressures caused by the recent hurricanes in the Gulf Coast, noted Don Lavanty, lab industry lobbyist at JT Rutherford & Associates and a regular speaker at Lab Institute.

Although there will be multiple winners for each competitive bidding demonstration site, Lebovic said that labs that don't win will not be paid for Medicare Part B lab testing. For additional news on competitive bidding plus more highlights from Lab Institute, see *Inside the Lab Industry*, pp. 5-7.

AmeriPath To Buy Specialty Laboratories

AmeriPath (Palm Beach Gardens, FL) has agreed to acquire Specialty Laboratories (Valencia, CA) for $305 million (net of approximately $40 million of cash on hand at Specialty). The deal values Specialty at two times its current annual revenue run rate of $151.4 million per year. The acquisition represents a major step in AmeriPath's new strategic focus of building up its esoteric testing business, but will also add to its sizable long-term debt. For Specialty, it will cap the end of a rocky past three years that has included a near-fatal regulatory crisis concerning employee licensing issues, an expensive move into a giant and under-utilized laboratory facility, and the departure of nearly all of its top management earlier this year.

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AMERIPATH TO BUY SPECIALTY, *continued from page 1*

Terms of the deal call for Specialty's minority shareholders to get $13.25 per share in cash. The company's majority shareholder, James Peter, M.D., Ph.D., who owns 14.4 million shares (60.4% stake), will exchange approximately five million shares for $13.25 per share in cash. The other nine million shares will be exchanged for a 20% stake in the combined company.

To fund the acquisition, AmeriPath will borrow $140 million, which will raise its debt to a total of $625.5 million. The investment firm Welsh Carson, which acquired AmeriPath in 2003 for $800 million, plans to invest another $165 million to help pay for the acquisition of Specialty.

AmeriPath says it plans to keep Specialty's new 200,000 sq. ft. laboratory facility in Valencia, California, in operation. Keith Laughman, who joined AmeriPath earlier this year, after a 30-year career at Mayo Medical Labs, is heading AmeriPath's esoteric testing business and will be in charge of Specialty Labs, which will keep its name.

Over the past three years, AmeriPath has shifted its focus from acquiring pathology groups to building up its esoteric testing business. The company currently generates about 8.5% (or about $45 million) of its annual revenue from esoteric testing. Its biggest esoteric testing lab—the Center for Advanced Diagnostics—is located in Orlando, Florida. With the addition of Specialty, AmeriPath will now generate nearly $200 million per year from esoteric testing.

AmeriPath & Specialty Labs at a Glance

	AmeriPath	*Specialty*	*Combined*
Revenue	$555,028	$151,356	$706,384
Pretax income	22,668	-13,488	36,156
Net income	13,638	-25,216	-11,578
Cash & investments	11,565	37,131	48,696
Long-term debt	485,500	0	625,500*
Bad-debt expense	13.1%	3.0%	—
Days in accounts receivables	56	67	—
Employees	2,729	689	3,418

Note: revenue, pretax income, and net income are annualized based on first-half 2005 results; cash & investments, bad-debt expense, and days in accounts receivables are as of June 30, 2005.

*Combined long-term debt includes $140 million that AmeriPath will borrow to help pay for its acquisition of Specialty.

Source: *LIR* from company reports

The deal must be somewhat disappointing to Specialty's shareholders. The company had its initial public offering (IPO) in December 2000 at a price of $16 per share. Assuming the deal with AmeriPath is completed, investors that bought at Specialty's IPO price will have earned an average annual return of -3%.

The transaction is expected to close early next year, but the agreement allows Specialty to accept a more attractive offer if another buyer steps forward before then. If it accepts an alternative offer, Specialty will be required to pay $13 million to AmeriPath.

Freeman Joins Board At Alliance Imaging

Alliance Imaging (Anaheim, CA) has appointed Ken Freeman, 55, to its board of directors. Freeman served as chief executive of Quest Diagnostics from January 1997 through May 2004 and is currently a managing director at the investment firm Kohlberg Kravis Roberts (KKR-New York City). KKR owns a 71% stake in Alliance Imaging and has three other executives on Alliance's board in addition to Freeman.

Alliance Imaging operates 478 diagnostic imaging systems that serve approximately 1,000 university hospitals, physician offices, and freestanding imaging centers in 43 states. In 2004, the company performed one million patient scans (mostly magnetic resonance imaging, or MRIs) and recorded $432 million of revenue. Alliance Imaging is a publicly traded company with a market value of $350 million as of mid-October.

Potential Diagnostic Imaging Acquisition Candidates for Quest

Company	2004 Revenue	Market Value
Alliance Imaging (Anaheim, CA)	$432M	$350M
InSight Health (Lake Forest, CA)	317*	privately held
MedQuest (Alpharetta, GA)	275	privately held
Radiologix (Dallas, TX)	251	84

*for fiscal year ended June 30, 2005

Source: *LIR* from company reports

Quest's new chief executive Surya Mohapatra, Ph.D., has stated that Quest is exploring the possibility of getting into the diagnostic imaging business (see *LIR*, January 2005, p. 5). And *LIR* speculates that Freeman, with his old ties to Quest and new ties with Alliance Imaging, might serve as a bridge to a future merger of the two companies. Other potential diagnostic imaging company acquisition targets for Quest could include InSight Health, MedQuest, and Radiologix.

In a presentation at this year's Lab Institute conference, Freeman noted that lab test results influence 70% of healthcare treatment decisions, while diagnostic imaging reports affect 20%. Combine the two and you've got a majority of the information contained in a patient's medical record, he said. Freeman said he could not predict exactly how or when the convergence of diagnostic imaging and lab testing would occur. However, he added, "It's coming your way. . . . Imaging system companies like GE have a lot of money. . . . They're looking at the 2% of healthcare spending that lab testing represents, and they're thinking."

Quest Diagnostics Gets Another Subpoena

Quest Diagnostics says it has received a civil subpoena from the New York office of the Department of Health and Human Services, which would not comment on the situation. The subpoena seeks various documents, including documents relating to Quests' relationship with HMOs, PPOs, IPAs, and group purchasing organizations from 1995 to the present. A Quest spokesman says the company does not know what the agency is looking for and is not aware of any criminal investigations. Earlier this year, both Quest and LabCorp received similar subpoenas from the U.S. Attorney's Office for New Jersey (see *LIR*, July 2005, pp. 1-2).

Will Health Alliance Keep Hospital Management Deal With Quest?

Quest Diagnostics' plan to purchase LabOne has been cleared by the Federal Trade Commission and the antitrust division of the Department of Justice, but another big hurdle remains. At a Lab Institute presentation, Ron Long, executive vice president and chief financial officer at the Health Alliance of Greater Cincinnati, said the hospital system had not decided whether it would transfer a hospital lab management agreement it has with LabOne over to Quest.

When LabOne acquired the core lab operations of the Health Alliance in January 2004, the deal included an $11 million per year contract to provide reference testing services to the six hospitals affiliated with the Health Alliance and another $8.5 million per year contract to manage the labs at those hospitals. Long said the reference testing contract is a five-year arrangement that can't be cancelled. However, he said Health Alliance has the option to terminate the hospital lab management contract. "No decision has been made yet," said Long.

Long said that Health Alliance had originally sold its lab operations to LabOne rather than Quest because LabOne was smaller and willing to hire the existing management team. "We felt we'd get more attention and have more clout with LabOne," said Long.

Long said the Health Alliance management has been pleased with LabOne's performance so far. But he noted that the system's "academic physicians didn't want this sale to happen and have not been as happy with the support they've gotten."

The management at Health Alliance found out about LabOne's decision to sell to Quest the night before the deal was publicly announced. "We always knew Quest would buy LabOne. We're just surprised at how quickly it happened," Long noted.

United HealthCare RFP Update

Bids for United HealthCare's ambitious plan to trim its $2 billion per year of lab test costs by 15% to 20% were officially due on September 30. And United had planned to announce a winner(s) on October 28, but this schedule will probably be delayed, *LIR* hears. That's because several large regional independent labs and major hospital outreach programs were never notified of the RFP in the first place. United has given these labs the RFP and extended the deadline for them by at least two weeks.

Meanwhile, after a review of utilization data and discussions with several labs and industry insiders, *LIR* believes that United's main target for savings is non-contracted hospital outpatient and outreach labs. Hospitals represent roughly one-third of United's lab spending, and many hospital labs are evidently billing United through their main hospital billing systems on a percentage-of-charges basis. As a result, United is often paying hospital labs more than double what it pays to contracted national and other independent labs.

This means that the two national labs and possibly some major independent and outreach labs would not have to cut their current negotiated prices to meet United's goal for savings, if they can figure out a way to eliminate the leakage to non-contracted hospital labs.

Lab Institute Highlights: Competitive Bidding, Maryland General, And More

This year's Lab Institute conference attracted a near-record crowd of 650 attendees, speakers, and vendors. The program featured presentations from more than 75 lab executives, consultants, and political figures. Below we've highlighted some key news and advice given by a variety of speakers:

Linda Lebovic, project officer for CMS, noted that the competitive bidding demonstrations would involve all labs that generally do not have face-to-face encounters with patients, including independent labs, hospital outreach, and physician office lab nonpatient testing (i.e., POL outreach); excluded are hospital inpatient and outpatient testing, and POL patient testing. Bids will be made for each CPT code on the Medicare Part B lab fee schedule. Other factors that will be considered in the selection process will include lab capacity, financial stability, and beneficiary access to patient service centers.

Senator Lindsey Graham (R-SC) noted that beginning in 2017, the Medicare program will be paying out more than it collects for the first time in its history. "The Part D prescription benefit was a big mistake in my opinion. . . .Drug utilization is going to go through the roof."

Sen. Lindsey Graham addresses the Lab Institute audience

Rep. Elijah Cummings (D-MD) said another breakdown in quality controls such as what was discovered at Maryland General Hospital last year "could result in a fundamental change in the way lab testing is done. . . .Having two congressional hearings for a subject like this was very unusual." Cummings presentation was part of G-2's Lab Quality Symposium, which preceded Lab Institute.

In 2004, an expose by the *Baltimore Sun* revealed that for 14 months, the laboratory at Maryland General Hospital released hundreds of HIV and hepatitis test results even though the instrument quality control indicators showed the patient results might not be accurate. The lab's management and techs who worked with the instrument, a LaboTech analyzer, had used unvalidated "work arounds" to try and ensure accurate tests were being sent out. But the work arounds were never documented, and the instruments quality control values were altered to make them fall within acceptable ranges, so the test results could be reported. These QC problems were not detected during previous CAP inspections and went unaddressed until a whistleblower's complaint brought in state inspectors in early 2004.

In response to the Maryland General controversy, Cummings has proposed legislation (HR 686) that would require the lab inspection agencies to conduct unannounced inspections and force individuals that tipped labs off on the timing of inspections to pay a fine of up to $2,000. The disruptions that unannounced inspections might cause are something I'm not worried about," he said.

On news that CAP plans to begin unannounced inspection next year, Cummings said, "I can't tell you how happy I was to hear this." He added, "What she did [whistleblower Kristin Turner] has had a rippling effect throughout the entire country."

SYLVIA SMITH JOHNSON, senior vice president and chief operating officer at Maryland General, said the early warning signs at the hospital lab had included a high rate of employee turnover, a lab staff that was 40% part time, and difficulties in recruiting workers due to a pay scale that was 25% below competing labs in the area. "It was a very cost-driven organization that lost the balance between cost and quality," she said.

Smith Johnson said the hard costs (excluding lost business) of correcting the situation have totaled $5 million. One of the largest costs was retesting some 2,500 patients, many of whom were Medicaid recipients. Tracking down these patients was difficult, and Maryland General hired "bounty hunters" that were paid for each patient they located. The cost of consultants—Chi Solutions was the project manager—was also expensive, she noted.

Smith Johnson said that during the 'media frenzy" that surrounded Maryland General, a patient died because of a hospital-staff error at "a world-renowned local hospital [Johns Hopkins] that didn't get much press."

Smith Johnson said lessons learned at Maryland General included: 1) don't count on regulators to tell you what's wrong; 2) listen to your staff; and 3) never sacrifice cost for quality.

JOHN BRAUN, M.D., the new laboratory director at Maryland General, said the retesting showed that the initial results had been 89.5% to 99.8% accurate for HIV and hepatitis testing. He said that one problem had been the lack of day-to-day pathologist involvement in lab quality. "If the whistleblower had not complained, these errors would have been very difficult to find in a focused inspection," he added.

KATHY MURPHY, PH.D., president of Chi Solutions Inc., said the first three months after the problems were discovered at Maryland General were spent responding to the accrediting agencies, which seemed to be playing "a game of one-upmanship in a contest to find deficiencies" they had missed in earlier inspections. In 2004, the Maryland General lab had 14 inspections from six different regulatory agencies, she noted.

KEN FREEMAN, ex-chief executive at Quest Diagnostics and now with the investment firm KKR, said, "We are near the end of decades of consolidation in the lab industry." In the future, success will depend more on information technology and the ability to bring new tests to the market.

Freeman noted that the Joint Commission on Accreditation of Healthcare Organizations recently formed a Healthcare Information Technology Advisory Panel that will focus on the improvement of patient safety and clinical processes as new healthcare information systems are implemented.

The advisory panel has more than 30 people on it, including representatives for hospitals, physicians, nurses, pharmacists, and HMOs, but not a single representative for the lab industry. "That is disgusting," said Freeman. "Petty differences" between

various lab organizations got in the way of choosing a lab representative, he said. "Labs need visibility and to create a united front. . . . The sad part will be that there will be no additional payment for lab information technology requirements," he added.

ROBERT MAZER, attorney at the law firm Ober/Kaler (Baltimore, MD), said there was a risk that deeply discounted capitation agreements for lab testing might be viewed by government regulators as a kickback to physicians to induce referrals of Medicare and Medicaid patients. "The question is: 'Did the discount cover the fully loaded charge of testing?'" said Mazer. His hope is that the OIG and U.S. Attorney will recognize which contracting practices are legal today and then change existing policies to ban what they consider to be abusive behavior, rather than try to go after labs under existing laws.

RICK NICHOLSON, president of Westcliff Medical Laboratories (Newport Beach, CA), said despite the exclusive managed care contracts held by Quest and LabCorp, it's the doctors that make the decisions as to which lab to use. "Doctors don't like being told what to do. . . . It's hard to control utilization," he noted.

Nicholson said personalized service was the way that Westcliff competes. He noted that Westcliff has a "live" person answer its phones (not an automated machine) and will fax reports to clients on demand within five minutes.

Nicholson says Westcliff is on track to generate revenue of approximately $47 million this year, up 17% from 2004. Its biggest sources of payment are fee for service, 69%; Medicare, 20%; Medicaid, 6%; and client bill, 5%.

JORGE LEON, PH.D., president of the consulting company Leomics Associates (Princeton, NJ), said venture capital firms are pouring millions of dollars into molecular diagnostics companies. "They think personalized medicine is the next 'Google' for healthcare," he said. He noted that more and more test developers, such as Genomic Health, were operating their own clinical laboratories. "They know this is where the money is," he added.

The key to gaining physician demand for new tests is not FDA clearance or massive marketing programs, but publication of studies in peer-reviewed journals (e.g., *The New England Journal of Medicine*) and endorsement from professional associations (e.g., American College of Obstetricians and Gynecologists-ACOG).

For example, Leon said Myriad Genetics' BRACAnalysis test has not succeeded in reaching its full market potential because it has not received an endorsement from the medical community.

MYLA P. LAI-GOLDMAN, M.D., executive vice president and chief scientific officer, advised, "Pathologists need to get out from behind the microscope and learn so they can talk about molecular diagnostics." She concurred with Dr. Leon and noted that ACOG's recommendation in 2001 that all couples seeking prenatal care get DNA screening for cystic fibrosis resulted in an immediate doubling in LabCorp's monthly cystic fibrosis testing volume for several months in a row.

"I know there has been resistance by the pharmaceutical industry to pharmacogenomics, but look at the newspaper. A new diabetes drug [Pargluva] has been developed that can cause heart attacks and strokes. . . . And when you see labels changed for drugs [i.e., genotyping patients before prescribing the chemotherapy drug Camptosar], that's going to cause doctors to order tests," noted Lai-Goldman.

Commercial Labs Show Billing & Collection Improvement

The average days in accounts receivable (DAR) at 10 commercial labs declined to 74 days in the first half of 2005 versus 77 days for full-year 2004. Bad-debt expense also showed improvement by dropping to an average of 6.2% from 8.6%. In other words, last year, these 10 lab companies received payment an average of 74 days after sending out their bills and had to write off 6.2% of their net billings (after contractual allowances) as uncollectible.

Most of the improvement came as a result of **Enzo Biochem** (Farmingdale, NY) and its clinical laboratory subsidiary, Enzo Clinical Labs (ECL). In the fiscal year ended July 31, 2005, Enzo grew its lab service revenue by 15% to reach $32.9 million. Net accounts receivable from lab operations were $12.5 million as of July 31, 2005, representing an average of 143 days worth of sales. This compares with $13.1 million and 173 days in fiscal year 2004.

Enzo says it reserves for or writes off 100% of all accounts receivable for all payers over 210 days and assumes all these accounts are uncollectible bad-debt expense. In fiscal year 2005, Enzo's bad debt totaled $5 million, or 15.2% of its revenue of $32.9 million. This compares with a bad-debt expense of 35.7% in fiscal year 2004.

Enzo says the decrease was primarily due to improved collection procedures and due to the change in the mix of the demographics of the patients from its recent expansion into the New Jersey market.

Meanwhile, at the two biggest labs:
QUEST DIAGNOSTICS had the lowest DAR at 47 days (versus 46 days in 2004), with a bad-debt expense of 4.4% (unchanged from 2004). Quest attributed part of the improvements to greater use of electronic ordering by its clients and patient service centers. As of June 30, 2005, Quest says approximately 44% of its test orders were being transmitted via the Internet, up from 40% in December 2004 and 30% in December 2003.

LABCORP'S DAR was 55 days, up slightly from 52 days in 2004; bad debt was lowered to 5.4% from 6.3%. LabCorp says it is implementing numerous initiatives related to self-pay accounts, which typically have the worst collection rates, including collecting payment at the time of service.

Billing & Collection Management at 10 Commercial Labs

	Average Days in Accounts Receivable			Bad-Debt Expense		
Company	First-Half 2005	Full-Year 2004	Full-Year 2003	First-Half 2005	Full-Year 2004	Full-Year 2003
AmeriPath	56	55	61	13.1%	15.1%	14.7%
Bio-Reference	116	110	110	13.2	12.9	11.7
Enzo Clinical Labs*	143	167	174	15.2	35.7	29.6
LabCorp	55	52	54	5.4	6.3	7.3
LabOne	58	57	61	2.2	2.1	1.8
Medtox Scientific	63	53	59	0.9	1.0	1.2
Myriad Genetics**	76	90	73	2.7	3.6	0.1
Quest Diagnostics	47	46	47	4.4	4.4	4.8
Specialty Laboratory	67	72	68	3.0	4.0	3.2
ViroLogic	55	72	67	1.7	0.9	0.3
Unweighted averages	74	77	77	6.2	8.6	7.5

*Data for Enzo is for the fiscal years ending July 31. **Data for Myriad Genetics is for fiscal years ending June 30. Source: *LIR* from company reports

UBS Highlights: LabCorp, Prometheus, XDx, Orchid, Monogram

At the UBS Global Life Sciences Conference, Sept. 26 to 29 in New York City, several publicly traded labs made presentations to money managers. Here are some highlights:

LabCorp currently gets about 40% of its revenue from managed care contracts, and that percentage is likely to rise to more than 50% over the next few years, said **Tom Mac Mahon**, chairman and chief executive. "Now more than ever, managed care companies are willing to discuss pricing with you, if you have good ideas that can help grow their membership or reduce lab spending," he said. "Managed care won't go away and will continue to consolidate. It's a very important part of our growth strategy," he added.

Joseph Limber, president and chief executive of **Prometheus Laboratories** (San Diego, CA), said the recent controversy surrounding Cox II inhibitors has helped illustrate the need for personalized medicine. "In a very short period of time, $5 billion to $6 billion dollars of [pharmaceutical] revenue was wiped out with the elimination or reduction of the use of these products. In fact, these were products that treated patients pretty well. Ninety-nine percent or so of patients seemingly had good results from these products, and they tolerated them quite well."

"If there was a time machine that would enable our industry to go back and be able to determine who were those 1% or less of patients that should not be on Cox II inhibitors, what would that be worth?" asked Limber.

Limber said Prometheus has a business model that can help avoid situations like the Cox II inhibitors. Currently, Prometheus markets a combination of proprietary esoteric tests and pharmaceutical products specifically to gastroenterologists. In 2004, the company posted revenue of $90 million, including $51 million from esoteric testing and $39 million from pharmaceutical sales. Prometheus has 250 employees, including 120 salespeople.

Prometheus, which operates a CLIA-certified lab in San Diego, charges an average price of $260 per test, with some tests as high as $760, according to Limber. Among its proprietary tests is Pro-PredictRx, a pharmacogenomic test that helps physicians monitor toxicity levels and individualize dosing for patients on the drug Imuran. This drug is made by Prometheus and is prescribed to treat Crohn's disease, a serious bowel disorder.

Limber said Prometheus was on track to reach $115 million to $120 million of revenue (40% diagnostic/60% pharmaceutical) in 2005. And he said the company was looking to expand into additional disease areas, including possibly oncology, endocrinology, neurology, and/or urology.

Pierre Cassigneul, president and chief executive of **XDx Inc.** (South San Francisco, CA), said the company's first test product, AlloMap, was launched as a home brew test late last year and is now actively being used by nine heart transplant centers, including Cleveland Clinic, Columbia University, and Stanford University. AlloMap is a real-time PCR-based blood test that analyzes 20 genes to check for immune-system rejection for heart transplant patients.

AlloMap is priced at $2,950 per test, and Cassigneul said insurance companies are reimbursing an average of 86% of the list price.

There are 2,085 heart transplants performed each year in the United States, and these patients each typically have approximately 28 cardiac biopsies in the two years following the operation at a cost of $4,000 to $5,000 per biopsy, including the cost of the heart cath lab and cardiologist and pathologist fees. These invasive and expensive procedures are necessary despite the fact that over 75% of the time, they provide a negative result—the patient's immune system is not rejecting the transplanted heart.

The AlloMap test is intended as a noninvasive and less-costly alternative for monitoring rejection for stable outpatients, according to Cassigneul. He estimates that the U.S. market potential for AlloMap is $150 million per year. He said XDx plans to have a similar test for lung transplant patients on the market in the second half of 2006.

Paul Kelly, M.D., president and chief executive of **Orchid Cellmark**, said the U.S. DNA forensic testing market has the potential for explosive growth given the changes occurring in the criminal justice system. He cited President Bush's DNA Initiative, the "Justice for All Act of 2004," should provide increased funding over the next several years to private forensic laboratories to process DNA sample backlogs in criminal investigations.

The legislation authorizes an infusion of more than $1 billion in federal funds over the next five years to eliminate the current backlog of more than 500,000 unanalyzed DNA specimens languishing in police department evidence rooms and crime labs.

The growing backlog is the result of the limited capacity at public crime labs, according to Kelly. He noted that the 350 public crime labs in the United States had an average budget of only $1 million per year and a technical staff of just 12 employees.

He pointed to statistical studies that have shown that every $1 spent on forensic DNA testing for violent crimes saves $33 for the criminal justice system.

Kelly also cited Orchid's growing "relationship" testing business, which includes DNA-based paternity testing, employers' DNA profiling of workers in high-risk jobs (e.g., workers in Afghanistan or Iraq), and identification testing for those deceased in natural disasters.

William Young, chairman and chief executive of **Monogram Biosciences** (formerly ViroLogic), said the company expects to have its first cancer tests on the market sometime next year. These tests will make use of the company's proprietary eTag technology, which was gained through the acquisition of Aclara Biosciences in December 2004. Young said the eTag technology directly measures proteins and protein complexes on the surface and within targeted cancer cells.

Drugs currently on the market for specific segments of patients with cancer include Gleevac, Evastin, Herceptin, Erbitux, Iressa, and Tarceva, according to Young. He said Monogram has eTag tests under development for predicting patient response for Tarceva (colorectal cancer) and Herceptin (breast cancer).

Young said that combinations of cancer drugs are beginning to be used in the same way that "drug cocktails" for HIV are prescribed. This will further increase the need for advanced tests to predict cancer treatment responses, he added.

Lab Stocks Down 7% Year To Date

The G-2 Laboratory Stock Index has fallen 7% so far this year through October 24, with three stocks up in price and nine down. Over the same time period, the S&P 500 Index is down 3% and the Nasdaq is has fallen 4%.

The leading gainers year to date are **LabOne** (Lenexa, KS), up 37% to $43.85 per share, and **Specialty Labs** (Valencia, CA), up 18% to $13 per share. Both companies are being acquired: Quest Diagnostics is buying LabOne and AmeriPath is buying Specialty Labs.

At the two biggest lab companies: **Quest Diagnostics** has dipped 2% to $46.68 per share and **LabCorp** is also off 2% to $49.05 per share.

Meanwhile, the least expensive lab stock on a market capitalization/annual revenue basis is **Medtox** (St. Paul, MN), which currently trades at just 0.9 times its annualized revenue of $53.9 million. LabOne is second cheapest at 1.5 times its annualized revenue of $503.9 million. **Bio-Reference** (Elmwood Park, NJ) is next, trading at 1.6 times its annualized revenue of $153.8 million.

The most expensive lab stocks are **Enzo Biochem** (Farmingdale, NY), 10.2 times annualized revenue; **Myriad Genetics** (Salt Lake City, UT), 8.1 times; and **Monogram Biosciences** (formerly named ViroLogic), 6.7 times.

Quest and LabCorp each trade at about 2.0 times their annualized revenue.

Year-to-Date Performance of Lab Stocks

Company (ticker)	*12/31/04 Price*	*10/24/05 Price*	*YTD % Chg*	*Market Cap ($ millions)*	*Annual Revenue* ($ millions)*	*Market Cap/ Revenue*
Bio-Reference (BRLI)	$17.40	$18.53	6%	$239.6	$153.8	1.6
Clarient Inc. (CLRT)	2.16	1.17	-46	60.6	18.4	3.3
Enzo Biochem (ENZ)	19.47	13.78	-29	442.9	43.4	10.2
LabCorp (LH)	49.82	49.05	-2	6,560.0	3,304.8	2.0
LabOne (LABS)	32.04	43.85	37	766.8	503.9	1.5
Medtox (TOX)	9.00	6.78	-25	53.9	63.1	0.9
Monogram Biosciences (MGRM)	2.79	2.37	-15	299.4	44.8	6.7
Myriad Genetics (MYGN)	22.51	21.50	-4	664.2	82.4	8.1
Orchid Cellmark (ORCH)	11.50	8.90	-23	218.2	61.0	3.6
Psychemedics (PMD)	12.95	12.65	-2	65.3	21.9	3.0
Quest Diagnostics (DGX)	47.78	46.68	-2	9,460.0	5,394.0	1.8
Specialty Labs (SP)	11.04	13.00	18	308.7	151.4	2.0
Unweighted average			-7%			3.7

*Revenue figures are based on annualized results for the six months ended June 30, 2005 Source: *LIR*

INDUSTRY buzz

Is America ready for an over-the-counter HIV test? OraSure Technology's OraQuick HIV test is already CLIA waived and now Food and Drug Administration is considering permitting it to be sold over-the-counter at drug stores.

In a nutshell, the test involves swabbing the inside of your mouth, then putting that swab into a vial of test fluid. Twenty minutes later, an indicator will light up if the test detects the presence of HIV-1 or HIV-2 antibodies.

Supporters of home kits say they will spur more people to get tested and get treatment sooner if infected. About one million people in the United States are estimated to have HIV, including nearly 300,000 people who have the virus but don't know it, according to the Centers for Disease Control and Prevention.

On November 3, FDA's Blood Products Advisory Committee will consider whether to recommend the product for over-the-counter sales. The FDA has the final say; it usually follows the advice of its advisory committees. The biggest concern is the mental anguish that someone would have upon learning they have HIV when they are alone.

OraSure says it has not decided how much it will charge consumers for the kit (assuming FDA approval). The company currently sells the CLIA-waived version of the test to doctor's offices and clinics for between $12 and $17.

References in this issue

Alliance Imaging 714-688-7100

AmeriPath 800-330-6565

LabCorp 336-229-1127

Monogram Biosciences 650-635-1100

OraSure 610-882-1820

Orchid Cellmark 609-750-2200

Prometheus Labs 858-824-0895

Quest Diagnostics 201-393-5000

Specialty Laboratories 661-799-6543

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