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LABORATORY INDUSTRY REPORT®

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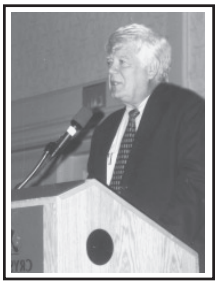
HIGHLIGHTS

WASHINGTON G-2 REPORTS

Lab Legislation Bumped To "Back Seat"

Until Sept. 11, the 107th Congress had been working toward possible action this fall on a wide array of healthcare issues—including significant changes backed by laboratory trade and professional groups in how Medicare Part B pays for clinical lab services. But after the terrorist attacks on Sept. 11, there is widespread recognition that most, if not all, of these measures have shifted to a lower priority on Capitol Hill. "In light of recent events and the huge price tag associated with our nation's war efforts, every other priority has taken a back seat," noted **U.S. Rep. Jim McDermott (D-WA)** in his Oct. 25 keynote presentation at Lab Institute 2001, sponsored by Washington G-2 Reports.



According to McDermott, if you add up all the unplanned federal spending since Sept. 11—including aid to New York City, increased military spending, airline relief, an economic stimulus package plus interest costs for borrowing this money—the total is some $400 billion over the next 10 years. "In this context, to come with a Medicare bill where you try to do upgrades [raise spending] is going to be very tricky."

McDermott is a lead House sponsor of HR 1798, The Medicare Patient Access to Preventive & Diagnostic Tests Act. The Act would establish a new process for setting Medicare fees for new lab tests, raise fees for existing tests on local fee schedules to 100% of their national cap and authorize a lab fee inflation update in 2002. For more lab payment policy news, see *Inside The Laboratory Industry*, pp. 5-7.

Mayo Clinic Develops One-Hour Anthrax Test

The Mayo Clinic (Rochester, MN) says it has developed a new DNA test that can identify exposure to anthrax in human and environmental samples in less than one hour (including sample preparation time). "This rapid identification will enable doctors to begin more timely treatment of patients who have been exposed to anthrax, and it will more quickly alleviate undue anxiety for people who haven't been exposed," says Franklin Cockerill III, MD, the Mayo microbiologist who led the development team. The test was developed using Roche Diagnostics' LightCycler instrument for polymerase chain reaction (PCR)-based assays.

Roche, which is manufacturing the reagent mix for the Mayo-developed test, says it will soon send 100 reagent kits each to *Continued on page 2*

■ MAYO CLINIC, *from page 1*

about two dozen geographically dispersed LightCycler-equipped labs in the U.S. at no charge. Roche has received permission from the Food & Drug Administration to distribute the test on a limited basis. The company hopes to get an expedited approval from FDA by the end of the year.

A Mayo spokeswoman tells *Laboratory Industry Report* (*LIR*) that the Roche/Mayo anthrax test is quick because it can identify small numbers of DNA and, therefore, requires less amplification time to complete the PCR cycle. Additional details were not available on why this test is so much quicker than traditional PCR-based testing methods, which typically take 4-8 hours to complete. Mayo says that for security reasons, discussion of the technology behind the test must be limited, and even the names of other associated researchers are being kept confidential.

Speed is of the essence in detecting anthrax, because it can kill within days if it gets into the lungs

To date, there have been four confirmed anthrax deaths in the U.S. in what President George W. Bush has called a second wave of terrorism after the Sept. 11 suicide attacks on the World Trade Center Towers and the Pentagon. Scientists have said a quick test for exposure to anthrax is the key to saving lives, because antibiotics only work if administered soon after the victim is exposed and because widespread vaccinations are considered impractical.

Currently, nearly all anthrax testing in the U.S. is being performed at public health laboratories or the Centers for Disease Control & Prevention. Public health labs are predominantly using culture-based tests, which can take 1-3 days to detect anthrax exposure. CDC has the capability to do PCR-based tests for anthrax that provide results in as soon as four hours. But if anthrax testing demands were to overwhelm capacity at government labs, experts say the government would need to contract with commercial and hospital labs to help with testing. It is under this scenario that the Roche/Mayo anthrax test kit would be most needed, Dennis Coverdale, a spokesman for Roche Diagnostics, tells *LIR*.

In addition to rapid results, the Roche/Mayo test would bring testing closer to the patient, reducing time lost during specimen transport. For example, the Florida Health Department's Miami-Dade Bureau of Laboratory Services is the only facility in Miami-Dade, Broward, Palm Beach, Monroe and Collier counties capable of testing for anthrax. This lab was inundated with samples after the first anthrax spores were detected last September in the American Media Inc. building in Miami. Roche says more than 400 U.S. hospital and commercial labs with LightCycler instruments are capable of running its new anthrax test.

Other IVD manufacturers, including Cepheid Inc. (Sunnyvale, CA), have developed rapid diagnostic tests for anthrax. However, the Roche/Mayo test appears likely to become the first to gain FDA approval and then widespread use.

Roche says it is also working to develop a test for smallpox, which could pose even more of a threat to the general population than anthrax. Smallpox, which was declared in 1981 to have been eradicated worldwide by mass inoculation, is highly infectious, unlike anthrax. The only defense against smallpox is prevention by vaccination. Those infected can also be vaccinated within four days of exposure, which makes quick diagnosis essential.

ACOG Recommends Wider Screening For Cystic Fibrosis

ACOG's recommendation was preceded by related guidelines issued earlier this year by the American College of Medical Genetics (ACMG-Bethesda, MD)—see LIR, May '01, p. 8

New guidelines put forth by the American College of Obstetricians and Gynecologists (ACOG-Washington, DC) stipulate that doctors should offer a genetic test for cystic fibrosis (CF) to "every Caucasian—or the partner of a Caucasian—who is pregnant or considering having a baby." Four million babies were born in the U.S. last year, 75% of them from Caucasian parents. The new guidelines mark the first time that a major physician association has recommended genetic screening for such a large population.

Cystic fibrosis is the most common serious genetic disease among Caucasians in the U.S. The disease results from a defective gene that causes the body to produce an abnormally thick, sticky mucus, due to the faulty transport of sodium and chloride (salt) within cells lining organs (such as the lungs and pancreas) to their outer surfaces. The build-up of mucus in the narrow airways of the lungs can lead to fatal infections. The thick CF mucus can also obstruct the pancreas, preventing enzymes from reaching the intestines to help break down and digest food. Approximately 30,000 people in the U.S. have CF. Their average life expectancy is 32 years, according to the Cystic Fibrosis Foundation (Bethesda, MD).

Cystic fibrosis cannot be treated before birth. ACOG says the purpose of CF testing is to help prospective parents decide if they want to have a baby. Testing of a pregnant mother and father can help them prepare to care for a child that may have special healthcare needs or aid in a decision to terminate the pregnancy.

About one in 28 Caucasians—more than 10 million people in the U.S.—is an unknowing carrier of a CF genetic mutation. Carriers themselves don't have CF, but if both parents are carriers, a child has a 1-in-4 chance of being born with the disease. There are about 1,000 known mutations in the gene that causes CF, and ACOG advises tests for a minimum of 25 of the most common mutations. Based on published data of carrier frequencies among various ethnic backgrounds, the overall detection rate of a 25-mutation panel is approximately 74%.

The success of widespread cystic fibrosis screening may have an impact on how other genetic tests are introduced into the general population

In the past, CF testing was generally offered only to prospective parents with a family history of the disease. Last year, an estimated 100,000 to 125,000 CF tests were performed in the U.S. at a price of roughly $250 per test, indicating a market size of more than $25 million. This market will likely see dramatic growth given the recent guidelines, says Mara Aspinall, president of Genzyme Genetics (Framingham, MA).

Genzyme Genetics currently performs more than 400,000 genetic tests per year, primarily in the area of DNA-based tests for CF and prenatal diagnosis of chromosome abnormalities. Last year, the company saw its revenue climb by 7% to $61.3 million. This year, revenue is growing at approximately 18% and is expected to exceed $70 million, due in part to increased demand for CF testing. In anticipation of further growth, Genzyme recently doubled the capacity of its molecular diagnostics lab in Framingham and launched an educational campaign to help physicians advance their knowledge of CF, notes Aspinall.

Quest Completes Purchase Of MedPlus For $17 Million

Quest Diagnostics (Teterboro, NJ) has completed its purchase of MedPlus (Cincinnati, OH) in a move that will greatly expand Quest's electronic and Internet connectivity services to physician and hospital customers.

Quest paid approximately $17 million to acquire the remaining 82% stake in MedPlus that it did not already own. Quest had an 18% stake in the company from a $9.5 million investment made in June 2000. As part of Quest, MedPlus will maintain its operations in Cincinnati.

Quest has been using MedPlus' OptiMaxx product for document management since 1999. OptiMaxx allows computer data to be saved to laser disc for patient records storage and retrieval. Other MedPlus products include ChartMaxx, an electronic patient record system, and eMaxx, an Internet portal that allows office-based physicians to access patient data via the Web. In total, MedPlus products are installed at more than 125 hospitals throughout North America, including Akron General Medical Center (Akron, OH), DCH Regional Medical Center (Tuscaloosa, AL), Lourdes Hospital (Paducah, KY) and Valley Children's Hospital (Madera, CA).

Miriam Javitch, vice president of management processes and business effectiveness at Quest, tells *LIR* that the key advantage MedPlus products offer physicians is the ability to complete patient charts from any location with an electronic connection to the hospital or with Internet access. "It saves doctors the expense of extra trips to the hospital, and this time-saving should allow charts to get completed faster so hospitals can bill faster." Quest intends to accelerate distribution of the MedPlus ChartMaxx, eMaxx and OptiMaxx product lines, according to Javitch.

In addition, Javitch says Quest will integrate its own internally developed "Quest on Demand" product into the MedPlus eMaxx portal product in early 2002. Quest on Demand allows physicians to order lab tests and receive results via the Internet. Quest launched the lab test results component last year, and several thousand physicians are now using it, according to Javitch. The order-entry component was launched earlier this year and has several hundred physician users. Both components are functional on standard 56K modems, Javitch says. Benefits to physicians using Quest on Demand include enhanced test result reports; Quest gets cleaner requisitions.

MedPlus At A Glance *($MM)*

	Six months ended	
	7/31/01	*7/31/00*
Revenue	$5.368	$5.394
Operating loss	-5.662	-2.800
Net loss	-6.272	-3.241

Source: MedPlus

The acquisition of MedPlus does not come without risks. MedPlus has posted operating losses every year since its inception in 1991 and was in danger of going out of business until Quest acquired it. In the six months ended July 31, 2001, MedPlus reported a net loss of $6.272 million on revenue of $5.368 million.

To date, physician adoption of new Internet services such as lab test ordering and results reporting has been slow. However, Javitch believes that acceptance is accelerating as physicians overcome fears about online security and as the speed and performance of Internet services improve.

New Budget Pressures Hurt Chances Of Lab Fee Legislation

Although creating room in the federal budget to raise lab fees under Medicare has become increasingly difficult, there are signs of a greater understanding among policy-makers of the economic and regulatory pressures facing lab service providers, including a need to address inadequacies in the existing Part B fee schedule

Prior to Sept. 11, there had been guarded optimism within the laboratory industry that a lab fee relief bill (HR 1798) might soon get passed into law as part of a larger Medicare reform package. "Two months ago, Congress was debating the Patients' Bill of Rights, prescription drug benefits and a whole series of other things, and then suddenly the whole world changed," U.S. Rep. Jim McDermott (D-WA) told the audience at Washington G-2 Reports' recent Lab Institute, held Oct. 24-27 in Arlington, VA. "It really is unclear what will happen [in Congress] in this next period of time," he added.

McDermott noted that increased spending following the Sept. 11 terrorist attacks, combined with a slowing economy, have turned the federal budget upside down and made passage of any healthcare legislation that costs money more difficult. Indeed, the Bush Administration recently announced a smaller-than-anticipated $127 billion surplus for the Federal Government in the budget year ended Sept. 30, 2001. This was well below the $158 billion the White House had projected as late as August. Most experts now believe that the government will post a deficit in the 2002 budget year vs. expectations earlier this year of a $176 billion surplus.

CMS Recognizes Appeal Of National Lab Fee Schedule

Thomas Gustafson, PhD, director of the Purchasing Policy Group within the Center for Medicare Management at the Centers for Medicare & Medicaid Services (CMS, formerly HCFA), told the Lab Institute audience that the agency is in favor of instituting a single national lab fee schedule. Last December, an Institute of Medicine study commissioned by Congress called for basing Medicare payment for outpatient clinical laboratory services on a single, rational, national fee schedule adjusted for geographic location.

CMS also recognizes the need for creating some mechanism to update the Medicare Part B fee schedule over time, Gustafson said. "The basic information contained in the fee schedule is antique. It is, to some extent, inexcusably antique. And we believe something needs to be done about that." However, CMS is struggling to determine the best methodology for providing periodic updates, he noted. "We like to make policy on the basis of good data and particularly on cost data," adding that CMS has yet to find adequate cost data for laboratory tests.

Gustafson said CMS has contracted with the Research Triangle Institute and the University of Wisconsin and Northwestern University to develop charge-based relative values for clinical laboratory tests. A charge-based method of updating the lab fee schedule over time may have distinct advantages, he noted, over other possible methods such as competitive bidding and micro-costing studies.

McDermott To Lab Industry: Get More Involved

Rep. McDermott, one of the few physicians serving in Congress, said he strongly believes that overall healthcare costs can be reduced through greater use of early prevention laboratory testing. "I can make the medical argument, but it's

very hard to make the argument to people who don't want to spend the money. You [the lab industry] have a real role to play in this … to talk about what the cost of an early prostate cancer test is, instead of waiting till the end and treating someone with advanced carcinoma … Part of your role in talking to members of Congress is to explain why laboratory tests in advance are not wasted. There is a real case to be made, but it doesn't get made very well."

This sentiment was echoed by James Koziarz, PhD, vice president, diagnostic products, R&D at Abbott Laboratories, in a separate presentation at Lab Institute. Koziarz called on IVD manufacturers and clinical laboratories to work together to change the perception of the laboratory from a "cost center to an investment center … We need to get the information together that shows that a buck spent in clinical labs is going to save 'X' number of dollars to the clinical system."

The Case For Raising Laboratory Reimbursement

HR 1798 was introduced on May 10, 2001 by U.S. Rep. Jennifer Dunn (R-WA), with co-sponsors Robert Ehrlich Jr. (R-MD), Jim McDermott (D-WA) and Jim Ramstad (R-MN). It has since received support from 26 additional members of the House. A similar bill (S 1066) has been introduced in the Senate and has gained the support of eight Senators.

Among other things, the bill would require the Secretary of Health & Human Services (HHS) to set the Medicare Part B fee schedule for all existing tests on local fee schedules at 100% of their national limitation amounts (NLAs) and authorize an inflation update to lab fees in 2002. The accounting and consulting firm PricewaterhouseCoopers (PwC-Washington, DC) has estimated that raising the fees to the NLAs would result in a 1.3% increase in Part B payments to labs. An inflation adjustment in 2002 would hike lab fees another 2.8%. The combined impact of both changes would increase payments by about 4.1% next year, according to PwC.

Longer-term, PwC estimates that Medicare outlays would be increased by a total of approximately $1 billion for fiscal years 2002-2006 if fees were raised to the NLAs and annual CPI adjustments were made.

According to the latest data from CMS, total Medicare Part B spending on laboratory services has risen by an average of only 1.8% annually from calendar-year 1991 to 2000. Over the same time period, overall Medicare spending on all healthcare services has increased by about 8% annually.

The latest estimates from CMS show that Part B lab spending was $4.017 billion in calendar 2000, comprising only 1.6% of the overall $244.5 billion spent by Medicare last year. A decade ago, Part B lab spending comprised approximately 3% of overall Medicare spending.

An analysis of the top 33 laboratory test codes (ranked by total allowed charges and excluding code G0001—drawing blood for specimen) from the 2000 Part B Extract and Summary System (BESS) shows that the average allowed charge is $10.52 per CPT code. If panel tests on the list are exploded into their individual test components, the

Medicare Part B Spending For Clinical Laboratory Tests

($MM on a calendar-year incurred basis)

Year	Carrier	Hospital	Total
1991	$2,538	$1,040	$3,578
1992	2,829	1,274	4,103
1993	2,951	1,342	4,293
1994	2,899	1,443	4,342
1995	2,793	1,437	4,230
1996	2,550	1,436	3,986
1997	2,367	1,501	3,868
1998	2,091	1,532	3,623
1999	2,081	1,659	3,740
2000	2,255	1,762	4,017

Source: CMS

average allowed charge per reportable test result is $3.70.

This average allowed charge of $3.70 per reportable test compares with a median operating cost per reportable test of $5.05 at 23 hospital labs with large outreach programs (*LIR, Sept.'01, p.9*).

These figures suggest that most hospital labs are incurring a loss on testing services reimbursed under Medicare Part B.

Top 33 Medicare Part B Laboratory Procedures, 2000 Nationwide

Code	Procedure Name	Billable Volume	Total Allowed Charges	Avg Allowed Charge
80061	Lipid panel (3 tests)	11,782,630	$164,414,150	$13.95
85025	Automated complete diff WBC (CBC)	11,640,016	123,663,453	10.62
80053	Comprehensive metabolic panel (14 tests)	8,882,962	105,159,145	11.83
85024	Automated partial diff WBC (CBC)	7,257,840	82,906,713	11.42
84153	PSA total	3,126,205	79,199,646	25.33
85610	Prothrombin time	13,809,757	74,941,198	5.42
83036	Hemoglobin; glycated	5,483,342	73,378,390	13.38
80048	Basic metabolic panel (8 tests)	5,889,046	57,266,364	9.72
83970	Parathormone (parathyroid hormone)	743,543	42,380,669	56.99
81000	Urinalysis, by dip stick or reagent	7,775,838	33,913,068	4.36
87086	Urine culture, colony count	2,708,987	29,997,005	11.07
80054*	Comprehensive metabolic panel (13 tests)	2,218,620	25,586,421	11.53
80162	Digoxin	1,348,249	24,728,249	18.34
82607	Vitamin B-12	1,189,607	24,677,934	20.74
82728	Ferritin	1,288,675	24,193,332	18.77
80076	Hepatic function panel (7 tests)	2,615,349	21,426,081	8.19
84436	Thyroxine; total	2,147,593	20,061,843	9.34
83550	Iron binding capacity	1,693,622	19,740,960	11.65
82947	Glucose; quantitative	4,962,328	18,601,255	3.74
83540	Iron	2,144,984	18,326,468	8.54
82746	Folic acid; serum	815,705	16,440,237	20.15
87340	Hepatitis B surface antigen (HBsAg)	1,152,796	16,173,798	14.03
83721	LDL cholesterol	1,236,008	16,117,646	13.04
80092*	Thyroid panel with TSH (3 tests)	389,779	16,080,225	41.25
85023	Manual differential WBC (CBC)	1,387,250	16,029,002	11.55
80049*	Basic metabolic panel (8 tests)	1,713,631	15,999,982	9.33
84439	Thyroxine; free	1,183,961	14,619,312	12.34
82378	Carcinoembryonic antigen	549,035	14,374,422	26.18
87186	Antibiotic sensitivity, MIC	1,201,755	14,035,330	11.67
81001	Urinalysis, automated, with scope	3,137,003	13,697,512	4.36
80051	Electrolyte panel (4 tests)	2,282,210	12,379,131	5.42
80185	Phenytoin	662,155	12,120,627	18.30
82565	Creatinine; blood	4,878,343	12,047,172	2.47
	Totals and averages	119,298,824	$1,254,676,740	$10.52

Source: The 2000 Part B Extract and Summary System (BESS) file for American Medical Association CPT codes 80000-87999. Note: BESS data include data from independent and physician office laboratories, but not services paid by fiscal intermediaries to facilities such as hospitals, nursing homes and home health agencies.
*These codes have been deleted.

Quest Builds NYC-Area Market Share With Purchase Of CDS

Quest Diagnostics (Teterboro, NJ) has signed a definitive agreement to acquire Clinical Diagnostic Services Inc. (CDS-Englewood, NJ). The acquisition will bring Quest one of the largest privately held labs in the nation and strengthen its already firm grip on the market in the greater New York City area.

CDS has approximately 500 employees and estimated annual revenues of more than $50 million. Guy Seay is president and the company's largest shareholder. The deal is expected to close this month. The purchase price has not yet been disclosed.

CDS operates a central lab in Englewood, which is approximately 10 miles north of central Manhattan and only about seven miles from Quest's headquarters and major testing lab in Teterboro. The company also runs a major billing and administrative facility in Tenafly, NJ (located a few miles north of Englewood). In addition, CDS operates more than 50 patient service centers in New York and New Jersey.

The planned acquisition of CDS is the second big coup for Quest in New York City this year. Quest earlier announced an agreement to provide laboratory services to HMO members of Empire Blue Cross Blue Shield (New York City)—(*LIR, Aug.'01, p. 3*).

Separately, documents filed with the Securities & Exchange Commission show that on Feb. 1, Quest paid $47 million to acquire Clinical Laboratories of Colorado LLC (Denver), which was partly owned by Centura Health. In connection with the transaction, Quest entered into an agreement to manage rapid turnaround labs at five Centura Health hospitals in the Denver area. In total, this transaction is expected to provide Quest with approximately $30 million in annual revenue.

More Consolidation In The Lab Industry…

Of course, Quest was not the only lab company making acquisitions this year. On Oct. 25, **Medtox Scientific** (St. Paul, MN) announced its purchase of privately held **Leadtech Corp.** (North Bergen, NJ), which specializes in testing for blood lead concentrations in children. The total purchase price of $6.2 million consists of $2.5 million in cash, $2.5 million in stock paid at closing and $1.2 million of seller financing payable over 24 months. Leadtech performs some 150,000 tests annually for 2,000 pediatric accounts and has an estimated annual revenue of $3 million per year. Medtox says Leadtech will be consolidated into Medtox's existing metals laboratory in St. Paul.

Unilab acquired **Medical Arts Clinical Laboratories** (MACL-Santa Barbara, CA) on July 21, for $6.8 million in cash plus a contingent payment of an additional $1 million to be paid in November 2002 if MACL meets certain revenue targets. MACL's annual revenue is $5 million.

Laboratory Corp. of America (Burlington, NC) purchased **Path Lab** (Portsmouth, NH) on April 30 for $83 million in cash plus future payments of $25 million based on the attainment of specific earnings targets. Path Lab's revenue for the year ended Dec. 31, 2000 was $51.6 million. In June, LabCorp acquired **ViroMed Inc.** (Minneapolis, MN) for $31.7 million in cash plus future contingent payments of $12 million. ViroMed is an esoteric lab with annual revenue of $25.2 million.

Specialty Laboratories (Santa Monica, CA) acquired **BBI Clinical Laboratories** (New Britain, CT) in February for $9.5 million in cash plus $648,000 in assumed liabilities. BBI, which had generated an estimated $9 million per year in revenue, has been consolidated into Specialty's central lab in California.

In June, **Dynacare** (Dallas, TX and Toronto, Canada) purchased I**MMC Laboratories** (Chicago, IL) for $1.4 million and under a separate transaction bought **Medstat Laboratories** (Beaumont, TX) for $800,000. In March, Dynacare acquired **Medical Arts Laboratory** and **Southern Medical Arts Laboratory** (both based in Oklahoma City) for $7.7 million. Their annual revenue is $20 million.

Dianon Systems Inc. (Stratford, CT) closed on its acquisition of **UroCor Inc.** (Oklahoma City) this month. Dianon paid approximately $193 million in stock for UroCor, or roughly three times UroCor's annual revenue of $63 million (based on annualized results for the six months ended June 30, 2001). For details, see *LIR, July '01, p. 1*.

Lab*One* (Lenexa, KS) completed its acquisition of **Osborn Group** (Olathe, KS) for $48.65 million in August. Osborn Group's annual revenue is $37 million.

Overall, average prices paid to acquire lab testing companies have reached 1.67 times annual revenue this year, up from 1.45 in 2000 and 0.80 times in 1999 (*LIR, Dec.'00, p. 1*).

David Nichols, president of Nichols Management Group (York Harbor, ME), says that the number of potential acquisition candidates of size (*i.e.*, privately held labs with $50+ million in annual revenue) is dwindling. Consequently, he believes that the best growth prospects for both commercial and hospital labs lie in educating physicians on appropriate test selection of both existing and new tests. "Many physicians are simply not up-to-date on the latest testing protocols and technologies," notes Nichols.

Laboratory Transaction Summary, 2001 *($MM)*

Date	*Buyer*	*Target*	*Purchase Price*	*Acquired Revenue*	*Price/ Revenue*
Feb-01	Quest	Clinical Labs of CO	$47.0	$30.0	1.57
Feb-01	Specialty Labs	BBI Clinical Labs	10.1	9.0E	1.26
Mar-01	Dynacare	Medical Arts of OK	7.7	20.0	0.39
Apr-01	LabCorp	Path Lab	108.0	51.6	2.09
Jun-01	LabCorp	ViroMed	43.7	25.2	1.73
Jun-01	Dynacare	IMMC Labs	1.4	NA	NA
Jun-01	Dynacare	Medstat	0.8	NA	NA
Jul-01	Unilab	Medical Arts (in CA)	7.8	5.0	1.56
Aug-01	Lab*One*	Osborn Group	48.7	37.0	1.32
Oct-01	Medtox	Leadtech Corp.	6.2	3.0E	2.07
Nov-01	Dianon	UroCor	193.0	63.0	3.06
Nov-01	Quest	Clinical Diag Services*	NA	NA	NA
Unweighted Average					1.67

E=estimated. *Pending deal. NA=not available Source: *Laboratory Industry Report* from companies

Athena Diagnostics Seeks Up To $120 Million From IPO

Athena Diagnostics Inc. (Worcester, MA), which specializes in lab tests for neurological disorders, has filed with the Securities & Exchange Commission for an initial public offering of as much as $119.7 million in common stock. The sole underwriter is UBS Warburg (New York City). The IPO is expected to be completed in early 2002.

The planned offering will involve only a portion of the existing shares held by Athena's sole shareholder, Elan Pharmaceuticals (Dublin, Ireland), which itself is a subsidiary of Irish drugmaker Elan Corp. (also in Dublin). Elan is a specialty pharmaceutical company focused on neurology and pain management; products include Skelaxin (a muscle relaxant), Permax (for Parkinson's disease) and Mysoline (for epilepsy).

Athena At A Glance *(in thousands)*

	1st-Half 2001	*1st-Half 2000*
Revenue	$16,975	$14,065
EBITDA*	6,201	4,374
Net income	3,081	2,019

*EBITDA=earnings before interest, taxes, depreciation and amortization Source: Athena

Athena markets approximately 70 esoteric tests in the field of neurology, including genetic tests for Huntington's disease and certain forms of mental retardation as well as tests to help diagnose Alzheimer's disease. The company, which has 121 full-time employees (including 45 in sales and marketing), performs all testing at a 20,000-square-foot lab and office facility in Worcester, MA.

In the six months ended June 30, 2001, Athena reported a net profit of $3.081 million vs. $2.019 million in the same period a year earlier; revenue was up 21% to $16.975 million. The company derives 14.6% of revenue from neurologists, 39.1% from hospital labs and 46.3% from commercial labs. Its largest single customer is Quest Diagnostics, which accounts for 18.5% of Athena's revenue.

Myriad Genetics To Launch Predictive Melanoma Test

Myriad Genetics (Salt Lake City, UT) says it will begin marketing a predictive test for malignant melanoma, a deadly form of skin cancer, later this month. The test, named Melaris, is used to assess an individual's risk of developing melanoma based on the detection of inherited mutations in the p16 (CDKN2A) gene. Individuals who carry a mutation in the p16 gene, resulting in a positive Melaris test, have an estimated lifetime risk of developing melanoma that is 50 times higher than the risk for those in the general population.

Myriad's Genetic Predisposition Testing Products

Indication	*Product*	*Launch*	*List Price*
Breast cancer	BRACAnalysis	10/96	$2,580
Salt-dependent hypertension	CardiaRisk	10/98	$295
Colorectal cancer	Colaris	9/00	$1,950
Melanoma	Melaris	11/01	TBA

Source: Myriad Genetics

Melaris will be Myriad's fourth genetic predisposition test to reach the market. The company is best known for its BRACAnalysis product, which tests for predisposition to breast/ovarian cancer and costs $2,580.

Lab Stocks Rise 6% In Latest Six Weeks

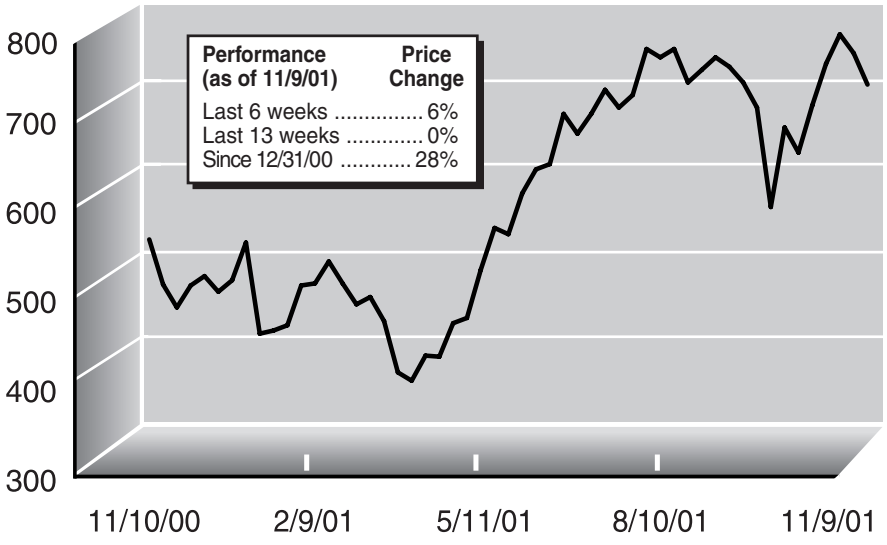
Laboratory stocks were up 6% in the six weeks ended Nov. 9, 2001, according to the G-2 Laboratory Stock Index, which tracks the average percentage price change of 15 lab testing service companies. Seven stocks rose in price during the period, another seven fell, one was unchanged. Year-to-date, the G-2 Lab Index has risen 28%. In comparison, the S&P 500 is down 15% and the Nasdaq is down 26%.

Shares of **Myriad Genetics** (Salt Lake City, UT) jumped 63% to $49.91 per share, giving the company a market capitalization of $1.2 billion. The company recently announced the launch of its fourth predictive medicine test—Melaris for malignant melanoma (*see p. 10*). In addition, Myriad reports that its net loss for the three months ended Sept. 30, 2001 shrunk to $1.185 million from $2.07 million in the same period a year earlier. Revenue for the quarter increased 22% to $13.19 million, including $7.673 million in research revenue from pharmaceutical companies and $5.518 million from genetic testing services.

Shares of **Bio-Reference Labs** (Elmwood Park, NJ) rose 53%, giving the company a market capitalization of about $52 million. The company recently announced that its contract with New York State to provide lab services to all the state's prisons has been renewed for the fourth consecutive year. Bio-Reference says the contract should bring in excess of $7 million of business over the next year.

Lab*One* (Lenexa, KS) was up 36% to $14.95 per share. The company recently reported a third-quarter net loss of $3.489 million vs. a net gain of $357,527 in the same period last year; revenue increased 33% to $58.234 million. The company's fastest-growing business in the recent third quarter was its life insurance applicant testing business, up 51% to $39.5 million.

G-2 Laboratory Stock Index



Source: The G-2 Laboratory Stock Index is tabulated weekly by *Laboratory Industry Report* from the average percentage price change of 15 laboratory testing service stocks.

% price change, 6 weeks ended 11/9/01

	Price	% Chg
UP		
AmeriPath	$26.97	3
Bio-Reference	5.50	53
Dynacare	10.90	4
Lab*One*	14.95	36
MDS	13.05	10
Medtox	13.45	12
Myriad	49.91	63
UNCHANGED		
Quest	61.75	0
DOWN		
Dianon	43.90	-13
Impath	33.71	-2
LabCorp	79.85	-1
PharmChem	1.00	-33
Specialty	24.30	-10
Unilab	19.30	-30
UroCor	16.90	-4

INDUSTRY buzz

Laboratories are counting on technology to improve efficiency…On-site real-time surveys of participants at the 19th annual Lab Institute, sponsored by Washington G-2 Reports on Oct. 24-27 in Arlington, VA, revealed that the nation's laboratories are counting on technology (*e.g.*, automation, the Internet, etc.) to improve efficiency. Using hand-held wireless polling devices, 28% of 213 respondents (most of them from hospital labs) cited "better use of technology" as the most important trend that will affect their laboratory over the next 2-3 years.

What's the most important trend that will affect your lab over the next 2-3 years?

Improve efficiency through better use of technology	28%
Expand genomics & specialty testing	20%
Expand total test volume	17%
Partner with other labs	14%
More rational pricing	10%
Selective acquisitions	8%
Growth in anatomic pathology	3%

Source: Lab Institute 2001 Poll. N=213.

In a separate poll, 26% of respondents (n=137) said their lab currently offers either Internet-based lab test ordering or results reporting or both; 52% said they don't currently offer Internet-based services, but had started considering their options to do so. Only 22% said they do not currently offer Internet-based services and had no immediate plans to do so.

References in this issue

Abbott Labs 847-937-6100

ACOG 202-638-5577

Athena Diagnostics 800-394-4493

Bio-Reference Labs 201-791-2600

Genzyme Genetics 508-872-8400

MedPlus 513-583-0500

Medtox 651-636-7466

Myriad Genetics 801-584-3600

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