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# LABORATORY INDUSTRY REPORT®

Dennis W. Weissman, Publisher

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## HIGHLIGHTS



WASHINGTON G-2 REPORTS

## "Lack of Strategic Vision" Cited As Biggest Barrier To Growth For Labs

Thirty-eight percent of 119 participants in an on-site survey at Washington G-2 Reports' recent Lab Institute said the biggest obstacle their company faces in growing its business is "lack of strategic vision." The next most frequently cited barrier to growth was "managed care penetration" (21%), followed by "lack of capital" (17%) and "pricing levels" (13%). Surprisingly, only 7% cited "government interference" as the top barrier—perhaps a sign that the lab industry has grown accustomed to the substantial government scrutiny it has received over the past 10 years.

With these survey results in hand and the New Year upon us, *Laboratory Industry Report (LIR)* thought it fitting to gather some insights on the outlook for the industry. Highlights of our exclusive interviews with chief executives from 10 of the Nation's largest commercial and hospital labs are featured in *Inside The Lab Industry*, pp. 5-9.

**What is the biggest barrier your company faces today in growing its business?**

| | |
|---|---|
| Lack of strategic vision | 38% |
| Managed care penetration | 21% |
| Lack of capital | 17% |
| Pricing levels | 13% |
| Government interference | 7% |
| Industry overcapacity | 4% |

n=119 (53% hospital lab directors and managers; 28% commercial lab; 19% other)
Source: Lab Institute 2000 Survey

## Quest Launches Direct Access Testing Pilots

Quest Diagnostics (Teterboro, NJ) has launched pilot programs for direct access testing in three midwestern states, *LIR* has learned. Under the program (dubbed Quest Direct—health testing you choose), consumers may walk in to select Quest patient service centers in Colorado, Kansas, and Montana and order a wide range of diagnostic tests without a physician's authorization. For example, according to a Quest Direct marketing brochure, Quest is offering a heart risk panel (cholesterol, triglycerides, HDL, and LDL) for $40; a diabetes screen (glucose and hemoglobin A1c) for $40; and a pregnancy test (blood) for $30.

*Continued on page 2*

**Quest Launches Direct Access Testing Pilots**, *from page 1*

Under Quest Direct, all tests are paid for directly by the customer (cash, checks, and credit cards are accepted). The customer generally receives test results in the mail within a week. Unless required by law (as in the case of some communicable diseases that must be reported to a state's health department), Quest sends the results to the consumer only.

Company chairman Kenneth Freeman would not comment specifically on the pilot program. He did tell *LIR*, however, that he continues to believe that over the next few years consumers will take increasing responsibility for managing their own healthcare. "A whole new industry is being created," says Freeman. He notes that one of the biggest challenges to growth in direct access testing is current state regulation. Of the 50 states, plus Puerto Rico and the District of Columbia, only half allow patient direct authorization of laboratory testing in some shape or form, including Colorado, Kansas, and Montana. Of the 11 most populous states, only two—Texas and Ohio—have no laws or regulations that specifically prohibit labs from performing tests based only on the request of an individual (*LIR, March '00, p. 4*).

## Sample Test Menu From Quest Direct

| | | | |
|---|---|---|---|
| ***Women's Health Profile ... $115*** | ***Men's Health Profile .... $115*** | ***Heart Risk Panel ... $40*** | ***Lyme Disease Confirmation ..... $110*** |
| Chem Screen | Chem Screen | Cholesterol | Borrelia burgdorferi Ab |
| HDL | HDL | Triglycerides | Western Blot reflex |
| LDL | LDL | HDL | |
| TSH | Coronary Risk Ratio | LDL | ***HIV (Home Test) ..... $50*** |
| Hemoglobin A1c | TSH | | ***Occult Blood (Home Test) ..... $50*** |
| Iron/IBC/Percent Transferrin Sat./Ferritin | Hemoglobin A1c | ***Diabetes Screen .... $40*** | ***Pregnancy Test ..... $30*** |
| CBC | Iron/IBC/Percent Transferrin Sat./Ferritin | Glucose | ***PSA ..... $45*** |
| Urinalysis | CBC | Hemoglobin A1c | ***Urinalysis ..... $20*** |
| | Urinalysis | | |

# Genelex To Offer Drug Response Gene Test To Consumers

*"I guess we took a little bit of a risk in doing this, but it's an important test"—Kenneth Coleman, Genelex chief executive*

Genelex Corp. (Seattle, WA), a privately held genetic testing laboratory with 25 employees, has begun offering drug response gene tests (a.k.a. pharmacogenetics) directly to the public. Its first offering is a screen for the CYP2D6 drug-metabolizing enzyme. The oral swab collection kit ($95 per kit) may be ordered via telephone or fax; an Internet ordering site is under development.

Prescription drugs that CYP2D6 is believed to metabolize include Prozac, Paxil, Zoloft, Effexor, Hydrocodone, and Risperdel; over-the-counter drugs include Allegria, Dytuss, and Tusstat. The CYP2D6 screen determines how fast an individual metabolizes these drugs. Slow metabolism may lead to dangerous toxic buildup in a patient's system; super-fast metabolism may limit or cancel the drug's effect by eliminating it from the body before it has time to act.

Genelex is offering the test directly to consumers despite the fact that the Food & Drug Administration has approved neither the test nor the collection kit. Company chief executive Howard Coleman claims that because the test is intended for informational purposes (not diagnostic), it falls outside FDA supervision.

## The Lab Opens 2 More Direct Access Testing Centers

*"Just like people choose Federal Express for peace of mind, knowing it will get there, they will pay to know about current and potential medical conditions"—David Carrozza, owner and president, The Lab*

The Lab (Folsom, CA), a privately held company, has opened two new direct-to-consumer lab testing centers within the past 12 months in physician office complexes in Carmichael and Folsom. The company now operates six retail lab facilities in the Sacramento area, including three at strip shopping malls and three at physician office complexes.

In total, The Lab handles approximately 120 requisitions per day, including 30-40 from self-referring customers, says the company's owner and president, David Carrozza. In California, consumers are able to order four tests (occult blood, pregnancy, glucose, and cholesterol) without a physician's authorization. The Lab charges consumers $10 for each self-ordered test. The most popular is cholesterol, says Carrozza; the next most popular is for pregnancy. The allure of self-authorized customers is up-front payment. In contrast, Carrozza says, "I might bill an insurance company, get paid 45 days later, and get only 20 cents on the dollar."

Carrozza notes that there are nearly 80 million baby boomers heading for the age 50+ category where demand for healthcare services grows. "Just like people choose Federal Express for peace of mind, knowing it will get there, they will pay to know about current and potential medical conditions," he believes.

## Aetna To Relax Medical Cost Management Practices

Aetna Inc. (Hartford, CT) has announced plans to relax the medical cost management policies contained in its contracts with physicians in California, Florida, and New Jersey, effective Jan. 1, 2001. The changes, which will be implemented in additional states over time, include eliminating the need for physicians to get approval from Aetna administrators before referring patients for laboratory services. "Aetna has had a contentious relationship with doctors in the past, and maybe there's a way out of this—not only in California, but across the Nation," said John Rowe, MD, Aetna chief executive, in a Dec. 18 conference call announcing the new policies.

**Promised Reforms At Aetna**

- ❑ *Physicians will have the option to elect to participate in all Aetna products, HMO-based products only, or PPO-based products only.*
- ❑ *Patients with certain serious or chronic conditions will have the option of using specialists as their primary physician.*
- ❑ *Obtaining pre-approval from Aetna administrators for laboratory service referrals will be eliminated.*
- ❑ *Overall improvements will be made in the efficiency of claim and member service processes to "reduce administrative hassles and get it right the first time."*

Source: Aetna Inc.

Patrick Finnegan, an HMO analyst at Moody's Investors Service (New York City), says the changes are likely to result in higher utilization of medical services by Aetna patients. "It's a favorable development for the company in terms of mending its relationships with physicians and improving its perception among consumers," he adds.

Aetna, which acquired Prudential Health in July 1999, is the Nation's largest health insurance provider with a total of 19 million members, including 8.8 million HMO and POS members. However, the company's membership has declined by about 1.5 million since the end of 1999 because of steep premium hikes (*e.g.*, 11% to 13%, effective Jan. 1, 2001) and poor provider relations. Quest Diagnostics and Laboratory Corp. of America each have national preferred provider agreements with Aetna.

## Dynacare To Offer National Genetic Testing Services

*Growth at Dynagene will be achieved by a combination of acquisitions and expansion into molecular testing and cancer diagnostics, says Kevin Pishkar, president*

Dynacare (Toronto, Canada and Dallas, TX) has formed a new division named Dynagene (Houston, TX) that will serve as a national provider of genetic testing services. Kevin Pishkar, formerly with Specialty Laboratories in Santa Monica, CA, has become president and CEO of the division. Pishkar is aiming to double Dynagene's current business over the next 12 months.

Dynagene currently generates approximately $8 million in annual revenue from laboratories in Houston (65 employees) and Seattle, WA (25 employees). The Houston lab—a new 11,000 square-foot facility—was formed by the consolidation of Laboratories for Genetic Services (acquired in December 1999) and cytogenetic testing operations at Hermann Hospital. Dynagene's Seattle operations include an 8,000 square-foot cytogenetic testing lab on the campus of Swedish Medical Center.

Separately, Dynacare has acquired Olympic Medical Laboratories (Bremerton, WA) and Shoals Medical Laboratory (Muscle Shoals, AL). The two labs represent combined annual revenue of approximately $8 million. Dynacare also has completed a laboratory partnership with Allegheny General Hospital (Pittsburgh, PA), which is part of the West Penn Allegheny Health System (*LIR, Oct.'00, p. 2*).

## TriCore Responds To Alleged QC, Financial Troubles

*None of the three hospital partners in the lab consolidation has any plans of pulling out of the venture, says TriCore president and chief executive Linda Cole*

Outcries from disgruntled employees at TriCore Reference Laboratories (Albuquerque, NM) were the source of a scathing article in the Dec. 24 *Albuquerque Journal* that focused on quality control and financial problems at the hospital lab venture, *LIR* has learned. Former and current employees fed the local paper with internal documents that showed TriCore lost $462,000 in 1999 and is projected to have lost another $190,000 in 2000. In addition, cost per test at TriCore increased 13% in 1999 and another 2.8% through July 2000, according to the paper.

Linda Cole, PhD, president and chief executive at TriCore, tells *LIR* that the consolidation of labs involving Presbyterian Hospital, University of New Mexico Hospital (UNMH), both in Albuquerque, and St. Vincent's Hospital in Santa Fe has been more difficult than initially planned. Among the challenges: integration of all three hospitals onto a new Sunquest laboratory information system, coupled with rising employee costs. "Marrying divergent cultures is difficult," adds Carmelita Lovett, vice president of consulting services at Chi Laboratory Systems (Ann Arbor, MI), which helped TriCore form its initial business plan. Cole says that while cost per test has risen, the increase would have been greater if not for TriCore.

TriCore, formed in 1998, operates a 30,000 square-foot core clinical lab and a 35,000 square-foot anatomic pathology/administrative facility in Albuquerque. It also manages two rapid response labs at Presbyterian plus a rapid response and specialty testing facility at UNMH. St. Vincent's handles its own rapid response lab, but sends non-time sensitive testing to TriCore. Altogether, TriCore employs 590 FTEs, handles 3.4 million tests per year, and generates $45 million in net annual revenue, according to Cole.

# Outlook For Labs In 2001: *Perspectives Of 10 Top CEOs*

To get a firsthand picture of what may be in store for the clinical laboratory industry this year, *LIR* interviewed the top executives at 10 of the Nation's largest commercial and hospital laboratories.

Industry trends we gleaned from these conversations include the desire of all labs to increase their share in the molecular and genetic testing market. In terms of pricing, capitated lab contracts are either moving dramatically higher or being converted to non-exclusive fee-for-service contracts. Other than Pap smear reimbursement, however, there has been little appreciable change in fee-for-service rates. Another trend is the shift away from joint ventures between commercial labs and hospitals; more and more frequently, they are choosing to collaborate through shared service agreements instead.

**Here are highlights from our exclusive interviews:**

**KENNETH FREEMAN**, chairman of Quest Diagnostics (Teterboro, NJ): "We'll remain extremely tough on price. We're prepared to continue to walk away from arrangements that don't make economic sense." Despite this tough negotiating stance, Freeman expects Quest's lab test volume to grow in line with industry rates—or 3-4% annually. "New business opportunities" will also add to topline growth, including Quest's foray into direct-to-consumer testing (*see p. 1*).

Freeman says that 2000 represented the fourth consecutive year that Quest raised its average revenue per requisition, following five straight years of decline. Part of the increase in revenue per requisition (currently estimated at $30-32) has come from the transition of several exclusive capitated contracts to non-exclusive fee-for-service arrangements, he notes. In addition, Quest now generates approximately $200 million per year from gene-based testing—a segment growing more than 25% annually at Quest, according to Freeman.

## Common Trends Identified By CEOs

- ❑ Nearly all hospital and commercial labs want a piece of the genetic testing market
- ❑ Pricing for capitated lab contracts has improved
- ❑ Fee-for-service reimbursement from managed care payers is flat
- ❑ Quest, LabCorp eschew joint ventures, seek shared service agreements with hospital labs
- ❑ Lab employees are in short supply, and salaries are rising
- ❑ Internet lab test ordering and results reporting can save costs, but physician office use is not guaranteed

Office-based physicians are integrating the Internet into their practices at a slow rate, Freeman notes. "In some parts of the country, there are still physicians who won't even accept a faxed copy of lab test results." But labs are limited, he observes, in what they can do to encourage physician use of the Internet (*e.g.,* paying for a DSL line) because of inducement prohibitions. "We will offer Internet-enabled processes, but in the end, physicians themselves have to make the decision to use the Internet."

Freeman expects Quest to complete all its planned lab consolidations by March 31, 2001. Standardization of billing practices and integration of information systems at Quest and the former SBCL are "on track and ongoing."

**MICHAEL O'CONNELL, MD**, director of regional reference laboratories for the Southern California Permanente Medical Group (SCPMG—North Hollywood), says the group is seeking to expand its esoteric testing business to SCPMG-owned hospitals and physician offices as well as non-SCPMG facilities.

SCPMG, which is part of Kaiser Permanente (Oakland, CA), operates two core lab facilities (80,000 and 100,000 square feet) on a 15-acre medical campus in North Hollywood. It also runs a 25,000 square-foot genetic testing and endocrinology lab in Glendale. "We'd like to [tap] some of the unused capacity at Glendale," says O'Connell.

In total, the three facilities employ more than 450 FTEs and handle nearly 50% (or 11 million tests per year) of the lab work for Kaiser's 2.9 million HMO members in southern California. The remaining 11+ million tests are run by labs at Kaiser/SCPMG's 11 hospitals in southern California.

SCPMG sends out less than 3% of its lab work, O'Connell says. American Medical Laboratories (Chantilly, VA) handles nearly all of Kaiser's reference testing specimens under a national contract that took effect in September 1999.

To help solve a lab employee crunch, O'Connell says Kaiser is underwriting a new histotechnology program at Mt. San Antonio Community College (Walnut, CA). Also, in 1999, SCPMG installed front-end automation equipment from Labotix (Peterborough, Ontario, Canada) at its 100,000 square-foot facility in North Hollywood, and it has "proven to be very cost-effective."

O'Connell says Kaiser/SCPMG is making a big push to integrate laboratory, pharmacy, and radiology data into an electronic medical record. "We want to add value to lab test results reports we send to physicians by adding follow-up test suggestions, 'most likely' diagnoses, and possible treatments."

**THOMAS MAC MAHON**, chairman of Laboratory Corp. of America (Burlington, NC): "I'm comfortable being a follower in terms of the Internet [*i.e.,* test ordering and results reporting], but I want to be the leader in molecular and genetic testing … There have been a remarkable number of new tests introduced in the past four years … Success will come to those companies that can drive through higher-margin tests. …That's where we are spending our resources."

In general, Mac Mahon believes the transition of lab test ordering and results reporting to Internet-based systems will proceed slowly. "The Internet and laptop computers are simply not part of the way that physicians practice medicine today … Most physicians are comfortable with the way things are and are too busy to make major adjustments."

In terms of commercial/hospital lab partnerships: "We used to want to take over all [hospital lab] management. Now, we are entering into 'trading relationships,' where we send a hospital our routine work and it gives us its esoteric tests." Closing these deals is a very slow process, he says. He expects LabCorp to sign 4-6 shared service agreements per year.

Mac Mahon anticipates that LabCorp's average revenue per requisition will increase by about 2-3% this year, driven by price increases and a mix shift toward more esoteric work. "We don't like the concept of capitation, but in some cases it makes sense." A key to negotiating contracts is "carving out newer, [more expensive] esoteric tests."

In terms of mergers and acquisitions, Mac Mahon says: "You can expect us to continue to make acquisitions with an emphasis on esoteric labs and routine labs in select regions of the country."

**MICHAEL SNYDER, MD**, chairman of the department of hospital laboratories at UMass/Memorial (Worcester, MA), says Memorial Hospital and the University of Massachusetts Medical Center recently opened a newly renovated 38,000 square-foot core lab on the UMass campus at a cost of $8.5 million. Memorial maintains a rapid response lab, but has shifted all non-time sensitive tests to the new core lab, which opened in May 2000. The core lab also receives reference work from five community hospitals owned by UMass/Memorial.

In total, UMass/Memorial (core and Memorial rapid response lab only) employs 240 FTEs and conducts 6.218 million billable tests per year, of which 38-40% are outreach, according to Snyder.

UMass/Memorial has installed an Internet-based lab test ordering system from Metricom (Weymouth, MA) at 13 of its affiliated physician offices. According to Snyder, most of the offices have a UMass/Memorial-employed phlebotomist on staff so usage of the new ordering system is guaranteed. Interfaces with additional physician offices plus introduction of Internet-based results reporting are high priorities for the coming year, he says.

Outreach testing contributed $12 million in net revenue to UMass/Memorial hospital labs last year, and Snyder is seeking to raise that sum to $14 million this year. He's hoping that new Internet-based systems will be a key factor in gaining new physician clients. The push to expand outreach volume is being driven by inpatient test volume declines of 5-7% per year, he notes.

Snyder says one of his biggest challenges is finding lab employees. There are 20 lab FTE positions open at UMass/Memorial despite its use of sign-on bonuses and a national advertising campaign.

**TIMOTHY SOTOS**, chairman, Clinical Reference Laboratories (CRL-Lenexa, KS): "Every lab out there wants to shift to higher-margin genetic testing. But every new test must answer the following question, 'Will it help improve the health of the consumer in a cost-effective manner?'" He expects many new tests to fail the cost/benefit formulae used by reimbursement analysts at Medicare and managed care companies. "We plan to offer new genetic tests, but we're not hanging the future of the company on them … Remember, it took 10-15 years for PSA to become regularly used as a screening test."

Separately, Sotos says that providing value-added services is the key to gaining and keeping customers and to eliminating the perception that laboratory testing is a commodity. For example, in addition to individual test results, CRL provides its life insurance and corporate drug testing customers with trend analyses for their specific populations.

CRL, a privately held company, employs approximately 400 FTEs at its 100,000 square-foot lab in Lenexa, located just outside Kansas City, MO. The company performs more than three million tests per year with an emphasis on the life insurance, substance abuse, and clinical research and trials markets.

**ROBERT DE CRESCE, MD**, chairman of pathology at Rush Presbyterian-St. Luke's Medical Center (Chicago, IL): "The laboratory industry is far better than it was a few years ago. Managed care exclusivity has loosened up, especially for time-sensitive tests, and prices have stopped going down."

De Cresce believes that after years of decline, inpatient test volume trends have stabilized. "There's only so much you can do on an outpatient basis … If you get admitted to a hospital today, you have to be very, very sick."

In the coming 12 months, De Cresce says Rush will seek to expand its specialty hema-

tology and genetic testing business. But he's not planning to significantly expand Rush's current outreach business, which is focused on local physicians on staff at Rush. "We're not going to be hiring sales reps and knocking on doors … It's tough competing against well integrated commercial labs."

On the prospects for direct access testing, De Cresce says the potential market consists of "worried, wealthy, and willing-to-pay consumers … It's not a huge market, but it's likely to develop if the service is easy and accessible."

Regarding personnel shortages, De Cresce says Rush has had its greatest difficulty in finding couriers and client service employees. "A lot of different companies are drawing from this group … We've moved our pay scales up, but there aren't a lot of people out there to hire, regardless of how much you pay."

The Rush laboratory employs 260 FTEs and conducts approximately 2.5 million billable tests per year. De Cresce says Rush is discussing various lab partnerships/shared service agreements with University of Illinois Hospital and Cook County (both in Chicago), but no decisions have yet been reached.

**ROBERT WHALEN**, president, Unilab (Tarzana, CA), says the disruption caused by bankruptcies at a number of large independent practice associations in California is leading consumers to switch from capitated HMO plans to fee-for-service PPOs. "Over time, this will provide for a more favorable laboratory reimbursement environment," he observes.

Whalen also notes that new safety needle laws, medical waste regulations, and a shortage of phlebotomists are causing more physician offices to stop drawing blood samples. As a result, more and more patients are being referred to independent lab facilities and hospitals for phlebotomy as well as lab testing services. "We draw half of the 50,000 specimens we test each night … One-third of my employees are phlebotomists … We've begun asking payers to reimburse us for this service."

Whalen expects the rate of deal-making between hospitals and commercial labs to accelerate. "It's taken some time, but hospitals are coming around to the view that partnering with a commercial lab may make sense … The sales cycle is lengthy, but the resulting contracts can be big."

Unilab is introducing a proprietary Web-based system for reporting lab test results to physicians this month. However, Whalen says lab order entry via the Web is a tough sell to physicians who are used to simply checking off a box on a hard copy requisition form. Unilab, which performs over 1.5 million Pap tests per year, will also roll out Cytyc's ThinPrep system in 2001, he says.

**JACK FINN**, chief executive, Centrex Clinical Laboratories (New Hartford, NY): "Our last round of negotiations [with managed care companies] resulted in much more reasonable contracts." Finn says capitated lab contracts in central New York that went as low as $0.50 per-member per-month have risen to roughly $1.50-$2.00 PMPM. "They're still not as high as they need to be, but they're getting there."

Centrex is a for-profit corporation owned by Faxton St. Luke's Healthcare (Utica, NY). The company manages a core lab at St. Luke's Hospital as well as stat labs at Faxton Hospital and Little Falls Hospital—all located in upstate New York in the Utica/Syracuse area. Centrex employs 350 FTEs and last year performed approximately 2.7 million billable tests (two-thirds from outreach). Centrex receives about 15-20% of its testing volume and about 10% of its $26 million in annual revenue from capitated contracts. Finn says Centrex is currently helping to form another lab network in Albany, NY.

According to Finn, Centrex has grown its top line by 10+% in each of the past two years. As a result of growth plus a shortage of lab personnel, the company plans to break ground this spring on a new facility (22,000 to 25,000 square feet) that will include a front-end automation system and possibly automated chemistry and hematology analyzers.

**JACK SHAW**, executive director, Joint Venture Hospital Laboratories (JVHL—Allen Park, MI): "Hospital lab networks are on the upswing. The initial organization is difficult, but the opportunity to capture market share is out there … HMOs want outpatient and physician office lab data, and hospital labs are in the best position to provide it."

JVHL, which includes more than 75 hospital-based labs throughout Michigan, won an exclusive statewide capitated contract to provide lab services to 610,000 managed care lives served by Blue Care Network of Michigan, effective last April. Shaw says the contract covers all testing ordered by physician offices, but excludes testing at ambulatory surgery centers, nursing homes, renal dialysis centers, and hospital emergency departments. JVHL is financially responsible for any physician office tests that are sent outside the network. The capitation payment is equal to about $1.75-$2.00 PMPM (or roughly $13.5 million in annual revenue), according to Shaw. In total, JVHL has more than a dozen contracts, and approximately two-thirds of its business is capitated. Shaw says the key to success is having good utilization data, negotiating an initial PMPM rate "that doesn't kill you," and having a wide network to limit leakage. JVHL, which has eight employees, collects 7% of network revenue for administrative costs.

Shaw says JVHL is considering expansion into Ohio and Indiana. "Hospitals that are subcontracting with commercial labs [for physician office work] in their markets are asking, 'Why not keep all of it for ourselves?'"

**THOMAS TIFFANY, PHD**, chief executive, Pathology Associates Medical Laboratories (Spokane, WA): "Finance people can create business plans showing that a partnership between a commercial lab and a hospital lab will work financially. But the hospital environment for inpatient testing and the commercial lab focus on outreach involve very different cultures and acumen. Mixing these cultures can be very difficult." In general, he expects new commercial/hospital lab partnerships to continue to be formed, but sees no great acceleration of the trend.

In terms of pricing, Tiffany says, "I've seen some ease in pricing pressure, but there are still some labs in the Northwest competing for capitated contracts at considerably less than $1 per-member per-month."

*"We were all busy figuring out what we [laboratories] want from the Internet. We need to figure out what our physician clients want." —Thomas Tiffany , Pathology Associates Medical Labs*

Goals for PAML this year, according to Tiffany, include the roll out of an Internet-based system for lab order entry and results reporting. E-health vendor Pointshare (Bellevue, WA) has helped PAML develop the system.

Tiffany says he has noticed that after years of decline, there is an upturn in inpatient testing volume, particularly in emergency room and trauma service testing. PAML, a for-profit subsidiary of Sacred Heart Medical Center (Spokane), provides reference testing and management services to hospital laboratory networks in Seattle and Spokane as well as in Idaho.

# Medicare Denies 15% Of Highest Volume Lab Claims, IOM Study Shows

Fifteen percent of claims for the 100 highest volume Medicare outpatient laboratory codes were denied by carriers in 1998, primarily related to medical necessity, according to data in a new, congressionally mandated Institute of Medicine report on Medicare laboratory payment policy. One of the most frequently denied was CPT 84153 (prostate-specific antigen, total): 1.472 million PSA claims, or 31%, were rejected. That code alone represented $37.4 million in uncollected annual revenue for labs (1.472 million unpaid claims times the national fee cap of $25.42).

"Experience has shown that the use of ICD-9 diagnosis codes is not a sound basis for making judgments regarding the medical necessity of a particular laboratory test … in many circumstances, it is likely to give the wrong answer," according to the IOM report. "Moreover, the current system is easily gamed, is administratively burdensome, and does not place sufficient responsibility on the physician." (Note: The ICD-9 diagnosis code is a five-digit number describing the diagnosis or symptoms of a patient.)

Christopher Young, president of Laboratory Management Support Systems (Phoenix, AZ), says the report understates the actual number of claims denied. Since 1998, Medicare's emphasis on compliance has "made it clear that you're not supposed to submit claims unless you have medical necessity documented, so a lot of tests got written off. They were never submitted to Medicare. If the [IOM study] committee had the real numbers in front of it, members would be horrified, not just concerned."

Not surprisingly, the IOM study recommends that the Health Care Financing Administration discontinue use of ICD-9 diagnosis codes as the basis for determining the medical necessity of lab tests. An alternative suggested: develop methods for holding physicians financially accountable for claims determined to be medically unnecessary.

## Sample Medicare Carrier Denial Rates, 1998

| *Code* | *Procedure* | *Total Claims* | *Percent Denied* |
|---|---|---|---|
| G0001 | Venipuncture | 54,308,311 | 7% |
| 80061 | Lipid panel | 10,012,394 | 19% |
| 85025 | Automated hemogram | 13,484,091 | 21% |
| 84443 | TSH | 5,871,658 | 22% |
| 80054 | Comp metabolic panel | 10,290,202 | 8% |
| 85024 | Automated hemogram | 8,662,269 | 15% |
| 84153 | PSA, total | 4,756,531 | 31% |
| 80092 | Thyroid panel w/TSH | 2,534,185 | 22% |
| 85610 | Prothrombin time | 14,291,139 | 12% |
| 83036 | Glycated hemoglobin | 5,066,357 | 18% |
| 81000 | Urinalysis, non-auto w/scope | 10,333,195 | 11% |
| 82728 | Ferritin | 1,676,425 | 28% |
| 83540 | Iron | 3,125,180 | 34% |
| Total Top 100 CPT Codes | | 266,287,495 | 15% |

Source: *Medical Laboratory Payment Policy*, Institute of Medicine, December 2000

# Lab Stocks Jump 155% In 2000; Quest Up 365%, LabCorp Up 261%

While the Nasdaq Composite Index plunged 39% and the S&P 500 sank 10%, laboratory stocks soared 155% in 2000, according to the G-2 Laboratory Stock Index. Last year's exceptional gain comes on top of the 105% increase in lab stocks in 1999. As a result, many lab companies now trade at 100+ times their annual net income and 2+ times annual revenue.

Quest Diagnostics (Teterboro, NJ) ended the year with the biggest market capitalization, $6.8 billion, after rising 365% to reach $142 per share. In the latest reported 12 months (ended Sept. 30, 2000), Quest generated net income of $62.19 million on revenue of $3.399 billion.

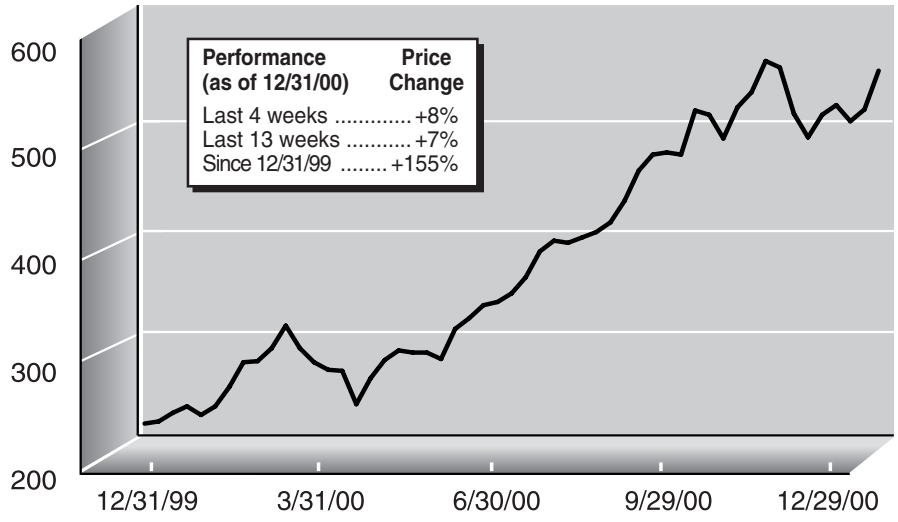
Shares of Impath (New York City) posted the biggest gain last year, vaulting 422% to $66.50 per share, giving it a market cap of $1.097 billion. In the latest reported 12 months, Impath generated net income of $10.936 million on revenue of $125.339 million.

Laboratory Corp. of America (Burlington, NC) ended 2000 with a market cap of $6.125 billion after its stock jumped 377% to reach $176 per share. In the latest reported 12 months, LabCorp generated net income of $57.4 million on revenue of $1.856 billion.

Shares of Myriad Genetics (Salt Lake City, UT) gained 260% to $82.75 per share in 2000, giving the company a market cap of $1.823 billion. In the latest reported 12 months, Myriad recorded a net loss of $8.6 million on revenue of $37.971 million.

Going public last year were two lab testing companies—Specialty Laboratories (Santa Monica, CA) and Dynacare (Toronto, Canada). A third, American Medical Laboratories (Chantilly, VA), is expected to complete its IPO early this year.

## G-2 Laboratory Stock Index




Source: The G-2 Laboratory Stock Index is tabulated weekly by *Laboratory Industry Report* from the average percentage change of 13 laboratory testing service stocks.

**% Price Change, 52 weeks ended 12/31/00**

**UP**

| | |
|---|---|
| AmeriPath | +205% |
| Cytyc | +105% |
| Dianon | +219% |
| Impath | +422% |
| LabCorp | +377% |
| MDS* | +6% |
| Myriad | +260% |
| Quest Diagnostics | +365% |
| UroCor | +104% |

**DOWN**

| | |
|---|---|
| Bio-Reference Labs | -50% |
| Lab*One* | –16% |
| Medtox | -29% |
| PharmChem | –4% |

*MDS began trading on the NYSE in April 2000. Reported price change is for the period 4/20/00 -12/31/00.

# INDUSTRY buzz

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Failure to act on abnormal lab test results can prove costly to doctors and insurers alike, a point underscored on Dec. 20, 2000, when a jury in King County (Seattle, WA) returned a unanimous record verdict in a medical malpractice case for delayed diagnosis of prostate cancer. Dan Peterson, MD, an internist from Yakima, was found negligent for not acting on rising abnormal PSA tests and ordered to pay $1 million to his patient Carl Pettijohn. Peterson's medical group was also ordered to pay $1 million and Pettijohn's HMO, Group Health Cooperative, $2.5 million. The total $4.5 million is the largest jury verdict ever in Washington State where a doctor's care was at issue.

According to the plaintiff, Peterson began screening Pettijohn in 1993 when the patient was age 52. The initial PSA reading was 2.5, rising to 3.7 in 1994, 4.0 in 1995, and 4.1 in 1996. Though the rising results were flagged as abnormal by the reporting medical lab, Pathology Associates Medical Labs (Spokane, WA), in 1995 and 1996, Peterson did nothing, according to Pettijohn's attorney Reed Schifferman of Lane Powell Spears Lubersky (Seattle, WA). *LIR* attempted to contact Peterson, but he was unavailable for comment.

In July 1998, Pettijohn referred himself to a urologist who performed a PSA test and got a result of 5.3. The cancer was found soon thereafter (both in and outside the prostate), and the prostate was surgically removed in December 1998. Today, Pettijohn is healthy, but Schifferman points out that the 2-4 year delay in a diagnosis has increased the risk of relapse from 20% to 80%. It should be noted that PAML's lab services in connection with this case were never in dispute.

## *References in this issue*

Aetna Inc. 860-273-0123

Centrex Labs 315-797-0791

Clinical Reference Labs 913-492-3652

Dynagene 713-798-9500

Genelex 800-523-3080

Impath 212-698-0300

Joint Venture Hospital Labs 313-271-3692

LabCorp 336-584-5171

Lane Powell Spears Lubersky 206-223-7954

Myriad Genetics 801-584-3600

Pathology Associates Medical Labs 509-926-2400

Quest Diagnostics 201-393-5000

Rush Presbyterian-St. Luke's Medical Center 312-942-5000

Kaiser Permanente 510-271-5910

The Lab 916-983-3522

TriCore 505-224-7999

UMass/Memorial 508-334-0280

Unilab 818-996-7300





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