Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT®

Dennis W. Weissman, Publisher

Vol. XII, No. 9/September 2003

HIGHLIGHTS

WASHINGTON G-2 REPORTS

Three Tests That Every Big Lab Should Consider Bringing In-House

Every big hospital and independent lab regularly checks its send-out test volumes looking for opportunities to cut costs by bringing tests in-house. The need to carefully review send-out testing trends has become an imperative, given that reference lab expenses now average more than $1 million per year at the nation's bigger labs (i.e., more than 1 million billable tests/year) and are growing by well over 10% per year, according to Washington G-2's newly published report: *U.S. Laboratory Reference Testing: Market Profile & Pricing Trends*.

With the above in mind, *LIR* recently analyzed a number of tests that bigger labs frequently send-out and came up with a short list of three tests that warrant strong consideration for bringing in-house. These include DNA-based HPV testing, cystic fibrosis genetic analysis, and lipoprotein subfractions. Recent recommendations from various medical professional groups have created growing demand for each of these tests, and reagent vendors are offering economically attractive systems for labs seeking to add them to their menus.

For the details, see *Inside The Laboratory Industry*, pp. 5-7.

Will Accounts Receivable Problems Sink Impath?

In news that underscores the importance of maintaining strong cash collection and billing management, Impath Inc. (New York City) has announced that its audit committee has begun an investigation into possible accounting irregularities involving its accounts receivable balance, which the company believes have been overstated.

The investigation is expected to lead to big write-offs in Impath's accounts receivables and has raised concern about the solvency of the company. In a recent press release, Impath stated that it "is considering all options to address its liquidity needs, including the commencement of a Chapter 11 [bankruptcy] case."

For years, Impath has maintained a bloated accounts receivable balance with an average collection cycle (or days in accounts receivable) of well over 100 days and bad-debt expense ranging from 15% to 20% of revenue, *LIR* observes.

➥ *p. 11*

Accounts Receivable Problems At Impath, *from page 1*

Impath says that given the preliminary stage of the investigation, it can not determine the financial impact but believes it will be significant. In addition, the company says its financial reports for the first quarter of this year, as well as the annual report for 2002 and prior periods, should not be relied upon by investors. As a result, the Nasdaq stock exchange delisted Impath shares on the morning of August 27—*see page 11*.

As of March 31, 2003, Impath reported an accounts receivable balance of $78.8 million with an average days in accounts receivable (DAR) of 156 days. For full-year 2002, Impath maintained a DAR of 134 days compared with 46 days at Quest Diagnostics, 57 days at LabCorp, and 69 days at AmeriPath.

Impath is also reviewing the value of its GeneBank tissue-and-serology archive, which will likely lead to more write offs.

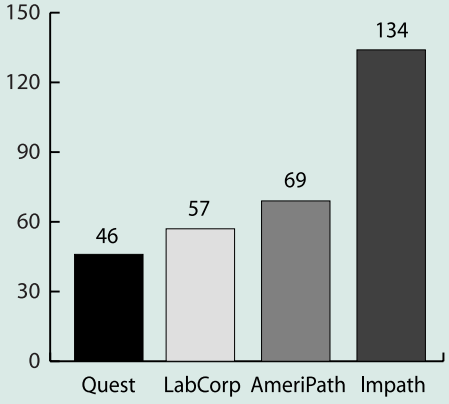
Most billing experts agree that a reasonable DAR for a lab business should fall in the range of 60 to 80 days, or roughly half of Impath's last reported figures. This suggests that as much as one-half of Impath's accounts receivable balance, or about $40 million, may need to be written off as bad debt, notes *LIR*.

An Impath spokeswoman declined to elaborate on possible problems with the company's accounts receivable, which will be restated following the audit investigation. But early last year red flags were raised by a Banc of America Securities report written by analyst Mark Miller (now with CS First Boston). In the report, Miller noted that Impath's poor collections are the consequence of its reluctance to negotiate discount-provider deals with managed care companies.

Miller noted that in many cases, Impath is working as an out-of-network provider and billing managed care companies at prices well above what it could reasonably expect to collect. Impath does not accept discounted payment from managed care companies as payment in full, but instead seeks payment for the remainder directly from patients (who are notoriously difficult to collect from).

Miller argued that as a result, Impath was billing for a lot more than it could reasonably expect to collect, booking all of it as revenue, and putting uncollected bills in its accounts receivable balance.

Average Days In Accounts Receivable At The Big Labs In 2002



Source: *LIR* from company financial reports

Meanwhile, Impath says that both its vice president of finance and corporate controller have resigned, effective immediately. Other management changes at Impath over the past year have included the resignation of its president and chief operating officer, Richard Adelson, in May (*see LIR, July 2003, p. 10*). In February, Carter Eckert was named chairman and chief executive, replacing Anu Saad, Ph.D., who stepped down following an internal review of expenses she submitted during the last three years (*see LIR, March 2003, p. 1*). In addition, the company's chief financial officer, David Cammarata resigned in May 2002, and *LIR* has learned that Joseph Durshaw, vice president of sales, also left the company within the past year.

Med Tech Labs Files For Chapter 11 Bankruptcy

Med Tech Labs (Clearwater, FL), a subsidiary and primary business of the publicly traded VitalLabs Inc., has filed for Chapter 11 bankruptcy reorganization and it looks like the company may be out of business for good. The phone lines to the offices at both VitalLabs and Med Tech Labs have been disconnected, and the company's 130 employees were all laid off earlier this year.

The company had operated a central lab in Clearwater and about 20 patient service centers that served hundreds of physician offices and nursing homes on the west coast of Florida. All of Med Tech Labs' clients and most employees have been transferred to two unnamed independent labs in Florida.

Med Tech Labs first gained the attention of *LIR* when it hired John R. Hadden as its chief executive last year. Hadden had been senior vice president of the national business development group at American Medical Laboratories, which was acquired by Quest in early 2002.

Hadden had hoped to build Med Tech Labs into a major commercial lab operation through acquisitions, and the company had even gone as far as to state a goal of $100 million in annual revenue by the end of 2003. But things didn't work out that way, and after less than a year on the job, Hadden resigned in February of this year.

As is the case with most labs that run into financial difficulty, Med Tech Labs had problems with its billing and collection systems. For the nine months ended Sept. 30, 2002, the latest date of available financial reports, the company recorded a net loss of $1.8 million on revenue of $5.2 million. Med Tech Labs' average days in accounts receivable for the period was a worrisome 100 days.

Med Tech Labs had a troubled history. It arose from Clearwater Clinical Laboratories, a company operated by James McKeown, Jr. and his father, James McKeown, Sr., that dissolved after they were charged with 68 counts of Medicare fraud, kickbacks, and conspiracy. The lab then changed hands a few times before winding up as the main subsidiary of VitalLabs with the new name: Med Tech Labs.

Med Tech Labs' bankruptcy filing showed a list of creditors owed a total of $1.4 million. The company's largest creditor is SCC Soft Computer (Palm Harbor, FL), a vendor of clinical information systems software, which is owed $125,460.

Esoteric Growth Offsets Sluggish Routine Testing At Big Labs

Mid-year financial results for Quest Diagnostics and LabCorp show each company posting strong revenue growth (driven by acquisitions) and increased profits. However, aside from acquisitions, both big labs seem to be having trouble growing their test volumes in the key routine physician office testing business. The saving grace for Quest and LabCorp has been their esoteric testing businesses, which are growing in the neighborhood of 15% to 20% per year and provide higher-than-average profits. A quick summary of mid-year results at each company is provided below.

Quest Diagnostics (Teterboro, NJ) reported net income of $208.4 million for the six months ended June 30, 2003, versus $153.8 million in the same period a year earlier; revenue climbed 15% to $2.3 billion. Revenue growth was fueled by the acquisitions of American Medical Laboratories (completed in March 2002) and Unilab (February 2003). After accounting for the effects of these acquisitions, Quest reports that its revenue growth was only 3%, comprised of a decrease in test volume of 1.6% offset by an increase in average revenue per requisition of 4% to 5%.

Quest attributes its declining test volumes to a number of factors, including physician strikes, bad weather, the Easter and Passover holidays, and "general economic weakness." Quest chairman Ken Freeman claims that the volume decline was not the result of any loss of clients.

Overall, Quest collected an estimated 65 million requisitions in the first six months of this year and generated average revenue of $34.22 per requisition (excluding clinical trials, kit manufacturing, and information technology revenues).

Among the bright spots at Quest is its esoteric testing (including gene-based testing), which is growing at roughly 15% annually and now represents 16% of the company's total revenue, or approximately $750 million per year.

In addition, Quest remains at the top of the lab industry in terms of its billing and collection efforts. Days in accounts receivable averaged 50 days for the first half of the year, with bad-debt expense at just 4.9% of revenue.

LabCorp (Burlington, NC) reported net income of $160.3 million for the six months ended June 30, 2003, versus $144.3 million in the same period a year earlier; revenue was up 21% to $1.5 billion.

Revenue growth was driven by the acquisitions of Dynacare (completed in July 2002) and Dianon (January 2003), as well as a number of smaller acquisitions including Cytology Screening Inc. (May 2002), Immunodiagnostic Labs (August 2002), and the northern California assets of Quest/Unilab (February 2003). After accounting for the effects of all of these acquisitions, *LIR* estimates that LabCorp's revenue growth was only about 4%, comprised of flat test volume growth and a 4% increase in its average revenue per requisition.

Overall, LabCorp collected an estimated 43.5 million requisitions, with an average revenue per requisition of $33.44. LabCorp's revenues are being pulled up by growth in its esoteric/genomics testing business, which now represents about 30% of the company's overall revenue and has an average revenue per requisition of $62.85.

In terms of billing and collection, LabCorp reports that its days in accounts receivable averaged 54 days for the first half of the year, with bad-debt expense at 7.7% of revenue.

Mid-Year Stats at Quest and LabCorp

(for six months ended 6/30/03)

	Quest	LabCorp
Revenue	$2,312,700,000	$1,455,900,000
Pretax income	352,200,000	271,700,000
Net income	208,400,000	160,300,000
Pretax margin	15.2%	18.7%
Net income margin	9.0%	11.0%
Requisitions	65,000,000	43,532,100
Revenue per requisition	$34.22	$33.44
Revenue per billable test*	13.69	13.38
Days in accounts receivable	50	54
Bad-debt expense	4.9%	7.7%

*Assumes 2.5 billable tests per requisition

Source: *LIR* from company reports

Is It Time To Bring HPV, CF, And Lipoprotein Subfractions In-House?

As every lab manager knows, one of the key ways to help curb reference expenses is to add higher-volume send-out tests to the in-house menu. The most common tests that higher-volume labs say they are adding to their menus this year include cystic fibrosis (CF) genetic analysis, HIV viral load, and parathyroid hormone (see table), according to Washington G-2's newly published report, *U.S. Laboratory Reference Testing: Market Profile & Pricing Trends*.

Higher-Volume Labs*:
Tests Expected To Be Brought In-House, 2003

Test	*% labs that will bring in-house*
Cystic fibrosis genetic analysis	18%
HIV viral load	16%
Parathyroid hormone	13%
Hepatitis C viral load	13%
B-type natriuretic peptide	8%
Lead, blood	8%
Factor V Leiden	8%
Hepatitis C genotyping	8%
High-sensitivity CRP	8%
DNA-based HPV testing	8%

*Based on 47 labs that each perform more than 1 million billable tests per year
Source: *U.S. Laboratory Reference Testing: Market Profile & Pricing Trends*

LIR observes that the number of labs seeking to add CF genetic analysis and DNA-based testing for human papillomavirus (HPV) is almost sure to grow, given recent screening recommendations issued by various influential medical advisory groups for each test. Given the growing interest in these two tests, *LIR* recently spoke with the vendors that manufacture them plus several labs that have recently brought CF genetic analysis and HPV testing in-house for some perspective on the economics behind these tests.

We also provide a thumbnail sketch on the economics behind lipoprotein subfraction testing, which is not among the top 10 tests that higher-volume labs are bringing in-house, but is becoming a growing send-out cost to labs nonetheless.

DNA-based testing for high-risk HPV types is rapidly becoming the standard of care as a follow-up to Pap tests with indeterminate results. Of the some 55 million Pap tests performed each year in the U.S., approximately 6% are found to have equivocal or abnormal results that require follow-up testing.

Clinical studies have shown that human papillomavirus (HPV) is the cause of 99% of cervical cancer cases.

Today, Digene Corp. (Gaithersburg, MD) is the only company on the market with an FDA-cleared HPV test. The company's Hybrid Capture2 High-Risk HPV test is currently used as a follow-up to more than half of all indeterminate Pap test results.

That means some 2 million Digene HPV tests are now being performed each year in this country. As a follow-up, the test is currently reimbursed by Medicare under CPT code 87621 with a national limit of $49.04. In addition, Digene says that its test (for follow-up purposes) is now reimbursed by health plans covering more than 200 million members in the U.S. with reimbursement ranging between $37 and $60 per test. And the major reference labs charge hospitals between $40 and $70 (after discounts) to perform the test.

The Digene Hybrid Capture analyzer system has a list price of $34,900, although the first labs to use the system got it for free, and several others that have installed it within the past 12 months say they paid around $30,000.

Three Tests To Bring In-House

Test	Reagent Cost Per Test	Reimbursement Per Test
DNA-based HPV testing	$20	$50
Cystic fibrosis genetic analysis	$40-$100	$200
Lipoprotein subfractions	$15	$35

Source: *LIR*

Digene sells reagents at a list price of $2,700 per 96-test kit (or $28 per test).

But after discounts, labs are paying closer to $20 per test. Assuming reimbursement to labs of $50 and a reagent cost of $20 per test, this leaves labs with a hefty $30 profit per test (before costs for labor and overhead).

More than 200 labs in the United States already offer Digene's HPV test, but a lot more will probably be adding it to their menus soon, given that it was recently cleared for expanded use by the FDA. In April, the FDA said the test could be used for cervical cancer screening in conjunction with a Pap test for any woman age 30 or older.

Furthermore, in July, the American College of Obstetricians and Gynecologists (ACOG) published new recommendations for cervical cancer screening that include the combined use of a Pap test and an FDA-approved test for high-risk HPV for women age 30 or older. ACOG says that if a woman tests negative on both, she should be rescreened with the combined tests no more frequently than every three years.

The combination of FDA approval plus the recommendation from ACOG and other organizations (see table below) has made HPV testing a must-have for most high-complexity labs, *LIR* observes. The next big boost will come when Medicare establishes a specific reimbursement policy for the "DNA Pap" (*i.e.*, combined Pap plus HPV test), which is expected to occur within a year or so. As a result, *LIR* estimates that the U.S. market for HPV testing could easily grow from its current 2 million tests annually to more than 10 million within the next three years.

Right now, Digene has the only FDA-cleared test for HPV, but Ventana Medical Systems is marketing analyte specific reagents (ASR) for a slide-based HPV test called "Inform," and Roche Diagnostics plans to have an ASR-based HPV test on the U.S. market next year

CF genetic analysis volumes have exploded since the ACOG issued guidelines in October 2001 recommending that all Caucasian women who are pregnant or considering having a baby be screened for the 25 most common gene mutations associated with cystic fibrosis.

Prior to the recommendation, CF testing was generally offered only to prospective parents with a family history of the disease; an estimated 100,000 to 200,000 CF tests were being performed each year in the United States. But that figure has now jumped to more than 1 million, reagent vendors tell *LIR*. And there's plenty of room for more growth given that four million babies are born in the United States each year (75% of them from Caucasian parents).

The majority of CF testing is performed by three reference labs—Quest Diagnostics, LabCorp, and Genzyme Genetics—which charge anywhere from $125 to $315 per test

with an average of about $200 per test (after discounts).

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.

CF is the most common serious genetic disease among Caucasians and results from a defective gene that causes the body to produce an abnormally thick, sticky mucus that builds up in the lungs and can lead to fatal infections.

There is no FDA-cleared CF test on the market today, but at least half-a-dozen IVD vendors sell ASR-based versions, among them are Roche Diagnostics, Abbott/Celera, Third Wave Technologies, Nanogen Inc., Orchid Biosciences, and Innogenetics.

Jake Orville, vice president of sales at Third Wave, says high-complexity labs that already have DNA extraction equipment (PCR amplification is not needed) and a standard fluorescent plate reader can run the company's ASR-based CF test with no need to purchase additional equipment. Third Wave sells reagents for its ASR-based CF tests at a list price of $50 per test (25 CF mutations) but after discounts the price is roughly $40 per test.

Labs should consider adding CF genetic analysis to their in-house menus once volumes reach 50 to 100 tests per month, according to Orville. One drawback to the Third Wave system had been that it only provides positive or negative results for CF and can not do full genotyping to identify the specific CF mutation for patients that test positive. But Orville says the company is now in the process of launching a full diagnostic CF test with genotyping.

There are other CF test systems on the market that can do full genotyping, but they require PCR amplification and are more expensive. For example, Nanogen just launched a CF test that runs on a system with a list price of $160,000. However, Bruce Huebner, chief executive of Nanogen, says the system is available on a reagent rental program at a reagent cost of $60 to $100 per CF test (depending on volume).

But *LIR* observes that the biggest barrier to bringing CF testing in-house may be deciding whether test results can be interpreted and signed off by a Ph.D. or M.D., or whether genetic testing requires the oversight of a certified medical geneticist.

As highlighted in the August 2003 issue of this newsletter, **lipoprotein subfraction testing** is starting to take off due to growing recognition of the limitations of traditional cholesterol tests. Right now only a handful of niche esoteric testing labs perform this type of test on a proprietary basis, including LipoScience, Atherotech, and Berkeley HeartLab Inc. But Quantimetrix Corp. (Redondo Beach, CA) manufactures an FDA-cleared test for lipoprotein subfraction testing called "Lipoprint."

Quantimetrix sells the analyzer system for Lipoprint at list price of $15,000 and reagents for $1,500 per 100-test pack (or $15 per test). The test is reimbursed by Medicare under CPT code 83716 at a national limit of $34.68.

LIR estimates that the market for lipoprotein subfraction testing now totals roughly $100 million per year in lab testing revenue and is growing well more than 30% annually.

Tips On Billing For Tests Sent Out To A Reference Lab

On July 30, Washington G-2 Reports held a special teleconference titled *"How To Reduce Your Lab's Reference Testing Expenses."* During the Q&A session, a question was raised regarding marking up prices for tests sent to a reference lab. This question was outside the scope of the faculty's area of expertise, so after the teleconference *LIR* hunted down the answer. Here's what we found out:

Medicare rules require hospitals to directly bill Medicare for outpatient lab claims, even if the tests were sent out to a reference lab, according to Rob Mazer, attorney at Ober, Kaler, Grimes & Shriver (Baltimore, MD). He says hospitals can bill their fiscal intermediary their "usual charge" for the test, which may exceed the amount paid to the reference lab. Mazer says that Medicare will reimburse the hospital either the amount billed or the Part B fee schedule rate, whichever is lower.

A lab decides what its usual charge is by analyzing various factors, including the market rate, says Mazer. Generally, the charge should be equal to or greater than what the highest-paying insurer would pay. For example, he says that if a Blue Cross plan will pay $120 for an HIV viral load, the hospital would not want its charge to be $115.

Yet in many cases reference labs charge far less than the Medicare Part B fee schedule for commonly sent-out tests (see table below). For example, the average price charged by the major reference labs for an antinuclear antibody (ANA) test is $8.21 versus a national Part B limit of $16.89. Theoretically, the discount arrangement between the reference lab and the independent or hospital lab can raise issues under the anti-kickback statute, but the discount safe harbor should be available, according to Mazer.

For non-Medicare work, state law applies regarding billing practices, according to Lale White, chief executive at Xifin (San Diego, CA), which provides accounts receivable and financial management services to labs. She cites California, Florida, Michigan, New York, and Oregon as states with anti-mark up laws. However, White says that labs in these and other states can charge a "reasonable" handling fee (*i.e.*, $10 to $20) to cover shipping and courier costs. She advises labs to bill this charge as a separate line item on their claims, but she adds that, while labs can bill for it, most managed care companies refuse to pay for handling charges.

Reference Lab Prices vs. Medicare Rates

Test Name	CPT Code	Reference Lab Avg.	Medicare Part B Natl Limit, 2003
Vitamin B12	82607	$10.35	$21.06
Hepatitis panel	86709, 86705, 86803, 87340	45.82	66.54
HIV antibody	86701	9.35	12.41
Chlamydia/GC DNA probe	87490 & 87590	16.66	56.04
Antinuclear antibody test (ANA)	86038	8.21	16.89
Folate	82746	9.23	20.54
HIV viral load	87536	109.79	118.89
Parathyroid hormone	83970	25.59	57.67
Hepatitis B surface antigen	87340	9.69	14.43
HCV viral load	87522	103.67	59.85

Source: *U.S. Laboratory Reference Testing: Market Profile & Pricing Trends*

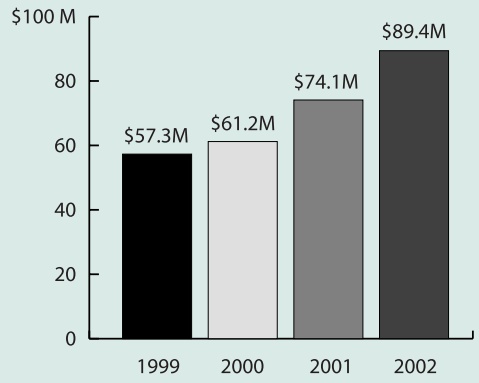
Genzyme Purchases Genetics Lab Business From GIVF

Genzyme Genetics (Westborough, MA), a business unit of Genzyme Corp. (Cambridge, MA), has acquired the molecular genetics and cytogenetics laboratory businesses of Genetics & IVF Institute (GIVF—Fairfax, VA). Financial terms of the acquisition, which was completed in July, were not disclosed.

The acquired GIVF lab businesses will be integrated into Genzyme Genetics' facilities in Massachusetts, New York, Florida, California, and New Mexico, according to Mara Aspinall, president of Genzyme Genetics.

Keith Blauer, M.D., president of the privately held GIVF, says his lab will continue to provide a wide range of infertility and genetic testing services, including in-vitro fertilization and specialty testing services such as molecular infectious disease testing, endocrinology, and DNA profiling used in identity testing, forensic analysis, and criminal databanking.

Genzyme Genetics' Annual Revenue



Source: Genzyme Genetics

Meanwhile, Aspinall says that Genzyme Genetics currently performs some 400,000 genetic tests per year, primarily in the area of cystic fibrosis genetic analysis and prenatal diagnosis of chromosome abnormalities. The company has a total of 700 employees, including 120 board-certified genetic counselors and medical geneticists. Last year, Genzyme Genetics reported $89.4 million of revenue, up 21% from $74.1 million in 2001.

Aspinall notes that Genzyme Genetics' cystic fibrosis genetic analysis tests for 87 mutations, far in excess of the 25 common mutations that most other labs test for. She says that expanded analysis catches more positive carriers, particularly in Hispanic and pan-ethnic groups.

Alfigen Buys East Coast Cytogenetics Lab

Alfigen Inc. (Pasadena, CA), a privately held company that specializes in genetic and esoteric testing, has announced the acquisition of Laboratory Diagnostics (Norwalk, CT), a cytogenetics lab with five employees.

Laboratory Diagnostics had been owned by a group of physician investors, who were not involved with the day-to-day operations of the lab. The purchase price was not disclosed. Ahmed Alfi, chairman of Alfigen, says the acquisition will allow Alfigen to better serve existing and new clients on the Northeast.

Meanwhile, after only one month on the job as chief executive of Alfigen, Jeff Lanzolatta has resigned over concern that his employment at Alfigen would conflict with responsibilities owed to his former employer Quest Diagnostics (see *LIR*, June 2003, p. 4). Prior to joining Alfigen, Lanzolatta had served as president of the southern California operations of Unilab, which was acquired by Quest earlier this year.

Expert Thoughts On The Potential Medicare Lab Co-Pay

For thoughts on the lab co-pay requirement contained in the Senate-passed Medicare reform bill now pending before a House-Senate conference committee, *LIR* sought out the opinions of three billing and collection experts plus Quest's Ken Freeman. Here's what they had to say:

John Leskiw, chief executive of Quadax Inc. (Cleveland, OH), says the economics of the potential lab co-pay are so terrible that, given the choice, many labs would probably opt to simply write it off as bad debt. However, he notes that this is not an option, and Medicare regulations require labs to send out at least one bill. But he believes a lot of labs will choose not to pursue co-pay collections with second or third billing statements. Furthermore, he says most collection agencies will not be willing to take on these low-dollar claims. As a result, he predicts that Medicare patients will learn that if they ignore the first bill, no one will go after them for payment.

Larry Peterson, president of Torrey Consulting Group (El Paso, TX), says that while the lab co-pay issue hasn't yet registered on the minds of most senior citizens, it will jolt them if and when they start getting the bills in the mail. Senior citizens are resistant to change and will be unwilling to pay for something that they've gotten free in the past, observes Peterson. He believes that the bad-debt expense for labs on any potential lab co-pay could wind up being as high as 50%. He also adds that the telephone time that the client service representatives will have to spend explaining the lab co-pay to Medicare recipients will not be a small expense. "You don't get off the phone quickly with the elderly," he adds.

Ten percent of Quest's 37,000 employees are connected with the company's billing and collection operations and LIR estimates that Quest spends an average of $1.50 to $3.00 on billing and collection per lab claim.

Lale White, chief executive at Xifin (San Diego, CA), says co-pay collection rates from Medicare beneficiaries with supplemental insurance will probably be substantially higher than those without secondary coverage. White says labs can set up systems under which their Medicare carriers will automatically and electronically forward lab co-pay bills to supplemental insurance companies. However, she notes that the time and money needed to set up these systems with each of the hundreds of supplemental insurance companies that do business in the U.S. will be substantial.

Ken Freeman, chairman of Quest Diagnostics (Teterboro, NJ), says, "I'm hopeful that the Medicare reform bill will fall under its own weight" given that the projected costs of the proposed plan keep rising. *LIR* observes that sponsors of the House and Senate versions each initially claimed their plans would cost about $400 billion over 10 years. But the Congressional Budget Office recently issued a report on the bills that estimated the Senate version would cost $432 billion and the House version would cost $425 billion.

Freeman believes a Medicare lab co-pay will have a disproportionate effect on smaller labs that don't have the same economies of scale as Quest. He says a co-pay could force some independent labs to choose not to participate in Medicare Part B or push them to sell out to a bigger commercial lab.

Lab Stocks Fall 6%; Nasdaq Delists Impath

Stock prices for the 11 companies in the G-2 Laboratory Index fell an unweighted average of 6% in the four weeks ended August 15, 2003, with six stocks declining in price and five rising. So far this year, lab stocks have risen 27%, while the S&P 500 is up 13%, and the Nasdaq is up 27%.

Shares of Impath had traded as high as $80 in late 2000 for a market cap of $1.3 billion. Now the company may be forced into Chapter 11 bankruptcy.

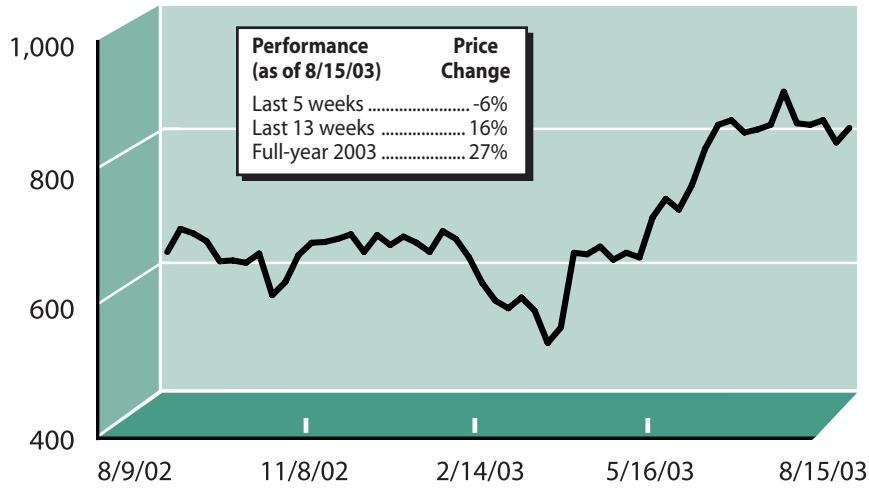
The Nasdaq Stock Market halted trading in shares of **Impath Inc.** (New York City) on the morning of July 30 after the company announced that it had initiated an investigation into possible accounting irregularities involving its accounts receivables (*see page 1*). Then, on August 27, Nasdaq delisted shares of Impath and the Securities & Exchange Commission announced it was investigating the company.

Immediately prior to the halt, Impath shares had been trading at $18.09 per share giving the company a market value of about $300 million. Andreas Dirnagl, analyst at the investment bank Harris Nesbitt Gerard (New York City) says the situation at Impath is "dire."

Dirnagl also notes that because Impath will need to restate its financial reports for the first quarter of 2003 and prior periods, the company has violated the terms of its loan agreements with its bank lenders. Impath currently has a total of about $61 million in bank debt outstanding and only $6 million in cash and liquid securities. In a worst-case scenario, Dirnagl says the banks could demand immediate repayment, thereby forcing Impath to sell off assets.

Meanwhile, sources tell *LIR* that the accounting irregularities at Impath may have first been discovered during the due diligence processes performed by several potential acquirers of the company, including the big venture capital firm, Welsh Carson (New York City), which completed the takeover of AmeriPath earlier 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 in the price of 14 laboratory testing service stocks.

% price change, 5 weeks ended 8/15/03

UP	Price	% Chg
Bio-Reference	7.51	4
Impath	18.09	1
LabCorp	31.37	0
LabOne	23.53	1
MDS	13.97	5
DOWN		
Enzo Biochem	18.95	-13
Medtox	6.22	-15
Myriad	13.89	-12
PharmChem	0.25	-17
Specialty	10.00	-9
Quest	59.31	-12

INDUSTRY buzz

Evidently, the state of Texas has become too small for Clinical Pathology Laboratories (CPL—Austin, TX), the largest privately held routine clinical lab in the nation. CPL has some 1,000-plus employees and estimated annual revenue of well over $125 million.

Until recently, CPL has been content to grow its business in the state of Texas by gaining market share from Quest and LabCorp and by acquiring smaller competitors throughout the state. But now the company has turned its attention to the rest of the southeastern United States. In June of this year, for example, CPL closed on its purchase of Fairfax Medical Laboratories (Chantilly, VA), a small lab located just outside of Washington, DC. In addition, CPL recently entered Oklahoma through the acquisition of a small lab in Midwest City (located near Oklahoma City). Finally, *LIR* hears that CPL is also aggressively expanding in Louisiana and Arkansas.

And CPL's expansion is sure to continue, given that it has the deep pockets of the venture capital firm Summit Partners behind it, *LIR* observes.

CPL and its president, David Schultz, have always tried to keep a low profile, but the company is now getting too big to ignore. "Schultz doesn't like to keep his cards close to his vest; he keeps them inside his vest," notes one industry consultant. "Unfortunately, we haven't been able to stay under the radar screen," Schultz recently told *LIR* in a rare and brief interview.

References in this issue

Alfigen 800-255-1616
Clinical Pathology Labs 512-873-1630
Digene 301-944-7000
Fairfax Medical Labs 703-222-2313
Genetics + IVF Institute 703-698-7355
Genzyme Genetics 800-255-7357
Impath 212-698-0300
LabCorp 336-584-5171
Nanogen 858-410-4600
Ober Kaler 410-347-7359
Quadax Inc. 440-777-6300
Quantimetrix 800-624-8380
Quest Diagnostics 201-393-5000
Third Wave 608-273-8933
Torrey Consulting Group 915-833-2294
Xifin 858-793-5700

Subscribers are invited to make periodic copies of sections of this newsletter for professional use. Systemic reproduction or routine distribution to others, electronically or in print, is an enforceable breach of intellectual property rights. G2 Reports offers easy and economic alternatives for subscribers who require multiple copies. For further information, contact Randy Cochran at 212-244-0360, ext. 640 (*rcochran@ioma.com*).

LIR Subscription Order or Renewal Form

❑ ***YES***, enter my one-year subscription to the ***Laboratory Industry Report (LIR)*** at the rate of $369/yr. Subscription includes the *LIR* newsletter, e-mail alerts, and yearly subject index. Subscribers outside the U.S. add $50 postal surcharge.

❑ Check enclosed (payable to Washington G-2 Reports)

❑ American Express ❑ VISA ❑ Mastercard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Name/Title _____

Company/Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

e-mail address _____

Mail To: Washington G-2 Reports, 29 W. 35th St., 5th Floor, New York, NY 10001-2299.
Or call 212-629-3679 and order via above credit cards or fax order to 212-564-0465. 9/03

© 2003 Washington G-2 Reports. All rights reserved. Reproduction in any form prohibited without express permission.

Laboratory Industry Report (ISSN 1060-5118) is published by Washington G-2 Reports, 1111 14th St NW, Ste 500, Washington, DC 20005-5663.
Tel: 202-789-1034. Fax: 202-289-4062. Order line: 212-629-3679. Website: *www.g2reports.com*

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 200.

Publisher: Dennis W. Weissman. Managing Editor: Jondavid Klipp, *labreporter@aol.com*