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From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Oncology Diagnostics Attracts Big Money

MORE SURPRISING DEVELOPMENTS for the anatomic pathology profession during the past three weeks! The impending $215 million acquisition of **IMPATH, Inc.** by **Genzyme Corporation**, announced on March 1, has the potential to send new ripples across the national market for oncology testing. *(See pages 2-7.)*

What makes the Genzyme–IMPATH combination particularly fascinating was the $1 billion Genzyme paid, just days before the IMPATH deal was disclosed, to acquire **Ilex Oncology, Inc.** As implied by its name, Ilex is developing therapeutic drugs for cancer. Its biggest product is CAMPATH®, approved for use in the United States for the treatment of B-cell chronic lymphocytic leukemia (B-CLL). It happens that leukemia and lymphoma make up a substantial portion of IMPATH's mix of cancer cases.

Therein lies the intrigue. Is Genzyme preparing to attack the oncology testing market with a strategy of offering clinicians both diagnostic testing for cancer and the therapeutic drugs appropriate for treating cancer? Our editor says yes. He also points out that this is the type of competitive innovation which has the potential to change the needs and expectations of clinicians. As this happens, local pathology groups which compete for outreach specimens will find themselves at a competitive disadvantage, particularly if they remain fixed in old business habits.

For my part, I see Genzyme's acquisition of IMPATH and Ilex as ominous portents. During the past five years, the scale of investment in laboratory companies has increased geometrically. The prices paid by **Quest Diagnostics Incorporated**, **Laboratory Corporation of Americ**a, and other acquirers of existing laboratories continue to surprise pathologists, especially those who sold their regional labs for proportionately less money more than a decade ago.

The ominous aspect to these acquisitions is that the "price to do business" in clinical lab testing and anatomic pathology is increasing. If this proves true, it will be tougher and tougher for local anatomic pathology groups to scrape together the investment capital needed to be fully competitive with a national laboratory. Should this occur during the coming years, it may result in the gradual decline of local pathology, the type of pathology most responsive to the needs of the particular healthcare community it serves. TDR

IMPATH Has a Buyer: Genzyme Pays $215 Mil

Latest entrant into oncology diagnostics may intensify marketplace competition

CEO SUMMARY: Two unexpected things happened in IMPATH's Chapter 11 bankruptcy action. First, it attracted a buyer willing to pay the premium price of $215 million for its assets. Second, the buyer was not another laboratory company. Rather, it is a new entrant into the oncology diagnostics marketplace. This raises interesting questions as to Genzyme's strategies—and how it may change the AP marketplace.

WHEN IT COMES to anatomic pathology (AP) services, oncology continues to attract big money bets from major corporations.

The latest entrant is **Genzyme Corporation**. On March 1 it announced it had signed an agreement and had become the lead bidder to purchase the assets of **IMPATH, Inc.'s** physician services business division. In a deal worked out under the auspices of IMPATH's bankruptcy court judge, Genzyme will pay approximately $215 million. IMPATH filed a Chapter 11 Bankruptcy action on September 23, 2003. *(See TDR, September 29, 2003.)*

Genzyme's investment of $215 million to acquire the anatomic pathology-based business of IMPATH follows by just 13 months the acquisition of another anatomic pathology company. In February 2003, **DIANON Systems, Inc.** was purchased by **Laboratory Corporation of America**. LabCorp paid around $598 million for DIANON. Also in 2003, **AmeriPath, Inc.** was purchased. In a transaction which took that anatomic pathology company private, **Welsh, Carson, Anderson & Stowe** paid approximately $840 million.

Collectively, these three deals represent an investment of almost $1.65 billion in companies which provide anatomic pathology services! Further, all three acquisitions occurred within the short span of 13 months.

The message to the pathology profession couldn't be clearer: oncology testing is expected to be a fast-growing *and* lucrative market—and big corpo-

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

rations want to compete for that business. Moreover, these big companies will invest major amounts of money on sales and marketing to capture specimens currently going to local pathology groups. This means more intense competition for anatomic pathology specimens.

Laboratory Acquisitions

Genzyme already has experience at buying market share in laboratory testing. In the mid-1990s, it became the dominant commercial lab company in cytogenetic testing by acquiring, one after another, almost all the nation's specialty laboratories offering pre-natal and post-natal cytogenetic tests. *(See TDR, February 26, 1996.)* It holds that market position today, eight years later.

In offering to pay $215 million for IMPATH, a company currently crippled by a variety of problems, Genzyme demonstrates its belief that oncology will provide the steady growth and profits needed to recoup this sizeable investment.

Genzyme's actions reinforce those of LabCorp. Following its acquisition of DIANON Systems last January, LabCorp Chair and CEO Thomas Mac Mahon, granted an exclusive interview with THE DARK REPORT. Mac Mahon made two powerful statements about the relationship of oncology to the success of anatomic pathology.

First, in explaining LabCorp's interest in DIANON Systems, he said "I believe any laboratory seeking to be a leader in laboratory medicine must be a leader in cancer diagnostics. And if a lab is to be a leader in cancer diagnostics, it must have a tissue business and work closely with pathologists to evaluate those tissue specimens."

Next, Mac Mahon pointed out that "to diagnose cancer requires tissue. To me, the greatest opportunity for a pathologist, moving forward, is to get control of molecular diagnostics. Pathologists should be expanding both their skill base and their business base, not only to read tissue, but to read tissue as it relates to molecular biology.

"Molecular pathology is expected to be the cutting edge of medicine as we move forward," he continued. "Ongoing scientific advances in genomics and proteomics guarantee this will be true...[LabCorp] wants to be a leading company in tissue-based diagnostics and recognizes the need to develop our capabilities in anatomic pathology. "

Mac Mahon's statements are both clear and powerful. Going forward, oncology is expected to play a leading role in laboratory testing. Control of tissue is a necessary business strategy for any laboratory that wants to compete in the oncology testing marketplace.

More Competition Ahead

Competition for oncology specimens will increase. More specifically, there are competitive threats for specimens originating in both physician's offices and community hospitals. The fact that professional money managers are willing to support $1.65 billion of investment into three anatomic pathology companies in only 13 months sends an unmistakable message. Cancer testing has a bright future, one which is expected to generate more profits than routine chemistry and hematology testing.

What is interesting is that, for the most part, anatomic pathologists are not among the investor-leaders and top executives in these enterprises. That means it is less likely that new companies offering diagnostic tests for cancer will respect traditional relationships between labs and clinicians. If this proves true, then the next few years may bring some of the fiercest competition for lab testing business yet seen in the lab industry. TDR

Is Genzyme's Strategy to Pair Up Diagnostics with Therapeutics?

GENZYME'S ACQUISITION OF **IMPATH** is only part of a recent buying spree that may have significant impact in the market for laboratory testing services.

Just four days before Genzyme's announcement about its status as the leading bidder to buy IMPATH, it released the news that it would pay approximately $1 billion to purchase **Ilex Oncology Inc.**, a drug development company with one cancer drug on the market and several others in the pipeline.

That acquisition was preceded three days earlier by another announcement, on February 23, that Genzyme had purchased "substantially all the assets" of **Alphigen, Inc.**, a cytogenetic laboratory based in Pasadena, California. Although the purchase price was not disclosed publicly, informed sources say that Genzyme paid in the range of $40 million for Alphigen, which had annual revenues totaling between $20 and $25 million.

Genzyme already has a sizeable national business in cytogenetics. The Alphigen acquisition is believed to be an opportunity for Genzyme to buy additional market share and keep its dominance in this diagnostic testing sector.

Genzyme's Strategy

Of more immediate interest to both laboratory directors and pathologists is Genzyme's motive in paying $1.2 billion dollars in four days for a company with cancer drugs and an anatomic pathology company which specializes in cancer diagnostics. Genzyme executives have yet to make extensive comments about their strategy for developing the cancer drug business of Ilex Oncology and the cancer diagnostic services of IMPATH. But there are tantalizing hints.

One clue is Genzyme's acquisition, last summer, of **SangStat Medical Corporation**. It paid $600 million to acquire the company. Among its drug products which are either on the market or in development, are several promising drugs in the areas of autoimmune, hematology/oncology, and immunosuppression. These drugs complement a main drug offered by Ilex, which is CAMPATH®. In the United States, CAMPATH is approved for use in the treatment of B-cell chronic lymphocytic leukemia (B-CLL).

One obvious conclusion is that Genzyme is building a portfolio that includes several drugs useful in treating leukemia and lymphoma. That makes IMPATH useful to Genzyme. IMPATH's case mix consists primarily of leukemia/lymphoma and breast cancer.

Selling Lab Tests & Drugs

Genzyme may have just placed a bet totalling almost $2 billion (for SangStat, Ilex Oncology, and IMPATH) that it can combine IMPATH's cancer diagnostic capabilities with the oncology drugs in its portfolio. IMPATH's relationship with community hospital-based pathologists and oncologists allows Genzyme to identify patients who could potentially benefit from one of its drugs—at the time that their cancer is diagnosed! It would then send out pharmaceutical reps to offer its therapeutic drugs to physicians treating those cancer patients.

Much has been written about the potential of pairing diagnostic laboratory tests with therapeutic drugs and offering both services to physicians under one company. Genzyme Corporation seems to be ready to pursue this strategy on a large scale.

Will Genzyme change the competitive market for oncology diagnostics with these acquisitions? If past history is an indication, the answer is probably yes. That's because Genzyme has already built the nation's largest business in cytogenetics and continues to successfully defend its market dominance. It has already demonstrated its ability to capture market share in cytogenetics. That makes it a credible threat in the market for cancer diagnostics.

New Competitors Line Up In Oncology Marketplace

Genzyme is the latest company to invest big bucks in oncology diagnostics

***CEO SUMMARY:** Local pathology groups are advised to more closely track developments in the national market for oncology testing. Not only is big money targeting cancer testing, but a number of nimble, entrepreneurial start-up companies have begun to compete for specimens. Genzyme's acquisition of IMPATH validates this trend and promises to bring more change to the anatomic pathology marketplace.*

By Robert L. Michel

IT SEEMS A GOOD NEWS/BAD NEWS story is developing which will have significant impact on the anatomic pathology profession in the United States.

The good news is known to all. Expectations are that aging baby boomers, combined with new healthcare technologies, will make oncology a high-growth segment within our healthcare system. Because of the role played by anatomic pathology in the diagnosis of most cancer cases, this bodes well for the future of the profession.

The bad news is that the existing business model for most anatomic pathology services—the independent pathology group practice based in a community hospital—may find itself unable to vigorously compete with new competitors already lining up in today's oncology marketplace.

Genzyme Corporation's impending acquisition of **IMPATH, Inc.** is powerful evidence that oncology is attracting serious investors. In recent years, as much as $2 billion has been invested by investors to support new business models to provide diagnostic services in the oncology marketplace.

As noted on pages 2-4, three different companies have invested $1.65 billion to position themselves in the diagnostics marketplace during the past 13 months, . They are Genzyme ($215 million to buy IMPATH), **AmeriPath** ($840 million buy-out by an equity investment company), and **Laboratory Corporation of America** ($590 million to acquire **DIANON Systems, Inc.**).

More New Competitors

However, the tally of new competitors in oncology diagnostics shouldn't stop there. **U.S. Labs, Inc.** of Newport Beach, California was launched a few years ago specifically to provide sophisticated cancer diagnostics to community hospital-based pathologists. Venture capitalists have invested tens of millions of dollars in this fast-growing company.

Another anatomic pathology start-up of recent years is **AD Path Labs**,

based in Southern California. Its business model emphasizes regionalized histology in support of client pathology groups. AD PathLabs has received substantial amounts of capital from venture capital firms.

Another new national anatomic pathology firm is **CBLPath, Inc.**, headquartered in Ocala, Florida. This firm launched last summer and its entrepreneurs include former executives from DIANON.

Potential Change Agents

When looking at the new competitors—and new types of business models—in cancer diagnostics, two other emerging players should be recognized. One is **IMPAC Health Systems**, which purchased **Tamtron** and IMPATH's Cancer Registry business from IMPATH last December. Although IMPAC's primary business is healthcare information systems, it is crafting a "total" oncology solution that may eventually lead it into the actual diagnostics.

Another developing trend involves physician groups in such specialties as urology or gastroenterology which hire an anatomic pathologist. The goal is to internalize anatomic pathology testing.

The other potential player is **G.E. Medical Systems Information Technologies** (GEMSIT). Last summer it acquired **Triple G Systems** of Toronto, Canada. Triple G offers a laboratory information system product. GEMSIT is a major player in radiology informatics and radiology instruments.

While recognizing both IMPAC and GEMSIT are informatics companies, it is possible that these two companies could develop a different cancer-testing business model. Because this model incorporates their informatics technology and provides a perceived competitive advantage, both companies would have an incentive to help entrepreneurial pathologists launch such a business—one which would compete against existing, local pathology group practices.

Another developing trend involves a new business relationship between physician groups and anatomic pathologist. In recent years, some forward-looking urology and gastroenterology medical group practices have shown an interest in hiring an anatomic pathologist to work within the group. The goal is to internalize anatomic pathology testing and allow the specialty group to bill for it directly.

The number of specialty groups taking this approach seems to be increasing. It is supported by another new phenomenon: newly-emerging anatomic pathology companies organized to provide contract management services for the specialty groups' histology and pathology needs. THE DARK REPORT is aware of two such companies, operating in two different states.

Target: Oncology Testing

These examples provide intriguing evidence that a variety of companies are targeting the oncology marketplace. In some cases, their strategy is exclusively focused on offering services to diagnose and monitor cancer patients. In other cases, performing anatomic pathology services is done to complement the company's core business services.

For example, there is plenty of evidence to support a conclusion that Genzyme purchased both IMPATH (diagnostics) and **Ilex Pharmaceuticals** (therapeutic drugs) because it wants to offer lab tests to identify cancer, then be in a position to offer the referring physi-

cian those prescription drugs appropriate for the newly-diagnosed patients. *(See page 4.)*

Further, because it is primarily a pharmaceutical company, Genzyme wants to access tissue specimens from cancer patients that it can use for research and development. IMPATH provides a way for Genzyme to identify sources of tissue, obtain informed consent from patients, then harvest the tissues.

Acquiring IMPATH also allows Genzyme to buy immediate access to IMPATH's 2,500 hospital clients and physicians who have referred cases. This access comes without the time and expense otherwise required of Genzyme to hire sales reps and build its cancer diagnostic testing business from scratch.

Change To The Status Quo

As identified in this briefing, the cancer testing marketplace is about to be changed by at least three new threats to the status quo. First is the arrival of Wall Street-backed national pathology labs, which made a collective investment of $1.6 billion in just 13 months to position themselves in oncology diagnostics.

Second are the smaller start-up anatomic pathology companies. Each has a business strategy and a slightly different business model. But they all share the same goal: capture specimens and market share currently going to locally-based pathology group practices.

The third threat is from non-traditional competitors. Whether it is healthcare IT companies like IMPAC or GEIMS or urology, gastroenterology, and dermatology specialty practices, these types of companies have a financial incentive to create new anatomic pathology arrangements which help them share in the profits of direct testing for cancer.

Across the nation, local pathology group practices face a new challenge in two dimensions. In the first dimension, there will be a steady increase in the number of competitors sending sales reps into the community to convince local physicians to send their anatomic pathology specimens to their firm.

As identified in this briefing, the cancer testing marketplace is about to be changed by at least three new threats to the status quo.

In the second dimension, these companies are developing new business models for providing anatomic pathology services. No one should be surprised if at least one of these business models turns out to meet the needs and expectations of referring clinicians better than today's standard business model—that of the pathology group based in a neighborhood hospital. When this happens, local pathologists need to be ready to incorporate the best qualities of this business model into their own group.

Response Of Local Paths

Such changes may require local groups to consolidate, to raise and invest more capital, to develop a professional sales and marketing team, and to establish other business resources currently not found in most pathology group practices. Failure to do so in a timely way will put local pathologists at a competitive disadvantage in the outreach market.

However, as with every good news/bad news story, there is opportunity along with the risk. Some local pathology groups already recognize the need to respond to changes in the oncology testing marketplace. They are developing strategies and building the resources necessary to defend their turf and expand their share of the market. TDR

Contact Robert Michel at 512-264-7103.

Lab Industry Briefs

UNINSURED PATIENT HOSPITAL CHARGES REDUCED AT HCA & TENET

FOR-PROFIT HOSPITAL COMPANIES moved swiftly to announce and publicize new policies for billing uninsured patients. These patients will see charges reduced to levels that are closer to what hospitals accept from HMOs and Medicare/Medicaid.

HCA, which operates 166 acute care hospitals, disclosed in its 2003 year-end financial report that it implemented a "charity care and financial discount policy to provide financial relief to more of its charity patients and needs-based discounts for uninsured patients who receive non-elective care at its hospitals." HCA disclosed that "charity care and related discounts" amounted to $821 million in 2003, compared to $579 million in 2002.

Tenet Healthcare Corp., which operates 114 domestic general hospitals, announced on March 3, 2004, that it was implementing discounts to uninsured patients in a five-point program it calls the "Compact With Uninsured Patients."

During the past year, consumer advocates and the *Wall Street Journal* have publicized the fact that many hospitals charge uninsured patients at a rate which is significantly higher than the reimbursement they accept from HMOs and Medicare/Medicaid. Moreover, some hospitals have policies which include collection suits, attachments, and even more aggressive collection tactics.

It was concerns about such practices at a not-for-profit hospital in Champaign, Illinois that caused local and state tax officials to void the hospitals tax-exempt status last month. *(See TDR, February 23, 2003.)*

In late February, the **Centers for Medicare and Medicaid Services** (CMS) issued a detailed ruling letter which declared that nothing in federal rules prohibited hospitals from extending discounted prices to uninsured patients. CMS pointedly hand-delivered the letter and a six page question and answer document to the offices of the **American Hospital Association** in Chicago.

ABBOTT MOVES FORWARD WITH ITS POC ACQUISITIONS

IN THE SPACE OF TWO MONTHS, **Abbott Laboratories, Inc.** announced the acquisition of two point-of-care testing (POCT) companies.

In December, it agreed to purchase **I-Stat Corporation** for $392 million. That transaction closed on January 28, 2004. *(See TDR, December 22, 2003.)*

In January, Abbott entered into a deal to acquire **TheraSense, Inc**. Abbott will pay $1.2 billion to purchase the company, which markets a self-monitoring blood glucose system. On February 24, the proposed acquisition cleared antitrust review and is expected to close in the second quarter of 2004.

Both I-Stat and TheraSense pioneered point-of-care testing systems that found growing acceptance in the marketplace. Abbott's willingness to spend $1.6 billion to purchase both companies shows it believes the POCT market will grow much more rapidly than the market for core lab tests.

Abbott received more good news during the month of February. The FDA approved 11 assays for hepatitis, PSA, and AFP. This approval is an additional sign that the expensive, multi-year feud between Abbott and the FDA has ended. TDR

CEO SUMMARY: Do clinical laboratories in any of the world's most developed countries have a performance advantage that makes them "best of breed?" Recently, a laboratory in the United States and a laboratory in the United Kingdom had the opportunity to evaluate their financial, productivity, and quality performance against each other. The results were unexpected—and point to a conclusion that most laboratories in developed countries are performing very well.

LOOKING FOR "WORLD CLASS" LABORATORIES

Side-by-Side Comparison: U.S. Lab Versus British Lab

IN THE SEARCH FOR "BEST PRACTICES" and "world class laboratories," is the American system of laboratory management pre-eminent in the world?

Are laboratories in the United States consistently better than those of other countries at utilizing resources and delivering a higher level of laboratory services? Answers to these questions are important because the urgency for lab administrators and pathologists to maximize the performance of their labs increases steadily.

Recently a lab director from the United States and his counterpart from the United Kingdom were given the rare opportunity to compare their laboratory organizations and report on the differences and similarities in performance of their laboratories.

Startling Conclusions

"Our conclusions startled both of us," declared John J. (Jack) Finn, CEO and President of **Centrex Clinical Laboratories, Inc.** of New Hartford, New York. "Given fundamental differences in the health system of the United States and the United Kingdom, we did not expect to find such close alignment on many operational elements.

"I agree with that statement and further say that our side-by-side case study provides useful management insights for laboratory leaders on both sides of the Atlantic," added Peter Wisher, Divisional General Manager of **Path Links Greater Lincolnshire Pathology**, a consolidated lab organization based in a rural region 200 kilometers north of London, England.

What brought these two laboratory leaders together was an invitation to compare their laboratories and report on the findings at the second annual "Frontiers in Laboratory Medicine" (FiLM), held in Manchester, England on February 3-4, 2004. This "U.K. War College" is co-produced by THE DARK REPORT and the **Association of Clinical Biochemists** (ACB). As with the *Executive War College* in the United States, it brings together laboratory leaders from both countries to explore the management successes of early-adopter laboratories.

Centrex Clinical Laboratories and Path Links comprised one of two side-by-side case studies. Both Centrex and Path Links are based in a semi-rural to rural region with comparable distances and population. The objective of this presentation was to evaluate and report on the significant similarities and differences between the two laboratories.

"Structurally, our two laboratory organizations are uncannily similar," observed Wisher. "Path Links was one of the first projects in the United Kingdom to create a consolidated, regional laboratory organization that unified laboratory testing services across multiple hospitals and clinics in five towns and cities to form a single, county-wide lab service organization. That was accomplished in 1997.

Integrated Regional Labs

"From that perspective, both Path Links and Centrex are integrated regional laboratory organizations," added Finn. "We each have a single IT system serving all sites, highly-integrated courier logistics, centralized histology, and centralized immunology.

"Our labs serve a population of about 1 million people each, along with hospitals as large as 500 to 600 beds," he continued. "Thus, our test menus are extensive and include support for point-of-care testing (POCT) done in hospitals and physician clinics."

The most fundamental difference in the two laboratory organizations was source of funding. "In the United Kingdom, funding for laboratory services comes from the Strategic Health Trust (SHT)," explained Wisher. "Our budgets and capital requests are established by the National Health Service (NHS) Acute Trust. In general, our annual funding has changed by rather modest percentages. Relative to the United States and its reimbursement cutbacks, we've had more stable, albeit tight, finances. That's allowed us to concentrate on our clin-

ical mission. The fact that we have no laboratory competitors also simplifies our management decisions."

"That's not the case at Centrex," countered Finn. "Financial considerations are ever-present in almost every management decision. Our funding comes from public and private payers and we must compete for lab testing business and the revenues attached to them. Also, compliance is a major issue in our laboratory. Medical necessity regulations limit the types of tests that physicians can order."

Test Ordering Limitations

"We are fortunate not to have those compliance requirements," Wisher responded. "There is more freedom for clinicians to order the tests they deem necessary. However, because physicians are aware that the overall healthcare budget is limited, pathologists in the U.K. are able to take a more aggressive role in providing instruction and direction in how physicians should order laboratory tests."

What may be of greatest interest to clients and regular readers of THE DARK REPORT are the financial and productivity measures achieved by Centrex and Path Links. Both Finn and Wisher were surprised when they put their labs' numbers side-by-side.

Comparing Cost-Per-Test

"Each laboratory counts the number of tests differently," said Finn. "However, the scale of our testing is proportional. Centrex does 3.1 million tests per year and Path Links performs 4.4 million tests per year. Using an agreed formula for average-cost-per-test, we found the number to be similar: US $8.90 (£4.53) at Centrex versus US $7.84 (£4.26) at Path Links."

"Most of the cost differential could be attributed to the increased specimen transport costs in the U.S.," explained Finn. "Centrex operates 20 specimen collection centers and its couriers drive 1.5 million miles annually. At Path Links, patients travel farther to have samples collected, a consequence of having no lab competitors in the region.

"We are confident this is a reasonable comparison because other measures track within 10% or 15% between our two labs," Wisher explained. "For example, Centrex and Path Links had, in U.S. dollars, a personnel cost-per-test of $4.80 and $4.31, respectively. Supply cost-per-test was $1.96 and $2.19, respectively."

One fascinating opportunity in this side-by-side case study was the potential to gauge annual test utilization across the population served. "Centrex and Path Links both serve a population of about 1 million people," observed Finn. "Because Path Links is the only laboratory in its service region, it is easy to divide the annual tests performed by the population and come up with a test utilization ratio of 3.4 tests per person per year.

Annual Test Utilization

"That's harder to calculate for our market," he said. "Although Centrex is doing most of the hospital inpatient testing in our service region, there are other laboratories providing laboratory testing services to office-based physicians. Since we do 3.1 million tests per year, but don't do 100% of the testing for the 1 million people living in our service area, it is probable that our annual test-per-person-per-year ratio is reasonably close to Path Link's figure of 3.4 tests."

From the British perspective, Wisher was envious of the extensive consolidation and standardization across all laboratory sites that Centrex has achieved. "One clear limitation we have in consolidating tests across several hospitals is the time required to transport specimens," he observed. "Our road network does not support

Key Performance Indicators

Listed below are key performance indicators from the side-by-side case study presented by Centrex Clinical Laboratories of New Hartford, New York and Path Links, Greater Lincolnshire, England at the second annual "Frontiers in Laboratory Medicine" meeting in Manchester, England on February 3-4, 2004.

Centrex Clinical Laboratories

Key Performance Indicators

- **Total tests performed** . . . . . 3.1 million
- **Cost per test** $8.90 (£4.80)
- **Personnel costs/test** . . . $4.80 (£2.60)
- **Supply costs/test** $1.96 (£1.06)
- **Net revenue** $30.3m (£16.4m)
- **Annual capital spending** $1.2m
- **Profit per test** . . . . . $0.87 (£.47)
- **Full time employees:**
  - Pathologists 8
  - Technical 102
  - Non-technical 212
  - Management 8

Top Tests with Volume

- **CBC (FBC)** 277,996
- **PT (INR)** 130,871
- **Blood group (ABO&RH)** 30,620
- **Crossmatch units** 10,840
- **Lipid profile** 127,673
- **Comp chemistry profile** 182,496
- **Basic chemistry profile** 104,537
- **PSA** 29,570
- **TSH** 102,545
- **HBA1C** 46,804
- **Biopsy level 3** 37,018
- **Cervical smears** 60,405
  - Thin Prep 46,908
  - Conventional 13,497
- **Urine culture** 51,244

Turnaround Times

	STAT	Routine
CBC	1 hr	4 hrs
Coag screen	1 hr	4 hrs
Cross match	1 hr	4 hrs
Renal	1 hr	4 hrs
Liver	1 hr	4 hrs
Thyroid	4 hrs	8 hrs
Histo/Breast	n/a.	24-48 hrs
Histo/Ovarian	n/a.	24-48 hrs
Cervical smear	n/a.	3-5 days
Urine cult (-)	n/a.	24 hrs
Blood cult (+)	n/a.	48 hrs

Path Links

Key Performance Indicators

- **Total tests performed** . . . . . 4.4 million
- **Cost per test** $7.84 (£4.26)
- **Personnel costs/test** . . . $4.31 (£2.34)
- **Supply costs/test** $2.19 (£1.19)
- **Net revenue** $34.78m (£18.9m)
- **Annual capital spending** $.55m (£0.3m)
- **Profit per test** $0 (£0)
- **Full time employees:**
  - Pathologists . . . . 28 wte
  - Technical . . . . . 219 wte
  - Non-technical . . 150 wte
  - Management. . . . 10 wte

Note: £1 = $1.84

Top Tests with Volume

- **FBC (CBC)** 658,579
- **Coag screen** 75,910
- **INR (PT)** 195,894
- **Blood group** 61,315
- **Crossmatch units** 72,061
- **Lipid profile** 190,000
- **Renal** 572,485
- **Liver FT** 395,828
- **PSA** 34,287
- **TSH** 207,203
- **HBA1C** 82,241
- **Histology requests** 56,540
- **Cervical smears** 71,179
  - Thin Prep . . . . . Nil
  - Conventional 71,179
- **Urine culture** 174,992

Turnaround Times

	STAT	Routine
FBC	1.0 hrs.	4 to 12 hrs
Coag screen	1.0 hrs.	4 to 12 hrs
Cross match	0.75 hrs.	24+ hrs
Renal	1.0 hrs.	4 to 12 hrs
Liver	1.0 hrs.	4 to 12 hrs
Thyroid	2 hrs	4 to 12 hrs
Histo/Breast	n/a.	48 hrs
Histo/Ovarian	n/a.	150 hrs
Cervical smear	n/a.	6 weeks min
Urine cult (-)	n/a.	24 hrs
Blood cult (+)	n/a.	48 hrs

fast travel times. For that reason, Path Links has not been able to concentrate as much testing in its core laboratory sites as is true with Centrex.

"I am also impressed with Centrex' success at consolidating microbiology," added Wisher. "In the United Kingdom, clinicians are reluctant to support moving microbiology out of their hospital. There are few examples in our country where microbiology consolidation has successfully been implemented. It is on our 'to-do' list and Path Links now has plans to consult with Centrex on how we can best accomplish this step."

Comparing Conclusions

Asked to state their conclusions about this pioneering side-by-side look at comparable laboratories in the United States and the United Kingdom, both Finn and Wisher had similar things to say. "Despite the differences in funding, I was surprised at the consistent similarities in our laboratory organizations," noted Finn.

"I believe each of us could be dropped into the other's laboratory and perform well without much orientation," responded Finn. "Both the test menus and instrument systems are similar. Probably the most surprising conclusion we made was how our cost and productivity performance measures were right on top of each other. Neither laboratory had a clear and significant performance advantage."

"For my part, I was surprised to see how pervasive the economic element was in the decisions made at Centrex," explained Wisher. "We have yet to reach that point in my country. On the other hand, so many of the operational issues and strategic goals are uncannily alike.

"Because the Centrex and Path Links productivity measures are so close, it supports a conclusion that both laboratories operate with a high degree of efficiency," continued Wisher. "From the U.K.'s perspective, that is one validation that laboratory consolidation and regionalization does deliver worthwhile benefits. In my country, laboratory consolidation is just beginning. That is not the case in the United States and Canada, where consolidation and regionalization became widespread almost ten years ago."

For laboratory managers and pathologists, the results of this unique, international side-by-side case study provides several useful insights. First, despite the differences in how lab services are funded in the United States and the United Kingdom, these two examples of a rural, consolidated laboratory organization posted remarkably similar cost and productivity outcomes. This argues that the fundamental principles of laboratory management, along with test technology and instrument systems, probably don't vary much in developed countries.

Teaching Opportunities

Second, the differences in the experience of labs in the U.S. and the U.K. reveal opportunities for each to teach the other. In the case of the U.S., labs here are much better at getting the capital necessary to fund improvements. American lab managers are better at combining financial and clinical parameters into their decisions.

In the U.K., the emphasis on clinical support and the closer relations maintained between pathologists and clinicians is a strength. The types of clinical collaborations achieved by labs in the U.K. would have high value if duplicated in the United States.

For lab directors and pathologists interested in participating in upcoming side-by-side U.S./U.K. case studies, contact Editor Robert Michel at the offices of THE DARK REPORT. TDR

Contact John Finn at johnf@centrexlabs.com and Pete Wisher at pete.wisher@nlg.nhs.uk.

Similarities & Differences

Listed below are observations and findings that resulted from the side-by-side case study involving Centrex Clinical Laboratories and Path Links Greater Lincolnshire Pathology, as reported at the "Frontiers in Laboratory Medicine" meeting.

Shared Characteristics of Centrex & Path Links

- Regional rural laboratories
- Single managed service organization
- One platform, multi-site IT system
- High quality (nationally regulated) service standards
- Highly integrated courier system
- Populations served (circa 1 million)
- Serving 500-600 bed hospitals
- Point-of-care testing performed at offsite clinics and GP settings
- Centralized histology department
- Centralized immunology department
- Commitment to the early detection of disease to reduce treatment costs and improve clinical outcomes
- Reagent costs are higher than equipment costs

Centrex Differences

- Decisions driven by finance
- A for-profit organization
- Competes with other laboratories for testing
- Many insurance carriers
- CEO manages pathologists
- Centralized microbiology department
- Medical necessity regulations limit test ordering by GPs
- Standardized methodologies throughout system
- Key staff incentive schemes
- Capital investment high (x%)

Path Links Differences

- Decisions driven by clinicians served
- Part of a regional health system
- No competition in laboratory service area
- Aspirational—4 hour AED target
- Single NHS funding
- Pathologists "managed" by Trust
- Microbiology at acute sites
- Little regulation of test limiting especially by Trust or PCT
- Slow but sure development of standardized methodologies throughout system
- No incentivization schemes
- Capital investment low (x/2 %)

Centrex Themes & Lessons

- Service strategy driven by turnaround times and efficiency
- Allows maximum automation and use of informatics technologies
- Unlocks hidden service benefits as a result of overall improvement in turnaround times, quality, and other operational efficiencies
- Capital investment unlocks service change and progress

Path Links Themes & Lessons

- Lab service strategy is more sensitive to "local" funding and arrangements to maintain quality
- This can, in turn, "lock in" problems and jeopardize services
- Minimal capital investment in the laboratory inhibits service change and development

Dark Index

Public Labs' Year-End Earnings Demonstrate Continued Growth

Lab acquisitions boost two blood brothers, Bio-Reference and LabOne post solid numbers

BECAUSE OF ACQUISITIONS, there remain only four public laboratory companies which do substantial business in testing referred by physicians' offices.

As public companies, their quarterly financial reports provide useful insights into the competitive marketplace for lab testing services. That is true of the year-end financial reports for both **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**.

For 2003, Quest Diagnostics generated revenues of $4.7 billion. This was an increase of 15.3%, compared to revenues of $4.1 billion in 2002. LabCorp's revenues grew 17.2%, from $2.5 billion in 2003 to $2.9 billion in 2004.

On that revenue base, Quest Diagnostics generated EBITDA (earnings before interest, taxes, depreciation, and amortization) of $951 million, or 20.1% of revenues. LabCorp's EBITDA was 24.2%, totalling $711 million.

For fourth quarter 2003, both companies disclosed that accessions had increased (12.7% at Quest, 7% at LabCorp) and average revenues per requisition were up (3.5% for Quest, 5.5% for LabCorp) over those of 2002.

The next largest public lab companies offering testing to physicians' offices are **Bio-Reference Laboratories, Inc.** and **Lab*One*, Inc.** Bio-Reference ends its fiscal year on October 1, so it closed its 2003 fiscal year earlier than Lab*One*.

For 2003, Bio-Reference reported revenues of $109 million, a 13.5% increase over 2002 revenues of $96.6. Lab*One* generated 2003 revenues of $346 million, a growth rate of 16%. Lab*One*'s health services business includes testing done for office-based physicians. For 2003, those revenues were $88.5 million. This is an increase of 45% from the $61 million posted in 2002.

Ongoing Double-Digit Growth

All four of these public laboratory companies generated double-digit growth in revenues for 2003. This reflects the influence of two parameters. Specimen volume increases and price increases together contribute to higher revenues.

Among other conclusions, double-digit revenue growth demonstrates that these laboratory companies are seeing a shift in test mix toward assays which are reimbursed at higher rates. For example, Bio-Reference Laboratories noted that esoteric testing comprised 29% of its test mix for its fiscal quarter ending January 31, 2004 and helped contribute to a revenue per accession which increased 2.5%, from $49.56 to $50.85.

All four laboratories are posting respectable profits. This is certainly a contrast from the mid-1990s, when most public laboratories were posting sizeable losses. TDR

Useful Info at War College On Molecular, Lean, et al

Answers to lab management challenges as healthcare's new change cycle commences

CEO SUMMARY: When the nation's leading laboratory administrators and pathologists gather in New Orleans on April 27-28, they will get the best and latest developments in laboratory management. From Aetna's National Medical Director to the former Chief of the Industry Guidance Branch of the OIG, the Ninth Annual* Executive War College *offers powerful information and insights to help labs succeed.

MOLECULAR DIAGNOSTICS continues to be a big question mark for most clinical laboratories. In many cases, it comes with lots of expenses and without adequate reimbursement.

Along with the rapid acceptance of quality management systems such as Six Sigma and Lean in laboratories, there are ever more opportunities for laboratories to establish and expand molecular diagnostics testing programs. These "twin trends" are bringing swift changes in the operational and financial structure of many laboratories.

To help lab managers and pathologists prepare their laboratory for molecular diagnostics and other challenges, this year's *Executive War College on Laboratory and Pathology Management* features a powerful line-up of faculty speakers who've already mastered aspects of molecular diagnostics in their own laboratory. Now in its ninth year, the *Executive War College* will take place on April 27-28 in New Orleans.

Of great interest will be the presentation of James D. Cross, M.D., **Aetna, Inc.'s** National Medical Director. He will speak to how and why payers like Aetna make coverage decisions and establish reimbursement for new diagnostic tests. This will be the first time Dr. Cross has addressed a group of senior laboratory executives, and it is a rare opportunity for laboratorians to learn what happens on the other side of the payer table.

Molecular Lab Case Studies

Complementing Dr. Cross' presentation with be detailed case studies by both academic center laboratories and community hospital laboratories which developed financially-viable molecular testing programs. Attendees will learn, first-hand, how **Medical College of Virginia** (Richmond, Virginia), **St. Luke's Regional Laboratories** (Kansas City, Missouri), **UCLA Medical Center** (Los Angeles, California), and **Hartford Hospital** (Hartford, Connecticut) developed and maintain thriving molecular diagnostic programs.

Quality management systems are helping laboratories achieve radical improvements in short periods of time.

Competitive Lab Compliance Practices Get Scrutiny

IN A WAR COLLEGE EXCLUSIVE, Medicare compliance practices in the competitive marketplace will be scrutinized in a candid, detailed discussion—extended to two hours by popular request.

The panel of experts brings attendees face-to-face with knowledge and experience never before assembled in a public lab management forum. Speaking from experience about how the OIG views compliance issues will be Kevin G. McAnaney, Attorney, **Law Offices of Kevin G. McAnaney** in Washington, DC. Until last year, McAnaney served as the Chief of the Industry Guidance Branch of the Office of Investigator General.

Representing the perspective of laboratory managers is John McCarty, Chief Financial Officer of **Lab*One*, Inc.** of Kansas City, Missouri. The legal view of pathologists and clinical laboratories will be provided by Jane Pine Wood of **MacDonald Hopkins** (Cleveland, Ohio) and Jeffrey J. Sherrin, **O'Connell and Aronowitz** (Albany, New York), respectively.

For lab directors and pathologists frustrated with "uneven" compliance practices in the marketplace, this is the perfect opportunity to get insightful answers to tough questions.

Rick Panning, Vice President of Laboratory Services at **Fairview Health Services** in Minneapolis, Minnesota will provide an in-depth look at why his seven-hospital system is deploying Lean management techniques into the high-volume core laboratories and histology laboratories as fast as feasible. In Fairview's first core laboratory Lean project, inpatient test turnaround times were slashed by 50%, labor productivity increased 60%, and the hospital laboratory gained new respect among clinicians, nurses and other staff.

Advances in lab automation get attention as well. With the title "Confessions of a Sinner: I Automated Bad Work Processes in My Core Laboratory!", Leo Serrano, Administrative Director of Laboratories at **Middle Tennessee Healthcare** in Jackson, Tennessee will reveal the important lessons they learned from their total laboratory automation project.

The automated lab, constructed in 2000, underwent a Lean project makeover last year. The results were stunning. "After our first major Lean project, average test turnaround time fell 42%. It was reduced from 71 minutes to 51 minutes," observed Serrano. "And remember, that's in a highly-automated core laboratory which is performing in the top percentile of its peers! We also achieved comparable percentage gains in labor productivity and quality. Physicians love the changes in our laboratory."

"Real Time" Anatomic Path

For anatomic pathology groups, there are exciting case studies about automation in histology. For example, at the **University of Miami Medical School** in Miami, Florida, 70% of pathology cases are signed out the same day. "We have also built a 'point-of-care' histology laboratory upstairs next to the oncology department," stated Azorides Morales, M.D., Chief of Pathology Services. "With our automated histology systems, we are providing full pathology reports at the same time patients are wheeled out of the recovery room."

Complementing these powerful topics are a total of 40 presentations. These include direct access testing (**Ohio State University Laboratories**), Getting Your Best Deal from Molecular Test Vendors (**NorDx Laboratories**), and Anatomic Pathology's Three-Way Informatics Collision (**UPMC Health System**).

Full details for the *Executive War College* and these important sessions can be found at *www.darkreport.com*. TDR

INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

Bar codes will soon be an essential element in most laboratories. Final regulations published on February 26 by the **Food and Drug Administration** (FDA) will take effect during the next two years. The FDA is requiring that prescription and over-the-counter drugs given to hospital patients have bar codes. Vaccines and certain blood and blood products will have bar codes. To prevent errors, patients in hospitals will have bar code wrist bands to allow providers to verify patient identification and the drugs or other products prescribed for that patient. Estimates are that bar codes will prevent 500,000 adverse events and transfusion errors during the next 20 years.

Did you catch "National Patient Safety Awareness Week" last week? Officially, it ran from March 7 to 13. This event precedes the widespread concerns over medical errors that followed the IOM's report on that subject two years ago. "National Patient Safety Awareness Week" was actually launched in 1996 by the AMA and several corporate sponsors.

WATCH OUT! THE "ZIPPIES" ARE COMING!

In the 1960s, it was "hippies." By the 1980s, "yuppies" was in the lexicon. Prepare yourselves. The next socio-economic label is going to be "zippies." Moreover, it may be zippies who transcribe pathology cases long-distance, who provide customer service for your laboratory vendors, and may even read pathology slides at some future point. The term is used in India to describe the host of educated youth who are getting jobs to serve the developed world. *Outlook*, a weekly news magazine published in India, recently profiled zippies with a story headlined "The Zippies Are Here."

ADD TO: *"Zippies"*

Laboratory directors and pathologists should not underestimate the potential of zippies to affect many dimensions of laboratory testing—from the other side of the globe. In India, 55% of the population is under age 25. That's 555 million people. A zippy working as a telemarketer (selling services to Americans or answering the service calls made by customers of American companies), generally earns around $300 per month. This is more than double what that telemarketer's middle class father earned in professional positions. For that reason, zippies have economic clout in India. Zippies speak English, often have sophisticated technical skills, and provide services at a price that is a fraction of the compensation paid in North America and Europe. THE DARK REPORT knows of at least one laboratory IT vendor now outsourcing software code development and other services to a contractor in India.

Glucose testing in Japan has entered a new dimension. **Matsushita Electric Industrial Co.** of Japan has built a toilet that checks a person's temperature, blood pressure and blood sugar. This data can then be electronically transmitted to a medical professional monitoring the patient's status from afar.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 4, 2004.

PREVIEW #5

EXECUTIVE WAR COLLEGE

April 27-28, 2004 • Astor Crowne Plaza Hotel • New Orleans

Direct Access Testing (DAT): Unique Partnership Between Kroger Grocery & Ohio State Univ. Labs

Can a direct access testing (DAT) collaboration between a chain retailer and a local health system laboratory bring additional benefits to both partners? Go behind the scenes of this unusual arrangement and find out why the DAT retail program launched by Kroger Grocery Stores and Ohio State University Medical Center Labs outlasted a similar marketing trial in Columbus, Ohio between Quest Diagnostics and CVS Pharmacies. Lots of unexpected twists and useful insights in this story!

Full program details available now!

visit darkreport.com or call 888.291.2525

UPCOMING...

- ***Point-of-Care Testing: What IVD Companies Know That Their Laboratory Customers Don't.***
- ***Value-Added Clinical Pathology Attracts Additional Outreach Business.***
- ***Regional Idiosyncrasies That Hamper Or Enhance Marketing of Lab Testing Services.***

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