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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

Recognizing What the Marketplace Teaches Us

IT IS ONLY IN HINDSIGHT THAT MOST PEOPLE UNDERSTAND THE TRUTH of a situation. Unfortunately for laboratory employees in New York City, the lack of foresight by their leaders must inevitably lead to job cutbacks at three recently constructed laboratories.

As you will read in our "Tale of Two Cities" starting on the next page, at the same time that laboratories in Los Angeles were feeling the full impact of managed care and cutting back on underutilized laboratory capacity, several prominent integrated healthcare systems in the Big Apple were embarking upon major projects to expand and automate their laboratories.

At the *Executive War College* in New Orleans last week, a number of New York-based laboratory executives spoke off the record to our editor about the situation in New York City. Even as **LabCorp** is eliminating underutilized capacity between its Raritan (New Jersey) and Mitchell Field (Long Island) facilities, the three hospital systems which built automated laboratories continue to subsidize their unproductive facilities.

I would remind our clients and readers of an important fact. Healthcare in the United States is undergoing a similar transformation in every metropolitan area. The pace of the transformation varies, as does its composition, given the unique healthcare resources in, say, Houston compared to Chicago. But the themes are constant: lower reimbursement, consolidation among providers, integration of clinical and operational systems, and demand for better information that can improve outcomes and lower costs.

Most experts agree that California is the cutting edge of this transformation. What happens in California is a reasonable indicator of how managed care will transform other cities as it grows in influence. Assuming the truth of that fact, how could laboratory leaders in New York City ignore events in Los Angeles during the mid-1990s that literally drove labs into bankruptcy and blithely proceed to build more laboratory capacity than New York City will need for years to come?

Whatever the answer, it is a lesson to the rest of us. It is important for laboratory executives to look outside their organization at the experience of labs in other cities and in other healthcare markets. We must all learn to recognize what the marketplace teaches us. The market is an unfailing guide to success strategies...but only if we heed its lessons. **TDR**

A Tale of Two Cities: New York Versus L.A.

One city squeezed out excess lab capacity while the other built unneeded lab capacity

CEO SUMMARY: Here's a dramatic comparison of the effects of advanced managed care on West Coast laboratories as compared to East Coast laboratories. While Los Angeles labs endured radical downsizing and bankruptcy, New York experienced significant increases to existing laboratory capacity. The consequence could be that some New York laboratories may yet have to undergo radical restructuring.

IT IS TRULY A TALE OF TWO CITIES. In the last three years, the experience of laboratories in Los Angeles was vastly different than those of New York.

In Los Angeles, the theme has been to eliminate laboratory overcapacity. Both commercial laboratories and hospital laboratories endured one round of downsizing and cutbacks after another. This process is still under way.

In California, intense pressures from a highly-competitive managed care marketplace quickly put laboratories in a financial vice. Since 1995, laboratories found themselves literally forced to eliminate excess capacity or go broke.

In New York, it is a different tale. In the Greater New York Metropolitan Area, an expansion of laboratory capacity took place during 1995-1998. Yet no comparable increase in lab testing volume accompanied this new construction.

As a result, operators of these expanded laboratories in New York City watch glumly as the shiny new "totally automated lab palaces" operate at minimal capacity.

For New York, it is proof that the philosophy of "build it and they will come" doesn't necessarily apply to laboratory services. These beautiful new state-of-the-art laboratories run at 25% or less of capacity. Consequently, none of these projects has delivered the lower cost per test promised by their developers.

THE DARK REPORT writes regularly about the California experience because the state is considered leading

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edge for healthcare trends. As a result, clients and regular readers know the story of how California's managed care companies put clinical laboratories into a financial hammerlock.

Reimbursement for lab testing declined so rapidly in California that laboratories literally found themselves at the brink of bankruptcy unless they took radical action and slashed costs by precipitous amounts.

Probably the best example of this situation was **Physician Clinical Laboratories** (PCL), based in Sacramento. A publicly-traded lab partially owned by two major healthcare systems, it was a $110 million laboratory in 1995.

Both PCL's former CEO, Nate Headley, and its CFO, Rich Brooks, told THE DARK REPORT a similar story. In a 24-month period between November 1994 and November 1996, PCL saw reimbursement for the same volume of laboratory tests decline by $2 million per month!

This means that PCL, while still processing the same volume of laboratory tests, saw annual reimbursement decline by $24 million in two years. This was a 26.4% reduction in income, with *no change* in testing volume.

Owners of clinical laboratories in California confirm a similar decline in reimbursement paid to their laboratories. That is why the state has been littered with the corpses of defunct laboratories.

New York Ignored Lessons

Yet in New York, laboratory operators seemed to ignore the lessons to be learned from the California experience. Three significant laboratory expansions took place in recent years.

Probably the best known is **Beth Israel Health Care System**. Its laboratory administration was very proud of the decision to construct a facility designed around total laboratory automation (TLA).

Yet at the same time, **Mt. Sinai Medical Center** in Manhattan and **North Shore Laboratories** on Long Island were similarly building expanded laboratories designed around TLA. During the 1997-1998 period, these three new laboratories were completed and became operational.

Each of these three new laboratories was built by an integrated healthcare system, based upon a similar business strategy:

1) premise: an automated laboratory, running at near full capacity, will

California Sheds Lab Overcapacity

Managed care in California quickly put all laboratories under pressure to slash costs and remove underutilized lab capacity. Huge chunks of laboratory infrastructure have disappeared from the state since 1996. Here's a partial list:

Physician's Clinical Laboratories: *Chapter 11 Bankruptcy–1996*

Bio-Cypher Laboratories: *Sale to Unilab–1999*

Meris Laboratories: *Chapter 11 Bankruptcy–1997; sale to Unilab–1998*

BSI, Inc.: *Chapter 11 Bankruptcy–1996; sale to Bio-Cypher–1997*

Watson Medical Laboratories: *Chapter 7 Bankruptcy–1996*

Diversified Medical Laboratories: *Chapter 7 Bankruptcy–1996*

Unilab: *Significant operational restructuring–1996-1997*

SmithKline Beecham Clinical Labs: *Significant operational restructuring–1996-1997*

Laboratory Corp. of America: *Significant operational restructuring–1996-1997*

Tenet Healthcare: *Regionalization of 30 hospital labs in Southern California–1998*

New York City Adds Lab Capacity

New Lab Construction During 1996-1998

Even as laboratory overcapacity was taken down in Los Angeles during the years 1996-1998, New York City was seeing a significant expansion in laboratory capacity. The three laboratories noted in the map at left are located within 30 miles or less of each other. Each became operational within a single 12-month period. Since start-up, none of these three labs has been able to generate enough test volume to use more than 25% of potential capacity.

lower costs and improve turnaround time; thus,

2) the hospital's existing specimen volume can support the automated laboratory; and,

3) lower cost per test, combined with faster turnaround time for results will cause hospital labs affiliated with the system to refer specimens to the automated laboratory, filling unused capacity; and,

4) the hospital will launch an outreach sales program to physician offices and fill up unused lab capacity with specimens from this source.

Competitors Knew Plans

It is interesting to note that all three institutions were aware of plans by their cross-town peers to expand laboratory capacity and fill that capacity with referral testing and outreach specimens.

Insiders tell THE DARK REPORT a similar story about all three automated laboratories. Each runs at between 12% and 25% of capacity. Because of this fact, laboratory costs have actually increased for each lab owner.

More importantly, none of these three facilities has succeeded in achieving a key objective of their pre-construction business strategy: generating additional specimens through both hospital testing referrals and outreach specimens from physicians' offices.

This tale of two cities illustrates the value of studying the laboratory marketplace in other cities around the country. There are important lessons to be learned from the experience of laboratories in different areas of the United States.

While labs in Los Angeles were furiously eliminating overcapacity, labs in New York City were optimistically expanding their capacity in anticipation of increased volumes of specimens. The question which must be asked now is: how long will hospitals in New York continue subsidizing this unused laboratory capacity? **TDR**

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CONSOLIDATION CREATING INDUSTRY GIANTS

Diagnostics Companies React To Changing Lab Marketplace

CEO SUMMARY: During the last five years, extensive consolidation among in vitro diagnostics (IVD) manufacturers has created a new class of industry giants. Their increased dominance of the IVD marketplace promises significant change to how laboratories acquire and use reagents, test kits, and new IVD instruments. Here's how and why the IVD industry transformed itself through consolidation.

Part One of an ongoing series

MOST LABORATORIANS FAIL to appreciate how consolidation reshaped in vitro diagnostics (IVD) companies during the decade of the 1990s.

In 1990, the ten largest IVD companies had only 62% of the total market. By 1998, the ten largest IVD manufacturers controlled 80% of the international market for in vitro diagnostics.

Concentration Of Power

This concentration of power is now changing the way diagnostics companies provide products and services to clinical laboratories. As market power concentrates in the hands of fewer and bigger IVD companies, it leaves clinical laboratories with reduced options for purchasing new instruments.

It also increases the risk that clinical laboratories might buy the "wrong" technology when purchasing new instruments. This is because THE DARK REPORT predicts a stratification of the diagnostics industry into two categories of companies.

One category will be the IVD powerhouses. These might be described as the behemoths of the industry. They are huge, offer a broad array of instruments, and have extensive sales and service resources. The three largest IVD firms, **Roche**, **Abbott Laboratories**, and **Johnson & Johnson**, provide good examples of companies in this category.

Innovative Products

The other category will be IVD companies offering innovative products built upon emerging technologies. Generally, these companies will be developers of new technology that has the potential to bring increased value to clinical procedures. Examples in this category are **Affymetrix**, **Idexx Laboratories**, **Ventana Medical Systems**, and **Epitope**.

Dealing with companies in this second category entails a greater risk for laboratories. These companies must demonstrate the clinical and economic value of their diagnostic technology. Since most are start-up companies, they only have a limited capital base to accomplish this goal.

Without Service Or Support

That means laboratories which are early adapters of such new technology might find themselves without service and support if their vendor fails. A recent example of this was the bankruptcy in April of **Neuromedical Systems, Inc.**, maker of the PapNet system for Pap smear diagnosis. Labs using PapNet now must get service and support through other means.

Three fundamental market trends caused the IVD industry to consolidate and evolve into this two-tier structure. The trends were a logical consequence of widespread consolidation among hospital and commercial laboratories.

One, IVD manufacturers used mergers and acquisitions to achieve economies of scale. Larger production runs mean lower manufacturing costs. This allows the IVD company to maintain competitive pricing as GPOs (group purchasing organizations) and integrated healthcare networks seek to drive down prices when acquiring new diagnostics systems.

Two, by offering a unified product line of instruments, IVD companies gain an advantage over firms which only offer a limited number of instruments. The growing interest in automated workcells and upcoming generations of total laboratory automation (TLA) systems further reinforce this trend.

This strategy was clearly at work when **Beckman** purchased **Coulter Corporation** in 1997. This combined Coulters's respected portfolio of hematology instruments with Beckman's line of chemistry instruments. *(See TDR, October 6, 1997.)* **Bayer**'s acquisition of **Chiron Diagnostics** last year was another example of using an acquisition to broaden a product line. *(See TDR, September 28, 1998.)*

Increase Capital Base

Third, it takes increasing amounts of money to research and develop new diagnostic instruments. This was recognized by the largest IVD manufacturers. It was an important reason why they used acquisitions as a way to increase capital available to fund research and development.

These three consolidation trends are rooted in an important fact about the IVD industry. Like the commercial laboratory industry, in vitro diagnostics is considered to be in a mature phase. Growth prospects are limited.

Top Ten IVD Companies

Revenue and Market Share

This table demonstrates how the top ten in vitro diagnostics companies increased their dominance of the worldwide market for IVD products and services. Acquisitions and industry consolidation were the primary business strategies used to build these companies.

($ in millions)		1997		1998	
Rank	***Company***	***$'s***	***% Share***	***$'s***	***% Share***
1	Roche Diagnostics	$3,100	17%	$3,247	18%
2	Abbott Diagnostics	$2,706	15%	$2,827	16%
3	Johnson & Johnson	$1,949	11%	$1,973	11%
4	Bayer/Chiron	$1,637	9%	$1,677	9%
5	Beckman Coulter	$1,426	8%	$1,447	8%
6	Dade Behring	$1,400	8%	$1,330	7%
7	Becton Dickinson(1)	$830	5%	$824	5%
8	bioMerieux Vitek	$506	3%	$528	3%
9	Instrumentation Labs	$252	1%	$232	1%
10	Organon Teknika	$240	1%	$238	1%
Total Top 10 IVD Firms (2)		***$14,046***	***77%***	***$14,323***	***80%***
Total IVD Market		***$18,300***	***100%***	***17,934***	***100%***

Notes:
(1) BD sales exclude vacutainer and labware sales.
(2) All acquisitions are recognized on a pro forma basis.

Source: Company reports and Warburg Dillon Read LLC estimates.

Financial analysts predict that the entire IVD industry will see growth of just about 1% per year through 2002. Even the top ten IVD companies, as a group, are expected to average sales increases of only 5% per year during that same period.

IVD Growth Projections

Compare IVD growth projections with those for sales of personal computers, where analysts see annual revenue increases of 25% to 50% per year. IVD companies must compete for capital. Laboratory executives should understand that IVD companies are under constant pressure from Wall Street to increase sales and earnings.

That does not mean, however, that growth prospects for the IVD industry are totally glum. Specific technologies are expected to deliver rapid revenue gains as clinical usage increases.

In fact, these are technologies which laboratory executives should watch with interest. Because of their potential to enhance clinical outcomes, laboratories will want to add these assays to their offerings as early as possible in the market introduction curve.

Four areas of diagnostic testing are expected to grow rapidly. DNA probes are already a $616 million market for IVD companies. It is projected to grow at 20% per annum.

Whole blood glucose testing is currently a $2.8 billion market and should grow at 12% per year. Increased point of care and home testing kits mean the clinical laboratories will not see as much benefit from this segment.

Point of care testing is currently worth $400 million to IVD companies. This is an area of diagnostics which directly impacts the number of specimens moving away from core laboratories. Estimates are that this segment will grow at 20% per year.

In situ hybridization, currently at $300 million per year for diagnostics companies, is expected to grow at a yearly rate of 15%.

In contrast to these four high-growth technologies, IVD companies still generate substantial sales from technologies considered mature. These are the slow-growth products for which demand is flat or even shrinking.

Technologies considered mature, are cell counting, clinical chemistry, microbiology, and immunoassay. Clinical chemistry is the largest segment. It is estimated that clinical chemistry comprises nearly 40% of the $18.3 billion IVD market. On a unit volume basis, between 50% and 60% of all IVD procedures involve clinical chemistry.

Mature Technologies

IVD companies with the biggest stake in mature technologies are not expected to see strong year-to-year increases in revenues from such technologies. This is one reason for the steady flow of acquisitions by leading IVD manufacturers.

For example, Bayer's acquisition of Chiron Diagnostics last year gave it access to a strong intellectual property position in nucleic acid diagnostics. Of particular value was access to Chiron's HCV technology, its high volume immunoassay system (the Centaur), and a number one market position in the blood gas market.

Bayer's access to Chiron's products helped it diversify away from mature products such as clinical chemistry, immunoassay, and hematology. It demonstrates how selective acquisitions are necessary if IVD companies are to field a competitive mix of products which have high growth potential during the next five years.

Another interesting example of how IVD companies are restructuring their product mix is **Dade Behring**. during 1997 and 1998, Dade Behring's sales declined by 9% and 5%, respectively.

According to Scott Wilkin, a healthcare analyst at **Warburg Dillon Read**, Dade Behring's revenue declines are actually a sign of postive developments at the company. "It is not surprising that sales [at Dade Behring] have declined over the past two years," he wrote last fall. "as the company has been judiciously eliminating unprofitable product lines and redeploying resources in higher-growth, higher-margin businesses."

Wilkins continued "while sales growth has been lacking, management has delivered impressive operating margin and cash flow results."

(continued on page 11)

IVD Firms Serve Four End-User Segments

In vitro diagnostics companies provide products to four distinct types of end-users. They are:

- ***Central Laboratory**–Includes all centralized sites in the hospital or reference laboratory.*
- ***Ambulatory**–Includes all decentralized testing sites in physician offices, clinics, and at the point of care.*
- ***Patient Self Testing**–Includes all testing performed by the patient such as pregnancy or ovulation monitoring.*
- ***Blood Processing and Screening**–Includes all screening sites of donor blood and blood products for quality control purposes.*

Consolidation of In Vitro Diagnostics Firms Leads to Concentration of Market Share

Ten Largest IVD Companies Control 80% of Worldwide Market

	1995	1996	1997	1998	1999
1.	ABBOTT	ABBOTT	ABBOTT	ROCHE DIAG.	ROCHE DIAG.
2.	BMC	BMC	BMC	ABBOTT	ABBOTT
3.	J & J	J & J	J & J	J & J	J & J
4.	BAYER	BAYER	DADE BEHRING	DADE BEHRING	BAYER/CHIRON
5.	COULTER	DADE INT'L	BAYER	BECKMAN COUL	DADE BEHRING
6.	B - D	COULTER	B - D	BAYER	BECKMAN COUL
7.	BEHRING	BEHRING	BECKMAN	B - D	B - D
8.	DADE	B - D	COULTER	CHIRON	BIOMERIEUX
9.	BECKMAN	BECKMAN	ROCHE	BIOMERIEUX	IL
10.	ROCHE	ROCHE	CHIRON	IL	SYSMEX
11.	CHIRON	CHIRON	BIOMERIEUX	SYSMEX	
12.	DU PONT	BIOMERIEUX			
13.	HYBRITECH	MEDISENSE			
14.	IMMUNOTECH			INT'L MUREX	

This table shows the acquisitions which occurred among the world's largest IVD companies since 1995. It is a remarkable demonstration of how consolidation has profoundly changed the IVD industry in just four years. As the table demonstrates, further consolidation among the remaining ten largest IVD companies is possible, but only where the acquisition would complement the buying company's strategic position.

IVD Consolidation Brings Product Breadth

	Lab Auto	Clin Chem	Blood Gas	Immuno diag	Infect Diseases	Nucleic Acid	Hemato-logy	Flow Cyto	Coag-ulation	Micro-biology	Urine Chem	Diabetes
Roche Diagnostics	❍	☆		❍	❍	☆			☐		❍	❍
Abbott Diagnostics		☐		☆	☆	❍	❍					☐
Johnson & Johnson	☐	❍		❍	❍	☐		☐	❍			☆
Bayer / Chiron	❍	☐	☆	❍	☐	❍	❍				☆	❍
Dade Behring					☐				☆	❍		
Beckman Coulter	❍	❍		☐	☐		☆	❍				
Becton Dickinson						☐	☐	☆		☆		
bioMerieux Vitek				☐	❍				☐	❍		
Instrumentation Labs		☐	❍						❍			
TOA/Sysmex							❍					

☆ Market Leader ❍ Significant Participant ☐ Player/New Entrant

During the 1990s, leading IVD companies used acqusitions to create a diversified line of products. Increasingly, one single IVD firm can provide a laboratory customer with a wide range of instruments and reagents.

Wilkin's comments about Dade Behring illustrate how the major IVD manufacturers are juggling their product lines to drop money-losers and add breadth to the products they offer laboratories.

To summarize, during the 1990s, several trends dominated the IVD industry. These trends are changing, in fundamental ways, how diagnostics companies and clinical laboratories interact with each other.

Predominant Trend

The predominant trend has been consolidation. IVD firms used acquisitions to build size, increase volume, and generate economies of scale in manufactoring and sales.

Second, the largest IVD firms have used acquisitions to build a broad offering of products. As the chart above demonstrates, the larger IVD companies are able to offer a broader menu of products as a single source.

Third, consolidation of laboratories is changing the way IVD companies sell their products. The emergence of integrated healthcare systems and stronger GPOs caused IVD firms to concentrate on meeting the different needs of this new class of buyers.

Coming issues of THE DARK REPORT will provide profiles of the leading IVD companies. The fortunes of clinical laboratories and the IVD industry go hand-in-hand. It is important for laboratory executives to understand the market forces now transforming the IVD industry. Such knowledge makes it possible to make more informed purchasing decisions. TDR

Managed Care Update

Insurance Premiums Climb 9.7% For Calpers in Calendar 2000

MORE VALIDATION that healthcare premiums will trend upwards at near double-digit rates came from California this week.

The **California Public Employees' Retirement System** (Calpers) announced it will pay average rate increases of 9.7% to HMOs starting in 2000. This is significant because Calpers is considered one of the shrewdest buyers of healthcare in the nation.

The 9.7% increase for 2000 comes after average rate increases of 2.7% and 5.1% in 1997 and 1998, respectively. It is considered a sign that HMOs in other parts of the country will have better success in negotiating aggressive premium increases from employers.

Competition For Business

Will these aggressive premium increases help boost laboratory reimbursement? Probably not, for several reasons.

First, in most markets there are still laboratories willing to bid at low prices to acquire new business. This gives HMOs the ability to play one lab provider against another during contract renewals.

Second, many HMOs are financially-strapped. Large increases to premiums are necessary to offset significant losses suffered by these insurers during recent years.

For example, **Kaiser Permanente** negotiated an 11.7% rate increase with Calpers for the year 2000. Kaiser insures about 40% of Calpers' beneficiaries and posted sizeable losses during the past two years. Kaiser extracted a 10.8% rate increase from Calpers for 1999 and is now one of Calpers' higher-cost HMOs.

Modest Rate Increase

Those laboratories dealing with **PacifiCare** will be interested to know that PacifiCare's rate increase to Calpers was only 6%, the third lowest among Calpers' HMOs. PacifiCare also agreed to extend a long-term contract with Calpers by three years.

This is evidence that PacifiCare's business plan may be relatively more successful than those of competing HMOs. If true, it means that PacifiCare could be evolving into a tougher competitor. Unburdened by the financial problems of other HMOs, it is free to concentrate on expanding its presence in many markets.

Because of the size and clout of Calpers, its announcement of premium rate increases for 2000 will set the tone in a number of other markets. With inflation still running about 2% per year, premium increases approaching 10% mean that HMOs will probably be criticized for their failure to control healthcare costs.

This improves the opportunity for clinical laboratories and pathology practices to increase their value to HMOs by demonstrating how lab services improve healthcare outcomes while reducing the cost of patient care. TDR

Lab Industry Briefs

AMERIPATH INKS PACT WITH MEDAPHIS, BUYS FLORIDA PATH PRACTICE

Things are busy at **AmeriPath, Inc.** of Riviera Beach, Florida. The pathology practice management company announced a number of accomplishments.

First, it signed an agreement with **Medaphis Corporation** of Atlanta. Medaphis will provide "comprehensive reimbursement services" for 20 AmeriPath practice locations. These will include billing, AR, and enhanced reporting.

Second, AmeriPath announced the recent acquisition of **Hialeah and South Florida Pathology**. One interesting aspect of the transaction is that this pathology practice provides AP services to **SmithKline Beecham Clinical Laboratories** (SBCL) under their managed care contracts. AmeriPath is also an AP provider to SBCL in Florida.

With the acquisition of this $3.5 million pathology practice, AmeriPath now operates 12 pathology practices in Florida and has 80 pathologists in the state. The total number of pathologists under the AmeriPath umbrella now numbers 231, working in ten states.

Finally, AmeriPath released first quarter earnings. Net revenue was $52.3 million, up 38% over first quarter 1998's $38.0 million. AmeriPath says that "same practice" revenue jumped by 5% during the year. Net income increased by a comparable amount, from $3.8 million last year to $5.3 million this year, a gain of 48%.

AmeriPath also stated that it has signed letters of intent with four other pathology practices. These deals are expected to close during the second quarter. It projects a minimum of ten additional acquisitions will be closed by the end of 1999.

AmeriPath disclosed that it plans to open an outpatient pathology laboratory in the New York City area by the end of September. It described this initiative as "a catalyst for the Company's expansion into the northeast region of the United States."

CYTYC'S LIQUID PREP GETS A BOOST

ONE CRITIQUE of the liquid preparation method for Pap smears is that it adds cost without providing a compelling clinical benefit.

AS THE DARK REPORT has written, the challenge for new diagnostic technology in the managed care marketplace is to demonstrate, in a convincing way, that benefits of a new technology are appropriate to its cost.

Cytyc Corporation has worked closely with **Digene Corporation** to demonstrate that its ThinPrep® liquid preparation system has distinct benefits over traditional Pap smear preparations. Digene markets a Hybrid Capture II® HPV (human papillomarvirus) test.

The companies recently released news of a clinical study led by Michele Manos, Ph.D. M.P.H. of the **Northern California Kaiser Permanente Medical Group**. The study selected 995 women with borderline abnormal Pap smears from a group of 46,009 women undergoing routine Pap smear screening.

The study was published in the May 5 issue of the *Journal of the American Medical Association* and used Digene's Hybrid Capture II PHV test and compared it to the current method of doing repeat Pap smears and colposcopy exams to detect high grade cervical lesions.

The study determined that "patient management incorporating the Digene HC II HPV test detected 96.9% of women with high grade cervical disease compared with 75.8% using the traditional method of repeat Pap testing alone. The negative predictive value of the Digene HC II HPV test was 98.8%."

Should further studies validate this conclusion, it strengthens Cytyc's claims that a liquid preparation Pap smear, accompanied by Digene's HPV test in certain cases, improves healthcare outcomes at a reasonable cost.

This demonstrates how the added value of a new technology can change over time. Refinements to the technology and new discoveries can make subsequent generations of technology increasingly cost-effective. Expect Cytyc to diligently identify enhancements which can justify the cost and use of its liquid prep system.

UNILAB OFFICIALLY BUYS BIO-CYPHER LABORATORIES

ON MAY 10, **Unilab Corporation** confirmed that its purchase of **Bio-Cypher Laboratories** was complete.

With the acquisition of Sacramento-based Bio-Cypher, Unilab becomes the big dog in California, with consolidated revenues approaching $300 million per year.

Once Unilab completes its integration of Bio-Cypher's laboratory operations, another $60 million of annual lab capacity will have disappeared from the California market. Bio-Cypher was formerly known as **Physicians Clinical Laboratories**.

Unilab also released earnings for first quarter 1999. Revenues were $63.6 million, up 16.6% from the $54.5 million of first quarter 1998. Much of the gain was attributable to Unilab's purchase of **Meris Laboratories** last fall. Prices jumped 4% over the same quarter of 1998.

NAIAD TECHNOLOGIES OFFERS LABS A SOLUTION FOR HAZARDOUS WASTE

LABORATORIANS OUGHT to check out some intriguing technology offered by **Naiad Technologies, Inc.** of Portland, Oregon.

This is an unabashed plug for one of THE DARK REPORT'S neighbors here in the Northwest. Naiad has several proprietary technologies for dealing with hazardous waste in the clinical laboratory.

Its newest product extracts DAB (diaminobenzidine) from aqueous waste solutions generated by automated immunohistochemistry staining machines.

The company's products segregate, reduce, and solidify hazardous substances found in liquid waste streams. In many cases, the laboratory can recycle the carrier solution, further reducing costs.

Naiad has exhibited at various lab industry trade shows in recent years. It is a start-up company utilizing technology developed by a research lab at an Oregon university. THE DARK REPORT has toured Naiad's corporate facilities and seen some of the technology in action.

Although Naiad's hazardous waste technology is new, early adapters among clinical laboratories have been enthusiastic about its effectiveness in actual use. TDR

The Dark Index

LabCorp Making Steady Progress On Path Back to Financial Health

By launching new services in the market, LabCorp is raising customer expectations

MOST OF THE LAB INDUSTRY is watching the impending acquisition by **Quest Diagnostics Incorporated** of **SmithKline Beecham Clinical Laboratories** (SBCL).

This big news overshadows the steady gains made at **Laboratory Corporation of America** in its efforts to return to financial stability. After several years of financial struggle, the company is showing improved financial performance for the first quarter of 1999.

More importantly, LabCorp is returning to the marketplace with several new strategic sales programs. It seems to validate THE DARK REPORT'S prediction that, as the three blood brothers regain financial strength, each will increase its sales and marketing activities against other laboratory competitors.

Competition For Business

Further, LabCorp's new products demonstrate how competition for business in the marketplace causes laboratory customers to expect a higher standard of service and quality. These new products also demonstrate that improved turnaround time and added value information (not just test results) can help laboratories acquire new clients.

For first quarter 1999, LabCorp showed a revenue increase of 7.8% over the same period in 1998. Net revenues were $417.9 million versus $387.7 in first quarter 1998.

LabCorp officials said that 4.4% of the revenue increase was attributable to increased prices for laboratory testing. The remaining 3.4% increase was from a larger volume of specimens.

LabCorp has stated that it will not bid for laboratory testing using prices based upon marginal cost. Assuming it followed that principle, a 4.4% gain in pricing for first quarter provides evidence that such a business strategy can work in today's healthcare marketplace.

New Added Value Services

Laboratory executives should pay particularly close attention to recent announcements by LabCorp concerning its product offerings. LabCorp, like Quest and SBCL, has enough financial strength to introduce new added value laboratory services to the market.

The most interesting development was the joint announcement last month by LabCorp and **PCS Health Systems** that the two firms had signed a contract with the **Mail Handlers Benefits Plan**. The two companies will provide laboratory testing and pharmacy services to the one million members of the Mail Handlers Benefits Plan.

This is significant because it marries laboratory testing with pharmacy services. PCS is a multibillion dollar pharmacy benefits manager owned by **Rite Aid Corporation**. PCS had joined with LabCorp in 1997 to form a laboratory benefits program.

PCS formerly handled **Lab*One's*** LabCard™ program as a third party administrator. *(See TDR, March 18, 1996.)* Under this program, Lab*One* offered lab tests to self insured employers at discounted fee-for-service prices. By showing their LabCard to physicians, beneficiaries could get lab testing done without the need for a copay, deductible, or out-of-pocket payment.

Combine Lab And Pharmacy

PCS later joined forces with LabCorp to develop a similar program, now called "Performance Lab." Both companies wanted to combine benefits for laboratory testing and pharmacy services under a single administrative umbrella.

What is particularly interesting about this venture is that both parties want to convert primary data—laboratory test results and pharmacy prescriptions—into useful information. They recognize the value in matching laboratory results with prescriptions ordered by the physician for the patient.

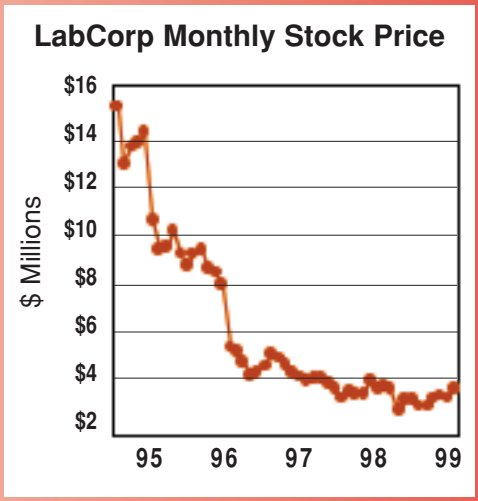
Both companies believe such cross-matching of information can identify patients who are not being properly treated. By combining lab results with prescriptions, they can possibly identify patients who are being under-treated or getting inappropriate medication for their condition.

Demonstrate A Benefit

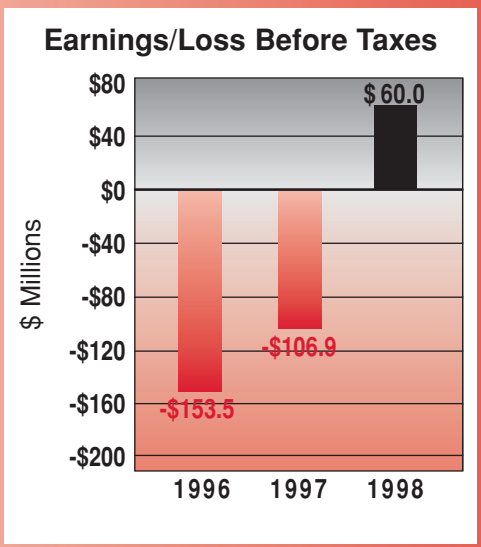
As with all new marketplace experiments, it will take some time for the two companies to collect data, convert it into added value information, and demonstrate a significant benefit in matching laboratory results with prescriptions. But it represents another forward step in the development of the integrated clinical environment toward which the market is evolving.

The second marketplace initiative is LabCorp's announcement last week of a drugs of abuse testing program that can deliver results "in less than one

LABCORP'S DECLINING STOCK PRICE REFLECTS PAST LAB INDUSTRY WOES



Stock prices and earnings for Laboratory Corporation of America show how brutal the last four years were to many clinical laboratories.



hour." The program, which LabCorp calls "RAdar (for Rapid Assessment of Drug and Alcohol Results), will use Roche's TesTcup® technology. This is described as a "self-contained, integrated collection and testing device that provides results in minutes."

Although initial positive results still will undergo a confirmation at one of LabCorp's SAMSA-accredited laboratories, it does introduce a new factor into the intensely competitive market for drugs of abuse testing.

Taken together, these two marketing programs announced by LabCorp should be recognized by laboratory executives as "raising the bar" for laboratory services. Regardless of whether both programs are discernably better today than other services offered by competing labs, they do elevate the expectations of customers.

Interesting Facts About LabCorp

Managed care contracting and hospital alliances are two issues of concern to laboratories throughout the United States.

During 1998, LabCorp held approximately $90 million in capitated contracts. This represents about 6.7% of its $1.61 billion revenues in 1998.

During 1998, LabCorp developed 58 new "strategic alliances" with hospital labs. These involve a variety of service relationships. Based on past numbers provided by LabCorp, THE DARK REPORT estimates that these alliances represent less than $80 million in annual revenues. Combined with existing "strategic alliances," LabCorp probably generates about $150 million per year from its hospital alliance program.

For those interested in revenue per requestion, LabCorp says that managed care represents between 35% and 45% of its accessions in 1998, and generated between $10 and $40 per requisition. Commercial clients are the source of between 20% and 25% of total accessions, with revenues of $15 to $25 per accession.

Ordering/Reporting Systems

Remember when commercial laboratories first introduced PC-based lab test ordering/reporting systems into physicians' offices in the early 1990s? Once customers recognized the benefit of such a system, it became necessary for any competing lab to offer the same type of PC system if they were to compete for the business.

That is why it is important for laboratory executives to view these marketing initiatives by LabCorp, and similar product launches by Quest and SBCL, as a sign that the market is forcing clinical laboratories to add tangible real value to a simple test result if they are to retain and increase their customer base.

Said in another way, THE DARK REPORT wants its clients and readers to recognize that the market is dynamic. Any lab which sits still and only offers the same laboratory services it did five years ago will find itself at a competitive disadvantage. It is essential for regional and hospital-based labs to innovate and develop added value services if they are to remain competitive and financially viable.

Intense Battle For Clients

As LabCorp, and the other two blood brothers restore their focus on sales and marketing, competing labs can expect a more intense battle over new client accounts. The financial struggles and internal distractions of 1996, 1997, 1998 are passing.

Regional laboratories should recognize that competitive success in the future rests on offering their clients innovative laboratory testing services which add value. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Maybe the clinical laboratory industry is finally getting its political act together. Last issue of THE DARK REPORT, we noted that the **New York State Clinical Laboratory Association** (NYSCLA) is working to get the New York **Department of Health** to issue an opinion as to whether "below-cost" lab contract pricing is an inducement under existing statutes. Now comes news that, on the West Coast, the **California Clinical Laboratory Association** (CCLA) is invoking a little-known provision of state law to request that the **California Department of Health** adopt a regulation to mandate the use of ICD-9 codes by prescribers. It would be good news for all labs should both trade groups prevail in their efforts and state regulators respond favorably on these issues.

Neuromedical Systems, Inc. (NSI), maker of PapNet, is the first casualty of the automated Pap smear technology wars. **AutoCyte, Inc.** confirmed this week that it's acquired NSI's intellectual property, including patents, from NSI's bankruptcy action.

PREDICTION: MONEY WOES AHEAD FOR NATION'S HOSPITALS

Laboratories are not the only category of healthcare provider to be hit hard by Medicare reimbursement cutbacks. In the last 18 months, home health agencies, long term care facilities, and physical rehabilitation providers reported financial difficulties directly attributable to reduced Medicare reimbursement. THE DARK REPORT predicts that an increasing number of hospitals will soon begin reporting significant losses, as the impact of recent Medicare reforms works its way through the system. It may take another 24 months for a clear picture of deteriorating hospital finances to develop.

ADD TO...HOSPITALS

Any widespread deterioration of hospital finances will become a political hot potato because, unlike laboratories, hospitals have lobbying clout at the local, state, and federal level. However, until lobbying is under way, hospital laboratories will feel the full weight of any financial difficulties plaguing their institution.

Wonder what's up with the impending acquisition of **SmithKline Beecham Clinical Laboratories** by **Quest Diagnostics Incorporated**? The comment period by antitrust regulators (**Department of Justice** and **Federal Trade Commission**) expired without action by either agency. Next step is a vote by Quest shareholders, scheduled to occur in early June. Indications are that Quest will become owner of SBCL on July 1, 1999.

How much do employers spend on employee healthcare and related issues? Over $8,600 per year, according to a national survey of 17 large employers, including **Dow Chemical**, **Lucent Technologies**, and **Xerox**. This number covers costs in 1997 for healthcare ($5,000), turnover ($1,900), unscheduled absences ($700), nonoccupational disabilities ($630), and worker's compensation ($400). The survey was done by **Medstat Group** and the **American Productivity and Quality Center**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 7, 1999

THE DARK REPORT

UPCOMING...

- *Work Cells and Modular Automation: New Products Finally Move into Laboratories.*
- *Are Pathology PPMs Dead? Inside Scoop On "Behind the Scene" Developments.*
- *Useful Management Wisdom From Innovative Laboratory Leaders.*
- *200-Bed Hospital Uses Outsourcing To Create Winning Outreach Lab Program.*