

From the Desk of R. Lewis Dark...

THE **RED** DARK REPORT

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

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Commentary & Opinion by...

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Professional Management Does Get Results

IF YOU TAKE THE TIME TO STUDY THE FINANCIAL PERFORMANCE of certain public laboratories in 1999 and into 2000, you will be struck by the strong growth and profit numbers. That is contrary to the popular wisdom, which says that the clinical lab industry is in financial doldrums.

But the strong financial gains posted by companies such as **DIANON Systems, Inc.**, **IMPATH, Inc.**, **LabOne, Inc.**, **Quest Diagnostics Incorporated** and others in 1999 and the first two quarters of 2000 illustrate an undeniable fact: professional management, diligently applied, gets results. Even the executives from these lab companies will agree that reimbursement for testing is declining; that test utilization patterns are changing, usually for the worse; and that basic costs are rising year-by-year faster than lab test reimbursement.

So why do some of these companies show revenue and profit growth ranging from 20% to 40%? (*See page 8.*) And why do these companies financially outperform most of their independent commercial lab and hospital lab outreach competitors? I believe it is because they are ahead of most laboratory organizations in shedding the old management conventions of the prior generation of technically-trained lab administrators. In their place, these lab companies are adopting new models of professional corporate business management.

For example, these companies are willing to declare a growth goal of 10% or 30% per year. Then they ask their managers and employees to contribute in making that goal a reality. I mention this first because, if your lab team doesn't have a goal, it can't achieve things which might be considered improbable or even impossible. Yet an essential part of professional management is to establish goals, then help the organization achieve those goals.

I would be remiss in failing to also point out the important role of sales and marketing to professional management. Organizations need to grow to retain their vitality and momentum. Yet in most hospital lab outreach programs, sales and marketing is underappreciated and fails to get the support it should from senior administration. This despite the fact that increased test volumes usually mean employment stability, career opportunity, and increased profits for expansion.

I believe today's most successful laboratory organizations are possessed of good management discipline. The strong financial performance of these lab companies during 1999 and into 2000 demonstrates that professional management methods do make a positive difference!

Lab Industry Attracting New Investment Dollars

Professional investors becoming interested in clinical lab & anatomic pathology services

CEO SUMMARY: Professional investors with access to hundreds of millions of dollars of investment capital are closely scrutinizing the clinical laboratory industry. They are encouraged by the recent financial performance of public laboratory companies. For independent laboratory owners, this may be a golden opportunity to sell or restructure their business on favorable terms.

RECENT FINANCIAL GAINS by the nation's highest profile laboratory companies have caught the attention of the professional investment community.

Indications are that these investors intend to act upon their heightened interest by making significant investments across the spectrum of laboratory and diagnostic companies. If this occurs, then the face of the clinical lab industry in the United States may change significantly during the coming 24 to 36 months.

This coming investment boom is fueled by the soaring stock prices of several laboratory and diagnostics companies. Since January, stock prices of several laboratory and diagnostics companies literally skyrocketed

upwards. For example, shares of **Quest Diagnostics Incorporated** now trade at \$105, up from \$30 in early January.

Laboratory Corporation of America, looking to boost its share price, which was \$3.50 per share as recently as January, completed a 1-for-10 reverse stock split and saw its share price jump to \$103. (See *TDR*, June 19, 2000.)

It is a similar story at **DIANON Systems, Inc.** and **IMPATH, Inc.**, where strong revenue growth in anatomic pathology services boosted revenues and earnings. DIANON's share price doubled in the last seven months and is currently trading at about \$31 per share. Since January, IMPATH's shares increased 200%,

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climbing from \$26 to \$62 in recent trading.

Probably the most spectacular run-up in a lab industry stock has been **Cytec Corporation**, manufacturer of the ThinPrep® liquid preparation Pap smear technology. Just 12 months ago, in July 1999, its shares were trading at \$12. By January, the price was up to \$36 and the stock split. Recently its shares sold for about \$65.

Good News For Lab Owners

All this may be good news for the owners of the remaining independent commercial laboratories in the United States. It means there will be more buyers, with strong financial backing, looking to acquire viable commercial laboratory operations.

But it isn't just the soaring stock prices of the public lab companies which caught the attention of Wall Street investors. During recent years, two high-profile private equity companies made significant investments in clinical laboratory companies. These investments took place at times when the lab industry's finances were depressed and prospects were poor.

First into the lab industry marketplace was **Golder, Thoma, Cressy & Rauner Partners** (GTCR), based in Chicago, Illinois. This private equity investment firm made two big commitments. First, it provided financing and assistance to allow Harvey Shapiro and his executive team to take **Dynacare, Inc.**, the Canadian lab company, private in 1995.

Purchase Of AML

GTCR's next foray into the lab industry was to help Timothy Brodник, Jack Bergstrom, and Jerry Glick finance the acquisition of **American Medical Laboratories, Inc.**, located in Chantilly, Virginia. This transaction was completed in May 1997. During 1999, GTCR again provided capital

and expertise when Las Vegas-based **Associated Pathologists Laboratories** (APL) joined up with AML to form an expanded laboratory company. (See *TDR*, May 12, 1997 and September 20, 1999.)

The other major lab investment was made by **Kelso, Inc.** of New York City. In 1999, it purchased **Unilab, Inc.** of Tarzana, California and took the company private. Kelso paid approximately \$420 million to acquire Unilab and its annual revenues of \$300 million. (See *TDR*, June 7, 1999.)

As of this date, indications are that both GTCR and Kelso are pleased with the performance of their investments in laboratory companies. When Wall Street combines this fact with the soaring stock prices of Quest Diagnostics, LabCorp, DIANON, IMPATH, Cytec, and others, it motivates professional investors to consider additional investment opportunities within the lab, pathology, and diagnostic industries.

Sizeable Investment Dollars

THE DARK REPORT is aware of several investment groups that are willing to commit sizeable investment dollars into a laboratory company or diagnostics vendor. In aggregate, these investment groups can tap up to several billion dollars of capital to fund any lab-based investments that catch their eye.

That is why the commercial laboratory segment of the lab industry may see significant change in the next 24 months. There are several ways that new investors may impact the market.

First, THE DARK REPORT predicts that Wall Street investors will tend to build their strategic business plan around the concept that the most profitable laboratories are high volume labs with the lowest cost-per-test.

Thus, these investors will tend to look for "roll-up" opportunities. They want to consolidate several lab organi-

How New Investors Can Create Change in the Lab Testing Market

PROFESSIONAL INVESTORS CAN CAUSE significant change to the clinical laboratory marketplace. The recent example of **American Medical Laboratories, Inc.** provides a good example.

In May 1997, three individuals purchased American Medical Laboratories (AML), located in Chantilly, Virginia. The private equity investment firm of **Golder, Thoma, Cressy & Rauner** (GTCR) provided advice and acquisition capital.

At the time of the purchase, AML was a classic example of the independent commercial laboratory which had an excellent reputation among physicians and hospital lab clients. Over several decades, the existing owners had steadily built the laboratory into a regional power. But for many reasons, these existing owners were content to maintain only modest growth.

That was not the case with AML's new owners. They had a different vision for AML. They wanted to convert AML into a national reference laboratory. They also wanted to put AML on a fast-growth track. In doing this, they placed AML in full competition with the

existing national reference labs, such as **ARUP Laboratories, Mayo Medical Laboratories, and Specialty Laboratories**, as well as the two blood brothers.

It's been three years since the AML acquisition. Its new owners, working in tandem with the previous owners who remained part of the executive team, have instilled a more aggressive management philosophy into the laboratory. It didn't take long before AML was able to double its size and annual revenues.

More significantly, AML has roiled the national market for reference and esoteric testing services. As a serious competitor, it has increased the level of competition among reference laboratories for major clients. *(See TDR, August 30, 1999.)*

Hospital lab clients welcome this increased competition, because it means lower prices and more "extras." But the important lesson is this: new laboratory owners, capitalized by private equity investors, entered the lab marketplace and forced a change in the way this segment of the lab industry competes for new business.

zations to harvest economies of scale. The expectation is that large size and huge testing volumes should generate improved profit margins. This is the business strategy that fueled fast growth (as well as subsequent financial difficulties) at **Allied Clinical Laboratories, Damon Clinical Laboratories, MetPath, National Health Laboratories, Nichols Institute**, and others during the 1990s.

Because this new crop of professional investors are "outsiders," they seldom appreciate the subtle differences that quality of service contribute to lab profits. Yet it is quality of service that allows most surviving indepen-

dent commercial labs to do a stable, if not thriving, business with local physicians. They compete successfully despite the fact that these independent labs have a higher cost-per-test than the two blood brothers and often are excluded from national managed care contracts.

Multiple Buyers Possible

Second, all independent laboratories with some size and regional clout will probably find themselves approached by multiple buyers during the next 24 months. If someone wants to invest in the clinical lab business, there are only a limited number of acquisition targets. Thus, it may be a sellers market.

Third, labs operated by these new owners will have a different characteristic from those labs which continue under existing ownership. They will be run under the accepted management philosophies advocated by W. Edwards Deming and ISO-9000 guidelines.

Continuous Improvement

Internally, these labs will be managed with the goal of continuous improvement to regularly lower costs while simultaneously improving quality. Externally, they will maintain a professional sales and marketing program that generates steady growth in specimens and revenues.

What will constrain professional investors is the limited number of independent commercial laboratories that are appropriate prospects for acquisition and subsequent expansion. In many metropolitan areas, only hospital-based lab outreach programs exist to compete against the blood brothers. Sizeable independent lab operations no longer exist in such markets.

It is easy to speculate on the most likely targets for such acquisition activity because the list is pretty short. A representative list of regional independents that might be large enough to be attractive acquisition targets includes companies such as **PathLabs, Inc.** in Portsmouth, New Hampshire; **Medical Arts Laboratories, Inc.** in Oklahoma City, Oklahoma; **Boyce and Bynum Laboratories** in Columbia, Missouri; and **Sunrise Medical Laboratories** in Hauppauge, New York.

Likely Acquisitions

These examples represent likely acquisition candidates for several reasons. One, they are independently owned and operated by individuals, not hospital systems. This means that new owners can move quickly to institute changes and expand into

new geography. This was the case when Dynacare, Inc. purchased **Laboratory of Pathology (LOP)** in Seattle, Washington in 1995. Once Dynacare closed on the sale, it immediately expanded the areas serviced by LOP.

Two, the specimen volume and operational infrastructure of independent clinical labs like these is usually large enough to support expanded sales and marketing without requiring an expensive expansion of lab capacity.

The new owners of both LOP in Seattle and AML in Chantilly were able to double the specimen volume moving through their lab systems without any significant new construction or expansion of lab capacity.

Top Service In The Region

Third, these laboratories have a lengthy history of providing top service to their regional market. But for many reasons, existing owners have chosen not to pursue obvious growth opportunities. This gives the new owners an easy starting point to boost revenues. Again, LOP and AML demonstrate this principle. New owners doubled the annual revenues of these labs in under 36 months!

THE DARK REPORT expects that new investment groups will join the existing lab buyers, such as Dynacare and **Laboratory Corporation of America**, in approaching independent lab owners. During the next 12 to 18 months, some very interesting lab deals will result from all of this buying activity.

In recent years, only a handful of significant lab sales were completed. But that could change if new buyers are willing to pay healthy prices for existing independent commercial laboratory companies.

TDR

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Several Labs Planning A Public Stock Offering

These laboratory firms have the motive, the size, and the capability to go public

CEO SUMMARY: *During the past six years, no general clinical laboratory company has undergone an initial public stock offering (IPO). That will certainly change during the next 24 months. There are several private lab companies which want to go public. But this business strategy can only succeed if the stock market stays flush and the financial performance of individual labs remain at acceptable levels.*

SEVERAL INDEPENDENT LABORATORY companies are preparing themselves for an initial public stock offering (IPO) in the next couple of years.

Lab company IPOs have been a tough sell in recent years. The financial performance of the clinical lab industry was so dismal that Wall Street investment bankers gave little encouragement to lab companies seeking to tap the public stock market.

But this gloomy financial environment has turned around during 2000. Shares of the two blood brothers have climbed to record levels. A surging stock market and booming economy in the United States have improved the prospects for a clinical laboratory company to go public.

One laboratory company that plans to launch an IPO is **Esoterix, Inc.**, based in Austin, Texas. Esoterix is the parent company for a consortium of eight well-established specialty laboratories, such as **Cytometry Associates** and **Endocrine Testing**.

Collectively, Esoterix represents about \$65 million per year in lab revenues. During the past year it has actively worked with investment bankers. It is integrating operations between the various laboratories and developing the management structure and financial reporting systems required to be a public company.

Pursuing an IPO

Another laboratory known to be pursuing an IPO is **Dynacare, Inc.**, headquartered in Toronto, Canada. Since going private in the mid-1990s, it has actively developed laboratory operations in several cities around the United States. (*See TDR, January 3, 2000.*)

Dynacare executives have told employees that a desired time line for an IPO would be in the second half of 2001. Dynacare's U.S. revenues are estimated at about \$360 million per year.

Another likely candidate for a public stock offering is Unilab, Inc., based in Tarzana, California. Its majority owner, **Kelso, Inc.**, is a private equity investment company that generally

exits a business by either taking it public or selling it to a corporation. (See pages 2-5.)

However, it may be several years before Unilab is ready for an IPO. Kelso paid a rather high price and Unilab must generate a substantial increase in revenue and earnings before it will be profitable for Kelso to sell it or take it public.

Another IPO Prospect

Of course, another prospective lab company which could likely succeed with an IPO is **AML-APL, Inc.**, the lab company made up of **American Medical Laboratories, Inc.** (AML) in Chantilly, Virginia and **Associated Pathologists Laboratories, Inc.** (APL) of Las Vegas, Nevada. Combined, THE DARK REPORT estimates the two labs have combined revenues in the range of \$250–\$300 million dollars.

There has never been a public declaration that AML-APL, Inc. intends to go public. Conversations with various lab executives there indicate they like their freedom of action and don't feel compelled to pursue a public stock offering in the immediate future.

This "short list" of four lab companies represents the most likely prospects for a public stock offering. Each lab company has the financial size to be attractive as a public company.

Beyond these four labs, the list of potential lab candidates for an IPO is limited. But there is one category of lab company which has the business reach and financial size to be attractive as a public stock. That category contains the national reference laboratories.

But the owners of these reference labs are not likely to want an IPO. **Mayo Medical Laboratories** is owned by the **Mayo Clinic**. **ARUP Laboratories, Inc.** is owned by pathologists at the **University of Utah**. Among the national reference laboratories, **Specialty Laboratories, Inc.**, would be easiest to package for an IPO. It has a single individual as majority owner, and a track history of rapid growth.

If lab industry finances continue to rebound during the next 18 months, any of these declared candidates can be the next lab company to become a publicly-traded corporation. **TDR**

Sizeable Laboratory Testing Companies Exist As Operating Divisions of Several Corporations

Often overlooked by the clinical laboratory industry are a number of specialty testing companies which are divisions of large corporations offering healthcare services.

One example of this is **Genzyme Genetics**, a division of **Genzyme Corporation**. With labs in Framingham, Massachusetts and Santa Fe, New Mexico, Genzyme Genetics provides a wide range of services, including "prenatal biochemistry, prenatal, postnatal, and cancer cytogenetics, and fluorescence in Situ hybridization (FISH); flow cytometry and molecular (DNA) analysis." Its annual revenues are not dis-

closed in Genzyme's financial reports, but it is estimated that Genzyme Genetics does around \$100 million per year in lab tests.

Athena Diagnostics, Inc. of Worcester, Massachusetts is a division of **Elan Corporation**, a pharmaceutical company headquartered in Ireland. Athena Diagnostics offers reference and esoteric testing to neurologists. Similarly, several of the national renal care companies offer lab testing. **Total Renal Care, Inc.** has a division called **Total Renal Laboratories, Inc.** which specializes in "End State Renal Disease" testing.

Public Laboratory Rankings

General Reference Laboratories

Ranking By 1999 Annual Revenue (\$s in millions)

Rank	Laboratory	1999 Revenue	% Change	1998 Revenue
1.	Quest Diagnostics Incorporated ¹	\$2,205	+47.2%	\$1,498
2.	Laboratory Corporation of America	\$1,699	+4.7%	\$1,612
3.	LabOne, Inc.	\$120	+17.6%	\$102
7.	Bio-Reference Laboratories, Inc. ²	\$54	+14.9%	\$47
Total: General Reference Laboratories		\$4,078	+25.1%	\$3,259

1. Quest Diagnostics acquired SmithKline Beecham Clinical Laboratories in August 1999.

2. BRLI's fiscal year ends 10/31/99.

3. Unilab, Inc. became a private company in October 1999.

3. DIANON Systems moves to list below as "niche & pathology laboratory company."

Public Lab Companies Doing Well

As the tables above and below demonstrate, almost without exception, public lab companies posted strong gains in revenues and operating profit during 1999.

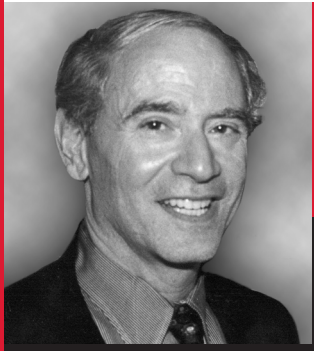
Financial reports for Q1 and Q2 2000 validate that this trend continues. During the past 18 months, there has been neither a significant improvement in lab test reimbursement nor an increase in lab specimens due to new assays.

Thus, the generally-positive financial performance of public lab companies during 1999 can probably be attributed to a stabilized healthcare market for lab testing services, combined with improved management execution by the executive teams of these lab companies.

Niche & Pathology Lab Companies

Ranking By 1999 Annual Revenue (\$s in millions)

Rank	Laboratory	1999 Revenue	% Change	1998 Revenue
1.	AmeriPath, Inc. (pathology management)	\$232.8	+31.3%	\$177.3
2.	IMPATH Inc. (oncology)	\$85.4	+51.7%	\$56.3
3.	DIANON Systems, Inc. (anatomic pathology)	\$76.1	+22.6%	\$62.2
4.	UroCor, Inc. (urology)	\$45.5	-4.4%	\$47.6
5.	PharmChem, Inc. (substance abuse)	\$44.4	+2.8%	\$43.2
6.	MedTox (substance abuse)	\$31.0	+4.7%	\$29.6
Total: Niche & Path Lab Companies		\$515.2	+23.7%	\$416.2



"These five trends will have great impact on the way clinical lab data is generated, reported, stored, and accessed."

—Bruce A. Friedman, M.D.



Dr. Friedman Identifies Market Dynamics Driving Lab Information

He sees five dynamics actively shaping the future content and delivery of laboratory information

CEO SUMMARY: *Probably no one is better positioned to identify the evolution of laboratory information services than Bruce Friedman, M.D., Professor of Pathology at the University of Michigan Medical School in Ann Arbor. For almost 20 years, he has hosted the pre-eminent meeting in laboratory informatics, known as AIMCL—Automated Information Management for Clinical Laboratories. Dr. Friedman recently chaired the Laboratory Web Informatics Day at the Executive War College in New Orleans. He shares his thinking about the important forces currently driving the rapid evolution of laboratory information services and products.*

EDITOR: Many laboratory executives and pathologists are now grappling with the concept of e-health services. The transformation of the Internet into a useful and effective platform for managing laboratory and other clinical information is happening at lightening speed. Do you see a rapid adoption of Web-enabled lab information products by our industry?

DR. FRIEDMAN: Yes, it will be a fast transformation. Of equal interest, I believe it will be impossible to identify any single product or technology in the e-laboratory domain that will spark the changeover from today's methods of collecting, processing, and sharing laboratory information. Instead, we will see a stream of new technology breakthroughs that reinforce and complement each other.

EDITOR: Give me an example.

DR. FRIEDMAN: Let's look at wireless transmission of laboratory data to customers. To accomplish this, emerging products incorporate Internet technology

and combine that with wireless transmission methods developed by the telecom industry. The internet appliance device, whether cell phone with a browser and screen or a palmtop computer, incorporates computer hardware chips and software technologies developed from the information technology industry.

EDITOR: Your point, then, is that each new generation of laboratory information products and services will utilize technologies from any number of technology disciplines.

DR. FRIEDMAN: Exactly, which already makes it difficult to predict, with any precision, how fast and in what ways the management of laboratory information will evolve in the coming years.

EDITOR: It's part of your business to evaluate new lab information system products. From a broad perspective, what forces do you see in the marketplace that will shape and influence the way clinical labs capture and use laboratory information?

DR. FRIEDMAN: May I tackle that question as one of business strategy? During the past 60 days, I led the Laboratory Web Informatics Day at your *Executive War College* in New Orleans, then hosted a record crowd at my *Automated Information Management of Clinical Laboratories* (AIMCL) in Ann Arbor. All that interaction with speakers and attendees gave me new insights about how the next wave of laboratory information services will unfold. If laboratory administrators and pathologists can understand the underlying drivers that are shaping laboratory information services, then it will help them develop a business strategy for their laboratory organization which keeps it at the cutting edge.

EDITOR: In other words, the strategic overview is what should guide the specific initiatives of the lab in both in clinical services and business goals.

DR. FRIEDMAN: That's correct. Right now, I see five fundamental forces unfolding in the healthcare marketplace. From a strategic perspective, I believe these five market dynamics will have as much to do with reconfiguring laboratory information systems as the underlying LIS hardware and software technologies.

EDITOR: Are you saying, then, that these are forces, some outside the lab industry, which will cause change?

DR. FRIEDMAN: Essentially yes. Let me describe these five trends, then we can look at their collective potential as lab industry change agents.

EDITOR: Okay. What's first?

DR. FRIEDMAN: With no order of priority, number one is the globalization of clinical laboratories. I see signs that laboratory organizations are beginning to look

across national borders for useful tools in laboratory medicine, laboratory management, and lab information.

EDITOR: What market signs do you see involving the globalization of lab services?

DR. FRIEDMAN: I actually tumbled onto this insight in a roundabout way. We used the AACC's foreign mailing list for my AIMCL program this spring and got 40 attendees from abroad. At your *Executive War College* in May, I spoke to lab owners from Germany, New Zealand, and Australia. When I spoke at an AACC program in New York City earlier this year, there were people from 22 different countries in attendance. Also, AACC is now running CME programs abroad.

EDITOR: I see a similar phenomenon with clients and readers of THE DARK REPORT. We have subscribers on five continents and the number of overseas clients is increasing. So how does globalization of lab services play out?

DR. FRIEDMAN: Simple. With overnight package delivery services, specimens can be sent anyplace in the world in 48 hours. Combine that with Internet-connectivity between labs and referring physicians for test order entry and results reporting, and you have the capability to conduct laboratory business anywhere on earth from anyplace on earth. My prediction is that international interaction will increase at a steady rate. There will be cross-pollination from a number of things, like CMEs. Medicine itself will increasingly cross borders. It has to happen. As it does, laboratory organizations will become international.

EDITOR: What is the second market trend on your list?

DR. FRIEDMAN: Number two is the technology that most American laboratories are starting to evaluate. It is the ASP (application service provider) and e-business information package. This ASP model is also a first cousin to the emergence of laboratory portals and e-health content wrapped around information pertaining to lab testing.

EDITOR: You're describing the remote hosting of laboratory applications and information, accessed through Web browsers.

DR. FRIEDMAN: With ASP technology, the actual LIS server and functionality is going to move to a site remote from the physical laboratory. Lab test orders, lab results, and content will all be delivered on the Web.

EDITOR: Does this lead to a different form of laboratory organization?

DR. FRIEDMAN: It can lead to modular outsourcing. For example, let's say I have a 500 square foot laboratory in a specialty clinic located 50 miles from my reference lab. If prices are reasonable, I may choose to outsource both my lab information management and the actual production of test results to some outside party. As long as the diagnostics instruments speak TCP/IP, they can communicate test data directly to my ASP provider for storage in my remote LIS database. Under this outsourcing arrangement, I may choose to pay a specific amount of money for each test result that hits the database. But my outsource "lab services" vendor will actually handle specimen collection and test performance.

EDITOR: This new business model creates new flexibility in how lab testing can be performed and reported, doesn't it?

DR. FRIEDMAN: Certainly. Technology is making it feasible for testing to occur on instruments located in a physician's office or even in a local community pharmacy, but clinical laboratory expertise is still required to maintain quality and accuracy, as well as to evaluate the

results generated by instruments in locations distant from the core lab.

EDITOR: It sounds like the arrival of the long-predicted "virtual laboratory."

DR. FRIEDMAN: For several years I've talked about the organizational model where some labs may not physically perform any testing at all. The totally virtual lab simply outsources all testing but retains strategic functions such as QC, marketing, customer liaison, and information management. Essentially, it retains its business strategists and its data managers, who do the marketing and integration of clinical data inputted from multiple test-performing sites. It allows laboratorians to concentrate on the clinical application of laboratory medicine.

EDITOR: So you think we may be getting closer to the day when a virtual laboratory is actually feasible. What is your third trend?

DR. FRIEDMAN: Number three on my list is the growing interest of national reference and esoteric labs in becoming a lab information services provider to their client hospital labs.

EDITOR: You must be referring to companies such as **American Medical Laboratories, ARUP Laboratories, Mayo Medical Laboratories, Specialty Laboratories** and the like. But what aspect of their lab information services would be transformational within the laboratory marketplace?

DR. FRIEDMAN: There are two aspects. One is that reference labs can develop expertise in lab information technology and share that across the organizational boundaries of hospital labs and regional lab networks. The other reason is the coming explosion in the sheer volume of lab data which must be stored in a database and made accessible when needed.

EDITOR: Elaborate, please on why you think reference laboratories will become vendors of lab information management tools.

DR. FRIEDMAN: Let me answer that by describing what I saw recently on a lab tour. After my presentation at the *Executive War College*, Dr. James Peter, the Chairman of Specialty Labs, came up and invited me to tour his laboratory in Santa Monica, California. Within the last month, I did get to Specialty Laboratories and I saw several interesting things. Specialty Labs is developing information service capabilities that fit right in with the kinds of services that traditional LIS vendors are attempting to bring to market.

Friedman's Five "Change Trends" For Lab Info

- 1 **Globalization of clinical laboratories.**
- 2 **Acceptance and adoption of ASP and e-commerce technology by clinical laboratories.**
- 3 **Movement by national reference laboratories into laboratory information products and services.**
- 4 **Movement by in vitro diagnostics companies into laboratory information products and services.**
- 5 **Influence and investment by pharmaceutical firms into diagnostics and clinical laboratory operations.**

EDITOR: Then what you've observed is that Specialty Labs, along with other national reference labs, is preparing to move beyond simply performing tests and will provide other services to hospital lab clients.

DR. FRIEDMAN: Yes on two counts. First, Specialty Labs has developed its DataPassportMD[®] product suite, involving Web-enabled lab test ordering, host-to-host links, and clinical data repository

services. But the thing that really caught my eye was their interest in offering information technology and lab data base support for lab networks. Specialty Lab's arrangement with **Florida Reference Laboratory Network** is an example of this strategy.

EDITOR: Are you saying that, by providing services in lab information management and data storage, the reference lab eliminates one of the political impediments to regional laboratory networks?

DR. FRIEDMAN: Certainly, since anyone who's been involved in regional laboratory networks knows that participating lab members are concerned about ownership of the lab test data, where it is stored, and who gets access. Having a reference laboratory manage this function and act as a neutral broker can make that reference laboratory into a valuable partner for the lab network. It's quite a different proposition than either **Quest Diagnostics Incorporated** or **Laboratory Corporation of America** can offer a hospital laboratory.

EDITOR: Tell me how this service ties in with the explosion of lab data.

DR. FRIEDMAN: One of the hot topics at the AIMCL meeting this spring was the explosion of lab test data from the genomics area. I am concerned that labs will not have sufficient storage to keep up with the huge volumes of data that will be generated by genetic testing. So far, the ASP model looks like the best solution.

EDITOR: Explain that, please.

DR. FRIEDMAN: When a lab is using a remotely-hosted ASP, it only has to call its provider and ask it to "bolt on" another terabyte of storage capability at the back end. But Dr. Peter discussed with me his idea that reference labs would not only perform the test, but would store the data for the referring lab.

EDITOR: Yes, go on...

DR. FRIEDMAN: Well, this would take reference labs out of their current business model of simply performing tests. It

would convert them into a service provider with long-term revenue coming from the information services it provides to laboratories.

EDITOR: That's quite feasible. In today's business model, the reference lab offers "commoditized" testing, usually at the lowest price. This would shift reference labs into a business model where information services such as data storage and retrieval have added-value to their hospital laboratory clients.

DR. FRIEDMAN: So stay with me, because this raises another fascinating issue, which is the notion of a virtual clinical data repository, where hospitals and patients would have patient data stored in multiple, physically-separate data bases...

EDITOR: ...you are describing multiple server farms...

DR. FRIEDMAN: ...precisely, and "pointers" (addresses for the physically distributed data) would be used to find and integrate the laboratory test results and clinical results for a single patient.

EDITOR: What you described sounds like Napster, the software college students use to search each others computers to find MP3 music files that they can copy and download to their hard drive.

DR. FRIEDMAN: That's a perfect comparison. Napster demonstrates that the technology already exists to search all computers hooked onto the Internet for specific pieces of information, like the lab test results for an individual patient. Can we assume, though, that the courts will not intervene as quickly with the distributed lab data solution as they have done with Napster?

EDITOR: This fits in with what **Clinical Laboratories, Inc.** of Throop, Pennsylvania is doing. They are creating a patient data "lockbox." They will allow their patients to put lab test data into the lockbox so that any physician treating them can have access to that data, regardless of where the doctor is located.

DR. FRIEDMAN: "Lockbox" is a good description. It closes the loop on efforts, early in the 1990, to create CHINs (community health information networks).

EDITOR: What is your fourth trend?

DR. FRIEDMAN: Number four is the involvement of in vitro diagnostics companies in laboratory information management services.

EDITOR: Does that mean a shift away from purely selling test instruments and reagents to laboratories?

DR. FRIEDMAN: Diagnostics companies are perfectly positioned to offer information management products because they have the instruments and reagents

"...this raises another fascinating issue, ... the notion of a virtual clinical data repository, where hospitals and patients would have patient data stored on multiple data bases..."

which generate the lab test results. I believe they can link their existing business, that of providing instruments and reagents, to a new business, which is moving lab test data into clinical repositories which they might be able to manage for the laboratories.

EDITOR: You're describing a shift to long-term revenue flowing from information management services, just like the reference laboratory example you discussed earlier.

DR. FRIEDMAN: That's right. Both diagnostics companies and reference laboratories have an "inside" leverage point to generate lab data for their client laboratories, then offer database and data access as well.

EDITOR: What you describe is a marketplace where three different players want to offer clinical laboratories identical

services involving lab data storage, lab data access, and lab data processing.

DR. FRIEDMAN: Yes. It brings the traditional LIS vendors into competition with diagnostic vendors and reference laboratories. However, each of these players comes to the table with a different set of core competencies. All three industry groups will pursue the revenue opportunities generated from lab information services.

EDITOR: Would you discuss the fifth trend you believe will alter the laboratory services are organized and delivered?

DR. FRIEDMAN: My list cannot ignore the pharmaceutical companies. They are the fifth trend. I believe that laboratory testing will become so important to the way drugs are prescribed that drug companies will have a major impact on changing the way clinical laboratories conduct business.

EDITOR: Are you referring to the emerging science of pharmacogenomics?

DR. FRIEDMAN: Yes, much of which will be organized around SNIp scoring. (Single nucleotide polymorphism). SNIps are the minute differences between individuals' DNA that are hypothesized to be responsible for why one person may respond favorably to a specific drug while another individual might have a negative reaction.

EDITOR: So an important component of clinical testing will be SNIp scoring. But since SNIp scoring measures differences, or "deltas", will there still be huge test result storage requirements in the lab?

DR. FRIEDMAN: I think so. There is synergy between pharmaceutical drugs, drug interactions, and clinical lab tests as the necessary green light before a doctor prescribes a drug for a specific patient.

EDITOR: This is the prescription model currently typified by Clozaril and Herceptin, I would assume.

DR. FRIEDMAN: Yes. And it's very easy to see why pharmaceutical companies will have a strong interest in generating and

storing laboratory information. I believe the drug industry will push for the integration of the two data bases; merging pharmaceutical data and lab test data. Pharma has a huge stake in this process—the ability to recycle previously-developed drugs, withheld from the market because they caused adverse reactions, presumably in patients with minute genetic variations. Diagnostic tests could screen out such patients, allowing these drugs to enter the market.

EDITOR: What mechanisms do you think will be used by the drug companies to change current clinical lab industry practices?

DR. FRIEDMAN: I believe it will come through the increased use of SNIp scoring. At some point, it will be good medicine to do a complete SNIp score on every individual admitted into the hospital or who is a candidate for drug therapy. I think the first clinical area where SNIp scoring will be cost-justified is in organ transplants. It will make it easier to search for an appropriate organ, as well as easier to perform successive transplants. And don't forget, every transplant patient becomes a candidate for long-term drug therapy.

EDITOR: Then your view is that ongoing developments in pharmacogenomics will lead drug companies to invest in a spectrum of diagnostic testing capabilities.

DR. FRIEDMAN: Essentially correct. Because the science and the technology of this field are moving so fast, it is difficult to predict the precise ways in which drug companies will reshape laboratory testing as we know it today.

EDITOR: Dr. Friedman, your list of five market forces demonstrate that many different influences will be reshaping the clinical laboratory industry during the next 36 months. I would like to go back to your first item, the ASP and e-health trend. Could you speak further on how fast this may cause hospitals to abandon their existing fat client LIS products and adopt ASP-based lab information products?

DR. FRIEDMAN: I thought it was going to be slow until I heard Tim Rich, President of the Antrim Division for Sunquest, speak at the *Executive War College*. He talked about how Sunquest took some Antrim software off the shelf and used it to create an ASP-based LIS product. They wanted a quick, low-cost ASP solution for small hospital labs.

EDITOR: Yes...

DR. FRIEDMAN: Here's the interesting part. According to Rich, the up-front capital cost to the hospital labs was about \$25,000 and it took only six weeks to install the software and go live with the system. Better yet, operating cost of the installed ASP LIS software was less than half that of licensed LIS software running on a local hospital computer! That's when it occurred to me, with this type of huge financial advantage, hospitals and hospital labs will be compelled to switch to the ASP model, and it will happen sooner, not later.

EDITOR: Economic advantage is always a motivation to swift action.

DR. FRIEDMAN: True, but there is another aspect to the ASP model which will also help it win rapid acceptance in the hospital laboratory marketplace.

EDITOR: Please explain.

DR. FRIEDMAN: Everyone has seen the angst that occurs when hospital laboratories consolidate. By using an ASP with remote hosting, that angst goes away. There is no political baggage about which hospital is going to run the LIS, because none of them run it!

EDITOR: Have any of the traditional LIS vendors commented on how quickly they believe the LIS market will flip to ASP-based lab information services?

DR. FRIEDMAN: At **Triple G Systems**, President Lee Green predicts that as much as 50% of his company's revenues will come from ASP-based LIS installations within relatively short time, such as two years. Tim Rich of Sunquest/Antrim believes it will be a rapid transi-

tion, but he has not made specific revenue projections.

EDITOR: Last fall, THE DARK REPORT predicted that lab test ordering and results reporting between labs and physician offices will move to Web-browser enabled systems in as little as 24 months. How fast do you think fat client-based LIS systems, which collect the test data from instruments and move it to the data repository, will be replaced by thin client LIS products?

DR. FRIEDMAN: I think fat client-based LIS software will disappear rapidly. The overhead on computers running fat client software is extremely high. Hospitals cannot afford to maintain these systems when such a cheaper alternative is available. That makes inexpensive PCs or Internet appliances running only browsers a very attractive alternative.

EDITOR: Are there any technology barriers to this transition?

DR. FRIEDMAN: Not that I can see. Today, in Japan, cellular telephones with screens and browsers are the most common means for surfing the Web—not PCs.

EDITOR: Dr. Friedman, do you have any concluding observations to add to your provocative concepts about the future of lab information services?

DR. FRIEDMAN: Just one. I would recommend that laboratory executives and pathologists think "out of the box" when it comes to how their laboratory generates, reports, stores, and processes laboratory test data. The true product of a clinical laboratory is information. That's why it is a critical success factor for lab administrators and pathologists to use emerging lab information technology to the benefit of their lab and their client physicians.

EDITOR: Dr. Friedman, thanks for sharing your insights about the rapid evolution of laboratory information services! **TDR**

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Qualigen's POL PSA Test Cleared for Sale by FDA

Goal is to introduce in-office PSA testing to urologists in a fall marketing campaign

CEO SUMMARY: *Qualigen, Inc. gained FDA approval to sell its FastPack™ System for PSA testing in the United States. Qualigen is one more example of a technology company that expects to shift diagnostic testing out of core laboratories and closer to the patient. Initially Qualigen will sell this system to urologists, where it believes the 15-minute turnaround time for PSA results will make it a winner.*

AFTER ONLY FOUR YEARS of development, **Qualigen, Inc.** gained approval from the **Food and Drug Administration (FDA)** to sell its FastPack™ System for total PSA testing in the United States.

FastPack is actually a diagnostic instrument platform designed to perform a broad spectrum of quantitative immunoassay testing in a physician's office laboratory or small lab setting. To establish a foothold in the lab testing marketplace, Qualigen will initially focus on urology tests such as total PSA, free PSA, and testosterone.

Concentrate On Urology

"Our business strategy is to concentrate on meeting the diagnostic testing needs of urologists," said Nicholas Kuhn, Vice President of Sales and Marketing at Qualigen. "We expect to launch sales early in the fall. Right now we are scaling up manufacturing and finalizing distribution arrangements in the United States.

"We have high expectations for this product," continued Kuhn. "The

instrument was placed in a number of urology offices for evaluation and study. Urologists became very excited when they saw results from PSA tests were available in only 15 minutes!"

According to Kuhn, urologists also recognize the potential to improve specimen integrity. The test can be performed within minutes of the blood draw, minimizing the problems of specimen degradation, lost specimens, and accessioning errors that inevitably affect specimens transported for overnight testing at commercial labs.

Qualigen's product has some interesting technical features. "Our assay uses plasma, as well as serum," explained Kuhn. "Literature suggests that free PSA testing done on plasma may yield better results.

"For laboratorians concerned about quality issues, our instrument is designed to maximize the quality and reproducibility of results," he continued. "For example, the instrument will not accept out-of-date reagents and calibrators. Nor will it

run a test if the calibration period has expired.

“As a moderate complexity test, controls must be run daily. The instrument notifies operators when controls are out of range,” Kuhn noted.

Additional Income

List prices for the FastPack instrument and PSA test kits is expected to be \$11,300 and \$8.50, respectively. Since reimbursement for immunoassay tests are at much higher levels than routine chemistry tests, urologists should be able to generate additional income from in-office PSA testing.

Armed with its FDA approval, Qualigen becomes only the newest market entrant among a growing number of technology companies actively developing near-patient and point-of-care diagnostic products. Qualigen is one more sign in the marketplace that technology is nearing the point when the performance and economics of near-patient testing is at least as competitive as core lab testing.

Laboratory executives and pathologists will find several other intriguing aspects to the Qualigen story. First, it is bringing an immunoassay testing solution to the physician's office environment. If Qualigen's FastPack proves a hit with the urology profession, it will eventually divert a sizeable volume of lucrative testing away from commercial laboratories.

Lab Outsourcing Potential

Although it will probably be 24 months before it happens, both **DIANON Systems, Inc.** and **UroCor, Inc.** may be first to experience revenue drain from this phenomenon. Both companies do high volumes of PSA testing for urologists nationally. It will be interesting to see if their response will be to embrace in-office PSA testing and act as “lab managers” for urologists. Precisely that type of lab outsourcing is predicted by Bruce A.

Friedman, M.D. in the newsmaker interview on pages 9-16.

Second, Qualigen's FastPack will be a market test of whether urologists are willing to accept the responsibility for in-office PSA testing (including issues of test result quality), in exchange for the benefit of presenting the patient with his test results in 15 minutes.

Third, Qualigen's entry into the clinical marketplace will demonstrate whether near-patient testing technology is ready for “prime time.” If so, the company can be expected to expand the immunoassay tests it offers on its FastPack system, as well as the physician specialties that it wants to convert to in-office testing.

In-Office Testing Benefits

Fourth, companies with point-of-care diagnostics for physician office use will be using arguments that physicians should do in-office testing because it: 1) enhances test result quality due to better quality specimens; 2) creates happier patients from faster test results; and 3) can generate additional income for the physician.

The competitive marketplace will determine whether Qualigen's in-office testing technology is clinically and economically viable. What **THE DARK REPORT** considers noteworthy is that Qualigen represents that growing category of diagnostic vendors who are ardently committed to making near-patient and point-of-care testing a viable and sizeable part of the lab testing community.

The success of **Cytec Corporation** in converting as much as 20% of the nation's Pap smear testing to its ThinPrep liquid preparation product in only four years demonstrates that these new POC diagnostic vendors have the potential to cause significant changes in how and where diagnostic testing is performed.

TDR

Contact Nicholas Kuhn at 760-918-9165.

INTELLIGENCE

LATE & LATENT
Items too late to print,
too early to report



Medical Management Programs, Inc. (MMP) of Southfield,

Michigan is the new owner of the TPA (third party administrator) business formerly held by **Universal Standard Medical Laboratories**. MMP purchased the TPA business involving lab testing and home health services from USML's Chapter 7 bankruptcy case last fall. During the 1990s, USML was unique among the nation's laboratories in offering TPA services.

MERGER RUMORS

New rumors predict that a well-known lab information systems vendor will merge with a healthcare e-commerce company. The announcement may come at any time. As an interesting side note to this merger, the e-commerce partner already has a direct-to-consumer Web site which allows consumers to order clinical laboratory tests.

GENETIC TEST FOR MELANOMA ALMOST READY FOR MARKET

"Predictive medicine" will soon get a new diagnostic tool. **Millennium Pharmaceuticals, Inc.** has developed a genetic test that predicts whether or not a patient has a virulent, generally fatal, form of melanoma. Clinical studies indicate that melanoma patients with normal melastatin levels have a 95% chance of remaining cancer-free for up to a decade following therapy. Millennium's new assay is expected to receive FDA clearance soon. But because there are no effective therapies for the aggressive form of melanoma, some physicians are uncomfortable with the idea of using this predictive test.

MORE ON: GENETIC TEST

Millennium's new melanoma assay will be manufactured and distributed by **Becton, Dickinson & Co. (BD)**. The fact that Millennium chose a diagnostics company as partner indicates that both firms expect clinical laboratories will be the best channel to educate physicians about how to order and use the new

genetic assay. The melastatin assay is a direct result of research into RNA strands responsible for creating proteins. Melastatin's precise function in skin cells remains unknown, but its absence is linked to aggressive melanomas.

HEALTHEON/WEBMD TURNING OVER STAFF

Interesting things are afoot at **Healtheon/WebMD Corporation**. In January, Nancy Ham "retired" unexpectedly. Ham was in charge of the company's Dx product, which uses the Internet to enable laboratory test ordering and results reporting. Now Cheryl Cruver has departed, to assume duties with the newly-organized **LabPortal.com**. As recently as late May, Cruver was doing public presentations on behalf of Healtheon/WebMD's Dx product. During the last half of 1999, Healtheon/WebMD inked contracts with **Laboratory Corporation of America, DIANON Systems, Inc.**, and **UroCor, Inc.** to provide Web-based lab test ordering and results reporting services. However, implementation of these services seems to be taking longer than projected.

*That's all the insider intelligence for this report.
Look for the next briefing on Monday, August 21, 2000.*

THE **IR** **REPORT** DARK

UPCOMING...

- *How Lab Innovators are Marrying Hand-Held POC Instruments With Thin Server LIS Technology to Improve Test Quality.*
- *Sales and Marketing of Laboratory Testing Hits New Levels as HMOs Change Contract Strategies.*
- *Inside Look at Clinical Lab Services in the State of Florida—Surprising Changes To Outreach Competitors.*
- *Consumer Movement Toward Direct Test Ordering Supports a New Type of Laboratory Provider.*